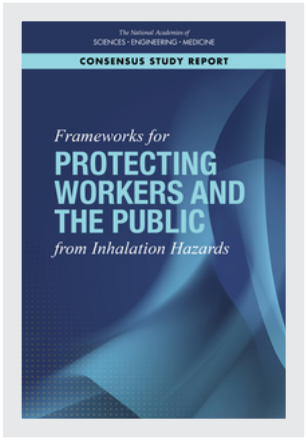
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Frameworks for

PROTECTING WORKERS AND THE PUBLIC

from Inhalation Hazards

Jonathan Samet, Autumn Downey, and Olivia C. Yost, *Editors*

Committee on Respiratory Protection for the Public and Workers Without Respiratory Protection Programs at Their Workplaces

Board on Health Sciences Policy

Health and Medicine Division

A Consensus Study Report of

The National Academies of

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Reviewers

This Consensus Study Report was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We thank the following individuals for their review of this report:

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Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations of this report nor did they see the final draft before its release. The review of this report was overseen by **ELI Y. ADASHI,** Brown University, and **DAVID L. EATON,** University of Washington**.** They were responsible for making certain that an independent examination of this report was carried out in accordance with the standards of the National Academies and that all review comments were carefully considered. Responsibility for the final content rests entirely with the authoring committee and the National Academies.

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Preface

In November 2020, as the Committee on Respiratory Protection for the Public and Workers Without Respiratory Protection Programs at Their Workplaces held its first meeting, the COVID-19 pandemic was beginning a deadly surge, and the nation had just seen the end of one of its most severe wildfire seasons. A gap in providing respiratory protection for workers exposed to SARS-CoV-2 (the virus that causes COVID-19) was evident, and the number of workers needing an effective respiratory protective device was mounting as the exposure risks for essential workers became apparent. The public also sought effective respiratory protection and in some locales was mandated to do so, although there was uncertainty about what devices should be used, and misinformation concerning respiratory protection for the public circulated widely.

In addressing its charge, the committee understood the urgent context of its work and the need for change in the national approach to respiratory protection, both for workers and for the population at large. The committee's approach to this study began with a broad assessment of what is known about respiratory protection for its two target populations—workers not covered by a workplace respiratory protection program and the public—and what systems are in place to provide such protection when needed. Summarizing a substantial body of material, the committee found that too many workers are left unprotected because of such failures as inadequate enforcement of existing Occupational Safety and Health Administration (OSHA) regulations, lack of relevant standards, and lack of OSHA coverage. The committee also found that the public has received little attention with respect to respiratory protection, with the exception of the major

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pollutants regulated by the Environmental Protection Agency, particularly as regards airborne particulate matter, as well as wildfire smoke. The COVID-19 pandemic has brought attention to the critical role of aerosols (small infectious particles) in spreading the disease, but systems are generally lacking for guiding the population on what devices to use for protection against these airborne hazards.

In this report, the committee provides its approach to creating the frameworks needed to protect workers not covered by a respiratory protection program and the general population. The committee recognized that only a systems approach would remedy the failings and gaps it had identified. It also found that the needed frameworks could not be implemented without action at the highest levels of government, and that authorities need to be designated through agency, congressional, and White House actions if the nation is to provide respiratory protection equitably for the entire U.S. population.

The committee's proposed frameworks and its associated recommendations constitute a template for action, detailing the steps that need to be taken. There are still choices to be made among the options for moving forward that are laid out in this report, and the committee details which of these options it believes are best supported whenever its findings provided a clear direction. Regardless, we are unified in urging that the proposed frameworks should be implemented without delay.

In addressing its complex charge, the committee gathered input from diverse sectors, including federal, state, local, and tribal public health; occupational safety and health; labor unions and other worker organizations; private-sector manufacturers; and federal regulatory agencies. We wish to express our gratitude to the many individuals who gave presentations and participated in discussions during our public meetings, as well as the reviewers whose constructive feedback on the draft of this report made for a much stronger final product.

The committee is particularly grateful to Arden Rowell, professor at the University of Illinois College of Law and consultant to the committee. Professor Rowell authored a remarkably comprehensive paper on the regulatory landscape for respiratory protection that guided us through the maze of regulations and laws relevant to our task. She also provided always thoughtful and timely reviews of the draft report. The committee would also like to recognize Todd Aagaard, professor at the Villanova University Charles Widger School of Law and consultant to the committee, for his review of and commentary on the regulatory landscape paper and input to the committee. We appreciate as well the assistance provided by John Beckman, BS, California Department of Public Health, with the analysis of OSHA citation data.

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The committee is deeply grateful to the staff of the National Academies of Sciences, Engineering, and Medicine, led by Autumn Downey, senior program officer. The members of the staff team included Olivia C. Yost, Aurelia Attal-Juncqua, Claire Giammaria, Michael Berrios, Lydia Teferra, Scott Wollek, and Andrew Pope. We single out Autumn for bringing a deep understanding of our task and contributing invaluable insights as she kept the committee focused and on time, and she was always available at "crunch time" as we completed and revised the report. The team was ably supported by the skillful writing efforts of Erin Hammers Forstag and editing work of Rona Briere and Allison Boman.

Finally, as chair, I thank the committee for its engagement with completing our task. Of necessity, we were a diverse group with the needed wide breadth of expertise and experience. We learned from each other and made our way through challenging discussions as we resolved tough issues. Thank you for making my job as chair easy and fun.

We will all be watching and waiting for the next steps called for in our report. Taking them will benefit public health.

Jonathan Samet, *Chair*
Committee on Respiratory Protection for the Public and Workers
Without Respiratory Protection Programs at Their Workplaces

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Acronyms and Abbreviations

AIV	avian influenza virus
ANSI	American National Standards Institute
APF	assigned protection factor
APR	air-purifying respirator
AQI	air quality index
ASPR	Office of the Assistant Secretary for Preparedness and Response
ASSP	American Society of Safety Professionals
ASTHO	American Society of State and Territorial Health Officials
ATD	aerosol transmissible disease
ATSDR	Agency for Toxic Substances and Disease Registry
BLS	Bureau of Labor Statistics
CBRN	chemical, biological, radiological, and nuclear
CDC	Centers for Disease Control and Prevention
CEL	Certified Equipment List
CEN	European Committee for Standardization
CLAS	culturally and linguistically appropriate services
COPD	chronic obstructive pulmonary disease
CPSC	Consumer Product Safety Commission
CPWR	Center for Construction Research and Training

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DALY	disability-adjusted life year
DoD	Department of Defense
DPA	Defense Production Act
EID	emerging infectious disease
EPA	Environmental Protection Agency
ETS	emergency temporary standard
FDA	Food and Drug Administration
FE	filtration efficiency
FEMA	Federal Emergency Management Agency
FFR	filtering facepiece respirator
FHSA	Federal Hazardous Substances Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	Government Accountability Office
HAZWOPER	Hazardous Waste Operations and Emergency Response
HCW	health care worker
HHS	Department of Health and Human Services
ICRP	International Commission on Radiological Protection
IDLH	immediately dangerous to life and health
IEC	International Electrotechnical Commission
ISA	Integrated Science Assessment
ISEA	International Safety Equipment Association
ISO	International Organization for Standardization
JIT	just-in-time
MCM	medical countermeasure
MSHA	Mine Safety and Health Administration
NAAQS	National Ambient Air Quality Standards
NACCHO	National Association of County and City Health Officials
NCEH	National Center for Environmental Health
NEP	National Emphasis Program
NFPA	National Fire Protection Association
NIEHS	National Institute of Environmental Health Sciences
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NPPTL	National Personal Protective Technology Laboratory
NRC	Nuclear Regulatory Commission

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NTTAA	National Technology Transfer and Advancement Act
NWCG	National Wildfire Coordinating Group
OSHA	Occupational Safety and Health Administration
PAHPA	Pandemic and All-Hazards Preparedness Act
PAPR	powered air-purifying respirator
PCA	principal component analysis
PEL	permissible exposure limit
PERC	Pesticide Educational Resources Collaborative
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PM	particulate matter
PNOR	particulates not otherwise regulated
PPE	personal protective equipment
RPED	respiratory protective escape device
RPD	respiratory protective device
RPP	respiratory protection program
SCBA	self-contained breathing apparatus
SES	socioeconomic status
SLTT	state, local, tribal, and territorial
SNS	Strategic National Stockpile
SOII	Survey of Occupational Injuries and Illness
SV	spontaneous volunteer
SWPF	simulated workplace protection factor
TCID	Texas Center for Infectious Disease
UFCW	United Food and Commercial Workers Union
USDA	United States Department of Agriculture
VA	Department of Veterans Affairs
VOAD	National Voluntary Organizations Active in Disasters
VOC	volatile organic compound
WHO	World Health Organization
WPS	worker protection standard
WSPEHSU	Western States Pediatric Environmental Health Specialty Unit

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Glossary

A variety of terms are used to describe personal devices worn to reduce adverse health effects from inhalation hazards. Definitions and descriptions of these devices vary, and no one consistent definition is used by federal agencies and other authoritative stakeholders for such terms as respirator, face covering, and mask (see Annex 1-1 in Chapter 1 for a table of terminology used by federal agencies and others). This glossary is intended to provide general committee-generated definitions of key concepts and devices discussed in this report. Where definitions were taken from other sources, the source is noted in a footnote.

Assigned protection factor: The workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by section 29 CFR 1910.134.[1]

Barrier face covering: A product that conforms to ASTM F3502-21 and that is worn on the face, specifically covering at least the wearer's nose and mouth, with the primary purpose of providing source control and a degree of particulate filtration to reduce the amount of inhaled particulate matter.[2]

[1] OSHA (Occupational Safety and Health Administration). 2009. Assigned protection factors for the revised respiratory protection standard. OSHA 3352-02.

[2] ASTM International. 2021. ASTM F3502–21 standard specification for barrier face coverings. https://www.astm.org/Standards/F3502.htm (accessed October 5, 2021).

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Conformity assessment (CA): Demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled.[3]

Dust mask: Also known as nuisance masks, these are non-approved devices that are worn to reduce exposure to airborne contaminants when working in dusty environments. They do not protect against toxic dusts and are not approved as respirators. Unlike medical or surgical masks, there are no standards that govern their construction or the quality of their filtration.

Face covering: A type of device that covers the nose and mouth but does not conform to any specific standard and does not provide a known degree of protection. The device may be constructed of single or multiple layers of cloth, filtering material, or a combination of base material and filter elements and may appear visually similar to barrier face coverings or surgical/medical masks.

Hazard: Anything (substance, situation, or behavior) that has the ability to cause an adverse outcome, including fatal or nonfatal injury or illness.

Inhalation hazard: Any type of gas, vapor, or particle, including airborne transmissible microorganisms (bacteria, viruses, molds), that can be breathed in and potentially cause harm.

Mask: With the notable exception of dust masks (defined above), these are devices worn by individuals that cover the nose and mouth and are designed and intended to reduce the spread of infectious agents found in large droplets such as from saliva, sneezes, and coughs.

Respirator: A device that is designed to protect the wearer from the adverse effects of inhalation hazards by removing contaminants from the surrounding air or by supplying clean air from a safe source.

Respiratory protection: Broadly describes any approach designed to reduce exposure to hazards that can be inhaled (i.e., inhalation hazards). Devices worn to provide respiratory protection can either protect the wearer or, for some hazards (e.g., airborne transmissible microorganisms), protect others from an infectious source. Some devices may provide some level of protection to both the wearer and to others.

[3] ISO (International Organization for Standardization). 2020. ISO/IEC 17000:2020 conformity assessment—vocabulary and general principles. https://www.iso.org/standard/73029.html (accessed October 5, 2021).

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Respiratory protective device: Any personal device that provides protection against inhalation hazards when used effectively, acknowledging that each device may offer either personal protection or source control or both at varying levels. The blend of personal protection and source control is context specific (i.e., depends on both the device and the hazard in question).

Risk: The likelihood that a hazardous exposure will result in an adverse outcome.

Source control: An approach to eliminating or reducing the introduction of harmful substances into the environment. In the context of an infectious aerosol, devices worn by individuals that cover the nose and mouth may be used for source control to reduce the emission of harmful infectious agents from the wearer, thereby decreasing the potential danger to others in the immediate environment.

Surgical/medical mask: Unfitted devices generally regulated by the Food and Drug Administration for use in health care settings. They provide a physical barrier to fluids and particulate materials, and may provide some protection against contamination of the surrounding environment by their wearer by reducing the amount of infectious agents released during exhalation, coughing, or sneezing.

Susceptibility: An individual's risk for harm when exposed to a particular hazard.

Vulnerability: An individual's likelihood of being exposed to a hazard because of who they are; where they work, study, or play; or where they live.

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Abstract

INHALATION HAZARDS AND RESPIRATORY PROTECTIVE DEVICES

Respirators have long been used in work settings to keep individuals from breathing in inhalation hazards—dangerous substances in the air, such as gas or particles, including infectious agents (e.g., viruses and bacteria). In contrast to respirators, medical masks (and cloth face coverings, which have not typically been used in workplaces) are designed primarily to protect others nearby against infectious droplets produced by their wearers. Health care workers, for example, wear medical masks to avoid spreading infectious agents to their patients and use respirators, such as N95 filtering facepiece respirators, to protect themselves from becoming infected with such airborne agents as SARS-CoV-2 (which causes COVID-19). While the levels of protection vary across devices, personal devices that provide protection against inhalation hazards when used effectively are, for the purposes of this report, called respiratory protective devices. Whether they provide protection for the wearer and/or others nearby depends on both the specific device and the hazard in question.

The threats posed by inhalation hazards extend far beyond specific worker groups that have historically used respiratory protective devices in the workplace. The COVID-19 pandemic and extreme natural events, such as wildfires and mold growth indoors due to flooding after storms, have highlighted how these threats can reach every individual in the United States. More than ever, people are aware of the dangers present in the air they breathe and the damages to health that can result, including respiratory

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infections and worsening of such common conditions as asthma and heart disease. It has also become clear that there are gaps in the nation's ability to meet the needs of the public and workers for timely access to respiratory protective devices and guidance and support in their effective use.

GAPS IN THE CURRENT SYSTEM

In the United States, employers are required to ensure that employees are protected from hazards, including inhalation hazards. The Occupational Safety and Health Administration (OSHA) has primary responsibility for ensuring that employers meet those requirements and that workers have access to respiratory protection when needed. Respirators used in OSHA-mandated workplace respiratory protection programs (RPPs) adhere to specific requirements and are tested and approved by the National Institute for Occupational Safety and Health (NIOSH). However, not all workers are covered by OSHA or any other governmental authority. Workers exposed to inhalation hazards not usually found in their workplaces, such as wildfire smoke or airborne viruses, including SARS-CoV-2, may not have access to RPPs or may be unaware of how and when to use respiratory protective devices.

Although face coverings, medical masks, and respirators may be used by the public, none are specifically approved by federal agencies for use outside of occupational settings. Additionally, there is no formal, coordinated system in place to guide and educate the public on when and how to use a respiratory protective device and which devices individuals, including children, should wear. During the COVID-19 pandemic, this lack of trusted guidance, along with widespread misinformation, contributed to persistent confusion and disagreement concerning the need for use of and the protection provided by different kinds of devices. The COVID-19 pandemic also exposed severe limitations in the capacity of existing supply chains to meet demands for respiratory protective devices during public health emergencies.

RECOMMENDATIONS OF THE COMMITTEE

Increasing levels of air pollution, fueled in part by wildfires, and growing recognition of the importance of airborne transmission of infectious agents have focused attention on the need for respiratory protection against hazards beyond those faced by the small percentage of workers covered by RPPs. While it is impossible to know what will come next, the nation can be better prepared.

The Committee on Respiratory Protection for the Public and Workers Without Respiratory Protection Programs at Their Workplaces, convened

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by the National Academies of Sciences, Engineering, and Medicine, used the best available science and drew on lessons learned to make recommendations addressing the critical need for a coordinated effort to improve communication and engagement around respiratory protection, secure the supply chain for these devices, and ensure that all individuals have access to the devices and associated guidance needed to protect themselves from inhalation hazards.

For the public, the committee's recommendations focus on filling gaps in authorities and addressing fragmentation in responsibilities (see Chapter 7). The committee recommends that Congress establish an entity within the Department of Health and Human Services (HHS) with the authority, resources, and expertise necessary to coordinate and oversee the development, approval, and use of respiratory protective devices for the public. Working with federal partners and other relevant organizations, this entity would ensure that processes are in place to evaluate hazards continuously, identify appropriate respiratory protective devices when needed, engage with the public regarding what devices they should use and how to use them, and guide efforts to ensure adequate supplies of and access to such devices. The committee also recommends that HHS designate a laboratory to oversee the development of standards for and the assessment and approval of respiratory protective devices intended for use by the public.

While workplaces are generally under the oversight of OSHA, guided by its scientific partner NIOSH, there is room for improvement in worker protection. OSHA coverage has significant gaps that leave millions of workers without adequate respiratory protection. As discussed in Chapter 6, the committee recommends that OSHA's respiratory protection requirements apply to all workers, a recommendation necessitating revision of the Occupational Safety and Health Act and updates to current state-level occupational safety and health programs. The committee also recommends that OSHA develop new standards and guidelines for such inhalation hazards as wildfire smoke and airborne infectious agents to indicate when respiratory protection is needed. Since many employers and workers will be unfamiliar with RPPs, OSHA and NIOSH will need to expand their programs to ensure that employers and workers know how to gain protection against inhalation hazards. These efforts will need to be built on a strong scientific foundation, and the committee also recommends that NIOSH conduct additional research to better understand and meet the needs of workers, including members of the most vulnerable and underserved populations, facing inhalation hazards.

While the COVID-19 pandemic was not the driving force for this report, the pandemic revealed gaps needing urgent attention, providing insights into current respiratory protection practices and systems for protecting workers and the public during a crisis, and pointing to what needs to change in the future. Immediate action is needed.

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Summary[1]

Recent disasters—including the COVID-19 pandemic and the devastating wildfires recurring annually in the western United States—have highlighted major gaps in the nation's system for ensuring timely access to and guidance on appropriate respiratory protection[2] for the public and for many workers. The enormity of the scale of these events, with a reach extending across the entire nation, and the magnitude of their impacts on public health have underscored the need to take action now to close these gaps and meet the respiratory protection needs of the public and all workers. Recognizing this imperative, three federal sponsors (the National Institute for Occupational Safety and Health [NIOSH], the Environmental Protection Agency [EPA], and the Department of State) and the CDC Foundation requested that the National Academies of Sciences, Engineering, and Medicine convene an ad hoc committee of experts to formulate recommendations for a framework of responsibilities and authorities that would provide a unified and authoritative source of information and effective oversight for the development, approval, and use of respiratory protection.[3] To inform the development of its framework, the committee was also charged with determining the need for guidance on respiratory protection

[1] This Summary does not include references. Citations for the discussion presented in the Summary appear in the subsequent report chapters.

[2] Respiratory protection broadly describes any approach designed to reduce exposure to hazards that can be inhaled (i.e., inhalation hazards).

[3] During early meetings, the study sponsors clarified that the focus of the study was not limited to respirators but also included other devices, such as barrier face coverings, face coverings, and masks, which are defined in the following section.

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for the public and workers without respiratory protection programs (RPPs) based on an assessment of existing knowledge regarding factors necessary to ensure that respiratory protection is effective for its intended use, as well as gaps in existing standards and guidance. The full charge to the committee is presented in Chapter 1 of this report.

As a result of the ongoing COVID-19 pandemic and widely visible wildfire smoke, often at levels exceeding the National Ambient Air Quality Standards for particulate matter, the public has become increasingly aware of various devices intended for use in reducing the adverse effects of inhalation hazards. Nonetheless, much of the technical terminology used in this area—such as "respiratory protection" and the distinctions among masks, face coverings, and respirators—is unfamiliar to the public. Box S-1 defines

BOX S-1
Key Respiratory Protection Terminology Used in This Report

A number of terms are used to describe the various devices used for reducing adverse health effects from **inhalation hazards** (defined as gases, vapors, or particles, including airborne transmissible microorganisms [e.g., bacteria, viruses], that can be breathed in and potentially cause harm).

Those devices used in workplace respiratory protection programs that are mandated by the Occupational Safety and Health Administration are required to adhere to specific requirements and be tested and approved by the National Institute for Occupational Safety and Health. These approved devices are all termed **respirators.** A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is purposefully designed to reduce the wearer's risk of inhaling hazardous airborne contaminants by removing them from the surrounding air or by supplying clean air from a safe source. Many respirators are designed to have a tight fit to the wearer's face and must be fit tested to prevent leakage.

Masks are devices worn on the face which cover the mouth and nose and are designed to capture large particles from the wearer (e.g., from saliva, sneezes, and coughs). They are not designed to provide a tight fit to the face. Masks worn in medical contexts (sometimes called medical masks, surgical masks, or procedure masks) have the primary purpose of preventing medical personnel (the wearer) from contaminating patients with potentially infectious materials (i.e., source control, which, in this context, refers to the reduction of the release of infectious agents from the wearer). These unfitted devices, which are regulated by the Food and Drug Administration (FDA) when sold as medical devices, may provide some protection to the user against liquid splash and droplets, but they are not tested or intended as protection from inhalation hazards as they are not designed to fit tightly to the face. Other masks, often called dust or nuisance masks, have long been worn by the public and some workers in dusty circumstances to reduce the amount of material inhaled. These dust or nuisance masks

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key terminology used in this report and a more detailed terminology discussion can be found in Chapter 1.

CURRENT SYSTEMS FOR RESPIRATORY PROTECTION: GAPS AND CHALLENGES

Historically, the use of respiratory protection in the United States has been associated with occupational settings where workers are exposed to defined inhalation hazards—for example, health care workers exposed to tuberculosis, structural firefighters exposed to smoke, and miners exposed to coal dust and silica. The United States has an employer-based approach to respiratory protection whereby employers are required to ensure that

are not intended to protect the wearer from toxic materials and are not governed by any performance standards or regulations.

Face coverings are a type of device that covers the nose and mouth and may be mask-style (i.e., products that look like surgical/medical masks but are not FDA cleared), bandanas, gaiters, or other configurations. For the purposes of this report, face coverings are distinguished from masks, and they are not governed by any performance standards. Like masks, face coverings are used primarily as source control and are *not* approved as respirators.

Barrier face covering is the term for face coverings that are designed and manufactured to comply with a specific ASTM* standard released in February 2021 (ASTM F3502-21) and are intended primarily to provide source control and a measured degree of particulate filtration. They are designed to provide better fit relative to surgical/medical masks or other face coverings.

Note that while surgical/medical masks, face coverings, and barrier face coverings all are intended primarily for use in source control, there are no standard methods for evaluating the effectiveness of devices for this purpose.

The committee refers to the various types of devices now in use with the specific terms reflecting their characteristics and the processes under which they are manufactured: respirators, masks (e.g., surgical/medical masks), face coverings, and barrier face coverings. However, for the purposes of this report and the committee's frameworks as described herein, the term **respiratory protective device** is used to describe any personal device that provides protection against inhalation hazards when used effectively. This function-based definition acknowledges that each device may offer either personal protection or source control or both at varying levels. The blend of personal protection and source control is context specific (i.e., depends on both the device and the hazard in question). This umbrella term is intended to accommodate devices developed in the future that may not fit into existing device categories. However, the committee anticipates that terminology and definitions will be refined as its recommendations are pursued and it may be that a different umbrella term will be implemented.

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their workplaces are safe and their employees are protected from hazards, including inhalation hazards; compliance with this requirement is overseen primarily by the Occupational Safety and Health Administration (OSHA). The spectrum of approaches taken to limit exposures is referred to as the hierarchy of controls, which prioritizes removal of the sources of hazards and identifies personal protective equipment as a final line of defense when other, higher-level controls are not fully protective. In the context of an epidemic caused by an airborne infectious agent, for example, vaccination would represent an important form of control.

In workplaces where more effective measures—those higher in the hierarchy of controls, such as substitution or engineering controls—are insufficient to reduce hazardous exposures and respirators are therefore necessary to protect the health of employees, employers are required by OSHA, or by other federal or state agencies with oversight authorities for specific populations or hazards, to establish an RPP. The RPP guides the selection and the safe and effective use of respirators—specifically, those that have been approved by NIOSH following a conformity assessment process that is overseen by NIOSH's National Personal Protective Technology Laboratory (NPPTL) and demonstrates that the devices meet preestablished standards and provide the defined level of respiratory protection. To comply with OSHA's Respiratory Protection Standard, employers are required to provide all employees covered by the RPP with respirators that are appropriate for the intended purpose and fitted (where tight-fitting respirators are used) to each individual employee, along with training and medical evaluations, at no cost to the worker.

These interconnected systems for approving respiratory protective devices for use in workplace RPPs and for generating requirements and guidance on their use are grounded in the science of exposure assessment and understanding of the risks posed by specific hazards. While exposure limits may be lacking for some workplace inhalation hazards, data can generally be collected with regard to concentrations and durations of exposures. In the context of an RPP, the risks of these workplace exposures can reasonably be predicted, and performance requirements for respiratory protection can be established and translated into standards. In contrast, the United States has no coordinated system supporting the development of standards and guidance for respiratory protection for workers outside of an RPP or for the public. For these populations—which are diverse and varying in demographic characteristics, vulnerability,[4] and susceptibility—the agents of concern and the circumstances of exposure are broad, encompassing

[4] The committee defines vulnerability as individuals' likelihood of being exposed to a hazard because of who they are and where they work, study, play, or live. This concept is distinct from susceptibility, which is defined as an individual's risk for harm when exposed to a particular hazard.

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both acute emergency scenarios and ongoing or more routine exposures. The exposures and risks for these populations are often difficult to fully quantify. The current system also creates siloes and does not recognize that workers with specific exposures are also members of the public with other exposures. As such, the regulatory landscape for these populations is highly fragmented, with notable gaps in authorities, and there is no cohesive national strategy for addressing their respiratory protection needs. As a result, the needs of many workers and the public for adequate respiratory protection are not being met, and significant disparities exist. It is essential, moreover, that efforts to address respiratory protection more comprehensively acknowledge and address the needs of those who are most vulnerable, including but not limited to those who live in underresourced communities; those in low-paying positions; people with disabilities; those with limited English proficiency; workers who cannot work remotely; and gig workers, migrant workers, day laborers, and other workers for whom there is little paperwork to track their movements.

Gaps and Challenges for Workers

The regulatory system for workplace respiratory protection is focused primarily on occupational settings with well-defined hazards and clear employer–employee relationships. While this system, properly implemented, should provide respiratory protection for workers covered by RPPs, large numbers of workers remain exposed to inhalation hazards that increase their risk of illness but are not covered by these OSHA-mandated programs. Such incomplete coverage may occur either when employers covered by OSHA (i.e., workplaces where OSHA is a governing authority and to which OSHA regulations apply) fail to comply with RPP requirements or when workers are excluded from OSHA coverage.

There are several reasons for these gaps in coverage. OSHA standards, including the RPP requirements and standards limiting workplace exposure to hazardous substances, are applicable only to employers covered under provisions of the Occupational Safety and Health (OSH) Act of 1970, which created OSHA. From its inception, OSHA did not cover all workers and workplaces. Excluded from OSHA coverage, for example, are state and local government workers in states whose private-sector employers are under the authority of federal OSHA.[5] Furthermore, a long-standing congres-

[5] Many states and some U.S. territories administer their own occupational safety and health programs via OSHA-approved State Plans, which must meet baseline federal OSHA safety standards. In places with State Plans, workers—including state and local government workers—are supposed to have protections "at least as effective" as OSHA standards regarding inhalation hazards in the workplace. State and local government workers in 24 states and the District of Columbia, the Northern Mariana Islands, Guam, and American Samoa are not covered by OSHA standards or by OSHA-approved State Plans.

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sional appropriations provision prohibits OSHA from any involvement in farms with 10 or fewer workers. Additional gaps in coverage have resulted from changing work practices in the United States and OSHA's interpretation of the OSH Act: currently, independent contractors, self-employed workers, and gig workers are not considered employees of an employer and are therefore not covered by OSHA requirements. Furthermore, the misclassification of some workers as self-employed when specific labor requirements for that designation have not been met increases the number of workers who remain outside of OSHA jurisdiction.

Further challenges stem from workplace exposures to inhalation hazards that arise in the context of public health and environmental emergencies, such as infectious disease outbreaks and wildfires. Relevant examples include agricultural and other outdoor workers exposed to wildfire smoke, as well as workers who are at increased risk of exposure to SARS-CoV-2, the virus responsible for COVID-19, as a result of their interactions with the public, clients, patients, customers, and other workers. Because these hazards are not typically encountered by workers outside of emergency situations (i.e., in the normal course of work), their employers may not have instituted an RPP.

While workers not covered by workplace RPPs may still have access to NIOSH-approved respirators through the commercial marketplace, such devices are approved on the assumption that they will be used in the context of an RPP. In the absence of an appropriate hazard assessment, fit testing, medical clearance, training, and other RPP components, the protection afforded to workers by such devices may be diminished.

Gaps and Challenges for the Public

While OSHA and NIOSH have primary oversight for respiratory protection in the United States, their authorities are limited to occupational settings; there is no central authority responsible for respiratory protection of the public. In the absence of comprehensive federal regulation, significant authority regarding the use of respiratory protective devices by the public is left to the states. Although the states may receive guidance from federal agencies, there is no formal system for coordinating the development and distribution of such guidance to state and local health agencies or the public. The situation is even more complex with respect to U.S. government workers and their families stationed in foreign countries that have high levels of air pollution.

The landscape of devices used by the public with the intent of reducing exposure to inhalation hazards includes NIOSH-approved respirators; surgical/medical masks designed for workplace use, some of which are cleared by the Food and Drug Administration; respirators marketed as approved

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in other countries (e.g., KN95); and products (e.g., face coverings) that are not intended to be used as respiratory protective devices in the workplace and thus are currently subject to no certifying body or formal oversight designed to ensure that the devices are effective for their intended use. The lack of a comprehensive regulatory framework makes it difficult to understand the level of protection provided by a product against a known or unknown inhalation hazard, especially given the challenges of ensuring proper fit for individuals across a population with considerable physical and demographic heterogeneity and the sociobehavioral considerations that impact access to and effective use of a device (e.g., attitudes and beliefs, safety culture).

The elements of the occupational respiratory protection model, including the fundamental program components of hazard assessment to guide respirator selection, medical clearance, regular fit testing, and user training, are not easily scalable to or suitable for application to the use of respiratory protection by the public. For the public, then, a new paradigm is needed that is directed at reducing both population harm and individual risk and supports particularly vulnerable groups, including those with limited autonomy to access protection. Such a paradigm must also consider the emerging social and political factors that contribute to resistance to the use of respiratory protective devices in certain subpopulations.

A GENERAL FRAMEWORK FOR OVERSIGHT AND GUIDANCE TO MEET RESPIRATORY PROTECTION NEEDS

In response to its charge, the committee used a systems approach to develop a general framework to be applied to both workers and the general population. Figure S-1 depicts the functional elements of this framework. Several foundational principles guided the framework's development. Foremost among these is the primacy of primary prevention of exposure to inhalation hazards for all. Equity is an overarching principle that should underpin the framework, recognizing the heterogeneity of the populations needing functional and acceptable respiratory protection across multiple dimensions, including age, racial and ethnic background, variation in facial profiles, underlying health and disease status, presence of a disability, level of education, income, language, and geographic location, among others. Moreover, while respiratory protective devices may be necessary to protect against such hazards when elimination and engineering, administrative, and other controls are not feasible or available, efforts should first be made to control exposure sources. Furthermore, all stakeholders—including federal, state, local, tribal, and territorial government agencies; employers; manufacturers; standards development organizations; and individuals—need to understand that respiratory protection does not confer absolute protection.

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FIGURE S-1 Core functions in the committee's framework for oversight and guidance for respiratory protection.
NOTE: See Box S-2 for definitions of these core functions.

Nonetheless, although some level of risk remains even with use of available devices, respiratory protection decreases the risk for harms to health from inhalation hazards, and when details of a hazard are known, appropriate respiratory protection should decrease risk to a level considered acceptable based on structured evaluation of the risk. When information is incomplete and rapidly evolving, however, decisions will need to be made in the face of uncertainty.

The committee's systems approach to developing its general framework was designed to incorporate the many elements necessary to ensure effective respiratory protection (e.g., hazard identification and assessment, product design and manufacturing, device selection and use) for a wide range of stakeholders and reflects the relationships among those elements. Central

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to this approach was recognition of the need for an entity accountable for coordination of efforts and the incorporation of multiple feedback loops across the elements to ensure ongoing improvement in the diverse functions encompassed by the framework (see Figure S-1). Moreover, the framework would need to focus not just on response to specific incidents but also on preparedness at all levels to prevent failures during emergencies and other times of acute need or stress.

The resulting foundational construct incorporates the seven core functions depicted in Figure S-1 and described in Box S-2. Each function comprises specific subfunctions, which may be ongoing or triggered by the occurrence of a specific hazard. In the context of respiratory protection needs for emergencies, the ongoing subfunctions represent critical aspects of national preparedness. It should be noted that while the functions are ordered for purposes of describing the framework, this structure is not intended to imply a specific sequence in which they must occur; rather, the functions are dynamic, and their sequencing will be determined by the specific exposure situation, with some occurring simultaneously. Use of the term "respiratory protective device" in the function titles makes clear that the general framework includes the functions of both personal inhalation protection and source control. It is important to note as well that the framework is intended to evolve and be sustained over time, and to be agile in anticipating and responding to new threats that may emerge in the future.

After developing the general framework detailed above, the committee applied that framework's functions in developing two specific frameworks: one focused on meeting the respiratory protection needs of workers without RPPs, and one on meeting the respiratory protection needs of the public. The committee's recommendations for applying the functions of its general framework to these two populations are presented in the following sections.

The core functions of the frameworks for these populations are comparable, as reflected in the parallel structures for the sections that follow. For workers, several components of the existing system for occupational respiratory protection correspond to the committee's proposed general framework, but as described above, respiratory protection for workers not covered by RPPs is a notable gap. To address this gap, the committee considers that the current system featuring strong central roles for OSHA and NIOSH could function more broadly. For the public, the current landscape of respiratory protection is substantially more complicated to address, characterized by considerable fragmentation across multiple federal and subfederal stakeholders and many gaps in authorities. As a result, it has been necessary to rely on ad hoc structures and processes to fill gaps in respiratory protection needs in emergency settings. A framework for the public needs to provide a formalized structure that addresses both authority gaps and critical coordination needs.

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BOX S-2
Core Functions of the Committee's General Framework

Function F0: Develop and approve respiratory protective devices
Function F0, which is foundational in nature, encompasses the continuous development and approval of respiratory protective devices as technologies evolve and needs and standards change. Product performance standards may be developed or refined in response to scenario planning and form the basis for the conformity assessment process on which product approval depends.

Function F1: Assess hazard and determine need for respiratory protection
Function F1 encompasses the ongoing monitoring and assessment of hazards to determine whether there is a need for respiratory protection, considering first whether the hazard can be adequately mitigated through other measures higher in the hierarchy of controls.

Function F2: Determine the necessary respiratory protective devices
In Function F2, the hazard assessment from Function F1 is used to determine the protective devices that best meet the respiratory protection needs posed by the hazard. Also considered are such user-centric factors as the usability of the device across different population subgroups. Once the necessary protection has been determined for the specific hazard, a determination is made as to whether one or more approved devices with the required specifications exist in the marketplace. If so, guidelines are developed for the effective use of respiratory protection to address the specific inhalation hazard. If not, the framework triggers the design and development of a new product that meets the specified requirements.

Function F3: Ensure availability and access pathways for respiratory protective devices
Function F3 covers processes for ensuring the availability of the appropriate respiratory protective devices in terms of both supply and the pathways by which end users can access the devices. This function includes maintaining and regularly

APPLYING THE COMMITTEE'S GENERAL FRAMEWORK TO MEET THE RESPIRATORY PROTECTION NEEDS OF WORKERS WITHOUT RESPIRATORY PROTECTION PROGRAMS

Ensuring Adequate Coordination (Function F6) and Authorities to Protect Workers from Inhalation Hazards

As described above, the current system for respiratory protection for workers involves interactions among multiple parties in the private sector and is shaped by the regulatory activities of federal agencies, particularly NIOSH and OSHA. In recognition of its current authority in the realm of worker health and safety, the committee identifies OSHA as the appropriate

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evaluating the supply of the devices in the Strategic National Stockpile and other places, as well as consulting with manufacturers of the devices with respect to supply and demand. If adequate inventory of the necessary device is not available, short- and long-term actions may be triggered to ensure adequate capacity and capability to produce and supply the devices.

Function F4: Engage, inform, and ensure access for the target community
Engaging, informing, and ensuring access to respiratory protection for the target community, the focus of Function F4, begins with the development of guidance, which must be uniform, consistent, timely, and continuously updated as new facts emerge and misinformation spreads, especially in the event of an ongoing public health emergency. Building on guidelines developed under Function F2, this guidance needs to be targeted specifically to the distinct audiences responsible for last-mile communications with end-user communities so they can use the guidance documents to tailor their communications according to the characteristics of those communities. Communications and strategies for access to respiratory protection need to consider the local context and linguistic, cultural, and socioeconomic needs of end users.

Function F5: Incorporate lifecycle learning and continuous improvement
Function F5 covers the ongoing learning and continuous improvement that are critical to catalyzing advances in each of the other core functions. It relies on a cyclical process for collecting performance data, identifying knowledge gaps and problems, investigating potential solutions through research, implementing evidence-based strategies, and finally returning to evaluation of performance.

Function F6: Coordination
The coordination function (F6) is at the heart of the framework. It is actualized by a coordinating entity charged with harnessing the domain-specific expertise of all stakeholders and integrating their efforts to ensure that all of the above functions are carried out seamlessly, and in ways that consider the needs and resources of vulnerable groups.

coordinating entity for the development, functioning, oversight, evaluation, and continuous improvement of its proposed framework for ensuring that workers not currently covered by RPPs are adequately protected from inhalation hazards. In its role as coordinating entity, OSHA, in partnership with NIOSH, would need to consult with other federal agencies as well as state and local agencies, as appropriate, when those agencies have regulatory authority over employers or are charged with recommending workplace health protections.

OSHA's failure to meet the respiratory protection needs of all workers has, in part, resulted from the constrained application of its Respiratory Protection Standard as a result of outdated statutory interpretations that

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limit the applicability of the standard to workers in traditional employer–employee relationships and from statutory language that displaces OSHA's authority when occupational safety and health are regulated by another government agency. The following two recommendations are intended to address the significant gaps in OSHA coverage that prevent the agency from requiring that employers provide respiratory protection for many millions of workers not currently covered by an OSHA-compliant RPP.

Recommendation 6-1: ***Ensure That Occupational Safety and Health Administration (OSHA) Respiratory Protection Requirements Apply to All Workers***

Congress should revise the Occupational Safety and Health (OSH) Act to clarify the definitions of employer and employee such that OSHA has the authority necessary to ensure respiratory protection for all types of workers, including all private-sector workers, over whom OSHA currently does not exercise its authority. Revised language in the Act should make clear that persons and entities conducting a business have a primary duty and thus are required to ensure, to the extent reasonably practicable, that the health of their workers—as well as that of other workers influenced or directed by the business, consumers, and the public—is not put at risk by inhalation hazards resulting from the business's activities. OSHA should have primary oversight responsibility for this requirement and should promulgate and enforce regulations accordingly. Where federal agencies other than the Department of Labor have regulatory responsibilities to protect workers from inhalation hazards, OSHA should have oversight of those agencies' requirements and programs, which should meet minimum requirements set by OSHA.

Pending revisions to the OSH Act:

- **OSHA should adopt the broadest permissible interpretation of "employees" and "employers" under the act such that workers currently excluded based on existing interpretation, including individuals considered to be employees under other Department of Labor statutes or regulations, are not excluded from respiratory protection requirements. If OSHA does not take action to this end within 1 year, the White House should direct OSHA to reconsider its interpretation of the statute.**
- **Congress should ensure that OSHA's respiratory protection requirements can be applied to and enforced for farms with 10 or fewer workers.**

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Although Congress has made minor changes to the OSH Act in the 51 years since its enactment, there have been no substantive changes such as those the committee is recommending. The committee understands that there are difficulties involved in taking what may be considered a radical step and that doing so has broader implications beyond respiratory protection for inhalation hazards; however, the evolving nature of the workforce and the hazards it faces, together with the identified gaps in coverage of workers under the current OSH Act, calls for such change. Attempts to close these gaps through administrative means would be difficult and potentially temporary (i.e., subject to reversion to a narrower interpretation) absent a statutory redefinition of OSHA's authority. Moreover, revision of the OSH Act would not address gaps in protection for state and local public-sector workers; action by state governments is needed to ensure respiratory protection for these workers.

Recommendation 6-2: ***Ensure Protection from Inhalation Hazards for Workers Not Covered by Federal or State Occupational Safety and Health Authorities***

Until and unless Congress acts to modify the Occupational Safety and Health (OSH) Act to ensure that the Occupational Safety and Health Administration's (OSHA's) respiratory protection requirements apply to all private-sector employers and workers facing inhalation hazards, or OSHA expands its definitions of employer and employee to cover all private-sector workers, states should require employers to protect workers who are not currently under OSHA jurisdiction from inhalation hazards through the passage of new laws or promulgation of new regulations.

In those states with their own occupational safety and health programs, coverage should be expanded to include these additional employers and workers not currently covered by the OSH Act. In those states without their own occupational safety and health programs, state legislatures should create such programs to provide better workplace protections from inhalation hazards for the state's public-sector workers. Furthermore, for those inhalation hazards for which federal OSHA has no standards, all state legislatures should enact requirements for their states to develop appropriate protections from inhalation hazards for all workers employed in the state and authorize their state occupational safety and health programs, including those newly created, to enforce these requirements.

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Developing and Approving Respiratory Protective Devices (Function F0)

As the oversight entity for respirator conformity assessment in the United States, NIOSH is responsible for product testing in its laboratories, specifically those of NPPTL; no alternative laboratories are available should there be a disruption caused by a malfunction of equipment or a problem with the facility (e.g., due to a flood or fire). The requirement for NIOSH testing of respirators contributes to delays in the approval process and may make it difficult to respond to emergency situations because of capacity limitations. Third-party laboratory testing could improve surge capacity for respirator testing and enable NIOSH to meet expanded needs for respiratory protection for new groups of workers.

NIOSH also faces delays in advancing necessary standards for respirator testing. Because such standards are contained in regulation, the establishment of new standards or revision of current standards is subject to lengthy rulemaking processes, including publication in the *Federal Register* and solicitation and receipt of public comments. To ensure that Function F0 is optimized, the committee makes the following recommendation:

Recommendation 6-3: ***Improve the Timeliness and Capacity of the National Institute for Occupational Safety and Health's (NIOSH's) Respirator Conformity Assessment Processes***
NIOSH should expand its National Personal Protective Technology Laboratory to improve the timeliness and surge capacity of its respirator conformity assessment processes. In doing so, NIOSH should (1) use recognized consensus standards where appropriate, and (2) incorporate third-party laboratory testing into its respirator approval program.

As with the current system, the committee envisions that NIOSH would continue to oversee conformity assessment, and respirators tested by third-party organizations would still require NIOSH approval to be used in OSHA-compliant RPPs. Additional appropriated funding from Congress will be necessary for the expansion of NIOSH/NPPTL's respirator approval program to meet the needs of a broader group of workers.

Assessing Hazards and Determining the Need for Respiratory Protection (Function F1)

Under the current system, employers are required to determine the need for respiratory protection for their employees, and employers must adhere to any standards issued by OSHA (or other agencies with regulatory

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authorities, such as the EPA and the Mine Safety and Health Administration [MSHA]). Employers are obligated to initiate an RPP only if they conduct an assessment and determine that an RPP is necessary. Most workers are not covered by an RPP or by mandatory workplace safety standards addressing the use of respiratory protection. Yet recent experiences with worsening and novel, unanticipated threats, such as wildfire smoke and SARS-CoV-2, point to the potential need to introduce respiratory protection measures at an expanded number of worksites when inhalation hazards exist and other control measures are not feasible. The absence of an OSHA standard for airborne infectious disease agents and the outdated nature of the existing standard for particulate matter (PM), as discussed further below, impede efforts to systematically institute respiratory protection measures when workers are exposed to such hazards. One approach to addressing this gap is for OSHA to modify its respiratory protection regulations to expand the types of exposures and circumstances in which workers in establishments that fall under its authority are enrolled in RPPs. OSHA has both the statutory authority to implement new RPP requirements when inhalation hazards pose a "significant risk"[6] to workers covered by OSHA—even if these risks are periodic in nature—and the expertise to guide employers in implementing these requirements.

Recommendation 6-4: ***Establish Comprehensive Workplace Exposure Standards That Serve to Trigger Respiratory Protection Program Requirements***

The Occupational Safety and Health Administration (OSHA) should establish and regularly update science-based, comprehensive workplace exposure standards for particulate matter indicators (e.g., from wildfire smoke), as well as airborne infectious disease agents, that would trigger respiratory protection program requirements, including for those workplaces in which respirators would not otherwise be required. To assist employers in meeting these requirements, OSHA should expand its technical assistance capabilities and efforts in this area. Given the urgency of the respiratory protection needs of workers facing these and other inhalation hazards, Congress should set deadlines for OSHA's promulgation of these standards. In the interim, OSHA, in conjunction with the National Institute for Occupational and Safety Health (NIOSH), should develop comprehensive guidelines, including the use

[6] OSHA is authorized to promulgate health and safety standards in the workplace only after it has satisfied the need for a threshold finding that "a significant risk" of material health impairment exists. This requirement flows from an influential Supreme Court case, *Industrial Union Department v. American Petroleum Institute* (generally referred to as the "Benzene decision").

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of NIOSH-approved respirators, for workers who are at high risk of exposure to these hazards.

OSHA currently covers exposure to particulate matter that is not included in hazard-specific standards, such as that for crystalline silica, through the Permissible Exposure Limit (PEL) for Particulates Not Otherwise Regulated (PNOR), also known as the "nuisance dust" standard. The PNOR PEL averaged over 8 hours is 15 mg/m^3 (measured as total particulate) and 5 mg/m^3 (measured as the respirable fraction). Of note, the 24-hour National Ambient Air Quality Standard for fine particulate matter ($PM_{2.5}$) of 35 µg/m^3 is orders of magnitude less than the PNOR PEL. OSHA's PNOR PEL far exceeds levels the EPA considers hazardous to human health on the Air Quality Index and levels shown to result in increased morbidity and mortality during wildfire smoke events. As it currently stands, the PNOR PEL does not provide adequate protection for workers exposed to wildfire smoke. Accordingly, in Recommendation 6-4, the committee proposes that OSHA issue a new evidence-based particulate matter standard with more health-relevant indicators and greater protection to replace the legacy standard of 5 mg/m^3 for particulate matter.

While Recommendation 6-4 focuses on particulate matter and airborne infectious disease agents as high-priority targets for comprehensive exposure standards, the committee recognizes that standards for many other inhalation hazards faced by workers are outdated or lacking. Protecting workers without RPPs from inhalation hazards will require a more expansive effort to establish or update workplace exposure standards. Given the scope of such an effort, OSHA will need to explore creative approaches to undertaking it effectively and efficiently and, where feasible, without regulation. Given the challenges involved in implementing such approaches, consideration could be given to the potential application of modern technologies and advances in qualitative methods, such as control banding, that have been incorporated into regulatory systems outside the United States and provide an alternative to establishing quantitative exposure limits and standard setting on a contaminant-by-contaminant basis.

Determining the Necessary Respiratory Protective Devices (Function F2)

Under the committee's proposed framework for worker protection, employers, following any relevant OSHA standards and regulations, would be responsible for determining which approved respirators should be used by workers exposed to particular hazards and under what circumstances. This determination would need to be based on completed or ongoing hazard assessments, taking into account the specific characteristics of the exposures

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and workplaces, as well as the exposed workers. Based on its review of the literature on the performance of respiratory protective devices, the committee believes the filtration and fit characteristics of face coverings and masks currently do not adequately protect workers facing inhalation hazards. Therefore, in the context of workplace exposures to inhalation hazards, recommendations regarding the use of face coverings (including barrier face coverings) and masks should be avoided, and employers should be advised to institute an RPP and provide employees with respirators as described by OSHA's Respiratory Protection Standard (1910.134).

Recommendation 6-5: ***Recommend only National Institute for Occupational Safety and Health (NIOSH)-approved Respirators in Guidance for Workers Facing Inhalation Hazards***
When other forms of control (e.g., engineering, administrative) fail to protect workers from inhalation hazards, the Occupational Safety and Health Administration and other agencies with authority over worker safety (e.g., Environmental Protection Agency, Mine Safety and Health Administration, Department of Energy) require that only NIOSH-approved respirators be selected. Other agencies that provide guidance for workers facing inhalation hazards but lack this specific regulatory authority should recommend that only NIOSH-approved respirators be used.

Ensuring Availability and Access Pathways for Respiratory Protective Devices (Function F3)

The COVID-19 pandemic exposed severe limitations in existing supply chains for all forms of respirators, contributing to a lack of adequate protection for many workers. While the nation does have a system for stockpiling respirators, surgical/medical masks, and other materials needed for pandemic response, this system has proved inadequate to meet the needs for respiratory protective devices during the pandemic. The Strategic National Stockpile (SNS) was designed to supplement state and local jurisdictions during emergencies, but given its resource limitations and the inevitable delays associated with distribution of stockpiled materials, employers whose workers require respiratory protection, including health care and long-term care institutions, need to ensure ongoing access to sufficient stocks of those devices to meet worker needs, with consideration of storage requirements.

Expansion of OSHA respiratory protection requirements to a much broader population of workers (Recommendations 6-1 and 6-4) would likely bring new challenges to the task of ensuring adequate availability of and access to respirators, particularly during such large-scale events as a pandemic. This broader group of workers may have needs that differ from

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those of workers traditionally covered by OSHA-mandated RPPs. For example, beyond the obvious issue of scale, the timing of their need for respiratory protection may be more unpredictable. Under the committee's proposed framework, OSHA would need to work closely with employers, recommending appropriate quantities and characteristics of respirators to stock, to ensure that workplaces would not experience shortages during future emergencies. OSHA and NIOSH would also need to collaborate with federal authorities responsible for the supply chain to aid in understanding the potential scope of respiratory protection needs for workers during a large-scale incident involving inhalation hazards.

Recommendation 6-6: ***Prepare to Meet Expanded Worker Respiratory Protection Needs***

The Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health should undertake an evaluation to understand and predict the potential scope of the increased need for respiratory protection associated with the expansion of worker coverage and the risk of future large-scale incidents or situations involving inhalation hazards (environmental and infectious agents). This information should be shared with the Office of the Assistant Secretary for Preparedness and Response and other relevant federal authorities to inform stockpiling and distribution guidelines regarding respiratory protective devices.

Engaging, Informing, and Ensuring Access for the Target Community (Function F4)

OSHA and MSHA, along with NIOSH, other units within the Centers for Disease Control and Prevention (CDC), and other federal agencies (e.g., EPA, the National Institute of Environmental Health Sciences [NIEHS]), produce and disseminate guidelines and other materials related to respiratory protection, written primarily for employers, worker organizations, and workers. However, this broad information, often distributed through government websites, may not be adequately accessible to the diverse workers who may need to use respirators for protection from inhalation hazards or address the multitude of psychosocial factors that impact choices and practices related to respiratory protection for these populations. To fill this gap, a number of labor, academic, and nonprofit groups have created materials designed and tailored for specific worker populations. However, such efforts are fragmented and ad hoc. Expanded efforts by OSHA, NIOSH, and other relevant federal agencies are needed to ensure that guidance and training on the use of respiratory protection meet the needs of workers, particularly those who may be incidentally exposed to inhalation hazards

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while performing their work (i.e., those whose work itself generally does not pose a threat from inhalation hazards but may do so in certain situations, such as wildfires) and whose employers have not established an RPP. Engaging labor, academia, and nonprofit groups already working closely with specific worker populations in these efforts would help ensure that materials are designed in collaboration with, meet the needs of, and are provided to workers, particularly those in difficult-to-reach settings who are most vulnerable, including those not currently under OSHA's jurisdiction.

Recommendation 6-7: ***Support the Development of Targeted and Tailored Guidance and Training for Workers***
The National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, the Environmental Protection Agency, the National Institute of Environmental Health Sciences, and other relevant federal agencies should expand grant programs and other support mechanisms to facilitate the translation of existing technical information on respiratory protection into tailored and culturally appropriate guidance and training materials designed for workers, particularly those who may be using respirators outside of a respiratory protection program. These agencies should recognize the administrative structures and power dynamics, local contexts, and psychosocial and political factors that influence uptake, and increase their support mechanisms to ensure the training of more workers, including those from diverse communities that otherwise might not be reached through training programs. To this end, these support mechanisms should be targeted to those institutions and organizations (e.g., labor organizations, worker centers, nonprofits, academic research centers) that have established relationships and regularly interface with end-user groups.

To be effective, training programs need to be developed based on best practices for training development and be competency based, scalable, and accessible. Having established competencies from the funding organization can help ensure message consistency while allowing flexibility for tailoring of materials to different populations. The programs would benefit from expertise in all relevant fields, including but not limited to adult education methods, instructional design, human factors engineering, and cognitive engineering. Examples of mechanisms that could be leveraged to implement this recommendation include OSHA's Susan Harwood Training Grant funding opportunity and NIEHS's Worker Training Program. Other models for reaching vulnerable groups should also be considered, including use of community health workers and others with personal knowledge of local communities (e.g., peer safety liaisons, *promotoras*).

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Incorporating Lifecycle Learning and Continuous Improvement (Function F5)

A framework for workers needs to be grounded in an understanding of the scope and contexts of respiratory protection needs in occupational settings. Currently, however, such understanding is limited by regulatory and public health agencies' inadequate collection of data needed for assessing and evaluating risks of workplace hazards and compliance with respiratory protection regulations. Moreover, the science and research foundation for understanding the successful implementation of RPPs for all workers (implementation science) is relatively sparse, limiting the ability of public health and regulatory agencies to disseminate best practices, ensure their proper implementation, and enforce RPPs. These gaps need to be addressed as part of a process for continuous improvement of the committee's worker framework. The committee envisions NIOSH assuming a leadership role in the development of a robust research program that includes both intramural and extramural research and focuses on basic respirator design and implementation science. Workers currently prevented from using traditional tight-fitting respirators because of physical limitations will need to have respiratory protection that does not pose additional physiologic burdens. Gaps in protection for workers whose religion requires wearing a beard, those who must communicate extensively while at work, and others who are not currently served by readily available respirators will also need to be addressed. The increased level of NIOSH effort necessitated by the committee's recommendations, including the personnel and data requirements of such research and surveillance programs, will require substantial resources.

Recommendation 6-8: ***Launch Expanded National Institute for Occupational Safety and Health (NIOSH) Research and Surveillance Programs***

In consultation with the Occupational Safety and Health Administration and in collaboration with relevant federal agencies (e.g., Defense Advanced Research Projects Agency, Biomedical Advanced Research and Development Authority), NIOSH should launch expanded surveillance and intramural and extramural research programs to better understand and meet the needs of all workers facing inhalation hazards. The surveillance program should generate data on the population sizes and characteristics, exposures to inhalation hazards and associated risks, and respiratory protection needs of these workers, including workers with disabilities, other underserved populations, and volunteers. The research program should include topics such as, but not limited to

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- **respirator design, including filtration efficiency, breathability, fit, comfort (especially during periods of prolonged use), usability, ability to communicate when worn, and use by workers with a range of impairments;**
- **characterization of the source control effectiveness of different respiratory protective devices;**
- **innovative approaches for respirator manufacturing and distribution;**
- **implementation research; and**
- **methods and tools for sampling and characterization of workplace inhalation hazards, including airborne infectious agents.**

An important objective of this research program should be to generate information that can help address knowledge gaps regarding the choice, acquisition, use, and disposal of respirators by employers and workers in this broader workforce. Additional appropriated funding from Congress will be necessary for this expanded scope.

Recommendation 6-9: *Conduct Research on Models for Respiratory Protection Program (RPP) Requirements*
The National Institute for Occupational Safety and Health should conduct research to assist the Occupational Safety and Health Administration (OSHA) in evaluating RPP requirements for routine workplace exposures, exposures to inhalation hazards during response to emergencies, and incidental exposures in the workplace. The effectiveness of different RPP models (e.g., those that do not require standard fit testing, such as the mini RPP for health care workers established under OSHA's 2021 Emergency Temporary Standard) should be evaluated and RPP requirements continuously refined.

APPLYING THE COMMITTEE'S GENERAL FRAMEWORK TO THE RESPIRATORY PROTECTION NEEDS OF THE PUBLIC

Ensuring Adequate Coordination (Function F6) and Authorities to Protect the Public from Inhalation Hazards

While largely centralized oversight authorities for occupational inhalation hazards exist in NIOSH and in OSHA, there is no corollary structure in the context of public protection, and there are gaps in critical authorities, particularly related to conformity assessment and approval of respiratory protective devices. Stakeholders and authorities may vary depending on whether the hazard in question is an infectious agent, such as SARS-CoV-2, or an environmental hazard, such as wildfire smoke, as well as on where

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the exposure occurs. Given this complex landscape, there is a critical need for a coordinating entity with the necessary leadership, resources, and oversight to integrate the efforts of all stakeholders so as to enhance the nation's preparedness and provide an actionable response when the public is exposed to inhalation hazards. An entity responsible for ensuring that the right respiratory protection is available to the public at the right time, with guidance on its effective use and responsibility for eliminating disparities in access and use, is an urgent need.

With respect to potential organizational structures to facilitate such coordination, the committee favors a hub-and-spoke model whereby functions can be distributed across multiple stakeholder entities (the spokes), but the coordinating entity serves as a central hub and functions as a unified and authoritative source of information and effective oversight in the development, approval, and use of respiratory protective devices. This model would allow the domain-specific expertise and infrastructure of existing stakeholders to be leveraged while providing mechanisms for coordinating these multiple efforts toward a shared objective. Of note, while this coordinating entity should be focused on the respiratory protection needs of the public, coordination with OSHA on respiratory protection issues that overlap with the needs of workers is critical to reducing the potential for conflicting messages and confusion, and to ensuring a seamless system for the nation. Issues requiring collaboration with OSHA might include designing communication and messaging, ensuring a robust supply chain for both workers and the public, and carrying out coordinated research on respiratory protection.

Recommendation 7-1: ***Establish a Coordinating Entity to Oversee the Framework for Respiratory Protection for the Public***

Congress should expeditiously establish a coordinating entity within the Department of Health and Human Services (HHS) with the necessary responsibility, authority, and resources (financial, personnel, and infrastructure) to provide a unified and authoritative source of information and effective oversight in the development, approval, and use of respiratory protective devices that can meet the needs of the public and protect the public health. Given the urgent need for action, the Secretary of HHS should immediately establish an interim office to take on priority near-term tasks of the coordinating entity until Congress acts to establish the coordinating entity. Pending such congressional action, the White House should establish an interagency task force focused on respiratory protection for the public to ensure that the activities of the interim HHS office are coordinated with other stakeholder federal agencies.

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While a coordinating entity is necessary to harness the authorities, resources, and domain-specific expertise of all stakeholders and ensure that the functions encompassed by the committee's framework are carried out seamlessly to meet the respiratory protection needs of the public, each function may require one or more leads with the necessary domain-specific expertise, resources, and authority to serve in an oversight role (see Table S-1). One critical task as the framework for the public is implemented will be to identify the various entities and stakeholders that are active with regard to carrying out these functions, as well as those that could be engaged.[7]

Recommendation 7-3: ***Assign and Coordinate Roles and Responsibilities for the Framework Functions***
The coordinating entity proposed in Recommendation 7-1 should assign and organize roles and responsibilities of federal and other stakeholders through a structured process that matches their capabilities to the committee's framework functions. Where gaps in authorities are identified, Congress should address them to ensure the necessary oversight for each of the framework functions. This process should build on the committee's work to identify the necessary capabilities and oversight authorities of stakeholders for each function and to consider potential stakeholders to fill current gaps.

Developing and Approving Respiratory Protective Devices (Function F0)

In contrast with NIOSH/NPPTL for occupational settings, no federal entity is responsible for overseeing the development, approval, marketing, and postmarketing surveillance of all respiratory protective devices for the public, or for generating or overseeing a conformity assessment program that would manage these processes. Current devices used by the public in the face of inhalation hazards are a mix of NIOSH-approved industrial respirators, medical and nuisance dust masks, and a variety of other commercial and homemade face coverings. No comprehensive study has been undertaken to characterize the public as users of respiratory protection or to assess their equipment needs. As a result, the numerous factors that affect the design and appropriate use of respiratory protection for the public (e.g., facial characteristics and fit, acceptable breathing resistance, wearability, the need for an end-of-service-life indicator) are not well understood.

[7] Note that the order in which the committee's recommendations are presented in this Summary differs from that in the respective chapter of the full report. Recommendation 7-2 can be found later in this Summary.

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TABLE S-1 Key Expertise, Resources, and Authorities of a Lead Oversight Agency, Organized by Framework Function

FUNCTION	EXPERTISE	RESOURCES* AND AUTHORITIES
Function F0: Develop and approve respiratory protective devices	• Respiratory protection • Product development, including knowledge of market forces and incentives • Conformity assessment • Standards development	• Access to testing laboratories • Access to standards development organizations • Regulatory authority to approve devices • Enforcement mechanisms for corrective action for nonconforming products (including recall authority)
Function F1: Assess hazard and determine need for respiratory protection	• Hazard monitoring • Hazard and exposure assessment • Risk evaluation and hazard control	• Access to a multidisciplinary group to monitor the hazard, conduct hazard assessment, and judge the acceptability of risks • Hazard monitoring infrastructure
Function F2: Determine the necessary respiratory protective devices	• Respiratory protection: hazard-based assessment and determination of level of protection • Product development, including knowledge of market forces and incentives	• Relationships with manufacturers • Access to the Certified Equipment List
Function F3: Ensure availability and access pathways for respiratory protective devices	• Supply chain management • Understanding of diverse population needs related to access to respiratory protective devices	• Relationships with manufacturers • Relationships with state, local, tribal, and territorial authorities responsible for distributing devices • Access to Strategic National Stockpile (SNS) information • Authorities related to the SNS, including purchasing and distribution

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TABLE S-1 Continued

FUNCTION	EXPERTISE	RESOURCES* AND AUTHORITIES
Function F4: Engage, inform, and ensure access for the target community	• Public health messaging and risk communication • Sociobehavioral science • Health equity • Guidance development	• Networks to reach target audiences • Authority to approve guidance
Function F5: Incorporate lifecycle learning and continuous improvement	• Inhalation hazards and respiratory protection • Sociobehavioral science • Implementation science • Continuous improvement	• Research infrastructure • Infrastructure to monitor and evaluate for ongoing improvement purposes

* All functions will require adequate financial resources.

To address these major shortfalls, a robust research and approval program is needed to evaluate these needs and requirements systematically, and to guide the development of comprehensive performance standards and innovative respiratory protective devices designed specifically for the wide range of public users, including infants, children, and the frail elderly.

Recommendation 7-4: ***Establish a Capability to Oversee Standards Development for and Approval of Respiratory Protective Devices Used by the Public***
Congress should mandate that the Department of Health and Human Services establish and adequately resource a laboratory responsible for overseeing standards development, conformity assessment, and approval for respiratory protective devices intended for use by the public, as described for Function F0.

Two approaches could be taken to establishing the necessary capability, each with pros and cons such that the committee did not identify one as preferable to the other: (1) expand capacity and funding for NPPTL; or (2) establish a new laboratory within HHS, separate from but collaborating with NPPTL. The choice between these two approaches should be based on consideration of the differences between the populations to be covered (i.e., the general population versus workers) and the implications for the necessary capabilities of the laboratory, the comparative efficiencies of the two approaches, and the administrative infrastructure that would need to be created around providing respiratory protection for the public.

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Assessing Hazards and Determining the Need for Respiratory Protection (Function F1)

To protect the public from such diverse inhalation hazards as wildfire smoke, dust storms, infectious aerosols, and mold, among others, the coordinating entity will need to survey, on an ongoing basis, existing and/or emerging hazards that might warrant the public's use of respiratory protection, and to oversee a standardized, rigorous process for compiling existing knowledge on exposure and risk to guide the public on their need for respiratory protection. This core function will require coordination across multiple agencies (e.g., CDC, EPA) based on the relevant scientific and administrative expertise of each and the nature of the inhalation hazard in question.

Recommendation 7-5: ***Establish and Use a Standardized Process for Determining the Public's Need for Respiratory Protection***
The coordinating entity should work with the Centers for Disease Control and Prevention, the Environmental Protection Agency, and other relevant federal stakeholders to establish a timely, responsive, and standardized process for expert scientific review of inhalation hazards and evaluation of risk to the public (including susceptible subgroups of the population) so as to identify those hazards that warrant the public's use of respiratory protection. The coordinating entity should oversee each of the steps in this process and engage stakeholders with the relevant expertise to perform the scientific review and risk evaluation, and use this information to inform evidence-based decisions on the need for public use of respiratory protective devices.

Determining the Necessary Respiratory Protective Devices (Function F2)

Current processes for generating recommendations on devices to meet the public's needs for respiratory protection are ad hoc and often rely on collaborative relationships among multiple federal stakeholders. Needed is a formalized and enduring process and structure with a clear lead organization responsible for determining which existing respiratory protective devices best meet the needs of the public based on evaluation of the particular hazard and risks (Function F2) and review of the technical specifications and capabilities of existing devices.

Recommendation 7-6: ***Use Hazard and Risk Evaluations to Determine the Necessary Respiratory Protective Devices for the Public***
The laboratory called for in Recommendation 7-4 should use the hazard and risk evaluations generated through the standardized process

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described in Recommendation 7-5 to identify and make recommendations to the coordinating entity on approved respiratory protective devices that best meet the respiratory protection requirements of the public. When no approved device exists that meets the identified requirements, the laboratory should oversee efforts to address this gap, consistent with its role in Function F0.

Ensuring Availability and Access Pathways for Respiratory Protective Devices (Function F3)

The COVID-19 pandemic has exposed severe limitations in existing supply chains for respiratory protective devices, including N95 filtering facepiece and other types of respirators. National shortages of NIOSH-approved respirators prompted the importation and production and public use of products with unknown efficacy in protecting against specified hazards. There were also clear disparities in who had access to respiratory protective devices, leading to a widening of the differences in COVID-19 risk across some groups. A strategy for ensuring effective supply chain management for respiratory protection that addresses health equity needs is a critical component of and gap in the nation's preparedness infrastructure.

Recommendation 7-7: *Ensure Availability of and Access to Respiratory Protective Devices*
The coordinating entity should organize efforts to make respiratory protective devices available and accessible to the public. It should interface with relevant stakeholders, including the Office of the Assistant Secretary for Preparedness and Response and the Occupational Safety and Health Administration, to guide stockpiling decisions regarding respiratory protective devices, including necessary quantities and characteristics (e.g., fit, reusability). To prepare for the occurrence of a large-scale incident involving inhalation hazards and ensure an adequate supply of respiratory protective devices in the event of such an incident, the entity should also work with the White House and the Federal Emergency Management Agency, as well as manufacturers, regarding the need to trigger the Defense Production Act and to provide incentives for manufacturing the necessary devices, especially during public health emergencies.

Engaging, Informing, and Ensuring Access for the Target Community (Function F4)

The public needs clear, consistent, and timely guidance on the selection, acquisition, and effective use of appropriate respiratory protective devices

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for specific hazards. Such guidance needs to address their risk perceptions, preferences, and beliefs around each hazard. It is critical that messages be developed with input from a broad range of experts to ensure accuracy, and tested with members of the target audiences to ensure that they have the intended effect in different population groups. While guidance can and should be provided directly to the public, its acceptability and use are amplified when it is conveyed through trusted sources who routinely engage with and communicate health information to the public, including health care providers and health systems, faith leaders, community leaders, and community-based organizations with broad reach to specific population groups.

Currently, the critical responsibility of providing guidance to the public on the medical indications for and use of respiratory protection falls to health care providers and public health professionals. Many of these professionals lack adequate training and the tools and resources needed to perform this function well. To be effective in this role, they need to be equipped with a level of knowledge that will enable them to support members of the public in selecting, fitting, using, and caring for respiratory protective devices that will help protect them from inhalation hazards. There are currently no formal requirements or mechanisms for health care and public health professionals to be trained in respiratory protection, a gap that needs to be addressed.

Recommendation 7-8: ***Develop Culturally Appropriate Guidance and Training on the Use of Respiratory Protective Devices by the Public*** **The Centers for Disease Control and Prevention should lead the development of culturally appropriate guidance and training related to the use of respiratory protective devices by the public. This guidance and training should address which respiratory protective devices should be used, when they should be used, and how they should be worn to reduce harm from inhalation hazards. The coordinating entity should facilitate the engagement of and gathering of input from key stakeholders to advance these efforts, and ensure that the approaches developed consider the needs, cultural and socioeconomic factors, and local contexts of vulnerable groups and those facing persistent health burdens.**

Specifically, the committee suggests the following considerations:

- CDC should serve as the focal point for assurance that guidance materials are accessible to and appropriate for the general population and its many subgroups. While other federal agencies (e.g., EPA, the Federal Emergency Management Agency) will be involved in developing the guidance, harmonization will be necessary to avoid

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conflicting information. CDC should develop formalized mechanisms for that purpose.

- In addition to partner federal agencies, CDC should gather input from other key stakeholders, such as local, state, and tribal partners and nongovernmental groups, including medical care providers and health systems, faith leaders, community leaders, and community-based organizations with reach to specific population groups.
- CDC should test the guidance as part of ongoing preparedness activities and periodically following its dissemination to ensure that it is appropriate for diverse population groups and determine whether it needs to be refined as information and contexts change.
- CDC should ensure that mechanisms for reaching critical partners for dissemination, including local, state, and tribal agencies, as well as community organizations, have been explored and tested, along with routes for direct dissemination to individuals. CDC should map the reach of its communications to ensure that they can reach all segments of the population.
- CDC should partner with medical and public health professionals and societies, as well as device manufacturers and retailers, to develop, test, and disseminate training modules and guidance appropriate for health care and public health professionals and community health workers so they will be prepared to provide guidance to and respond to questions from the public about health risks associated with inhalation hazards and respiratory protective devices.
- If CDC is made aware of the spread of misinformation, it should develop and disseminate improved versions of the guidance to counter such misinformation.

Incorporating Lifecycle Learning and Continuous Improvement (Function F5)

To ensure that the framework evolves and can anticipate and be responsive to future threats, learning and improvement need to be purposefully driven and reinforced by mechanisms for accountability. Progress needs to be evaluated continuously against established benchmarks, and the roadmap for the future of respiratory protection for the public regularly updated. For example, the development of respiratory protective devices that best meet the needs of the public will require tracking and analyzing technology advances and directing research to the most pressing knowledge gaps. Developing the nascent knowledge base related to public use of respiratory protective devices will require a directed and expansive science- and policy-driven effort that needs to be guided by a coordinated research agenda.

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Recommendation 7-9: *Continuously Evaluate Progress toward Goals, and Enhance the Framework's Operations*

Based on ongoing monitoring and evaluation, the coordinating entity should

- **develop and update plans with objective and transparent milestones and ensure that changes needed to continuously enhance the framework are made;**
- **regularly assess and publicly report on progress;**
- **ensure that available funding and its allocation enable goals to be achieved;**
- **coordinate linkages across partners in government, academia, nonprofits, and industry;**
- **conduct periodic exercises to evaluate national preparedness for respiratory protection for the public; and**
- **lead the development of a coordinated, strategic research agenda to develop the knowledge base and address knowledge gaps in respiratory protection for the public.**

COORDINATION BETWEEN THE WORKER- AND PUBLIC-FOCUSED FRAMEWORKS

As described above, in responding to its charge, the committee developed a general framework for oversight and guidance to meet respiratory protection needs, and from that general framework, frameworks targeted to two broad population groups: workers, including those not currently covered by respiratory protection programs, and the public. The frameworks for workers and the public are grounded in the seven functions of the general framework. Consequently, the elements of the two frameworks cover these functions, and there is inherent overlap in the activities of the groups tasked with carrying out these functions and in the science guiding those activities. While workers and the public are addressed separately by these frameworks, it also bears acknowledging that there is in fact overlap between these two target population groups; outside of the work setting, workers make up a substantial proportion of the general population. Thus, harmonization between the two frameworks and coordination between those entities serving in oversight roles for each is vital.

While the coordinating entities for the two frameworks are likely to be housed in different agencies—the Department of Labor/OSHA and HHS—the committee urges that pathways for coordination and collaboration be established from the outset as the new frameworks are implemented. Points for collaboration and coordination include but are not limited to the following:

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- Function F0: Collaboration and coordination will benefit the development of respiratory protective devices, particularly to reflect the heterogeneity of the populations to be covered. The testing and certification processes of NIOSH/NPPPTL will be a useful starting point for developing laboratory capacity for testing devices designed for use by the public.
- Function F1: For hazards of concern to both workers and the general population, risk evaluations can be shared for those agents to which both groups are exposed (e.g., wildfire smoke).
- Function F4: Substantial investment and effort will be needed to develop diverse communication materials that are effective for all segments of the population. Some materials might be developed jointly and successes and failures shared.
- Function F5: Research to address gaps and improve the functioning of the framework will be an ongoing need. Coordination on developing and maintaining a strategic research agenda will lead to efficiency and beneficial synergies.

Given the benefits of collaboration and coordination, the committee offers the following recommendation:

Recommendation 7-2: ***Ensure Collaboration and Cooperation Between the Coordinating Entities for the Worker and Public Frameworks***
As the two frameworks are implemented, the heads of the two agencies housing them—the Department of Labor (in which the Occupational Safety and Health Administration resides) and the Department of Health and Human Services—should ensure that mechanisms are established to support collaboration and cooperation between them.

Including ongoing evaluation of harmonization of the two frameworks among the requirements for regular assessment and reporting proposed in Recommendation 7-9 will serve to ensure that objectives related to collaboration and coordination are met.

CONCLUDING THOUGHTS

For decades, the nation's systems for ensuring respiratory protection have been focused on a small subset of the U.S. population—those workers who are exposed to inhalation hazards as an intrinsic consequence of their jobs and for whom RPPs are required by law. As described in this report, the threats from inhalation hazards extend far beyond this group of workers, and indeed impact every person in the United States, as well as Americans abroad. The wildfires that have ravaged the western United

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States in recent years are likely to remain a recurring threat to the quality of the air people breathe. Air pollution in foreign countries will also continue to affect the health of U.S. workers and their families stationed overseas. The future for SARS-CoV-2 remains unclear, but history makes clear that future epidemics of emergent airborne infectious agents can be expected.

It is impossible to know what is coming next, but the nation must be better prepared for future airborne threats. Given the human and financial costs of inaction, the nation cannot afford to repeat the ad hoc efforts made during the COVID-19 pandemic to address safety and respiratory protection. All workers and the public need to be able to turn to a clear and authoritative source of information on inhalation hazards and how they can protect themselves from those hazards, and a system for providing accurate guidance and support to ensure access to and effective use of respiratory protective devices needs to be in place. Furthermore, the needs and resources of the most vulnerable population groups must be considered. The problem is of such magnitude and the current systems are so fragmented that action is required at the highest levels. As climate change increases the incidence and severity of wildfires, hurricanes, floods, infectious disease outbreaks, and other phenomena that impact air quality and human health, it is imperative that the United States close the gaps addressed by this report and ensure that the respiratory protection needs of all workers and the public are met.

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1 Introduction

Almost 2 years into the COVID-19 pandemic and with wildfire smoke visibly and frequently permeating the air in much of the western United States, the American public and many workers still have questions: Why do I need to wear a mask? Is it safe? What product is best to protect myself, my family, and my community? How do I obtain the right device for my situation? Having the right answers to these questions and having the right devices available for use can prevent illness and save lives. However, substantial gaps in existing approaches for making devices for respiratory protection and getting them into people's hands impair timely access to appropriate devices and guidance on their effective use. As the nation reflects on this time and looks to the future, its leadership has a fundamental responsibility to address these gaps and establish a system that is better prepared and resourced to react swiftly and effectively to the next threat. As this report goes to press, more than 800,000 lives have been lost to COVID-19 in the United States (CDC, 2021a), with millions more affected. The burden has not been borne equitably, with low-income groups and communities of color experiencing excess morbidity and mortality due to COVID-19 compared with other groups (Moore et al., 2020). Clearly, then, the time to take action to ensure that respiratory protection can be provided for all when needed is now.

Individuals in the United States and Americans abroad are exposed to inhalation hazards from a variety of sources—some in workplaces, some indoors, and some outdoors—and these hazards can have short- and long-term adverse effects on health. For example, exposure to wildfire smoke,

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which contains particulate matter (PM) and toxic chemicals, can lead to respiratory problems (e.g., worsening of asthma symptoms), increased risk for heart attacks, and other adverse health outcomes (Chen et al., 2021; Holm et al., 2021). Individuals also may be exposed to airborne infectious agents through aerosol or droplet transmission, and as demonstrated by the COVID-19 pandemic, the individual and public health consequences of these exposures can be severe. Storms, floods, and hurricanes can increase exposure to moisture-driven hazards, such as mold, and to accidental releases from production facilities or transport vehicles that may result in chemical exposures (NIOSH, 2019b).

These and other inhalation hazards can adversely impact the public generally, as well as workers whose jobs typically do not require respiratory protection, such as teachers, grocery store workers, and federal civilian workers (e.g., Foreign Service officers) and their families stationed in locations where ambient air pollution levels are routinely or periodically elevated to unsafe levels (e.g., from agricultural burning, dust storms, and industrial emissions). As with COVID-19, the burden of these hazards is not shared equally across the population: poorer communities and some racial and ethnic groups experience greater exposure to certain inhalation hazards and may be less able than other population groups to avoid or mitigate those hazards (American Lung Association, 2020a). Furthermore, some individuals, including children, the elderly, and people with underlying health conditions, are at heightened risk of adverse health outcomes associated with inhalation hazards (American Lung Association, 2020b; CDC and HUD, 2006).

While more permanent solutions are required and are preferable to relying on individual action to reduce these exposures, the use of individual respiratory protection nevertheless remains an important protective measure of last resort. Currently, however, the United States has no coordinated system to support the development of standards and guidance[1] for respiratory protection for the public and those workers whose employers are not required to have a respiratory protection program (RPP) by the Occupational Safety and Health Administration (OSHA) or other entities. The current regulatory system is focused primarily on ensuring access to respiratory protection in occupational settings characterized by well-defined hazards and clearly defined employer–employee relationships. With this narrow regulatory focus on selected worker groups, the respiratory protection needs of the public and many workers are not being met.

[1] Agency actions that are not legally enforceable are generally characterized as "guidance." Guidance includes interpretive rules, general statements of policy, memoranda, manuals, bulletins, and advisories. It also often includes some forms of interagency cooperation, such as those imbedded in interagency memoranda of cooperation (Rowell, 2021).

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As climate change increases the incidence and severity of wildfires, hurricanes, floods, infectious disease outbreaks, and other phenomena that impact air quality and human health, it is imperative that the United States close the gap and ensure that the respiratory protection needs of the public and all workers are met. Recognizing the urgent need to address the gaps in the nation's ability to meet the respiratory protection needs of the public and workers without workplace RPPs, three federal sponsors (the National Institute for Occupational Safety and Health [NIOSH], the Environmental Protection Agency [EPA], and the Department of State) and the CDC Foundation asked the National Academies of Sciences, Engineering, and Medicine to convene an ad hoc committee charged with formulating recommendations for a framework of responsibilities and authorities that would provide a unified and authoritative source of information and effective oversight for the development, approval, and use of respiratory protection. The committee's full Statement of Task is presented in Box 1-1. This report presents the committee's findings, conclusions, and recommendations.

STUDY SCOPE AND KEY TERMINOLOGY

The types of inhalation hazards and circumstances of exposure that may require respiratory protection are wide-ranging. During its first meeting on November 5, 2020, the committee had an opportunity to clarify the scope of the study with representatives of the sponsoring organizations. In the course of that discussion, the study sponsors helped the committee focus the scope of this report by presenting a matrix laying out the priority hazards and populations to be addressed (see Table 1-1, provided by the study sponsors). The highest-priority hazards reflect the current context: air pollution (including wildfire smoke) and infectious biological agents (including respiratory viruses). Target populations are the public and groups of workers not covered by an RPP; these groups include some worker populations that face occupational exposures to inhalation hazards and arguably should be covered by an RPP (e.g., some wildland firefighters, home care workers). While worker populations covered by RPPs were not a priority focus for this report, the committee acknowledges that an RPP may not by itself ensure adequate protection from inhalation hazards, as may be the case, for example, when OSHA RPP requirements are not adequately implemented or enforced within workplaces.

The committee uses the term **respiratory protection** to broadly describe any approach designed to reduce exposure to hazards that can be inhaled (i.e., **inhalation hazards**), which may be in the form of gases, vapors, or particles, including airborne transmissible microorganisms (bacteria, viruses, molds). Inhalation hazards relevant to this report are described later in this chapter. As clarified by the sponsors, the scope of this study is limited to

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BOX 1-1
Statement of Task

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will conduct a study to examine and consider processes for ensuring effective and appropriate respiratory protection for individuals facing inhalation hazards outside of workplaces with known respiratory hazards subject to requirements for respiratory protection programs. These inhalation hazards would include those associated with severe air pollution, wildfires, pandemics such as COVID-19, and other disasters and public health emergencies. Regulatory approaches to meeting respiratory protection needs will be explored for a broad range of workers who may need to use respiratory protective devices in the absence of a respiratory protection program, as well as for the general public, including vulnerable populations such as children, the elderly, and people with respiratory or cardiovascular disease.

Specifically, the committee will:

1. determine the need for guidance on respiratory protection for the general public (including children and adults) and workers facing inhalation hazards outside of workplaces with known respiratory hazards subject to requirements for respiratory protection programs, including during disasters and public health emergencies. This should be based on an assessment of existing knowledge regarding the necessary factors (e.g., fit, filtration, fabric, airflow, leakage, etc.) to ensure respiratory protection is effective for its intended use (i.e., source control and/or protection) across different hazard scenarios and the identification of gaps in existing standards/guidance;
2. describe current and potential options for oversight and approval of respirators for these populations (i.e., workers who may need to use respiratory protective devices in the absence of a respiratory protection program and the general public); and
3. make recommendations for a framework of responsibilities and authorities, including those of federal agencies, to provide a unified and authoritative source of information and effective oversight in the development, approval, and use of respirators, including conformity assessment processes to meet the needs of these populations. As needed, the committee may consider recommendations to Congress regarding the implementation of the framework and the types of resources necessary for doing so.

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TABLE 1-1 Matrix of Populations and Hazards for Consideration in Selecting Respiratory Protection Use Scenarios as Focus Areas for This Study

	Air pollution (including wildfire smoke)	Biological agents (respiratory viruses, molds)	Chemicals from disasters/public health emergencies (accidental spills/environmental release following a disaster, chemical weapons)	Chemicals from regular occupational use (e.g., pesticides, cleaning solvents)	Inhaled radionuclides (accidental or intentional release)
Wildland firefighters					
Other trained emergency responders (paid and volunteer)					
Outdoor workers, including day laborers and other workers with temporary/informal occupational arrangements (e.g., agricultural workers)					
Indoor workers, including those with formal or temporary/informal occupational arrangements (e.g., grocery store workers, domestic day laborers, and home health workers)	(wildfire smoke)				
U.S. government workers overseas					
The public (adults and children, including those overseas, with nonoccupational exposures)					

NOTE: Colors indicate the priority of focus areas for the study: green indicates the highest-priority areas, yellow lower-priority areas, and orange the lowest-priority areas (which should be acknowledged but not be a major focus).
SOURCE: Adapted from D'Alessandro, 2020.

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personal devices that are worn to provide respiratory protection. In using this definition of respiratory protection, the committee recognizes that such devices can protect the wearers or, for some hazards (e.g., airborne microorganisms), protect others because infected people are the source, and the device reduces the amount of the agent they release into the air. Some devices may provide some level of protection to both the wearer and to others. While acknowledging that other forms of control (e.g., ventilation systems or vaccination) may be more protective when feasible to implement, the committee notes that such controls are not within the scope of this study.

A number of terms are used by federal agencies and others to describe the various personal devices designed and worn to reduce adverse health effects from inhalation hazards (see Annex 1-1 at the end of this chapter); however, no consistent descriptions of these devices—respirators, masks, face coverings, and barrier face coverings—exist. Below, the committee provides its descriptions of these devices for the purposes of this report, using terminology intended to be generally understood. Examples of these devices are depicted in Figure 1-1. In meetings with the committee, the study sponsors clarified that the focus of the study was not limited to respirators, but also included masks and face coverings.

Respirator is the term used in this report to describe personal devices designed to protect the user from the adverse effects of inhalation hazards. In the United States, respirators are designed, manufactured, tested, and approved for use in the workplace, and performance standards for respirators are embodied in federal regulation at 42 C.F.R. § 84. This regulation also assigns responsibility for testing and approving respirators to NIOSH—a research agency within the Centers for Disease Control and Prevention (CDC) focused on occupational safety and health.[2] NIOSH's rigorous conformity assessment program for respirators includes premarket evaluations, laboratory testing, examination of the manufacturers' quality control programs, and postmarket surveillance. NIOSH maintains a publicly available list of those respirators that have been approved and are authorized to use the NIOSH certification mark. The use of respiratory protection in the workplace is regulated by OSHA and other regulatory agencies at the federal and state levels. OSHA-mandated **respiratory protection programs** provide an established administrative structure for integrating control methods into

[2] Manufacturers in other countries produce respirators, and there are a number of different national and international respirator standards. These manufacturers can submit their respirators to NIOSH for testing and certification. NIOSH-approved respirators are the only respirators accepted for use in U.S. workplaces by OSHA and other regulatory agencies. Respirators that are tested and approved only to other international standards (for example, KN95s, FFP2s) are not acceptable for use in workplaces except under an emergency use authorization by the Food and Drug Administration.

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FIGURE 1-1 Examples of respirators, medical masks, face coverings, and barrier face coverings.
SOURCES: Photo of powered air-purifying respirator provided courtesy of 3M. Photo of barrier face covering provided courtesy of Puraka Masks, www.puraka-masks.com.

the workplace so as to effectively assess, control, and evaluate inhalation hazard exposures for workers. The regulatory landscape for respiratory protection is described in detail in Chapter 2. In an OSHA-mandated RPP, selection of a respirator must be based on an assessment of the hazard. Proper training of wearers on its use and fit testing are also required since many respirator types must be fitted to the individual user to ensure proper performance. (See Box 1-2 for further description of respirator types and factors influencing their selection.)

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BOX 1-2
Overview of Respirator Types and Factors That Influence Their Selection

This study focuses primarily on inhalation hazards from infectious agents and outdoor air pollution, including smoke from wildland fires, although its findings are broadly applicable to inhaled agents. Respirators selected for these hazards will likely be classified as air-purifying devices—those that remove harmful contaminants from the air—and fall into three general categories: filtering facepiece respirators (FFRs), elastomeric facepiece respirators, and powered air-purifying respirators (PAPRs). The term "N95," frequently used to refer to an FFR, denotes a NIOSH classification of the performance of a particulate respirator, embedded in regulation at 42 C.F.R. 84.170. An FFR or an elastomeric facepiece respirator that is approved as an N95 respirator has a filter that is at least 95 percent efficient at removing a highly penetrating submicron test aerosol; it is not approved for use in an environment where oil mist that may degrade the filter capability is present.

Air-purifying respirators, such as FFRs and elastomeric facepiece respirators, are generally designed to fit tightly to the wearer's face so that the contaminated air goes through the filter (or gas and vapor sorbent) and not through leaks around the facepiece. The proper use of these respirators requires that a fit test be performed to determine the size and model that fit the wearer. In addition, the wearer must perform a seal check each time the respirator is donned to determine that head straps are properly adjusted for a tight seal. These methods are thoroughly described in the OSHA Respiratory Protection Standard, discussed further in Chapter 2. PAPRs that utilize hoods or helmets are designed not to require a tight seal to the face as they provide a sufficient volume of air to minimize contaminants entering the facepiece other than through the filter or sorbent cartridges. These PAPRs do not require fit testing and can accommodate wearers with facial hair

For the purposes of this report, with the notable exception of dust masks[3] (or nuisance masks), **masks** are personal devices designed and intended to reduce the spread of infectious agents found in large droplets, such as those from saliva, sneezes, and coughs. They also may provide a barrier to infection by preventing users from touching their mouth or nose with contaminated fingers, although concerns have been raised that use of masks may increase face-touching behaviors, and thereby the risk of infection (Chen et al., 2020; Lucas et al., 2020). While they may be similar in construction and appearance, masks are not respirators. **Medical or surgical masks** (also commonly referred to as medical procedure, dental, or isolation

[3] Dust masks or nuisance masks are nonapproved devices that are worn to reduce exposure to airborne contaminants when working in dusty environments. They do not protect against toxic dusts and are not approved as respirators. In contrast with medical or surgical masks, no standards govern their construction or the quality of their filtration.

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that would be prohibited if FFRs or elastomeric facepiece respirators were being used.

In addition to air-purifying respirators, there are also atmosphere-supplying respirators, which supply breathable air from a safe source. However, these devices have limited relevance to the public and workers without respiratory protection programs and are not discussed in this report.

Different respirators and other devices confer differing levels of protection, and which device is appropriate will depend on the level of risk, which will vary with the context (e.g., type of hazard, severity of its impact on health, immediacy of impact, and likelihood and predictability of exposure or occurrence). The performance of respirators is tested in laboratories and in the field. Based on these results, OSHA assigns respirators a protection factor representing an estimate of the risk reduction expected when they are worn and used in an RPP that complies with OSHA requirements.

For most air-purifying respirators, fit and filtration efficiency are important characteristics that influence performance and selection. Filtration efficiency is a measure of how well the material of a respiratory protective device prevents particles from penetrating through the filter medium. Fit is a function of a device's seal to the face during use and determines the degree to which there may be leakage around the edges of the device. Fit characteristics vary across respirators, even among those of the same type, which can impact the level of protection achieved (Coffey et al., 2004). Other factors that may influence device selection include those that influence the comfort and usability of the device, including how difficult it is to breathe through the device (breathing resistance) and interference with communication. These factors are described in more detail in Appendix B.

While the text above addresses respirators, the committee recognizes that in some circumstances the general public may use masks and barrier face coverings rather than respirators, as with the current COVID-19 pandemic.

masks) are unfitted devices that may provide some protection against contamination of the surrounding environment by their wearers by reducing the amount of infectious agents released during exhalation, coughing, or sneezing. Surgical/medical masks may also provide some protection to the user against liquid splash and droplets, but they are not tested or intended as protection from inhalation hazards as they are not designed to fit tightly to the face. As discussed further in Chapter 2, medical or surgical masks sold as medical devices are required to be cleared by the Food and Drug Administration (FDA).

Face coverings are devices that cover the mouth and nose, but, absent testing at present, do not provide a known degree of protection. Face coverings may be mask-style devices (i.e., products that look like surgical/medical masks but are not FDA cleared and do not conform to any specific standard), bandanas, gaiters, or other configurations. They may be constructed

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of cloth in a single layer or multiple layers, filtering material, or a combination of base material and filter elements. **Barrier face coverings** are designed and manufactured to comply with the ASTM F3502-21 standard, which was released in February 2021 in response to the COVID-19 pandemic. These devices cover at least the wearer's nose and mouth, provide a measured degree of particulate filtration, and are intended to provide a better fit than masks and other face coverings, but there is no requirement for fit testing of the wearer.[4] They do not meet OSHA requirements for use in the context of an OSHA-mandated RPP, including training and fitting. The ASTM F3502-21 standard and the required testing are described further in Chapter 2. Barrier face coverings are not respirators and are not intended for medical use. In Europe, similar devices are known as community masks.

As described above, personal devices designed to reduce exposure to inhalation hazards may be used for personal protection and/or to protect others (i.e., source control). **Source control,** in the context of this report,[5] denotes reduction of the release of infectious agents from the wearer, which decreases the potential danger to others in the immediate environment. While respirators are designed specifically to protect the individual wearing the device from the risks of inhalation hazards, these devices also will function as a form of source control in the context of airborne infections when people become the source of the inhalation hazard, thus additionally serving to benefit public health. Masks and face coverings (including barrier face coverings) are intended primarily to reduce emissions of infectious agents by the wearer, and may also provide more limited protection against inhaling airborne infectious agents (and various forms of air pollution), depending on the device's fit and filtration characteristics. However, there are no standards for evaluating these devices for source control. FDA relies on ASTM tests for filter efficiency to determine that cleared devices are suitable to protect others. A similar approach applies to barrier face coverings, with the additional requirement that the manufacturer make some statement regarding the fit capability of the device. NIOSH-approved respirators will likely provide greater source control relative to masks or barrier face coverings because of their superior filter performance and because they are tight

[4] The purpose of fit testing is to determine that a respirator model and size adequately fit the individual user's face (NPPTL, 2021), which is important to minimize leakage around the sealing surfaces.

[5] Source control, in other contexts outside of this report, may refer more broadly to an approach designed to eliminate or reduce the introduction of harmful substances into the environment (e.g., curbing emissions into the air).

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fitting[6] (the filtration and fit of different devices are discussed in Appendix B). Many respirators, especially elastomeric facepiece respirators, have exhalation valves to improve comfort by reducing the resistance to exhaled air from the respirator. There has been debate and speculation regarding the significance of exhalation valves as a source of viral contamination from the wearer, leading some respirator manufacturers to redesign their elastomeric facepiece respirators so that they no longer have exhalation valves or have covers for these valves. The lack of a specific standard(s) for source control limits the proper selection of respirators, masks, face coverings, and barrier face coverings based on the hazard because the hazard arises from being in proximity to an infected individual or in an airspace containing infectious aerosol.

The ongoing COVID-19 pandemic and widely visible wildfire smoke, often present at unsafe levels, have heightened the public's awareness of various personal devices used to reduce exposure to these inhalation hazards, although likely not the distinctions among the devices that are often based on technical specifications and standards as described above. Much of the technical terminology used in this area is unfamiliar to the public, and the nuanced details that are appreciated by the technical community are hindrances to effective communication of key messages to workers and the public generally. For example, the public may not appreciate the differences among the various types of devices used to reduce the spread of airborne infection and the fact that some devices can function both as a form of source control to protect others and as a means of individual protection to reduce the inhalation of transmissible agents. Consequently, the committee views effective communication as a critical element of any framework for providing respiratory protection for the public.

In this report, the committee refers to the various types of devices now in use with the specific terms reflecting their characteristics and the processes under which they are manufactured: respirators, masks (e.g., surgical/medial masks), face coverings, and barrier face coverings. However, the absence of a field-accepted term encompassing all personal devices that provide protection against inhalation hazards when used effectively presented challenges during the course of this study, and if not addressed, the lack of an umbrella term will continue to pose impediments to effective communication regarding respiratory protection, particularly as device technology continues to evolve. To fill this need and for the purposes of this report and the framework described herein, the committee uses the term

[6] PAPRs, which are not tight fitting but are designed to keep contaminants from entering the hood by creating a positive pressure with a blower, dilute but do not filter exhaled air that is released into the environment.

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respiratory protective device.[7] This function-based definition acknowledges that each device may offer either personal protection or source control or both at varying levels. The blend of personal protection and source control is context specific (i.e., depends on both the device and the hazard in question). At present, this function-based definition is qualitative until data quantifying the efficacy of devices when used for personal protection and/or source control in different use scenarios, particularly for the public, are available. This function-based definition also should prove useful in the future as additional devices that may not fit into existing device categories are developed. However, the committee anticipates that terminology and definitions will be refined as its recommendations are pursued and it may be that a different umbrella term will be implemented.

STUDY CONTEXT

Inhalation Hazards and Their Contribution to the Burden of Disease

An understanding of how exposures to inhalation hazards occur in occupational or general environmental settings is critical for the design of respiratory protection strategies. Consistent with its charge, while acknowledging the important contribution of regulated workplace exposures to the burden of disease in the United States, the committee did not conduct a review of common and well-characterized occupational inhalation hazards (e.g., silica, coal dust), but instead focused on ambient air pollution and wildfire smoke, along with various forms of biological, chemical, and radioactive agents that may be encountered during public health emergencies or other incidents.

Harmful inhaled agents may present as PM of varying sizes and composition, as gases, as vapors, or as a combination thereof. The form and composition of an inhaled agent dictate the type of respiratory protection needed to prevent or limit exposure.

Exposure occurs when people come into contact with air that has been contaminated by inhalation hazards. Exposure is calculated for air pollutants as the product of the pollutant concentration in the place(s) where time is spent and the amount of time spent in that place. Intake refers to the amount of material entering the respiratory tract over the exposure period. Following intake, hazards must deposit in various regions of the respiratory tract in order to deliver a dose to the target site. For example,

[7] The committee recognizes that this usage constitutes an expansion of a term defined in existing international standards to refer to devices designed to protect the wearer against inhalation hazards.

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larger particles tend to deposit in the upper airways; smaller particles are generally of greater concern as they are more likely to penetrate to and deposit in the deepest portions of the respiratory tract, including the narrow, distal airways and the alveolar spaces where gas exchange takes place (Hinds, 1999); and some particle sizes deport with minimal efficiency and tend to get exhaled back into the environment (Hinds, 1999). Thus, dose refers to the amount of material that ultimately reaches a target organ or tissue. Exposure to inhalation hazards can lead to an array of adverse health outcomes, contributing to, causing, and exacerbating respiratory illnesses and increasing risk for such conditions as cardiovascular disease and cancer, among others (Bowe et al., 2019; EPA, 2019). The influence of the exposure time profile on the risk of adverse health outcomes resulting from an exposure depends on the dynamics of the underlying processes of injury. For exacerbation of asthma, for example, relatively brief periods of exposure may be relevant, even minutes at sufficiently high concentrations; such brief time periods are also relevant for airborne infections. For carcinogens, far longer timeframes are relevant.

The upstream drivers of exposure—the determinants of the potential for exposures—encompass the social determinants of health. For example, industrial sources of exposure are often located more densely in poorer neighborhoods in urban areas, as are busy roadways, increasing exposures to air pollution and the potential for unintentional spills or releases that create higher concentrations of airborne pollutants. To protect against the adverse effects of exposure, people may choose to leave a location where airborne contamination (e.g., wildfire smoke) poses a threat, or to modify the environment to be more protective (e.g., by reducing air exchange or adding air-cleaning devices). However, the ability to leave or modify one's environment to reduce exposure to a hazard will be limited for some groups (e.g., the elderly or infirm, workers housed by their employers and required to continue outdoor work), and the ability to do so will be influenced by the social determinants of health. During the COVID-19 pandemic, for example, workers in the service, food processing, and transportation sectors, typically in lower-wage jobs, were at elevated risk for infection because their jobs demanded contact with others and could not be carried out from remote locations.

Ambient Air Pollution and the Contribution of Wildfire Smoke

Ambient air pollution is a mixture of toxic substances that can arise from natural sources, such as wildfires, dust storms, and volcanoes, or from sources both stationary (e.g., manufacturing plants) and mobile (e.g.,

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combustion engines in motor vehicles, airplanes) associated with human activity. PM in ambient air pollution includes particles of varying sizes that are defined by cut-points in sampling (see Figure 1-2): PM_{10} refers to particles with aerodynamic diameters of 10 micrometers or less, while $PM_{2.5}$ denotes fine particles with aerodynamic diameters of 2.5 micrometers or less (EPA, 2021a). Both particle size and composition have implications for risk of adverse health outcomes.

Ambient air pollution contributes substantially to death and disability worldwide. In 2019, ambient PM pollution was one of three risk factors responsible for more than 1 percent of total disability-adjusted life years (DALYs) globally, with exposure levels increasing at a rate greater than 1 percent annually (Murray et al., 2020). In the United States, 100,000–200,000 excess deaths every year are attributable to air pollution, a figure that does not include the burden caused by wildfire smoke (Thakrar et al., 2020). $PM_{2.5}$ exposure in particular has well-established associations with

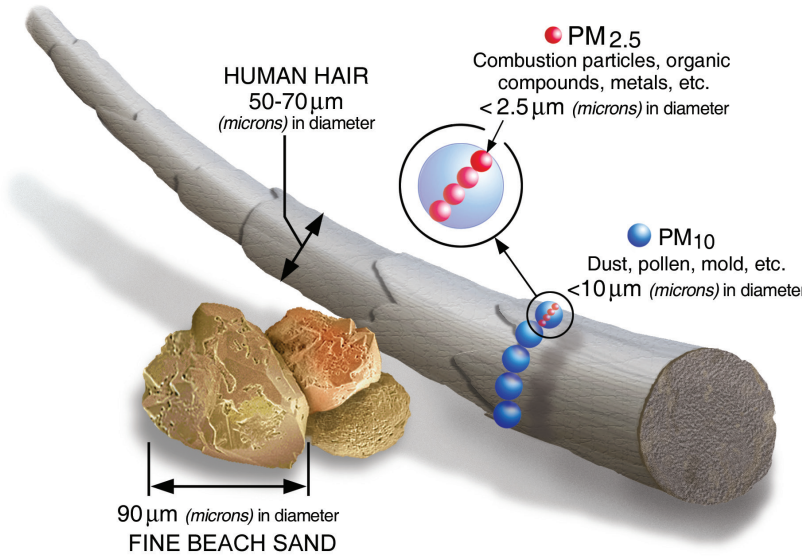


FIGURE 1-2 Comparison of particulate matter (PM) size fractions. PM exists in a variety of sizes—currently categorized by the Environmental Protection Agency (EPA) as $PM_{2.5}$ and PM_{10}—based on the aerodynamic diameter of the particles. The figure shows examples of PM that fall into each category and compares them against the diameter of a human hair.
SOURCE: EPA, 2021a.

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cardiovascular disease, type 2 diabetes, pneumonia, lung cancer, chronic obstructive pulmonary disease (COPD), and other adverse outcomes (Bowe et al., 2019; EPA, 2019), and this burden of disease is borne disproportionately by communities of color and those with lower incomes (Bowe et al., 2019). Climate-exacerbated air pollution is anticipated to increase the burden of related adverse health effects among disproportionately exposed populations, further contributing to the health disparities seen throughout the nation (Rudolph et al., 2018).

Wildfire smoke is an increasingly important source of high-level exposure to hazardous air pollution. $PM_{2.5}$ levels attributable to wildfire smoke have increased in recent years, particularly in the western United States but also in locations many hundreds of miles to the east (Burke et al., 2021). Beyond $PM_{2.5}$, wildfires generate other air pollutants, including ozone precursors (Xu et al., 2020), carbon monoxide, oxides of nitrogen, methane, and volatile organic compounds (Cascio, 2018; Flannigan et al., 2009; Urbanski et al., 2008).

Globally, approximately 339,000 deaths annually are attributable to exposure to smoke from wildland fires (Cascio, 2018; Johnston et al., 2012), as are various forms of respiratory morbidity, including exacerbation of symptoms of COPD, asthma, bronchitis, and pneumonia (Cascio, 2018; Doubleday et al., 2020; Liu et al., 2015; Reid et al., 2016; Stowell et al., 2019; Youssouf et al., 2014). Some populations may be especially susceptible to the adverse health effects of wildfire smoke, including older individuals and people with preexisting respiratory illness and chronic disease (Liu et al., 2015; Reid et al., 2016), as well as pregnant women (CDC, 2021e). There is also some evidence suggesting that exposure to wildfire smoke during gestation can be associated with preterm birth and birthweight reduction (Amjad et al., 2021; Heft-Neal, 2021). Children are susceptible because, compared with adults, they breathe more air relative to their body mass (i.e., they receive a higher dose), their lungs are still developing, and they are more likely to be exposed to smoke since they spend more time outdoors (EPA, 2018; Holm et al., 2021).

Biological, Chemical, and Radiological Inhalation Agents

Biological, chemical, and radiological agents are significant inhalation hazards faced by the public and workers not covered by RPPs. Whether these hazards are naturally occurring, originate from accidental releases, or are the result of acts of terrorism, the associated adverse health effects necessitate a wide range of respiratory protection methods.

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Biological agents of concern include bacteria, fungi, and viruses that can produce adverse health effects through infection and, for some agents, associated toxins (OSHA, 2021a). Communicable biological agents, such as respiratory viruses (e.g., influenza, measles, and chicken pox viruses), can be transmitted from person to person, while other biological agents may be infectious but not generally communicable. Molds, for example, which can pose risks to homeowners and recovery workers in the aftermath of a flood or hurricane (HUD, 2015), are not communicable from person to person, but inhaled spores can cause allergic reactions and hay fever symptoms, and potentially trigger asthma attacks (AAFA, 2015). Likewise, legionella bacterium, which causes severe respiratory disease in 10,000 to 28,000 individuals per year in the United States, is infectious via aerosol transmission but not communicable from person to person (Legionella.org, 2021).

Droplet transmission of communicable infectious agents occurs when particles greater than 100 micrometers in aerodynamic diameter (Samet et al., 2021) are propelled a short distance from an infectious source onto the mouth, nose, or eyes of a susceptible person (Jones and Brosseau, 2015; WHO, 2020). Airborne transmission, a term sometimes used interchangeably with aerosol transmission, involves the inhalation of aerosols or droplet nuclei—solid or liquid particles smaller than 100 micrometers in aerodynamic diameter—that are present in the air (Samet et al., 2021) and can remain infectious over a period of time and over longer distances (Jones and Brosseau, 2015; WHO, 2020). Additionally, compared with exposure to ambient air pollution, exposure to these agents tends to be spatially nonuniform and highly temporal.

Whether an infectious agent is communicable via the inhalational route and the mode of its transmission have implications for the selection of respiratory protection and where and when it is used. For example, surgical masks can be effective against larger-sized droplets by acting as a physical barrier and preventing these particles from reaching the respiratory tract (Tellier et al., 2019). By contrast, smaller-sized aerosols have a greater propensity to follow air flows, thus requiring a respiratory protective device with a tighter seal to protect the airways and a better filtering capacity than what a surgical mask can provide to ensure proper protection (Tellier et al., 2019).

Table 1-2 shows the enormous scale of the burden of disease associated with *Mycobacterium tuberculosis* (the cause of tuberculosis), influenza viruses, and coronaviruses, all of which are airborne transmissible biological agents.

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TABLE 1-2 Burden of Respiratory Disease Due to Select Airborne Transmissible Biological Agents as of November 2021

TYPE OF AGENT	PREVALENCE		MORTALITY	
	Global	U.S.	Global	U.S.
Mycobacterium tuberculosis	1.7 billion infected[a] 10 million ill	7,174 cases[b] (2020)	1.5 million[a]	526[b] (2019)
Influenza viruses	1 billion total cases[c] 3–5 million severe cases	35 million influenza-related cases[d] (2019–2020)	290,000–650,000[c]	20,000[d] (2019–2020)
Novel coronaviruses:				
a. SARS	8,098 cases[e] (2003)	8 cases[e] (2003)	774[e]	—
b. SARS-CoV-2	249,743,428 cases[f]	46,405,254 cases[g]	5,047,652[f]	752,196[g]
c. MERS-CoV	2578 cases[h]	2 cases[i]	888[h]	—

[a] CDC, 2020b.
[b] CDC, 2020a.
[c] WHO, 2019.
[d] CDC, 2021c.
[e] CDC, 2017.
[f] As of November 2021 (WHO, 2021b).
[g] As of November 2021 (CDC, 2021b).
[h] As of October 2021 (WHO, 2021a).
[i] CDC, 2019.

Chemical and radiological inhalation hazards are less frequent causes of public health disasters compared with biological hazards but can be extremely harmful to human health and the environment. Acute chemical incidents may result from leakages, explosions, and fires from, for example, damage to chemical plants and releases from railroad transport of chemicals (Bongers et al., 2008), such as chlorine gas. There have been several dozen public health disasters since 1940 during which large populations of people were exposed to chlorine gas (Culley and Svendsen, 2014).

Only specific types of respiratory protection are effective against a chemical inhalation hazard. Therefore, it is important to give careful consideration to proper respiratory protection in preparation for such an event, including the challenges of meeting surges in demand following large-scale incidents. Preparedness activities also need to take into account the

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respiratory protection and guidance needs associated with the potential for inhalation of radioactive dust during radiation emergencies. Preparedness needs to focus not just on those "responders operating within Radiation Control (Fallout) Areas" (DHS, 2016, p. 31), but also on a larger group of emergency responders and public health workers working outside of these "hot zones" who may not be covered by an RPP but may be exposed while attending to contaminated people being evacuated from the area (Ansari, 2021).

Current Approach for Providing Respiratory Protection in the United States

As discussed previously, the use of respiratory protection in the United States has historically been associated with occupational settings in which workers are exposed to defined inhalation hazards—for example, health care workers exposed to tuberculosis, firefighters exposed to smoke, and miners exposed to coal dust and silica (NIOSH, 2019). The United States has an employer-based approach to occupational respiratory protection whereby employers are required to ensure that their workplaces are safe and their employees are protected from hazards, including inhalation hazards; compliance with this requirement is overseen primarily by OSHA. Other federal agencies oversee safety and health for specific types of workplaces (e.g., the Mine Safety and Health Administration [MSHA] for mining-related inhalation hazards) or exposures (e.g., pesticide exposure for pesticide handlers, regulated by EPA).

Respiratory protection is best realized when considered in the context of a larger system for injury and illness prevention that allows for the identification of hazards, the development of prevention and control measures to address these hazards, and evaluation of the efficacy of this system as part of an ongoing feedback loop. The hierarchy of controls (see Figure 1-3) is a framework initially developed for occupational settings[8] as a component of such systems to limit the number of workers exposed to hazardous materials, reduce the intensity of exposures, and provide the most effective protection available (NASEM, 2019). Control methods at the top of the

[8] Although the hierarchy of controls has traditionally been used as a means of determining how to implement control measures to protect workers, it can also be applied to protecting the health and safety of the public from such inhalation hazards as smoke and infectious agents. Management of COVID-19, for example, has required the concurrent implementation of administrative and engineering controls, such as mandated social distancing protocols (CDC, 2021d) and improved ventilation within schools, as means of protecting public health (NASEM, 2020).

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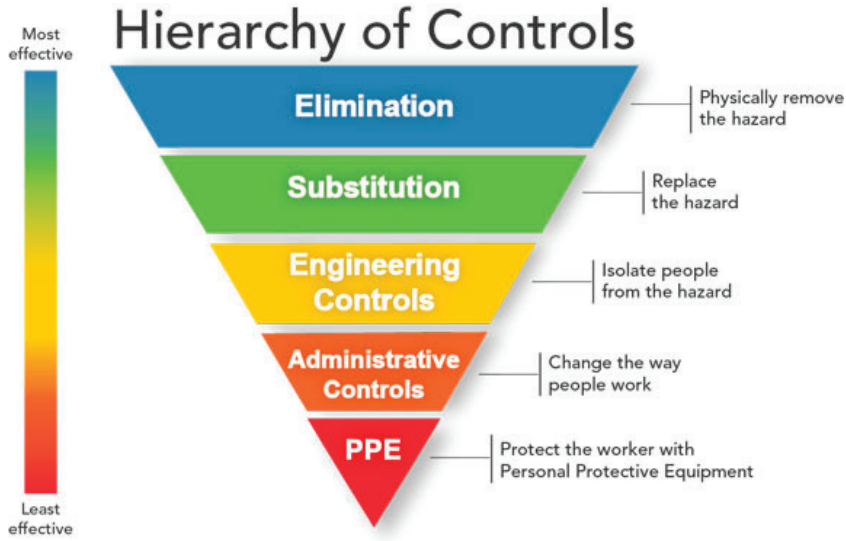


FIGURE 1-3 The hierarchy of controls, defining the categories of actions that can be taken to prevent the exposure of workers to known inhalation hazards.
NOTE: PPE = personal protective equipment.
SOURCE: NIOSH, 2015b.

hierarchy, such as *elimination*, *substitution, or engineering controls*, are typically more effective and reach more broadly than those at the bottom, such as *personal protective equipment* (PPE), use of which often occurs concurrently with other control methods. However, those higher-level controls may be more difficult to implement (NIOSH, 2015b) and, particularly in the case of engineering controls, can require higher initial capital costs, even though they may be more financially sustainable in the long term (NIOSH, 2015a). Compared with engineering controls, the use of PPE incurs a lower initial capital expense but is costly to maintain over time and requires adequate distribution, a system of oversight, and individual-level training on the devices' use and maintenance. The conduct of hazard and exposure assessments to determine which hazards are present and the potential for exposure forms the basis for understanding the effectiveness of different control strategies and is the first step in ensuring people's protection.

In workplaces where measures higher in the hierarchy of controls are insufficient to reduce hazardous exposures to known inhalation hazards and PPE in the form of respirators becomes necessary to protect the health

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of employees, employers may be required by OSHA (or by other federal agencies with oversight authorities for specific populations or hazards) to establish an RPP to guide the selection and the safe and effective use of respirators that have been approved by NIOSH. Thus, while OSHA sets and enforces standards for use of respirators in workplaces to ensure safe and healthful working conditions, NIOSH—a research agency within CDC focused on occupational safety and health—establishes and enforces performance standards for respirators for workers. While some inhalation hazards are limited primarily to specific occupational settings, others, such as wildfire smoke, ambient air pollution, and respiratory viruses, may be ubiquitous, with exposures not limited to the workplace. Yet for members of the public and workers not covered by an RPP, no clear authorities are tasked with ensuring that respiratory protection meets user requirements or with providing information and guidance on the selection and use of these devices.

Origin of the Study

While the recommendations of this report will necessarily be viewed through the current lens of the global experience with the COVID-19 pandemic, recognition of critical gaps in the nation's system for meeting respiratory protection needs preceded the emergence of SARS-CoV-2. Prior to the pandemic, NIOSH and its National Personal Protective Technology Laboratory (NPPTL) initiated efforts to address these gaps through discussions with the Department of State, EPA, the United States Forest Service, and other federal public health stakeholders regarding respiratory protection needs associated with exposure to wildfire smoke for the public and workers not covered by RPPs. As a result of increasing concerns among the public about wildfire smoke and associated poor air quality, NIOSH/NPPTL, along with EPA, had to field questions about the use of respiratory protection to mitigate this hazard (D'Alessandro, 2020). EPA also was asked for guidance on mitigating the harmful effects of mold exposure following flooding, which has become a frequent phenomenon in certain parts of the country. In parallel, Americans working overseas in locations with high levels of air pollution—such as China, India, and Indonesia—have sought guidance from the Department of State on safe and effective respiratory protection for themselves and their families (Huson et al., 2020). As noted, however, there are no clear authorities for providing such guidance.

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A New Sense of Urgency

When the COVID-19 pandemic hit the United States in early 2020, it underscored the need to address gaps in oversight and messaging around respiratory protection for the public and for workers not previously considered at risk from inhalation hazards. An initial ad hoc approach to respiratory protection for the public and unclear messaging created significant confusion as to the purpose of respiratory protection and when to use it. Even after the use of respiratory protective devices had become common practice amongst the public, confusion persisted as to their purpose (protecting the wearer versus protecting others), the type of products that should be used (e.g., cloth face covering versus surgical mask versus respirator), who should wear them, and when and where they should be worn. Inconsistent public health messaging and widespread misinformation worsened the confusion (Schwellenback and Zagorin, 2020; Shelus et al., 2020; Stoller, 2021). Moving forward, the nation cannot afford to repeat the ad hoc and inconsistent measures taken during the pandemic to address safety and respiratory protection; the same holds for wildfires. The public and all workers need to be able to turn to a clear and authoritative source of information, and a system for providing accurate guidance and effective messaging needs to be in place.

STUDY APPROACH

Given the complexities of the systems for respiratory protection described throughout this report, the committee undertook its charge by taking a systems approach. As discussed below, this approach had to build on a foundation of concepts of risk and how it can be reduced. Illustrative examples of inhalation hazards, most notably related to wildfire smoke and COVID-19, are woven throughout the report to ground the discussion in real-world scenarios requiring the use of respiratory protection.

Guiding Principles

The committee's approach to its charge was grounded in guiding principles that emerged from discussions among its members. These principles reflect issues that will underlie the development and functioning of all components of a future system for respiratory protection, and accordingly guided the development of the committee's framework and its recommendations:

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- No person should be subject to adverse health effects from inhalation of respiratory hazards. All possible measures should be taken to control the risk of exposure to such hazards at their source. When elimination, engineering, administrative, and other controls are not feasible or available, effective respiratory protective devices should be available for the public as well as all workers.
- A framework for respiratory protection should incorporate a systems approach, given the diverse processes (e.g., hazard identification and assessment, product design and manufacturing, device selection and use) and the many and diverse stakeholders involved. Feedback loops are critical components supporting refinement and improved effectiveness of the system over time.
- Respiratory protection does not confer absolute protection. Although a level of risk remains with available devices, respiratory protection decreases the risk for harms to health. When details of a hazard are known, appropriate respiratory protection should decrease risk to a level considered acceptable based on a structured risk assessment.
- Recommendations on respiratory protection for the public, especially during public health emergencies, will be based on evolving and incomplete information, which will necessitate decision making under uncertainty. Therefore, the actions taken and recommendations made in response to such emerging evidence must be guided by the ultimate aim of optimizing benefits to public health. Decisions should be justified and explained in a transparent fashion, and should take into account the context, cultural characteristics, socioeconomic conditions, and linguistic needs of those who are most vulnerable.
- The framework for a respiratory protection system needs to incorporate preparedness into every process, or failures may occur during times of acute need or stress (i.e., during disasters or public health emergencies). Efforts to enhance preparedness need to have a broad reach, from individuals and systems to private- and public-sector entities. Preparedness must also include robust mechanisms for surveillance and scientific research (to address the aforementioned uncertainties).
- The population requiring access to functional, acceptable, and accessible respiratory protection is highly heterogeneous across multiple dimensions: age, racial and ethnic background, variation in facial profiles, underlying health and disease status, level of education, income, language, geographic location, and others. Ensuring equitable access to effective respiratory protection for all people in

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all subgroups of the population, as defined by these and other factors, represents a challenge that must be met by all aspects of the framework.

A Risk-Based, Systems Approach to the Development of a Framework for Ensuring Access to and Effective Use of Appropriate Respiratory Protection

Framing Risks

In the context of this report, the term "risk" refers to the likelihood that a hazardous exposure will result in an adverse outcome. A further imperative for respiratory protection comes from the severity of the potential adverse outcomes. The goal of respiratory protection, regardless of who is using it, is to reduce the risk of adverse responses to inhaled agents. Figure 1-4 provides a simplified version of a toxicological paradigm that extends from the sources of hazardous agents to the consequences of exposures—an increase in risk for one or more adverse health outcomes. Control measures within the hierarchy of controls (described earlier in this chapter) are directed at the connection between the source and exposure. Examples include engineering controls to reduce emissions or to increase ventilation of indoor spaces so as to reduce the concentration at which exposure occurs, and administrative controls, such as social distancing. When such higher-level forms of protection in the hierarchy are unavailable, insufficient, or inapplicable, respiratory protection reduces the amount of hazardous agent inhaled (and, by extension, the dose received). This paradigm applies to both target populations for this report: workers not covered by RPPs and the general population.

The NIOSH conformity assessment framework for PPE, which provides a structure for ensuring that a product will perform as intended (see Chapter 2), has "hazard & risk assessment" as a primary driver. For those workers covered by an RPP mandated by OSHA or MSHA, the goal is to prevent the consequences of known exposures to hazardous substances with identified adverse outcomes. For those specific agents and environments targeted by RPPs, the hazards are well established, and dose-response relationships are generally characterized. The circumstances of workplace exposures are also generally known with regard to concentrations typically encountered, the temporal profile of exposure, and the duration of exposure. The risks of these exposures can reasonably be predicted without great uncertainty. In contrast, the evidence is far more limited for many agents that pose risks to workers not covered by RPPs and to the public.

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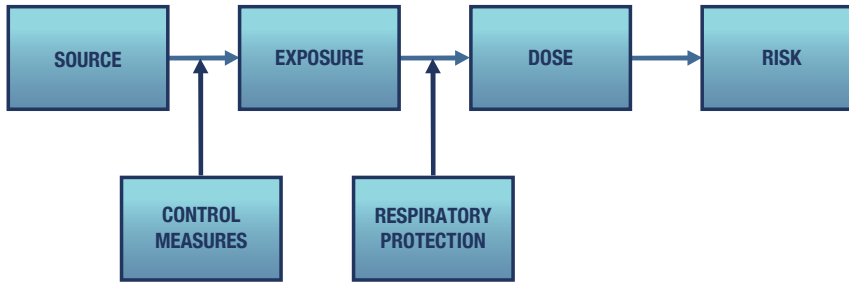


FIGURE 1-4 A general risk reduction paradigm for protection against inhaled agents. This figure provides a simplified view of the risk reduction paradigm, and shows the role of control measures and respiratory protective devices in reducing risk in the context of hazard exposure and dose.

The model for workplace RPPs offers a useful benchmark for considering the hazards faced by the general population and by those workers not covered by an RPP. However, for the populations—workers not covered by an RPP and the public—that are the targets of this study, the specificity that characterizes the OSHA and MSHA programs is lacking; the agents of concern and the circumstances of exposure are broad and not readily specifiable; the populations affected are diverse and varying in demographic characteristics, vulnerability,[9] and susceptibility;[10] and exposures and risks may not be readily quantified.

With regard to the committee's charge, an overall goal of any new respiratory protection system is to reduce risk from inhalation hazards to an acceptable level. In his 1976 book *Of Acceptable Risk: Science and the Determination of Safety*, William Lowrance writes: "A thing is safe if its risks are judged to be acceptable" (Lowrance, 1976). As the committee proposes a new framework for respiratory protection, that framework should have the goal of ensuring that risk remains within acceptable levels. To that end, first, risks need to be quantified so they can be judged, and, second, the acceptability of those risks needs to be determined. The challenges inherent in addressing these two tasks to achieve acceptable risk are evident.

The acceptability of risk is determined on a national level through legislation, executive branch regulations and enforcement, court decisions, and

[9] The committee defines vulnerability as the likelihood of an individual being exposed to a hazard because of who they are or where they work, study, play, or live. Interindividual variability across these factors and others is associated with differences in exposure. For example, living closer to the source of an inhalation hazard may increase exposure and thus vulnerability.

[10] Susceptibility can be defined as an individual's risk for harm when exposed to a particular hazard. Susceptibility may be influenced by such factors as genetics, health status, and age, depending on the particular hazard.

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public engagement through a variety of channels (e.g., nongovernmental organizations). Risk assessment is a central feature in some of these contexts, providing a mechanism for evaluating public health issues, developing policy, prioritizing research, and directing funding (NRC, 2009). EPA has formal procedures for risk assessment that include identifying the hazardous exposure and characterizing its health effects, measuring the level of exposure in environmental media, and estimating the dose received by individuals through various known routes of exposure. Risk communication and risk management follow.

U.S. regulatory efforts for environmental and occupational exposures assume that society will tolerate some risk to obtain the potential benefits of use of the hazardous substance. Societal acceptance has changed dramatically over time, but in general is lower for hazards that affect children or those for which exposure is perceived to be involuntary. EPA regulations typically are aimed at reducing the risk of lifetime adverse health effects, such as cancer, to between 1 in 10,000 and 1 in 1,000,000 excess deaths (EPA, 2021b). By contrast, the Occupational Safety and Health Act's economic and technological feasibility requirements, as well a Supreme Court decision,[11] have limited OSHA's ability to set risk levels as low as those of EPA, allowing it to identify an acceptable exposure level above which it can issue fines or take other enforcement actions. In contrast, regulatory agencies in the European Union, upon determining that a hazard exists, require that it be reduced to levels that are as low as is reasonably achievable.

These regulatory and judicial precedents, however, have limited applicability to the target populations for this report. The methods for determining whether a hazard exists and quantifying risk are applicable, but the risk thresholds described above have uncertain relevance to establishing a framework for respiratory protection.

For workers not currently covered by an RPP, there are many gaseous and particulate workplace contaminants that might contribute to risk. The list is similarly expansive for the public. Some of these hazards (e.g., dust storms and accidental releases at chemical plants) have been long-standing, while others, such as airborne infectious agents and wildfire smoke, are emerging with greater intensity and are likely to become more frequent and severe. Moreover, exposure profiles are likely to vary in time, place, and intensity. In the case of wildfires, for example, persons adjacent to a fire or directly impacted by smoke plumes may be exposed to high levels of smoke with $PM_{2.5}$ concentrations exceeding health-based National Ambient Air Quality Standards by a factor of 10 or more. Typically, people would tolerate such conditions only briefly and take steps to distance themselves

[11] *Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607 (1980) (generally referred to as the "Benzene decision").

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if possible. Yet, some exposures, albeit at lower levels, may last for weeks and even months, as occurred with recent fires in California, Colorado, and Canada.

For both workers not covered by an RPP and the public, judgments about the acceptability of the risks posed by inhalation hazards cannot readily and immediately be made, given the wide range of exposures and broad spectrum of susceptibility, as well as the present lack of a path for achieving consensus on what constitutes an acceptable level of risk. There are also two broad perspectives to be taken: reduction of individual risk and of population risk. Finally, the potential for limiting exposure varies across subgroups of the population. In its general framework for respiratory protection and its frameworks for the two populations targeted by this study—workers not covered by an RPP and the public—the committee addresses the need to incorporate estimates of risk and consideration of its magnitude, but does not provide guidance on specific methods for doing so, an issue beyond the scope of the committee's charge.

Adopting a Systems Approach to Respiratory Protection

In early discussions with the study sponsors regarding the study scope, the committee was encouraged to adopt a systems view of respiratory protection in addressing its task.

A systems approach, as conceptualized by the committee, seeks to understand the system elements that influence the desired outcome (in this case, access to and effective use of respiratory protection), as well as the relationships among those elements. Based on this understanding, approaches (e.g., designs, constructs, processes, policies) to achieving the desired outcome can be identified. In the context of this report, the systems approach has two distinct applications. The first is the committee's development of a framework of authorities and responsibilities, central to its charge, which required consideration of complex and interdependent roles, processes, and resources of stakeholder organizations. The second application relates to the committee's review of the evidence on factors that influence the effectiveness of respiratory protective devices, as measured by reduced exposures and risk of adverse health outcomes from inhalation hazards, along with associated gaps. In this application, the committee adopted an ecological model (see Figure 1-5) as a foundation for exploring the varied system components (e.g., devices, users, societal factors) involved and their interrelationships. Thus, the committee's information-gathering approach included not only the specific characteristics of different devices (e.g., fit, filtration), but also a range of factors within a broader system related to how, whether, and when respiratory protection is used (e.g., sociobehavioral,

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environmental, and regulatory factors). This approach is particularly crucial for understanding use of respiratory protection by the public and by workers not covered by an RPP because for these populations, no structure currently exists for selecting and providing an appropriate device and then, importantly, ensuring its effective use.

Approach to the Development of the Committee's Frameworks

In developing and defining its frameworks, the committee

- evaluated other frameworks and systems in place (e.g., National Planning Frameworks for National Preparedness, Public Health Emergency Medical Countermeasures Enterprise) to ensure the health and safety of the nation during unforeseen events, such as terrorist incidents and natural disasters;
- applying the set of guiding principles presented above, identified the key characteristics or capabilities required to ensure access to and effective use of respiratory protective devices while overcoming the shortcomings of the current system, as enumerated in the conclusions presented in Chapters 2 through 4;
- identified the current stakeholders, if any, engaged in carrying out activities to evaluate inhalation hazards and ensure the availability and effective use of respiratory protective devices;
- explored the potential to expand the existing responsibilities and authorities of these current stakeholders to carry out the necessary activities in the committee's proposed frameworks and associated challenges, if any; and
- identified a set of key strategic, organizational, regulatory, and operational factors important to ensuring successful implementation of the proposed frameworks.

The committee was charged with recommending a framework of responsibilities and authorities related to oversight and guidance for respiratory protection; the implementation of this framework is beyond the study scope. Moreover, given the diversity of inhalation hazards and scenarios for use of respiratory protection, the framework's implementation will necessarily be complex and iterative. Accordingly, the committee does not explore implementation approaches in depth in this report, but provides illustrative examples of approaches that might be considered when such examples are helpful in describing the framework.

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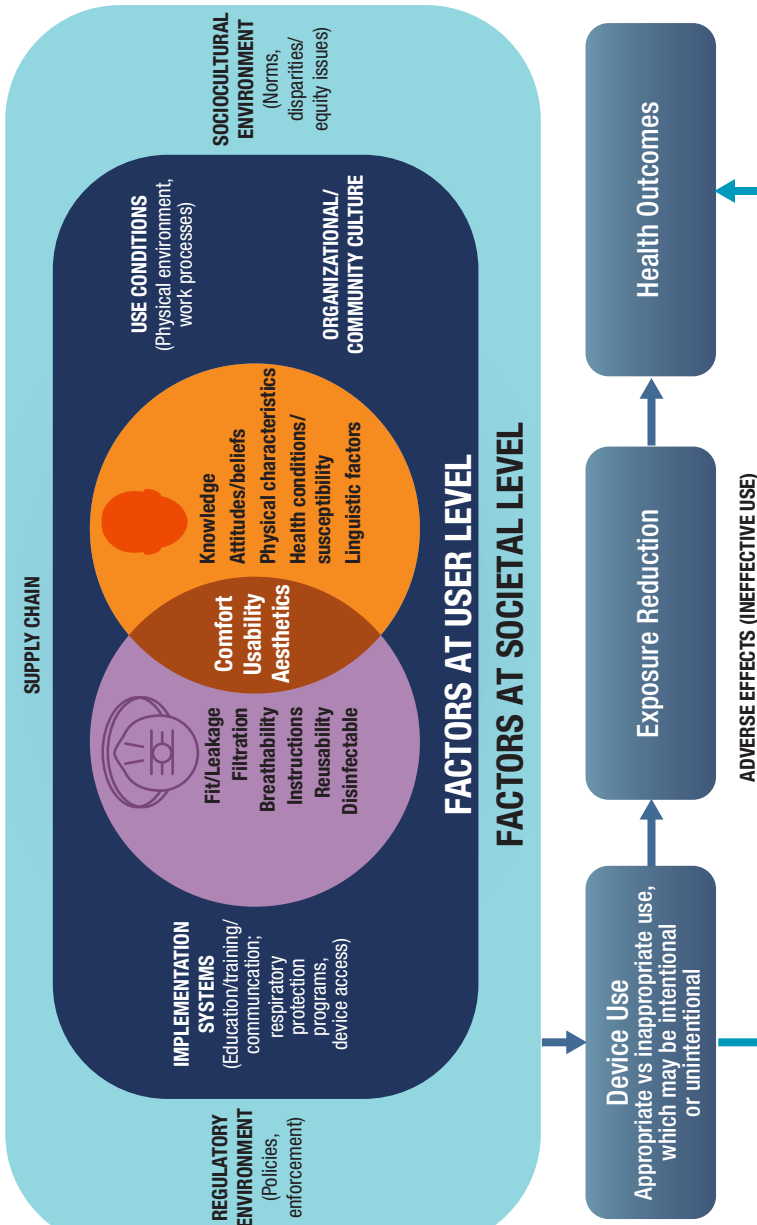


FIGURE 1-5 A system model depicting factors that influence the effectiveness of respiratory protective devices. This model shows the many interrelated factors that function within the system of respiratory protection.

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Comprehensive Literature Reviews

The committee was charged with determining current gaps in and the need for guidance for the public and workers not covered by an RPP across a range of inhalation hazards (see Table 1-1). In the language of the charge and during the first committee meeting, one of the sponsors emphasized that this evaluation of gaps in guidance should be based on an assessment of existing knowledge about the spectrum of factors that influence the effectiveness of respiratory protection used by specific user populations for specific inhalation hazards. The committee approached this aspect of its charge by carrying out comprehensive reviews of the literature to capture what is currently known about these factors across a set of prioritized use scenarios (see the section "Prioritizing Comprehensive Review Topics" below). Using this approach, the committee sought to capture literature on the breadth of interrelated factors within the system model depicted in Figure 1-5 above and to assess where research may be needed to understand the nuances of effective use of respiratory protection across different use scenarios. For example, the committee reviewed literature on traditional measures of performance, such as fit and filtration efficiency, but also on user-oriented considerations—such as comfort, usability, and attitudes and perceptions—as well as broader factors within the user's environment and society, such as the regulatory environment, access to and availability of products, and education and training, among others.

The committee uses the term "comprehensive reviews" to denote the deep dives requested by the sponsors, and notes that these were not systematic reviews using, for example, Cochrane or other methods. Given the constraints of time and available resources, such formal systematic reviews were not feasible. The findings from its reviews informed the committee's understanding of user needs across the prioritized use scenarios (see Appendix B). The committee notes that the paucity of literature on respiratory protection in the context of some of those scenarios limited the conclusions that could be drawn and instead indicated where research is needed to inform future guidance. Gaps and needs related to guidance are discussed in Chapters 3 and 4 for workers not covered by RPPs and the public, respectively, and draw on the findings from the literature reviews and an assessment of existing guidance related to inhalation hazards faced by these populations, including SARS-CoV-2 and wildfire smoke. However, the development of guidance for specific inhalation hazards was beyond the scope of the committee's charge.

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Prioritizing Comprehensive Review Topics

In approaching its comprehensive reviews, the committee needed to establish priorities in addressing an expandable matrix of agents, exposure scenarios, and populations (see Table 1-1). An initial matrix, which was provided by the sponsors, included six different populations of interest and five different sets of agents, some comprising complex mixtures (e.g., ambient air pollution and wildfire smoke). The agents identified as potential foci for the committee's reviews are all known to pose health risks, but through quite diverse mechanisms: inflammation (e.g., wildfire smoke), infection (e.g., respiratory viruses), and radiation (e.g., internal emitters). Exposure scenarios are also quite diverse, extending from acute to chronic (e.g., brief exposures to high levels of particles during a dust storm versus sustained exposures of wildland firefighters across repeated fire seasons). The scope of populations involved is also wide-ranging, from the entire U.S. population to particular worker groups.

From this matrix, cells defined by population and agent were selected based on the potential size of the exposed population, the likelihood of different exposure scenarios, and the risk posed by the agent. Together, these parameters define the potential burden of risk that could occur and provide insights as to the potential benefits of respiratory protection measures. The nature of the health outcome consequent to exposure was also considered.

For example, as of this writing, the COVID-19 pandemic is ongoing. The entire global population is at risk, with a range determined by the likelihood of exposure. For the public, the spectrum of risk reflects characteristics determining the likelihood of a more serious outcome (e.g., hospitalization or death). For workers, risk depends on the likelihood of face-to-face contact with infected individuals, also covering a range that is defined at its high end by front-line health care workers.

The committee used its judgment around these determinants of individual- and population-level risk, specifically

- the likelihood of exposure to the agent,
- the profile of exposures in time and place,
- the size of the population(s) potentially exposed,
- the distribution of susceptibility within the exposed population(s),
- the nature of the adverse health effects caused by the agent, and
- the burden of ill health and disease caused by the agent and the potential for a respiratory protection program to reduce that burden.

Based on these considerations, the committee prioritized its work to focus on specific exposure scenarios (defined by agent and population) in the matrix (see Table 1-1).

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Methods for the Reviews

Appendix A describes the detailed methodology and supporting materials for the committee's comprehensive reviews; a brief overview of the methodology is included here. To reiterate, the committee did not conduct systematic reviews; consequently, PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagrams are not provided, and a formal system for study evaluation was not implemented.

Literature searches for each of the ten comprehensive reviews were carried out in PubMed, Scopus, and EMBASE using lists of search terms developed through review of relevant articles and committee discussion. In some cases, additional articles were identified for inclusion in a review through reference mining, targeted searches, and committee input. Article titles and abstracts were screened for further full-text assessment for inclusion in the review based on the committee-approved criteria of interest described above (population, exposures, and outcome of interest). Articles that failed to meet these screening criteria were excluded. Full article texts were assessed using the criteria described in Appendix A. Committee members applied judgment in selecting articles for ultimate inclusion in the synthesis and excluded those that had limited relevance or applicability to the U.S. context, as well as those for which there were concerns regarding major methodological limitations (e.g., failure to use reproducible test methods and controls). A table summarizing the number of articles retrieved through the searches and remaining after screening can be found in Appendix A. A narrative synthesis of the evidence from the included articles was generated, and the committee identified key findings for each summarizing the salient points regarding what is known about factors that influence the effectiveness of respiratory protection within these use scenarios (see Appendix B).

The findings from the comprehensive reviews identify factors that influence the effective use of respiratory protection within the contexts of specific use scenarios, as well as many gaps where further research is needed. Findings from the reviews were integrated into Chapters 3 and 4 as part of the evidence base for descriptions of the current state of and critical needs for use of respiratory protection by workers not covered by an RPP and the public, respectively.

To address the aspect of its charge related to determining the need for guidance, the committee supplemented its reviews of the peer-reviewed literature with a separate assessment of the landscape of standards and guidance on respiratory protection for selected use scenarios in Table 1-1. For the purposes of this assessment, guidance included written, visual, or auditory information on webpages provided directly to users or to other stakeholders with roles in guidance dissemination (e.g., employers, public

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health professionals, clinicians) for the purpose of supporting the selection, proper use, care, and disposal of respiratory protection for the hazards of interest. Information on standards and guidance was collected through a search of the gray literature, from sources that included PPE-Info;[12] consensus standards organizations; and reports and webpages of federal agencies, state and local public health and air quality agencies, labor unions, professional associations, and academic and nonprofit institutions.

Other Information-Gathering Approaches

To supplement the evidence captured from its comprehensive literature reviews, the committee employed a multipronged approach to addressing knowledge gaps. Committee meetings held in November 2020, January 2021, July 2021, and October 2021 included public information-gathering sessions that provided an opportunity to hear from various stakeholders, including worker populations; representatives of national, state, local, and tribal public health agencies; manufacturers of respiratory protective devices; and federal agencies with oversight responsibilities and authorities related to respiratory protection and/or inhalation hazards (see Appendix A for all public meeting agendas and description of the committee's deliberative process). Additionally, a request for clarifying information was made to NIOSH/NPPTL in September 2021 as follow-up to information shared at the July 2021 public meeting.

Finally, recognizing that the development of a framework of authorities and responsibilities would need to be grounded in a clear understanding of the existing statutes and regulations that address inhalation hazards and respiratory protection, the committee commissioned a paper on the regulatory landscape for respiratory protection (see Appendix C).

ORGANIZATION OF THE REPORT

This report is organized into seven chapters. Following this introductory chapter, Chapter 2 provides an overview of the regulatory landscape for respiratory protection, including critical gaps in current systems for ensuring access to and effective use of respiratory protective devices. Chapters 3 and 4 examine the needs, experiences, and challenges related to use of respiratory protection by workers and the public, respectively. Chapter 5 presents the committee's general framework for respiratory protection,

[12] NIOSH's PPE-Info database serves as a compendium of federal regulations and consensus standards relevant to PPE and can be accessed at https://wwwn.cdc.gov/PPEInfo (accessed September 24, 2021).

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including core functions, stakeholder responsibilities, and the authorities necessary to address current gaps in the nation's system for oversight of respiratory protection. In Chapters 6 and 7, the committee explores the application of this general framework in frameworks specifically targeting workers and the public, respectively, and presents recommendations designed to ensure access to and effective use of respiratory protective devices by these two populations.

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ANNEX 1-1 RESPIRATORY PROTECTIVE DEVICE TERMINOLOGY

ANNEX TABLE 1-1 Definitions and Descriptions of Respiratory Protective Devices from Federal and Other Sources

DEVICE	AGENCY	DEFINITION
Respirator	Food and Drug Administration (FDA)[a]	An **N95 respirator** is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. Note that the edges of the respirator are designed to form a seal around the nose and mouth.
	42 C.F.R. 84[b]	**Respirator** means any device designed to provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.
	Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard (ETS)[c]	**Respirator** means a type of personal protective equipment (PPE) that is certified by the National Institute for Occupational Safety and Health (NIOSH) under 42 C.F.R. § 84 or is authorized under an emergency use authorization (EUA) by FDA. Respirators protect against airborne hazards by removing specific air contaminants from the ambient (surrounding) air or by supplying breathable air from a safe source. Common types of respirators include filtering facepiece respirators, elastomeric respirators, and powered air-purifying respirators (PAPRs). Face coverings, facemasks, and face shields are not respirators.

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Face mask	FDA[a]	A **face mask** is a product that covers the wearer's nose and mouth. Face masks are for use as source control by the general public and health care personnel (HCP) in accordance with CDC recommendations, and are not personal protective equipment. Face masks may or may not meet any fluid barrier or filtration efficiency levels; therefore, they are not a substitute for N95 respirators or other filtering facepiece respirators.
	OSHA ETS[c]	**Face mask** means a surgical, medical procedure, dental, or isolation mask that is FDA-cleared, authorized by an FDA EUA, or offered or distributed as described in an FDA enforcement policy. Facemasks may also be referred to as "medical procedure masks."
Surgical mask	FDA[a]	A **surgical mask** is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. Surgical masks are regulated under 21 C.F.R. § 878.4040.
	OSHA ETS[c]	**Surgical mask** means a mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests. Surgical masks are generally regulated by FDA as Class II devices under 21 C.F.R. § 878.4040—Surgical apparel.

continued

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ANNEX TABLE 1-1 Continued

DEVICE	AGENCY	DEFINITION
Barrier face covering	FDA[a]	A **barrier face covering,** as described in ASTM F3502-21, is a product worn on the face specifically covering at least the wearer's nose and mouth, with the primary purpose of providing source control and a degree of particulate filtration to reduce the amount of inhaled particulate material. Barrier face coverings are not a substitute for N95 respirators and other filtering facepiece respirators.
	ASTM[d]	A **barrier face covering** is a product worn on the face, specifically covering at least the wearer's nose and mouth, with the primary purpose of providing source control and a degree of particulate filtration to reduce the amount of inhaled particulate matter.

[a] FDA, 2021.

[b] 42 C.F.R. § 84.174.

[c] OSHA, 2021b.

[d] ASTM, 2021.

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2 The Regulatory Landscape for Respiratory Protection

This chapter describes the regulatory landscape for respiratory protection in the United States, which involves multiple agencies at the federal and subfederal levels with varying responsibilities and authority regarding different inhalation hazards. The chapter examines separately the authorities related to use and approval of respiratory protection, as well as supply issues. The evaluation of gaps and overlaps in authority highlighted in this analysis is intended to inform the need for a framework to ensure access to and effective use of respiratory protection by the public and all workers (see Chapter 5). The chapter also describes conformity assessment processes for respiratory protection and the challenges and limitations of current approaches.

USE OF RESPIRATORY PROTECTION IN THE WORKPLACE[1]

This section summarizes the federal and state authorities relevant to protection of workers from inhalation hazards, including approval of devices and requirements for use of respiratory protection in the workplace.

[1] This section draws on a paper commissioned by the committee on "The Regulatory Landscape Regarding Respiratory Protection," by Arden Rowell, J. D. (see Appendix C).

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Federal Oversight of Use of Respiratory Protection in the Workplace

The Occupational Safety and Health (OSH) Act of 1970[2] gave the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) substantial authority over regulation of the health and safety of many workplaces and over respiratory protection of workers in those workplaces. Other federal agencies, including the Environmental Protection Agency (EPA), have authority over specific inhalation hazards and in specific workplaces. The authority of different federal agencies for use of respiratory protection in the workplace are described in the sections below.

OSHA's Oversight Authorities Regarding Use of Respiratory Protection in the Workplace

OSHA is empowered to issue and enforce safety standards to ensure that workers are protected from safety and health threats in the workplace.[3] OSHA's Respiratory Protection Standard[4] requires employers to establish and implement a respiratory protection program (RPP) for workplaces where respirators are necessary to protect the health of employees from known inhalation hazards when higher forms of protection are insufficient (see Box 2-1 for the components of an OSHA-compliant RPP). At workplaces where respirators are not found to be "necessary to protect the health of the employee," no RPP is required.[5] As discussed further in Chapter 3, the Respiratory Protection Standard does allow for voluntary provision and use of respiratory protection in these workplaces, though it imposes limitations on that voluntary use. The employer is required to provide the employee with guidance developed by OSHA, "Information for Employees Using Respirators When Not Required Under the Standard."[6] In addition to regulation, such guidance provides another mechanism for OSHA to address the respiratory protection needs of workers. Guidance such as that available through OSHA's respiratory protection website[7] may be general or hazard-specific, and may function as the primary vehicle for providing government direction on respiratory protection for workers not covered by current regulations.

[2] 29 U.S.C. § 651.
[3] 29 U.S.C. § 655.
[4] C.F.R. § 1910.134(c)(1).
[5] 29 C.F.R. § 1910.134(c)(2).
[6] 29 C.F.R. § 1910.134, Appendix D.
[7] See https://www.osha.gov/respiratory-protection.

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OSHA has also issued comprehensive exposure standards for a few agents that pose inhalation hazards, including asbestos and silica. These standards require employers to follow the hierarchy of controls, first attempting to remove the hazard from the workplace or use engineering controls to reduce or eliminate exposure. Depending on the circumstances, however, employers may provide their employees with respirators to ensure that exposure levels are below the permissible exposure limits (PELs). In these cases, the employer must establish and implement an RPP.[8]

Most workers are not covered by an RPP or by mandatory workplace safety standards addressing the use of respiratory protection. Consequently, in the face of novel or unanticipated threats, such as wildfire smoke or SARS-CoV-2, there is for most workers no preexisting foundation on which employers can build to ensure adequate respiratory protection. OSHA has the statutory authority to implement new or expanded requirements for RPPs for workers who are not part of a statutorily excepted group (e.g., state and local government workers in federal OSHA states or the self-employed) if it finds that the inhalation hazards faced by those workers pose a "significant risk." OSHA also has the authority to issue emergency temporary standards requiring respiratory protection against such threats if it determines "that employees are exposed to grave danger from exposure," and that the emergency temporary standard is "necessary" to reduce the danger.[9] In June 2021, OSHA implemented an emergency temporary standard for health care workers to address COVID-19 risk. It has also issued multiple enforcement response plans during the pandemic[10] and directed implementation of a National Emphasis Program (NEP) in an effort to ensure that employees in high-hazard industries (e.g., meat processing, warehousing, retail grocery, food service, corrections) would be protected from exposure to SARS-CoV-2 (OSHA, 2021). OSHA's oversight authorities are described more fully in Appendix C.

Other Federal Agency Oversight Authorities Regarding Use of Respiratory Protection in the Workplace

Although OSHA has the primary authority for regulating workplace safety, the OSH Act prohibits OSHA from issuing workplace safety standards in any workplace where another federal agency creates or enforces workplace safety and health standards.[11] This provision contributes to the complexity of the regulatory landscape and limits OSHA's authority.

[8] 29 C.F.R. § 1910(Z).
[9] 29 U.S.C. § 655(c).
[10] 29 C.F.R. §§ 1910.132, 1910.134, 1910.141, 1910.145, 1910.1020.
[11] 29 U.S.C. § 653(b)(1).

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BOX 2-1
Respiratory Protection Program Requirements Under the Occupational Safety and Health Administration (OSHA)

The components of an OSHA-compliant respiratory protection program (RPP) in accordance with the Respiratory Protection Standard are as follows:

1. Program administration overseen by a program administrator who is qualified by appropriate training or experience
2. Written respiratory protection program with worksite-specific procedures
3. Procedures for selection of respirators for use in the workplace, based on a hazard assessment with a requirement to use NIOSH approved respirators.
   i. If the employer cannot identify or reasonably estimate the employee exposure, the employer shall consider the atmosphere to be immediately dangerous to life or health (IDLH).There are specific respirator requirements for IDLH atmospheres covered in component (f)
   ii. For atmospheres that are not IDLH, employers must use the assigned protection factors to select a respirator that meets or exceeds the required level of employee protection
4. Medical evaluations—The employer shall provide a medical evaluation to determine the employee's ability to use a respirator, before the employee is fit tested or required to use the respirator in the workplace
5. Fit testing procedures to assure that the respirator selected is capable of fitting the worker to reduce inward leakage of airborne contaminants
6. Procedures for proper use of respirators—includes (among others):
   i. prohibiting conditions that may result in facepiece seal leakage (e.g., facial hair)
   ii. ensuring employees using tight-fitting respirators perform a user seal check each time they put on the respirator
7. Training of personnel in the inhalation hazards to which they are potentially exposed and in the proper use of respirators
8. Procedures for maintenance (cleaning, disinfecting, repairing), inspection, and storage of equipment
9. Procedures for regular respirator program evaluation
10. Record keeping (medical evaluation and fit testing records, written copy of RPP)

SOURCE: Excerpted from 29 C.F.R. § 1910.134.

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EPA has authority for regulating a number of environmental inhalation hazards, some of which arise in workplaces. When it issues occupational safety and health standards under its statutory authority, these standards displace OSHA protections that would otherwise apply. There are areas of overlap between the authorities of EPA and OSHA, and the agencies generally coordinate their efforts. Examples include worker protection against pesticides and asbestos (Aagaard, 2011). Under the Federal Insecticide, Fungicide, and Rodenticide Act,[12] EPA has issued the Agricultural Worker Protection Standard (WPS) to protect agricultural workers from pesticide exposures. It has used its authority under the Toxic Substances Control Act[13] to protect state and local government workers engaged in asbestos abatement activities by implementing a requirement for an RPP that mandates use of NIOSH-approved respirators (Aagaard, 2011). This is of particular note since state and local government workers constitute an excepted group under OSHA. To eliminate possible duplication, EPA has harmonized its regulations with OSHA's by cross-referencing them, thereby requiring state and local government employers to comply with OSHA's asbestos regulations (and with any changes to those regulations that OSHA subsequently promulgates) (Aagaard, 2011).

Other agencies have statutory authority that displaces OSHA's with regard to particular workplaces and the inhalation hazards those workplaces present. The chief example of this is the Mine Safety and Health Administration (MSHA), the successor to the Bureau of Mines. The primary statute empowering MSHA is the Federal Mine Safety and Health Act of 1977, which requires MSHA to establish mandatory health and safety standards for "coal and other mines."[14] MSHA thus has broad authority to regulate both use and oversight of respiratory protection, though this authority applies to the relatively limited set of workplaces that is made up of mines. The Nuclear Regulatory Commission (NRC) is the coordinating agency for incidents at or caused by nuclear facilities. In the event of a radiological release, the NRC is specifically responsible for providing recommendations for protective actions at the nuclear facility and for performing postincident surveillance and monitoring (DHS, 2016).

Gaps in Federal Oversight of Use of Respiratory Protection in the Workplace

Some workers appear to fall into gaps such that for them, no clear authority is responsible for regulating occupational respiratory protection.

[12] 7 U.S.C. §§ 136 et seq.
[13] 15 U.S.C. §§ 2601 et seq.
[14] 30 U.S.C. § 3; Federal Mine Safety and Health Act of 1977, 30 U.S.C. §§ 801.

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These include self-employed persons, gig workers,[15] unpaid volunteers, sole proprietors, partners, family members of farm employees, domestic workers in a residential setting, and independent subcontractors. These workers are exempted under OSHA's interpretation of the OSH Act, and do not appear to be protected by occupational safety and health standards issued by any other federal authority.

The definitions of "employer" and "employee" in the OSH Act are vague and circular: "'Employer' means a person engaged in a business affecting commerce who has employees"; "'Employee' means an employee of an employer who is employed in a business of his employer which affects commerce." OSHA has chosen to interpret these definitions narrowly, and reinterpretation of the definitions could result in coverage of additional workers not currently under OSHA's jurisdiction. Other gaps in OSHA oversight are created by statutory language, such as that included in the general duty clause,[16] which limits OSHA's authority to conditions faced by an employer's employees, thereby excluding workers not considered to be employees (e.g., gig workers). OSHA's interpretation of the definitions of employer and employee in the OSH Act and its regulatory language focused on employer–employee relationships reflects the occupational landscape when the act was enacted, but it does not provide adequate protection for workers given the contemporary range of employment models (Michaels and Barab, 2020).

Conclusion 2-1: OSHA's ability to ensure that the respiratory protection needs of all workers are met is constrained by outdated statutory language and interpretations that limit the applicability of its Respiratory Protection Standard to workers employed in traditional employer–employee relationships and by statutory language that displaces its authority where occupational safety and health are regulated by another government agency.

[15] Gig workers represent a subset of contingent workers for whom "gigs," generally short-term jobs, are mediated through a digital online platform. Contingent workers are those whose work arrangement does not include an explicit or implicit contract for long-term employment (Tran and Sokas, 2017). Currently, platforms through which gig workers are assigned and paid are not considered employers under OSHA (Bloom, 2019).

[16] The General Duty Clause of the OSH Act stipulates that employers have a general duty to furnish to their employees "employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to [their] employees" (Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 654).

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State and Local Authorities Regarding Use of Respiratory Protection in the Workplace

State and local authorities retain substantial authority over the regulation of several types of workplaces, most notably state and local government workplaces. Many states also administer their own occupational safety and health programs via OSHA-approved State Plans. There are currently 22 State Plans covering private and public state and local government workers and six State Plans covering only state and local workers (DOL, 2021). Analysis of census data suggests that 3.1 million state and local government workers in states without State Plans are not covered either by OSHA standards or by OSHA-approved State Plans (Maciag, 2014).

State Plan states must meet federal OSHA requirements but also may implement additional regulations to address specific hazards that pose threats to the health and safety of workers in their states. For example, California has promulgated two regulations that specifically address inhalation hazards and controls, including respirators for wildland fire smoke and for aerosol transmissible diseases (see Boxes 2-2 and 2-3, respectively). These standards set requirements for evaluating the risk of these hazards and specific respiratory protection requirements when they are needed. Washington (WAC 296-62-085 Wildfire Smoke) and Oregon (Oregon OSHA, 2021a) have issued temporary standards similarly intended to protect workers from exposure to unhealthy levels of wildfire smoke. All three states use EPA's Air Quality Index for $PM_{2.5}$ to trigger mitigation measures, including respirator use.

Authorities Regarding Development, Approval, and Marketing of Respiratory Protection for Use in the Workplace

NIOSH, with its division the National Personal Protective Technology Laboratory (NPPTL), is the primary federal authority for researching and approving respirators for the workplace. (See Box 2-4 for an explanation of certification versus approval.) While other federal and state organizations are involved in oversight for some workers in some industries or some hazards, these recommendations tend to be coordinated with NIOSH/NPPTL, which plays a critical role in centralizing evaluation of occupational respiratory protection. NIOSH also provides guidance for workers outside its programs, and in some cases has acted historically as a consultant on matters of respiratory oversight that touch on its expertise. However, NIOSH's mandate, authority, and consequent testing protocols are directed toward workplace respiratory protection rather than public protection.

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BOX 2-2
State Regulations to Protect Workers from Wildfire Smoke

In 2019, California's Division of Occupational Safety and Health Standards Board (Cal/OSHA) passed an emergency standard requiring that employers protect their workers from the potentially harmful particulate matter present in wildfire smoke (Title 8 Cal. Code of Regulations § 5141.1). This regulation applies to all workplaces where workers may be exposed to high levels of airborne particulate matter resulting from active wildland fires, including both outdoor settings and enclosed buildings or structures lacking mechanical ventilation or the ability to seal windows and doors.

The standard is tied to the Environmental Protection Agency's (EPA's) Air Quality Index (AQI) for $PM_{2.5}$, with initial employer actions required when the AQI is 151 or greater, and additional actions triggered when the AQI exceeds 500. Required measures include the following:

- Identification of exposure: Monitor the AQI before each shift, and "periodically throughout the day" to determine the need for actions.
- Engineering and administrative controls to reduce employee exposure to $PM_{2.5}$ to below an AQI for $PM_{2.5}$ of 151.
- Hazard communication program: Establish a two-way communication system between employers and employees to provide updates on the status of wildfire smoke at the workplace and related adverse events.
- Respiratory protection: Provide National Institute for Occupational Safety and Health (NIOSH)-approved respirators to all employees, and encourage their voluntary use.
- Training of employees: Provide employees with training on wildfire smoke hazards, control measures, and use of respirators.

Under the current standard, use of respirators is *mandatory* when the AQI for $PM_{2.5}$ exceeds 500 and work activities are not suspended. Employers in these situations are required to adopt all components of a respiratory protection program as outlined in Cal/OSHA's respiratory protection standard, including training, fit testing, and medical evaluation (Title 8 Cal. Code of Regulations § 5144).

A variety of other federal agencies have authority over some aspects of oversight of the development, approval, marketing, or postmarket surveillance of devices used for the purpose of occupational respiratory protection. For example, some masks and respirators are intended for occupational use in a health care setting, and thus subject to Food and Drug Administration (FDA) regulation.[17] Several years ago, concerns arose that some medical workers were using NIOSH-approved respirators that were not FDA

[17] 21 C.F.R. § 878.4040 (2020).

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At AQI levels above 151 but lower than 500, employers are required to provide respirators that may be used voluntarily by employees. The regulation includes an appendix with details on training requirements that include a focus on storage and maintenance such that the devices do not present a health hazard to the users. These requirements for voluntary use are separate from those included in Appendix D of the Occupational Safety and Health Administration's (OSHA's) Respiratory Protection Standard (discussed further in Chapter 3).

The regulations allow for the following workplace exemptions:

- enclosed buildings or structures where the air is filtered by a mechanical ventilation system;
- enclosed vehicles where the air is filtered by a cabin air filter;
- workplaces where the concentration of $PM_{2.5}$ is below an AQI of 150;
- firefighters engaged in wildfire firefighting; and
- emergency response personnel performing lifesaving emergency rescue and evacuation.

The temporary standards of Washington and Oregon are similar to those of California. In Washington state, employers are encouraged to supply NIOSH-approved filtering facepiece respirators at no cost to their employees when the AQI is 69 or above. The provision of respirators becomes a requirement of employers at an AQI of 151 or more, which is the same AQI cutoff used for provision of respirators in California's standard. Oregon's regulation is more stringent. When the AQI reaches 101, employers must provide respirators to their employees, to be used voluntarily. At an AQI of 201, employers must use administrative or engineering controls where feasible to reduce employee exposure to particulate matter, but if employees are still exposed to an AQI of 201 even after such controls have been enacted, the employer must ensure that employees wear NIOSH-approved respirators. Use of respirators and the implementation of a full respiratory protection program are mandatory when the AQI exceeds 500.

SOURCES: CCR Title 8, 5141.1; Oregon OSHA, 2021a,b.

cleared[18] (NASEM, 2017). FDA and NIOSH have since coordinated their overlapping authority for respirators used in medical care workplaces via a memorandum of understanding (FDA, 2017b).

During a public health emergency (as declared by the Secretary of Health and Human Services), FDA has the authority to issue an emergency use authorization (EUA) to allow the use of devices that are not approved (or are approved for a different use) if certain conditions are met (FDA,

[18] Respiratory Protective Devices Used in Healthcare, 79 Fed. Reg. 14,515 (March 14, 2014).

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BOX 2-3
California's Aerosol Transmissible Diseases Standard

California's Aerosol Transmissible Diseases (ATD) Standard is designed to protect employees in health care and certain other high-risk environments from disease agents spread through aerosols (Title 8 Cal. Code of Regulations § 5199) The standard was enacted in 2009 in the immediate wake of the H1N1 influenza epidemic, which was responsible for the deaths of at least four nurses in the state, but it also reflected a recognition of the increased risk faced by health care workers from endemic aerosol transmissible diseases, such as tuberculosis, meningitis, measles, and influenza (UCI, 2020). The ATD Standard translates best practices from the realms of occupational health and industrial hygiene into legally enforceable requirements that employers must follow.

The ATD Standard applies most directly to workplaces and operations where workers may face an elevated risk of exposure to aerosol transmissible diseases, including hospitals and acute care facilities, skilled nursing facilities, emergency medical services, and some public health operations, as well as correctional facilities, homeless shelters, drug treatment programs, and laboratories that handle aerosol transmissible pathogens. (Medical settings such as primary care clinics and medical offices, dental practices, long-term care facilities, and school-based clinics have limited requirements under the standard since they are not designed to diagnose or treat patients with airborne infectious diseases.) Occupational exposure is not limited to employees engaged in direct patient care, but may also include environmental service workers, administrative and maintenance staff, and laboratory personnel with potential exposure to pathogens transmitted through airborne or droplet routes. In worksites where the standard applies, employers are required to take a number of measures to prevent ATD exposure among workers and to respond when exposures do occur:

2021b). EUAs issued during the COVID-19 pandemic (and later revoked) allowed respirators that had not been NIOSH approved but had been tested and approved under international standards (e.g., KN95s, FFPs) to be used in health care settings in the United States for a limited period of time (FDA, 2020, 2021c).

MSHA has substantial authority over a wide range of standards-setting and oversight functions within U.S. mines. It manages this authority via collaboration with OSHA and NIOSH for both functions. This coordination is robust with regard to respirator oversight, an area in which MSHA has established a memorandum of understanding with NIOSH whereby NIOSH has the lead role in respirator approval, while MSHA and NIOSH

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- Written Exposure Control Plans, including details about who is responsible for administering the plan, job classifications with occupational exposure, a list of high-hazard procedures, tasks requiring personal protection, and methods for implementation
- Engineering and administrative controls, including use of face coverings and other forms of source control, cleaning and sanitizing protocols, and adequate ventilation in spaces used to treat patients with airborne infectious diseases
- Personal protective equipment, including use of National Institute for Occupational Safety and Health (NIOSH)-approved respirators for workers with potential exposure to airborne infectious disease pathogens
- Preventive medical services, including vaccinations and tuberculosis screening
- Post-exposure procedures when exposure events occur
- Training and communication with workers regarding ATD hazards and control measures

The respiratory protection requirements in the ATD Standard apply to workers who diagnose or treat patients with suspected or confirmed airborne infectious diseases, as well as other workers who may be in patient care areas without the benefit of other protections (e.g., janitorial or maintenance staff working in airborne infection isolation areas). N95 filtering facepiece respirators (FFRs) are the minimum level of respiratory protection required, although certain high-hazard procedures may require use of powered air-purifying respirators or other higher levels of protection. Employers at facilities with employees facing potential occupational exposure to airborne infectious diseases are required to adopt all components of a respiratory protection program as outlined in California's Division of Occupational Safety and Health Standards Board (Cal/OSHA)'s respiratory protection standard, including training, fit testing, and medical evaluation.

SOURCE: Title 8 Cal. Code of Regulations Section 5144.

jointly review and approve the respirators used for mine emergencies and rescues.[19] MSHA also retains primary responsibility for several testing and oversight requirements specific to the use of respirators in mines, including investigation of complaints and potential deficiency of approved respirators that are used in mines, and for testing and approval of electrical and electronic components of respirators for use in potentially explosive atmospheres (an unusual feature of some mining contexts that poses additional hazards beyond those presented in many other workplaces).[20]

[19] 42 C.F.R. § 84.3 (2020). See also Respirator Protective Devices, 60 Fed. Reg. 30,336; 30,339 (June 8, 1995).

[20] Respirator Protective Devices, 60 Fed. Reg. 30,338-39; 30,343; 30,349–30,351.

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BOX 2-4
Certification Versus Approval

The committee recognizes that there can be confusion regarding the use of the terms "approved" and "certified" when referring to respiratory protective devices. For example, respirators are "NIOSH [National Institute for Occupational Safety and Health] *approved*" and published on the "Certified Equipment List." The enabling regulation for respirator conformity assessment is 42 C.F.R. § 84, titled "*Approval* of *Respiratory Protective Devices*." However, the Occupational Safety and Health Administration (OSHA) requires the use of "NIOSH-*certified*" respirators.

The term "certification" has a specific meaning in the context of conformity assessment: it refers to third-party attestation of a product, process, or person that conveys assurance that specified requirements have been demonstrated (ANSI, 2011). The term denotes a system in which an accredited third-party organization manages all aspects of conformity assessment, issues a certification document when all requirements have been met, and conducts surveillance to ensure continued conformity. "Approval" may imply recognition of a product by a regulatory authority as being acceptable for use.

The use of both NIOSH approval and NIOSH certification is accurate with regard to respirators, and the two can be used interchangeably in this context. However, differentiation between the terms might be needed if an outside organization's certification of a respirator were recognized by NIOSH as acceptable. In such a case, the product could be said to be certified by a different organization and NIOSH approved. For the purposes of this report, the committee uses the term "NIOSH approved," which has the same meaning as "NIOSH certified."

RESPIRATORY PROTECTION FOR THE PUBLIC[21]

While OSHA and NIOSH have primary oversight roles in respiratory protection in the United States, their authorities are limited to occupational settings. No central federal authority is responsible for respiratory protection for the public, nor is there even any centralized repository of information on which authorities are responsible for which hazards. This section summarizes the federal and state authorities relevant to protection of the public from inhalation hazards, including authorities to mandate or provide guidance on use of respiratory protection and authorities related to approval or clearance of devices that may be used by the public for that purpose.

[21] This section draws on a paper commissioned by the committee on "The Regulatory Landscape Regarding Respiratory Protection," by Arden Rowell, J. D. (see Appendix C).

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Federal Oversight of Use of Respiratory Protection by the Public

EPA and the Centers for Disease Control and Prevention (CDC) have the broadest mandates regarding use of respiratory protection by the public, as described below, but no federal agency is currently tasked with addressing respiratory protection for the public from all hazards. In the absence of comprehensive federal regulation in this area, significant authority is left to the states. States may receive guidance from federal agencies; however, there is no formal system for coordinating the development and distribution of such guidance to state and local health agencies or the public.

EPA

EPA has authority to regulate some inhalation hazards faced by the public, although that authority is limited to environmental hazards, such as those resulting from exposure to toxic chemicals or air pollution, and it is not always clear how much authority the agency has to manage those hazards via respiratory protection. The Clean Air Act and the Toxic Substances Control Act, both administered by EPA, give the agency most of its authority in this realm.

EPA maintains substantial public resources regarding wildfires, including guidance for the public on how to address high levels of wildfire-related air pollution with respiratory protection (EPA, 2021f). It has developed information on reducing exposure to wildfire-related air pollution, highlighting that "the right respirator and proper fit can reduce your exposure to wildfire smoke" (EPA, 2021b), that respirators are not designed to fit children, and that facial hair prevents a proper fit (EPA, 2021b). EPA also maintains a downloadable app, SmokeSense, to help the public learn about health risks from wildfire smoke in their area and advise them on taking actions to reduce their exposure, such as wearing a well-fitting N95 filtering facepiece respirator (FFR) (EPA, 2021e).

EPA has adopted a number of voluntary programs addressing indoor air quality (EPA, 2021d). It has provided consumer information on best practices for remodeling and reducing radon, as well as advice on adequate and proper ventilation, much of which encompasses use of respiratory protection (EPA, 2021d).

As an example of how EPA has expanded its activities beyond the environmental hazards that have in the past been its primary focus, during the COVID-19 pandemic it issued guidance and conducted research related to SARS-CoV-2. For example, it issued information to the public regarding the coronavirus and indoor air (EPA, 2021c) and investigated the filtration performance of face coverings (Sickbert-Bennett et al., 2021).

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CDC

Various centers within CDC have oversight responsibilities related to exposure of the public to inhaled agents, including, most notably, infectious diseases. Such oversight includes issuing guidance and, in limited cases, requirements related to respiratory protection. For example, CDC issued an emergency action requiring the use of face coverings on public transportation conveyances and at transportation hubs during the pandemic for purposes of source control (CDC, 2021c). It also has issued information for members of the public entering homes that have been flooded (CDC, 2019), including recommendations regarding the use of respirators (CDC, 2021b).

CDC's National Center for Environmental Health (NCEH) performs and coordinates applied research on a number of environmental hazards, including inhalation hazards; engages in public communication and education; and takes part in public health emergency training (CDC, 2021a). The Agency for Toxic Substances & Disease Registry (ATSDR) was created to protect the public from hazardous wastes and environmental substances (ATSDR, 2018).[22] NCEH and ATSDR have established significant expertise regarding the health impacts of respiratory and other environmental hazards within CDC. Notably, these agencies, unlike NIOSH—an agency within CDC with a distinct occupational safety and health mission—are focused on health hazards faced by the public. Currently, there appears to be no division within NCEH/ATSDR working as a counterpart to NPPTL in NIOSH.

State and Local Authorities Regarding Use of Respiratory Protection by the Public

In the absence of a coherent federal system for addressing public use of respiratory protection, authority is left to state and local governments for creating and administering schemes for ensuring adequate public protection. States may choose to address respiratory protection for the public via proactive regulatory regimes, such as mask mandates, when those regimes have not been preempted by comprehensive federal action. Variation in state laws addressing public respiratory protection have been particularly salient during the COVID-19 pandemic. While no state has issued public mandates for respirators, many states have issued "mask mandates" requiring face coverings, the specific requirements, duration, and enforcement of which have varied by state (Chiwaya, 2021). The management of source control through mask mandates is legally justified by states' "police power,"

[22] See Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. §§ 9601–9675; Resource Conservation and Recovery Act of 1976, 42 U.S.C. §§ 6901–6992 (as amended).

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which gives them authority over matters of public safety[23] (Berman, 2020; Blum, 2020; Gostin, 2003; Richards, 2020), as well as by states' authority to declare and enforce quarantine within their borders (Thaler, 2021). Such power is particularly broad where, as is the case with the COVID-19 pandemic, no federal action preempts state authority on communicable diseases (Blum, 2020).

Authorities Regarding Development, Approval, and Marketing of Respiratory Protective Devices for Use by the Public

In the absence of an equivalent to NPPTL for nonoccupational settings, no single federal entity is responsible for overseeing the development, approval, marketing, or postmarketing surveillance of respiratory protective devices for the public, or for generating or overseeing a conformity assessment program for managing these processes.

FDA is responsible for regulating foods, drug products, and medical devices.[24] When respiratory protection is provided by a medical device intended for a medical purpose, such as preventing disease, it is subject to regulation by FDA, through both potential premarket approval processes and control over device adulteration and misbranding. Respiratory protection not intended for medical purposes is not subject to FDA oversight or control. Yet, given that many inhalation hazards—including environmental hazards—can produce such diseases as cancer, it can be difficult to determine how far FDA's authority reaches. Thus far, the agency does not appear to have claimed authority for regulating all respiratory protective devices for use in all circumstances to protect against any inhalation hazard that can cause any disease, and it has specifically disclaimed authority, for instance, over N95 FFRs used in "construction" (FDA, 2021a). The question of just how far FDA's authority over respirators as devices reaches and how it interacts with the authorities of EPA, OSHA, and other entities, remains ambiguous.

During the COVID-19 pandemic, FDA claimed authority under the Federal Food, Drug and Cosmetic Act for regulating all face masks, shields, and respirators used by the public for a medical purpose (FDA, 2021a), including FFRs,[25] which are classified as Class II devices. FDA had established this latter classification in 2007 (FDA, 2007) (see Box 2-5), and it was applied in 2009 during the H1N1 influenza pandemic, when two manufacturers received regulatory approval for four respirator models for

[23] *Gibbons v. Ogden*, 22 U.S. 1, 203 (1824).

[24] Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301–392.

[25] 21 C.F.R. § 880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies.

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BOX 2-5
Overview of FDA Guidance on Filtering Facepiece Respirators for Use by the General Public in Public Health Medical Emergencies

FDA issued a regulation and guidance document in 2007 assigning class II (special controls) to filtering facepiece respirators (FFRs) for use by the general public in public health emergencies. Manufacturers intending to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act, including the premarket notification requirements described in 21 C.F.R. § 807(E); (2) address the issues of safety and effectiveness posed by an FFR for use by the general public in public health medical emergencies that require special controls, as identified in the guidance; (3) satisfy the other special controls designated in 21 C.F.R. § 880.6260, the classification regulation for this type of device; and (4) obtain a substantial equivalence determination from FDA prior to marketing the device.

The special controls designated in the regulation are (1) ensuring filtration and breathability, (2) ensuring proper fit, (3) avoiding adverse skin reactions, and (4) ensuring proper use. To ensure proper filtration and breathability, a respirator must be approved by NIOSH as a nonpowered air-purifying particulate respirator with a minimum filtration efficiency classification of N95. For fit assessment, FDA recommends evaluating the fit characteristics of the respirator using a panel of test subjects who adequately represent the intended users. To address the risk of adverse skin reactions, FDA recommends evaluating biocompatibility using FDA guidance. Labeling is to include the information required in the NIOSH approval, as well as additional information including proper selection, use, seal check, maintenance, and disposal (FDA, 2007).

use by the public (FDA, 2009). Two of these devices were discontinued in 2013 because of the lack of a market for them (McCullough, 2021), and it is unclear whether the other two models are currently available. Under current FDA classifications, face masks that are not surgical masks are regulated as Class I devices, and thus are not subject to performance standards or postmarket surveillance.[26] In response to product shortages during the pandemic, FDA issued guidance indicating that for the duration of the pandemic, it would not object to the distribution and use for source control of face masks, barrier face coverings, and non-NIOSH-approved respirators that do not comply with its regulations as long as their use does not create an undue risk (FDA, 2021a).

The Consumer Product Safety Commission (CPSC) has some authority regarding face masks and respirators when they qualify as "products" for

[26] 21 C.F.R. § 878.4040 (2021) and § 880.6260.

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regulation under the Federal Hazardous Substances Act (FHSA). It applies labeling, testing, and certification requirements, as well as flammability testing requirements, to consumer face masks (CPSC, 2021). It has disclaimed authority for regulating either face masks that qualify as "medical devices" or respirators (CPSC, 2021). CPSC does, however, consider consumer and children's face masks to be apparel that is subject to the flammability testing requirements of the Flammable Fabrics Act.[27]

In the void left by the lack of a centralized federal authority, multiple agencies have issued nonbinding guidance to advise the public on use of respiratory protection in particular situations, such as when they are remediating mold in flooded homes (CDC, 2019; EPA, 2021a). This guidance often relies on oversight and approval provided by NIOSH for occupational contexts. However, neither NIOSH nor NPPTL appears to have any current guidance to provide to other agencies or authorities seeking to transfer NIOSH's approval standards for public use. As a result, there appears to be no centralized authority identifying the ways in which approval of occupational respirators may be a misfit for or address needs other than respiratory protection for the public.

An additional legal factor that may affect the development and approval of respirators for the public is judicial liability regimes, such as retroactive liability in tort, that affect the liability of manufacturers and sellers of respiratory protection. Torts are civil wrongs that can arise when a wrong by one person or company causes harm to another (Garner, 2009). They generally arise out of state law and are often adjudicated in state courts (see, e.g., Dobbs, 2000; Kritchevsky, 2010). In environmental and public health contexts, tort law can provide additional incentives for manufacturers and sellers of respirators and other protective gear, thus forming part of the regulatory landscape that can affect the actions taken by firms and individuals with regard to manufacturing, selling, and marketing of respiratory protective devices for the public[28] (Schwartz et al., 2009). In many cases, designers, manufacturers, and sellers of protective gear, including respirators, can be liable under products liability law[29] if their products cause harm to others—even if their products were designed and manufactured according to regulatory standards such as those set by NIOSH for N95 FFRs (Schwartz et al., 2009). Additionally, potential liability for fraud may incentivize honest marketing of products, including respiratory protective devices available to the public. In Colorado, for example, the state attorney general secured a settlement with a company that had made misleading

[27] Flammable Fabrics Act, 15 U.S.C. §§ 1191–1204. CPSC has indicated that consumer face masks must be tested to either 16 C.F.R. § 1610 or 1611.

[28] 30 U.S.C. § 811(a)(6)(A).

[29] Products liability is an area of law that seeks to ensure that products are reasonably safe.

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claims about the masks and respirators it sold during the COVID-19 pandemic (State of Colorado Office of the Attorney General, 2021).

Conclusion 2-2: While multiple agencies, including EPA and CDC, may provide guidance to the public related to the selection and use of respiratory protection, the absence of a coordinating structure impedes the delivery of consistent and hazard-appropriate guidance to the public.

Conclusion 2-3: No federal agency is charged with ensuring the development of the necessary standards for respiratory protection intended for use by the public or for ensuring conformance with such standards. As a result, there is no system in place for ensuring the quality and effectiveness of respiratory protective products marketed for and used by the public.

CONFORMITY ASSESSMENT OF RESPIRATORY PROTECTION

Overview of Conformity Assessment

Conformity assessment is at the core of the ability to regulate products; it demonstrates that the "specified requirements relating to a product, process, system, person, or body are fulfilled" (ISO/IEC 17000), and verifies that a "particular product meets a given level of quality or safety" (ANSI, 2014, p. 3). The process of conformity assessment can provide information about a product and its characteristics, describe the product's performance and consistency, increase a buyer's confidence in the product, and help substantiate advertising and labeling claims (ANSI, 2014), as well as help regulators and buyers make decisions about safety and suitability by assessing whether a product conforms to a particular standard (ANSI, 2014).

The specific process of conformity assessment varies depending on the product in question, the organization conducting the assessment, and the governing standards and policies. Conformity assessment programs exist for a wide variety of products, including medical devices; aircraft; nuclear reactors; and personal protective equipment (PPE), such as helmets and respirators. Oversight of these programs is performed by various organizations, both federal and nonfederal (RTI, 2014). Such organizations are referred to as the "scheme owners"[30] for those products.

[30] A scheme owner is the person or organization responsible for the development and maintenance of a conformity assessment system (ISO/IEC 17000:2020).

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In 2017, NIOSH published a National Framework for Personal Protective Equipment Conformity Assessment (NIOSH, 2017) to help the PPE industry meet the need for a consistent risk-based approach to PPE conformity assessment (see Figure 2-1).

Within this framework, the steps shown as "direct activities" are the primary activities of conformity assessment:

- determining the level of conformity assessment appropriate to the PPE type, intended use, and risk of failure;
- identifying the product requirements and standards against which conformity is to be assessed;
- collecting examples of the products to be assessed;
- gathering evidence of conformity through testing, inspection, examination of technical documentation, and/or auditing of the supplier's quality system, as appropriate;
- reviewing the evidence and making a determination about conformity;
- attesting to conformity, through a supplier's declaration, third-party certificate, and conformity marks as applicable;
- conducting market surveillance to determine ongoing conformity;
- taking enforcement or corrective action where necessary; and
- ensuring that all service providers in the process are competent through accreditation, auditing, and peer evaluation (NIOSH, 2017).

Organizations with roles in the conformity assessment process include

- manufacturers and suppliers whose products are assessed;
- standards-development organizations, governmental or private-sector, that provide product performance requirements and test procedures;
- testing organizations that evaluate products and provide test reports;
- certification organizations that manage the process of third-party certification;
- accreditation organizations that audit and determine the competence of testing and certification bodies; and
- government agencies that oversee conformity assessment processes and mandate the use of standards and conformity assessment in regulation.

Not all of these entities may be involved in every conformity assessment program. For example, a manufacturer may conduct testing of its products in its own laboratory or have a third-party laboratory do that testing. These labs may be third-party accredited. A certification body may have its own laboratory or contract with another organization to conduct the testing.

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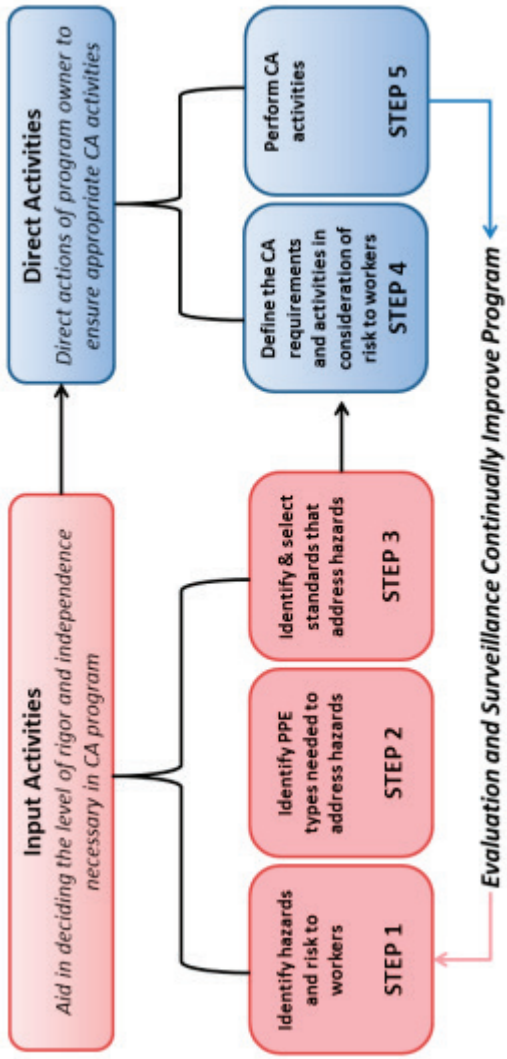


FIGURE 2-1 Personal protective equipment (PPE) conformity assessment (CA) framework. The figure shows the input activities for CA, which include identifying hazards and risks, identifying PPE types needed, and identifying standards to address these hazards, and the direct activities, which include defining the CA requirements and performing CA activities based on the input activities.
SOURCE: NIOSH, 2017.

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Product standards used for conformity assessment may be developed by government agencies or voluntary consensus standards bodies. These standards may include product physical and performance requirements, test procedures for measuring or determining conformity with these requirements, and requirements for conformity assessment (NIOSH, 2017).

Conformity assessment has benefits for manufacturers, regulators, consumers, and the public (IOM, 2011). Manufacturers can gain valuable quality control feedback from the process, which can enable consistency in manufacturing and help avoid the costs of product failure. The process may also help differentiate a product from a competitor's and validate marketing claims. Regulators benefit from conformity assessment by having a designated pathway to follow for determining that product claims are valid and verifying the consistency of the manufacturing process, which provides a platform for enforcing health, safety, and environmental regulations. The conformity assessment process gives consumers valuable information about a product, its intended use, and its limitations, all of which may assist them in evaluating label claims and making purchasing decisions. Finally, the public benefits from conformity assessment because it provides a common language with which to discuss a product (e.g., "NIOSH approved") and because it ensures that products conform to standards designed to protect workers and the public from illness, injury, or death. Workers and the public may be more likely to use a product appropriately if they are confident that it will provide the intended protection (NIOSH, 2017).

Conformity Assessment Process for Respiratory Protective Devices

In the United States, the conformity assessment process for PPE entails a patchwork of different standards, policies, and organizations. Multiple public and private organizations conduct conformity assessment for PPE, and these conformity assessment programs "vary along a continuum of rigor in requirements and testing as well as independence from the PPE supplier" (NIOSH, 2017). Each approach to conformity assessment results in a different dynamic and culture among certifiers, users, and manufacturers (NASEM, 2021). In contrast with other PPE types, the conformity assessment processes for respiratory protective devices is comparatively regimented. The processes for different types of devices are described in the sections below.

Conformity Assessment for Respirators

NIOSH is the principal governmental agency with responsibility for testing and approving respirators. NIOSH's NPPTL carries out all conformity assessment activities, including defining conformity assessment

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requirements, conducting site qualifications for first-time applicants, performing testing and inspection, carrying out all preapproval activities (e.g., engineering and quality assurance review), and conducting postmarket surveillance (both approved product and approval holder site audits). NPPTL also conducts research, develops guidance and recommendations, develops and conducts intervention studies, and disseminates information as part of its mission to "to prevent disease, injury and death for millions of workers by advancing the state of knowledge and application of personal protective technologies (PPT)." (NIOSH, 2018b). The standards used by NIOSH include mandatory government standards outlined in 42 C.F.R. § 84 and those required by FDA as outlined in 21 C.F.R. § 878.4040, as well as voluntary consensus standards. The NIOSH Respirator Approval Program approves all classes of respirators used in workplaces across the United States; OSHA and MSHA require the use of NIOSH-approved respirators in certain occupational settings (NASEM, 2021). Importantly, NIOSH approval of respirators is premised on their use in the context of a workplace RPP.

To begin the NIOSH approval process, a manufacturer completes and submits a Manufacturer's Questionnaire (NIOSH, 2021c). NIOSH reviews the completed questionnaire and assigns a manufacturer code if the information is satisfactory. Next, the manufacturer submits a Standard Application Form with all required documentation, including a written description of the product, drawings and specifications, and sample hardware for evaluation (IOM, 2011; RTI, 2014). The approval process is depicted in Figure 2-2. Specific tests required vary, depending on the type of respirator, hazard, and intended use, but may include such tests as

- airflow resistance test,
- exhalation valve leakage test,
- filter efficiency test,
- fit test,
- noise level test,
- particulate loading test,
- silica dust test, and
- communication performance test.

Of note, a fit test is not required as part of the approval process for FFRs—for such products, fit, which varies across devices and is critically important to achieving the intended level of protection, is ensured solely through the workplace RPP-based user fit testing (Coffey and Miller, 2019). As there is no equivalent user fit testing program for the public, the lack of a fit test during the conformity assessment process contributes to problems with public use of FFRs approved by NIOSH for workers. No single agency is charged with setting requirements for or conducting testing on all

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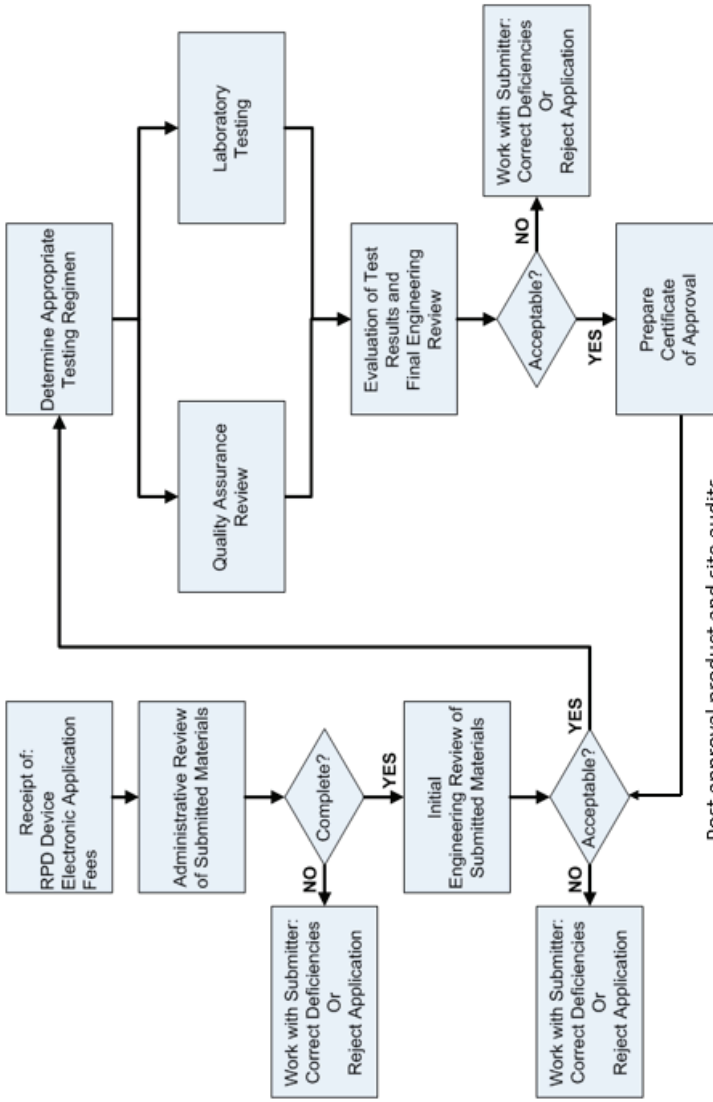


FIGURE 2-2 National Institute for Occupational Safety and Health (NIOSH) process for respirator approval. This flow chart illustrates the multiple steps in the NIOSH respirator approval process, from receipt of the devices by the manufacturer, to application for approval, to associated fees, to preparation of the certificate for approval.
SOURCES: D'Alessandro and Peterson, 2020; NASEM, 2021.

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products intended for public use. While some respirators have been found to have good fitting characteristics, others have been found to perform poorly in comparison (ASTM, 2021b). Fit capability testing (see Box 2-6) could provide users—both the public and workers—with some assurance that a respirator is capable of fitting a wide variety of faces, but it is not a substitute for user fit testing (Coffey et al., 2021). Users who are unable to perform respirator fit testing should expect lower respirator performance relative to the devices' use in an RPP that includes fit testing.

In addition to conducting testing on a product, NPPTL evaluates the manufacturer's quality assurance program and quality control plan (RTI, 2014). If the product is approved, NIOSH grants the manufacturer authorization to market the respirator as "NIOSH certified," and adds the product to the Certified Equipment List on the NIOSH website (RTI, 2014). If the product is found not to be in compliance with the necessary standards, NIOSH issues a letter to the manufacturer explaining the problem and the corrective action that can be taken (RTI, 2014). Once products enter the market, NIOSH audits them by testing samples obtained through normal sales channels, and also investigates user complaints and products involved in serious illnesses, injuries, or fatalities (RTI, 2014). Every other year, NIOSH also conducts an inspection of a product's manufacturing facility and its quality assurance program. These postmarket investigations can

BOX 2-6
Fit Capability Testing

ASTM F3407-20 provides a standard test method for evaluating respirator fit capability. Fit capability testing does not ensure that a respirator will fit every individual, but is intended to exclude from the market those products that are unlikely to achieve a good fit even with fit testing conducted for workplace respiratory protection programs. Prior to ASTM F3407-20, there were no consensus or government standards for testing the fit capability of a filtering facepiece respirator (FFR), despite lengthy and unsuccessful efforts by the National Institute for Occupational Safety and Health (NIOSH) to incorporate total inward leakage into 42 CFR § 84. This standard is intended to enable respirator manufacturers to develop better-designed respirators that fit a greater portion of the population, ultimately providing more workers with better protection. Despite NIOSH's leadership role in the development of the standard, ASTM F3407-20 has not been incorporated into 42 C.F.R. § 84 and is not part of the NIOSH Respirator Approval Program, but could be incorporated into regulation by reference in the future.

SOURCE: Coffey et al., 2021.

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result in voluntary product recalls, product retrofits, sales stops, or revocation of approval (RTI, 2014).

FDA is generally responsible for oversight of respiratory protective devices used in medical settings, which are classified as medical devices. In 2018, FDA and NIOSH entered into a memorandum of understanding aimed at streamlining the regulatory oversight for surgical respirators between the two agencies and allowing certain manufacturers to submit a single application to NIOSH instead of having to obtain approval from both agencies (NIOSH, 2018c). Since 2018, NIOSH has had the authority to approve surgical N95 FFRs without the need for FDA 510(k) clearance, except when applications submitted to NIOSH are determined to exceed CDC's and FDA's mutually agreed-upon threshold evaluation criteria. Applicants must supply NIOSH with documentation of testing for fluid resistance, flammability, and biocompatibility performed by a laboratory meeting FDA good laboratory practices (NIOSH and FDA, 2017).

Conformity Assessment for Nonrespirator Masks and Face Coverings

FDA 510K requirements for surgical masks Surgical masks—also called dental or medical masks—are cleared for marketing through FDA's 510(k) process (FDA, 2004). This process requires a manufacturer to submit information to FDA demonstrating that its product is as safe and effective as—that is, substantially equivalent to—a product that is legally marketed (the "predicate") in the United States. Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Public Law 75-717) describes this process and the requirements for demonstrating substantial equivalence. For a 510(k) submission for a surgical mask, FDA recommends that manufacturers include information including any identified risks from using the product, as well as measures for mitigating these risks (FDA, 2004). FDA also recommends that manufacturers test their products for

- fluid resistance,
- filtration efficiency,
- differential pressure,
- flammability, and
- biocompatibility.

For each of these characteristics, FDA provides recommended test methods or standards (FDA, 2004). For example, FDA recognizes the ASTM F2100-21 Standard Specification for Performance of Materials Used in Medical Face Masks, among others (FDA, 2021d). Once FDA has

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determined that a product is substantially equivalent to the predicate, the manufacturer may market it.

Conformity assessment for barrier face coverings In the context of the COVID-19 pandemic, ASTM developed a voluntary consensus standard (ASTM F3502-21) for barrier face coverings. ASTM defines barrier face coverings as devices that are "worn on the face, specifically covering at least the wearer's nose and mouth, with the primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter" (ASTM, 2021c). Barrier face coverings are neither medical masks nor respirators. The standard notes that barrier face coverings can vary significantly, and that a wide range of factors (e.g., perspiration, length of time worn) could affect their performance. The conformity assessment process for barrier face coverings follows ASTM Guide F3050, Annex A3, Model A, which outlines requirements for design, performance, labeling, and user information. The standard also requires barrier face coverings to be tested by an accredited laboratory for

- submicron particle filtration efficiency, and
- airflow resistance.

Two levels of filtration efficiency (20 percent or higher and 50 percent or higher) and breathing resistance (15 mm H2O or below and 5 mm H20 or below) are established by the standard and require the use of testing methods similar to those used by NIOSH (Szalajda et al., 2021). While manufacturers are required to perform a design analysis to assess leakage of exhaled air from a barrier face covering, the ASTM standard does not require testing to demonstrate the effectiveness of the device for source control. Quantitative testing of leakage is optional, as is bacterial filtration efficiency testing. User instructions for barrier face coverings must include information about sizing, proper use and care, and product limitations.

Conformance with the standard is not predicated on third-party certification; instead, the manufacturer provides a declaration of conformity. It is also important to note that this is a voluntary standard, and as of this writing, there is no regulatory requirement for manufacturers to demonstrate that their products conform to the standard prior to sale.

Following the release of the ASTM standard for barrier face coverings, NIOSH issued interim guidance with criteria for workplace performance masks that build on the standard. The specifications are intended for masks that will be worn in the workplace to prevent the spread of SARS-CoV-2, but masks meeting the NIOSH criteria are not meant to serve as a substitute for respirators. In addition to the ASTM criteria for filtration and breathability, NIOSH has set criteria for leakage and requires quantitative

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leakage testing, which is optional under the ASTM standard. Based on performance related to filtration, breathability, and leakage, masks can be labeled as Meets Workplace Performance or Meets Workplace Performance Plus (NIOSH, 2021a).

Standards Development for Respiratory Protective Devices

Before a product can be tested to ensure that it conforms to standards, those standards must be in place. The standards for respirator testing and approval are by statute issued by NIOSH and codified in 42 C.F.R. § 84. As a result, any new standards development process undertaken by NIOSH necessitates a change in regulations, which can be a lengthy process.

There are also voluntary consensus standards developed by nongovernmental organizations, which are often incorporated into government standards by reference[31] (RTI, 2014). Use of voluntary standards helps harmonize standards, eliminates the cost to the government of developing its own standards, and provides incentives to establish standards that serve national needs (OMB, 1998). The National Technology Transfer and Advancement Act (NTTAA),[32] signed into law in 1996, required government agencies to use voluntary consensus standards to the extent possible, and directed the National Institute of Standards and Technology (NIST) to eliminate unnecessary duplication by coordinating the conformity assessment activities of federal, state, and local entities with private-sector activities on technical standards and conformity assessment. Circular A-119, which is published and periodically revised by the Office of Management and Budget, establishes the policies on federal development and use of voluntary consensus standards and conformity assessment activities (OMB, 2016). Government agency staff often participate in the development of voluntary consensus standards, and in some cases take leadership roles in moving these standards through the consensus process. For example, NIOSH, which has extensive involvement and leadership in consensus standards for PPE (e.g., gloves, protective clothing, eye protection, hearing protection),[33] helped initiate and participated in the development process for the above-described ASTM barrier face covering standard. In addition to the operational benefits of developing a new consensus standard, the process allows

[31] "Incorporation by reference (IBR) allows Federal agencies to comply with the requirement to publish rules in the Federal Register and the Code of Federal Regulations (CFR) by referring to materials already published elsewhere" (NIST, 2020).

[32] Public Law 104-113.

[33] NPPTL staff members have served on standards committees at ASTM, the American National Standards Institute (ANSI), the International Organization for Standardization (ISO), and the National Fire Protection Association (NFPA).

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for a more collaborative and responsive relationship between NIOSH and stakeholders who are critical for adoption. Despite these benefits, however, the incorporation of a consensus standard by reference can be a lengthy process (Smith, J., 2021).

Voluntary consensus standards are developed or approved by a number of national and international organizations. ANSI is the national standards body of the United States; it does not develop standards itself, but coordinates, facilitates, and promotes the development of voluntary standards (ANSI, 2021). ANSI accredits the procedures of organizations that develop standards and approves standards as American National Standards (ANS). ANSI-accredited organizations that develop standards for PPE, including respiratory protective devices include NFPA, the American Society of Safety Professionals (ASSP), ASTM International, and the International Safety Equipment Association (ISEA). Some of these organizations develop test specifications, while others develop standards that include requirements for conformity assessment. These voluntary consensus standards are used by a number of government agencies in their oversight of products. For example, FDA uses ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks (ASTM, 2021a).

International Organization for Standardization (ISO) brings together experts to develop voluntary international standards, and establishes standards and principles used for conformity assessment worldwide. Members of ISO include 165 national standards bodies; ANSI serves as the U.S. member body. ISO partners with the International Electrotechnical Commission (IEC) to form the system of worldwide standardization. Numerous ISO/IEC standards cover elements of conformity assessment systems, including standards for conformity assessment principles, guidelines for drafting standards suitable for conformity assessment, requirements for conformity assessment bodies, requirements for accreditation of those bodies, requirements for test laboratory competence, and requirements for certification bodies (ISO/IEC, 2020). In addition, a number of ISO product standards are related specifically to respiratory protection, including standards for testing leakage, particle filter penetration, resistance to flame, and fit testing (ISO, 2021).

Across the globe, there have been recent trends toward harmonizing standards, with a focus on such human factors as fit and comfort and on defining how different respirators can be selected and used for a variety of populations and purposes (Miller, 2020).

Conformity Assessment Approaches Outside the United States

The regulatory schemes for and approaches to conformity assessment vary from country to country. The Technical Barriers to Trade agreement

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within the World Trade Organization prohibits the signatories (including the United States) from having conformity assessment procedures that are more trade-restrictive than necessary to meet their legitimate regulatory objectives. The United States employs a "license to use" model for respirators, whereby a respirator must meet set requirements for use in an RPP, and OSHA requires employers to select these respirators from the NIOSH Certified Equipment List. Thus, responsibility for ensuring that NIOSH-approved respirators are used falls on the employer. The public and workers without RPPs in their workplaces may have access to nonapproved devices on the market that do not meet a set standard. Other countries, including those in the European Union (EU), use a "license to sell" model whereby a product must have the certification mark in order to be sold, imported, or distributed, thereby putting responsibility on the manufacturer (European Commission, 2020). Unlike the United States, which has no path for approval of respirators intended for use outside of the workplace, some countries and regions, including China and the European Union, do not have separate respirator performance standards for occupational and public use (McCullough, 2021).

European requirements for PPE are established by regulation applicable to all member countries of the European Union. The PPE Regulation, which was approved in 2016 and became effective in 2018, superseded a PPE Directive that had been in place since 1989.[34] Under the regulation, respirators are classed as Type III PPE, designed to protect against life-threatening hazards. They must be tested and certified by a Notified Body, a certification organization approved by a member state, and bear the "CE" mark, which ensures that the PPE will be acceptable for use anywhere in the EU. To qualify for the CE mark, respirators are tested to standards developed by the European Committee for Standardization (CEN) or ISO standards that are recognized by CEN.

Finally, there is a difference between "system approval" and "component approval." System approval—which is used by NIOSH and countries including Brazil, Japan, and China—requires that respirators be tested and approved in every unique configuration possible. Component approval, on the other hand, requires that each individual component be held to a particular standard. CEN uses a component approval system, but also requires manufacturers to detail all combinations and issue recommendations for use, and it uses postmarket surveillance to monitor for compliance (Miller, 2020).

[34] Regulation (EU) 2016/425.

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Challenges and Limitations of the Current Conformity Assessment Approach in the United States

The current approach to conformity assessment for respiratory protection involves a number of challenges and limitations. While a certification or approval demonstrates conformance to a certain set of standards, it does not necessarily ensure that the standards themselves are sufficient and appropriate for the intended use and specific hazard (NASEM, 2021). Standards for respiratory protective devices have traditionally focused on device performance and less on such human factors as comfort and usability. Moreover, 42 C.F.R. § 84 does not specify standards for evaluating the fit of FFRs. The lack of a standard has resulted in issues that include approval of devices that do not fit the intended population and higher costs for the fit test required by OSHA (Coffey and Miller, 2019). The potential mismatch between standards and use may be particularly relevant when respiratory protective devices are used by the public for protection from a variety of hazards (e.g., wildfire smoke and SARS-CoV-2). Such devices were designed for use by healthy workers in occupational settings and for defined hazards, but as respiratory protection is increasingly used by the public and workers not subject to RPP requirements, challenges may arise with respect to defining the hazards and developing standards that are sufficient and appropriate for the intended use (NASEM, 2021).

The rigidity of the conformity assessment process—specifically, requirements for NIOSH testing of respirators—makes it difficult to respond to emergency situations. For example, during the COVID-19 pandemic, the demand for NIOSH-approved respirators skyrocketed, making it difficult for health care personnel and other workers to obtain the PPE they needed (Andrews et al., 2021; Friese et al., 2020). In response, NIOSH, FDA, and OSHA implemented a crisis strategy designed to improve the availability of respirators (de Perio et al., 2020); for example, NIOSH assessed international respirators against standards to which the international devices claimed conformance, rather than the U.S. standards (Andrews et al., 2021). However, these efforts were insufficient to meet the demand, and several other laboratories throughout the United States adopted NIOSH testing methods to evaluate the effectiveness of uncertified products (Irby and Nelsen, 2020; Manning, 2020). Existing laboratories that meet ISO quality standards and can conduct respirator testing in accordance with NIOSH requirements could be beneficial in responding to circumstances (e.g., pandemics) in which demands on NIOSH testing personnel result in delays in approvals and in enabling NIOSH to focus its unique expertise and resources on higher-level activities, such as research (Smith, A., 2021).

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Conclusion 2-4: NIOSH's reliance on regulatory standards that can be changed only through rulemaking impedes its efforts to generate new and update existing standards on a timely basis. NIOSH would benefit from incorporating consensus standards into the respirator approval process.

Conclusion 2-5: The NIOSH system for conformity assessment, unlike FDA regulatory processes used for medical masks, relies on government laboratories rather than third-party laboratories for testing of respirators. This approach limits NIOSH's capacity to rapidly expand testing and diverts resources from other activities, such as research.

OVERSIGHT OF THE SUPPLY CHAIN FOR RESPIRATORY PROTECTIVE DEVICES

The supply chain for respiratory protective devices in the United States is part of a global marketplace, driven by supply and demand. Most respirators are sold through distributors—safety specialist and industrial distributors for industrial users and medical distributors for respirators used in health care. Manufacturers source raw materials, and in many cases finished products, from around the world. Customers order respirators through distributors with which they have ongoing business relationships, maintaining only enough inventory to supply immediate needs. Distributors respond by ordering respirators from manufacturers, who schedule their production and procurement of imports accordingly. This system is efficient and cost-effective, but it is subject to disruption when there is a sudden surge in demand due to a pandemic or other public health emergency (Patel et al., 2017).

With minimal inventories, customer demand can quickly outstrip product availability. Many manufacturers lack the excess capacity to increase production quickly; distributors are swamped with demands from existing customers and others seeking supplies; and customers seek sources of respirators outside their normal channels, placing orders from multiple vendors (Patel et al., 2017). Opportunistic brokers enter the market, often overcharging or providing questionable products.

Against this background, the sections below describe the nation's existing systems for ensuring consistent supplies in emergency situations.

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Federal Authorities[35]

The federal government has two primary mechanisms for stockpiling respirators and/or amplifying respirator availability during pandemics and other large-scale incidents: the Strategic National Stockpile (SNS) and the Defense Production Act (DPA). Federal authorities related to these two mechanisms are discussed below.

Authorities Related to Manufacturing of Respiratory Protection in Emergency Scenarios

The SNS, described below, can be only a short-term stopgap; the federal government's more robust solution in the face of a pandemic and spiking demand is the DPA. Under the DPA, the president can address matters of critical infrastructure, technology, national economic security, and national public health and safety, from human-made and natural disasters as well as wartime concerns, through a series of mechanisms that mobilize national industrial capacity. The DPA allows the government to jump to the front of the line in purchasing goods and empowers the President to allocate resources as "necessary or appropriate"; it authorizes the government to assist private manufacturers, either by supporting existing supply chains or stimulating new technologies or modes of production; it authorizes the President to assess the industrial base, with power to obtain information by subpoena if necessary; and it facilitates partnerships with the private sector, including in the form of voluntary agreements, to build capacity (Anderson and Burris, 2021). The Federal Emergency Management Agency (FEMA) Administrator chairs the Defense Production Act Committee, which advises on effective use of the DPA and also reports to Congress.

Authorities Related to Stockpiling of Respiratory Protection

The SNS is the nation's repository of medical countermeasures (e.g., antibiotics, antiviral drugs, vaccines) and other medical materiel, including respiratory protective devices (NASEM, 2016). The SNS is currently run by the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS). The stockpile's origins lie in a charge from Congress in 1999 to HHS and CDC to acquire a pharmaceutical and vaccine stockpile that could counter potential biological and chemical threats (HHS, 2021c). The program has expanded over the years to include additional supplies and has undergone name and

[35] This section draws on the commissioned paper "The Regulatory Landscape Regarding Respiratory Protection," by Arden Rowell, J. D. (see Appendix C).

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oversight changes. Federal stockpiling authority is governed largely by the Public Health Services Act of 1944,[36] amended by the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006.[37]

The SNS was designed to supplement the supplies of and resupply state and local public health agencies in the event of a national emergency. It consists of a series of large, strategically placed warehouses ready to distribute necessary materials across the country in the event of a health crisis, when states can request supplies from the SNS.

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), led by ASPR, is a federal interagency group established by HHS that is charged with determining which items make up the SNS formulary[38] based on a review of material threat determinations (CDC, 2014; Gerstein, 2020; NASEM, 2016). The PHEMCE works to define requirements for every medical countermeasure (MCM) to be included in the stockpile, leads research and procurement efforts based on these requirements, and also considers the most effective deployment strategies for these supplies (NASEM, 2016). The selection of every item to be included in the formulary is based on specific criteria, including a product's ability to be rotated back into the commercial market, its demonstrated effectiveness against specific agents or threats, "its supply availability in the commercial market," and considerations relating to its storage and cost (CDC, 2014). SNS products are organized in accordance with their effectiveness against specific threats, including those posed by biological, chemical, and radiological agents, as well as natural disasters and pandemic influenza. To determine the selection of PPE, subject matter experts are tasked with reviewing products against federal guidelines and creating performance standards designed to ensure that each item can meet the needs of affected communities during a public health crisis (NASEM, 2016). Moreover, ASPR can utilize its rapid purchasing power to buy medical supplies not included in its inventory by utilizing preestablished contracts with vendors (CDC, 2014).

The inclusion of PPE as a critical component of the SNS was expanded in 2006, when HHS purchased 104 million N95 FFRs for the SNS as preparation against a possible influenza pandemic (HHS, 2006). The decision making behind this purchase was based on "the need for protection, funding, and availability of products on the market that could immediately increase US readiness" (Patel et al., 2017). In 2009, this supply was largely depleted when the H1N1 pandemic caused demand for N95 FFRs to

[36] Public Health Service Act, Public Law 104-321; Codified at 42 U.S.C. § 247d.

[37] Public Law 109-417.

[38] The wide variety of medical supplies and medical countermeasures (MCMs) included in the SNS are known as its formulary.

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spike, and the federal government dispersed approximately 85 million of the N95 FFRs in the stockpile to state health departments to reduce shortages in health care settings. At the time, the supply was not replenished. A 2015 study estimated that the United States would need 3.5 billion N95 FFRs in a scenario in which 30 percent of the U.S. population became ill from pandemic influenza (Carias et al., 2015). The SNS currently holds multiple models of surgical and standard N95 FFRs, in addition to face shields, surgical gowns and coveralls, goggles, and gloves; the amount of stockpiled PPE has also increased in response to the COVID-19 pandemic (HHS, 2021b).

As with other materials included in the SNS that expire, the shelf life of stockpiled respirators and masks and the need for disposal and replacement present a challenge to ensuring that effective products are available for distribution when needed during emergencies. For this reason, ASPR is charged with routinely evaluating medical supplies on a quarterly or annual basis to ensure quality maintenance, monitor storage and environmental conditions, and oversee the proper rotation of products that have exceeded their shelf life (ASTHO, 2021).

Of note, NIOSH does not designate specific requirements related to the shelf life or ideal storage conditions of particulate-only air-purifying respirators as part of its respirator approval program, having left this responsibility to the approval holder of each product (NIOSH, 2021b). To examine the performance and quality of stockpiled respirators, NIOSH conducted a series of evaluations across federal, state, regional, and county facilities (NIOSH, 2021b). The results from one of the studies conducted at a federal facility showed that all 430 of the N95 FFRs that were tested "maintained their inhalation and exhalation resistance and filtration performance in accordance with NIOSH performance standards" after being stored for 12–13 years (NIOSH, 2020b, p. 1). Given that these respirators were not designed for long-term use, however, continual quality assurance is still necessary for all PPE included in the SNS.

Authorities Related to Distribution of Respiratory Protection

FEMA, the federal agency responsible for managing critical response to national emergencies, has an expanded role in respiratory protection during emergencies and natural disasters. When emergencies present inhalation hazards, as with COVID-19, wildfires, and radiological disasters, FEMA has a coordinating role that can affect the oversight of respiratory protection in both occupational and nonoccupational settings. For example, the agency issued a series of temporary final rules aimed at managing the distribution and availability of PPE during the COVID-19 pandemic (FEMA, 2020). While these responsibilities do not conflict with NIOSH's

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authority for oversight of respiratory protection, they may affect the availability and provision of PPE, including respiratory protection, in emergency circumstances.

Respiratory Protection Supply Chain During the COVID-19 Pandemic: Experiences and Lessons Learned

In the face of the sudden surge in demand resulting from the COVID-19 pandemic, shortcomings in the supply chain for PPE were not a surprise. Demand-based N95 FFR production, overreliance on imports, and insufficient government coordination of PPE supply and distribution were all recognized issues during the 2009 H1N1 influenza pandemic and the 2014 Ebola virus epidemic (Patel et al., 2017). In 2017, CDC staff outlined strategies for improving the acquisition and use of PPE during a public health emergency. Their recommendations included the creation of additional stockpiles at the federal, state, and local levels; improved domestic manufacturing surge capacity at the time of an event; and improved sharing of situational and supply information between the federal government and the private sector (Patel et al., 2017). These strategies, however, were not implemented in the 3 years prior to the COVID-19 pandemic's arrival in the United States. As evidenced by the scarcity of N95 FFRs throughout most of 2020 and as seen in previous pandemics and epidemics, global supply chains and just-in-time manufacturing undermine the nation's ability to respond to sudden surges in demand.

N95 FFRs are currently manufactured in multiple countries worldwide. In the years leading up to the COVID-19 pandemic, U.S. companies transferred the vast majority (~90 percent) of N95 FFR production overseas (Dai et al., 2020). This global supply chain keeps costs down for manufacturers and consumers, but exposes respirator supply to external pressures. At the start of the COVID-19 outbreak, global shortages of respirators and other PPE products emerged as many affected countries imposed export controls and sought ways to boost domestic output (Cohen and Rodgers, 2020; Gruley and Clough, 2020).

In addition to global export fluctuations, respirator availability is limited by the industry's embrace of just-in-time manufacturing and purchasing. Under that framework, goods are manufactured and purchased in limited quantities—enough to meet current demand without creating excess inventory. This approach helps suppliers control costs, but leaves them unable to respond to sudden spikes in demand (Gereffi, 2020; Kim, 2020; Whalen et al., 2020). In addition, the current just-in-time business model prioritizes products made in low-cost foreign locations, such as China (Gereffi, 2020), which adds export vulnerabilities to the limited supplies. For instance, the grounding of the container ship *Evergreen* in the Suez Canal

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in March 2021 led to significant disruptions in the supply chain, since nearly 12 percent of the annual volume of world trade passes through the canal (Kumon, 2021). Moreover, manufacturers are not alone in reducing inventory; hospitals have adopted just-in-time purchasing of such items as N95 FFRs as a cost-saving measure (Gereffi, 2020; Whalen et al., 2020).

Surge manufacturing can help meet a sudden large and unpredictable demand, but it is relatively uncommon because of the costs of maintaining unused assembly lines. Following the epidemic of severe acute respiratory syndrome (SARS) of 2002–2003, 3M acknowledged that it was not equipped to handle spikes in demand and developed surge capacity in its respirator factories around the world (Gruley and Clough, 2020). However, the need generated by the COVID-19 pandemic outstripped 3M's production surge for most of 2020.

Furthermore, even if manufacturers have surge capability to meet potential demands, production bottlenecks can slow output. Early in the COVID-19 pandemic, for example, the supply of meltblown nonwoven polypropylene, which serves as the primary filter material in N95 FFRs, quickly became a bottleneck (Gereffi, 2020; Handfield, 2020; Mendoza et al., 2020). Polypropylene is a commonly produced material, but creating meltblown nonwoven polypropylene fiber requires specialty machinery with a high capital investment (OECD, 2020), which limits the number of companies producing the fabric. The shortage of raw materials made it difficult for respirator manufacturers to quickly increase their N95 FFR supplies or switch to producing N95 FFRs to meet surging demand during the pandemic (Gereffi, 2020). To address this material shortage, new manufacturers entered the scene and developed partnerships to increase output. For example, a collaboration between Cummins Inc. and the Carbon Fiber Technology Facility at the Department of Energy's Oak Ridge National Laboratory resulted in the capacity to manufacture enough filter media to produce more than 1 million face masks and respirators per day for use in health care facilities (ORNL, 2020). Additionally, the inherent challenges involved in producing certain respiratory protective devices, such as FFRs, that require molding during the manufacturing process can cause bottlenecks due to the expense and time demands of the molding process. Alternative designs using flat filters that do not require the use of molding equipment represent a design modification that could allow for improved surge capacity (Couch, 2021).

As the country headed into the COVID-19 pandemic in 2020, the SNS housed only 12 million N95 FFRs and 30 million surgical masks (Sun and Goldstein, 2020). To complicate matters, the PPE in the SNS had not been rotated out in a timely manner, resulting in respirators that were past their shelf life. Given the nationwide N95 FFR shortage, NIOSH examined the stockpile and recommended use of the expired N95 FFRs during the

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pandemic (CDC, 2020). Also during the pandemic, NPPTL focused significant efforts on increasing the supply of respirators available to workers, conducting a series of limited assessments for respirators in the following categories: (1) respirators that are stockpiled beyond their shelf life, (2) respirators that purport to meet an international certification standard but are not NIOSH approved, (3) respirators that have been decontaminated, and (4) non-NIOSH-approved respirators produced by novel commercial equipment (NIOSH, 2021d).

Should the stockpile be replenished, product shelf life will continue to be an issue. Patel and colleagues (2017) recommend a strategic approach to stockpiling with expiration dates in mind: For products, such as respirators, with a 5-year shelf life, 20 percent of the required target number of products could be purchased annually over 5 years to achieve 100 percent of the target; in year 6, product would begin to be replenished (Patel et al., 2017). Improvements in respirator design (e.g., exchangeable elastics) could also potentially extend shelf life.

As supplies in the SNS dwindled during the COVID-19 pandemic, the SNS mission diminished in scope. In April 2020, the language on its website text changed. Until then, the website stated:

> The Strategic National Stockpile is the nation's largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out.... When state, local, tribal, and territorial responders request federal assistance to support their response efforts, the stockpile ensures that the right medicines and supplies get to those who need them most during an emergency.

According to the revised language,

> The Strategic National Stockpile's role is to supplement state and local supplies during public health emergencies.... Many states have products stockpiled, as well. The supplies, medicines, and devices for life-saving care contained in the stockpile can be used as a short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available. (Blake, 2020)

This new emphasis on the SNS as a stopgap measure reflects the government's inability to keep pace with the demand for PPE.

From the onset of the COVID-19 pandemic, the federal government has failed to coordinate PPE production and distribution. Early on, the SNS had inadequate supplies to meet the immediate need, and the Trump Administration did not use the DPA to increase supply. Thus instead of using the DPA to require U.S. manufacturers to share information and work together to ramp up N95 FFR production, the government allowed them to

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continue to protect their manufacturing processes as intellectual property, making it difficult for new manufacturers to rapidly design and produce respirators that would meet NIOSH specifications (Contrera, 2020). In addition, the Trump Administration initially opted into private contracts for N95 FFR procurement, a strategy that led to unfulfilled obligations, fraud, and other criminal activity (Sinha, 2020). When the administration finally implemented the DPA for N95 FFRs, it was to require that manufacturers sell their products to the federal government. However, the federal government did not disperse an adequate supply of respirators to the states, which led to competition for the still-scarce respirators between states and the federal government (Anderson and Burris, 2021).

In March 2020, the federal government committed to spurring respirator production by purchasing 500 million N95 FFRs for the SNS. In its news release announcing the purchase, HHS acknowledged manufacturers' hesitancy to produce respirators without a guaranteed market, stating, "These guaranteed orders offer reassurance to manufacturers that they will not be left with excess supplies if private sector orders are cancelled once the COVID-19 response subsides" (HHS, 2020, para. 2). The government also used the DPA to order 3M to import more than 166 million respirators. By May 2020, FEMA had issued more than $600 million in new contracts for N95 FFRs to both large U.S. suppliers (3M and Honeywell) and smaller entrants to the market (Gereffi, 2020).

Throughout 2020, U.S. respirator production and imports grew significantly. 3M quadrupled its monthly domestic manufacturing output from 22 million to 95 million respirators/month and doubled its worldwide annual output. The manufacturer also provided a total of 228.4 million N95 FFRs, KN95, and KN90 respirators from 3M plants in the Asia-Pacific (APAC) region for FEMA to import to the United States (3M, 2020). By 2021, 3M and Honeywell were producing a combined 120 million masks/month. Meanwhile, new manufacturers entered the respirator market, churning out millions of N95 FFRs, but not always finding customers (Jacobs, 2021). Major online retailers, trying to follow CDC's request that N95 FFRs be reserved for health care workers, did not allow manufacturers to advertise N95 FFRs to the public. Meanwhile, major health care buyers preferred to work with well-known companies such as 3M and Honeywell, leaving new N95 FFR manufacturers with excess inventory and few customers (Jacobs, 2021). This disconnect led to continued scarcity for both the public and health care workers.

Despite increased production and imports, 12 months following the first recorded COVID-19 case in the United States, N95 FFRs were still difficult to come by for both health care workers and the public. Medical

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professionals continued to ration their respirators, and N95 FFRs were sparsely available to the public (Noguchi, 2021).

In early 2021, the incoming Biden administration announced it would use the DPA to ramp up PPE manufacturing. In an executive order ("A Sustainable Public Health Supply Chain"), the administration directed agency heads to review the availability of critical supplies, such as N95 FFRs, and "take appropriate action using all available legal authorities, including the Defense Production Act, to fill those shortfalls as soon as practicable by acquiring additional stockpiles, improving distribution systems, building market capacity, or expanding the industrial base" (Executive Office of the President, 2021, sec. 2[B][ii]). The same executive order also directed the development of a new Pandemic Supply Chain Resilience Strategy, which was released in July 2021 (HHS, 2021a).

This massive push to acquire and stockpile PPE during the height of the COVID-19 pandemic later resulted in an excess of supplies as the number of cases began to drop, with hospitals and manufacturers sitting on inventory that exceeded the demand for respiratory protection. This glut in supplies was due in part to the nature of the contracts signed during the worst part of the pandemic. Since manufacturers had to rapidly ramp up the production of PPE in a short timeframe, hospitals had to sign "very large, multiyear contracts" to enable this level of production (West, 2021). As a result, manufacturers were left with large stockpiles of masks and other PPE that have become a major strain on their finances; in August 2021, Cardinal Health Inc. reported that this stockpile was one of the main contributors to a 40 percent drop in earnings in the most recent quarter (Smith, J., 2021).

Conclusion 2-6: The SNS was inadequate to meet needs for respiratory protective devices during the COVID-19 pandemic. In addition, the increase in global trade and just-in-time manufacturing of respirators has particularly undermined the nation's ability to respond to surges in demand.

OVERARCHING CONCLUSION

The gaps and overlaps in authority highlighted in this chapter point to the need for a framework for ensuring access to and effective use of respiratory protection by the public and all workers. The specific needs and challenges for workers and the public, respectively, are examined in the two chapters that follow.

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Conclusion 2-7: The regulatory landscape for respiratory protection is highly fragmented, with notable gaps and overlaps in authorities. In some cases, the result is inadequate protection for workers and the public.

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3 Respiratory Protection in the Workplace

Respiratory protection has long been part of a broader set of controls designed to protect the safety and health of workers, but as described in this chapter, gaps in the current system have resulted in inadequate protection against inhalation hazards for some worker populations. Such workers include those who are not covered by respiratory protection programs (RPPs) but who may face occupational exposures on a regular or intermittent/episodic basis; they also include workers who are not usually exposed to inhalation hazards in the course of their job duties but may be exposed in exceptional circumstances (e.g., epidemics, wildfires and other extreme pollution events). In approaching the goal of ensuring adequate respiratory protection for all workers, the committee reviewed the salient literature to identify lessons learned that are applicable to broadening the scope of current programs and policies to address unmet needs.

The chapter begins by providing a rationale for expanding the reach of RPPs to worker groups not currently covered, as well as for developing modified respiratory protection options when warranted. This discussion focuses on the scope of the need and contributing factors, including hazards associated with public health and environmental emergencies, as well as the changing organization of work (e.g., growth of the gig economy, rise of temporary and contract work). The chapter then examines the formal industrial hygiene approach to use and oversight of respiratory protection in the workplace, including the extensive experience with RPPs that are based on requirements of the Occupational Safety and Health Administration (OSHA), as well as voluntary initiatives and programs developed by other

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agencies. The chapter concludes with in-depth analyses of the respiratory protection needs of several specific worker groups for which hazardous respiratory exposures are well documented. The committee acknowledges that this is not an exhaustive analysis of worker groups and that there are a multitude of work settings in which workers do not receive sufficient protection from inhalation hazards, both recognized and unrecognized.

UNMET RESPIRATORY PROTECTION NEEDS IN THE WORKPLACE

Unmet needs for respiratory protection result when workers are exposed to inhalation hazards but either do not have access to respiratory protection or use such devices outside of an RPP, resulting in reduced protection or even health risks from the device itself. The imperative to address these unmet needs is clear. The Occupational Safety and Health (OSH) Act of 1970[1] was passed with the intent to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions," in part by encouraging employers to establish and continuously refine programs for providing safe and healthful working conditions and by enabling the development of enforceable occupational safety and health standards. To this end, OSHA's Respiratory Protection Standard[2] and employer-instituted respiratory protection programs mandated by the standard, or by other regulatory agencies,[3] when use of respirators is necessary to protect worker health (see Chapter 2) have been key elements of a system designed to address inhalation hazards in the workplace. In such cases, employers are required to provide all employees with respirators appropriate for the intended purpose, as well as training and medical evaluation, at no cost to the employee. OSHA-mandated RPPs are intended to provide an established administrative structure for integrating control methods into the workplace to assess and control inhalation hazard exposures effectively, and to evaluate and assure the quality of control programs. However, there have long been gaps in coverage by RPPs and exposure scenarios have changed over time. Relevant and recent examples include the rising problem of wildfire smoke exposure and the expansive scope of worker exposure to SARS-CoV-2. The sections below explore the factors contributing to current gaps in respiratory protection for workers and the challenges characterizing the scope of the need.

[1] 29 U.S.C. § 651.

[2] 2 29 C.F.R. § 1910.134.

[3] The Mine Safety and Health Administration (MSHA) and the Environmental Protection Agency (EPA) have RPP requirements for exposures in mines and for pesticide handlers, respectively.

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Factors Contributing to Gaps in Respiratory Protection for Workers

The constrained application of OSHA's Respiratory Protection Standard has contributed to gaps in respiratory protection for workers. As discussed in Chapter 2, OSHA standards, including the RPP requirements and standards limiting workplace exposure to hazardous substances, are applicable only to employers covered under provisions of the OSH Act. From OSHA's inception, its requirements have not covered all workers and workplaces, only those workplaces where OSHA is a governing authority and to which its regulations apply, which includes those workplaces in states with OSHA-approved State Plans. There are 22 State Plan states where employers are subject to state rather than federal (OSHA) regulation and enforcement. Another six states have plans that cover public-sector workers through limited OSHA-approved State Plans and other workers through federal OSHA (OSHA, 2021g). By law, OSHA-approved State Plans include coverage of public-sector workers, but the state and local government agencies in 28 states and territories, including the District of Columbia, the Northern Mariana Islands, Guam, and American Samoa, are under no legal obligation to provide RPPs or to meet other OSHA requirements. Federal OSHA's purview does not extend to the approximately 3.1 million nonfederal,[4] public-sector workers employed in states without OSHA-approved State Plans (Maciag, 2014).

Other workers not covered by OSHA include many volunteer emergency responders, including some firefighters, rescue and recovery workers, and others who provide unpaid assistance in situations in which hazardous exposures may occur. Prisoners who do paid or unpaid work in prisons operated by 28 states and territories also are not covered by OSHA (OSHA, 2011b). Furthermore, a long-standing congressional appropriations provision has prohibited OSHA from any involvement in farms with 10 or fewer workers since 1976, when the provision was first passed (OSHA, 2014b).

Additional gaps in coverage have resulted from changing work practices in the United States. The traditional employer–employee relationship that was common 50 years ago is far less frequent today, and occupational safety and health is becoming more complex with the transition away from long-term, fixed-site employment relationships. Individuals may work for many different organizations throughout their lives, with a growing number involved in a nontraditional employer–employee relationship, such as independent contracting or temporary work, as well as what is often called the sharing or gig economy (Weil, 2014). Independent contractors,

[4] OSHA protections are extended to nonmilitary federal workers by Executive Order 12196 (see https://www.archives.gov/federal-register/codification/executive-order/12196.html [accessed August 17, 2021]).

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self-employed workers, and gig workers[5] are not currently considered employees of an employer under the OSH Act and are therefore not covered by OSHA requirements. The law has not been updated to reflect these employment relationships that have developed or become more prevalent in recent decades (Michaels and Barab, 2020). It should be noted that misclassification of workers as self-employed to avoid employer responsibilities is also common and contributes to gaps in worker protections, but is subject to existing Department of Labor regulation and enforcement (Carre, 2015).

Many workers in temporary jobs are hired either through staffing agencies or from day-labor pools. While many temporary workers are covered by OSHA, there is often confusion over whether the staffing agency or the worksite employer has responsibility for including such workers in an RPP. Per OSHA guidance on temporary workers, responsibility for the safety and health of these workers is shared between the staffing agency and the host employer. Staffing agencies are responsible for inquiring into the conditions in the workplace and verifying that the host employer has made conditions safe for the temporary worker. Host employers in turn are required to treat the temporary worker the same as any nontemporary worker in the workplace and provide the necessary training and protections (OSHA, n.d.b).

In addition to the gaps in worker protections created by the changing nature of work and employer–employee relationships in the United States, further challenges stem from workplace exposures to inhalation hazards that arise only in the context of public health and environmental emergencies, such as infectious disease epidemics and wildfires. As discussed later in this chapter, relevant examples include agricultural and other outdoor workers exposed to wildfire smoke, workers at increased risk of exposure to SARS-CoV-2 as a result of their interactions with the public and other workers, and volunteers and emergency responders involved in disaster response and recovery work. Because these hazards are not typically encountered by these workers outside of emergency situations, their employers may not have instituted an RPP. This is not to say, however, that an RPP cannot be required under OSHA for these types of nonroutine exposures. For example, OSHA has cited numerous employers for noncompliance with the Respiratory Protection Standard as a result of workplace hazards posed by both the H1N1 (Washington State Nurses Association, 2010) and COVID-19 (OSHA, 2021e) pandemics. Moreover, OSHA implemented an Emergency Temporary Standard for health care workers in June 2021 and a National Emphasis Program in March 2021 to ensure that employees in other high-hazard industries (e.g., meat processing, warehousing, grocery

[5] As noted in Chapter 2, platforms through which gig workers are currently assigned and paid are not considered employers under OSHA (Conger, 2021). Federal and several state labor agencies are currently exploring whether to classify gig workers as employees (Bose, 2021).

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retail, food service, corrections) would be protected from exposure to SARS-CoV-2 (OSHA, 2021c). However, OSHA's Respiratory Protection Standard requires that employers make a judgment that an RPP is needed when no permissible exposure limit (PEL) has been established; as a result, there are workers who experience potentially dangerous exposures who are not protected by an RPP.

Even for those workplaces and workers covered by OSHA regulations, the agency has been slow to issue new standards that would result in more comprehensive respiratory protection. OSHA has standards for only a small percentage of chemicals that are encountered in commerce. The majority of current PELs date to industry consensus standards set in the 1960s or earlier, and the agency has no specific requirements for the application of the hierarchy of controls to reduce exposure levels to the PEL. OSHA itself has recognized that existing PELs are outdated and may fail to sufficiently protect workers (OSHA, n.d.a), but its attempts to address this gap have been largely unsuccessful (OSHA, 2014a). In more recent decades, OSHA's policy has been to issue comprehensive standards limiting chemical exposures; these standards include requirements to apply the hierarchy of controls, and many include specific requirements for respiratory protection. However, OSHA's standards-setting process is slow, and since its inception, the agency has issued comprehensive standards for only approximately 32 chemicals, only 18 of which are still present in workplaces. Moreover, there are no such federal standards for wildfire smoke (Layton, 2020) or infectious agents similar to the aerosol transmissible disease standard promulgated by the state of California (Cal/OSHA, 2020b). The regulatory processes required to issue new standards pose significant challenges to addressing emerging threats.

These gaps in respiratory protection for workers need to be addressed.

Scope of the Problem

It is difficult to estimate the number of workers who are exposed to inhalation hazards at their workplace but are not covered by an RPP. Part of the challenge stems from the fact that, with the exception of a few chemical-specific standards, OSHA does not specify industries or worker groups that are subject to its Respiratory Protection Standard. Rather, this determination must be made at the workplace level based on a hazard assessment, with consideration of whether any potential inhalation hazards can be adequately mitigated through other controls. Several data sources, including those from the Bureau of Labor Statistics (BLS) and the National Institute for Occupational Safety and Health (NIOSH), are potentially useful for indirectly identifying and estimating the size of the unprotected

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worker population (see Box 3-1), but each is subject to significant data gaps and limitations.

The scope of unprotected workers could be estimated by calculating the number of workers in industries who are exposed to inhalation hazards but not covered by an RPP because of noncompliance with or exclusion from OSHA standards, as well as those working in locations that usually

BOX 3-1
Data Sources for Estimating the Scope of Unprotected Workers Exposed to Inhalation Hazards

The following sources of data on workforce statistics, hazardous exposures, occupational disease rates, and respiratory protection programs could inform the scope of the problem related to unprotected workers exposed to inhalation hazards.

- Workforce numbers and industry and occupational data from the Bureau of Labor Statistics (BLS, 2020)
- Exposure data
  - National Institute for Occupational Safety and Health (NIOSH) Occupational Hazards Survey data (historical data from 1981 to 1983)
  - Health and Safety Practices Survey of Healthcare Workers (2011) (NIOSH, 2017a)
  - O*NET exposure data (Cifuentes et al., 2010)
- Data on the incidence and/or prevalence of workplace respiratory illnesses
  - NIOSH's Work-Related Lung Disease Surveillance System, which since 2008 has provided data, provided in downloadable spreadsheets, on morbidity, mortality, and workplace exposures with respect to work-related respiratory diseases by geographic region, industry and occupation, and demographic group (NIOSH, 2021c)
  - BLS's Survey of Occupational Injuries and Illnesses, which estimates the number and rate of employer-recorded respiratory illnesses by industry (BLS, 2021b)
  - The Health and Retirement Study, a longitudinal panel study that surveys a representative sample of approximately 20,000 people in the United States biennially and allows for assessment of associations among industry and occupation, workplace exposures, and chronic lung conditions (University of Michigan, 2020)
  - The National Health and Nutrition Examination Survey, developed to assess the health and nutritional status of adults and children, which combines interviews with physical examinations (CDC, 2017)
- Data on respiratory protection programs
  - OSHA compliance data from employer citations related to OSHA's Respiratory Protection Standards (1910.134)
  - The BLS/NIOSH Survey of Respirator Use and Practices (DOL and NIOSH, 2003)

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require protection only in unusual circumstances. However, this approach to generating numerical estimates has a number of important limitations, which include but are not limited to the following:

- BLS data provide only a rough approximation of worker populations, as the number of workers in some industries (such as agriculture) or demographics (such as day laborers or school-aged workers) will vary depending on the season (NASEM, 2018).
- Data concerning workplace respiratory illnesses are either sparse, outdated, or lacking in sufficient detail. For example, Survey of Occupational Injuries and Illnesses (SOII) data on the workplace incidence of respiratory diseases exclude the self-employed, workers on farms with 10 or fewer employees, private household workers, volunteers, and federal government workers, as well as workers from some states based on variability in state participation each year. In addition, SOII estimates are based on only those respiratory disease cases that the reporting employer learns about, recognizes as work-related, and then decides to record on its OSHA log, so they unquestionably represent an underestimate of the actual numbers and rates of illnesses (BLS, 2020).
- Workers within the same industry may be working in very different environments with different requirements for respiratory protection (Tarlo and Malo, 2013).
- OSHA compliance/citation data are of limited value given the infrequency of OSHA workplace inspections and the fact that OSHA is most likely to cite a workplace where there is a complaint-driven inspection or workplace fatality, or if the workplace is selected for inspection as part of an "emphasis program," where exposure to a particular hazard is expected (e.g., the Silica National Emphasis Program). Therefore, unless a formal complaint is made or the hazard is already known to OSHA, most workplaces with inhalation hazards are likely to avoid citation. Moreover, these data do not capture those workers excluded from OSHA coverage.
- The BLS/NIOSH Survey of Respirator Use and Practices provides valuable insights into inhalation hazards and use of respiratory protection in the United States but has not been updated since 2001, although plans are under way to do so (BLS, 2021a).
- Linking data from different sources (e.g., BLS, occupational illness surveillance) is complicated by the use of different industry/occupational categories and codes.
- Most of the existing data on occupational exposures and illnesses cover only workplace exposures to traditionally regulated hazards, and do not account for workers who are exposed to inhalation

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hazards in the course of their work only during exceptional circumstances (e.g., elevated ambient pollution levels, wildfires, pandemics). Data on such exposures are often not collected systematically. For example, the Centers for Disease Control and Prevention (CDC) does not require reporting of occupational, demographic, exposure, or health outcomes data for COVID-19.

Given these limitations, any estimation of the number of workers not covered by RPPs who are potentially exposed to inhalation hazards at their workplaces will necessarily be a gross undercount and incomplete. The ability to generate a reasonable estimate would require NIOSH, in conjunction with OSHA, the Mine Safety and Health Administration (MSHA), and BLS, to update previous worksite hazard surveys and conduct more widespread exposure surveillance and intervention assessment to better understand workplace exposures and which worker populations are covered by RPPs. A national occupational disease registry, similar to those used in other countries (ILO, 2013), would facilitate improved assessment of occupational respiratory illness.

Summary and Synthesis

The above discussion demonstrates that significant gaps likely exist in respiratory protection for high-risk worker populations. The growing number of employers who employ workers in settings outside of the formal employment relationship—such as temporary, gig, informal, or contingent workers—has likely increased the potential for gaps in respiratory protection for workers. Moreover, emergency situations such as wildfires and COVID-19 have highlighted occupations and settings in which known and emerging hazards occur and for which RPPs are needed to prevent acute and chronic health effects when workers are exposed incidentally. However, the full scope of the problem is unknown because of the significant gaps that exist in the data needed for both understanding compliance with and evaluating the impact of regulations in preventing inhalation exposures and adverse health effects. Existing federal and state data systems are fragmented and incomplete, precluding a clear picture of the extent to which workers continue to be exposed to inhalation hazards without needed and OSHA-mandated RPPs. For workers not covered by OSHA, the lack of information is even more problematic. Acknowledging that previous National Academies reports have identified the need for investment in improved occupational safety and health surveillance (NASEM, 2018), including surveillance of occupational exposures to inhalation hazards and associated occupational diseases (IOM and NRC, 2008), the committee further emphasizes the importance of a focus on populations not covered by OSHA

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regulations (e.g., informal workers) and exposures that may be encountered by workers only in emergency settings.

Conclusion 3-1: The changing nature of employment relations and emerging hazards, such as wildfires and COVID-19, have increased the number and types of workers who may be exposed to inhalation hazards but are not currently covered under OSHA-required RPPs. This may occur when workers are excluded from OSHA coverage in general, or when employers covered by OSHA fail to comply with RPP requirements, or elect not to provide RPPs in situations in which workers are exposed to inhalation hazards but the employers are not required to provide RPPs.

Conclusion 3-2: Regulatory and public health agencies do not collect adequate data for assessing and evaluating the risk posed by hazards in the workplace and compliance with respiratory protection regulations. This inadequate data collection impedes understanding of the scope of workers exposed to inhalation hazards but not covered by RPPs.

SYSTEMS FOR ENSURING RESPIRATORY PROTECTION IN THE WORKPLACE

In considering approaches for addressing the above-described gaps in respiratory protection for some groups of workers, the committee sought to understand the benefits and limitations of RPPs, considering their implementation in the context of the hierarchy of controls and the factors that influence their effectiveness.

Respiratory Protection Programs and the Hierarchy of Controls in the Workplace

Chapter 1 introduces the hierarchy of controls (see Figure 1-2) as a general framework consisting of multiple layers of control methods (e.g., engineering, administrative) for reducing the exposure of workers to hazards and promoting occupational safety and health (NASEM, 2019b), ideally in the context of a comprehensive program (safety and health management system or injury and illness prevention program). Personal protective equipment (PPE), such as respiratory protective devices, is at the lowest level of the hierarchy. Unlike controls at higher levels, its effectiveness depends on having an integrated system (i.e., RPP) in place to ensure the availability of

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efficacious equipment and its proper use by individual workers at all times. Consequently, individual PPE requires adequate distribution, a system of oversight, worker-level training on its use, and maintenance of the devices. Additionally, the use of respiratory protection may itself pose secondary safety hazards related to impaired visibility and communications (Hampton et al., 2020; Hignett et al., 2020) and increased stress on the wearer, associated, for example, with increased facial heat and effort to breathe (McPherson, 2008).

Compared with implementing worksite environmental engineering controls, the use of PPE generally has a lower up-front cost. The higher initial cost and other logistical challenges associated with higher-level control methods may contribute to an overreliance on PPE in some workplaces (NIOSH, 2015a), but sustaining a PPE program for workers can be costly over time. Using the World Health Organization's (WHO's) cost-effectiveness analysis framework, for example, Lahiri and colleagues (2005) showed that engineering controls are more cost-effective than other interventions, including respiratory protection, for prevention of occupationally acquired silicosis.

Despite the limitations of PPE as a control method, some work tasks by their very nature (e.g., firefighting, caring for infectious patients) involve potential exposures to inhalation hazards that cannot be mitigated through engineering controls or other mechanisms higher on the hierarchy of controls. In such cases, it may be necessary to use respirators in the workplace in the context of an RPP to prevent specific illnesses and exacerbation of chronic illnesses caused by breathing contaminated air.

Effectiveness of Respiratory Protection When Used in the Context of a Respiratory Protection Program

Evidence of Effectiveness

As discussed in Chapter 1 (see Box 1-2), the assigned protection factor (APF) for a respirator provides a standardized measure of the device's workplace level effectiveness (OSHA, 2009). Yet, while protection factor studies can provide an estimate of the effectiveness of respirators at reducing exposure (when used in the context of a comprehensive RPP), understanding the effectiveness of RPPs themselves is more challenging.

Few peer-reviewed studies have evaluated the impact of OSHA-mandated RPPs on the safety and health of workers, although anecdotal reports suggest that the presence of a defined RPP provides measurable benefit in protecting employees from inhalation hazards. One example is offered by

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the Texas Center for Infectious Disease (TCID), a long-term care hospital specializing in the management of difficult-to-treat tuberculosis cases. Prior to 1986, TCID had no formal infection control plan, and annual tuberculin skin tests revealed that 40–50 percent of the center's staff had positive results, with 1–2 percent of staff developing tuberculosis (NASEM, 2019b). TCID instituted an RPP for its staff in 1995. Employees receive extensive training in how to properly use, disinfect, and store their TCID-supplied elastomeric facepiece respirators, culminating in a written test to ensure correct understanding of the elements of the RPP. Additionally, all staff who enter patient rooms are required to undergo qualitative fit testing (NASEM, 2019b). Since this RPP was implemented, no TCID employees have tested positive on a tuberculin skin test (NASEM, 2019b; The Joint Commission, 2014).

Beyond such anecdotal reports, few studies have directly measured protection against acute or chronic health effects from inhalation hazards following implementation of an RPP. Informative examples can be drawn from the literature on hazards for which biological monitoring is ongoing, such as with the OSHA lead standard. Numerous studies have demonstrated reductions in exposure biomarkers associated with use of respirators in the workplace (Burgess et al., 2001; Grauvogel, 1986; Hyatt, 1984; Liu et al., 2016). However, a notable challenge to assessing the benefits of an RPP is the difficulty of disentangling the consequences of the program from those of use of the respirator itself. An early study by Harris and colleagues (1974) on the effectiveness of respirators for protection from coal dust in underground coal mines showed that even in the absence of an RPP, use of respirators reduced exposures to the dust (Harris et al., 1974).

Further evidence for the potential benefits of RPPs is reported by Cowan and colleagues (2017), who examined fatalities associated with the use of respiratory protection in industrial settings between 1990 and 2012. The authors note a reduction in fatality rates during that time period that appears to be associated with the 1998 publication of OSHA's revised Respiratory Protection Standard, which included new language designed to ensure that employers would have sufficient guidance to support the selection and maintenance of respiratory protective devices. The findings they report show that historical fatalities associated with respirator use appeared to be associated primarily (>90 percent) with employee error and/or lack of employer compliance with the OSHA Respiratory Protection Standard (e.g., lack of a written RPP, lack of or improper training). The authors conclude that the implementation of the revised OSHA standard, as well as enforcement, outreach, and compliance assistance, had a significantly favorable impact on fatality rates over time (Cowan et al., 2017).

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Compliance as a Limiting Factor for the Effectiveness of Respiratory Protection Programs

In addition to evidence of benefit, the committee sought to understand the limitations of RPPs, finding that they relate primarily to employers' lack of compliance with the OSHA Respiratory Protection Standard. Employers' failure to comply with program requirements will limit the effectiveness of such systems for protecting workers from occupational respiratory illnesses, although empirical data to demonstrate such impacts are sparse. The reasons for inadequate adoption of and compliance with RPP requirements are not well understood, but research suggests that financial constraints play a major role in the failure to establish health and safety programs more broadly for small businesses (NIOSH, 2018; Vinberg, 2020). A 2007 survey of Kentucky fire departments, for example, found that funding and lack of understanding were the greatest barriers to RPP implementation (Easterling and Prince, 2007).

Several survey-based studies have demonstrated shortcomings of institutional RPPs. In 2001, NIOSH and BLS undertook a broad survey of respirator use and practices among U.S. private-sector employers (DOL and NIOSH, 2003). The survey was mailed to approximately 40,000 private-sector establishments. Based on the survey results, the authors report that respirator use was required in 4.5 percent of these establishments and for 3.1 percent of their employees. Importantly, the survey showed that among establishments requiring respirator use, 91 percent had at least one indicator of a potentially inadequate RPP, while 54 percent had at least five such indicators (Doney et al., 2005). Of the businesses surveyed in which respirators were used, 65.5 percent had no written program detailing how respirators would be used, 49.9 had no written procedure for maintaining their respirators, and 43.3 percent offered no form of fit testing (Doney et al., 2005). These findings suggest that large numbers of employers may not adhere to OSHA requirements for RPPs, putting their workers at risk. However, these data are 20 years old, and the survey was conducted shortly after the 1998 revision of the Respiratory Protection Standard, limiting the conclusions that can be drawn about RPP compliance today. NIOSH and BLS recognize the need to update this survey, and a new survey is planned (BLS, 2021a).

More recently, a study of California hospitals during the 2009–2010 H1N1 influenza pandemic showed that although health care workers reported knowing that they should wear N95 filtering facepiece respirators (FFRs) when in close contact with patients with confirmed or suspected cases of the disease, an evaluation of the hospitals' written RPPs revealed deficiencies in the areas of recordkeeping, designation of a program administrator, program evaluation, employee training, and fit testing procedures

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(Beckman et al., 2013). Other studies have found similar shortcomings in workplace RPPs for both health care and public safety workers (Sietsema, 2017; Sietsema et al., 2015).

OSHA citation data support the findings of the survey-based studies described above, further indicating that many employers are not adequately complying with the Respiratory Protection Standard. Mendeloff (2013) carried out an analysis to complement the study undertaken by BLS and NIOSH in 2001. He examined the OSHA database of all inspections in manufacturing establishments in 47 states from 1999 through 2006 (after the OSHA Respiratory Protection Standard had been revised). The study identified inspections and establishments in which respiratory protection violations had been cited, and compared the prevalence of violations by industry with the prevalence reported in the BLS survey of respirator use. The most frequent violation of the OSHA standard (representing one-third of the total) was the failure to have a written RPP. The author found that the probability of citing a respiratory protection violation was comparable across establishment sizes, except for a large decrease at establishments with more than 200 workers. For those workers covered by OSHA, increased enforcement could address RPP limitations related to compliance. However, increased enforcement will not address gaps related to those workers not covered by OSHA's Respiratory Protection Standard, and the root factors that lead to noncompliance need to be understood.

Summary and Synthesis

How well respiratory protection works in practice depends on a sequence of steps, each representing a potential failure point (see Figure 3-1). These determinants of effectiveness include a hazard assessment that leads to the proper selection of a respirator based on its APF and use of the device in the context of a comprehensive RPP, with ongoing surveillance. Extending this framework more broadly to other groups of workers, it is important to consider the extent to which each element of this framework needs to be replicated to ensure effective programs for worker groups not currently covered by RPPs. It should be noted, however, that even for those workplaces clearly subject to the requirements of OSHA's Respiratory Protection Standard, there is evidence of failure to implement RPPs (or to implement them adequately). The Respiratory Protection Standard is consistently among the top 10 most frequently cited OSHA standards (OSHA, 2021h). However, addressing the issue of compliance with OSHA RPP requirements will require more than increased enforcement. Efforts to better address the respiratory protection needs of workers need to include a focus on improved safety culture (IOM and NRC, 2008).

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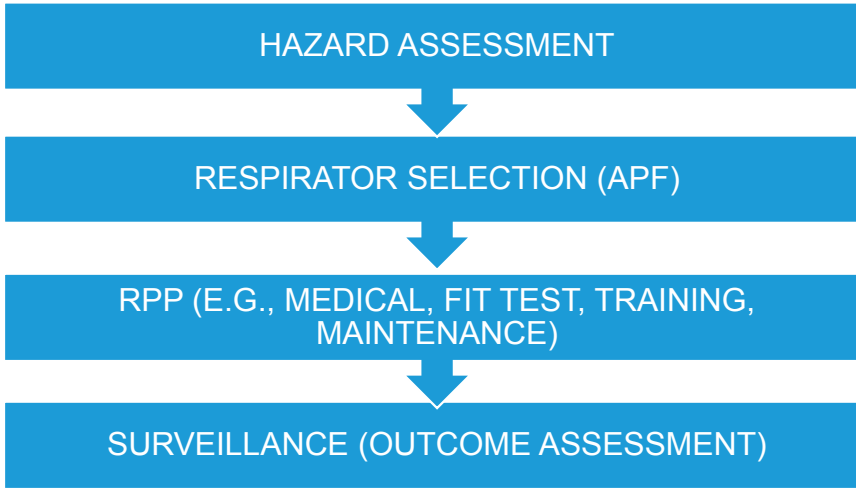


FIGURE 3-1 Potential failure points for workplace use of respiratory protection.
NOTE: APF = assigned protection factor; RPP = respiratory protection program.

While challenges related to latency of outcomes and confounding factors limit the availability of direct evidence on the effectiveness of RPPs, it can be inferred from indirect evidence in the form of exposure reduction studies and dose-response relationships that RPPs, when implemented appropriately and enforced, protect workers from inhalation hazards. Importantly, the committee found relatively little rigorous and systematic evidence for evaluating the best methods and strategies for implementing an RPP. More robust collection of data on the use of respiratory protection in a workplace environment is needed, applying methods recommended in the National Research Council review of the 2001 BLS/NIOSH Survey of Respirator Use and Practices, including the collection of data from employers and employees on respirator use in the workplace (NRC, 2007). Standardized measures for evaluating respirator use in the context of RPPs will also be important (Yarbrough et al., 2016). Consistent with past evaluations (IOM and NRC, 2008), the committee found that more research is needed on the facilitators of and barriers to effective use of respiratory protection in the workplace, including human factors, individual and organizational behaviors, and workplace safety culture. Such efforts will need to address previously recognized challenges to data collection and research, including lack of access to work environments and historical records, as well as lack of cooperation from employers (IOM and NRC, 2008).

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Conclusion 3-3: The science and research foundation for understanding the successful implementation of RPPs for all workers ("implementation science") is relatively sparse, limiting the ability of public health and regulatory agencies to disseminate best practices, ensure their proper implementation, and enforce RPPs.

BEYOND RESPIRATORY PROTECTION PROGRAM (RPP) REQUIREMENTS IN OSHA'S RESPIRATORY PROTECTION STANDARD

Although the requirements laid out in OSHA's Respiratory Protection Standard may represent the best-known model for workplace RPPs, the committee sought to explore alternative approaches by which worker respiratory protection needs could be met. This section reviews programs regulated by other government agencies, as well as other respiratory protection models—including voluntary programs—that could be implemented when full RPPs are not required.

Other Program Types

Other Federal and Nonfederal Programs

The requirements laid out in OSHA's Respiratory Protection Standard are widely accepted and referenced by other entities with identified inhalation hazards in their workplaces. Federal and state regulations that require respirators in the workplace generally adopt the OSHA standard by reference in whole or in part. Accreditation bodies such as The Joint Commission, a health care accreditation organization, also refer to the OSHA requirements for RPPs as the basis for their respiratory protection guidelines. The Joint Commission cites 1910.134 and the NIOSH–OSHA Hospital Respiratory Protection Program Toolkit: Resources for Respirator Program Administrators.

In some cases, regulations specific to hazards or work practices may go further, specifying the type of respirator to be used and/or specifics of how to administer the respiratory protection program. For example, the Environmental Protection Agency's (EPA's) worker protection standard (40 C.F.R. § 170.507) includes requirements for fit testing, medical evaluation, and training that conform to the OSHA Respiratory Protection Standard but requires pesticide handlers to be provided with respirators as specified on the product label. The U.S. Army, which requires compliance with OSHA's Respiratory Protection Standard per Army Regulation (AR)

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11-34 (Department of the Army, 1990), has established Toxic Chemical Agent Safety Standards (Department of the Army, 2018) and provides additional guidance related to respirator selection based on chemical type and concentration. Similarly, some states simply adopt the federal OSHA standard, while others have their own regulations that go beyond what OSHA requires.

Alternative Approaches in the Context of the COVID-19 Pandemic

SARS-CoV-2, which was recognized belatedly as an airborne inhalation hazard, presents extensive challenges for protecting workers and has altered the landscape for regulation of worker respiratory protection. On January 21, 2021, the Biden administration issued an executive order directing OSHA to take action to reduce the risk to workers of contracting COVID-19 at their workplaces (Executive Office of the President, 2021). OSHA issued nonmandatory guidelines for non–health care employers in late January 2021 (OSHA, 2021f) (see Box 3-2), and in June 2021, it issued an emergency temporary standard (ETS) under 29 CFR 1910 Subpart U for workers in health care settings where suspected or confirmed cases of COVID-19 are being treated. The ETS requires employers in health care settings to develop and implement effective plans for mitigating the threat of COVID-19, including developing a COVID-19 plan (in written form if they have more than 10 employees) with a designated safety coordinator, a workplace-specific hazard assessment, and policies and procedures for minimizing the risk of transmission of COVID-19 to employees (29 C.F.R. § 1910.502).

BOX 3-2
OSHA Guidelines for Employers on SARS-CoV-2

Employers are advised to implement a COVID-19 prevention program, including assignment of a workplace coordinator; identification of where and how workers may be exposed; and identification of measures to limit the spread of COVID-19, in line with the principles of the hierarchy of controls (e.g., physical distancing, ventilation, face coverings). The guidelines also include specific recommendations to protect higher-risk workers, educate and communicate effectively with workers in languages they understand, instruct infected or potentially infected workers to stay home and minimize the negative effects on those workers of quarantine and isolation, isolate workers who show symptoms at work, and take extra measures to clean and disinfect surfaces after people with confirmed or suspected COVID-19 have been in the facility.

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As part of the ETS for workers in health care settings, OSHA developed a "mini RPP" for use in the specific circumstances of the ETS when a respirator is not required but may provide enhanced protection for workers not exposed to confirmed or suspected cases of COVID-19. The mini RPP applies to workers not already covered by a traditional RPP and is not meant as a substitute or replacement for OSHA's normal Respiratory Protection Standard (29 C.F.R. § 1910.134). Table 3-1 provides a comparison of requirements under OSHA's standard RPP and the mini RPP when the respirators are employer provided.[6] The mini RPP has some similarities to OSHA's voluntary use provision (described below), but if an employer provides respirators to employees under the mini RPP (regardless of device type), that employer must provide training on the use of the device, ensure that seal checks are properly conducted, ensure that the respirators are reused properly, and ensure discontinuation of respirator use under certain conditions (OSHA, 2021d).

In the absence of a national standard to protect non–health care workers from transmission of SARS-CoV-2, states have developed their own

TABLE 3-1 Comparison of Requirements for Mini and Full Respiratory Protection Programs (RPPs)

KEY PROGRAM ELEMENT[a]	MINI RPP (1910.504)[b]	NORMAL RPP (1910.134)[c]
Medical Evaluation		√
Fit Testing		√
Written Program		√
User Seal Checks	√	√
Training	√	√

[a] This is not a comprehensive list of required program elements.

[b] These are key requirements pertaining to employer-provided respirators (as opposed to worker-provided respirators).

[c] For additional information about the Respiratory Protection Standard's requirements, see NIOSH/OSHA's "Hospital Respiratory Protection Program Toolkit Resources for Respirator Program Administrators" at www.osha.gov/sites/default/files/publications/OSHA3767.pdf (accessed September 27, 2021).

SOURCE: OSHA, 2021d.

[6] If employees provide their own respirators, employers are required only to provide them with a specific notice contained in 29 C.F.R. § 1910.504(c).

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regulations and protocols. Beginning in the early days of the pandemic, state governments issued public health orders covering workplaces, ranging from general guidelines to comprehensive safety and health standards. The first state to promulgate a comprehensive occupational safety and health standard was Virginia, in July 2020 (Virginia DOLI, 2020). This emergency standard required employers to conduct exposure assessments and determine whether a job task poses high, medium, or low risk. It incorporated the hierarchy of controls, and invoked OSHA PPE standards (including the respirator standard) if the assessment concludes that PPE is needed. Use of face coverings was considered to be an administrative control. Oregon and California also issued worker safety standards for COVID-19 exposure (Cal/OSHA, 2020c; Oregon OSHA, 2020).

In other states, governors issued executive orders, or regulatory agencies provided guidance, in some cases tied to general state orders for prevention of the spread of COVID-19, such as limitations on public gatherings, mandatory face coverings in public places, and social distancing, and in others tied to a state's plans for reopening. Public health agencies issued workplace-specific guidance for occupations posing a high risk of disease transmission. Many of these measures were instituted for a limited period of time, and as the pandemic ebbed in spring 2021, were being phased out or relaxed. California, for example, initially required employers to provide face coverings and ensure that their employees used them under its ETS (Cal/OSHA, 2020a); that requirement was revised on June 17, 2021, when employers were allowed to let fully vaccinated employees forego wearing face coverings indoors (Cal/OSHA, 2021b). Other states issued guidance on which types of masks should be worn by workers based on risk level, even though the requirement for vaccinated workers to wear a mask had ended (Washington State DOLI, 2021b).

Voluntary Use of Respiratory Protection in the Workplace

This section addresses cases in which an employer chooses to provide employees with respiratory protective devices or to allow employees to bring their own devices when their use is not covered or required under federal or state regulations. Voluntary use in this context refers to the worker's choice to use the device, not the employer's choice to offer an RPP, which is dictated by the hazard analysis. The experience with such programs offers insights into the potential effectiveness of less formal initiatives since in such situations, a comprehensive program meeting all the requirements of OSHA's Respiratory Protection Standard is unlikely to be followed. However, OSHA does have some mandatory requirements designed to ensure that the voluntary use of respirators does not by itself create a hazard. The discussion below reviews considerations for different types of respiratory

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protective devices that may be used in the workplace when not required under federal or state regulations.

Considerations for Voluntary Use of Respirators

In some cases, workers may wear respirators to avoid exposure to a hazardous substance even if that exposure does not exceed the limits set by OSHA standards. Voluntary use of respirators is included within the OSHA Respiratory Protection Standard 1910.134, with requirements specified in Appendix D. The concept of voluntary use of respirators was introduced when OSHA first published its revised Respiratory Protection Standard in 1998; it had not been included in the previous version. According to the revised standard, if "respirator use is not required, an employer may provide respirators at the request of employees or permit employees to use their own respirators, if the employer determines that such respirator use will not in itself create a hazard" (1910.134(c)(2)). As was clarified by OSHA in a letter of interpretation issued on April 26, 2018 (OSHA, 2018), employers are not required to pay for or provide these respirators to employees, but are required to ensure that employees are familiar with the training outlined in Appendix D of the OSHA Respiratory Protection Standard.

Respirators used voluntarily include those that are not filtering facepiece devices and those that are (see Figure 3-2). Under voluntary use, filtering facepiece respirators are not specifically required to be NIOSH approved; they do not require fit testing; employees can have facial hair; and medical clearance is not required (OSHA, 2018), although employees with known respiratory limitations should be advised to consult their physician prior to wearing such a device. "Employers are not required to include in a written respiratory protection program those employees whose only use of respirators involves the voluntary use of filtering facepieces" (1910.134(c)(2)). In contrast, use of elastomeric facepiece respirators or supplied-air respirators, even voluntary use, requires that the employer include all applicable elements in a written RPP to avoid hazards associated with use. The written RPP varies by respirator type selected for use, but must encompass the medical evaluation (which the employer must pay for), cleaning, maintenance, and storage components (OSHA, 2018).

A number of problems can potentially arise when respirators are used voluntarily in the workplace outside of an OSHA-mandated RPP (Gibbs and Nonnenmann, 2020). The use of non–NIOSH-approved devices may occur if employees bring their own devices purchased from retail stores or are unable to obtain approved devices from the marketplace because of shortages. In such cases, the risk is that the protection (e.g., filter efficiency) offered by alternative devices may be untested and insufficient. These devices may have higher breathing resistances relative to approved respirators

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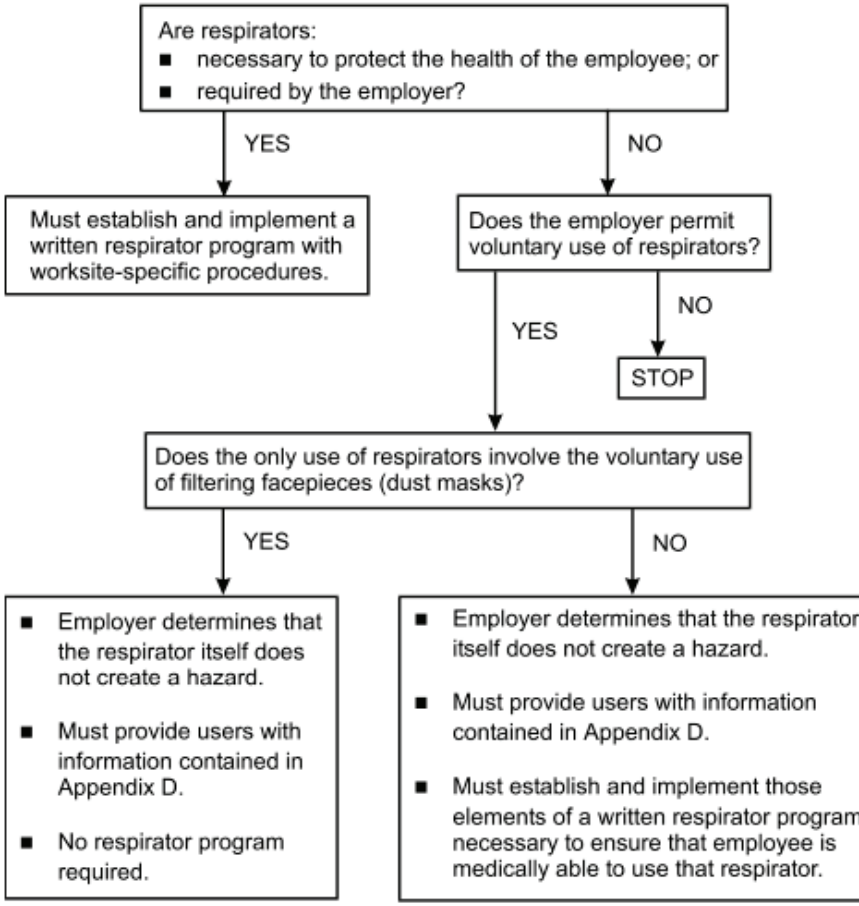


FIGURE 3-2 OSHA requirements related to voluntary use of respirators in the workplace in the absence of a formal respiratory protection program.
SOURCE: OSHA, 2006.

and cause unacceptable physiological stress to the user. The materials of construction that contact the face of these devices may cause irritation or rashes. Additionally, tight-fitting air-purifying respirators rely on a proper fit to ensure that the majority of air passes through the filter or cartridge and not through facepiece leaks. This assurance normally requires the combination of a fit test to select a proper respirator size and a seal check each time the device is donned. Users who wear respirators in the absence of such testing and/or checking may have a false sense of protection. Despite these concerns, employees' use of their own personally acquired respirator (i.e., not provided by the employer) may be warranted when employers do not or

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cannot provide access to protective equipment that is commensurate with the risk to which the workers are exposed (The Joint Commission, 2020).

Underlying the OSHA rules for voluntary use of respirators is the assumption that no significant inhalation hazard is present and that wearing a respirator does not by itself cause a hazard to the user. To ensure that the respirator provides adequate protection and to avoid any device-related problems for the user, the user should have some basic instruction on

- how to don the device properly, including the orientation on the face;
- any limitations of the device for the hazard at hand;
- the need to either dispose of the device after use or properly clean it;
- the need to disinfect the device when worn multiple times in the presence of an infectious agent;
- a proper method for safely storing the device if it will be reused; and
- the requirement that it not have exhalation valves when the hazard is an infectious agent.

Considerations for Voluntary Use of Medical Masks

Medical masks have historically been used to protect others from infectious diseases the wearer may have (source control), and not to provide inhalation protection against hazardous aerosols. Applicable Food and Drug Administration (FDA) regulations (discussed in Chapter 2) govern manufacturers and not employers or employees. Some employers (e.g., hospitals) may have specific rules for their employees governing the selection and use of masks in the workplace. When masks are selected, FDA-cleared devices or those tested to ASTM standards will ensure that the device has an acceptable level of performance in terms of filtration, construction (e.g., biocompatibility), and breathing resistance.

Fit testing is not a requirement for medical masks used in the workplace since the devices are not intended to provide a tight seal to the face of the wearer. However, workers using such masks voluntarily should have adequate instruction on

- how to don the device properly, including the orientation on the face;
- the need to either properly dispose of the medical mask or clean it after use;
- the need to disinfect the mask if the hazard is an infectious agent;
- a proper method for safely storing the device if it will be reused; and
- a requirement that it not have exhalation valves if the hazard is an infectious agent.

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Considerations for Voluntary Use of Barrier Face Coverings

Face coverings are an unregulated product that have been widely used to limit the spread of exhaled droplets or fine-particle aerosols during the COVID-19 pandemic. There are no regulations governing the use of barrier face coverings by employers or employees. As discussed above and in Chapter 2, a recent ASTM standard has established requirements for a barrier face covering to be used as a source control product, although the standard does not include a requirement to measure the performance or effectiveness of the product for that purpose. Barrier face coverings are not a substitute for respirators, since their performance in terms of inhalation protection is unknown. However, it may be anticipated that many workers will wear barrier face coverings in the workplace voluntarily even after indoor mask mandates and individual employer policies requiring their use have been lifted, although some may prefer respirators over barrier face coverings once supply issues have been resolved.

Summary and Synthesis

Circumstances in which respiratory protection might be used by workers outside of an OSHA-mandated RPP include voluntary use of respiratory protective devices on the part of employees and an array of situations in which agencies other than OSHA may call for RPPs, although OSHA regulations remain the starting point in such situations. The review in this section affirms that the OSHA-mandated RPP is the "gold standard" for respiratory protection and makes clear that voluntary initiatives can be fraught with gaps. Consideration also needs to be given to the potential for power dynamics in the workplace to impact the ability of employees to access respiratory protection under voluntary programs.

The urgency posed by transmission of SARS-CoV-2 highlights gaps in achieving sufficient respiratory protection for the wide range of potentially exposed and at-risk workers, as discussed in further detail later in this chapter. A range of state and local public health guidance has been issued using transmission control measures with broad reach, such as social distancing, shutdowns, and increased ventilation. However, the absence of federal enforcement of an RPP recognizing airborne transmission of COVID-19 has left many workers without adequate personal protection. Medical masks and commercial face coverings have been marketed, purchased, and used, often with the user's lack of understanding of the uncertainty of the inhalation protection provided by these devices resulting from variable fit and filtration characteristics, which are described in Appendix B. Likewise, while guidance issued by federal agencies has helped employers and employees

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understand the difference between source control devices and respirators, confusing terminology and the lack of standards have hindered the implementation of adequate respiratory protection for workers, both within and outside the health care sector.

While the OSHA RPP model could be adopted for use in other situations in which workers are exposed to environmental hazards, such as wildfire smoke, or infectious agents responsible for epidemics, such as SARS-CoV-2, covering all potentially exposed workers would require a substantial expansion of effort and cost. It would be necessary to provide fit testing of respirators for each worker, or to develop a device with acceptable off-the-shelf fit characteristics such that it would not require individual fit testing, but give the wearer some indication that it had been donned properly and was providing a good seal, and therefore increased protection (e.g., through a user seal check). While some loose-fitting powered air-purifying respirators (PAPRs) have these characteristics, other innovative technologies may be on the horizon.

Overall, the committee finds that expanded initiatives to provide respiratory protection cannot be based in frameworks less structured than OSHA's, despite the greater effort required. At the least, a structured framework will guide implementation of new programs and facilitate consideration of how rigorous each step needs to be to achieve the exposure reduction goal. The range of workers to be covered is broad, and as shown by the COVID-19 pandemic, prospective planning is needed for high-risk scenarios.

Conclusion 3-4: For employers and employees unfamiliar with traditional RPPs, adherence to and conformance with requirements for respiratory protective devices may seem complicated and confusing. Lack of familiarity with hazard assessment may contribute to underrecognition of inhalation hazards, and the large number of products available adds to the confusion regarding device selection.

Conclusion 3-5: A review of the existing literature and federal regulations for workers facing inhalation hazards makes clear that respirators approved by NIOSH will provide the required protection for workers. Face coverings (including barrier face coverings) and masks may provide limited protection against some hazards (e.g., liquid splashes), but inconsistent face seals and poor filtration prevent them from providing reliable protection for the variety of inhalation hazards (e.g., viruses, smoke) that workers may encounter.

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SPECIFIC WORKER GROUPS

This section examines a number of specific worker groups that face inhalation hazards but are not systematically covered by RPPs. The committee identified these groups as it considered its Statement of Task (see Box 1-1 in Chapter 1) and discussed high-priority targets for its efforts with the study sponsors (see Table 1-1 in Chapter 1). In selecting worker populations to highlight in this section, the committee aimed to include representative examples that would underscore the respiratory protection gaps for workers related to

- employment relationships (e.g., volunteers, temporary or day laborers) that exclude workers from OSHA's Respiratory Protection Standard or obscure employer responsibility; and
- hazards not typically encountered in the normal course of duties for certain groups of workers (e.g., agricultural workers exposed to wildfire smoke and increased risks for some essential workers during infectious disease epidemics based on close and frequent contact with other workers or the public).

These are not mutually exclusive categories. For example, many agricultural workers are hired as temporary or day laborers, and such workers may on occasion be exposed to smoke if required to work in proximity to wildfires. Moreover, some worker groups discussed in this section who may remain close to a hazard even when not working, including wildland firefighters and disaster workers, are exposed to inhalation hazards on an ongoing basis in the course of their work and face unique challenges beyond these two gap areas.

Of note, this section is not intended to cover every unprotected worker group exposed to workplace inhalation hazards and should not be interpreted as a comprehensive analysis of all such populations. Instead, the selection of appropriate example worker populations is intended to highlight gaps in the existing landscape for occupational respiratory protection to inform the development of a framework for ensuring adequate respiratory protection for all workers (see Chapter 6). Here, the committee reviews what is known about exposures of these representative groups and their use of respiratory protection—drawing on the comprehensive reviews described in Chapter 1 and Appendix B—and associated gaps and needs related to guidance.

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Wildland Firefighters

In 2020, a total of 10.1 million acres burned in the United States, compared to over 4.6 million acres reported in 2019 (NICC, 2020a). The increasing numbers of wildland firefighters required to combat this worsening threat bring new urgency to the need to address gaps in respiratory protection for this workforce.

Description of the Workforce, Work Environment, and Work Characteristics

Accurately estimating the number of wildland firefighters operating in U.S. states is difficult given the multiplicity of involved organizations and the seasonal variation in numbers (Butler et al., 2017). Organizations engaged in response to wildland fires span volunteer fire departments, municipalities, private contractors, and federal agencies. During extreme fire years, the National Guard or the U.S. military may be asked to respond. During the peak of the 2020 U.S. wildland fire season, 28,000 people (permanent and seasonal employees) were assigned to wildland fire management (NICC, 2020b) in the National Incident Resource Ordering Capability (IROC) system.

The work of wildland firefighters is necessarily strenuous and is carried out under harsh environmental conditions characterized by high heat. The job tasks for wildland firefighters are extremely variable and many require high levels of energy expenditure (Ruby et al., 2002). Most wildland firefighters also camp at the fire location, which can potentially lead to 24-hour smoke exposure. A study by West and colleagues (2020) followed wildland fire resources across the western United States found that 43.2 percent of the firefighters' shifts was spent in the sedentary activity category, while 47.5 percent was in the moderate/high category (see Table 3-2). The main nonsedentary job task identified by the authors was hiking (19.2 percent). Using GPS trackers, Sol and colleagues (2018) calculated oxygen (VO_2) requirements for different hikes during a shift and quantified the high level of exertion (which can be upwards of 10 metabolic equivalents [METS]) based on terrain and high load carriage (26.6±6.9 kg, 32.7±9.0 percent of body weight). As discussed below, these strenuous working conditions have implications for the kinds of respiratory protective devices that would be suitable for wildland firefighters.

Exposure and Health Impact Data

Wildfires generate a toxic mixture of particulate and chemical vapor inhalation hazards that pose significant risks to the respiratory health of

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TABLE 3-2 Wildland Firefighters' Job Tasks Categorized into Four Groups Based on Activity Level and Percentage of Total Person-Task Observations in the Data Set in the Wildland Firefighter Heat Related Illness Study, Western United States, 2013–2016

SEDENTARY ACTIVITY	%	LIGHT PHYSICAL ACTIVITY	%	MODERATE PHYSICAL ACTIVITY	%	HIGH PHYSICAL ACTIVITY	%
ICP Stationary	1.7	Handline Direct Pump	0.1	Mop Up	5.1	Handline Direct Scratch	0.7
ICP Other	0.2	Handline Indirect Pump	0.02	Cold Trailing	0.6	Handline Direct Sawyer	0.5
Briefing	6.7	Handline Indirect Dozer Boss	0.02	Improving Direct Line	0.2	Handline Direct Swamper	0.6
Driving	6.9	Holding Direct Line	1.3	Improving Indirect Line	1.1	Handline Direct Engine	0.1
Lunch Break	3.6	Holding Indirect Line	0.2	Felling Sawyer	0.6	Handline Direct Squad Leader	0.1
Rest Break	3.3	Holding Firefighter	0.7	Felling Swamper	0.6	Handline Direct Fire-fighter	0.2
Operational Break	19.5	Holding Squad Leader	0.2	Working with Aviation	0.1	Handline Indirect Scratch	0.4
Staging	0.9	Holding Engine	0.1	Scouting Hazard Trees	0.7	Handline Indirect Sawyer	0.6

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Other	0.5	Suppression Holder	0.8	Grid the Black	1.5	Handline Indirect Swamper	1.2
Total	**43.2**	Engine Pump Operator	0.2	Grid the Green	0.6	Handline Indirect Squad Leader	0.3
		Holding Pump	0.1	Tool Up/Tool Down	8	Handline Indirect Firefighter	0.2
		RX Holder	0.2	**Total**	**19**	Live Preparation	0.5
		Refurb Tools	3.3			Initial Attack	0.1
		Structure Protection	1.1			RX Lighter	0.2
		Compound Work	1.4			Suppression Lighter	0.8
		Total	**9.4**			Physical Training	1.3
						Project Saw	0.6
						Project Stacking	0.7
						Hiking	19.2
						Medical	0.1
						Total	**28.4**

SOURCE: Reproduced from *Occupational and Environmental Medicine*, M.R. West, S. Costello, J. A. Sol, and J. W. Domitrovich, vol. 77, 433-438, 2020 with permission from BMJ Publishing Group Ltd.

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wildland firefighters. Wildland fire smoke has been a concern of the National Wildfire Coordinating Group (NWCG)[7] since the 1980s (Sharkey, 1997). Studies over the past 30 years have focused on exposure quantification and potential health effects. Wildland firefighters experience other sources of health hazards, such as ground disturbance of silica, combustion engines, and site-specific hazards; in this report the committee focuses on vegetation smoke exposure.

The first study to quantify exposure to wildland fire smoke was conducted by Reinhardt and Ottmar in the early 1990s (Reinhardt and Ottmar, 2004). They found concentrations of carbon monoxide (CO), particulate matter (PM), benzene, formaldehyde, and acrolein, and their initial findings indicated that exposure to all smoke components was higher during prescribed burns compared with wildfires. They also found correlations with increased smoke exposure during higher ambient wind speeds (wind is a critical component of fire growth).

The study by Reinhardt and Ottmar (2004) was limited to a few selected locations on the West Coast. From 2008 to 2011, the United States Forest Service's National Technology and Development Program (NTDP) conducted a larger-scale follow-up study of smoke exposure to increase the sample size and diversity of fuel models across a larger geographic region of the United States[8] (Broyles, 2013; Domitrovich et al., 2017). Given the high correlations among smoke components found by Reinhart and Ottmar, this study focused on CO and PM. A novel aspect of this study was that wildland firefighters were trained as research assistants and performed direct observation on potential compounding factors in smoke exposure. The findings of this NTDP study regarding smoke exposure were similar to those of the Reinhardt and Ottmar (2004) study. More recently, Wu and colleagues (2021) studied wildland fire exposure in the Midwestern United States during prescribed burns, finding that the overall exposure levels were higher than those reported in studies of wildland firefighters in the western and southeastern areas of the United States, providing evidence for the role of fuel models and operational tasks in the smoke exposure of wildland firefighters. The authors also reported that no value was over the 8-hour OSHA PEL (Wu et al., 2021).

The NWCG created a task group, which recommended minimizing

[7] The National Wildfire Coordinating Group, established in 1976, provides national leadership to enable coordination of programs and interoperable wildland fire operations across the participating federal, state, local, tribal, and territorial partners. Additional information is available at https://www.nwcg.gov (accessed September 29, 2021).

[8] This study includes 7,517 hours of CO measurements on firefighters and 1,554 hours of CO measurements at Incident Command Posts (ICPs) and spike camps (satellite locations separate from the main fire camp), and a total of 179 PM_4 (respirable dust) and SiO_2 (crystalline silica) firefighter samples and 78 samples from ICPs and/or spike camps (Broyles, 2013).

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mop up[9] and rotating crews out of heavy smoke areas as mitigation measures. This task group also defined a recommended exposure level, taking into account CO, PM, and other smoke components, based on an extended work shift of 16 hours and a 24-hour period, given that a typical wildland firefighter's shift often exceeds the 8-hour OSHA PEL. Navarro (2020) recently reviewed studies of wildland firefighter exposure to CO and PM and summarized the data in relation to the recommended exposure level and OSHA's PEL (see Figure 3-3).

A large number of studies have examined the health effects of wood smoke, as reviewed recently (Cascio, 2018; Adetona et al., 2016), but only a limited number have focused specifically on wildland firefighters. There have been multiple short-term studies, with time scales ranging from the course of one shift to a whole season, and only one retrospective study on long-term wildland firefighter health. The latter study, conducted by Semmens and colleagues (2016) found two subclinical cardiovascular risk factors (hypertension, heart arrhythmia), as well as markers of musculoskeletal effects (knee surgery), with no other significant health effects. A major limitation of this study, however, was that the questionnaire was sent only to current wildland firefighters and not retirees. Other studies have shown both shift and seasonal changes in respiratory function (Gaughan et al., 2014; Liu et al., 1992). Navarro and colleagues (2019) extrapolated the relative risk of cancer and cardiovascular disease mortality over the course of a wildland firefighter's career, comparing long (100 days) and short (50 days) fire seasons (see Figure 3-4). These projections suggest the need for more long-term studies to assess the health risks of smoke exposure for wildland firefighters.

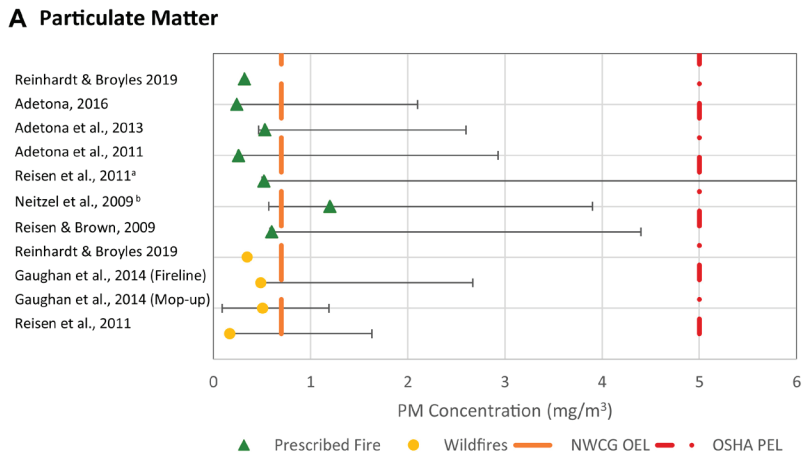
Respiratory Protection and Regulatory Frameworks (Standards, Guidance, and Oversight)

Oversight of use of respiratory protection by wildland firefighters is complicated by the diversity of employment relationships under which wildland firefighters work. Federal wildland firefighters fall under the safety programs of their respective employing federal agencies. Five federal agencies (United States Forest Service, Bureau of Land Management, National Park Service, U.S. Fish & Wildlife Service, and Bureau of Indian Affairs) across two departments (U.S. Department of Agriculture [USDA] and Department of the Interior) have wildland fire management programs. Additionally, each state has its own department of natural resources, and local volunteer

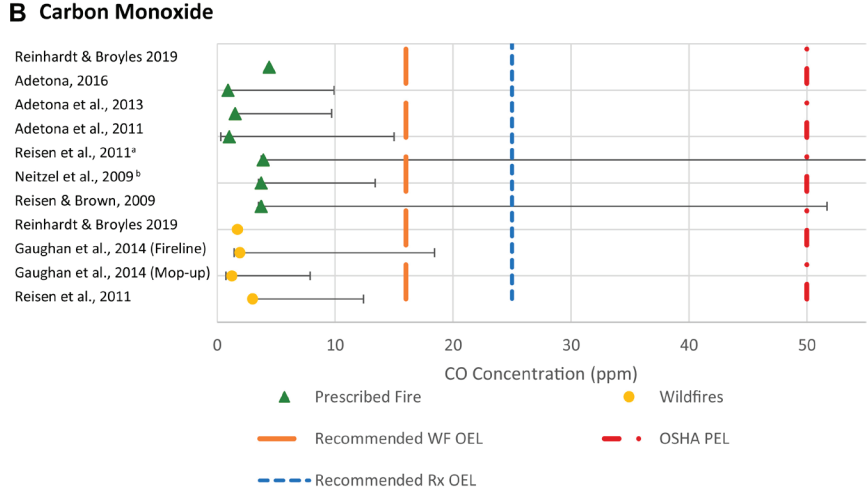
[9] Mop up is "extinguishing or removing burning material near control lines, felling snags, and trenching logs to prevent rolling after an area has burned, to make a fire safe, or to reduce residual smoke" (NWCG, 2021b).

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a. Maximum ranged reported was 16 mg/m3
b. All studies, except Neitzel et al. 2009 reported geometric mean



a. Maximum ranged reported was 120 ppm
b. All studies, except Neitzel et al. 2009 reported geometric mean
c. WF – wildfire; Rx – Prescribed Fire

FIGURE 3-3 Summary of particulate matter (PM) and carbon monoxide (CO) concentrations measured on wildland firefighters. These graphs show different levels of exposure to PM and CO captured in a review of relevant studies, and the difference between the recommended operational exposure limits (OELs) and OSHA's permissible exposure limit (PEL).
SOURCE: Reprinted from *Clinics in Chest Medicine*, vol. 41, ed. 4, K. Navarro, "Working in smoke: Wildfire impacts on the health of firefighters and outdoor workers and mitigation strategies," 763-769, 2020, with permission from Elsevier.

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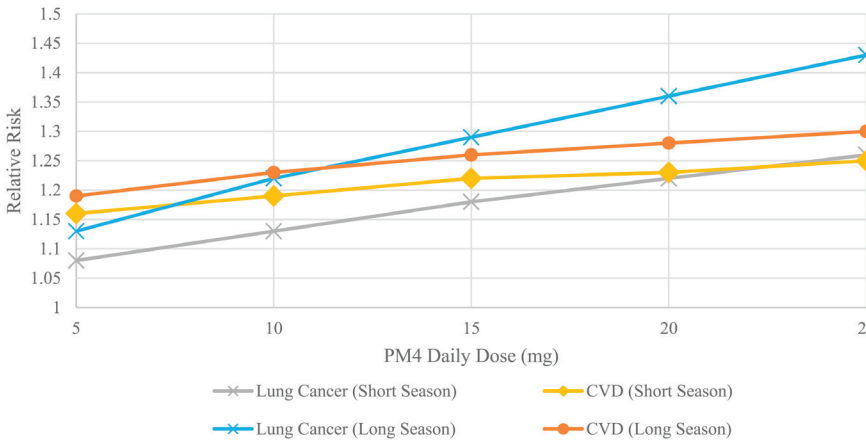


FIGURE 3-4 Relative risk of lung cancer and cardiovascular disease (CVD) associated with length of seasonal wildland firefighting work. Relative risk increases for lung cancer and CVD among wildland firefighters as the daily dose of particulate matter (PM) increases.
SOURCE: Reprinted from *Environmental Research*, vol. 173, K.M. Navarro, M.T. Kleinman, C.E. Mackay, T.E. Reinhardt, J.R. Balmes, G.A. Broyles, R.D. Ottmar, L.P. Naher, and J.W. Domitrovich, "Wildland firefighter smoke exposure and risk of lung cancer and cardiovascular disease mortality," 462-468, Copyright 2019, with permission from Elsevier.

and municipality organizations may have responsibility for wildland fire response. The need for respiratory protection for wildland firefighters must be determined by each of these entities.

Respiratory protection has been an area of concern for federal land management fire programs since the Yellowstone fires of 1988. To date, however, no respirator has been found that meets the unique needs of wildland fire management. The strenuous activity associated with wildland firefighting and poor fit due to facial hair are examples of barriers to effective use that could result in a poor face seal and the wearer's not receiving the intended level of protection (De Vos et al., 2006; Haston, 2007; Sharkey, 1997). Moreover, the impact of breathing resistance on work performance and interference with verbal and visual communications are a concern for firefighters wearing respirators (Beason et al., 1996; Haston, 2007; Reinhardt and Ottmar, 2000; Sharkey, 1997). Additionally, studies by the United States Forest Service's National Technology and Development Program in the 1990s found that full-face respirators were preferred for all-day prescribed fire activity because of decreased eye irritation. However, the full-face respirators did show increased heat stress, and study participants also reported headaches. Wildland firefighters often use eye irritation

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as a signal to leave a particular area—a concern also noted in the study (Sharkey, 1997).

Several types of products are marketed to wildland firefighters (e.g., shrouds with filtration devices) but are not NIOSH-approved respirators and have not been studied to validate their protection claims. The National Fire Protection Agency (NFPA) created a wildland fire respiratory performance standard (NFPA, 2022), for the first time in 2011, updated in 2016 and 2022, which outlines the minimal requirements for construction of a wildland fire respirator. NFPA's current model for such a respirator assumes long-duration, low-concentration exposure; design criteria include being lightweight and small, with easily replaceable filtration pieces. The key air purification required in this document includes carbon monoxide, organic vapors (cyclohexane), sulfur dioxide, nitrogen dioxide, formaldehyde, acrolein, hydrogen fluoride, and hydrogen cyanide. There are three different classes of respirator protection based on the performance requirements. However, no respirators have been designed or tested to the NFPA standard (Adetona et al., 2016).

A specific section in the USDA Forest Service Manual (FSM 5130, "Self-Contained Breathing Apparatus") allows for wildland firefighters to be trained on and carry self-contained breathing apparatus (SCBAs) that are compliant with NFPA 1981, the Standard on Open-Circuit Self-Contained Breathing Apparatus (SCBA) for Emergency Services. These devices are not to be used in a wildland fire event; SCBAs may be used only when contaminants cannot be avoided (e.g., fires involving vehicles, dumps, structures, or other nonwildland fuels).

The implementation of an RPP for wildland firefighters would be difficult given the nature of the multiagency coordination of agency-specific policy that would be required, in addition to the challenges related to equipment. Training and education on the effective use of respiratory protection would need to cover hazard assessment and the limitations of respirators for protection from wildfire smoke. For example, use of respirators designed to filter particulates without the aid of a CO dosimeter could provide a false sense of security in the field and increase immediate risk to the wearer's health (Haston, 2007). Administrative oversight and the development of a culture of safety are important for supporting the effective use of respiratory protection for wildland firefighters in the field (Reinhardt and Ottmar, 2000), but may be challenging to achieve in a workforce characterized by a large number of seasonal and volunteer workers.

Limited authoritative guidance is available on the use of respiratory protection by wildland firefighters and their agencies/departments for such hazards as wildfire smoke and infectious respiratory diseases. Federal guidance on the prevention of exposure to wildfire smoke mentions that

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wildfire-specific PPE should be used, but does not specifically recommend the use of respirators (NIOSH, 2013), and notes that if respiratory protection must be used, once administrative and engineering controls have been exhausted and as determined by the agency/department, it needs to occur within the context of an RPP (Haston, 2007; NIOSH, 2021b; NWCG, 2010). Thus, wildland firefighters face a near total absence of established federal guidance on the use of respiratory protective devices as respiratory protection from wildfire smoke.

In contrast with exposure to wildfire smoke, the emergence of COVID-19 has led to the development of more detailed guidance for this worker population with respect to the use of respiratory protective devices. Authoritative guidance on the use of respiratory protection for wildland firefighters available via the NWCG provides the most comprehensive approach to instituting respiratory protective practices specifically tailored to the needs of this worker group (NWCG, 2021a). However, federal guidance from CDC specific to wildland firefighters has now expired (CDC, 2020b, 2021d), and there has been no clear replacement to address the unique needs of deployed wildland firefighting units (e.g., communal living in bunkhouses, safety of wearing respiratory protective devices, and what devices—respirator or nonrespirator face covering—should be used).

Agricultural Workers

Description of the Workforce, Work Environment, and Work Characteristics

Agricultural workers are a diverse population. Migrant farmworkers in the United States, many of whom come from Mexico and Central America, often serve as field hands to tend to various forms of livestock or harvest a wide range of crops over the course of the growing season. These worker groups are considered vulnerable to health hazards for a number of reasons. The time-sensitive nature of much agricultural work creates pressure on agricultural businesses to maintain work activities despite such environmental risks as extreme heat and poor air quality. Worker literacy and language considerations, including limited proficiency in English and, in some cases, Spanish, can pose challenges for effective worker training and communication regarding hazard identification and controls. Precarious immigration status—whether workers are undocumented or hired through the H2-A visa program—coupled with piece-rate payment schemes common within the industry often serve as disincentives for workers to demand stronger protections from respiratory and other hazards in their work.

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Exposure and Health Impact Data

Inhalation hazards for agricultural workers may include inorganic dust from the soil; organic dust containing microorganisms, mycotoxins, or allergens; decomposition gasses; and various chemical agents, including pesticides. Exposures occur when harvesting, dealing with animals, and processing or storing grains or other plant matter, as well as when the soil, plants, or stables are treated with pesticides and disinfectants (Nguyen et al., 2018; Schenker et al., 1998; Viegas et al., 2013).

The need for adequate respiratory protection for agricultural workers has garnered additional attention in recent years in the context of large-scale wildfire events in the western United States (Riden et al., 2020). A recent review of the adverse health effects of such exposures identified risks for asthma, chronic obstructive pulmonary disease (COPD), bronchitis, and pneumonia (Cascio, 2018). Accounts of farmworkers being ordered to continue harvesting crops even as smoke and ash from nearby wildland fires filled the air led worker advocates in California to demand intervention from the California Division of Occupational Safety and Health (Cal/OSHA), which took the form of a new wildfire smoke standard promulgated as an emergency measure in 2019 and subsequently made permanent in 2021 (NASEM, 2019a).

Respiratory Protection and Regulatory Frameworks (Standards, Guidance, and Oversight)

Overall, few agricultural workers are covered by worksite RPPs (Culp et al., 2004; Greskevitch et al., 2007). This is particularly true for the large population of migrant farmworkers. As mentioned earlier in this chapter, a long-standing congressional appropriations provision has prohibited OSHA from any involvement in farms with 10 or fewer non-family workers (OSHA, 2014b).

The respiratory protection needs of agricultural workers exposed to dusts, molds, and chemicals from farm work are likely to differ in important ways from those of workers incidentally exposed to wildfire smoke. As discussed in Chapter 2, some states in the western United States have recently passed regulations designed to protect workers, including agricultural workers, from exposure to wildfire smoke. In July 2019, Cal/OSHA promulgated a standard requiring employers to institute various control measures when the Air Quality Index (AQI) for $PM_{2.5}$ reaches certain thresholds as a result of nearby wildfires (Cal/OSHA, 2021c). The standard includes requirements for respiratory protection: if the AQI for $PM_{2.5}$ exceeds 151, employers must provide filtering facepiece respirators and encourage their voluntary use; if the AQI for $PM_{2.5}$ exceeds 500, employers

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must require respirator use, along with mandatory fit testing, if work activities are to continue. Although the Cal/OSHA standard applies to all outdoor worksites, as well as indoor sites without adequate air filtration, a major focus has been on implementation of the standard in agriculture. Similar regulations have been passed in Washington and Oregon (Oregon OSHA, 2021; Washington State DOLI, 2021a).

Few employers in the agricultural industry have had prior experience with respiratory protection as part of their safety practices, and farmworkers often have limited understanding of the functional differences between filtering facepiece respirators and cloth face coverings (Riden et al., 2020). Increased knowledge and understanding of inhalation hazards is an important factor in promoting the use of respiratory protection among agricultural workers, particularly in cases in which hazards emanate from beyond the immediate work processes and procedures (e.g., wildfire smoke, aerosol transmissible diseases). Effective training and communication strategies need to take into account the unique needs and language, literacy, and educational characteristics of this workforce, particularly in the case of migrant and seasonal workers (Basinas et al., 2016; Earle-Richardson et al., 2014; Riden et al., 2020). However, training and education are not sufficient for ensuring proper and consistent use of respiratory protection. Such factors as device discomfort, increased heat load, difficulty breathing, and lost work hours associated with fit testing and medical clearance serve as notable disincentives for individual users (Earle-Richardson et al., 2014; Kusaka et al., 1993; Mpofu et al., 2002; Riden et al., 2020). In the absence of stronger regulatory requirements, employers may be discouraged from instituting RPPs. Larger and better-resourced agricultural operations are likely in a better position to institute such programs (Cramer et al., 2017; Kearney et al., 2014; Syamlal et al., 2013; Virolainen et al., 1987), suggesting the need for both education and resources to incentivize businesses of all sizes to adopt respiratory protective measures for their workers.

In reviewing the gray literature, the committee found several examples of authoritative guidance that addresses the use of respiratory protective devices by agricultural workers for occupational hazards inherent in farm work, as well as incidental exposures such as wildfire smoke and SARS-CoV-2.

CDC guidance specifically for agricultural workers with respect to COVID-19 (CDC, 2021a) has been superseded by universal guidance on mitigation of COVID-19 in workplaces, which is designated for unvaccinated workers or workers who are "otherwise at risk." Updated OSHA guidance indicates that workers in agricultural processing work settings are deemed to be in this "at-risk" category (OSHA, 2021f). However the general OSHA guidance does not reflect the diversity of job roles and titles captured in the original CDC guidance (e.g., workers on farms vs. ranches), and it is

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unclear whether the OSHA guidance for at-risk workers is intended to cover the broader category of agricultural workers. Both the now-expired guidance from CDC and the OSHA guidance provide information about the selection, use, and cleaning of respiratory protective devices.

NIOSH has developed guidance on the potential role of respiratory protective devices in controlling exposure to wildfire smoke as part of an RPP (NIOSH, 2021b); however, this guidance does not focus specifically on agricultural workers. Indeed, it appears that no federal guidance specific to this worker group and hazard that supports correct selection and use of respiratory protective devices is available beyond the recommendation to fulfill the components of an RPP. Similarly, guidance developed by Cal/OSHA to support the translation of its wildfire smoke standard into practice is employer focused (Cal/OSHA, 2018). Beyond following the requirements of an RPP once established, workers have little in the way of protection if their employers fail to comply. This gap in user-facing materials and tools for successful integration are addressed through such materials as those produced by the University of California, Davis's Western Center for Agricultural Health and Safety. These materials, targeted to workers and employers in the region, include training visuals, discussion guides, tools, and checklists designed to support effective implementation in the field (WCAHS, 2021). Such efforts to support the application of standards in the field are essential, but it remains unclear to what degree agricultural workers and employers in areas where wildfire smoke is of concern have access to and utilize these materials and training programs.

One notable exception within the agricultural workers category with regards to having access to respiratory protection and comprehensive guidance on its use is pesticide handlers. Under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulations preempt OSHA standards for pesticide applicators. For these workers, EPA administers a worker protection program that mandates respiratory protection. Occupational safety standards implemented under FIFRA to protect agricultural workers from pesticides include the pesticide applicator certification program, as well as the Agricultural Worker Protection Standard. As part of this responsibility, EPA published a guide directed at pesticide handlers (EPA, 1993) that provides guidance for users on different types of respirators and basic information about their use. Additionally, EPA, in coordination with the Pesticide Educational Resources Collaborative (PERC), developed resources to assist employers and business owners in complying with the worker protection standard (PERC, 2017). PERC also has developed and assembled a collection of resources for pesticide handlers and medical professionals that are both specific to respirator use for pesticide exposure (Rutgers University, n.d.) and more broadly pertinent

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to respirator use in general (NIOSH, 2017b; OSHA, 2011a), designed to support safe and effective use of the devices in the field. Among the guidance available to agricultural workers, that provided to support the use of respiratory protection from standard to application in the field appears to be most complete for pesticide exposures.

Construction Workers

Description of the Workforce, Work Environment, and Work Characteristics

Construction firms are overwhelmingly small employers—90 percent employ fewer than 20 people—with limited resources for proper PPE or training for their workers. Small firms represent a disproportionate percentage of construction fatalities (CPWR, 2018) and are more likely than their larger counterparts to hire workers considered at a greater risk for injury, including young workers, those who are less educated, and immigrants (Belman and Levine, 2004; NIOSH, 2015c). One study found that the communication of safety and health information to subcontractors was twice as common in larger (500+ employees) than smaller (1–9 employees) firms (Jones, 2016).

Construction is second only to agriculture in the numbers of foreign-born and temporary workers employed. Approximately 30 percent of construction workers are Hispanic (compared with 17.7 percent of workers in all industries) (Brown et al., 2020), and 15.5 percent are employed by temporary agencies, which adds complexity to determining who is responsible for worker training (CPWR, 2018).

In 2016, the construction industry had a higher rate of union representation than all other industries combined (15.5 percent versus 11.7 percent), although union participation among trades varies significantly (CPWR, 2018). Union membership is an important factor in the safety and health protection of construction workers. Building trade unions integrate safety and health training into their apprenticeship programs to ensure that a solid safety culture is part of the transition from apprentice to journeyman, irrespective of trade. The Center for Construction Research and Training (CPWR) (2018) and Dodge Data and Analytics conducted a survey in 2017 using Dodge's member contractor panel of roughly 3,000 construction firms, 334 of which participated, and found that union firms

- reported better performance of safety management and safety culture;
- were more likely to be aware of and practice Prevention through Design (a major NIOSH initiative);

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- adopted more of the organization safety practices, safety policies, and safety culture indicators considered important by the researchers; and
- were more likely to offer and require general safety and health training and OSHA 10-hour and 30-hour courses for their workers (Wang et al., 2018).

Exposure and Health Impact Data

Inhalation hazards are common in the construction sector. A longitudinal survey of U.S. adults over age 50 showed that the proportion of respiratory cancer–related deaths for workers whose longest-duration job was in construction trades was nearly double that for white-collar workers. Additionally, construction workers were approximately twice as likely to die of nonmalignant respiratory diseases compared with white-collar workers (CPWR, 2018; Wang et al., 2016). The risk of death from lung cancer associated with 5 years of work in the construction industry was comparable to the risk associated with a personal or family history of cancer or a diagnosis of COPD (Dement et al., 2020). Over a 45-year working life, 16 percent of construction workers develop COPD and the lifetime risk of an occupational disease is 2–6 times greater in the construction trades than in nonconstruction work (Ringen et al., 2014).

The onset of the COVID-19 pandemic presented new challenges for construction workers because they were deemed essential workers and could not work from home (NIOSH, 2021a). Construction worksites presented increased risks because multiple trades were forced to coordinate their efforts, often on sites with tight footprints and work practices that required person-to-person interactions, rendering social distancing difficult. Although much of this work can be done outside, projects eventually require working indoors where ventilation may be limited, particularly in cold winter months when heating is a higher priority than circulating outside air (Araya, 2021). Valuable guidance has been developed to improve ventilation on construction sites to prevent the spread of COVID-19 (CPWR, 2021b); research on the implementation of this guidance is needed prior to another pandemic.

A recent study looking specifically at COVID-19 risk factors in the construction sector found about 60 percent of the workers had at least one underlying factor—such as heart or lung disease, diabetes, or being 65 or older—that put them at elevated risk of serious health outcomes or death (Brown et al., 2020). Another study found that the observed relative risk of hospitalization from COVID-19 among construction workers compared with other occupational categories among adults aged 18–64 was 4.9 (95 percent confidence interval [CI], 3.8–6.2). The authors identify construction

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as a high-contact industry and describe its association with a higher level of community transmission of the disease and larger health disparities among racial and ethnic minority groups (Pasco et al., 2020).

Respiratory Protection and Regulatory Frameworks (Standards, Guidance, and Oversight)

Construction workers may have access to respirators, but they tend to be filtering facepiece respirators without accompanying training. A 2003 BLS survey showed that just under 10 percent of construction workers were required by their employer to use a respirator during a 12-month period (CPWR, 2007), and only half of those employers provided them with the training mandated by OSHA. The BLS survey indicated the respirators most commonly used in construction were for protection against paint vapors (44.7 percent), solvents (27.8 percent), and silica dust (24.1 percent). Where respirators were required, N95 FFRs and other disposable dust masks, which do not provide protection for the wearer against exposure to vapors and solvents, were used most frequently (77.8 percent), and elastomeric half-mask respirators were required for fewer than half of the tasks examined (40.5 percent). In the committee's analysis of data from federal OSHA violations related to 1910.134(c)(1) issued January 1, 2015–December 31, 2020 (see Appendix A), construction was the second most commonly cited industry.

Several federal agencies, labor unions, and professional associations provide guidance for the construction workforce on a variety of inhalation hazards, including SARS-CoV-2. CDC guidance for construction workers on COVID-19 (CDC, 2021c,j) has expired and been replaced by general OSHA guidance (2021f), which does not use the term "construction worker" and is oriented to any workers who are not vaccinated or are vaccinated but working in higher-transmission areas. OSHA also supplies a page with dedicated guidance on the use of cloth face coverings that provides information for both employers and construction workers on selection, use, and care of these devices in the context of construction work settings (OSHA, 2021a). Labor unions and nongovernmental organizations have taken an active role in calling for and providing details on COVID-19 exposure control by employers, including the use of respiratory protective devices (CPWR and NABTU, 2020; LHSF, 2021). CPWR and North America's Building Trade Unions (NABTU) standards for construction sites, updated in April 2020 in response to the COVID-19 pandemic, recommend the use of a fit-tested respirator as part of an established RPP, but notes that some local circumstances (e.g., recommendations by local governments or supply issues) may necessitate the use of cloth face coverings (CPWR and NABTU, 2020).

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The committee identified just one example of federal guidance for exposure to wildfire smoke that is inclusive of construction workers (NIOSH, 2021b). Additionally, as described earlier in the section on agricultural workers, some guidance is available for employers in California to assist in their compliance with the wildfire smoke standards (Cal/OSHA, 2018), although the committee found no supportive user-oriented guidance during a search for additional guidance materials for this worker population.

Day Laborers

Description of the Workforce, Work Environment, and Work Characteristics

The day laborer workforce in the United States is composed largely of immigrant workers hired by homeowners, business owners, and small contractors on a short-term basis to carry out any number of construction, gardening and landscaping, and property maintenance tasks. A 2006 nationwide study of day laborers estimates that on any given day, 117,600 individuals were either looking for day labor jobs at street corners, curbsides, and hiring centers, or working as day laborers (Valenzuela et al., 2006); numbers now are surely higher.

Employment relations for this group are characterized by temporary and informal work arrangements with few written contracts, and payments often made in cash (Riley and Guzman, 2017). Limited English-language proficiency and lack of authorized or permanent immigration status further contribute to the precarious circumstances of these workers (Fussell et al., 2018).

In addition to the standing day labor workforce, researchers have recently turned their attention to the role played by day laborers as "second responders" in the context of disaster response and recovery (discussed further in the section below on disaster response and recovery workers). Communities devastated by hurricanes, floods, wildfires, and other disasters have often seen an influx of day laborers in the weeks and months following disaster events, as immigrants and other contingent workers have sought jobs on cleanup and reconstruction projects (Cordero-Guzman et al., 2013; Costirilos, 2019; Delp et al., 2009; Fletcher et al., 2006; IDEPSCA, 2020; Theodore, 2017, 2020). Property owners, developers, and contractors, in turn, have come to rely on the ready availability of low-wage workers to serve as the backbone of disaster recovery efforts (Fussell et al., 2018).

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Exposure and Health Impact Data

The occupational hazards and work-related injuries faced by day laborers often mirror, in both frequency and severity, those of workers performing comparable tasks under more conventional work arrangements (Burgel et al., 2015; Riley and Majano, 2021). The tasks performed by day laborers—particularly those working in postdisaster settings—may put them at risk for exposure to any number of inhalation hazards, including vapors from paints or solvents; mold, lead, or asbestos; wildfire ash; and dust and debris.

Respiratory Protection and Regulatory Frameworks (Standards, Guidance, and Oversight)

RPPs for the day labor workforce are effectively nonexistent. The informal and short-term nature of most assignments, particularly when workers are hired by homeowners, means that OSHA standards and enforcement generally do not apply. Meanwhile, workers' reluctance to turn down dangerous assignments because of economic necessity and their lack of hazard awareness have led to little pushback from workers and little incentive for employers to invest in PPE or other forms of hazard control. In this context, the onus has largely fallen on worker advocates to educate these workers and encourage employers to take appropriate protective measures. Pilot projects to train workers on inhalation hazards and to distribute PPE through local worker centers have shown positive results in terms of raising workers' hazard awareness and encouraging more frequent use of protective equipment, such as N95 FFRs (Contreras and Buchanan, 2012). And in the absence of formal RPPs, a number of day labor hiring sites around the country have taken the lead in offering training and fit testing for these workers, and negotiating with would-be employers on working conditions and use of adequate protections.

Federal guidance on respiratory protection specifically targeting the day labor workforce are nearly nonexistent. While general federal guidance, such as that from NIOSH on exposure to wildfire smoke and outdoor workers (NIOSH, 2021b), may be applicable, these workers are unlikely to be employed in a situation in which an RPP is established. The committee identified no other guidance on other inhalation hazards addressing use of respiratory protection by day laborers or targeted employers of these workers.

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Frameworks for Protecting Workers and the Public from Inhalation Hazards

Health Care and Allied Health Workers

Description of the Workforce, Work Environment, and Work Characteristics

Consistent with the scope of the committee's charge, this section addresses only those health care and allied health workers who would not be expected to be covered by a permanent RPP.[10] These include home care workers, clinicians in solo private practices, dentists, and long-term care workers. Particularly warranting attention are those workers in informal settings who have no formal employers, including those who may be funded through state or local offices on aging through dual Medicare/Medicaid programs but are considered to have been hired by the client or the client's family.

Many of the nearly 2 million homebound adults over age 65 in the United States may rely on informal family caregivers as well as home care workers provided through state and federal support (Ornstein et al., 2015), and as of 2020, 2.5 million U.S. adults were living in nursing homes or residential care facilities (Scales, 2020). Home care workers (including home health workers and personal care attendants) are disproportionately older women of color. Half have more than two chronic illnesses, nearly half live in households with incomes below $30,000, and nearly half are Medicaid recipients themselves (Bercovitz et al., 2011; Muramatsu et al., 2017). These paid home care workers are not consistently considered to be part of a health care team (Reckrey et al., 2020). Nursing assistants working in nursing homes and long-term care facilities are predominantly (92 percent) females of color and are younger than the average home care worker, with a workforce median age of 37 and 20 percent of workers being under the age of 24. The average nursing home assistant earns $13.38 per hour and $22,200 annually, and nearly 36 percent of this workforce requires public assistance because of these low earnings (Scales, 2020). Dental hygienists provide primary oral health services in dental offices, public health clinics, schools, and nursing homes, among other locations; 226,400 dental hygienists are currently employed in the United States (ADHA, 2021) and are predominantly female (IOM, 2009). Little is known about the demographics of health care workers working in small or private practices, given the breadth of the fields of practice and the wide geographic area in which they work.

[10] As a result of the OSHA emergency temporary standard related to COVID-19, employers of some health care and allied health workers who typically have not had RPPs may now be required to implement such programs. However, this requirement is temporary.

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Exposure and Health Impact Data

Home care Although systematic data and studies are lacking, home care workers who are not part of a home care agency are vulnerable to inhalation hazards, in part because of limited legal protections (home care work is considered a domestic service in some states and therefore is excluded from basic health and safety protections) (Nasol and Francisco-Menchavez, 2021), and as seen during the COVID-19 pandemic, because of such factors as limited access to respirators, limited provision of training, and lack of any formal organizational preparedness and employer support (Gershon et al., 2010). In a study comparing work–life experiences of agency and nonagency home care workers, agency workers reported receiving significantly more training and supervision compared with nonagency workers (Benjamin and Matthias, 2004). A qualitative study of 33 home care workers (home health and personal care aides and home attendants) revealed that these workers received inadequate respiratory protection support during the COVID-19 pandemic, in part because of PPE shortages. Moreover, these workers did not feel that their essential front-line work during the pandemic was recognized; rather, they felt "invisible" (Allison et al., 2020; Sterling et al., 2020). In another study, 86 percent of 384 respondents had received no training specific to performing their job functions during a pandemic, and just 5 percent reported that their employer had an established pandemic plan (Gershon et al., 2010). Additionally, access to training does not translate to effective use of respiratory protective devices. In this same study, just 16 percent of home health care workers surveyed had received a respirator from their employer; of these, fewer than 72 percent had received training on how to use the device, and only 28 percent had been fit tested on the device (Gershon et al., 2010). And as discussed earlier, in addition to this lack of training and lack of access to fit-tested respiratory protective devices, use of these devices can be associated with discomfort, including difficulty breathing and feelings of overheating, as well as challenges with visual and verbal communication, issues that are perceived as a barrier to effective patient care (Gershon et al., 2010; Mojtahedzadeh et al., 2021). Furthermore, home health aides and personal care aides include a significantly higher proportion of immigrant workers compared with some other health care occupation categories; and immigrant workers are known to be disproportionally negatively affected by COVID-19 (Gelatt, 2020).

Long-term care Long-term care settings, which include nursing homes (1,300,000 residents in the United States) and assisted living facilities (800,000 residents) (Harris-Kojetin et al., 2019), have always been vulnerable to many health care safety hazards, including inhalation hazards (Nasol and Francisco-Menchavez, 2021). COVID-19 had a disproportionately

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negative impact on this health care sector, with a significantly higher positivity rate for both residents and care professionals, leading to transmission between unprotected care professionals and residents and across nursing home facilities. Although representing only 1 percent of the U.S. population, long-term care facilities have been linked to 4 percent of COVID-19 cases and 31 percent of deaths nationwide (*The New York Times*, 2021). As of September 2021, more than 136,500 residents and more than 2,070 care professionals in nursing homes had died from COVID-19 (CMS, 2021).

Care professionals who work in assisted living facilities experience similar safety problems, including inadequate protection against inhalation hazards. Assisted living facilities have notoriously failed to comply with wage and labor standards (Shah, 2017), and concerns about their inadequate preparation for a potential pandemic were reported well in advance of COVID-19 (Lum et al., 2014).

Care professionals working in dentistry settings Dentistry entails the use of rotary dental and surgical instruments (e.g., hand pieces or ultrasonic scalers and air-water syringes), which can aerosolize saliva, blood, microorganisms, and other debris. Given the unique nature of dental practice, which requires professionals to operate very close to the patient's mouth, the risk of aerosol transmission of infectious agents is high (Clementini et al., 2020; Gandolfi et al., 2020; Zemouri et al., 2017, 2020). A *New York Times* article titled "The Workers Who Face the Greatest Coronavirus Risk" identifies dentists and dental hygienists as more at risk than any other health care workers, including nurses, personal care aides, and general practitioners (Gamio, 2020).

Other care professionals in small or solo private practices Despite closures and telehealth-based alternatives, health care workers in solo practices have been disproportionately affected by COVID-19 (Rubin, 2020). An investigation of 1,004 COVID-related deaths among health care workers globally as of May 13, 2020, for example, found a significantly higher proportion of deaths from COVID-19 occurring among physicians who practice family medicine or primary care (general practitioners) (Gouda et al., 2020).

Respiratory Protection and Regulatory Frameworks (Standards, Guidance, and Oversight)

Inconsistent compliance with recommended guidelines for respirator use has long been a major problem in health care. NIOSH conducted a 2011 web-based survey of more than 10,000 health care workers who routinely use or are exposed to certain chemical agents (including nurses, pharmacy practitioners, technologists/technicians, anesthesia care professionals,

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respiratory therapists, and dental care professionals) in the United States (Wizner et al., 2018). Only 18 percent of respondents surveyed reported using a respirator as protection against chemical agents, of which 24.9 percent reported being fit tested for the respirator they used. When respondents were asked about their respiratory protection practices when potentially exposed to 1 of the 10 specific airborne hazards on which the survey focused, their responses varied widely (see Figure 3-5). The high percentage reporting use of a surgical mask when working with these specific airborne hazards raised concerns about inappropriate use of these masks in lieu of respirators (Wizner et al., 2018).

When the survey participants who reported not using a respirator when potentially exposed to one of the 10 aerosol hazards were asked about their reason for not following the recommended respiratory protection practices, factors related to organizational characteristics were found to play a major role: respirator use not part of the local protocol (32 percent of responses), exposure perceived as minimal (21 percent), respirator not provided by employer (12 percent), respirator not readily available in work area (11 percent), no other colleague or peer in the workplace using it (10 percent), and engineering control being used (8 percent). Furthermore, job characteristics (i.e., job type, involvement with direct patient care) and worksite characteristics (number of employees) were found to be predictive of appropriate respirator use. Specifically, those employees working in large organizations (number of employees >1,000) reported significantly greater respirator use when potentially exposed to one of the 10 specific aerosol hazards compared with those working in smaller organizations (<100 employees). On the other hand, characteristics of individual health care workers (e.g., age, education level) were not a significant predictor of respirator use, a finding consistent with those of other studies (Hines et al., 2014; Nichol et al., 2013). These findings are consistent with and highlight the importance of (1) a systems approach to respiratory protection and (2) a human-centered approach to respirator design to improve and sustain appropriate use.

The Hospital Respiratory Protection Program Toolkit was developed in 2015 by NIOSH to address these challenges and the need for a coordinated systems approach to incorporate respiratory protective device use into the hospital setting (NIOSH, 2015b).

The vast majority of health care workers in the United States, including those who work in states with OSHA-approved State Plans that do not provide this protection or those in states with federal OSHA programs, are not covered by a specific, formal, permanent aerosol transmissible disease standard. Such standards are currently under development and have been adopted by a number of states. Although these standards are necessary for prevention, existing risk assessments related to the pandemic suggest that all health care workers—from clinicians performing aerosol-generating

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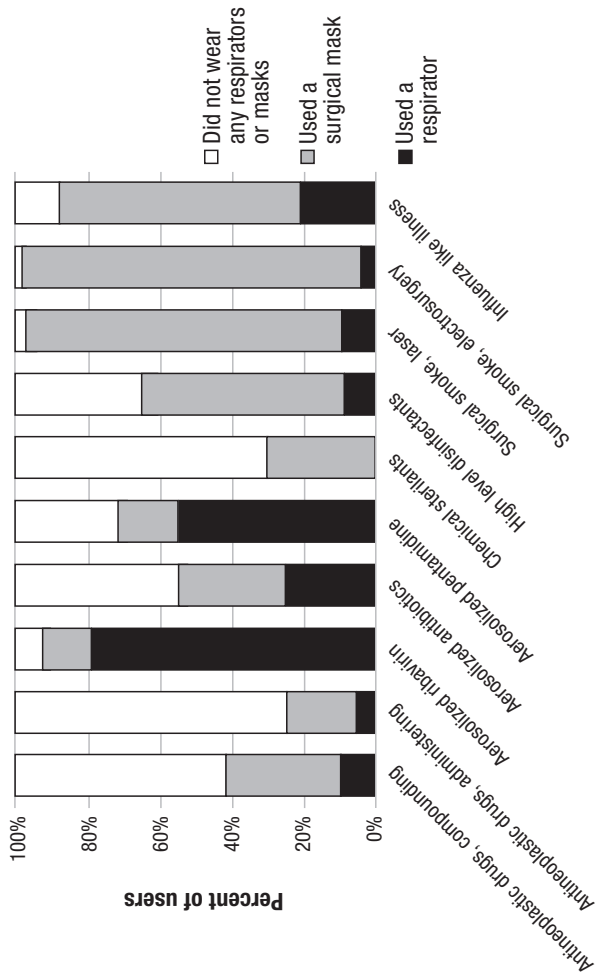


FIGURE 3-5 Respiratory protection practices for health care workers exposed to airborne hazards. This bar chart shows how the use of respirators and surgical masks and the use of no device vary by respondent across exposures to different types of hazards, indicating that use of respiratory protective devices varies for the same hazard and that worker safety may be at risk.
SOURCE: Wizner et al., 2018.

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procedures; to clinicians in general; to clerical, environmental services, dietary, security, and other support staff in hospitals, nursing homes, and other long-term care facilities or in home care—may need to be included in full formal RPPs under OSHA's Respiratory Protection Standard. Such programs need to extend to employees in private medical or dental offices as well, and to be strongly encouraged for self-employed practitioners. OSHA's ETS for workers in health care settings, while temporary, represented an important step forward in addressing this need. Many of these health care and allied health worker groups are also a focus for OSHA's National Emphasis Program, which targets inspections to high-hazard industries so as to better ensure that employees in those industries are protected from contracting COVID-19 (OSHA, 2021c).

Government underregulation of long-term care and assisted living facilities has been identified as a major factor in these facilities serving as "hot spots" for COVID-19 (Nasol and Francisco-Menchavez, 2021). As opposed to nursing homes, which are regulated at the federal level, assisted living facilities are regulated at the state level, and thus they vary greatly as to infection prevention and control requirements. Viral outbreaks are a major problem in these facilities because of gaps in infection prevention and control programs, written procedures, and training, so that staff have inadequate knowledge about appropriate respiratory protection (Bamberg et al., 2013; CDC, 2020a; Kossover et al., 2014).

Limited authoritative guidance is available that directly focuses on workers in long-term care and assisted living facilities with respect to the use of respiratory protective devices for COVID-19. However CDC definitions of health care workers are inclusive of these worker groups, so they can be encompassed by broader guidance for workers and employers in health care settings, such as CDC's interim guidance on infection control in health care settings (CDC, 2021e). State-level guidance, such as California's Interim Guidance for Protecting Workers at Skilled Nursing and Long-term Care Facilities, also exist, providing a structure for employers' expansion of respiratory protection for these groups (Cal/OSHA, 2021a).

Few small or solo private health care practices (such as those in family medicine, internal medicine, and pediatrics) have adequate infrastructure or resources for providing safe care during a pandemic, such as COVID-19, or have any formal RPP. Similarly, a substantial proportion of dental care professionals in the United States work in the private sector, half in solo practice, without a formal RPP (ADA, 2021), although in the wake of the COVID-19 pandemic, one might plausibly expect a substantial increase in the establishment of RPPs that comply with OSHA regulations among dental care practices (OSHA, 2021b). Yet, while some federal guidance is available for health care practitioners in small practices, such as dentists

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(OSHA, 2021b), to aid with such efforts, most of the available guidance is oriented to larger health care settings.

Workers at Increased Risk of Exposure to Infectious Diseases from Interaction with the Public or Other Workers During Epidemics and Pandemics

Description of the Workforce, Work Environment, and Work Characteristics

The COVID-19 pandemic and the 2009 H1N1 pandemic have demonstrated the importance of respiratory aerosol transmission to a wide range of public-facing workers, including teachers, wait staff, day care providers, public transportation workers, janitors, and workers in correctional facilities and homeless shelters, among many others. Those working in close proximity to others, such as in manufacturing and food processing, also have experienced high rates of worksite transmission. Ancillary personnel (e.g., Transportation Security Administration [TSA] workers in airports, USDA inspectors in meat and poultry processing plants) may be exposed as well. During the COVID-19 pandemic, many previously public-facing workers were able to work remotely, while others, chiefly in the hospitality industry, lost their jobs. However, large industry sectors, including housing construction, agriculture and food processing, energy, utilities, transportation, manufacturing, security, and others, were declared "essential," exempted from stay-at-home orders, and continued to work with inadequate respiratory protection. Many of these workers lacked paid sick leave and faced job loss for missed work, exacerbating the risk of disease transmission.

Exposure and Health Impact Data

During the H1N1 pandemic, differential increases in absences due to illness (Tora-Rocamora et al., 2012), in hospitalizations, and in mortality were identified among different industry and occupational categories, as well as among different racial and ethnic groups, indicating occupational risk (Luckhaupt et al., 2012). Tora-Rocamora and colleagues (2012) identified the health, education, and social services sectors as seeing the earliest and sharpest rise in illness-related absences relative to other industry sectors. Comparison of the occupational categories of hospitalized adults with confirmed influenza in 10 U.S. states with the proportions employed in those sectors using the National Health Interview Survey revealed disproportionate representation among workers in transportation and warehousing, administrative support, waste management and remediation

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services, health care, and accommodation and food service (Luckhaupt et al., 2012). The H1N1 pandemic also saw disparities by race, ethnicity, and socioeconomic status in self-reported influenza-like illnesses and increased household disease transmission associated with lack of available sick leave (Kumar et al., 2011).

Variation in COVID-19 impacts by industry and occupation Compared with the H1N1 pandemic, the current COVID-19 pandemic has been much more lethal for workers, although failure to capture surveillance data by industry and occupation for COVID-19 infections and deaths in the United States (with the exception of health care workers) has severely limited understanding of the pandemic's toll. The press has consistently outpaced public health agencies in identifying important trends, ranging from health disparities to worksite outbreaks (Jordan and Dickerson, 2020).

Despite limitations of the available data, some data are available on the differential impacts of COVID-19 by industry/sector:

- Early data from six Asian countries suggested excess infections among health care workers, drivers and transport workers, services and sales workers, cleaning and domestic workers, public safety workers, and religious professionals, with increases among different groups appearing at different times (Lan et al., 2020).
- In California, workers in the health care, facilities, food and agriculture, government and community, manufacturing, retail, transportation, and logistics sectors experienced significantly increased mortality risk ratios; again, different industries peaked earlier or later in the pandemic in this regard (Chen et al., 2021).
- Washington State reported COVID-19 infection and hospitalization rates disproportionate to employment levels in the food processing, air transportation, residential services, merchants/wholesalers of nondurable goods, justice/public safety, agriculture, and health care sectors (Wuellner, 2021). In some instances, worksites concentrated exposures, contributing to community outbreaks.
- Occupational information available for 555 death certificates among those aged 16–64 dying from COVID-19 documented excess rates in the health care support; transportation and material moving; food preparation and serving; building and grounds cleaning and maintenance; production; construction and extraction; installation, maintenance, and repair; protective service; personal care and service; arts, design, entertainment, sports, and media; and community and social service sectors (Hawkins et al., 2021).
- Finally, the Council of State and Territorial Epidemiologists recently adopted exposure criteria for classifying occupational transmission

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of COVID-19 based on Department of Labor O*NET work designation for three risk factors—public-facing work, working indoors, and working in close proximity (Council of State and Territorial Epidemiologists, 2021).

Characteristics of work and the workforce that increase risk and vulnerability include exposure to infectious aerosols among those not able to work remotely; lack of appropriate occupational safety and health protections, including training; densely populated, poorly ventilated, or enclosed work spaces; prolonged face-to-face or physical contact where social distancing is not practiced; demographic characteristics; comorbidities; and coexposures (Carlsten et al., 2021). Individuals working in grocery stores and pharmacies exemplify essential workers who would be expected to experience prolonged exposures to the public, with little or no safety and health precautions in place and significant socioeconomic and demographic challenges. An investigation of COVID-19 rates in a Massachusetts grocery store in May 2020 found that 20 percent of the 104 workers screened by polymerase chain reaction (PCR) testing had positive viral assays; fewer than 50 percent of the workers who tested positive were symptomatic (Lan et al., 2021). COVID-19 infection rates among grocery workers represented by a local United Food and Commercial Workers Union (UFCW) in the mid-Atlantic region were lower than background county rates for those stores in which managers implemented a variety of safety measures, including enforced mask use by customers (Crowell et al., 2021). In one of the earliest and most devastating outbreaks of COVID-19 identified among U.S. workers, employees in meat and poultry processing plants demonstrated an extraordinarily high risk not only for infection and death but also for seeding of community outbreaks. Based on incomplete data reported by 30 states through May 31, 2020, CDC identified 8,978 infected workers across 742 agricultural and food processing worksites, with 55 deaths (Waltenburg et al., 2021).

Transportation issues arose early in the pandemic, with cruise ships and a U.S. aircraft carrier reporting explosive outbreaks (Kasper et al., 2020), and deaths among bus drivers and other transportation workers being reported through news media and transit unions. By April 9, 2020, at least 33 New York City transit workers had died from COVID-19, with bus drivers being disproportionately impacted (Martinez, 2020).

Some of the highest COVID-19 infection rates were seen among public safety and correctional workers. As of April 21, 2020, an incomplete U.S. sampling revealed COVID-19 infections among 4,893 inmates and 2,778 corrections personnel, including 88 and 15 fatalities, respectively (Wallace et al., 2020). By November 24, 2020, Colorado had reported a total of 204,000 COVID-19 cases, including 15,526 hospitalizations and 2,821 deaths, among incarcerated individuals (Quan et al., 2021). Following

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compassionate early release, a project in Colorado found 4 of 165 formerly incarcerated individuals to be infected, as well as 4 of 20 staff working in community organizations assisting with community reentry (Quan et al., 2021). A seroprevalence study of SARS-CoV-2 antibodies in New York City identified the highest rate among correctional staff (39.2 percent seropositive), with traffic officers, security guards, firefighters, and others with first responder or security responsibilities having elevated rates as well (Sami et al., 2021). Furthermore, among 37,640 Federal Bureau of Prisons staff, SARS-CoV-2 infection was most prevalent among staff in institutions where social distancing by staff and inmates was limited (Toblin et al., 2021).

Workers and volunteers in homeless shelters have long been aware of respiratory transmission of tuberculosis and other infectious diseases. In March 2020, outbreak investigations at three King County, Washington, homeless shelters identified COVID-19 infections among 18 percent of residents and 21 percent of staff members (Tobolowsky et al., 2020). A subsequent cross-sectional study of 14 King County homeless shelters found a 2 percent infection rate by PCR testing; of 157 staff tested, 4 tested positive (Rogers et al., 2020).

Variation in COVID-19 impacts by race, ethnicity, and socioeconomic status Employees designated as "essential" and unable to work remotely are disproportionately low-wage racial and ethnic minorities (Hawkins, 2020). Black workers, for example, make up approximately 26 percent of public transit workers but just 11.9 percent of the total working population, while Hispanic workers constitute 40.2 percent of workers providing building cleaning services despite representing only 16.8 percent of all U.S. workers (see Table 3-3). The failure to protect large groups of these workers contributed to their widely disproportionate experience of infection and mortality from COVID-19 relative to other population groups. The demographics of the essential workforce are presented in Table 3-3, from the Center for Economic and Policy Research (Rho et al., 2020). The differential occupational exposures of these workers contributed to widespread infection among multigenerational households in populations with high rates of preexisting conditions associated with the social determinants of health, compounded by a lack of access to appropriate health care.

Respiratory Protection and Regulatory Frameworks (Standards, Guidance, and Oversight)

Evidence from the H1N1 pandemic and the severity of outcomes from COVID-19 point to the need for a complete safety and health program adhering to the hierarchy of controls, including a formal RPP, among large sectors of the U.S. workforce currently not likely to be covered by such a

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TABLE 3-3 Characteristics of Workers in Front-Line Industries

	ALL WORKERS	ALL FRONTLINE INDUS-TRIES	GROCERY, CONVE-NIENCE, AND DRUG STORES	PUBLIC TRANSIT	TRUCKING, WARE-HOUSE, AND POSTAL SERVICE	BUILDING CLEANING SERVICES	HEALTH CARE	CHILD CARE AND SOCIAL SERVICES
All Workers (16+)	152,600,169	31,673,098	6,817,890	804,495	3,128,922	1,484,993	16,103,877	3,332,921
Female	47.4%	64.4%	50.5%	29.1%	22.7%	53.2%	76.8%	85.2%
Full/Part-Time								
Full-Time	78.6%	73.3%	63.7%	81.0%	90.5%	62.6%	79.8%	67.4%
Part-Time	21.4%	24.7%	36.3%	19.0%	9.5%	37.4%	20.2%	32.6%
Race/Ethnicity								
White	63.5%	58.8%	59.5%	54.7%	56.4%	43.4%	61.1%	55.8%
Black	11.9%	17.0%	14.2%	26.0%	18.2%	12.6%	17.5%	19.3%
Hispanic	16.8%	16.3%	18.5%	14.0%	20.0%	40.2%	12.1%	18.0%
AAPI	6.6%	6.7%	6.6%	4.1%	4.2%	2.4%	8.0%	5.3%
Other	1.2%	1.2%	1.3%	1.2%	1.1%	1.3%	1.2%	1.5%
Foreign Born	17.1%	17.3%	15.7%	15.2%	17.9%	38.2%	16.2%	17.0%
Education Level								

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LTHS	9.3%	8.5%	13.0%	6.9%	12.7%	26.5%	4.3%	7.9%	
HS	24.5%	25.8%	36.0%	38.1%	42.6%	38.5%	17.2%	21.7%	
Some College	32.0%	36.3%	35.2%	39.4%	34.2%	26.0%	38.2%	34.7%	
College	21.6%	18.1%	11.9%	11.4%	8.7%	7.4%	22.8%	22.9%	
Advanced	12.6%	11.4%	4.0%	4.1%	1.8%	1.5%	17.5%	12.8%	
Age 50+	33.1%	33.9%	27.4%	46.7%	40.2%	35.6%	34.6%	34.4%	
Home Ownership	65.3%	63.6%	59.6%	68.2%	65.5%	50.0%	66.7%	60.1%	
Public Transit Commute to Work	5.1%	4.8%	4.5%	9.0%	2.4%	7.8%	4.6%	6.8%	
Compensation and Benefits									
Below Poverty Line	6.7%	7.2%	10.0%	4.5%	4.7%	15.9%	5.2%	10.8%	
<200% Poverty Line	20.6%	23.0%	30.1%	16.0%	19.2%	42.4%	17.8%	30.0%	
No Health Insurance	11.0%	9.9%	12.1%	5.8%	14.8%	29.1%	6.3%	10.4%	

continued

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TABLE 3-3 Continued

	ALL WORKERS	ALL FRONTLINE INDUSTRIES	GROCERY, CONVENIENCE, AND DRUG STORES	PUBLIC TRANSIT	TRUCKING, WAREHOUSE, AND POSTAL SERVICE	BUILDING CLEANING SERVICES	HEALTH CARE	CHILD CARE AND SOCIAL SERVICES
Family Responsibilities								
Child in home	35.8%	35.9%	33.9%	32.6%	33.3%	38.8%	36.9%	36.0%
Senior (age 65+) in home	14.8%	16.0%	16.8%	18.4%	14.9%	15.5%	15.3%	18.5%

SOURCE: CEPR's Analysis of American Community Survey, 2014-2018 5-Year Estimates. This work is licensed under a Creative Commons Attribution 4.0 International License. It is attributed to the Center for Economic and Policy Research, and the original version can be found at https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries.

SOURCE: Rho et al., 2020

NOTES: "Front-line industries" refers to the cumulative industries presented in the table (e.g., grocery stores, public transit, postal service). AAPI = Asian American and Pacific Islander; HS = high school; LTHS = less than high school.

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program. Employers of health care support, transportation, manufacturing, retail, service, and other workers at increased risk from infectious pandemic agents have a responsibility to provide them safe working conditions. However, this responsibility is not consistently met, impacting not only these workers' health but also their willingness to perform their job functions during a public health emergency. Organizational preparedness that includes enforcing existing safety and health protections, as well as providing access to respirators and developing and implementing formal RPPs, among other measures, is necessary to ensure worker safety and willingness to work (Gershon et al., 2010). Misclassification of transportation, cleaning, and other workers as self-employed results in large numbers of workers for whom safety and health protections are lacking. Here again, the primary response required is adequate enforcement of existing Department of Labor protections.

Failure to protect essential workers, including health care workers, marked the first year of the pandemic. Several factors may have contributed to this inadequate protection of workers and the lack of formal RPPs:

- Both WHO and CDC were slow to recognize and acknowledge the significant role of airborne transmission of SARS-CoV-2 by aerosols (Tanne, 2020). As late as July 2020, for example, WHO posted the following statement, effectively dismissing the need for RPPs against aerosols in most settings, except certain medical situations: "Current evidence suggests that SARS-CoV-2 is primarily transmitted between people via respiratory droplets and contact routes—although aerosolization in medical settings where aerosol generating procedures are used is also another possible mode of transmission" (WHO, 2020).
- Early on, the United States experienced a widely reported and acknowledged shortage of PPE, including respirators (CRS, 2020).
- Throughout the first year of the pandemic, OSHA failed to respond adequately to worker complaints about hazardous working conditions or enforce its Respiratory Protection Standard in settings characterized by SARS-CoV-2 exposures (Whoriskey et al., 2020).
- U.S. labor laws and changing hiring practices have contributed to a workforce with large numbers of at-will workers,[11] an absence of paid

[11] "At-will means that an employer can terminate an employee at any time for any reason, except an illegal one, or for no reason without incurring legal liability. Likewise, an employee is free to leave a job at any time for any or no reason with no adverse legal consequences. At-will also means that an employer can change the terms of the employment relationship with no notice and no consequences" (NCSL, 2021). However, any retaliation for raising safety and health concerns with the employer or OSHA is illegal under 29 C.F.R. § 1977.3, which outlines protections for employees for certain actions related to occupational safety, although it is not an easy law to enforce (29 C.F.R. § 1977.3).

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sick leave, and workers in informal working arrangements, leaving these workers without pathways for negotiating for basic safety and health protections, such as RPPs (Kumar, 2011; Quinlan, 2021).

Thus, for the vast majority of essential workers, meaningful improvements in overall safety and health during pandemics will require enhancing existing mechanisms designed to ensure that work does not endanger the workers or their families and communities.

On the other hand, the genuinely self-employed, such as those offering home day care services or owning very small groceries or laundries, and their employees may fall outside of current regulatory requirements and would appropriately rely on the types of protections available to the public. The same is true of essential workers who are able to socially distance, such as some utility workers, as well as workers in offices where social distancing and improved ventilation are rigorously maintained. The challenge these worksites may present is one of outreach and communication, often complicated by language or other barriers. Efforts to address the needs of the self-employed and small business owners will require specific focus, for example, on the leadership role small business owners may play in the use of respiratory protection (Jones et al., 2021).

While OSHA provides extensive enforcement and outreach guidance for RPPs, CDC/NIOSH, the National Institute of Environmental Health Sciences' (NIEHS's) Worker Training Program, and OSHA's Susan Harwood Training Grant program have developed or funded others to create extensive libraries supporting worker outreach and training (CDC, 2021f,h,i; NIEHS, 2021; OSHA, 2021i). A number of unions, educational institutions, nonprofit organizations, and worker centers have collaborated with end users to develop training for both workers and small businesses (CPWR, 2021a; SEIU, 2021). CDC maintains several occupation-specific guidance documents, including new or updated guidance for restaurant and bar operators, in-home social service providers, public transportation operators, and airline crews, which include links to general guidance on types of respiratory protective devices and their use (CDC, 2021b,g,k,l). OSHA guidance is available for small business owners who are required to establish an RPP to address occupational exposures that necessitate respiratory protection (OSHA, 2011a), but this guidance is not intended for use by employees and does not address the needs of all workers at increased risk of exposure to infectious agents. Future health communications about respiratory protection would benefit from clear messaging that is appropriate to workers' literacy levels (Pan et al., 2020). Moreover, research into improved respirator design is necessary to address the needs of workers who must communicate with the public while using a respirator; to assess the potential for respirator contamination under various use scenarios; to improve comfort, ease of use,

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and the ability to communicate during use; and to identify, evaluate, and determine how best to implement approaches to encouraging correct use.

Disaster Response and Recovery Workers

Description of the Workforce, Work Environment, and Work Characteristics

Various workers may be engaged in different phases of the disaster cycle (see Figure 3-6). The initial rescue phase of any disaster involves immediate action by responders to save lives. With the transition to the recovery and cleanup stage, other types of workers are brought in.

Construction workers are routinely pulled into disaster responses of all types. During the cleanup at the World Trade Center, for example, nearly all of the building trades were onsite: heavy equipment operators moved debris, ironworkers cut beams and rigged loads, electricians rerouted phone and electrical lines, laborers moved debris and sealed contaminated areas, carpenters built barriers, and teamsters hauled debris in large articulated dump trucks. Most of these workers had no training in disaster response and received no site safety and health training until 78 days after the towers had fallen (Lippy, 2002). Operators of heavy equipment are regularly pulled into much smaller disasters, such as house collapses or flooding, when the first hours are critical to saving lives.

Day laborers have also been engaged in response and recovery efforts for many disasters over the past two decades, including

- the attacks on the World Trade Center in 2001 (EHS Today, 2002);
- Hurricane Katrina in 2005 (Delp et al., 2009; Fletcher et al., 2006);
- Hurricane Sandy in 2012 (Berger, 2012; Cordero-Guzman et al., 2013);
- Hurricane Harvey in 2017 (Theodore, 2017); and
- California wildfires, including the Thomas Fire in 2017, the Woolsey Fire in 2018, and the Camp Fire in 2018 (Costirilos, 2019; IDEP-SCA, 2020).

Of note, day laborers have increasingly been engaged in both wildfire first response and recovery/cleanup efforts (Costirilos, 2020).

Volunteers from the public are another important population of workers during most disaster responses. They often are the first on the scene to respond to car crashes and house fires or to save neighbors during floods or wildfires, and are the primary rescuers of fellow citizens from collapsed buildings (Macintyre et al., 2006). Even among firefighters, volunteers greatly outnumber professionals: the NFPA estimates that of the total

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number of firefighters in the United States in 2018, 67 percent were volunteers (Evarts and Stein, 2020).

Volunteers often feel compelled to help during major disasters, as was the case with the many volunteers who helped serve food to responders at the World Trade Center through such organizations as the Red Cross, which also deployed an estimated 220,000 volunteers to hurricanes Katrina and Rita (American Red Cross, 2006). And many spontaneous volunteers show up at disaster sites with no affiliation, just a desire to help. Sauer and colleagues (2014) sought to understand the use of volunteers in disasters by surveying 24 of the 51 total member organizations in National Voluntary Organizations Active in Disaster (VOAD). Among those organizations, 79 percent reported regularly using spontaneous volunteers during disasters, and 68 percent found these volunteers to be useful (Sauer et al., 2014), although they were rarely credentialed, and only half (53 percent) of the organizations provided them with training.

Exposure and Health Impact Data

Workers engaged in the response to or recovery from disasters often work at uncontrolled sites where the hazards are not fully known. In the initial response phase, there is often a "risk a life to save a life" mindset. It is critical to delineate clearly when the rescue phase has concluded and the disaster has shifted to a more controlled recovery phase, during which the hazards may still be present but the pace can be slowed and the work shifts reduced, allowing responders to catch up on sleep and meals, which also reduces their risk; the key is to recognize that the longer the rescue phase continues, the greater is the risk. Yet, the shift from rescue to recovery operations is not always apparent, as was the case during the World Trade Center response, in which the rescue phase was reportedly extended through June 2002 for the entire 9 months of debris removal operations (Newman, 2013) even though the last survivor had been rescued on September 12 (Cloud, 2002). The Federal Response Plan that was in effect during the response assigned OSHA the role of making "available safety and health specialists to provide safety-specific assistance to affected disaster response agencies as required by the Federal Coordinating Officer" (FEMA, 1999, p. 260). However, enforcement was limited, and once workers were onsite, there was little leverage for ensuring compliance, and as a result, respirator use was documented as inconsistent (Lippy, 2002). Eventually, a disaster site can transition to a nearly normal construction site (see Figure 3-6), although risks to workers at the site may still be elevated. Three aspects of disaster recovery greatly increase the likelihood that construction workers will confront risks to health and safety:

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FIGURE 3-6 Evolution of health and safety risks across the phases of a disaster. This figure illustrates the transition from one phase of a disaster to the next and how risks to workers evolve with the transition between phases.
SOURCE: Courtesy of Bruce Lippy, committee member.

- "the rapid pace at which recovery operations are undertaken, including working long hours and without necessary rest breaks;
- the prevalence of multiple hazards at any given worksite; and
- the fact that hazards may be unknown to work crews that are entering a worksite." (Theodore, 2017, p. 8)

Inhalation hazards in disaster scenarios can include ash and debris, mold, asbestos, and other airborne contaminants, depending on the nature of the disaster (Delp et al., 2009). And as discussed at length above, in the case of wildfires, exposure to wildfire smoke has been associated with respiratory symptoms, as was the case, for example, with day laborers and domestic workers who reported breathing difficulties following the Woolsey fire (IDEPSCA, 2020).

Respiratory Protection and Regulatory Frameworks (Standards, Guidance, and Oversight)

Disaster response and recovery workers are a diverse population whose respiratory protection needs may differ. Studies of past disasters have shown that different types of disaster workers may be more or less likely to use respiratory protection, highlighting the need for improved training, selection, fit testing, and consistency in use for respiratory protection among emergency responders (Antao et al., 2011).

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An important factor impacting the respiratory risks to workers engaged in response and recovery efforts are the changes to regulations that may occur during disaster conditions. In some cases, OSHA standards and enforcement operations may be suspended in disaster-affected areas, removing incentives for employers to provide adequate protections (Fussell et al., 2018). The Army Corps of Engineers, often involved in disaster response and recovery, has its own regulations (EM385 manual), which are similar to OSHA's.

Construction workers Inadequate use of respiratory protection by construction workers at the World Trade Center is a well-documented problem. Fit testing was not widely available until more than 1 month into the disaster response. More than 100,000 elastomeric half-mask respirators were distributed but compliance with their use was routinely poor: operators of heavy equipment working in the restricted zone generally wore their elastomeric half-mask respirators less than 50 percent of the time (Lippy, 2002). In contrast, compliance with respirator use was reported to be around 90 percent at the Fresh Kills site where the debris was taken, an operation managed by the Army Corps of Engineers, which was effective at getting workers to wear respiratory protection during the World Trade Center cleanup effort (DePalma, 2006).

OSHA's Hazardous Waste Operations and Emergency Response (HAZWOPER) standard (1910.120) clearly stipulates the training needed for each type of responder, and specifically allows construction workers to have less training relative to other responders. Under 1910.120(q)(4), the agency identifies "skilled support personnel" as

> personnel, not necessarily an employer's own employees, who are skilled in the operation of certain equipment … and who are needed temporarily to perform immediate emergency support work that cannot reasonably be performed in a timely fashion by an employer's own employees and who will be or may be exposed to the hazards at an emergency response scene.

These skilled support personnel are not required to meet employers' training requirements for regular employees, merely to receive an initial briefing at the worksite before beginning response work. The briefing must include instruction in the wearing of appropriate PPE but can be of any length. The assumption is that workers deemed skilled support personnel will be onsite only briefly during the emergency phase and, if staying when the site transitions to cleanup activities, would then receive appropriate HAZWOPER training. However, this assumption proved incorrect during the World Trade Center response. To remedy this deficit, OSHA, working with safety and health representatives of the building trades unions, developed two OSHA Disaster Site Worker courses (OTI 7600 and OTI 5600)

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that are now delivered across the country. Both are voluntary, however, and it has proven difficult to convince construction employers of the need to have their workers trained in anticipation of a disaster.

An overlooked and rarely cited requirement in the HAZWOPER standard is 1910.120 (o) which requires employers to "develop and implement procedures for the introduction of effective new technologies and equipment for the improved protection of employees working with hazardous waste clean-up operations, and the same shall be implemented as part of the site safety and health program to assure that employee protection is being maintained." This requirement is essentially acknowledging the position of respiratory protection at the bottom of the hierarchy of controls and promoting more effective strategies. Limited but noteworthy efforts were made to implement control technologies at the World Trade Center cleanup (Lippy, 2003).

Day laborers Despite the increasingly frequent role of day laborers in disaster response and recovery efforts, employers often fail to provide them with PPE or training, let alone other aspects of an effective RPP (e.g., fit testing, medical clearance), and respiratory problems may result (Delp et al., 2009). In one study day laborers reported access to key types of personal protective equipment, such as respirators, but in many cases these devices were being used long after their effective use period had ended (Delp et al., 2009). In other cases, workers reported trying to protect themselves by tying a t-shirt over their mouth and nose or otherwise trying to prevent exposure to health hazards (Theodore, 2017). For example, most of the workers involved in recovery and cleanup activities at the World Trade Center site were day laborers performing tasks such as removal of asbestos. Many of these workers describe not being given training on the hazards faced and not being provided with any type of respiratory protection or protective clothing (EHS Today, 2002). Likewise, only 18 percent of day laborers in New Orleans after Hurricane Katrina reported having access to respirators (Fletcher et al., 2006). More than 60 percent of day laborers (nearly two-thirds) surveyed during the Hurricane Harvey cleanup had no respirator; many used inadequate equipment or simply covered their noses and mouths with t-shirts. Given the unpredictability of the specific conditions that will be encountered by second responders involved in post-disaster cleanup at a worksite, it is incumbent on employers to provide appropriate PPE, including respiratory protective equipment to their crews (Theodore, 2020). Making safety and health training for day laborers in disaster areas a priority is essential, as is providing them with PPE.

Volunteer disaster response and recovery workers Disaster volunteers routinely show up at disaster sites without PPE, such as respiratory protective

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devices, or knowledge of the risks they face, which places strains on the existing response infrastructure (Van Hoving et al., 2010). Among the tens of thousands of responders at Ground Zero, for example, spontaneous volunteers carried water to the heavy equipment operators on the smoking pile of debris at the World Trade Center unaware of the hazards to which they were being exposed.

From a risk standpoint, there is a great difference between affiliated and unaffiliated volunteers. The latter population receives little or no training for the most part and does not understand critical safety issues. It is not surprising then, that 42 percent of the volunteer organizations reported injuries and two fatalities among their volunteer responders (Sauer et al., 2014). The researchers concluded that while the use of spontaneous volunteers is widespread, nongovernmental organizations are "not necessarily structured to incorporate them effectively. More structured efforts to integrate [spontaneous volunteers] are critical to safe and effective disaster response" (Sauer et al., 2014, p. 65).

NIEHS's Worker Training Program has been a major force in protecting this vulnerable population, providing training in worker safety and health in disaster response to more than 20 grantees for more than 20 years. This adaptable training infrastructure is based on experience in training workers responding to Ground Zero, the Gulf oil spill, wildfires, and hurricanes and allows for just-in-time development of materials for future disasters (Rosen et al., 2015). In 2020, the Worker Training Program collaborated with the American Industrial Hygiene Association (AIHA) to develop user-oriented guidance for volunteers on COVID-19 prevention practices in response to growing concerns about infection-related health risks for volunteers (AIHA, 2020). Additionally, NIEHS (2013) has developed mold remediation guidance oriented toward disaster recovery volunteers and essential workers, providing them with detailed information about the selection and use of respiratory protection and other types of PPE.

Summary and Synthesis

This section has considered multiple worker groups that are potentially exposed to inhalation hazards in the workplace. The exposures discussed are diverse and may be intermittent (e.g., for those exposed to wildfire smoke and high levels of ambient air pollution) or more sustained (e.g., for construction workers). Some worker groups have situational exposures (e.g., those working in cleanup following a disaster, or those exposed to SARS-CoV-2 through contacts with people across multiple sectors beyond health care workers).

These worker groups share several characteristics: a wide range of employers, many with small numbers of employees; transient employment,

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sometimes initiated on an urgent basis; a wide range of sociodemographic backgrounds and characteristics, some of which may contribute to susceptibility; and variable access to health care. Additionally, there may be no central touch point for enumerating these employees and their employers and implementing programs to protect them from exposure to inhalation hazards. Unique challenges are faced by some of these workers, such as day laborers, who represent a fluid group that may be hired because the jobs may involve hazardous exposures; such workers are unlikely to file OSHA complaints, whether because of the informal and/or temporary nature of their work assignments, fear of employer retaliation, or potential loss of employment.

Some data have been collected for some worker groups, such as wildland firefighters, a group stressed by an increasing number of larger fires. Respiratory protection for wildland firefighters has been considered, but without resolution. Further complexity stems from the multiple groups that employ these firefighters.

The COVID-19 pandemic has highlighted the enormous needs for respiratory protection for large numbers of workers across many sectors both to provide protection for the individual workers and to reduce transmission. The pandemic has surfaced problems in supply chains; in understanding of the role and effectiveness of various devices for transmission control; and in rapid implementation of a broadly reaching, multisectoral program.

The landscape of guidance available to support use of respiratory protection by the diverse worker groups discussed here is variable and has been developed by a broad range of stakeholders, including federal agencies, labor unions, professional associations, academic institutions, and nonprofit organizations (see Box 3-3 for a selection of this guidance). Much of the federal guidance reviewed for this study (outside of that focused on clinical or allied health settings) provides information about the use of face coverings and medical masks rather than respirators and as of September 2021, was labeled as temporary or expired. Additionally, much of the guidance reviewed is oriented to employers and tends to be technical in nature; in general, the committee found a paucity of user-friendly tools and resources (e.g., checklists for employers, instructive graphics, Spanish translations) targeted to specific worker groups to support the selection and use of respiratory protective devices by both employers and workers, including those workers who are self-employed or day laborers. Such materials that were identified were generally produced by trusted organizations, such as unions, associations, dedicated nonprofits, or academic centers. However, not all occupations and businesses requiring respiratory protection are represented by such organizations and have access to the supportive services these organizations can provide with regard to translating and tailoring federal standards and guidance to the needs and contexts of that worker

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BOX 3-3
Selected Examples of Guidance on Use of Respiratory Protective Devices for Workers

Federal and State

- Occupational Safety and Health Administration (OSHA)—"Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace" (OSHA, 2021f)
- National Institute for Occupational Safety and Health (NIOSH)—"Outdoor Workers Exposed to Wildfire Smoke" (NIOSH, 2021b)
- NIOSH—"Hospital Respiratory Protection Program Toolkit" (NIOSH, 2015b)
- Centers for Disease Control and Prevention (CDC)—"Meat and Poultry Processing Workers and Employers: Interim Guidance from CDC and the Occupational Safety and Health Administration" (CDC, 2021m)
- California Division of Occupational Safety and Health (Cal/OSHA)—"The California Workplace Guide to Aerosol Transmissible Diseases" (Cal/OSHA, 2020b)
- National Institute of Environmental Health Sciences (NIEHS)—"Mold Remediation Guidance: Health and Safety Essentials for Workers, Volunteers, and Homeowners" (NIEHS, 2013)

Labor Unions and Professional Associations

- Laborers' Health & Safety Fund of North America—"Responding to COVID-19 in Construction" (LHSF, 2021)
- International Brotherhood of Teamsters—"Facemask and Respirator Use: Coronavirus" (International Brotherhood of Teamsters, 2020)
- AFL-CIO—"Is Your Face Covering Keeping You Safe?" (AFL-CIO, 2020)
- National Domestic Workers Alliance—"Using Facemasks and Other PPE" (NDWA, 2020)
- American Industrial Hygiene Association (AIHA) and NIEHS—"Guidance to Protect Volunteers from COVID-19 during Natural Disaster Response and Recovery" (AIHA, 2020)

Academic and Nonprofit Institutions

- National Safety Council—"Helpful Facts on Respirators and Face Coverings" (National Safety Council, 2020)
- University of California, Davis, Western Center for Agricultural Health and Safety—"Wildfire Resources" (WCAHS, 2021)
- Pesticide Educational Resources Collaborative—"How to comply with the 2015 revised Worker Protection Standard for agricultural pesticides—What owners and employers need to know" (PERC, 2017)

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population. Additional research and investment may therefore be needed to tailor, translate, and disseminate technical guidance and trainings for additional worker populations and hazards of concern.

For all worker groups, there are substantial gaps in the evidence available on the hazards faced, the levels of exposure, the feasibility of an RPP, and the types of devices needed. While NIOSH approves respirators for use under an OSHA RPP, it does not have a robust and ongoing targeted research or applied intervention program to evaluate the actual implementation and use of respiratory protective devices, especially in worker populations that have not been the traditional focus of guidance and compliance efforts. Such research needs to include an emphasis on usability issues, including comfort, ease of use, and the ability to communicate while using the device, as well as to identify, evaluate, and implement approaches for encouraging correct use. Small businesses and difficult-to-reach populations need to be a particular priority for research aimed at determining how best to establish and implement an RPP, carried out with worker participation.

Conclusion 3-6: For worker groups not covered by RPPs, regulatory and public health agencies have no coordinated approach to reducing workplace inhalation hazards and supporting employers of such workers in doing so.

Conclusion 3-7: Current respiratory protection technology for protecting workers from the diverse inhalation hazards they face has limitations.

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4 Respiratory Protection for the Public

The COVID-19 pandemic and the recent widespread wildfires in the United States have lent new urgency to the public's interest in and need for having appropriate and effective respiratory protection. As described previously, however, regulatory processes for respiratory protective devices have historically been limited to occupational use scenarios, so that there is no structure in place for ensuring that the respiratory protection needs of the public are met. This chapter examines experiences with the use of respirators, medical masks, and face coverings outside of occupational settings to mitigate inhalation hazards; the challenges that impede application of the occupational model to the public; and the need for an organizational and regulatory framework for addressing current gaps in processes for oversight of and guidance on respiratory protection for use by the public.

This chapter serves as a complement to Chapter 3, which examines respiratory protection for workers whose employment settings fall within the purview of a federal regulatory agency (e.g., the Occupational Safety and Health Administration [OSHA]) and are therefore covered by respiratory protection programs (RPPs), as well as workers who are not currently covered by such programs but may face inhalation hazards. Chapter 3 also provides evidence and lessons learned from the occupational context that are applicable to the general population. Together, Chapters 3 and 4 are foundational for the committee's recommended approach to addressing the needs of the two target populations for this study—workers not covered by an RPP and the public.

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NEEDS OF THE PUBLIC FOR RESPIRATORY PROTECTION

There are diverse circumstances in which the public might require respiratory protection. For example, consider the following three scenarios:

- It is March 12, 2020. An individual wakes up in Scranton, Pennsylvania, to learn that a day earlier, the World Health Organization (WHO) had declared that COVID-19 was a pandemic (WHO, 2021).
- On the evening of August 16, 2020, while driving home from work, an individual in Monterey, California, learns of dangerously high levels of smoke from raging fires in Pine Canyon and River Road, east of Salinas, about 20 miles away (CAL FIRE, 2020).
- An individual returning to home after a major flooding event finds significant mold growth requiring remediation (Riggs et al., 2008).

Beyond such emergency-related scenarios, the public may require respiratory protective devices in more routine aspects of daily life, such as while engaged in home maintenance or hobby-related activities that result in exposure to inhalation hazards. Many factors may affect the decision making of members of the public on the selection and use of respiratory protective devices, including their knowledge, skills, attitudes, and beliefs. In their decision-making process, members of the public may seek answers to such questions as those listed in Box 4-1 (framed as a user's practical questions on selecting, procuring, and safely and effectively using a respiratory protective device). Yet, because no single body or a group of coordinated entities has developed evidence-based answers to all of these questions, members of the public currently face substantial barriers to making informed decisions on when to use a respiratory protective device, what device to use, and how that device should be used for effective protection from specific hazards for their families and themselves. For many people, the cost of a device may be a further consideration, potentially limiting access. Misinformation, conflicting recommendations from different authorities, misleading product claims in advertisements, and counterfeit products add to the challenges faced by the public in determining whether to use a respiratory protective device and what device to select. In the face of such confusion, members of the public may choose such alternatives as staying indoors or leaving the affected area. However, those steps may be insufficient, leading to avoidable morbidity and even premature mortality. The following three sections explore in more detail the needs of the public with regard to device types, use, safety, and access.

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BOX 4-1
Questions the Public May Have About Respiratory Protective Devices

Device Type

- How much will this device reduce my risk of disease and the risk to others?
- Which of the myriad devices sold on the market meet measurable standards?
- Which respiratory protective devices will conform to my face to create a face seal (including if I am a child, elderly adult, or member of a racial or ethnic minority population)?
- Which respiratory protective devices will be comfortable and have minimal impact on my activities and ability to communicate?
- Are there any respiratory protective devices that I find aesthetically pleasing?
- Has the device been certified for safety and performance by an accredited organization?

Device Access

- Can I afford the recommended device?
- Where can I procure the device(s)?
- How do I distinguish a legitimate device from a counterfeit one?

Device Use

- Where should I look for information on the need for respiratory protection?
- Should I use a respiratory protective device (i.e., is there a device recommended for people like me for this hazard)?
- Why should I use a respiratory protective device (i.e., what is the hazard and why this device)?
- Where do I get information about how to use the device?
- How should I don (put on), use, and doff (take off) the device correctly so that it is effective?
- When should I use the device?
- Where should I use the device (indoors, outdoors, etc.)?
- How long should I use the device to be protected from the hazard?
- How do I know the device is protecting me (working properly as designed) during its use?
- How do I know when the device has reached its end of life, is no longer effective, and should be discarded?
- How safe is it for me to use the device?
- Will the materials in the device—including fabrics, filters, closures, and finishes (coatings)—cause me harm?
- What impact does use of the device have on me if I have health challenges, such as lung or cardiovascular disease?

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CURRENT DEVICES FOR THE PUBLIC AND NEEDS FOR FUTURE RESPIRATORY PROTECTIVE DEVICES

Landscape of Devices Available to the Public

Faced with a perceived need for respiratory protection, the public will seek to learn which devices are identified by authoritative sources as appropriate for use in their particular circumstances. However, credible and trustworthy guidance on the selection and use of devices for protection from such inhalation hazards as SARS-CoV-2, wildfire smoke, mold, and ambient air pollution is currently lacking. This unmet need for trusted guidance is exemplified by the ongoing COVID-19 pandemic. At times, the public has been confused by guidance regarding the level of personal protection, particularly against infectious airborne particles, provided by different devices (Clapp et al., 2020). This section briefly describes the landscape of devices that have been used by the public with the intent of reducing exposure to inhalation hazards during past public health emergencies as well as devices that have emerged in the market during the COVID-19 pandemic. These devices range from respirators, to surgical masks, to cloth face coverings, and also to newly emerging technologies. An overview of these various devices and their purposes is presented in Chapter 1; detailed information regarding factors that influence their performance (e.g., filtration efficiency, fit) can be found in Appendix B.

Respirators

A variety of respirator models are on the market in the United States, including elastomeric facepiece respirators and filtering facepiece respirators (FFRs). These devices are not intended or marketed for routine public use, however, because the full protection afforded by respirators, including N95 FFRs, is ensured only if the user undergoes fit testing and is trained to use and care properly for the respirator. Also, FFRs generally are not evaluated for facial fit as part of the National Institute for Occupational Safety and Health (NIOSH) respirator approval process, except in cases of a novel design (CDC, 2018). Given that FFRs are the primary form of respirator used by members of the public, who, unlike workers in RPPs, will likely not undergo fit testing, ensuring proper fit is a notable issue to be addressed for nonoccupational use of such devices.

Despite the lack of fit-testing requirements analogous to those designed to ensure appropriate protection in an occupational setting (discussed in more detail below), N95 FFRs have been deployed for public use during prior public health emergencies. For example, local governments and charitable organizations in the United States and Australia have provided

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N95 FFRs to the public during wildfire smoke events (Morain, 2020; Sacramento City Express, 2018).

While FFRs have been designed for use in an occupational setting, two 3M respirators—the 3M™ particulate respirators 8612F and 8670F—were cleared by the Food and Drug Administration (FDA) in 2008 for use by the public during public health emergencies caused by an outbreak of an airborne infectious disease. These respirators were briefly made available to the public during the H1N1 influenza pandemic in 2009–2010 (McCullough, 2021), but because of a lack of demand for the devices following the H1N1 pandemic, 3M discontinued their manufacture and sale in 2013 (3M, 2021).

Medical/Surgical Masks[1]

A simple search for surgical masks on Amazon in March 2021 yielded 100 "best sellers" with varying descriptions and prices. However, the public does not have authenticated information with which to make an informed decision among such offerings, including whether any of them could be considered a respiratory protective device offering some level of respiratory protection. Rather, the decision to buy a particular product is often driven by price and consumer ratings, which tend to reflect bias on the part of the individuals submitting the reviews (Amazon, 2021). Medical/surgical masks may also be supplied to users by governments and charitable organizations following a natural disaster or other public health emergency (Galea et al., 2018).

Cloth and Other Face Coverings

Also available to the public are a number of commercially marketed face coverings made of different types of fabrics and with varying designs (e.g., materials, structures, closure mechanisms, and finishes). The manufacturers of some such products claim that they provide protection and comfort for the wearer based on their filtration efficiencies, antimicrobial properties, and moisture management treatments.[2] Notably, however, data are lacking on the safety of chemical treatments used on some face coverings for antimicrobial and moisture management purposes. Such factors as the propensity of the chemical finish to leach, off-gas, or be ingested (if the

[1] As discussed in Chapter 1, the terms medical mask and surgical mask may be used interchangeably.

[2] The committee did not test or verify any of these claims, as doing so was beyond the scope of this study.

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tongue touches the mask during use) could influence the safety of masks with such finishes (Pullangott et al., 2021).

Leakage is a persistent problem with face coverings because of loose fit for some users. Data also are limited on the protection offered by face coverings relative to surgical or medical masks, further impeding the public's evidence-based decision making in selecting a device. A new class of face coverings, known as barrier face coverings, which comply with the ASTM F3502-21 standard (see Chapter 2) and provide a measured degree of particulate filtration and better fit (compared with other face coverings), is now available to the public.

Needs of Users in the Public for Respiratory Protective Devices

User needs for respiratory protective devices and how they influence the selection of a device are briefly described below. Factors related to performance, comfort, usability, and availability are discussed in more detail in Appendix B.

Is Comfortable and Aesthetically Pleasing

Users want a respiratory protective device that is comfortable (or is not perceived as uncomfortable), and some may select a more comfortable device over one that is more effective if they perceive that the more comfortable device provides adequate protection (Galea et al., 2018).

A major factor in a device's comfort is its breathability: a device that is breathable is less likely to substantially impact the physiological responses of the user during long periods of use (Roberge et al., 2010). Perceived and actual impacts on the ease of breathing and related changes in heat and humidity felt during use of a respiratory protective device—including feelings of suffocation, stickiness, and sweating—are frequently noted in the literature as a major cause of discomfort among members of the public (Al Naam et al., 2021; Chao, 2020a; Cheok et al., 2021; Ferng et al., 2011). Itching can contribute to discomfort as well (Szepietowski et al., 2020). Device designs should not cause discomfort, pain, or irritation for the user, which may discourage use (Al Naam et al., 2021).

Beyond comfort, aesthetics may influence selection and use of a respiratory protective device. There is a social dimension to how individuals feel about wearing such a device and how they are perceived by others, which in turn may affect decisions on use (Al Naam et al., 2021; Allison et al., 2010).

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Does Not Impair Vision or Communication

Because a respiratory protective device may be used for long periods of time, it should not impair the wearer's vision or communication, as such impairment may prompt the wearer to remove the device. In particular, fogging of glasses associated with use of a respirator, mask, or face covering (Al Naam et al., 2021; Chao et al., 2020b) has been reported as a barrier to use (Labiris et al., 2021). Additionally, several studies report issues with communication among members of the public using respiratory protective devices, including challenges with speaking and recognizing faces and facial expressions that could lead to misinterpretation of the wearer's intentions or otherwise impede interpersonal communication (Al Naam et al., 2021; Allison et al., 2010; Carragher and Hancock, 2020; Cheok et al., 2021; Freud et al., 2020; Saunders et al., 2021).

Includes Clear Labeling and Instructions for Use

Unclear, insufficient, or misleading labeling of and instructions for use of devices may contribute to improper selection and use by the public (CDC, 2021a; Plana et al., 2021). Current labeling, packaging, and instructions for respirators are produced with the assumption that their users will be covered by an RPP or will be voluntary users with an understanding of the risks involved in their work and proper respirator use. The online information provided to supplement the sales packaging of the devices also targets more sophisticated users, often assuming a level of knowledge that is not realistic except for trained workers within an RPP or those with experience in respiratory protection (NIOSH, 2003). With members of the public now using respirators outside of RPPs and occupational settings, labeling, packaging, and supplemental materials need to be reevaluated to ensure that they are accessible to all users. Changes can be made to improve labeling, packaging, inserts, and online educational materials to help users determine whether a device will address the hazard of concern, provide clarity on the device's limitations, and explain how to use the device properly to ensure the expected level of protection.

Ideally, respiratory protective devices could be used effectively absent instructional materials. As this is not the case, manufacturers of all respiratory protective devices would benefit from consulting with experts in health communications and health literacy in order to restructure information provided to users—such as clear indicators of the limitations of device use and instructions for donning and doffing—in a clear and accessible way. Consideration should also be given as to how educational materials can be provided to multiple users. Providing informational inserts with each device in a multipack or a QR code for digital resources may be helpful when

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multiple users are accessing respirators from a multipack. Also beneficial would be some means of indicating to users that devices meet expected levels of performance and of reducing the risk of purchasing counterfeit products. For example, a standard label system could be implemented (e.g., the NIOSH approval label) to ensure that labels are clearly visible to the user both on the packaging and on the device itself, and that basic information is provided on all external packaging (e.g., manufacturer name, model number, certification category, efficiency ratings, and QR code for digital resources).

Consistent minimum guidelines are needed across manufacturers regarding what information should be included on all labels, packaging, and instructions for respiratory protective devices. Such consistency in information across manufacturers would enhance users' ability to interpret and understand differences among devices and models and make appropriate selections.

Is Reusable, Stable, and Durable

Ideally, a respiratory protective device intended for use by the public should be easy to decontaminate at home and reuse, depending on the conditions of reuse and user preferences (CDC, 2020a). Reusable devices should have dimensional stability (i.e., retain their shape and size) after multiple uses so they continue to fit properly and remain effective over their intended lifespan.

Current FFR models offer the wearer no clear indication—such as a color change indicator or other such visual cue—as to when the device has reached the end of its functional lifespan. Given that FFRs are designed and manufactured to be disposable, users need to know when to stop using them because the filter medium or seal can no longer provide the intended level of protection. When a respirator is used as part of an RPP in an occupational setting, the RPP limits its use to performance of a specific task or a specific time period to ensure that the device is not used beyond its lifespan and continues to provide the intended level of protection. These limits are normally written into work policies and procedures. RPPs also ensure that wearers of FFRs are trained in assessing the device's quality and its capability to continue providing the intended level of protection (CDC, 2020b).

In the occupational setting, diminished breathability and/or filtration efficiency (e.g., as the device becomes laden with dust) and its contribution to total inward leakage and reduction of protection are key factors in determining when an FFR should be replaced. However, these factors may be less relevant for the public. When respirators are used by the public, they may be donned and doffed multiple times or worn for prolonged periods of time in low-concentration environments, similar to circumstances in the health

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care environment during the COVID-19 pandemic. In these circumstances, loss of elasticity in the FFR straps may be more salient than breathability or filtration efficiency as indicators of when the device has exceeded its lifespan. When the elasticity of the straps begins to fail, the fit of a device may not be as tight as during prior uses, and total inward leakage may increase, resulting in a reduced level of protection (Schumm et al., 2021). Thus, any FFR or other such respiratory protective device designed for use by the public outside of an RPP would benefit from inclusion of clear instructions on how to evaluate the device to ensure that it is still functioning as intended.

When emergency extended use and reuse of respirators become warranted in an occupational setting, an RPP's policies and procedures can be adjusted to provide education and training to ensure proper use of the devices. However, the respirator use patterns of the public differ from those of workers within an RPP. Extended use and reuse of respirators by the public need to be anticipated even when not recommended for occupational settings. Therefore, educational materials on FFR use by the public need to address safe and effective reuse and highlight the most likely failure points for the devices (e.g., the condition of straps/harnesses). An alternative or parallel approach would be for manufacturers to redesign FFRs specifically with extended use and reuse in mind—for example, by providing more durable or replaceable elastic straps or strengthening strap attachment points.

Respiratory protective devices and other forms of personal protective equipment (PPE) can become contaminated from the workplace environment where they are used. Respirators have been carefully evaluated over the years with this issue in mind, and procedures have been developed for removing the contamination (e.g., radioactive material) so they can be reused safely (RSA, 2001). In the health care environment, the significance of fomite[3] contamination has been recognized and addressed for many types of PPE by making the items disposable. During the COVID-19 pandemic, when supplies of respirators and other PPE were scarce and products were frequently reused, the significance of viral fomite contamination became a major issue. A National Academies report addressed the topic of reuse of N95 FFRs in health care settings during an influenza pandemic (IOM, 2006), recommending that research be conducted to understand likely contamination avenues and decontamination methods. While some research in this area has been conducted since that report was published (Chughtai et al., 2019; Fischer et al., 2020), the significance of fomite contamination in a nonclinical setting requires further evaluation so guidance on proper use and care of devices can be provided to the public.

[3] Fomites are surfaces or other objects that may become contaminated with a hazardous agent (e.g., infectious virus) and serve as a mechanism for transmitting the agent to a person or other susceptible organism.

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Innovation in Respiratory Protection Technology to Meet User Needs

Innovation in the design and manufacturing of respiratory protective devices has been accelerated notably in response to the shortages and user-experienced limitations of devices during the COVID-19 pandemic, offering promise for the emergence of more effective and user-accepted devices. For example, a new class of respiratory protective devices utilizing artificial intelligence (AI), three-dimensional (3D) image scanning, and 3D printing is emerging in the marketplace, and these devices may address challenges of ensuring adequate fit for a heterogeneous population (discussed later in this chapter) by enabling the creation of a bespoke device from an individual's facial measurements (Ishack and Liptner, 2021). Other innovations to address fit issues include attempts to minimize leakage at the face seal through the development of braces that fit over a fabric face covering (Fix the Mask, 2021); curved filter designs (Sheth, 2020); and flexible materials, such as those used in continuous positive airway pressure (CPAP) masks, that fit comfortably against the face (Envo Mask, 2021).

Still other innovations are intended to address user needs for respirators that enable better communication. Clear respirator models, for example (CleanSpace, 2021; Ford, 2021), allow people to communicate better with each other relative to conventional face coverings, masks, and respirators and enable those with hearing impairments to read lips. Additionally, concerns related to the exhalation valves on respiratory protective devices during the COVID-19 pandemic have led to the development and approval of elastomeric facepiece respirators without these valves (AIHA, 2020).

The federal government has a role in supporting private-sector investment in innovation. In 2021, NIOSH and the Biomedical Advanced Research and Development Authority (BARDA) launched the Mask Innovation Challenge: Building Tomorrow's Mask to accelerate the development of the next generation of respiratory protective devices.[4] Goals for the products developed through the challenge include

- improving the comfort, usability, and protection achieved when worn by the public in real-world circumstances when physical distancing is not possible,
- enabling users of the products to put them on and wear them appropriately with simple user instructions and in the absence of extensive fitting procedures, and
- designing devices capable of being mass produced with a low cost per use.

[4] For more information about the Mask Innovation Challenge, see https://www.challenge.gov/challenge/mask-innovation-challenge (accessed August 13, 2021).

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Summary and Synthesis

Many different types of devices have been available to and used by the public for a range of inhalation hazards. The landscape of devices used by the public with the intent of reducing exposure to inhalation hazards includes NIOSH-approved respirators; medical masks designed for workplace use, some of which are cleared by FDA; respirators marketed as approved in other countries (e.g., KN95); and products that are not intended to be used as respiratory protective devices in the workplace and thus are currently subject to no certifying body or formal oversight designed to ensure that the devices are effective for their intended use (e.g., face coverings). The efficacy of these products as used by the public is not established. With the COVID-19 pandemic acting as a catalyst for innovation, manufacturers have rapidly responded with devices for the public featuring new constructions and materials designed to enhance fit and wearability. However, the lack of a regulatory framework makes it difficult to understand the level of protection provided by any such product against a known or unknown inhalation hazard. It is unclear, moreover, whether the demand for innovation and the interest of manufacturers in pursuing the development of devices designed to meet the needs of the public will continue as the COVID-19 pandemic wanes.

Conclusion 4-1: Many elements need to be addressed to ensure that respiratory protective devices are effective in meeting the needs of the public.

AVAILABILITY AND ACCESS ISSUES FOR RESPIRATORY PROTECTIVE DEVICES FOR THE PUBLIC

The selection and use of appropriate respiratory protective devices by members of the public depend on the availability of the devices on the market and the ability to access them. Availability and access for the public are limited by multiple factors, however, including a complex, demand-based supply chain, reliance on foreign manufacturing, and inequitable distribution and affordability of devices in times of public health emergencies (Aburto et al., 2010). As discussed in Chapter 2, the COVID-19 pandemic has exposed the inadequacy of the current supply chain and the Strategic National Stockpile with regard to respiratory protective devices. Issues related to device availability and access for the public are laid out briefly in the sections that follow, building on the supply chain discussion in Chapter 2.

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Commercial Market During the COVID-19 Pandemic

Several useful lessons around availability of and access to respiratory protective devices for members of the public have been learned from the COVID-19 pandemic. During the early months of the pandemic, supply chain failures and the prioritization of available N95 FFRs for health care workers left the public largely on its own for respiratory protection. In March 2020, FDA issued an emergency use authorization (EUA) permitting the importation and use of non-NIOSH-approved respirators that met certain international standards. With N95 FFRs largely unavailable to the public, imported respirators, such as KN95s, which are certified in China (Andrews et al., 2021), flooded the consumer market, which was plagued by counterfeits and misrepresentations of filtration efficacy (see Box 4-2). The Centers for Disease Control and Prevention (CDC) responded to the influx of foreign respirators in April 2020 by publishing a list of respirators authorized under the EUA. No performance testing data were required from respirator manufacturers to corroborate performance claims before devices were included on this list (Sinha, 2021). In October 2020, FDA announced it would no longer review manufacturers' requests for their products to be added to the list of authorized respirators (FDA, 2020). According to the

BOX 4-2
Counterfeit Respirators on the Market

Counterfeit respirators are products that are falsely marketed and sold—for example, falsely claiming to be National Institute for Occupational Safety and Health (NIOSH) approved. Such counterfeits often look and are labeled like NIOSH-approved respirators, increasing the difficulty of proper respirator selection for consumers (CDC, 2021a).

The severe shortage of respirators during the COVID-19 pandemic led to a significant increase in the number of counterfeit respirators flooding the U.S. market. U.S. Customs agents seized nearly 13 million counterfeit respirators in the 12 months ending September 30, 2020 (Hayashi, 2021). Additionally, the public is largely unaware of the prevalence of counterfeit respirators on the consumer market. When NIOSH's National Personal Protective Technology Laboratory (NPPTL) becomes aware of counterfeit respirators or those misrepresenting NIOSH approval on the market, it posts warnings on its website to alert users, purchasers, and manufacturers (CDC, 2021a). The webpage also provides guidance for users on how to spot counterfeit respirators, as well as what to look for in a genuine NIOSH-approved respirator. Yet despite these efforts, counterfeit respirators remain widespread on the consumer market, and as of September 2021, a Centers for Disease Control and Prevention (CDC) guidance webpage stated that almost 60 percent of KN95s in the United States were counterfeit (CDC, 2021d).

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agency's announcement, KN95s were largely being unused by health care facilities, and the supply of NIOSH-approved N95 FFRs was catching up to demand at the time.

Throughout the COVID-19 pandemic, CDC has emphasized face coverings as source control for the public. As discussed previously, these face coverings were not intended to protect the wearer from infection but to slow the spread of disease in the population. CDC continued to recommended that N95 FFRs be reserved for health care workers even 1 year into the pandemic, when the supply of these respirators had begun to catch up to demand; mention of respirators was added to CDC's guidance for the public in September 2021 (CDC, 2021d). The agency's recommendations to the public on use of face coverings and disposable medical masks led to a consumer landscape overflowing with options (e.g., homemade cotton face coverings, commercial fashion face coverings, KN95s) offering unknown effectiveness for both source control and respiratory protection (Fonseca, 2020; Godoy, 2020). Recognizing this chaotic landscape for consumer products, in February 2021 ASTM[5] issued a voluntary standard laying out design and performance specifications for barrier face coverings (ASTM, 2021a). The standard was intended to provide a level playing field for demonstration of product claims and to reduce the general confusion related to device effectiveness. As discussed in Chapter 2, ASTM's standard specification establishes minimum requirements for design, performance (testing), labeling, user instructions, reporting and classification of performance properties, and conformity assessment[6] for barrier face coverings.

Equity of Access to Respiratory Protection

Because equity issues related to respiratory protection have not been adequately characterized, this section includes some lessons learned about these issues with respect to general emergency preparedness. The committee stresses that equity considerations need to be taken into account in communicating about respiratory protection, as discussed later in this chapter.

Socioeconomic indicators are linked to equity in disaster preparedness. Within a population, disaster preparedness is predicted by an individual's financial capacity, poverty status, and education level (Fothergill and Peek, 2004). Those with greater financial capacity to prepare for a disaster are more likely do to so (Boon, 2013), while those with fewer economic means

[5] ASTM International is a standards development organization that works through a consensus process involving relevant and interested stakeholder organizations (e.g., governmental, industry, nonprofit). The National Personal Protective Technology Laboratory (NPPTL) deputy director cochaired the ASTM committee that issued the barrier face covering standard.

[6] Conformity assessment is a process used to determine whether a device meets certain standards or requirements relating to its safety or quality.

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and resources tend to invest less in preventing and mitigating adverse effects of natural hazards and environmental hazards (Hallegatte et al., 2017).

While studies examining the link between socioeconomic status (SES) and disaster preparedness are generally focused on property improvements and disaster insurance, SES likely also plays a role in the public's ability to secure respiratory protection. The lack of standardization in sizing (discussed later in this chapter) means that consumers may need the means to purchase multiple different brands or styles of respiratory protective devices before finding one that fits adequately. Consumers wishing to access such devices must have the means to either travel to a point-of-sale location or place an online order, both of which may be limited by SES. Those wishing to make an in-person purchase for respiratory protective devices are limited by their transportation options. Individuals who do not live within walking distance to a point-of-sale location need accessible, efficient, affordable, and safe transportation alternatives (Malekafzali, 2009).

Online ordering is not necessarily an option for those with limited transportation options. Online ordering is less prevalent among households with lower income levels; those that are small in size or have a single member; those with less access to electronic devices; those with older members; those whose members have lower education levels, do not commute by automobile or work from home, or are non-White; and those in rural areas (Figliozzi and Unnikrishnan, 2021). According to the 2017 National Household Travel Survey, respondents in households above the poverty level were almost twice as likely to make online purchases compared with those in households below the poverty level (61 percent versus 33 percent). Broadband availability also affects online shopping habits and reflects some of the urban vs. rural online ordering trends. According to the 2016 American Community Survey's 1-year estimates, 83 percent of urban households had broadband subscriptions, compared with 76 percent of rural households (FHWA, 2018).

Social determinants of health[7] may also play into the likelihood of receiving assistance during a disaster, in the form of both direct assistance and information dissemination. For example, even a year into the COVID-19 pandemic, underresourced communities, such as American Indian and Alaska Native tribes and nations, including the Tohono O'odham and Navajo Nations, found it difficult to secure PPE and other infection control items despite improvements to the overall supply chain (Peery-Wolf et al., 2021). Some local and state governments made efforts to distribute PPE to low-income individuals, but efforts were piecemeal, and there was

[7] Social determinants of health include such factors as education, employment, health systems and services, housing, income and wealth, the physical environment, public safety, the social environment, and transportation (NASEM, 2017b).

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no overarching federal effort to ensure equity in PPE distribution or access. In a summer 2020 survey of 12 states conducted by the National Governors Association, only 3 states reported specific efforts to procure and distribute PPE and/or cloth face coverings for low-income individuals. These activities were performed through either a one-time purchase order, distribution via the Department of Human Services, or a Health Equity Task Force (NGA, 2020).

While federal disaster aid disbursed to counties through the Federal Emergency Management Agency (FEMA) has recently demonstrated an emphasis on equity, disaster response efforts on all levels run the risk of not reaching vulnerable and stigmatized populations, and there are still improvements to be made in addressing disaster recovery in areas with more socially vulnerable populations (Domingue and Emrich, 2019). In 2017, the Thomas fire in California illustrated how government disaster response can fail to reach all communities equitably. Although the fire affected people of all income levels, local immigrant rights and environmental justice groups had to step in to provide such essential services as access to emergency information in multiple languages (e.g., Spanish and Indigenous languages), labor protections for farmworkers threatened by exposure to smoke, and a relief fund for undocumented immigrants who were ineligible for aid from the federal government (Méndez et al., 2020). Domingue and Emrich (2019) argue that a wide range of social vulnerability[8] factors should be incorporated into decision-making processes around disaster funding allocations to prevent disparities (Domingue and Emrich, 2019).

Even if information about how to protect oneself from air pollution or infectious disease is disseminated equitably to all groups, preexisting health and social inequalities may be exacerbated if only the affluent can afford to adopt a public health recommendation for respiratory protection (McDonald et al., 2020). Being prepared for a disaster is not possible for those with financial barriers and limited social connections and support (Blake et al., 2017). And for those who can afford respiratory protective devices, the effectiveness of those devices will be undermined if they are chosen or used improperly (Seltenrich, 2017).

Summary and Synthesis

Although there were potential pathways for respirators to reach the population in the United States prior to the COVID-19 pandemic, these pathways proved insufficient to meet the needs of the public. Moreover, the existing supply of respirators was inequitably distributed across the many

[8] Vulnerability denotes individuals' likelihood of being exposed to a hazard because of who they are; where they work, study, play; or where they live.

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subgroups of the population. These findings suggest the need to reconsider how best to supply respiratory protective devices for the public and ensure that access is equitable.

Conclusion 4-2: At present, an adequate and equitable approach for ensuring a consistent and sufficient supply of respiratory protective devices for the population is lacking.

CHALLENGES AND LIMITATIONS WITH THE PUBLIC'S USE OF RESPIRATORY PROTECTIVE DEVICES

The previous section examined the gaps and challenges related to ensuring access to respiratory protective devices for the public. This section explores the challenges to the public's effective and safe use of respiratory protective devices. Considerations for education and communication strategies and other behavioral interventions are discussed in the section that follows.

Uncertainty of Effectiveness of Current Devices Against Varied Inhalation Hazards

As described in greater detail in Appendix B, the effectiveness of respiratory protective devices can vary considerably depending on the size distribution of the aerosol hazard in question (Leith et al., 2021). Various inhalation hazards, such as mold, influenza virus, and wildfire smoke, have different size characteristics; thus, for example, a respiratory protective device that is effective at controlling exposure to mold spores may be less effective for certain elements of wildfire smoke. While an RPP in an occupational setting is designed to respond to changing requirements for devices based on the identification and monitoring of established OSHA occupational exposure limits, public health agencies are challenged in establishing guidelines for the selection and use of respiratory protective devices because for many inhalation hazards facing the public, both exposure levels and safe levels are unknown. Determining the acceptability of risk is difficult. Moreover, variations in the efficacy of various devices in protecting against different inhalation hazards pose a challenge with respect to communicating uncertainties around the expected benefits of use by the public (i.e., the relative reduction in the risk from exposure).

Several additional factors beyond the efficacy of respiratory protective devices contribute to this uncertainty in expected benefits. First, data on dose-response relationships for some agents are inadequately characterized

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(e.g., emerging hazards) or have not yet been precisely described (e.g., pandemic influenza and mold). Moreover, such immunogenic hazards as mold can present unique challenges because acute exposures may prime the immune system for more chronic effects (i.e., sensitization) later on. While exposure responses are better known for wildfire smoke and urban air pollution (Cascio, 2018; Holm et al., 2021; Liu et al., 2015a; Reid et al., 2016; Richardson et al., 2012), and there is emerging evidence on the effectiveness of respiratory protective devices in protecting the public from these hazards (Holm et al., 2021; Kodros et al., 2021; Laumbach, 2019; Rajagopalan et al., 2020; Shi et al., 2017), the actual reduction in risk from the use of different devices across different levels of exposure remains unclear. Additionally, evidence of efficacy for respiratory protective devices from randomized controlled trials (RCTs) is generally lacking, as such trials have been underpowered (Bundgaard et al., 2020) and are challenging to implement when studying exogenous risk factors and nonclinical interventions. Finally, multiple and diverse potential exposure settings (e.g., home, school, transit, recreational facilities) complicate exposure assessment.

Population Heterogeneity

Greater heterogeneity in the general population than in worker populations (e.g., age, health status) creates unique challenges for the public's use of respiratory protective devices. The subsections below address some of the most critical population groups.

Infants and Children

Children are both uniquely vulnerable and uniquely susceptible to environmental hazards, including inhalation hazards (AAP Council, 2019; Holm et al., 2021). They breathe more air per kilogram of body mass relative to adults, and therefore receive a more concentrated dose following toxicant exposure. Additionally, children are more active than adults and spend more time at higher breathing rates in relation to body weight (Holm et al., 2021). Additionally, insults during periods of growth and development may have outsized effects by disrupting development.

As discussed above, because respirators are designed for use in conjunction with an RPP in an occupational setting, manufacturers do not account for the fit requirements of populations typically absent from the workforce, such as children (Goh et al., 2019). Children have a greater variety of face sizes relative to adults, with particularly rapid growth before age 10 (Smith et al., 2020). Indeed, regardless of the type of device (respirator, surgical mask, or fabric face covering), children are less protected from inhalation hazards than are adults. One study showed that both respirators and

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surgical masks reduced children's exposures, although the reduction was less than that in adults (van der Sande et al., 2008).

Children also have physiologic differences from adults that may make respirator use more challenging and necessitate innovations in device design. Compared with adults, lower inspiratory and expiratory pressures generated for breathing may make children (especially at younger ages) more sensitive to the increased breathing resistance (Verma et al., 2019) exerted by filtration material. Additionally, younger children may be unable to describe difficulties with respirator use because their conceptual understanding of causation is not fully developed (Koslowski and Masnick, 2010).

The Elderly

Relative to younger adults, elderly individuals tend to be more vulnerable to respiratory infections, such as influenza and COVID-19, as well as to air pollution from fossil fuel combustion and wildfire smoke (Cascio, 2018; Di et al., 2017; Wu et al., 2020). Thus they are a priority for respiratory protection and proper training in its use. However, the fit of respirators tends to be worse, on average, among older versus younger adults (Lee et al., 2004).

People with Chronic Health Conditions

People with chronic health conditions are more susceptible to airborne pollutants and viral infections relative to those without such conditions and so may appropriately be targeted for respiratory protection. For example, individuals with asthma (children and adults) are more susceptible than the general population to wildfire smoke (EPA et al., 2019; Holm et al., 2021). People who are immunocompromised (e.g., transplant recipients, cancer patients, and those with immune diseases treated with immunosuppressive medications) are especially susceptible to respiratory infections. These groups are likely to benefit greatly from respiratory protection, yet some chronic health conditions (e.g., advanced heart failure, lung disease) may also increase risks of adverse consequences from prolonged use of respiratory protective devices.

People with Physical or Mental Disabilities

Respirators are not designed with attention to the needs of users with physical or mental disabilities. For example, instructions and educational materials on the use of these devices are geared only to the end user, whereas for those with disabilities, such materials may need to be oriented

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to caregivers or partners to guide them in assisting with correct placement on the user (Kobayashi et al., 2020). Additional research would likely be needed to ensure that current or future FFRs could be used safely and effectively by these populations. More research is needed in general to understand what population accommodations are required and the extent to which those requirements can be met by currently available devices or necessitate the development of new products.

Ensuring Fit in the Absence of Fit Testing for the Public

The fit of a respirator to an individual's face is determined by many factors, including the respirator design and size and the user's facial dimensions. Assessing whether a user will receive the expected level of protection from a respirator therefore necessitates fit testing, a required component of workplace RPPs.

Although there is currently no universal or standard sizing for respirators, most are sold in three sizes (small, medium, and large), with some manufacturers making extra small and extra large models. Manufacturers design respirators to fit facial dimensions from a fit panel,[9] which is composed of a group of people intended to be physically representative of the facial characteristics of likely occupational users. However, fit panels are based on a standard set of dimensions that do not necessarily reflect the heterogeneity in facial features among members of the public. For example, such features as facial length and width are known to vary with age, sex, race, and ethnicity (McMahon et al., 2008; Wilkinson et al., 2010; Zhuang et al., 2016). The fit of respirators, particularly FFRs, has been shown to be disproportionately poor for female users and users of a variety of ethnic and racial backgrounds (Regli et al., 2021); workplace studies have demonstrated that women tend to pass respirator fit tests less frequently relative to men (Lee et al., 2004; McMahon et al., 2008), and Asians less frequently than other races (Wilkinson et al., 2010). Most of these variations have been explored in samples of working adults, and these findings may be generalizable to similar demographic groups among the public. Studies in children are more limited, however. Poor fit of devices on the faces of children and the resulting leakage around the edges of the device likely contribute to reduced protection. Smaller respirator models have been used for immunosuppressed children when they are in environments

[9] Fit panels are used by researchers, manufacturers, and regulators to guide research, product development, and the testing and certification of devices (Chen et al., 2009). An example of a fit panel currently in use is the NIOSH Bivariate Panel, which is two-dimensional, including face width and length. It was incorporated into the ASTM F3407 Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators (ASTM, 2021b).

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where they would benefit from respiratory protection (St. Jude Children's Research Hospital, 2021), but there are no respirators marketed specifically for children in the United States.

Beyond challenges related to variation in facial features, other physical characteristics of users can impede fit. Facial hair is a barrier to obtaining and maintaining a facial seal on tight-fitting half- or full-face negative pressure respirators (ANSI, 2015). Facial hair remains one of the most contentious topics in managing an industrial respirator program and is an even more challenging issue for the public in the absence of an RPP. Additionally, many tight-fitting respirator designs fail to accommodate certain hairstyles, and large quantities of hair can interfere with firmly seating the respirator straps on the head and affect the respirator seal, as well as the ability to wear the respirator at all (3M, 2020).

The ability of a user to don the device correctly is also critical for ensuring fit. Research quantifying the fit achieved by members of the public when respirators are used without fit testing is limited. In one study of naïve users, only 24 percent were able to don an N95 FFR correctly when asked by a researcher to do so (Cummings et al., 2007). Common errors included leaving the nose clip untightened, putting the straps in the wrong place, and wearing the device upside down (Cummings et al., 2007). Another study found that while the majority of untrained participants were able to don an N95 FFR properly and achieve a fit factor of 2, fewer than 25 percent were able to achieve a fit factor of 100, which is expected for use of the device in workplace settings (Brosseau, 2010).

These issues illustrate how, in the context of public use, there is no established system for ensuring that respiratory protective devices can provide all (or most) people with a sufficient level of protection. Because respirators are not designed to fit all user facial structures universally, devices with poor fitting characteristics prove to be a challenge for achieving the intended level of protection even when fit tested (Campbell et al., 2001). Innovation in product design—specifically in terms of improving the fitting characteristics of devices (see Chapter 2, Box 2-6)—therefore is essential to meet the requirements of all users and provide them access to devices that are both acceptable and effective for their intended purpose. In addition to such innovation, it is important to provide information to the public regarding the fitting characteristics of devices on the market. Thus, the need to ensure proper fit of respiratory protective devices for the public represents both a technology and a communication challenge.

Qualitative or quantitative fit testing is both time- and resource-intensive. Thus, scaling up the current occupational paradigm for this process to a nationwide level may be impractical, especially when time is of the essence, as is the case during public health emergencies and disaster events. Moreover, the number of professionals (i.e., industrial hygienists, trained technicians)

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needed to perform fit testing on a population level is insufficient. The development of both qualitative and quantitative fit tests that are scalable to members of the public or of devices for which such tests are not required is therefore an important need, as is understanding of the level of protection a device is capable of providing in the absence of fit testing.

Health Risks from Use of Respiratory Protective Devices and Medical Clearance for the Public

Limited research on the health risks associated with respiratory protective devices has been focused specifically on use by the public, whose health profile differs from that of workers. Much of the research that has been conducted in this area, some of which is described below, is related specifically to the use of respirators. Moreover, the majority of studies have involved healthy adults, and have not included such high-risk groups as children, the elderly, or those with chronic heart or lung disease.

Devices that cover the nose and mouth will create a small volume of "dead space" (a portion of each breath that occupies space within the device and does not participate in gas exchange). It is unclear whether the small increase in dead space volume and breathing resistance for certified respiratory protective devices is ever of significant physiological consequence and under what context of use (Bansal et al., 2009; Harber et al., 2009; Johnson, 2016; Jones, 1991; Morishita et al., 2019; Roberge et al., 2010, 2013; Shein et al., 2021). Of note, data on whether use of N95 FFRs can affect physiologic parameters in healthy pregnant women are mixed (Roeckner et al., 2020), although there is agreement that there is no effect on fetal heart rate (Roberge et al., 2014).

Respiratory impairments that might lead to poor tolerance of airflow resistance or the slight increase in dead space include obstructive lung diseases (e.g., chronic obstructive pulmonary disease [COPD] or emphysema, severe asthma, cystic fibrosis), respiratory muscle weakness, chest wall deformities (e.g., kyphoscoliosis), and restrictive interstitial lung diseases (e.g., pulmonary fibrosis, sarcoidosis, occupational lung diseases). Cardiovascular disease that might affect a person's ability to tolerate prolonged periods of increased work of breathing or slight increases in carbon dioxide levels due to decreased alveolar ventilation include congestive heart failure, ischemic heart disease, and some arrhythmias. Very few studies have evaluated physiologic effects of respirator use in these high-risk groups. With regard to cardiovascular impairments, there is some evidence of decreased cardiac output during use of positive pressure respirators (Arborelius et al., 1983; Bjurstedt et al., 1979), although the impact of common N95 FFRs has not been evaluated in the setting of cardiac disease. N95 FFRs may not be well adapted to COPD patients, and caution may be warranted in this

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population, in whom use of these devices may increase the risk of dyspnea and breathing discomfort (Kyung et al., 2020). Overall, the potential risks for members of the public with serious chronic health conditions—a group that likely would benefit the most from respiratory protection against inhalation hazards—remain unknown. Research is needed to

- determine what level of airflow resistance can be tolerated safely for prolonged use without adverse physiologic consequences among those with respiratory or cardiovascular impairment;
- evaluate the potential health benefits of using respirators to reduce noxious or infectious exposures in these high-risk groups compared with the potential health risks of prolonged respirator use; and
- assess how underlying health conditions may impact physiologic responses to use of respiratory protective devices in particular to identify and define safety thresholds for prolonged respiratory use in patients with heart and lung disease based, for example, on minimum inspiratory pressure (measure of inspiratory muscle strength), evidence of chronic hypoventilation, or reduced cardiac function.

Complicating understanding of the safety of respirators, unjustified fears have propagated in the public around a variety of respirator-related health concerns during the COVID-19 pandemic.

Despite the research gaps described above, the limited data generated to date suggest that respirator use is generally well tolerated. Abnormal pulmonary function may not be a serious concern with regard to complications of respirator use by the public. An increase in breathing resistance has been shown to have only a minimal impact on alveolar ventilation (Love et al., 1977; Raven et al., 1981, 1982). The few studies in children also suggest that their use of respirators is generally well tolerated, with minimal change in objectively measured outcomes (Goh et al., 2019; Holm et al., 2021; Lubrano et al., 2021).

To address concerns regarding potential health risks, medical clearance for respirator use is required for participation in a workplace RPP; however, a requirement for medical clearance to use a respiratory protective device is unlikely to be feasible for the public for several reasons. As described later in this chapter, the vast majority of medical providers (even pulmonologists) in the United States have not been trained in the principles of respiratory protection. Yet, physicians and other licensed health care professionals are expected to manage initial medical screening and examination for respirator use, clear people for use of the device, and provide related medical advice (Harber et al., 1996). Ultimately, the question remains as to the locus of responsibility for ensuring that a member of the public can use a respirator safely.

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Additionally, guidelines for medical clearance for respirator use in the workplace are outdated and have not yet been developed for use of these devices in other contexts. In occupational settings, there are generally no firm cardiovascular or pulmonary contraindications to respirator use. Despite a long list of "temporarily disqualifying conditions" for occupational clearance for respirator use, the American National Standards Institute (ANSI) concludes that most workers can be cleared if they can perform well on an exercise stress test (ANSI and AIHA, 2006). The health risks of use of respirators are likely to be negligible if a worker is already healthy enough to do the work that requires a respirator. However, many members of the public (e.g., the elderly, adults with chronic health conditions) would not pass this test of fitness, nor could it feasibly be extended to the general population.

The cost of implementing a nationwide program for "doctor's approval" for use of respiratory protective devices would likely be enormous under the current system. Once the health risks of respirator use, if any, had been defined, a modified model of the occupational approach (questionnaire or survey) could be developed and made available for the public to complete.

Summary and Synthesis

The methods formalized in the occupational respiratory protection model—typically an OSHA-mandated RPP—are not easily scalable to suit the needs and context of public use of respiratory protection. Relative to inhalation hazards in the workplace setting covered by an RPP, inhalation hazards experienced by the public are not entirely known or quantifiable prior to exposure, and fit testing as currently performed is not feasible for all members of the public because of the considerable logistical challenges and prohibitive costs involved in bringing these practices to scale. Additionally, medical clearance guidelines are outdated and lack applicability to the public, which includes users of all ages and health backgrounds not easily comparable to the traditional occupational user, who is likely to be in good enough health to use a respirator. Additional research is needed to understand what contraindications to respirator use might exist for public users and the costs and benefits of respirators for groups at risk of adverse effects from both use of respiratory protection and inhalation hazards. Given the challenges of applying such an occupational model in the context of public use, a new and distinctly different framework is needed to support decision making and practice around the public's use of respiratory protection in the absence of a formal RPP.

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Conclusion 4-3: The effective use of respiratory protection by the public is limited by multiple gaps along the sequence of product availability, selection, use, and conformity assessment. Logistical challenges and sociobehavioral considerations pose impediments to ensuring that products provide adequate fit and function for a heterogeneous population.

Conclusion 4-4: The occupational model of a respiratory protection program under OSHA, including the fundamental program components of hazard assessment to guide respirator selection, medical clearance, regular fit testing, and user training, is neither suitable nor feasible for the public.

BEHAVIORAL AND EDUCATIONAL CONSIDERATIONS FOR ENSURING EFFECTIVE USE OF RESPIRATORY PROTECTIVE DEVICES BY THE PUBLIC

Because respiratory protective devices, if used incorrectly, may not be effective, and in rare cases may even be harmful to the user, educating the public in their proper use is crucial. (See Box 4-3, which describes lessons learned from a respiratory protection distribution program in Israel regarding the importance of adequate education.) Box 4-4 lists essential questions that need to be addressed in communications aimed at meeting this need.

When respirators are used in occupational settings, OSHA requires training of employees in their proper use, including putting them on and taking them off, the limitations of their use, and how they should be cared for, in addition to requirements for fit testing and evaluation of the effectiveness of the RPP (OSHA, 2011). However, similar requirements for education are not in place for members of the public, contributing to their confusion about which respiratory protective devices they should use to protect against which hazards (Benjamin, 2021; Santana et al., 2020) (see Box 4-1). While guidance and other resources from federal, state, and local entities provide the public with information about the selection and use of various devices (as described later in this chapter), messages from these sources of guidance have not been systematically collected and evaluated (Conway, 2021). As a result, limited evidence is available on the effectiveness of existing educational materials and other interventions designed to promote effective use of respiratory protective devices by the public or by specific subpopulations in the context of specific hazards (see Box 4-4, question 9).

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BOX 4-3
Lessons Learned from a Respiratory Protection Distribution Program in Israel

The looming threat of Iraqi chemical missile attacks against civilians during the Gulf War (AP, 1990; Shlaim, 1994) forced the Israeli military to undertake an experimental distribution of respiratory protective devices to the nation's population of 4 million, an effort that was later increased after Iraq's invasion of Kuwait in August 1990 (Hiss and Arensburg, 1992). Lack of knowledge among the public regarding respirator use led to some deaths; between 4 and 13 people suffocated as a result of mishandling of the devices (Hiss and Arensburg, 1992). In fact, more casualties were due to the misuse of these devices than to the missile strikes themselves. The resultant deaths and cardiovascular respiratory issues could have been avoided with better planning, detailed hands-on training, and the development of special guidelines for older individuals (Barach et al., 1998). "Respirators intended for the public were subsequently redesigned to prevent accidental death and improve the efficacy and comfort of the equipment. Equipment developed in Israel included: hood-style mask and blower systems for civilian emergency responders; one size fits all hood and blower systems for adults and for children ages 3–7; and portable infant protection cribs" (IOM, 1999, p. 39).

The Israeli government made substantial efforts to strengthen its civil defense system in the aftermath of the Gulf War. The entire Israeli citizen population became entitled to personal protective kits, which included gas masks (Prince-Gibson, 2003). "Tent-like devices" were available for individuals with disabilities who could not maneuver normal masks, while people with assisted breathing devices were provided a tool that allowed them to connect their gas mask filter to their home ventilator (Prince-Gibson, 2003). The Israeli military collaborated with the education ministry to establish emergency drills in schools and teach students how to don their respiratory protective devices properly. As a result of these measures, the government estimated that around 90 percent of the Israeli population was equipped with gas masks (Prince-Gibson, 2003). In 2014, the Israeli government announced that it would halt the distribution of gas masks as the result of the military's assessment of a reduced threat of chemical attacks on the country, as well as a lack of sufficient funds to sustain this mass distribution initiative; a year prior to this announcement, the Prime Minister had proposed a $350 million initiative to equip every citizen with gas masks but could not follow through because of budget shortfalls (Fiske, 2013). At this point, around 60 percent of the population had access to the most up-to-date personal protection kits (Sobelman, 2014).

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BOX 4-4
Essential Questions for Effective Education and Communication

1. How should interventions and messages be designed to promote consistent and effective use of respiratory protective devices by the public for specific audiences and specific hazards?
2. Who should be responsible for designing and evaluating effective interventions and messages for the public?
3. Which respiratory protective devices are most effective for protection against which hazards, and how is that information best communicated?
4. How can common mistakes in use of respiratory protective devices be prevented?
5. How do misinformation and other barriers to consistent and accurate use of respiratory protective devices vary among specific audiences, and how can those barriers best be addressed in educational efforts?
6. When and how can respiratory protective devices be reused and for how long?
7. What other actions can people take to protect themselves, in addition to use of respiratory protective devices?
8. What are the trusted sources of accurate information for different user populations, and how can communicators work with these sources?
9. How effective are existing interventions and messages for promoting consistent and effective use of respiratory protective devices by the public for specific audiences and specific hazards?
10. Does promoting use of respiratory protective devices by the public improve protection against specific hazards?
11. What are the issues that most undermine effective use of respiratory protective devices by the public for specific threats and over time?
12. How can modified fit tests or other improvements to the fitting of respiratory protective devices for the general public be implemented?
13. How can public resistance and common barriers to consistent and effective use of respiratory protective devices, including lack of comfort, be overcome?

The sections below review evidence from RCTs focused on the effectiveness of providing respiratory protective devices to members of the public to promote protection against specific hazards, the role of "mask mandates" in promoting public use of such devices, and audience needs critical to improving compliance to achieve more effective use.

Evaluations of Interventions to Improve Use of Respiratory Protective Devices by the Public

A recent review reports on the few RCTs that have been conducted in community settings to examine the benefits of providing people with medical/surgical masks or N95 FFRs and educational materials in the form of

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written instructions to protect against the spread of coronaviruses and other respiratory viruses (MacIntyre and Chughtai, 2020). However, studies have typically not described these written instructions in detail, and while some evidence is promising, any potential contribution of such educational materials to proper use of the devices and protection against specific hazards remains unclear because of study limitations and confounding factors (see Box 4-4, question 1).

The most promising findings come from an RCT involving Australian adults who received surgical masks with information about infection control, respirators (with information about infection control but no fit testing), or no devices while living with a child with respiratory illness (MacIntyre et al., 2009). While these three groups showed no statistically significant differences in the incidence of influenza-like infections, those who adhered to the daily use of surgical masks and nonfitted respirators (adherence among intervention groups was poor) had a significantly reduced risk of influenza-like illness (MacIntyre et al., 2009).

Another intervention involved providing education, surgical masks, and hand sanitizer gel to crowded mostly Latinx households, together with instructions stating that the surgical masks should be worn by caretakers and sick persons (Larson et al., 2010). Individuals in the intervention group receiving surgical masks and hand sanitizer had reduced incidence of secondary influenza-like illness compared with the control group, who recieved only targeted education (Larson et al., 2010). However, compliance with mask use was poor, and the observed effects may have been driven by improved hand hygiene instead of mask use (Larson et al., 2010). Similar findings resulted from an RCT among students living in an American university's residence halls during the H1N1 influenza pandemic (Aiello et al., 2010). The trial evaluated three study groups: participants who received a medical mask[10] with written instructions for hand sanitizer and medical mask use, those who received only a medical mask with written instructions on use, and a control group. Influenza-like illness was less likely among students who received a medical mask and information about hand sanitizer and medical mask use compared with those receiving no intervention, but only in the later weeks of the intervention. The researchers found no beneficial effect of receiving a medical mask alone compared with the no-intervention group (Aiello et al., 2010). However, it is unclear what role existing handwashing habits, which were the same between the medical mask only and control groups, had on reduction of illness, and further research is needed to understand the effectiveness of different combinations of interventions (Aiello et al., 2010).

[10] Medical masks are also commonly refered to as surgical masks. The descriptions of studies in this section use the same term as that used in the published article.

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Other RCTs have yielded no significant findings, perhaps as a result of small sample sizes and/or limited compliance. One of these trials was conducted during the COVID-19 pandemic with a large sample of 4,862 adults in Denmark in April–May 2020. The use of respiratory protective devices had not yet been recommended in that country (Bundgaard et al., 2021). Providing (versus not providing) participants with surgical masks and written instructions for use did not result in a statistically significant reduction in SARS-CoV-2 infection rates 1 month later, but adherence to surgical mask use in the intervention group was variable (Bundgaard et al., 2021).

The RCT findings described in this section indicate primarily the need for larger studies to balance the potential impact of confounders, which limit the conclusions that can be drawn from existing evaluations of interventions involving respiratory protective devices. The lack of compliance with instructions among study participants also demonstrates the importance of understanding the sociobehavioral factors that influence the proper use of such devices.

Improving Effective Use of Respiratory Protective Devices During Public Health Emergencies

During the COVID-19 pandemic, public compliance with recommendations related to use of respiratory protective devices increased over time, possibly as a result of public health messaging and mask mandates. For example, a national longitudinal U.S. survey found that self-reported use of face coverings or masks[11] increased from more than 39 percent in April 2020 to nearly 89 percent in November 2020, a finding that may reflect improved public health messaging over the course of the pandemic (Crane et al., 2021). A limitation of such survey data, however, is that use of these devices is self-reported and may not reflect actual, consistent, or accurate use.

Epidemiological studies have found that state-issued mask mandates in the United States have been associated with a decrease in COVID-19 case and death growth rates (Guy et al., 2021; Lyu and Wehby, 2020). Such data are supported by evidence of increased uptake of device use behaviors following the issuance of mandates. Observations of shoppers in Wisconsin, for example, indicated an increase in correct use of masks and face coverings from 41 percent in June 2020 to more than 90 percent in August 2020, when a state mandate was put in place (Haischer et al., 2020). Similarly, a survey in Germany showed that a mandatory policy improved compliance with mask use, despite moderate acceptance of mask wearing as an effective intervention, while also reducing perceptions of mask wearers as being sick or vulnerable and increasing perceptions of fairness among individuals

[11] Terminology used in the publication.

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in at-risk groups (Betsch et al., 2020). While these data suggest that public health messaging and mask mandates may promote use of respiratory protective devices, it remains unclear which messages have been most effective or for which audiences (see Box 4-4, question 1).

As emphasized previously, the effectiveness of these devices is dependent not just on use but on correct use. Yet research suggests that improper use of such devices among the public is common, even when there is public support for their use. A Japanese survey showed that 83.5 percent of participants knew how to ensure that a medical or nonmedical mask covered the mouth and nose completely (Machida et al., 2020), but only 23.1 percent of respondents self-reported following all of the World Health Organization (WHO) recommendations for correct use. An observational study examining public compliance with a mask mandate in Honolulu and Waikiki conducted in July 2020 found that 77 percent of those observed wore the devices correctly, with the remainder using them incorrectly or not at all (Tamamoto et al., 2020). In another observational study conducted in Hong Kong during the COVID-19 pandemic, 13 percent of pedestrians (of 10,211 observed) were wearing their devices incorrectly—either below the nose (42 percent) or inside out or upside down (35.5 percent) (Tam et al., 2021).

Similar experiences with improper use of respirators by the untrained public were reported following Hurricane Katrina. Cummings and colleagues (2007) randomly selected homes in New Orleans, where public health messaging promoted use of respirators to protect against mold exposure during posthurricane clean up. A survey found that 68 percent of those interviewed were aware of the public health recommendation to use an N95 FFR during mold remediation activities and that at least 30 percent of those participating in remediation activities had used a NIOSH-approved respirator. However, only 24 percent of participants were able to don an N95 FFR correctly (Cummings et al., 2007). Thus, it is important to better understand how to help people avoid common mistakes in device use (see Box 4-4, question 4) and in the case of respirators, whether modified fit tests can be introduced to the public (see Box 4-4, question 12).

Understanding and Addressing Barriers to Effective Use of Respiratory Protective Devices

An important focus for identification of educational needs related to respiratory protection for the public, then, is that such public education be informed by the evidence-based recommendations of medical and public health experts as to which devices are most effective for protection against which hazards, as well as social science evidence regarding gaps and misconceptions in people's knowledge and other potential barriers to

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behavior change (Benjamin, 2021; Bruine de Bruin and Bostrom, 2013; Douglas, 2021; Morgan et al., 2001; NASEM, 2017a). Designing effective public health communication requires understanding why people struggle to implement expert-recommended behaviors. Intervention efforts need to focus on addressing these barriers, in particular those that most undermine effective use of respiratory protective devices for specific threats (see Box 4-4, question 11), and designing communications accordingly.

Barriers to using respiratory protective devices effectively, or using them at all, commonly stem from specific perceptions that need to be addressed in public education efforts (see Box 4-4, question 5). These include both risk perception (Covey et al., 2019; Ferng et al., 2011; He et al., 2021; Nakayachi et al., 2020; Rieger, 2020) and perceptions regarding the effectiveness of respiratory protection (He et al., 2021). Research has found, for example, that misconceptions spread through social media and other informal communication channels can undermine compliance with recommendations to wear a mask or face covering (Hornik et al., 2021; Roozenbeek et al., 2020). The importance of risk communication to address barriers related to (mis)perception of risk is further underscored by experiences from Taiwan with public use of respiratory protection in the context of highly pathogenic avian influenza, as described in Box 4-5.

Effective risk communication and community engagement efforts also need to address the myriad literacy challenges of the U.S. population to ensure that members of the public understand the risks posed by different inhalation hazards. Otherwise, it is unlikely that respiratory protective devices, even those well suited to the user and the hazard, will be used. In the United States, for example, public health messaging encouraging the use of N95 FFRs to protect against wildfire smoke was largely missed or ignored by the public during the 2007 California wildfires, and researchers found that the technical language used in the health messaging may have posed a barrier to compliance (Sugerman et al., 2012).

Findings of adult literacy studies show that the overall literacy rate in the United States is suboptimal, with approximately 43 million U.S. adults possessing low literacy skills such that they cannot compare and contrast information, paraphrase, or draw low-level inferences (ED, 2019). Also important in the present context is science literacy—the knowledge and understanding of scientific concepts and processes required for personal decision making, participation in civic and cultural affairs, and economic productivity (NRC, 1996). A person with scientific literacy can ask about and find or determine answers to questions raised by curiosity about everyday experiences; can describe, explain, and predict natural phenomena; and can read and understand scientific articles in the press and engage in conversation about the validity of their conclusions (NRC, 1996). Science literacy is generally associated with one's level of formal schooling

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BOX 4-5
Importance of Risk Communication in Addressing the Public Use of Respiratory Protection: Lessons from Taiwan

Taiwan has experienced multiple outbreaks of low pathogenic avian influenza (LPAI H5N2) and highly pathogenic avian influenza (HPAI H5N2) in live poultry markets since 2003 and 2012, respectively. In 2005, the government adopted a national education policy of "10 Nos, 5 Needs" to prevent occupational and public spread of avian influenza viruses (AIVs) by encouraging safety practices that reduce the chances of animal-to-human transmission (Liu et al., 2015b). Liu and colleagues (2015b) surveyed workers in live poultry markets and community residents—once in the aftermath of an LPAI H5N2 virus outbreak from 2007 to 2009, and again after the outbreak of HPAI H5N2 in 2012—to investigate the factors that influenced risk awareness (including awareness of the "10 Nos, 5 Needs" policy), attitudes, and willingness to use personal protective measures. In addition, they compared how these factors and people's responses differed between these two outbreaks, given the increase in viral pathogenicity that occurred. The results of this study showed that people with lower education, live poultry market workers experiencing high levels of exposure to AIVs, and residents living in areas with a low frequency of outbreaks had lower risk awareness with respect to AIVs (Liu et al., 2015b). Most notably, the level of risk awareness and willingness to engage in self-protective measures had risen considerably between the LPAI H5N2 and HPAI H5N2 outbreaks (Liu et al., 2015b). This particular result, along with the attitudes expressed by the live poultry market workers despite their high level of exposure to AIVs, shows the importance of proper risk communication, both before and in the midst of outbreaks, to encourage public acceptance of government control measures and prompt the use of personal protective equipment when needed.

and income (NSB, 2016). However, it also intersects with beliefs, values, and public controversies. For example, Drummond and Fischhoff (2017) found that individuals with more scientific knowledge, compared with the average American, are more likely to express beliefs that are consistent with their religious or political identities on issues that are polarized along those lines (e.g., stem cell research, human evolution), but not on issues that are controversial for other reasons (e.g., genetically modified foods). Environmental health literacy has emerged as a distinct form of health literacy focused on preventing environmentally induced diseases, highlighting the importance of community context to the health of various population groups (Finn and O'Fallon, 2017). Attention to environmental health literacy is especially important for underresourced and vulnerable populations whose communities may be more likely to face inhalation threats due to the environmental conditions in which they live (Simonds et al., 2019).

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Other reported barriers to effective use of respiratory protective devices to protect against such inhalation hazards as COVID-19, wildfire smoke, and air pollution include, but are not limited to, incorrectly storing, donning, and wearing the device (Lee et al., 2020b); confusion over the proper frequency of changing devices and methods for reuse and decontamination (Chao, 2020b; Matusiak et al., 2020; Scalvenzi et al., 2021; Yu et al., 2021); and usability issues, such as interference with communication, discomfort, and issues with fit (Chao, 2020b; Cheok et al., 2021; Ferng et al., 2011; Labiris et al., 2021; Shelus et al., 2020).

Barriers to effective respiratory protection for these inhalation hazards are also related to the social dimensions of device use and include user perceptions of social acceptability (Barceló and Sheen, 2020; Ferng et al., 2011; Nakayachi et al., 2020; Santana et al., 2020), feelings of embarrassment (Ferng et al., 2011; Seale et al., 2012), and concerns regarding physical appearance (Al Naam et al., 2021; Allison et al., 2010; Rieger, 2020). Santana and colleagues (2020) found that during the 2018 Camp fire, social norms were a salient driver of use of respiratory protection to protect against wildfire smoke. According to the authors, this finding is consistent with results of previous public health research suggesting that during novel events, when information is limited or uncertain, social norms influence decision making (along with the perceived health threat, emotional response, perceived benefits of using protection, and sense of self-efficacy). Logistical and situational barriers, such as lack of access to devices and conflicting guidance, may also interact with intended behavior, affecting actual use behavior (Santana et al., 2020), a finding that highlights the critical need to align policy, guidance, messaging, public awareness, and production and supply to support a rapid response to novel respiratory threats (see Box 4-6 for lessons learned from South Korea).

Understanding the Needs of Specific Subpopulations and Communities

It has long been recognized that effective education addresses the needs of the specific audience for the specific risk at hand. The studies discussed above suggest that barriers to consistent and correct use of respiratory protective devices may vary with particular audiences (Anderson and Stockman, 2021; Barceló and Sheen, 2020; Casola et al., 2021; Chan et al., 2015; Teasdale et al., 2014), and these barriers specific to subpopulations need to be better understood to inform targeted education and communication efforts (see Box 4-4, questions 5 and 8). Educational materials need to be clear to audiences that speak different languages, but also to address other challenges that may vary with sociodemographic characteristics (Clayman et al., 2010).

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BOX 4-6
The Importance of a Cohesive Strategy to Address Sociobehavioral and Logistical Barriers to Use of Respiratory Protection: Lessons from South Korea

In 2015, South Korea experienced an outbreak of Middle East respiratory syndrome coronavirus (MERS-CoV), with 186 confirmed cases and 38 deaths (Lim et al., 2020; Oh et al., 2018). The South Korean government was forced to quarantine around 16,993 individuals during this epidemic, which lasted approximately 2 months (Lim et al., 2020). After its experience with MERS, the Korean government made notable policy changes to improve its preparedness for future epidemics, ultimately enabling the government to respond to COVID-19 in a quick and aggressive manner while also inspiring a "willingness among people to wear masks, cooperate with contact tracers, and otherwise listen to public health officials" (Kim et al., 2020, para. 6). For example, when the first case was reported, the government advised that people wear respiratory protective devices in public places or in circumstances where practicing social distancing was difficult or impossible (Lee et al., 2020a). Among the South Korean public, wearing a respiratory protective device in public spaces became a social norm during the COVID-19 pandemic (Kim et al., 2020). A poll showed that more people followed public health protocols during the pandemic than during the MERS outbreak (Kim et al., 2020; Oh et al., 2018). In one international survey, the reported rate of wearing respiratory protective devices among the Korean public was 94 percent, the highest rate among 28 countries (Gallup, 2020; Lim et al., 2020). Cultural differences may also influence the wide acceptance of respiratory protective devices in South Korea. Whereas wearing a respiratory protective device may be perceived as a sign of illness in the European or North American context, this action is viewed as demonstrating modesty and thoughtfulness in Korean culture (Lim et al., 2020).

The Korean government also adopted a range of tactics for dealing with shortages of respiratory protective devices and other personal protective equipment (PPE): In Daegu, for example, a lack of PPE prompted the government to "purchase 80 percent of the respiratory protective device supply from Korean manufacturers, fully ban exports, set a price limit on respiratory protective device sales, and limit the number of respiratory protective devices sold weekly through retailers" (Kim et al., 2020, para. 41). Another notable strategy used to prevent shortages involved a 5-day rotation system for distribution of respiratory protective devices. Under this system, Korean citizens were allowed to purchase up to two respiratory protective devices per person each week, available only through public retail platforms and on designated days of the week depending on birth year (Government of the Republic of Korea, 2020).

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During the COVID-19 pandemic, for example, concerns were raised that stigma attached to the use of masks and face coverings was especially strong among African American men (Turner-Musa et al., 2020). However, findings of a nationally representative survey conducted in the United States in April–June 2020 suggest that White people were less likely to wear masks to protect against COVID-19 relative to African American, Latinx, and Asian respondents, with White men being the least likely (Hearne and Niño, 2021). Many anecdotal accounts indicate the added stress that wearing masks and other devices has placed on marginalized communities (Felix, 2020).

Residence in an urban or rural area may impact the likelihood of use of respiratory protective devices; however, findings from available studies (Anderson and Stockman, 2021; Callaghan et al., 2021) do not indicate a clear geographic pattern, and more research on this question is needed.

Political affiliation also may impact motivations to use or not use respiratory protective devices. Results of a nationally representative survey conducted in the United States in April 2020 showed the importance of understanding these motivations. Among the survey respondents, 88 percent of Democrats self-reported use of a device, compared with 73 percent of Republicans and 75 percent of third-party/independent voters; these differences could not be explained by differential risk perceptions (Bruine de Bruin et al., 2020).

Age and gender may also affect the likelihood of choosing to wear respiratory protective devices, although more research is needed to understand the contextual factors at play. Results of several studies indicate that women and younger people are more likely to wear devices intended to reduce exposure to air pollution events (Covey et al., 2019; Xiong et al., 2018). However, perceptions of risk lead to variations in this general observation. For example, Covey and colleagues (2019) found that perception of risk during volcanic ash fall is higher among older than among younger people in Japan, leading to greater use of such devices in that demographic.

Summary and Synthesis

Ultimately, respiratory protective devices are effective only if they are used properly. Public awareness, perceived risk, belief in the efficacy of the devices, and social norms all affect consumers' decisions about using respiratory protection, and public health messaging can play a significant role in the public's awareness and decision making about use. Numerous barriers, however, impede communicating to the public to address questions around device selection, use, and care. Engagement with the public—both broadly and in a targeted manner—is essential to educate users on best practices in

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selecting and using respiratory protective devices and to address resistance to use. This section has identified 13 open questions concerning the needed education for the public (see Box 4-4). Generally, greater public awareness about respiratory protection is necessary, provided by improved and coordinated communication materials. Depending on the particular barriers to effective use of respiratory protective devices, different educational and intervention approaches may be needed that are tailored equitably to all segments of the public. However, substantial data gaps limit understanding of best practices for conveying such information to the public, and further research is needed to test and evaluate optimal approaches.

For inhalation hazards, a combination of intervention approaches may be needed (Conway, 2021), based on a broad understanding of people's specific needs and other strategies (beyond use of personal respiratory protective devices) they can use to protect themselves (see Box 4-4, question 7). The United States can learn from the experiences in other countries to address the fractures and gaps in the current system and implement a more cohesive framework that can support the provision of respiratory protection to the public during public health emergencies.

Conclusion 4-5: Messages for the public about respiratory protective devices have not been adequately tested, and the most effective strategies for ensuring appropriate selection and use of these devices by the public are not known.

Conclusion 4-6: Examples from other countries show that a cohesive national strategy is critical for ensuring respiratory protection for the public.

STAKEHOLDER ROLES IN COMMUNITY ENGAGEMENT AROUND THE USE OF RESPIRATORY PROTECTION BY THE PUBLIC

The findings discussed above emphasize the critical role for engaging the broader community, including key stakeholder organizations, in connecting with target populations and scaling educational efforts. Key players in these communication efforts may include health care providers and health systems, public health agencies, and other community-based organizations that have broad population reach and engage with specific population groups.

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Role of Health Care Providers

Health care providers are often looked to for advice on when to use respiratory protective devices, but they receive little to no training on communicating the risks and benefits associated with respiratory protection, nor are they trained to evaluate whether such devices are safe to use for a given individual. The American Thoracic Society (ATS) has suggested (without providing practical guidance) that physicians are responsible for counseling patients on respirator use and its limitations outside of formal occupational RPPs (e.g., for hobbies or at a workplace that does not require an RPP) and ensuring proper fit testing and use (Harber et al., 1996). These ATS guidelines also state that while medical evaluations are necessary for the safe use of respiratory protective devices, the process for carrying out these evaluations has not been determined, and clinical judgment should be applied (Harber et al., 1996). As a result, the frequency of medical evaluation, which specific tests are performed, and the criteria used to determine fitness to wear a respirator have been shown to vary markedly among practitioners (Desautels et al., 2016).

Lack of knowledge about the proper use of respiratory protection among health care providers is evidenced by the clear gaps identified in physicians' knowledge about their own use of respirators (NIOSH, 2016), a lack of knowledge that extends to PPE more broadly. The use of respiratory protective devices is not systematically incorporated into medical training. John and colleagues (2017) found that fewer than half of medical students reported receiving training on donning/doffing gloves and gowns, and nearly all made errors. Qualitative research by Barratt and colleagues (2020) on overall PPE use among medical trainees again demonstrated large gaps in knowledge and practice. A Cochrane review found that computer simulation may lead to fewer errors among health care workers in donning PPE, including respiratory protection, and that face-to-face instruction, compared with written materials or video, may reduce noncompliance with donning guidance (Verbeek et al., 2020). No studies have documented the impact of training in personal use of PPE on providers' ability to counsel patients effectively about the safety of PPE use, which may be an important area for further study.

Lack of emphasis on knowledge about respiratory protection among health care providers is not limited to medical education, but also extends to practice. Hospitals have requirements related to respiratory protection for physicians and other health care workers that may increase their knowledge and skills related to PPE. However, although most hospitals adhere to the requirement that staff undergo an initial medical evaluation and fit testing before they are allowed to wear a respirator in the workplace, only two-thirds of hospitals give employees written notification of the model and

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size of the respirator for which they were fit tested (Peterson et al., 2015). Peterson and colleagues (2015), moreover, found that health care workers showed quite variable rates of specific competencies related to respirator use; for example, while 84 percent correctly positioned their respirator, only 15 percent completed seal check procedures, and only about half properly doffed and disposed of their respirators. Thus while health care providers are often pointed to as experts in public health guidance, they are challenged in this role by receiving little or no training in respiratory protection.

Role of the Public Health Community

Much like health care providers, the public health community is expected to serve as a primary resource for the public on the proper use of respiratory protective devices. Like the medical community, however, the public health community receives limited education in respiratory protection to support them in this role. Although a model training program for respiratory protection preparedness at local health departments has been developed, no data are available on the extent to which this training has been provided to public health professionals (Alfano-Sobsey et al., 2006).

There are 3,234 local, regional, and state-run public health agencies in the United States, and respiratory protection for the general population has not been a major focus for these agencies (Alfano-Sobsey et al., 2006). The public health community does focus on respiratory protection for medically vulnerable groups (e.g., the frail elderly), but primarily with an emphasis on communicable diseases, with less attention to wildfire smoke and other environmental exposures. Data from the Association of State and Territorial Health Officials (ASTHO) indicate that in 2019, state-level public health agencies in 36 states focused on indoor air quality, reflecting an increase of 28 percent over 2016. However, only 9 state public health agencies had a focus on outdoor air quality, reflecting a 31 percent decrease since 2016, and no information about the extent or quality of these programs was available (ASTHO, 2021).

Integration of Organizational Relationships to Improve Community Knowledge

Efforts to increase community knowledge of and participation in respiratory protection need to integrate a range of organizational relationships. A large number of organizational channels (e.g., parent- and family-focused organizations, schools, faith-based organizations, health-focused organizations) could be used to improve outreach and connection to different segments of the population with respect to protection against inhalation hazards. To date, these organizational connections have been sporadic and

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local, and thus have had limited impact. For example, Moms Clean Air Force is a national community of parents united against air pollution and climate change (Moms Clean Air Force, 2021). With its network of state-based community organizers and more than 1 million members, this is an example of a group that could be engaged to increase respiratory protection planning among families.

Summary and Synthesis

Health care providers and public health agencies are frequently viewed as sources of advice for the public's use of respiratory protective devices; however, these stakeholders often lack the expertise and resources to address the public's information needs. Health care providers, who receive little or no training in providing guidance on respiratory protection to their patients, are asked to rely on their clinical judgment in determining clinical fitness for device use and addressing patients' questions. Public health agencies, although charged with maintaining the health of their community, lack the training to develop their own evidence-based guidance and accessible messaging on the effective use of respiratory protection, and comprehensive guidance from state or federal agencies is not always available. Community organizations are also well placed to play a role in expanding public awareness and practice of respiratory protection behaviors; however, the integration of these groups into the local public health enterprise has been sporadic.

Conclusion 4-7: Health care providers and public health professionals play essential roles in providing guidance to the public on the use of respiratory protection. Yet they are not always adequately trained on providing such guidance (including details of medical indications or physiologic impacts associated with the use of respiratory protective devices), nor do they always have the resources and tools to perform this function well.

RESPIRATORY PROTECTION GUIDANCE CURRENTLY AVAILABLE FOR THE PUBLIC

If members of the public are expected to make informed decisions about their respiratory protection and that of others, they require clear, consistent guidance. Yet, both the COVID-19 pandemic and recent exposures to wildfire smoke have illustrated a landscape of confusing guidance.

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Examples of Challenges in Public-Oriented Guidance for Respiratory Protection

When transmission of COVID-19 surged in the United States in March 2020, CDC initially discouraged the public from wearing any kind of respiratory protective device because of a lack of clarity as to whether the virus could be transmitted via bioaerosols and out-of-date science on airborne transmission at a time of device scarcity. The rationale at the time was based on preserving respirators (N95 FFRs) for health care workers (Cichowicz et al., 2020). In April 2020, CDC recommended that individuals wear a face covering in public to help prevent transmission of the virus, and it continued to emphasize use of face coverings for source control rather than personal respiratory protection for nearly a year (Cichowicz et al., 2020). In February 2021, CDC changed its guidance to recommend that individuals wear two devices—a cloth face covering over a surgical mask—or improve the fit of a single device to provide better source control as well as respiratory protection for themselves. Despite this shift to urging respiratory protection for the public, the agency continued to recommend that the use of N95 FFRs be prioritized for health care workers (CDC, 2021c). Meanwhile, as SARS-CoV-2 variants began to spread globally, some U.S. public health experts urged universal wearing of N95 FFRs to reduce rates of infection (Allen, 2021). In early 2021, several European countries had already begun requiring individuals to wear more protective devices (N95 FFRs, KN95s, FFP2s, or surgical masks) while in public, arguing that cloth and homemade face coverings might not offer sufficient protection against the more highly transmissible coronavirus variants (Morris and Noack, 2021). It was not until September 2021, however, that respirators were incorporated into CDC guidance to the public (CDC, 2021d).

CDC is not alone in promulgating changing guidance. WHO initially encouraged the use of medical masks (surgical or procedural masks) only by individuals with respiratory symptoms and offered no advice about source control by the public (WHO, 2020a). In April 2020, WHO updated its guidance to emphasize reserving medical masks for the medical community and symptomatic persons, and encouraged the public to use social distancing and good hand hygiene to limit the spread of SARS-CoV-2 (WHO, 2020c). It did not begin to encourage the use of fabric face coverings for source control until June 2020 (WHO, 2020b). Despite the spread of more transmissible variants, in December 2020 WHO continued to urge the public to wear only fabric face coverings for source control and restrict the use of medical masks to medical workers, people with coronavirus symptoms, those coming into contact with symptomatic people, and those over 60 or at high risk (WHO, 2020d).

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As the vaccination rollout for the public began in 2021, CDC initially stated that vaccinated persons should continue wearing face coverings when around non-household members. Because evidence on the likelihood of COVID-19 transmission by vaccinated persons was not yet available, CDC followed precautionary principles in issuing its guidance. As more evidence became available, the agency released revised guidance in early March 2021, stating that vaccinated persons could gather with other vaccinated persons indoors without face coverings, and vaccinated persons could gather indoors with nonvaccinated persons without face coverings one household at a time (CDC, 2021e). CDC continued to encourage vaccinated persons to wear face coverings in public, when gathering with unvaccinated people from more than one other household, and when visiting with an unvaccinated person at increased risk of severe illness or death from COVID-19 or living with such a person (CDC, 2021e).

Developing situations by their nature require modifications in guidance as the situation changes, yet part of the issue with the above-described changing guidance is the perceived lack of a rationale for the changes. When messages need to change (e.g., transitioning from preserving masks for health care workers to "mask mandates"),[12] very clear communication about the science behind and reason for the change is essential. Because science is an iterative process, issuing guidance in real time is a challenge; rapidly evolving science necessitates rapidly evolving guidance. In the beginning of the COVID-19 pandemic, the science of airborne infectious disease transmission was outdated, and it evolved over the course of 2020 and 2021. These changes in the science and, by extension, the guidance issued can be difficult for a public that has little experience with the scientific process, and the changes can feel abrupt and arbitrary, leading to distrust and noncompliance.

Disagreements among agencies at various levels of government as to who should wear a respirator during a wildfire also left the public with conflicting and confusing advice. Local health agencies and their local governments have disagreed about whether it is appropriate to distribute respirators (e.g., N95 FFRs) to the public. During the Camp fire in 2018, for example, the City of Sacramento had a program in place for distributing N95 FFRs to the public, while supplies lasted, for protection from wildfire smoke. The respirators were dispersed to the city from the California Office of Emergency Services and the California Department of Public Health, with requests being routed through the County of Sacramento (*Sacramento City Express*, 2018). Sacramento County then released a statement that the

[12] A mask mandate is an enforceable requirement for the use of a respiratory protective device in specific settings (e.g., indoors, while on transit vehicles). The requirement is not limited to use of medical masks; use of face coverings and respirators will also meet the requirement.

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use of an N95 FFR for the Camp fire smoke was not recommended (Cremen and Estrada, 2018).

Disagreement and uncertainty also mark guidance on the use of respirators by children. The Environmental Protection Agency's (EPA's) Wildfire Smoke Guide for Public Health Officials states,

> Respirators are not made to fit children and will not protect them from breathing wildfire smoke.... NIOSH does not currently certify respirators for children. As new research findings on efficacy become available, guidance by U.S. government agencies may be issued on the proper use of respirators by children. (EPA et al., 2019, pp. 2, 27)

Meanwhile, the Pediatric Environmental Health Specialty Unit (PEHSU) released a factsheet stating, "some types of masks (face-coverings that go over your mouth and nose) can protect you and your children from breathing in wildfire smoke" (PEHSU, 2020, p. 1), but the EPA guidance has not yet been updated.

Gaps in Guidance on the Use of Respiratory Protection by the Public

Guidance on the use of respiratory protection by the public is developed and applied by a range of stakeholders, including federal, and state, local, tribal, and territorial (SLTT) agencies. To understand the current landscape of guidance for the public and where additional guidance is needed, the committee collected and reviewed examples of public-focused guidance on use of respiratory protective devices issued by federal agencies, and performed a targeted review of guidance developed or distributed by SLTT public health agencies and air quality agencies. The evaluation of federal guidance was used specifically to identify gaps in authoritative guidance to aid the committee in considering guidance needs, while the review of SLTT guidance allowed the committee to explore the variability of public-focused guidance developed or distributed by these agencies.

Gaps in Federal Guidance

Multiple federal agencies develop and disseminate guidance for the public on the use of respiratory protection. For example, EPA, which regulates environmental pollutants and provides air monitoring data, has produced guidance for public health officials on protecting the public from wildfire smoke, including the use of respiratory protective devices. As discussed above, CDC has published numerous guidance on the use of respiratory protection by the public during the COVID-19 pandemic. To explore

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existing gaps in federal-level public-oriented guidance, the committee focused its examination on examples of authoritative guidance that is broadly targeted to the public or is used by SLTT public health agencies to develop content for guidance targeting local communities (see Box 4-7 for selected examples). These authoritative examples of guidance were considered with reference to the identified knowledge gaps outlined earlier in Box 4-1 to identify gaps in guidance on the use of respiratory protection by the public.

Generally, the committee found that hazards of concern covered by these guidance examples vary by agency, with EPA and FEMA providing guidance on wildfire smoke and air pollution and CDC offering guidance on COVID-19, as well as wildfire smoke, air pollution, and mold in some instances. These examples of guidance are intended to serve different purposes, but are all oriented to the public's use of respiratory protection. For example, some of the information included is designed for use by SLTT public health agencies in developing consistent and comprehensive guidance on use of respiratory protection, while other examples are factsheets intended for use directly by the public. Across the guidance reviewed, the greatest variability in content relates to the level of detail on how, when, and why respiratory protection should be used for a given hazard and to the means used to enhance the accessibility of

BOX 4-7
Selected Examples of Federal Guidance on Public Use of Respiratory Protective Devices

Centers for Disease Control and Prevention (CDC)

- CDC: "Your Guide to Masks" (CDC, 2021f)
- CDC: "Types of Masks and Respirators" (CDC, 2021d)
- CDC: "Improve How Your Mask Protects You" (CDC, 2021b)
- NCIRD: "Interim Public Health Recommendations for Fully Vaccinated People" (CDC, 2021g)
- NCEH: "Wildfire Smoke and COVID-19" (CDC, 2021h)
- NIOSH: "Non-Occupational Uses of Respiratory Protection—What Public Health Organizations and Users Need to Know" (Shaffer et al., 2018)

Environmental Protection Agency (EPA)

- EPA: "Wildfire Smoke: A Guide for Public Health Officials" (EPA et al., 2019)
- EPA: "Wildfire smoke factsheet: Protect Your Lungs from Wildfire Smoke or Ash" (EPA, 2021)

Federal Emergency Management Agency (FEMA)

- FEMA: "Wildfires" (FEMA, n.d.)
- FEMA: "Be Prepared for a Wildfire" (FEMA, 2018)

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that information for the intended audience (e.g., use of graphics, multiple languages, alternative formats). Material from one source of guidance is often used to develop another source or includes links to other foundational information from the same or other federal agencies.

An assessment of this material guided by the information needs in Box 4-1 highlighted several content gaps in some or all of these examples regardless of the hazard of concern. First, few examples of public-oriented guidance provide sufficient detail on where respiratory protection can be purchased (e.g., local drugstore, direct from manufacturers), and none of the examples provide information about the approximate cost of products. In the context of the use of respiratory protective devices as source control for COVID-19, sufficient guidance is available on what type of product to use, but no clear information is included on how these products can be accessed and how the consumer can confirm that the correct product is being purchased. Guidance on the use of respirators for protection from COVID-19 directs the reader to purchase from a "reputable seller." Clear information for the potential users of respiratory protection about where they can find the appropriate devices, who reputable sellers are, and how they can know they are buying the right products would reduce confusion and increase the likelihood of an appropriate device being acquired.

Additionally, gaps in guidance exist around conveying all critical aspects of effective use of respiratory protective devices—specifically, how to ensure that the device fits, how to put it on and take it off correctly, when the device should be worn, when it has reached the end of its lifespan, and how it should be cared for. Relatively comprehensive sources of guidance, such as CDC's *Your Guide to Masks* and *Types of Masks and Respirators*, are available with respect to prevention of COVID-19 transmission and are included as links on multiple CDC webpages. Yet, available FEMA guidance lacks sufficient detail to support users in knowing how and when to use respirators to prevent exposure to wildfire smoke or how long a device can be used before it should be discarded. In general, the available guidance on exposure to wildfire smoke lacks clear information on when exactly a respirator should be worn, stating, for example, that respirators should be worn during an "extended period of time in smoky air or an ash-covered area" (EPA, 2021) without defining what length of exposure or what level of air quality calls for wearing a respirator outside or even indoors. Failure to provide such specifics of use causes confusion and creates the potential for incorrect use.

Available guidance for the public also lacks sufficient detail on who can safely use what type of respiratory protective device. In a few cases, certain users, such as very young children, are directed not to use respiratory protection at all. In other cases, the guidance provides only vague information about whether individuals with certain health conditions should use

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respiratory protective devices. *Wildfire Smoke: A Guide for Public Health Officials* notes that some users with heart and lung conditions may need to discuss respirator use with their medical provider to confirm that there are no significant health risks involved (EPA et al., 2019). Overall, the guidance offers only very limited information about the baseline health requirements for users and whether there are any risks to use.

Relatedly, the guidance lacks information on respiratory protection targeted specifically to vulnerable groups, such as children and others (e.g., pregnant women, the elderly), who are at particular risk from exposure to inhalation hazards but may be unable to find respiratory protective devices tailored to their needs. Public-oriented guidance needs to provide clarity around who can wear respiratory protective devices in what contexts, as discussed above, and evidence-based alternative precautions for reducing health risks for these groups.

Furthermore, gaps in guidance, as well as in research, relate to the degree of protection that can be expected from a respiratory protective device in different contexts of use. For occupational contexts, assigned protection factors indicate the level of protection a worker can expect when a respirator is used as part of an RPP. By contrast, no guidance for the public provides quantitative estimates of protection. For example, if a mask is worn during wildfire ash cleanup without formal fit testing, how much protection can be expected? Similarly, how much personal respiratory protection is provided by a device acting as source control? This information represents a critical research need and could be highly beneficial to users in improving their awareness of the protection they are receiving and ensuring that they select the appropriate device.

Emergency preparedness organizations at the federal and state levels could address respiratory protection more broadly and comprehensively. For example, the federal government's ready.gov website provides a packing list for a basic disaster preparedness kit that includes only a dust mask "to help filter contaminated air" (Ready.gov, 2021). A COVID-19 addendum to the site suggests including a "mask" for all family members, but with no specificity on type or fit. New York's preparedness website (Prepare.NY.Gov) provides two different lists of supplies for an emergency kit, one of which describes including "face masks," and the other N95 FFRs. A multilingual brochure on this same website recommends including dust masks (New York State, n.d.). None of these sources provide any information about the different circumstances under which different types of respiratory protective devices are appropriately used. Developing one set of coordinated messages that could be used by multiple groups would reduce confusion and duplication of effort in developing such materials.

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Guidance from SLTT Public Health and Air Quality Agencies

A paucity of literature addresses the extent to which public health and air quality agencies are able to reach the public, and particularly vulnerable groups, with accessible messaging. To explore this issue and understand the variability of public-focused guidance on respiratory protection across various agencies, the committee reviewed available guidance from SLTT agencies along four dimensions: (1) FEMA region;[13] (2) jurisdiction type (e.g., state, local, regional, territorial, tribal); (3) jurisdiction demographic (e.g., urban, suburban, rural); and (4) agency type (e.g., public health versus air quality). The committee devised a sampling strategy along these dimensions to guide the selective sampling of publicly available guidance from the webpages of 13 public health and air quality agencies (Alexandria Department of Public Health, 2021; BPHC, 2021; CDPH, 2019; Deschutes County Health Services, 2020; Franklin County Kansas, 2021; Fulton County Board of Health, 2021; Navajo Nation, 2021; NM DOH, 2020; OHA, 2021; Puerto Rico Department of Health, 2021; Tri-County Health Department, 2021; Utah Department of Environmental Quality, 2020). These agencies were selected to reflect the organizational heterogeneity and regional and demographic diversity that characterize such agencies throughout the United States. The databases of the National Association of County and City Health Officials' (NACCHO's) Directory of Local Health Departments and the National Association of Clean Air Agencies were used for this search. The committee found that the majority of the relevant content on these websites was focused on COVID-19, with only three agencies including wildfire smoke and none including mold or other inhalation hazards.

Several overarching themes emerged from this evaluation. First, related to selection of respiratory protective devices, there was wide agreement across the guidance surveyed that in the context of COVID-19, N95 FFRs and other such respirators should not be used by the public and should be reserved for health care workers. The public was instead encouraged to make use of face coverings, and the guidance often included how to select or make homemade face coverings. In the context of wildfire smoke, the reverse was true: the guidance stated that while cloth face coverings could be used to reduce the spread of COVID-19, they would not protect individuals against wildfire smoke or other small particulate matter.

Second, with respect to variability in types of information and level of detail provided, while the information presented across the public health and air quality sites was broadly accurate, it varied in the types of information provided, level of detail, and format:

[13] FEMA divides the continental United States and its territories into 10 geographic regions.

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- Selection: Almost all of the sites provided detailed guidance on when and where masks should be used, especially with regard to COVID-19.
- Use: About one-third of the sites addressed how to don and doff cloth face coverings safely.
- Accessibility of information: About half of the sites provided information via videos or infographics (or links to them) in addition to plain text. Only four of the sites provided translations of the guidance in multiple languages.
- Homogeneity of guidance: Despite differing levels of detail and formats, the guidance was largely consistent across the different public health and air quality websites reviewed. In the context of COVID-19, the guidance often cited CDC, and links to CDC and other federal resources were often provided.

It should be noted that this survey of public health and air quality guidance was conducted in April 2021, and that in the context of COVID-19 especially, respiratory protection guidance for the public may have been much different or more heterogeneous closer to the start of the pandemic and may have evolved as the supply of respirators increased.

Summary and Synthesis

The public requires clear guidance on when to use respiratory protective devices for protection against specific inhalation hazards, such as wildfire smoke, ambient air pollution, volcanic ash, and infectious agents. However, there is no unified, authoritative system for identifying inhalation hazards—either existing or emerging—that may warrant use of respiratory protection by the public. There also is no consistent system for evaluating the potential exposures and health risks to determine whether use of respiratory protection by the public is indicated under certain conditions. Consequently, authoritative guidance to the public on the use of respiratory protective devices has reflected the challenge of adapting to changes in the science and providing effective messaging to critical user populations. Additionally, the authoritative federal guidance that is available currently lacks sufficient information about the degree of protection provided by various devices in terms of both source control and personal respiratory protection in different use contexts that are relevant to the public. Finally, the public requires more guidance on the procurement of devices, as well as clearer statements on health risks associated with their use, to increase users' confidence in their selection of a respiratory protective device for the hazard of concern.

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Conclusion 4-8: The lack of a central and coordinated organizing body to provide guidance on respiratory protection for the public has led to a decentralized and fragmented process for public health recommendations and education. The public does not know where, which, and when respiratory protective devices should be used.

- ***There is no unified process for identifying and evaluating inhalation hazards that may warrant respiratory protection by members of the public.***
- ***No central or coordinating agency has been charged with making recommendations to the public about when (and when not) to use respiratory protective devices to mitigate the health effects of inhalation hazards.***
- ***There is no clear source of education and guidance for the public on the use of respiratory protective devices.***

CONCLUDING REMARKS

From a systems perspective, there are multiple failure points in the sequence from the selection of a respiratory protective device to achievement of the intended level of protection. There is a need for a stable supply chain with the capacity to respond to surges, and more concerted efforts to ensure equitable access to respiratory protective devices. There is an overarching need for training and education—efforts normally undertaken in the context of an RPP—on how to use respiratory protective devices to mitigate inhalation hazards, including guidance for users on length of use, donning and doffing, risks of fomite transmission, and physiologic limitations of using a device. There is a critical need for consistent messaging to the public to overcome these challenges and limitations. Above all, the committee finds that experience to date in providing respiratory protection to the public indicates the need for a systems approach that acknowledges the critical importance of addressing each failure point in a systematic way.

This need could be met by a unified and authoritative source that is empowered to ensure the availability of respiratory protective devices for diverse populations (including children), provide answers for the research priorities noted throughout this chapter, and address the knowledge gaps regarding respiratory protection for the public laid out in Box 4-1—a source that is dedicated to the health and safety of the public, especially in the event of a public health emergency. The architecture for such a framework for respiratory protection for the public is discussed in Chapter 7.

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5 A General Framework for Respiratory Protection Oversight and Guidance

Prior chapters have established the context for developing a framework in response to the committee's charge to

> make recommendations for a framework of responsibilities and authorities, including those of federal agencies, to provide a unified and authoritative source of information and effective oversight in the development, approval, and use of respirators, including conformity assessment processes to meet the needs of these populations (see Box 1-1 in Chapter 1).

Together, Chapters 2–4 provide this context by reviewing the regulatory, legal, and other measures currently in place for respiratory protection for workers not covered by a respiratory protection program (RPP) and for the general population. Many of the challenges highlighted in these chapters relate to the fragmented regulatory landscape and the lack of a cohesive national strategy for addressing the respiratory protection needs of these two populations. In this chapter, the committee sets out a general framework for meeting these challenges. Chapters 6 and 7 build on this general framing. Responding to its charge and building pragmatically on structures in place, the committee proposes two separate frameworks—one for uncovered workers and the other for the general population. We note that the underlying concepts related to these frameworks are comparable, with a systems approach being embraced as the path to risk reduction through assurance of respiratory protection. Perhaps a unified framework will be feasible in the future, but the committee did not perceive that approach as practicable at present.

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A SYSTEMS APPROACH TO REDUCING RISKS FROM INHALATION HAZARDS

The committee's frameworks have the purpose of ensuring effective respiratory protection for those needing it when exposure poses a risk deemed to be unacceptable. The committee took a systems approach to addressing how that purpose can be achieved, detailing the many steps and their components that are required to make respiratory protective devices available when needed and ensure their effective use. An overview of those diverse processes is depicted in Figure 5-1, which is a simplification of a complex system, as each step has its own components and operates in a societal context not easily distilled into graphical form. While the component processes depicted in Figure 5-1 are the same for workers and the public, differences in how they are implemented, as described below, signify the need for separate frameworks for the two populations.

The committee's approach to understanding respiratory protection as a system builds on a prior Institute of Medicine report, *Preparing for an Influenza Pandemic: Personal Protective Equipment for Health Care Workers* (IOM, 2008). That report describes the first step in the sequence depicted in Figure 5-1—the design of respiratory protective devices—as part of a lifecycle from evidence-based performance requirements to field testing. Figure 5-2, first published in that report, outlines a set of overarching performance requirements to guide the design and development of PPE in a manner that prioritizes functional characteristics, such as filtration efficiency, and user-centric needs. From this broad set of design requirements, more specific requirements can be identified for specific use scenarios, considering the hazard and the intended users, including challenges faced by vulnerable groups in terms of gaining access to respiratory protective devices.

The general system sequence outlined in Figure 5-1 begins with product design and manufacturing. The second major process is conformity assessment, which focuses on "product effectiveness—verifying and ensuring that a product meets specific criteria for use in workplaces and other locations" (IOM, 2011, p. 19). To reinforce the systems paradigm, conformity assessment has its own set of subprocesses or subsystems and distinct regulatory structures for workers and the public, as discussed in Chapter 2. Certification of the respiratory protective device (e.g., by the National Institute for Occupational Safety and Health [NIOSH]/National Personal Protective Technology Laboratory [NPPTL], or a third party) is next, providing a mark of assurance as to effectiveness and safety for users of the product.

As shown in Figure 5-1, the process steps associated with the manufacturer culminate in product marketing, sales, and distribution (e.g., to retailers or directly to purchasers). The next step is access to the product by users who need a respiratory protective device for protection against

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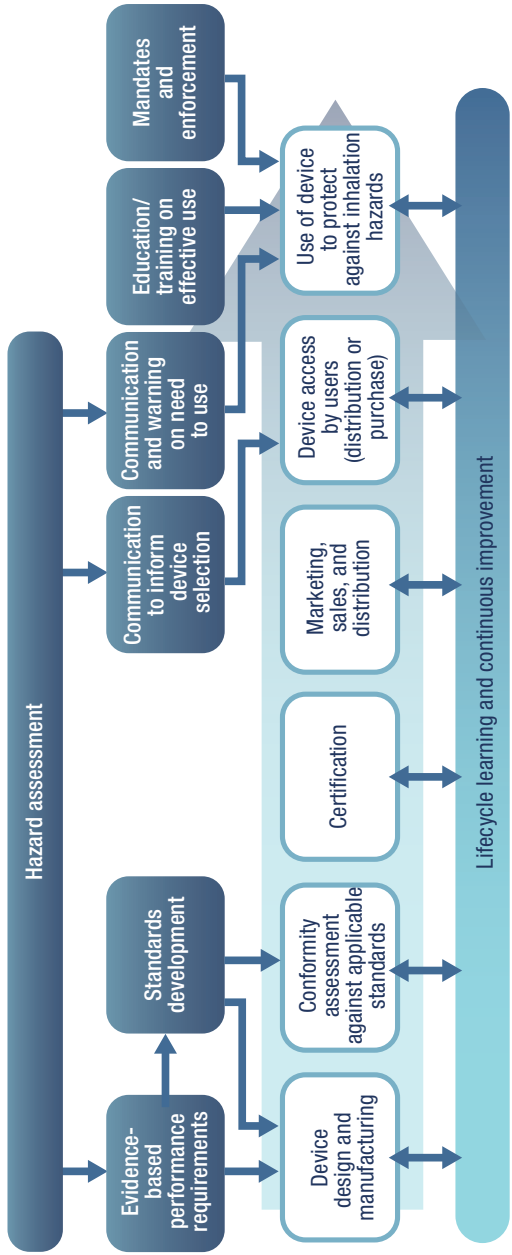


FIGURE 5-1 Processes needed to deliver respiratory protection from design and manufacturing to use, with continuous improvement through learning cycles at every step.

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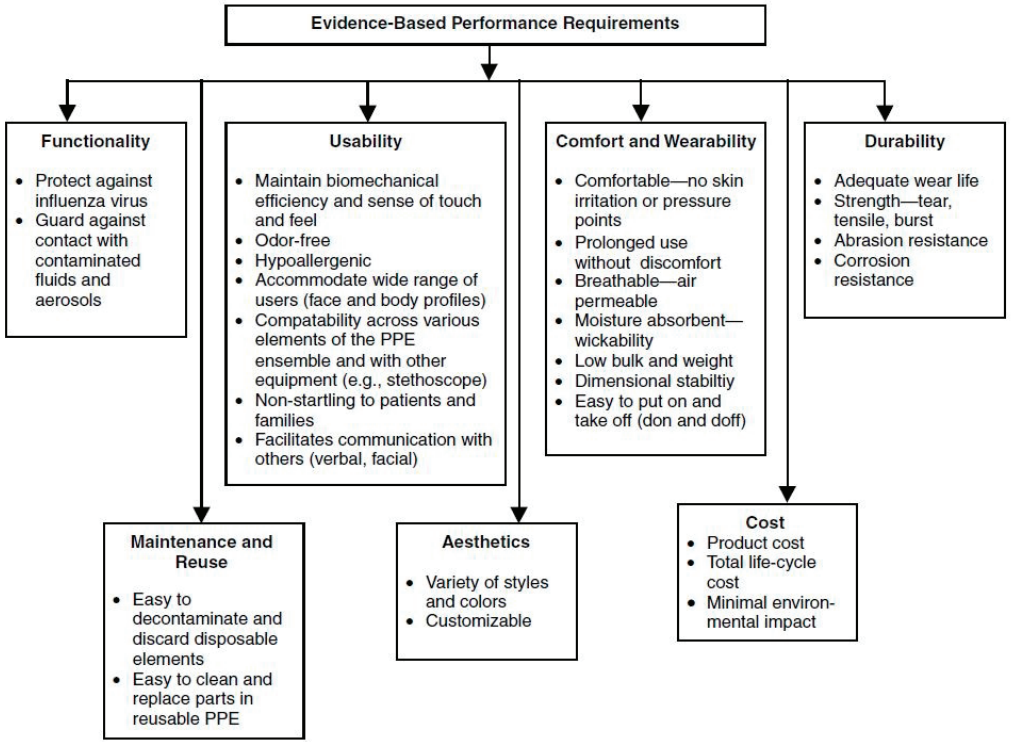


FIGURE 5-2 Examples of evidence-based performance requirements for respiratory protective devices in the context of an influenza pandemic. These requirements are aimed at balancing user needs with functionality.
NOTE: PPE = personal protective equipment.
SOURCE: IOM, 2008.

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a specific inhalation hazard. Access can occur in two ways: respiratory protective devices may be provided to users, or users may purchase them from a retailer. For example, an employer that has instituted an RPP may purchase respiratory protective devices and provide them to employees to protect them against inhalation hazards in the workplace. Or a family might choose to purchase and store such devices because of potential risks from wildfire smoke or airborne infectious agents. Thus, the workers not covered by an RPP and members of the public could procure the product directly in the marketplace for personal use, if affordable. For both employers and individuals purchasing a device, communication of hazard-specific specifications for the device need to be provided to ensure selection of an appropriate product.

The next critical process step is effective use of the respiratory protective device, triggered by a specific inhalation hazard for which it has been determined that other controls cannot adequately prevent exposure. Communication regarding the need to use the device and education and training in its use (e.g., donning, doffing, cleaning, and storage) are critical inputs to this step. In some cases, as in workplaces where workers are exposed to inhalation hazards that cannot otherwise be controlled, use of respiratory protection may be mandated and compliance monitored.

Finally, underlying these six process steps is the paradigm of ongoing learning and continuous improvement that is critical to catalyzing advances in each step and ensuring the robustness of the system in responding to changes. Examples of such processes include postmarket audits and ongoing usability evaluations.

It should be noted that, although depicted in Figure 5-1 as sequential, these process steps could occur simultaneously and iteratively as processes are modified based on experience. The dynamic nature of the continuously evolving system is indicated by the bidirectional arrows connecting each process step to the ongoing process of lifecycle learning and continuous improvement at the foundation of the system.

Across the general sequence of process steps depicted in Figure 5-1, the components are comparable for the two targets of this report—workers not covered by RPPs and the public. This chapter acknowledges these parallels, while Chapters 6 and 7 describe the committee's specific frameworks for these two groups, respectively. As described in Chapters 2 through 4, some of the processes are carried out by existing entities to varying degrees and are highly fragmented. For instance, the identification of evidence-based requirements to inform product design is carried out by manufacturers, occupational safety and health professionals, and researchers for the worker group. In the case of the public, roles are not as well established, although researchers are engaged in doing some groundwork for the identification of such requirements. Similarly, those employers with Occupational Safety and

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Health Administration (OSHA)-required RPPs are responsible for training employees in the use of respirators, while there is no such designated authority for the public.

In the sections below, the committee introduces its approach to addressing the element of its charge concerned with making recommendations for the requested framework. The committee's proposed framework extends from the design, manufacturing, and testing of respiratory protective devices to their delivery to users who need to be prepared to use them in a way that will provide the desired level of protection, as depicted in Figure 5-1. The frameworks for workers without RPPs and the public (Chapters 6 and 7, respectively) address each process in this sequence and reflect the diversity of the populations that are potential users of respiratory protective devices.

A GENERAL FRAMEWORK FOR OVERSIGHT AND GUIDANCE TO MEET RESPIRATORY PROTECTION NEEDS

The framework described in this section is designed to ensure that the processes depicted in Figure 5-1 can be implemented, evaluated, and modified with experience over time. Key terminology used here is defined as follows:

- *framework*: the overall structure for reducing risk from inhalation hazards among workers not covered by an RPP and the public
- *functions*: what the elements of the framework need to accomplish
- *subfunctions*: the various activities needed to accomplish each of the functions
- *coordinating entity*: the unified and authoritative entity responsible for coordination, and decision making, and effective oversight with respect to the framework's functions

The committee's framework was guided by the six principles introduced in Chapter 1. In proposing the framework, the committee adopted a four-step process along the lines of the National Planning Frameworks within the National Preparedness System, proposed by the Department of Homeland Security[11]:

- describing the core functions (i.e., needed capabilities);
- aligning key roles and responsibilities for delivering those capabilities;

[11] See https://www.fema.gov/emergency-managers/national-preparedness/frameworks (accessed August 20, 2021).

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- describing coordinating structures that will enable all stakeholders to work together; and
- laying the foundation for further operational coordination and planning that will synchronize efforts of all stakeholders across the public and private sectors.

The subsections that follow describe the key functions that must be carried out within the framework. The chapter then goes on to consider the general needs related to aligning roles and responsibilities with the framework and potential models for coordinating structures. The mapping of stakeholder roles and responsibilities to functions and specific coordination structures are discussed for workers and the public in Chapters 6 and 7, respectively.

The Core Functions

Figure 5-3 shows the core, high-level functions that must be carried out as part of the framework:

- Function F0: Develop and approve respiratory protective devices;
- Function F1: Assess hazard and determine need for respiratory protection;
- Function F2: Determine the necessary respiratory protective devices;
- Function F3: Ensure availability and access pathways for respiratory protective devices;
- Function F4: Engage, inform, and ensure access for the target community;
- Function F5: Incorporate lifecycle learning and continuous improvement; and
- Function F6: Coordination

These core functions make up a comprehensive framework that builds on the experience reviewed in Chapters 2 through 4 and addresses the identified gaps. For example, the eighth conclusion in Chapter 4 states that the public does not know where, which, and when respiratory protective devices should be used. Therefore, the core function "Determine the necessary respiratory protective device" is an essential element of the framework. Similarly, the other core functions are designed to fill gaps identified in the conclusions presented in Chapters 2–4. As discussed above for the process steps shown in Figure 5-1, while the functions are ordered numerically, this is not intended to imply a specific sequence in which they must occur; the functions are dynamic, and their sequencing will be determined by the specific situation, with some occurring simultaneously.

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FIGURE 5-3 Core functions in the framework for oversight and guidance for respiratory protection.

Each of the functions has component functions, or subfunctions, as depicted in Figures 5-4 through 5-7. These subfunctions may be ongoing processes or may be triggered by a specific hazard (see Table 5-1). In the context of respiratory protection needs for emergencies, the ongoing subfunctions represent critical aspects of national preparedness.

Function F0 (see Figure 5-4) encompasses the continuous development and approval of respiratory protective devices as technologies evolve and needs and standards change. Its subfunctions are linked directly to the first three processes depicted in Figure 5-1. Within this function, new product development is informed by ongoing scenario planning, which considers both the range of potential hazardous agents for which respiratory protection may be needed and the heterogeneity of the population that may require respiratory protection. Product performance standards may

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TABLE 5-1 Ongoing and Event-Triggered Activities for Each of the Core Framework Functions

	Function	Preparedness (Ongoing) Activities	Postevent Activities
F6. Coordination	F0. Develop and Approve Respiratory Protective Devices	• Definition of respiratory protection requirements for different hazard use scenarios • Development of performance standards • Design and manufacturing of respiratory protective devices • Conformity assessment and approval	• See F2
	F1. Assess Hazard and Determine Need for Respiratory Protection	• Ongoing surveillance for inhalation hazards • Ongoing assessment of known hazards (e.g., dose-response, toxicity)	• Hazard-specific surveillance • Hazard and risk evaluation • Evaluation of the feasibility and availability of different control measures (e.g., engineering, administrative) • Determination of the need for use of respiratory protection
	F2. Determine the Necessary Respiratory Protective Devices	• See F0	• Identification of devices that meet protection requirements for the identified hazard • Evaluation of whether approved devices meet requirements • If no approved device meets requirements, identification of product for immediate use and triggering of product development (F0)
	F3. Ensure Availability and Access Pathways for Respiratory Protective Devices	• Stockpiling • Support for the manufacturing base • Establishment of access pathways and support for distribution capacity • Marketing and sales distribution	• Checking of stocks of devices meeting requirements • Triggering of production if needed (Defense Production Act [DPA], incentives) (F0) • Ensuring access to devices
	F4. Engage, Inform, and Ensure Access for the Target Community	• Ongoing education and training • Development and testing of guidance templates • Understanding of needs and concerns of stakeholders	• Warning on need to procure and use a respiratory protective device • Development and dissemination of hazard-specific guidance (which device, when and how to use it) • Testing and refinement of messaging
	F5. Incorporate Lifecycle Learning and Continuous Improvement	• Developing and updating plans with transparent milestones • Coordinating linkages across all stakeholders • Conducting periodic exercises to evaluate national respiratory protection preparedness	• Assessing and publicly reporting on progress • Ensuring funding and coordinating its allocation to achieve goals

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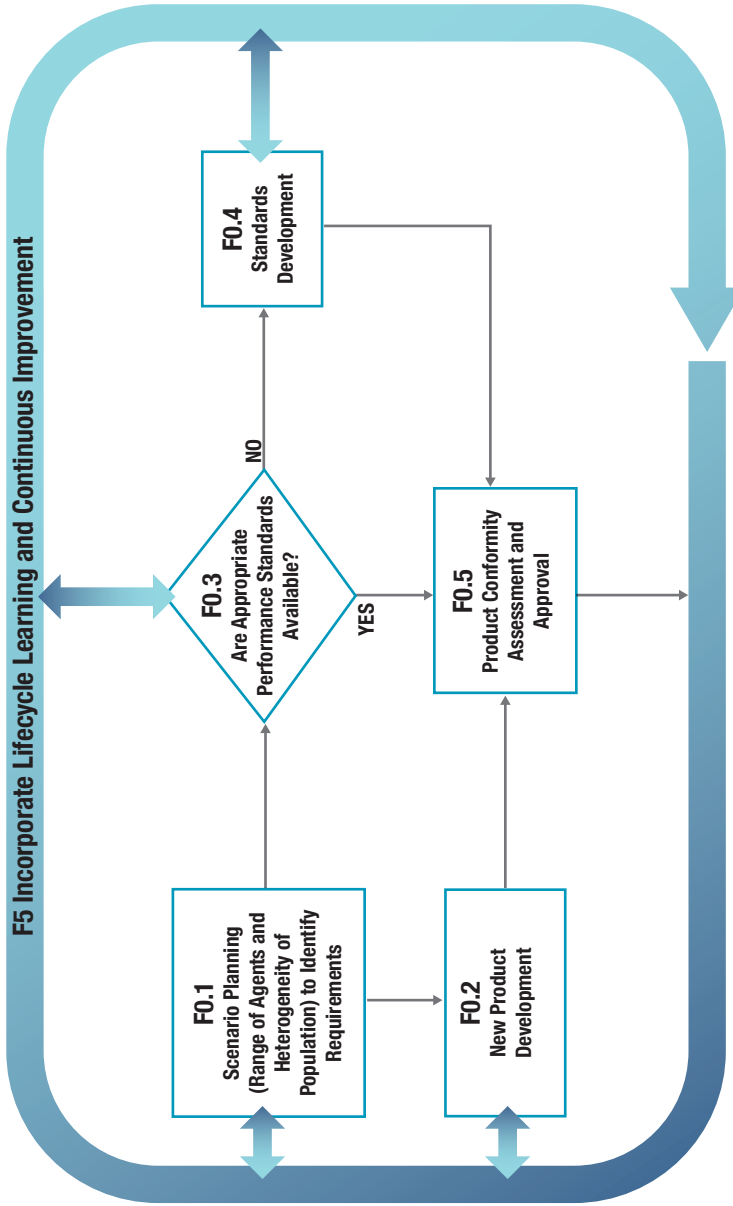


FIGURE 5-4 Function F0: subfunctions related to ongoing development and approval of respiratory protective devices.

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be developed or refined in response to such scenario planning and form the basis for the conformity assessment process on which product approval depends. Postmarket surveillance is an important element of the conformity assessment process, facilitating continuous improvement in the development of respiratory protective devices.

Function F1 (see Figure 5-5) encompasses the ongoing surveillance for and assessment of a hazard to determine whether there is a need for respiratory protection, considering first whether the hazard can be adequately mitigated through other measures higher in the hierarchy of controls, with consideration of the acceptability of the risk posed. In Function F2 (see Figure 5-6), the hazard assessment from Function F1 is used to determine the protective device that best meets the respiratory protection needs posed by the hazard, as determined by the type, risk, and duration of exposure; peak exposure concentration; degree of susceptibility; and feasibility of mitigating the exposure. This is a challenging task in the workplace, since "well-validated air sampling and analytic methods are not readily available" for infectious aerosols (Brosseau et al., 2021). The challenge is compounded in determining respiratory protection needs when the agent may be ubiquitous, such as the needs for the public exposed to infectious agents and workers engaged in fighting wildfires. Consequently, predicting the required characteristics of a respiratory protective device that needs to be effective in multiple environments posing difficult-to-characterize risks, such as SARS-CoV-2 or wildfire smoke, will necessitate effective tools, and such approaches as qualitative and computational methods (Kochenderfer, 2015) may be worth considering. Also to be considered are such user-centric factors as the usability of the device across different subgroups of the population.

Once the necessary level of protection (e.g., filtration efficiency) has been determined for the specific inhalation hazard of interest (e.g., SARS-CoV-2), the next subfunction is to determine whether an approved respiratory protective device with the required specifications exists in the marketplace (see Figure 5-6). For respirators for workers, this step might be carried out by utilizing NIOSH/NPPTL's Certified Equipment List (CEL)[22]—a tool designed "to help respirator users, safety managers, industrial hygienists, and others to determine if the respirator they are currently using or considering using is NIOSH-certified" (NIOSH, 2020). By enabling approved respiratory protective devices to be identified and ordered directly from their manufacturers, this function will also limit use of the counterfeits currently plaguing the supply chain and adversely affecting both manufacturers and users. As shown in Figure 5-6, once the availability of the

[22] NIOSH's CEL is available at https://wwwn.cdc.gov/niosh-cel (accessed September 28, 2021).

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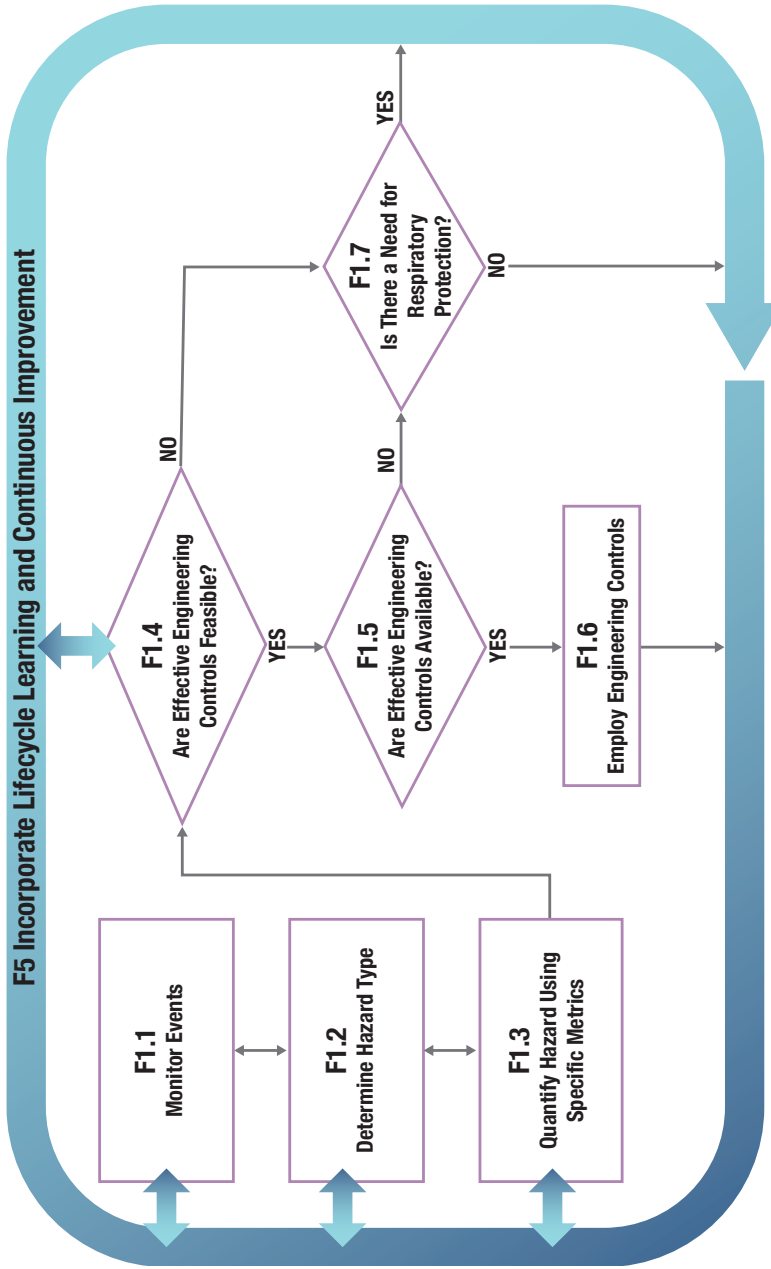


FIGURE 5-5 Function F1: subfunctions related to assessing a hazard and determining the need for respiratory protection.

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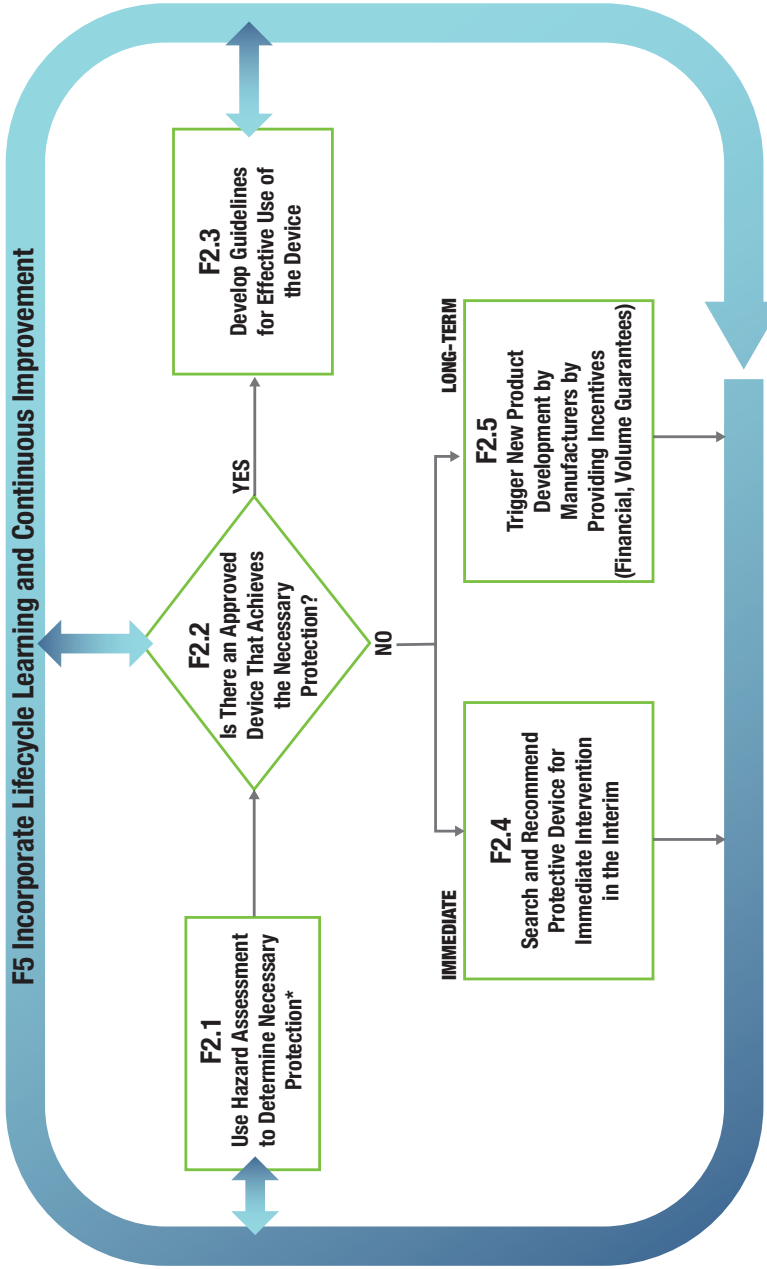


FIGURE 5-6 Function F2: subfunctions related to determining the necessary respiratory protective devices.
* Factors considered in determining the necessary protection include the type, risk, and duration of exposure; peak exposure concentration; degree of susceptibility; and feasibility of mitigating the exposure.

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desired respiratory protective device(s) is confirmed, the next subfunction is to develop guidelines for its effective use to address the specific inhalation hazard. These guidelines will then be used to tailor guidance for last-mile communication with the target community with regard to effectively addressing the inhalation hazard (Function F4).

If a device with the needed specifications does not exist, the framework triggers the design and development of a new product with the engagement of manufacturers (Function F0). One major concern of manufacturers is the inconsistent demand and absence of volume guarantees for products designed to meet specific needs that require large infrastructure investments for design, development, and manufacturing (McCullough, 2021). The framework therefore needs to incorporate mechanisms for incentivizing manufacturers to produce new products when needed and in sufficient quantity, as well as for incentivizing the development of an adequate market for these products. Since developing a new product will take time, the framework initiates efforts to rapidly find and recommend a respiratory protective device for immediate and interim use. This immediate solution of using the best available device while waiting for manufacturers to design and develop the required respiratory protective device for the specific hazard at hand may raise liability concerns for manufacturers. This issue can be addressed by such measures as that adopted for some respiratory protective devices during the COVID-19 pandemic—extension of liability protection to manufacturers and distributors by invoking and including such devices as covered countermeasures under the 2005 Public Readiness and Emergency Preparedness (PREP) Act (CRS, 2021).

If an approved device that meets the needs for the specific hazard at hand exists, availability needs to be ensured in terms of both supply and pathways by which end users can access the devices (see Function F3, Figure 5-7). Evaluation of supply can be accomplished by consulting with the devices' manufacturers and by checking the Strategic National Stockpile (SNS). Stockpiling is a critical ongoing subfunction within Function F3 for ensuring adequate supplies of respiratory protective devices during a large-scale emergency. While manufacturers may not share their inventory levels publicly for competitive reasons, the framework needs to include a mechanism for facilitating the confidential sharing of that information for purposes of further action.

If adequate inventory of the desired device is not available, the framework triggers two actions as shown in Figure 5-7. The first is short-term, and could include invoking the Defense Production Act (DPA) and providing incentives for manufacturers of the needed products, such as financial and volume guarantees. In the long term, a mechanism for developing a sustainable manufacturing base with surge capability is necessary to ensure adequate capacity and capability to produce and supply the necessary

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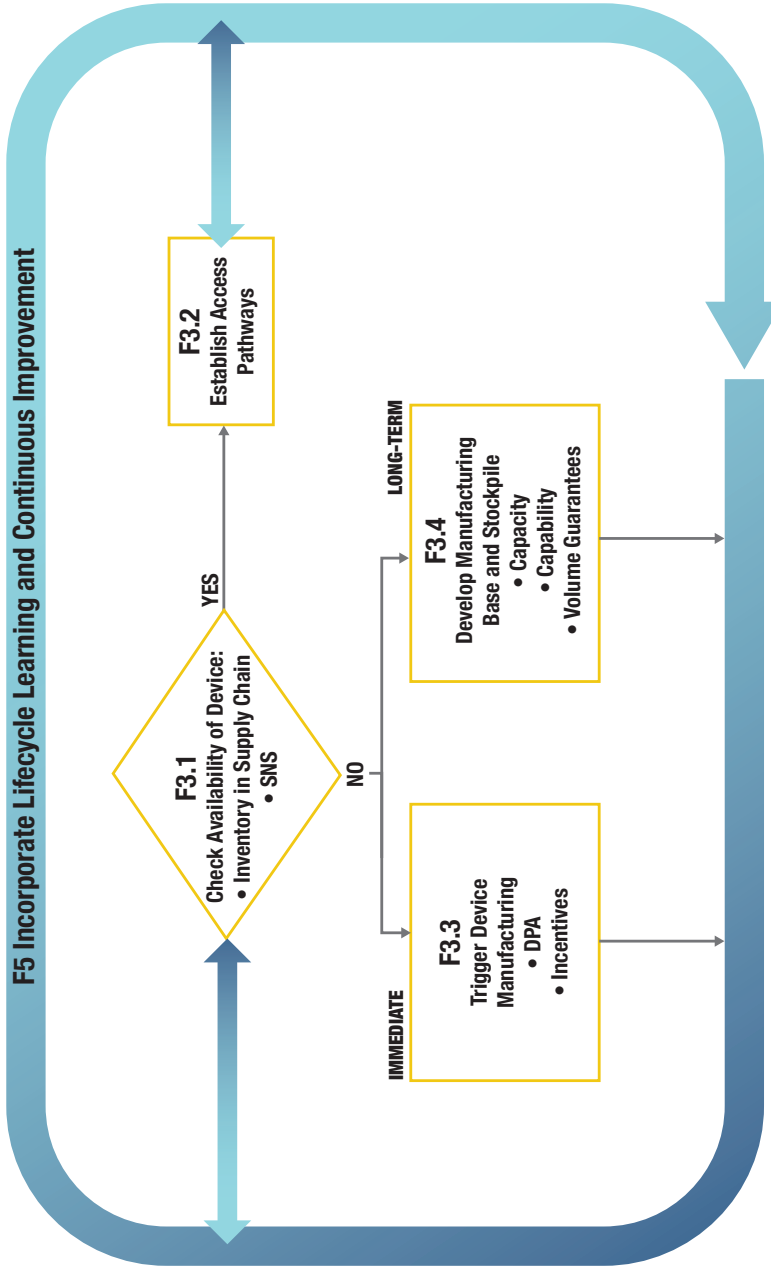


FIGURE 5-7 Function F3: subfunctions related to ensuring availability and access pathways for the respiratory protective devices.
NOTE: DPA = Defense Production Act; SNS = Strategic National Stockpile.

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devices. Public–private partnerships with delineated responsibilities and accountabilities will be needed to meet this need.

The next major function (F4) is to engage, inform, and ensure access for the target community (see Figure 5-8). The first step here is to develop guidance, which must be uniform, consistent, timely, and continuously updated as new facts emerge, especially in the event of an ongoing public health emergency. The guidelines developed under Function F2 with hazard-specific recommendations for a respiratory protective device serve as the foundation for the development of guidance for target audiences. The approach taken to this step needs to address the technical aspects of the recommended protection (e.g., which device, when and why to use it); how the target populations may react to the recommendations given local, cultural, and socioeconomic factors; and how the target populations will best be reached with accessible information. Therefore, as shown in Figure 5-8, the next step is to identify individuals and organizations that will be responsible for conducting the outreach and engaging the target population to communicate guidance on effective use of respiratory protection against the inhalation hazard in question. Engagement is not limited to the one-way dissemination of information; it is important that mechanisms for engaging with target audiences be bidirectional. Feedback mechanisms need to be developed and implemented to enhance the guidance documents and outcomes. Furthermore, guidance needs to be targeted specifically to the distinct audiences responsible for last-mile communication with users, such as employers, worker organizations, and medical and public health professionals. In turn, these stakeholders can use this guidance in tailoring their communications to reflect the characteristics of their target communities. Additionally, the approach taken in this step will need to facilitate direct communication with users. An important aspect of this function is continuously monitoring for and countering the spread of misinformation.

The next major function (F5) covers the ongoing learning and continuous improvement that is critical to catalyzing advances in each of the core functions and reflects the preparedness–response cycle. The dynamic nature of the continuously evolving framework is denoted by the bidirectional arrows connecting the other core functions to F5 in Figures 5-3 through 5-8. Periodic reporting on progress toward established goals and objectives serves as a mechanism for ensuring ongoing accountability and national preparedness for respiratory protection.

The final function (F6)—coordination—is at the heart of the framework as shown in Figure 5-3. It is the "glue" that binds the core functions and is critical to realizing the framework's ultimate goal. To carry out this essential function, a coordinating entity is needed, on an ongoing basis, to harness the domain-specific expertise of all stakeholders in respiratory protection in enhancing the nation's preparedness and providing an actionable

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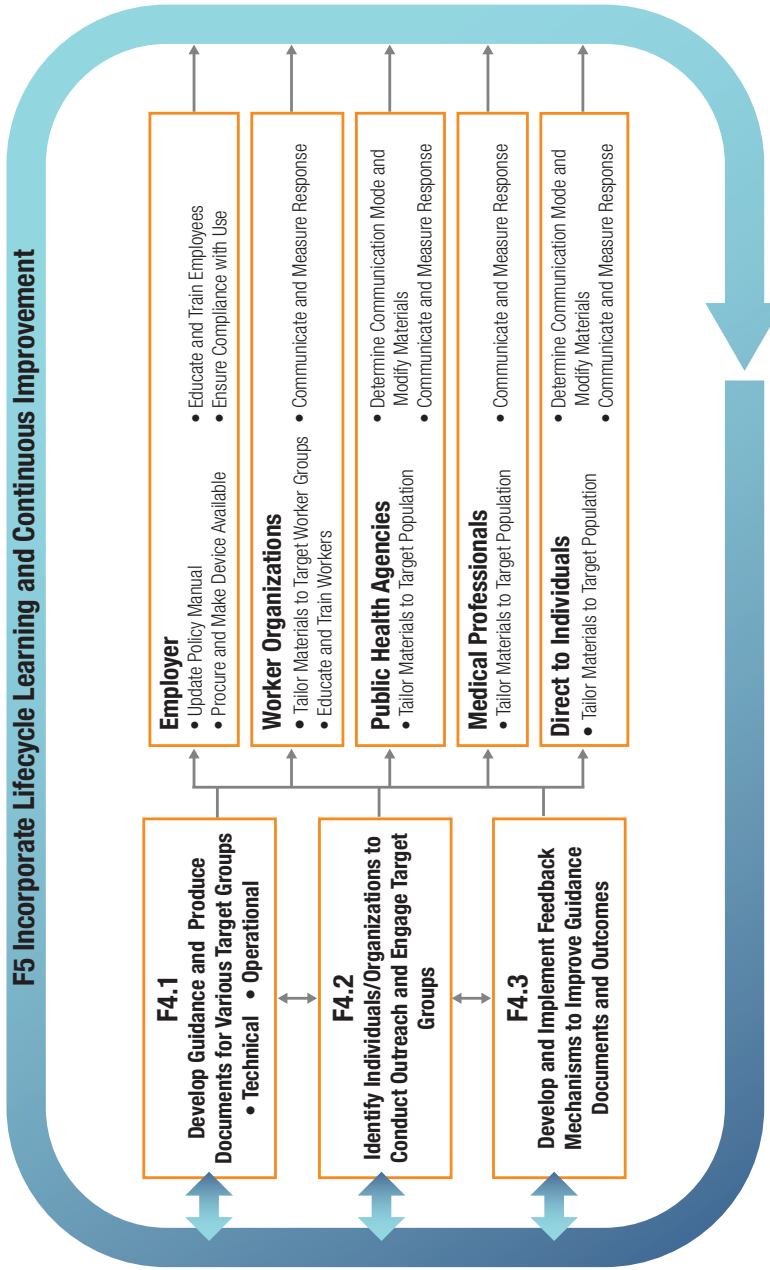


FIGURE 5-8 Function F4: subfunctions related to engaging, informing, and ensuring access for the target community via multiple stakeholders and pathways.

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response for workers not covered by RPPs and members of the public facing inhalation hazards.

Scope of the Coordination Function (F6): Current Stakeholder Authorities

The findings presented in Chapters 2 through 4 demonstrate that the existing system for the provision and oversight of respiratory protection for workers not covered by RPPs and the public is highly fragmented, and for the public, there are gaps in critical authorities, related in particular to conformity assessment and approval of respiratory protective devices. As depicted in Table 5-2, current stakeholders have jurisdictions that are tied

TABLE 5-2 Fragmentation of Governmental Stakeholder Responsibilities and Authorities Based on the Hazard Type and Exposure Context

	Workplace Exposures	Nonoccupational Exposures
Requirements for Respiratory Protective Devices	**Respirators** • National Institute for Occupational Safety and Health (NIOSH)/National Personal Protective Technology Laboratory (NPPTL) **Surgical/medical masks and some surgical respirators used in health care** • Food and Drug Administration (FDA) **Respirators used in mining** • Mine Safety and Health Administration (MSHA) and NIOSH	**Respiratory protective devices used for medical purposes, including source control** • FDA **Flammability requirements for face coverings** • Consumer Product Safety Commission (CPSC)
Requirements and Guidance on Use of Respiratory Protective Devices	• Occupational Safety and Health Administration (OSHA) **Mining** • MSHA **Pesticide handling** • Environmental Protection Agency (EPA) **Radiological inhalation hazards** • Department of Energy (DOE)	**Guidance for communicable and environmental hazards and requirements in limited situations** • Centers for Disease Control and Prevention (CDC) **Guidance for environmental hazards** • EPA **Guidance for emergency preparedness** • Federal Emergency Management Agency (FEMA) **Guidance for Americans abroad** • Department of State (DOS) **Guidance and requirements** • State, local, tribal and territorial government

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to the characteristics of the hazard at hand, the locus of exposure (i.e., whether the exposure occurs in an occupational or nonoccupational setting, in the United States or abroad), and the population exposed. This fragmentation and the lack of a cohesive national strategy for informing, educating, and providing guidance for workers without RPPs and the public as to how they can protect themselves from inhalation hazards highlight the need for a central, accountable entity to perform a coordinating function across the framework. Absent such an entity, the goal of providing respiratory protection for workers without RPPs and the public may not be met satisfactorily.

Potential Organizational Configurations of the Coordinating Entity (F6)

This section describes several potential models for a unified and authoritative coordinating entity, drawing on the reviews in Chapters 2 through 4 and other findings from the committee's information-gathering process. Such an entity or entities will be needed for both targets of this report, workers without RPPs and the public; the general considerations that follow are potentially applicable to both of these target groups. Note that the committee is not proposing here that a single entity should cover both groups, but offering a general discussion of options to set the stage for Chapters 6 and 7, wherein the specific considerations informing the preferred configuration for the coordinating entity for the worker and public frameworks, respectively, are discussed. The following discussion is thus conceptual and is not intended to designate roles for existing agencies or to describe the development of specific new entities.

The committee considered a range of configurations for a coordinating entity, from a single stand-alone entity—the centralized single-agency model—to a coalition of federal or possibly other agencies charged with accomplishing a specific operational goal—the interagency task force model. Between these two extremes of centralization, the committee considered a third configuration—the hub-and-spoke model—in which the coordinating entity would be empowered to harness and build on the expertise and experience of current stakeholders engaged in respiratory protection while having some degree of authority and the ability to remedy gaps. These three models, which are further described in the subsections below, are not necessarily mutually exclusive. It is possible that one model could be implemented initially and the architecture could later transition to another form as needs and conditions changed or new actions were taken, such as by Congress.

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The Centralized Single-Agency Model

In the centralized single-agency model, a single entity or agency would be tasked with carrying out all the activities included within Functions F0 through F5. To an extent, the combination of OSHA and NIOSH/NPPTL reflects this model for those workers currently covered by RPPs, although OSHA and NIOSH have separate designated roles and do not function as a single entity. Implementing such a model de novo would necessarily entail reassignment of some authorities away from entities currently holding them. As discussed earlier in this chapter and conveyed in Table 5-2, there are current stakeholders throughout the federal government and at the state and local levels associated with some of the framework's functions; these stakeholders harness the foundational knowledge and core competencies built over the years to carry out those activities. Building such core competencies in a new centralized agency would require significant investments in capacity building and entail a potentially lengthy timeframe. Moreover, reassigning responsibilities of current stakeholders or expanding their responsibilities and authorities could pose significant organizational, operational, and regulatory challenges and could impede successful realization of the centralized single-agency model. For example, the Environmental Protection Agency (EPA) holds responsibility for monitoring ambient air quality in partnership with states and municipalities. It fulfills this role adequately, and assigning it to a new centralized agency would not be useful. Furthermore, the establishment of a new federal agency or department would pose additional legislative challenges, such as requiring new legislation and/or appropriations from Congress, which could be time-consuming and politically fraught (Rowell, 2021).

In presenting the centralized single-agency model, the committee considers it a useful starting point for discussion while recognizing that it could not readily be imposed on existing structures, such as those currently overseeing the protection of workers from inhalation hazards. For the public, it is a potential approach.

The Interagency Task Force Model

At the other end of the continuum of centralization, a coalition of stakeholders could be charged with working collaboratively to serve as the coordinating entity. This same model could be used for carrying out specific functions on an ongoing or ad hoc basis. One advantage of the interagency task force model is the relative ease with which it could be established. The temporal/ad hoc nature of this model makes it suitable for narrowly scoped initiatives, such as the COVID-19 Health Equity Task Force, whose charge is "to identify and eliminate health and social disparities that result

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in disproportionately higher rates of exposure, illness, hospitalization and death related to COVID-19" (HHS, 2021a).

On the other hand, task forces that bring together multiple agencies face challenges that could impede their performance. According to the Government Accountability Office (GAO) (2010), these challenges include the following:

- Developing and implementing overarching strategies can be hindered by the lack of information on roles and responsibilities of organizations involved or coordination mechanisms. Additionally, incorporating information drawn from multiple sources poses challenges with respect to managing and integrating that information.
- Organizational differences, including differences in agencies' structures, planning processes, and funding sources, can hinder interagency collaboration. Agencies lack adequate coordination mechanisms to facilitate this collaboration during the planning and execution of programs and activities.
- Agencies involved in such a task force do not always have the right people with the right skills in the right jobs at the right time to meet the challenges they face, including having a workforce able to rapidly address crises. Moreover, agency performance management systems often do not recognize or reward interagency collaboration, and training is needed to understand other agencies' processes or cultures.

Additionally, in contrast with the mission of a transient interagency task force charged with carrying out an assigned task for a defined period of time and then disbanding, the activities associated with Functions F0 to F5 in the committee's framework must be carried out on a continuous basis by the stakeholders involved. This important requirement featured in the committee's deliberations on the interagency task force model as a potential model for the proposed coordinating entity. Additionally, empowerment and accountability within the task force model could be problematic.

The Hub-and-Spoke Model

This model moves away from the interagency task force model toward an empowered coordinating entity. In the hub-and-spoke model, the coordinating entity serves as the hub that is empowered to harness and build on the expertise and experience of current stakeholders engaged in respiratory protection for carrying out all the activities within Functions F0 through F5 (the spokes). However, issues could still arise in joint decision making

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under this model, such as when consensus among stakeholders cannot be achieved.

The committee found a precedent for such an architecture in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which "coordinates Federal efforts to enhance chemical, biological, radiological and nuclear threats (CBRN) and emerging infectious diseases (EID) preparedness from a medical countermeasure (MCM) perspective" (HHS, 2021b). The central hub in the PHEMCE is the Department of Health and Human Services' (HHS's) Office of the Assistant Secretary for Preparedness and Response (ASPR). Partner agencies include three HHS internal operating divisions—the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH)—as well as the Department of Defense (DoD), the Department of Veterans Affairs (VA), the Department of Homeland Security (DHS), and the U.S. Department of Agriculture (USDA). The PHEMCE also works closely with a variety of nonfederal partners, including state, local, tribal, and territorial governments; public health systems; academia; and private industry (ASPR, 2015). It focuses on the entire continuum from preparedness against potential threats to effective deployment of medical countermeasures should such threats eventuate. In adopting this broad and overarching concept of an "enterprise" and constituting a "core" group of agencies, the PHEMCE has a coordinating role, led by ASPR, with the authority and responsibility for achieving the overall mission while harnessing the strengths and capabilities of current organizations for the various activities necessary to realize its mission. For each mission component under the PHEMCE, a lead HHS agency with the necessary domain expertise and regulatory authority has been identified and assigned responsibility for that activity. For instance, ASPR is responsible for the "requirements setting" component, while FDA is responsible for "regulatory science management" (ASPR, 2015).

Thus, the PHEMCE provides a real-world example of a coordinating structure that could meet the need to address gaps in oversight related to respiratory protection. A coordinating structure with an architecture similar to that of the PHEMCE model could be well suited to drawing on the domain expertise, experience, and regulatory authority of the stakeholders enumerated in Table 5-2.

Successful Realization and Operation of the Coordinating Entity: The Essential Attributes

In considering the above three examples of potential architectures for a coordinating entity, the committee sought to identify essential attributes for the successful realization and operationalization of any such structure.

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Box 5-1 summarizes the key takeaway messages gathered from current and former federal officials during a public meeting held by the committee (see Appendix A), which capture factors critical to the success of the coordinating entity whether it be focused on workers or the public. First, it is essential to articulate clearly the policy goal or vision for the entity, which will need to be supported at the highest levels, potentially including the White House and the Congress, to empower and guide the coordinating entity in carrying out its activities. The success of the leadership for the coordinating entity would be defined by its ability to establish a strong culture of collaboration and partnerships with other stakeholders in the respiratory protection enterprise to harness their domain-specific expertise. To that end, it will be essential for the entity to have the necessary level of authority and leadership commitment. Resources—financial, human, and infrastructure—will also be critical to ensuring that the coordinating entity can carry out its functions. The coordinating entity will need as well to ensure that decision making is based on a strong science, engineering, and technology foundation that guides its operations; therefore, the entity will

BOX 5-1
Characteristics Essential to Success of the Coordinating Entity

- **Policy Goal:** Articulate a strong and shared policy goal up front. Empower the organization and individuals through support from the White House and Congress.
- **Leadership:** Identify a champion with a vision, authority, and commitment. Lead and drive the organization's operations, and establish the organizational culture.
- **Funding:** Ensure access to funds. Funding enables meaningful stakeholder engagement.
- **Partnership:** Work collaboratively with other organizations. Harness the domain-specific expertise in other organizations.
- **Decision-Making Processes Based on a Strong Science Foundation:** Perform knowledge management through collaborative research and development. Invest in addressing scientific knowledge gaps and implementing evidence-based activities focused on innovation and the future.
- **Strategic Structuring of Operations:** Solicit and build on perspectives of different stakeholders. Engage users, manufacturers, regulators, and research institutions.
- **Development-through-Implementation Lifecycle:** Address implementation as essential for success. Extend relationships from the federal to the state and local government levels where implementation occurs.
- **Clear Channel of Communication:** Build a unified, adaptive/responsive system. Develop messaging that is consistent, coordinated, and current throughout the system.

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need to support evidence-based activities focused on preparedness, innovation, and advances for the future.

It will be important for the coordinating entity's organizational structure to bring together different perspectives—e.g., product users and manufacturers, regulators, research institutions—in developing and implementing an overall strategy that encompasses the product lifecycle (see Figure 5-1) while embracing the guiding principles listed in Chapter 1. The entity will need to establish and sustain relationships at the federal, state, and local government levels so the developed policies, practices, and guidance can be seamlessly implemented to reach workers and the public. Well-defined channels of communication will be essential to complement these relationships so that the messaging is consistent, coordinated, current, and responsive at all stages of the information and implementation chain. These essential factors, along with regulatory, operational, and organizational considerations related to forming such an entity, need to be taken into account in considering different models for a coordinating entity.

Framework Requirements Concerning Diversity and Equity

As stated in Chapter 1, the committee believes strongly that its framework must incorporate equity as an overarching principle. This principle needs to be considered and addressed by the coordinating entity and other participants in the framework enterprise across each of the functions, as follows:

- **Function F0: Develop and approve respiratory protective devices.** Devices need to reflect the age range, gender, facial profiles, racial and ethnic diversity, and cognitive and physical abilities of potential users—both workers and the public.
- **Function F1: Assess hazard and determine need for respiratory protection.** Hazards need to be monitored with consideration of the range of exposures and the increased likelihood of exposures among certain groups.
- **Function F2: Determine the necessary respiratory protective devices.** Devices need to be available that match both the hazard and the populations that will use them, including their needs and resources.
- **Function F3: Ensure availability and access pathways for respiratory protective devices.** Access to devices needs to be ensured for all populations, addressing the challenges posed by some locations (e.g., rural areas subject to wildfire smoke, dense urban areas) and the socioeconomic status of subpopulations.

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- **Function F4: Engage, inform, and ensure access for the target community.** Strategies for reaching target communities and ensuring access to respiratory protective devices need to address diversity and local context in all dimensions of communication: modality, language, cultural appropriateness, and socioeconomic and educational background, for example. The challenge of communication needs to be considered prospectively to ensure preparedness.
- **Function F5: Incorporate lifecycle learning and continuous improvement.** This critical aspect of ensuring effective functioning of the framework needs to be sufficiently broad in its reach to provide information on major and high-risk subgroups.

Consistent with its overarching nature, the principle of equity is woven throughout the discussion of the frameworks for workers not covered by RPPs and the public in Chapters 6 and 7, respectively.

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6 Respiratory Protection Oversight and Guidance for Workers

The current system for respiratory protection for workers involves interactions among multiple parties in the private sector and is shaped by the regulatory activities of federal agencies, particularly the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA). This system, properly implemented, should ensure that employers provide respiratory protection for workers covered by respiratory protection programs (RPPs). As discussed in Chapters 2 and 3, however, there remain large numbers of workers who are exposed to inhalation hazards that increase their risk of illness but are not covered by these OSHA-mandated programs (or programs required by other federal agencies, such as the Mine Safety and Health Administration [MSHA], the Environmental Protection Agency [EPA], and the Department of Energy [DOE]). Self-employed workers and independent contractors, gig workers, some public-sector and farm workers, and unpaid (volunteer) workers fall outside OSHA's authority. As a result, for many workers and for many types of exposures (e.g., wildfire smoke and airborne infectious agents such as coronaviruses), there is no authority that requires provision of an RPP. Therefore, a system is needed to ensure that when inhalation hazards are present in the work environment, workers are provided with protection that is sufficient to eliminate or adequately reduce their exposure to prevent future disease. Given legislative limitations, the variability and uncertainty in risk estimates for emerging hazards, and the large numbers of workers potentially affected, the committee recognizes the challenges inherent in extending the current OSHA model to cover most workers.

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ENSURING ADEQUATE AUTHORITIES TO PROTECT WORKERS FROM INHALATION HAZARDS

The Occupational Safety and Health (OSH) Act of 1970 established OSHA within the Department of Labor, giving it substantial authority over regulation of the safety and health of many workplaces and respiratory protection for workers in those workplaces. The Act specifically applies to "employers," defining an employer as a "person engaged in a business affecting commerce who has employees," although this definition "does not include the United States (not including the United States Postal Service) or any State or political subdivision of a State."[1] Under the Act, states that choose to have their own occupational safety and health plans must cover state and local government agencies in those states, and states that are under federal jurisdiction may elect to have occupational safety and health plans for state and county workers not covered by the federal agency. Currently, 21 states and Puerto Rico have state plans covering private- and public-sector workers, and 5 states and the U.S. Virgin Islands have plans covering only state and local workers (OSHA, 2021). Meanwhile, both the OSH Act and Executive Order 12196 require federal agencies to be responsible for establishing and maintaining an occupational safety and health program that complies with the terms of the OSH Act.[2]

Similarly, the OSH Act extends protection to "employees," who are defined as: "an employee of an employer who is employed in a business of his employer which affects commerce."[3] As detailed in Chapter 2, OSHA has interpreted its authority under the OSH Act to exclude many contract workers, as well as unpaid volunteers, sole proprietors, family members of farm employees, domestic workers, and the self-employed. Under this interpretation, a business owner who uses contract labor may be largely outside the authority of OSHA.

Additionally, the OSH Act limits OSHA's authority in circumstances in which other federal agencies "exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."[4] In some cases, those agencies defer to OSHA standards for worker protection, including the Respiratory Protection Standard, but they are under no obligation to do so.

OSHA's workplace safety and health standards, most notably its Respiratory Protection Standard and regulations issued by other federal agencies, such as MSHA, EPA, and DOE, require employers to establish and

[1] 29 U.S.C. § 652.

[2] See https://www.archives.gov/federal-register/codification/executive-order/12196.html (accessed September 21, 2021).

[3] 29 U.S.C. § 652.

[4] 29 U.S.C. § 653(b)(1).

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implement an RPP for workplaces where respirators are necessary to protect the health of employees from known inhalation hazards. As discussed in Chapter 3, however, only a small percentage are covered by RPPs or by mandatory workplace safety standards addressing the use of respiratory protection. Consequently, in the face of novel or unanticipated threats, such as wildfire smoke or SARS-CoV-2, there is no preexisting foundation for ensuring adequate respiratory protection for most workers not covered by RPPs.

The committee examined other models of worker safety and health regulation around the world, particularly worker protection laws based on the legal concept of "duty of care" (Commission for Occupational Safety and Health, 2005). Under this system, the person or institution conducting a business has a primary duty of care to ensure the health and safety of everyone in the workplace, including visitors. Regulations are written to codify these duties and requirements, and their broad applicability encompasses everyone in the workplace.

The committee recognizes that Congress has the ability to expand OSHA's coverage of employers and workers to explicitly encompass many categories of workers currently excluded from that coverage and can enact legislation requiring that workers, as well as nonworkers, be provided appropriate respiratory protection in the workplace. Such congressional action is required to make needed and significant changes in OSHA authority and employer responsibility to ensure that protections are accessible and equitable. The categories of workers who could be covered under expanded definitions include unpaid volunteers, family members of farm employees, domestic workers in residential settings, gig workers, and many workers now categorized as independent contractors.

An appropriations provision passed annually by Congress since 1976 prohibits OSHA from any activity on farms with 10 or fewer nonfamily employees (OSHA, 2014), essentially turning small farms into OSHA-free zones. Elimination of this provision would be an important step toward improving respiratory protection for farm workers, a category of workers at greatly increased risk of exposure to wildfire smoke and SARS-CoV-2 (Lewnard et al., 2021; Riden et al., 2020).

Much more could be done by states as well to improve respiratory protection for workers not currently covered by an OSHA-compliant RPP. One clear gap in coverage comprises state and local public-sector workers in states in which private-sector employers are covered by federal OSHA. While Congress may not be able to expand federal OSHA coverage of these workers because of constitutional concerns, it could provide monetary incentives for states to create occupational safety and health plans for their own public-sector workers and disincentives for those who fail to do so. Such a step could help mitigate the equity issues that arise with

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state-by-state approaches to meeting workers' respiratory protection needs. States with OSHA programs that currently cover both private- and public-sector workers could also directly address gaps in coverage by passing legislation to expand the categories of workers covered by those programs, including the same categories cited above.

The committee observes that it is inconsistent as well as ineffective for the government to have rules that make an employer responsible for providing an RPP for some workers on its premises but not others, nor for nonworkers who are on its premises or nearby and whose health is directly impacted by the employer's actions.

As discussed in Chapter 2, OSHA's definitions of employer and employee are vague and circular, and the agency has substantial discretion to adopt broader definitions for both. Without waiting for congressional action, OSHA could reinterpret the types of workers covered under current law, potentially expanding coverage for categories of workers cited above, including unpaid volunteers, family members of farm employees, domestic workers in residential settings, and many workers now categorized as independent contractors.

The following two recommendations represent the committee's attempt to address the significant gaps in OSHA coverage, gaps that preclude the agency from requiring employers to provide respiratory protection for many millions of workers not currently covered by an OSHA-compliant RPP.

Recommendation 6-1: ***Ensure That Occupational Safety and Health Administration (OSHA) Respiratory Protection Requirements Apply to All Workers***

Congress should revise the Occupational Safety and Health (OSH) Act to clarify the definitions of employer and employee such that OSHA has the authority necessary to ensure respiratory protection for all types of workers, including all private-sector workers, over whom OSHA currently does not exercise its authority. Revised language in the Act should make clear that persons and entities conducting a business have a primary duty and thus are required to ensure, to the extent reasonably practicable, that the health of their workers—as well as that of other workers influenced or directed by the business, consumers, and the public—is not put at risk by inhalation hazards resulting from the business's activities. OSHA should have primary oversight responsibility for this requirement and should promulgate and enforce regulations accordingly. Where federal agencies other than the Department of Labor (DOL) have regulatory responsibilities to protect workers from inhalation hazards, OSHA should have oversight of those agencies'

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requirements and programs, which should meet minimum requirements set by OSHA.

Pending revisions to the OSH Act:

- **OSHA should adopt the broadest permissible interpretation of "employees" and "employers" under the act such that workers currently excluded based on existing interpretation, including individuals considered to be employees under other DOL statutes or regulations, are not excluded from respiratory protection requirements. If OSHA does not take action to this end within 1 year, the White House should direct OSHA to reconsider its interpretation of the statute.**
- **Congress should ensure that OSHA's respiratory protection requirements can be applied to and enforced for farms with 10 or fewer workers.**

Although Congress has made minor changes to the OSH Act in the 51 years since its enactment, there have been no substantive changes such as those the committee is recommending. The committee understands that there are difficulties entailed in taking what may be considered a radical step and that there are broader implications beyond respiratory protection for inhalation hazards; however, the evolving nature of the workforce and the hazards it faces, together with the identified gaps in coverage of workers under the current OSH Act, calls for such change. Attempts to close these gaps through administrative means would be difficult and potentially temporary (i.e., subject to reversion to a narrower interpretation) absent a statutory redefinition of OSHA's authority. Moreover, revision of the OSH Act would not address gaps in protection for state and local public-sector workers; action by state governments is needed to ensure respiratory protection for these workers.

Recommendation 6-2: ***Ensure Protection from Inhalation Hazards for Workers Not Covered by Federal or State Occupational Safety and Health Authorities***
Until and unless Congress acts to modify the Occupational Safety and Health (OSH) Act to ensure that the Occupational Safety and Health Administration's (OSHA's) respiratory protection requirements apply to all private-sector employers and workers facing inhalation hazards, or OSHA expands its definitions of employer and employee to cover all private-sector workers, states should require employers to protect workers who are not currently under OSHA jurisdiction from inhalation hazards through the passage of new laws or promulgation of new regulations.

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In those states with their own occupational safety and health programs, coverage should be expanded to include these additional employers and workers not currently covered by the OSH Act. In those states without their own occupational safety and health programs, state legislatures should create such programs to provide better workplace protections from inhalation hazards for the state's public-sector workers. Furthermore, for those inhalation hazards for which federal OSHA has no standards, all state legislatures should enact requirements for their states to develop appropriate protections from inhalation hazards for all workers employed in the state and authorize their state occupational safety and health programs, including those newly created, to enforce these requirements.

MEETING WORKER NEEDS: APPLICATION OF THE COMMITTEE'S FRAMEWORK

Chapter 5 introduces the committee's general framework for respiratory protection for workers not covered by RPPs and the public. The overall system described by this general framework comprises seven functions necessary to ensuring access to and appropriate use of respiratory protection when needed. This section details how the current system for workers covers each of these functions and the steps necessary to implement a framework targeted specifically to workers not covered by RPPs in order to fulfill each function. Several components of the current system that involves OSHA and NIOSH through the National Personal Protective Technology Laboratory (NPPTL) correspond to the committee's general framework, but gaps in this system with respect to workers not covered by RPPs (described in Chapter 3) need to be addressed. To that end, the committee considers that the current arrangement could function more broadly. One critical element toward success for a framework targeting workers currently not within OSHA's purview, pending adoption of the above recommendation, would be designating OSHA, in collaboration with NIOSH, as the overall coordinating entity to oversee the functions of the committee's general framework.

Function F0: Develop and Approve Respiratory Protective Devices

In the context of worker health, a NIOSH-approved respirator is currently the only appropriate respiratory protective device for protecting workers facing inhalation hazards. Development and approval of respirators in the United States involves a partnership between the private and public sectors. Private companies conduct research, develop new products,

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manufacture those products, and distribute them to users. Manufacturers design their products to comply with performance standards established by regulation, conduct premarket testing to applicable standards and regulations, and continually test their products as part of their quality management processes. NIOSH conducts research and conformity assessment for respirators, and OSHA and MSHA require employers to select only those devices approved by NIOSH. Both private and public entities participate in standards setting through consensus standards bodies such as the American National Standards Institute (ANSI), ASTM, and the National Fire Protection Association (NFPA), as well as through participation in the rulemaking process for government standards. The committee has concluded that additional research (see Recommendation 6-8 under Function 5) and increased coordination between public- and private-sector entities are needed to ensure the development of respirators that address the respiratory protection needs of workers who are not currently covered by OSHA-mandated RPPs and who face a diverse group of hazards. Under the committee's proposed framework for these workers, NIOSH would be responsible for applying the findings of this research to ensure the applicability of its standards for respirators. In response to these new requirements, private firms would design and develop appropriate respirators for different exposure circumstances and worker populations.

As the oversight entity for respirator conformity assessment[5] in the United States (i.e., the scheme owner), NIOSH has responsibilities that include product testing in its laboratories, evaluation of manufacturers' quality control management systems, periodic testing of products being offered in the marketplace, and inspection of manufacturing facilities. NIOSH provides a certification mark for those respirators that meet its requirements and maintains a listing of those respirators that are approved for users and purchasers. Importantly, there has been a recent expansion of the manufacture and use of devices (i.e., nonmedical masks and face coverings) that are not used within RPPs and do not fit within NIOSH's current conformity assessment activities (NIOSH, 2021). There is no formal government certification or approval of these devices.

Because NIOSH's testing standards for various types of respirators are contained in regulation, establishment of new or revision of current standards must go through rulemaking, including publication in the *Federal Register* and the process of soliciting and receiving public comments. This method has at times proven to be inefficient, with the potential to result in substantial delays in advancing necessary standards (IOM and NRC, 2008).

[5] Conformity assessment is the demonstration that a product meets specified requirements. Conformity assessment can verify that a particular product meets a given level of quality or safety.

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The National Technology Transfer and Advancement Act directs federal agencies to adopt voluntary consensus standards wherever possible (avoiding the development of unique government standards) and establishes reporting requirements.[6] The Food and Drug Administration (FDA) relies on consensus standards when clearing medical masks for sale. Consensus standards and test methods are incorporated by reference in the 42 C.F.R. § 84 regulations, and NIOSH participates in committees that develop consensus standards. For example, following an unsuccessful attempt to incorporate total inward leakage testing into its regulatory standard for air purifying respirators, NIOSH took a leadership role in the development of the ASTM voluntary standard F3407-20 for respirator fit capability testing (Coffey and Miller, 2019). However, this ASTM standard does not affect respirator certification requirements as it was not promulgated through the NIOSH regulations.

NIOSH conducts all testing of respirators for certification. This testing is carried out by NIOSH personnel at NPPTL. No alternative laboratory is available in case of a disruption caused by a malfunction of equipment or problem with the facility (e.g., flood or fire). The requirement for NIOSH testing of respirators contributes to delays in the approval process and may make it difficult to respond to emergency situations. Moreover, the committee expects that NIOSH's responsibilities and associated capabilities in this area will need to expand in response to increased needs for research addressing respiratory protection for new groups of workers. To ensure the capacity to respond to this increased need under the committee's proposed framework, the agency could incorporate into its respirator approval program a third-party laboratory testing process, an approach used in other conformity assessment programs outside of respiratory protection (RTI International, 2014). Challenges are involved in such an approach, including ensuring the competency of third-party laboratories to conduct suitable tests and establishing a system for evaluating and confirming these laboratories' test results. The director of NPPTL has confirmed that NIOSH is actively exploring ways in which it could incorporate the use of independent third-party laboratories into its respirator approval program.

Recommendation 6-3: ***Improve the Timeliness and Capacity of the National Institute for Occupational Safety and Health's (NIOSH's) Respirator Conformity Assessment Processes***

NIOSH should expand its National Personal Protective Technology Laboratory to improve the timeliness and surge capacity of its respirator conformity assessment processes. In doing so, NIOSH should (1) use recognized consensus standards where appropriate, and (2)

[6] U.S.C. § 3701—National Technology Transfer and Advancement Act.

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incorporate third-party laboratory testing into its respirator approval program.

As with the current system, the committee envisions that NIOSH would continue to oversee conformity assessment, and respirators tested by third-party organizations would still require NIOSH approval to be used in OSHA-compliant RPPs. Additional appropriated funding from Congress will be necessary for the expansion of NIOSH/NPPTL's respirator approval program to meet the needs of a broader group of workers.

Function F1: Assess Hazard and Determine Need for Respiratory Protection

Under the current system for occupational safety and health in the United States, employers are required to determine the need for respiratory protection, and must comply with standards issued by OSHA (or other agencies with regulatory authorities, such as EPA and MSHA). However, OSHA does not require employers to provide an RPP in all contexts in which inhalation hazards are present. In the absence of a recognized inhalation hazard, OSHA does not require employers to conduct monitoring (e.g., air sampling) that could result in the identification of a hazard and the requirement to implement an RPP, and many likely do not do so in order to avoid having to initiate such a program.

OSHA does have hazard-specific comprehensive standards that require employers to follow the hierarchy of controls to limit workers' exposure, and in many cases, the use of respirators will be necessary to maintain exposure levels at or below the permissible exposure level (PEL), which is one element of the standard. Absent a comprehensive standard, OSHA has PELs for a number of chemical exposures (Howard, 2005) that do not require application of the hierarchy of controls, and employers are obligated to initiate an RPP only if they conduct an assessment and determine that such a program is necessary (Ryan, 2001). Despite these regulatory limitations, the committee firmly supports use of the hierarchy of controls for emerging hazards and encourages research to reduce the need for respiratory protection wherever possible.

The respiratory protection needs of workers not covered by OSHA-mandated RPPs may also be addressed in nonenforceable guidance documents issued by OSHA, NIOSH (e.g., recommended exposure limits), and other agencies. While OSHA and NIOSH have produced these sorts of documents, the current landscape calls for the issuance of more comprehensive guidelines.

Under the committee's proposed framework, employers, including those whose employees generally do not require respiratory protection to

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carry out their job duties, would monitor situations in which workers are exposed to inhalation hazards, examining and quantifying the hazards and associated risks. In cases in which effective engineering or administrative controls were not feasible or available, employers would evaluate the need for their workers to use respirators.

As noted in Chapter 2, most workers are not covered by an RPP or by mandatory workplace safety standards addressing the use of respiratory protection. Yet recent experiences with novel and unanticipated threats, such as wildfire smoke and SARS-CoV-2, indicate the potential need to introduce respiratory protection measures at an expanded number of worksites when inhalation hazards exist and other control measures are not feasible. The absence of an OSHA standard for airborne infectious disease agents and the outdated nature of the existing standard under which particulate matter (PM) is covered, as discussed further below, impede efforts to institute respiratory protection measures systematically when workers are exposed to such hazards.

One approach to addressing this gap is for OSHA to modify its respiratory protection regulations to expand the types of exposures and circumstances in which workers in establishments that fall under its authority are enrolled in RPPs. For example, OSHA's recognition of additional inhalation hazards as significant through investment in additional hazard identification would trigger employers' responsibilities under the OSH Act's General Duty Clause, which requires them to furnish their employees with "employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to [their] employees."[7] As noted below, this approach is consistent with current Supreme Court precedent as long as OSHA finds that workers face a significant risk from respiratory hazard(s).[8] This approach could have been applied during the COVID-19 pandemic, for example, when OSHA could have required that employers in high-risk workplaces other than health care settings implement RPPs and provide workers with appropriate respirators. However, absent other changes in how "employees" are defined, expansion of RPP requirements under current law would not include volunteers, gig workers, independent contractors, and other workers not covered by OSHA.

OSHA has both the statutory authority to implement new RPP requirements when inhalation hazards pose a "significant risk" to workers under its authority—including when those risks are periodic in nature—and the

[7] 29 U.S.C. § 654(a)(1).

[8] OSHA is authorized to promulgate health and safety standards in the workplace only after it has satisfied the requirement for a threshold finding that "a significant risk" of material health impairment exists. This requirement flows from an influential Supreme Court case, *Industrial Union Department v. American Petroleum Institute* (generally called the "Benzene decision") 448 U.S. 607 (1980).

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expertise to guide employers in implementing such requirements. States including California, Washington, and Oregon have recently introduced standards for workers exposed to wildfire smoke that include triggers for RPP requirements based on Air Quality Index levels for $PM_{2.5}$ (Cal/OSHA, 2021; Oregon OSHA, 2021; Washington State DOLI, 2021), while several state-level emergency temporary standards for COVID-19 prevention include RPP requirements if certain exposure thresholds are met (Oregon OSHA, 2020). California's Aerosol Transmissible Diseases standard further requires use of respiratory protection when workers are exposed to novel pathogens for which airborne transmission cannot be ruled out, thereby adopting a precautionary approach when scientific evidence is lacking.[9] Working with states that have already promulgated such standards and building on those examples, OSHA could address the need for national-level standards for PM and airborne infectious disease agents. However, the federal OSHA standards-setting process is slow and cumbersome (Howard, 2005), and it would not be easy for OSHA to issue standards of this type. During the HIV/AIDS crisis, Congress facilitated the prompter issuance of OSHA standards by legislating deadlines; this approach was implemented in the Needlestick Safety and Prevention Act,[10] which directed OSHA to strengthen its existing Bloodborne Pathogens Standard to incorporate the hierarchy of controls (Foley, 2004). Further research on both the health risks of various respiratory exposures and the effectiveness of existing standards would help guide OSHA in implementing new requirements that would adequately protect worker groups currently not covered by RPPs (see Recommendations 6-8 and 6-9 under Function 5).

In circumstances in which employees are exposed to "grave danger from exposure," and improved respiratory protection is "necessary" to reduce the danger, OSHA is also authorized to require additional respiratory protection by issuing an Emergency Temporary Standard (ETS).[11] OSHA used this authority to issue the mini RPP for health care workers as part of its 2021 ETS for COVID-19.[12] Such an approach may be useful in emergency circumstances when increased respiratory protection is needed for emergent dangers, including situations involving wildfire smoke or airborne pathogens such as SARS-CoV-2. However, the protection offered by an ETS is temporary, and must generally proceed to additional rulemaking procedures. In addition, where this approach is used to adopt modified or less comprehensive (or expensive) RPPs, as with the COVID-19 ETS, it is

[9] Cal. Civ. Code § 5199 Aerosol Transmissible Diseases.

[10] *Needlestick Safety and Prevention Act*, Public Law 106-430.

[11] 29 U.S.C. § 655(c).

[12] See C.F.R. § 1910.504—Mini Respiratory Protection Program; https://osha.gov/laws-regs/regulations/standardnumber/1910/1910.504 (accessed October 3, 2021).

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important to understand the impact of dropping or modifying some of the required RPP components, including medical examinations; fit testing; and training in, among other areas, care and maintenance of the respirator. Information on the fit characteristics of respirators when used outside of an RPP would be useful as approaches such as that of the mini RPP are considered. Important as well would be to conduct appropriate research to develop respirators that would address any current deficiencies.

Recommendation 6-4: ***Establish Comprehensive Workplace Exposure Standards That Serve to Trigger Respiratory Protection Program Requirements***

The Occupational Safety and Health Administration (OSHA) should establish and regularly update science-based, comprehensive workplace exposure standards for particulate matter (PM) indicators (e.g., from wildfire smoke), as well as airborne infectious disease agents, that would trigger respiratory protection program requirements, including for those workplaces in which respirators would not otherwise be required. To assist employers in meeting these requirements, OSHA should expand its technical assistance capabilities and efforts in this area. Given the urgency of the respiratory protection needs of workers facing these and other inhalation hazards, Congress should set deadlines for OSHA's promulgation of these standards. In the interim, OSHA, in conjunction with NIOSH, should develop comprehensive guidelines, including the use of NIOSH-approved respirators, for workers who are at high risk of exposure to these hazards.

OSHA currently covers exposure to PM that is not included in hazard-specific standards such as that for crystalline silica through the Permissible Exposure Limit for Particulates Not Otherwise Regulated (PNOR), also known as the "nuisance dust" standard. The PNOR PEL averaged over 8 hours is 15 mg/m^3 (measured as total particulate) and 5 mg/m^3 (measured as the respirable fraction) (NIOSH, 2011).

Of note, the 24-hour National Ambient Air Quality Standard (NAAQS) for fine PM ($PM_{2.5}$) of 35 µg/m^3 (CRS, 2013) is orders of magnitude less than the PNOR PEL. OSHA's PNOR PEL far exceeds levels EPA considers hazardous to human health on the Air Quality Index, and levels shown to result in increased morbidity and mortality during wildfire smoke events (Adetona et al., 2016; Doubleday et al., 2020; Reid et al., 2016; Rice et al., 2021). Thus the current PNOR PEL does not provide adequate protection for workers exposed to wildfire smoke.

With Recommendation 6-4, the committee proposes that OSHA issue a new evidence-based PM standard with more health-relevant indicators and greater protection to replace the legacy standard of 5 mg/m^3. The

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outdated nature of OSHA's current PEL underscores the need for regular review and updating of the standards. Also important in the development of science-based standards is consideration of the appropriate PM indicator. As discussed in Chapter 1, PM includes particles of varying sizes, and particle size has implications for deposition in the respiratory tract and associated health effects.

While Recommendation 6-4 focuses on PM and airborne infectious disease agents as high-priority targets for comprehensive exposure standards, the committee recognizes that standards for many other inhalation hazards faced by workers are outdated or lacking. Protecting workers without RPPs from inhalation hazards will require a more expansive effort to establish or update workplace exposure standards. Given its scope, OSHA will need to explore creative approaches to undertaking such an effort effectively and efficiently and, where feasible, without regulation. Given the challenges involved in implementing such approaches, consideration could be given to the potential application of modern technologies and advances in qualitative methods, such as control banding (NIOSH, 2013; Sietsema et al., 2019), which have been incorporated into regulatory systems outside the United States[13] and provide an alternative to establishing quantitative exposure limits and setting standards on a contaminant-by-contaminant basis.

Function F2: Determine the Necessary Respiratory Protective Devices

Currently, OSHA, NIOSH, and other agencies may provide recommendations for use of respirators by workers not covered by RPPs, although there is no system in place to ensure that these recommendations are issued or updated. Under the committee's proposed framework, employers, following any relevant OSHA standards and regulations, would be responsible for determining which approved respirator should be used by workers exposed to the hazard in question and under what circumstances. This determination would need to be based on completed or ongoing hazard assessments, taking into account the specific characteristics of the exposures and workplaces, as well as the exposed workers.

As discussed in Chapter 2, in 2021 NIOSH issued interim guidance with criteria for Workplace Performance and Workplace Performance Plus masks (NIOSH, 2021). The new NIOSH criteria, which build upon the ASTM F3502-21 standard for barrier face coverings, were intended to guide the manufacture of devices that can help protect people in the workplace from SARS-CoV-2. However, based on a review of the literature on the performance of face coverings, medical masks, and respirators (see Appendix B), the committee believes the filtration and fit characteristics of

[13] See, for example, the Canadian Respiratory Protection Standard CAN/CSA-Z94.4-18.

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face coverings and masks currently do not adequately protect workers facing inhalation hazards, including fine inhalable particles ($PM_{2.5}$ or smaller) or the tiny aerosol particles through which SARs-COV-2 and influenza are transmitted. Therefore, in the context of workplace exposures to inhalation hazards, recommendations regarding the use of face coverings (including barrier face coverings) and masks should be avoided, and employers should be advised to institute an RPP and provide employees with respirators, as described by OSHA's Respiratory Protection Standard (1910.134). As innovation drives advances in technology, evaluations by NIOSH will be needed to determine whether respiratory protective devices other than respirators might be appropriate for use by workers facing inhalation hazards in the future. The committee expects that implementation of its framework would result in maintenance and distribution of an adequate national supply of NIOSH-approved respirators. If shortages did occur, OSHA and NIOSH would need to recommend alternatives.

Recommendation 6-5: ***Recommend Only National Institute for Occupational Safety and Health (NIOSH)-Approved Respirators in Guidance for Workers Facing Inhalation Hazards***
When other forms of control (e.g., engineering, administrative) fail to protect workers from inhalation hazards, the Occupational Safety and Health Administration and other agencies with authority over worker safety (e.g., Environmental Protection Agency, Mine Safety and Health Administration, Department of Energy) require that only NIOSH-approved respirators be selected. Other agencies that provide guidance for workers facing inhalation hazards but lack this specific regulatory authority should recommend that only NIOSH-approved respirators be used.

Function F3: Ensure Availability and Access Pathways for Respiratory Protective Devices

The COVID-19 pandemic exposed severe limitations in existing supply chains for all forms of respirators, ranging from disposable N95 filtering facepiece respirators (FFRs) to reusable elastomeric facepiece respirators and powered air-purifying respirators (PAPRs). The shortage of NIOSH-approved N95 FFRs early in the COVID-19 pandemic contributed to the lack of adequate protection for many health care (Grimm, 2020; Mason and Friese, 2020) and other workers who require respirators to conduct their job duties safely (EPA, 2020), necessitating the implementation of contingency and crisis strategies (Andrews et al., 2021; de Perio et al., 2020). Market limitations also reduce manufacturers' interest in developing and

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marketing new respiratory protective products absent government regulation or guaranteed purchase (Patel et al., 2017). For example, although the needs of wildland firefighters have been assessed, and NIOSH worked with the NFPA to develop requirements for respiratory protection a decade ago, no manufacturer has produced a commercially available respirator meeting the requirements of NFPA 1984 (NASEM, 2021). NIOSH recognizes this gap in its Research to Practice portfolio, but would benefit from the additional purchasing power of other federal agencies (Watney, 2020), such as the Department of Defense, the Veterans Health Administration, the U.S. Department of Agriculture, the Department of the Interior, and EPA.

While the nation does have a system for stockpiling respirators, medical masks, and other materials needed for pandemic response (NASEM, 2016), the COVID-19 experience has shown that this system is not currently functioning adequately. The Strategic National Stockpile (SNS) was designed to supplement state and local jurisdictions during emergencies (NASEM, 2016). However, given its resource limitations and the inevitable delay associated with distribution of stockpiled materials, employers whose workers require respiratory protection, including health care and long-term care institutions, need to ensure access to sufficient stocks of those devices on an ongoing basis to meet worker needs (Yarbrough et al., 2016), taking storage requirements into account. Reusable devices, such as elastomeric facepiece respirators, may reduce the numbers of devices organizations need to stock in preparation for an emergency (NASEM, 2019) and could be a particular consideration for health care organizations in light of the lessons learned from the COVID-19 pandemic.

Expansion of OSHA's respiratory protection requirements to a much broader population of workers (Recommendations 6-1 and 6-4) is likely to bring new challenges to ensuring adequate availability of and access to respirators, particularly during such large-scale events as a pandemic. The nature of the needs of this broader group of workers may differ from those of workers traditionally covered by OSHA-mandated RPPs. Beyond the obvious issue of scale, for example, the timing of the need for respiratory protection may be more unpredictable. Under the proposed framework, OSHA would need to work closely with employers, recommending appropriate quantities and characteristics of respirators to stock, to ensure that workplaces would not experience these same shortages during future emergencies. This determination would be informed by the ongoing hazard assessments discussed above. OSHA and NIOSH would also need to collaborate with federal authorities responsible for the supply chain to aid in understanding the potential scope of respiratory protection needs for workers during a large-scale incident involving inhalation hazards.

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Recommendation 6-6: *Prepare to Meet Expanded Worker Respiratory Protection Needs*

The Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health should undertake an evaluation to understand and predict the potential scope of the increased need for respiratory protection associated with the expansion of worker coverage and the risk of future large-scale incidents or situations involving inhalation hazards (environmental and infectious agents). This information should be shared with the Office of the Assistant Secretary for Preparedness and Response and other relevant federal authorities to inform stockpiling and distribution guidelines regarding respiratory protective devices.

Function F4: Engage, Inform, and Ensure Access for the Target Community

With the establishment of OSHA's workplace exposure standards for wildfire smoke, $PM_{2.5}$, and airborne infectious diseases that would trigger RPP requirements (Recommendation 6-4), as well as the expansion of OSHA oversight to a broader group of workers (Recommendation 6-1), employers (especially those running small businesses) and others would likely need assistance in assessing inhalation hazards and facilitating the selection of and training on appropriate respirators. Consequently, as described in Recommendation 6-4, OSHA would need to increase its technical assistance activities aimed at this now expanded group of employers and workers, including those not currently under its authority. For incidents involving airborne transmissible diseases or high levels of air pollution, including wildfire smoke, the coordinating entity for the committee's framework for the public (as discussed in Chapter 5 and further described in Chapter 7), in consultation with OSHA and NIOSH, would issue warnings to the public (including employers and workers) based on ongoing hazard assessment and surveillance data, with OSHA disseminating information specific to workplace exposures. OSHA would ensure that guidance documents were produced, adapted, and disseminated for a wide range of additional stakeholders. These materials would be tailored to state and local public health agencies, health care professionals, employers, worker organizations, and workers, with a particular focus on those who are currently vulnerable and underserved. These two agencies would also specifically target employers and workers who were not under formal OSHA jurisdiction but needed exposure-specific RPPs.

As described in Chapter 3, OSHA and MSHA, along with NIOSH, other units within the Centers for Disease Control and Prevention (CDC), and other federal agencies (e.g., EPA, the National Institute of Environmental

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Health Sciences [NIEHS]) produce and disseminate guidance and other materials related to respiratory protection, written primarily for employers, worker organizations, and workers. However, this broad information, often distributed through government websites, may not be adequately accessible to the diverse workers who may need to use respirators to protect against inhalation hazards. To fill this gap, a number of labor, academic, and nonprofit groups have created materials designed for specific worker populations (PERC, 2017; WCAHS, 2021). However, such efforts are fragmented and ad hoc. Expanded efforts by OSHA, NIOSH, and other relevant federal agencies are needed to ensure that guidance and training on the use of respiratory protection meet the needs of workers, particularly those who may be incidentally exposed to inhalation hazards while carrying out their work (i.e., those whose work itself does not generally pose a threat from inhalation hazards but may in certain situations, such as wildfires) and whose employers have not established an RPP. Engaging labor, academia, and nonprofit groups already working closely with specific worker populations in these efforts would help ensure that materials are designed in collaboration with, meet the needs of, and are provided to workers, particularly those in difficult-to-reach settings who are most vulnerable, including those not currently under OSHA's jurisdiction.

Recommendation 6-7: ***Support the Development of Targeted and Tailored Guidance and Training for Workers***

The National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, the Environmental Protection Agency, the National Institute of Environmental Health Sciences, and other relevant federal agencies should expand grant programs and other support mechanisms to facilitate the translation of existing technical information on respiratory protection into tailored and culturally appropriate guidance and training materials designed for workers, particularly those who may be using respirators outside of a respiratory protection program. These agencies should recognize the administrative structures and power dynamics, local contexts, and psychosocial and political factors that influence uptake, and increase their support mechanisms to ensure the training of more workers, including those from diverse communities that otherwise might not be reached through training programs. To this end, these support mechanisms should be targeted to those institutions and organizations (e.g., labor organizations, worker centers, nonprofits, academic research centers) that have established relationships and regularly interface with end-user groups.

To be effective, training programs need to be based on best practices for training development, and be competency based, scalable, and accessible.

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Established competencies from the funding organization help ensure message consistency while allowing flexibility for tailoring materials to different populations. OSHA's Susan Harwood Training Grant Program[14] and NIEHS's Worker Training Program (NIEHS, 2018) are examples of mechanisms that could be leveraged, and both have generated documents describing training best practices[15] that include the importance of using approaches targeted to the specific language and literacy needs of the intended audience, activity focused, and competency driven to meet the particular needs of adult learners. The development of training programs for workers proposed in Recommendation 6-7 would benefit from expertise in all relevant fields, including, but not limited to, adult education methods, instructional design, human factors engineering, and cognitive engineering. Other models for reaching vulnerable groups should also be considered, including use of community health workers and others with personal knowledge of local communities (e.g., peer safety liaisons, *promotoras*). The training would benefit as well from assessment of the educational needs of particular worker subpopulations and evaluation of training outcomes and impacts (Cohen and Colligan, 1998).

Function F5: Incorporate Lifecycle Learning and Continuous Improvement

Continuous learning and improvement relies on a cyclical process that entails collecting performance data, identifying knowledge gaps and problems, investigating potential solutions through research, implementing evidence-based strategies, and finally returning to evaluation of performance. Recognizing that respiratory protection is the least effective approach to reducing risks from inhalation hazards in the hierarchy of controls (although a necessary one), this cycle needs to be integrated into comprehensive research efforts aimed at reducing inhalation hazards (e.g., vaccine development, approaches to reducing greenhouse gas emission, the design of improved engineering controls).

Chapters 2 and 3 identify a number of important research needs that range from developing new respiratory protective devices (e.g., off-the-shelf devices that can utilize a user seal check to ensure proper fit), to identifying

[14] Information on the Susan Harwood Training Grant Program is available at https://www.osha.gov/harwoodgrants (accessed October 3, 2021).

[15] The NIEHS Worker Training Program publishes "Minimum Criteria for Worker Health and Safety Training for Hazardous Waste Operations and Emergency Response," available at https://tools.niehs.nih.gov/wetp/public/hasl_get_blob.cfm?ID=11266&file_name=WTP_Minimum_Criteria_062818_Final_508.pdf (accessed October 7, 2021). Best practices from the OSHA Susan Harwood Training Grant Program are available at https://www.osha.gov/harwoodgrants/best-practices (accessed October 7, 2021).

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and overcoming deficiencies in production that may arise from market failures, to conducting outreach and education for adequate implementation of respiratory protection in the workplace. Also needed are increased research and data collection on the characteristics and extent of workplace inhalation hazards, as well as methods for preventing exposure.

A paucity of information is available about the effectiveness and scope of OSHA-mandated RPPs among workers exposed to currently regulated inhalation hazards. While OSHA requires employers to maintain written RPP plans and certain data, no attempt is made to collect these data. Even less information is available with which to characterize the needs of workers whose normal working conditions do not require respiratory protection, but who may on occasion encounter high levels of wildfire smoke, other sources of extreme ambient air pollution, or airborne-transmissible infectious agents. Existing RPP requirements for medical clearance and fit testing for respirators address some of the design limitations of these devices, including increased resistance, visual field limitations, and fit characteristics. These RPP requirements identify a number of conditions, including cardiopulmonary disease, claustrophobia, facial disfiguration, or religious requirements for having a beard, that may interfere with the use of FFRs (OSHA, 2000). Workers failing medical clearance or repeated fit testing may be assigned either alternative respiratory protection, such as a PAPR, or alternative work not requiring protection. These RPP components may be poorly understood or perceived as burdensome by employers without previous experience in their implementation, and alternative work options may not be available for emerging hazards. The cost of implementing an RPP is likely one of the barriers to the use of more and better respiratory protection in many workplaces, but barriers to compliance with RPP requirements are not well understood and warrant investigation. To address these gaps, NIOSH would need to expand its research portfolio to support respiratory protection programs, including a focus on a wide range of potential exposure scenarios and workforce needs.

While recognizing the challenges placed by full RPPs on small employers or those lacking prior experience with the requirements, the committee believes that eliminating the requirement for medical clearance or fit testing of respirators for any working population would require additional research data to confirm both the safety of the devices for prolonged use by all workers and their effectiveness in real-world situations. The committee also highlights the need for research into respirator design for fit or for broadly accessible alternatives, such as devices that use blowers with filters and loose-fitting hoods. Additional research is needed to understand how to facilitate prolonged user comfort, reduce impediments to communication, and minimize work effort and heat stress.

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Finally, the United States has a number of vulnerable working populations for whom implementation research is needed. The COVID-19 pandemic revealed particularly high exposure risks for workers in various front-line and essential industries—including agriculture, food processing, manufacturing, warehousing, and retail—many of which employ large numbers of low-wage and immigrant workers (Waltenburg et al., 2021). Outdoor workers—such as those engaged in agriculture, construction, and landscaping—are at increased risk from $PM_{2.5}$ exposure during wildfire events that impact air quality over large areas (Fenske and Pinkerton, 2021; Zuidema et al., 2021). Moreover, those responding to disasters may include informal and/or temporary workers, such as day laborers, who are often afforded few protections. And the proportion of the U.S. population working with impairments from chronic medical conditions has increased over time (Jinnett et al., 2017). It is important for approaches to be tailored to identify and meet the specific needs of these worker populations, considering not only distinctions by occupation but also other characteristics that may define worker groups.

The following two recommendations focus on surveillance related to inhalation hazards and associated occupational diseases and research aimed at respirator design and use, as well as the specific program elements necessary for effective respiratory protection. These recommendations do not describe a comprehensive research agenda, but instead represent the research areas that could be pursued in the identification of gaps and needs in respiratory protection. It bears emphasizing that these recommendations narrowly target the lowest form of protection in the hierarchy of controls and should be integrated into an overarching research program that addresses primary prevention and engineering and administrative controls. If, for example, "far" ultraviolet-C radiation proved safe, effective, and scalable, it might reduce the risk of infectious exposure to the point where respiratory protection would become unnecessary in certain indoor settings. Likewise, primary pollution prevention could obviate the need for respiratory protection.

Recommendation 6-8: ***Launch Expanded National Institute for Occupational Safety and Health (NIOSH) Research and Surveillance Programs***

In consultation with the Occupational Safety and Health Administration and in collaboration with relevant federal agencies (e.g., Defense Advanced Research Projects Agency, Biomedical Advanced Research and Development Authority), NIOSH should launch expanded surveillance and intramural and extramural research programs to better understand and meet the needs of all workers facing inhalation hazards.

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The surveillance program should generate data on the population sizes and characteristics, exposures to inhalation hazards and associated risks, and respiratory protection needs of these workers, including workers with disabilities, other underserved populations, and volunteers. The research program should include topics such as, but not limited to

- **respirator design, including filtration efficiency, breathability, fit, comfort (especially during periods of prolonged use), usability, ability to communicate when worn, and use by workers with a range of impairments;**
- **characterization of the source control effectiveness of different respiratory protective devices;**
- **innovative approaches for respirator manufacturing and distribution;**
- **implementation research; and**
- **methods and tools for sampling and characterization of workplace inhalation hazards, including airborne infectious agents.**

An important objective of this research program should be to generate information that can help address knowledge gaps regarding the choice, acquisition, use, and disposal of respirators by employers and workers in this broader workforce. Additional appropriated funding from Congress will be necessary for this expanded scope.

Recommendation 6-9: ***Conduct Research on Models for Respiratory Protection Program (RPP) Requirements***
The National Institute for Occupational Safety and Health should conduct research to assist the Occupational Safety and Health Administration (OSHA) in evaluating RPP requirements for routine workplace exposures, exposures to inhalation hazards during response to emergencies, and incidental exposures in the workplace. The effectiveness of different RPP models (e.g., those that do not require standard fit testing, such as the mini RPP for health care workers established under OSHA's 2021 Emergency Temporary Standard) should be evaluated and RPP requirements continuously refined.

As noted, the research needs are extensive and encompass a wide range of technical expertise. NIOSH is unique among CDC centers and institutes in the absence of a National Institutes of Health (NIH) counterpart (e.g., the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry has NIEHS as a related organization) as a complementary federal source of research. In addition to intramural expertise,

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NIOSH has established Education and Research Centers[16] and other centers of excellence that make use of extramural researchers (Robison et al., 2020). However, funding for these entities has been constrained. Analogous Personal Protective Technology Centers of Excellence have previously been recommended to support extramural research that would support advances in personal protective equipment (PPE) (IOM and NRC, 2008), but have not been realized because of a lack of funding. NIOSH issued a *Federal Register* notice in November 2021 to solicit comments on the need to establish personal protective technology centers of excellence to address research and practice gaps (CDC, 2021). Such centers, adequately funded, would support the robust and community-engaged extramural research program envisioned by the committee.

The committee envisions NIOSH assuming a leadership role in the development of a robust research program that would include intramural and extramural research and a focus on basic respirator design and implementation science. Some aspects of this research may be dual-purpose, applying also to use of respiratory protection by the public. The increased level of NIOSH effort anticipated by the committee's recommendations, including the personnel and data requirements of such research and surveillance programs, would require substantial resources, and could justify additional appropriations from Congress. Moreover, the research would need to be coordinated with other research and purchasing entities within the Department of Health and Human Services (HHS) (e.g., NIH, the Biomedical Advanced Research and Development Authority), the Department of Defense, and the Department of Veterans Affairs to bring proven devices to market; evaluate their use and effectiveness in the field; and track gaps in implementation, especially among the most precarious workers.

Function F6: Coordination

At present, there is little formal coordination among agencies or other entities involved in preventing exposure to inhalation hazards among workers not covered by OSHA-mandated RPPs. The committee's proposed framework for these workers envisions a system that includes ongoing data collection and interaction with manufacturers, distributors, and purchasers of devices, as well as federal, state, and local government agencies. These functions would make active coordination more important and require a system committed to lifelong learning and continuous improvement. To

[16] More information about NIOSH Education and Research Centers can be found at https://www.cdc.gov/niosh/oep/ercportfolio.html (accessed October 3, 2021).

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this end, OSHA, as the entity responsible for coordinating these functions, would have to make this a high priority.

CONCLUDING REMARKS

Addressing gaps in the provision of respiratory protection for workers not covered by RPPs will require a concerted effort from NIOSH, OSHA, Congress, and others. Table 6-1 summarizes the actions each stakeholder would need to take to make this happen.

TABLE 6-1 Recommended Actions for Stakeholders

STAKEHOLDER	RECOMMENDED ACTIONS
Occupational Safety and Health Administration (OSHA)	Recommendation 6-1: Ensure That Occupational Safety and Health Administration (OSHA) Respiratory Protection Requirements Apply to All Workers Recommendation 6-4: Establish Comprehensive Workplace Exposure Standards That Serve to Trigger Respiratory Protection Program Requirements Recommendation 6-5: Recommend Only National Institute for Occupational Safety and Health (NIOSH)-Approved Respirators in Guidance for Workers Facing Inhalation Hazards Recommendation 6-6: Prepare to Meet Expanded Worker Respiratory Protection Needs Recommendation 6-7: Support the Development of Targeted and Tailored Guidance and Training for Workers

continued

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TABLE 6-1 Continued

STAKEHOLDER	RECOMMENDED ACTIONS
NIOSH	Recommendation 6-3: Improve the Timeliness and Capacity of the National Institute for Occupational Safety and Health's (NIOSH's) Respirator Conformity Assessment Processes Recommendation 6-5: Recommend Only National Institute for Occupational Safety and Health (NIOSH)-Approved Respirators in Guidance for Workers Facing Inhalation Hazards Recommendation 6-6: Prepare to Meet Expanded Worker Respiratory Protection Needs Recommendation 6-7: Support the Development of Targeted and Tailored Guidance and Training for Workers Recommendation 6-8: Launch Expanded National Institute for Occupational Safety and Health (NIOSH) Research and Surveillance Programs Recommendation 6-9: Conduct Research on Models for Respiratory Protection Program (RPP) Requirements
Other Federal Agencies (Environmental Protection Agency, Mine Safety and Health Administration, Department of Energy, National Institute of Environmental Health Sciences)	Recommendation 6-5: Recommend Only National Institute for Occupational Safety and Health (NIOSH)-Approved Respirators in Guidance for Workers Facing Inhalation Hazards Recommendation 6-7: Support the Development of Targeted and Tailored Guidance and Training for Workers
Congress	Recommendation 6-1: Ensure That Occupational Safety and Health Administration (OSHA) Respiratory Protection Requirements Apply to all Workers Recommendation 6-4: Establish Comprehensive Workplace Exposure Standards That Serve to Trigger Respiratory Protection Program Requirements

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TABLE 6-1 Continued

STAKEHOLDER	RECOMMENDED ACTIONS
States	Recommendation 6-2: Ensure Protection from Inhalation Hazards for Workers Not Covered by Federal or State Occupational Safety and Health Authorities Recommendation 6-5: Recommend Only National Institute for Occupational Safety and Health (NIOSH)-Approved Respirators in Guidance for Workers Facing Inhalation Hazards

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7 Respiratory Protection Oversight and Guidance for the Public

Chapter 4 broadly reviews the state of the evidence and practice around providing respiratory protection for the public. That chapter draws on a fragmentary body of evidence, much of it related to wildfire smoke and ambient air pollution, along with the more recent experience with the COVID-19 pandemic. The eight conclusions in that chapter describe gaps that relate to one or more functions of the general framework described in Chapter 5. In this chapter, which is organized around the functions of that general framework, the committee addresses how to fill these gaps to create a cohesive framework specifically targeting respiratory protection for the public. The chapter begins with consideration of different options for a coordinating entity in this framework that would be charged with integrating the efforts of all stakeholders to ensure that the various functions are carried out seamlessly to meet the public's respiratory protection needs broadly—those of both the general population and members of population groups that are vulnerable to specific hazards. This discussion builds on the examples of coordination models discussed in Chapter 5. The chapter then goes on to discuss, for each of the framework functions, the responsibilities and authorities necessary to close the gaps identified in Chapters 2 and 4, as well as considerations for the different stakeholders that could play key roles in carrying out the activities encompassed by each function.

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ENSURING ADEQUATE COORDINATION AND AUTHORITIES TO PROTECT THE PUBLIC FROM INHALATION HAZARDS

While largely centralized oversight authorities for occupational inhalation hazards exist in the National Institute for Occupational Safety and Health (NIOSH) and in the Occupational Safety and Health Administration (OSHA) (as discussed in Chapters 2 and 6), there is no counterpart structure in the context of public protection. As a result, the current landscape of respiratory protection for the public is substantially more complicated to address relative to that of occupational respiratory protection, with considerable fragmentation across multiple federal and state authorities and gaps in critical authorities, particularly as relates to conformity assessment and approval of respiratory protective devices. Stakeholders and authorities may vary depending on whether the hazard is an infectious agent, such as SARS-CoV-2, or an environmental hazard, such as wildfire smoke, as well as on where the exposure occurs (e.g., in a transportation or business environment, indoors or outdoors). This complexity is increased by the lack of a centralized repository of information capturing which authorities are responsible for which hazards under which circumstances. Additionally, there are overlapping federal responsibilities and authorities; state and local public health agencies have specific authorities and act under local control; and manufacturers have a key role, as does the health care sector (see Table 7-1). Given this complex landscape, there is a critical need for a coordinating entity with the leadership, resources, and oversight necessary to integrate the efforts of all stakeholders in order to enhance the nation's preparedness and provide an actionable response when the public is exposed to inhalation hazards, including ensuring that the right respiratory protection is available to the public at the right time, together with guidance on its effective use.

Organizational Considerations for a Coordinating Entity

Chapter 5 presents a range of options for such a coordinating entity, including several example models. Three different architectures can be envisioned for an organizational structure designed to address the respiratory protection needs of the public. The first is a fully centralized model characterized by a single entity that carries out all functions. On the opposite end of the organizational spectrum is a distributed model with a collection of entities operating autonomously, with ad hoc coordination on specific initiatives through such mechanisms as an interagency task force or working group. A hub-and-spoke model is a third option that lies between the two. In this model, functions may be distributed across multiple stakeholder entities (the spokes), but the central hub provides a formalized, ongoing

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TABLE 7-1 Current Stakeholder Responsibilities and Authorities Related to Respiratory Protection for the Public

STAKEHOLDER	RESPONSIBILITIES AND AUTHORITIES
Local governments	Local government officials are responsible for the public safety and welfare of the people in their jurisdiction, and response to emergency incidents that may require the public to use respiratory protection generally begins at the local level. Decision making and public communication by local officials regarding inhalation hazards may be guided by such local governmental authorities as emergency management, public health, and air quality agencies, which may also communicate directly and indirectly with the public through established channels. In some states, requirements for use of respiratory protective devices for purposes of source control may be set at the local level. During the COVID-19 pandemic, mask requirements have been set by some public school systems.
State, territorial, and tribal governments	State, territorial, and tribal governments have significant authority over matters of public safety. These authorities enable state governments to issue so called "mask mandates" requiring the use of respiratory protective devices by the public for purposes of source control. At the request of local governments or when incidents span more than one local jurisdiction, states may supplement local government response efforts, including through coordination of warnings and public information and distribution of stockpiled supplies. States also serve as a critical intermediary in the dissemination of information from the federal to the local level. For example, state public health agencies interface directly with the Centers for Disease Control and Prevention (CDC) and translate and disseminate CDC guidance for local public health agencies.

continued

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TABLE 7-1 Continued

Federal government	Federal capabilities and oversight functions regarding public use of respiratory protection are distributed across multiple federal agencies, with critical functions that include support for product development when needed to address gaps; oversight of conformity assessment for respiratory protective devices; surveillance and hazard assessment; oversight and management of the supply chain in anticipation of and during emergencies; and the development and dissemination of information and guidance related to public use of respiratory protection. Information may be communicated directly to the public or disseminated through existing channels mediated by state and local governments. The federal government has limited authority to issue requirements for public use of respiratory protective devices, except in those areas in which it has jurisdiction, such as interstate travel, federal property, and transportation hubs.
Private/ Nongovernmental organizations	The private sector has the lead role in the United States for the development (design and manufacturing) of respiratory protective devices, although the government may support such efforts through public–private partnerships. Researchers, including those at academic institutions, may also play a role in device design, as well as contribute to efforts to understand the public's respiratory protection needs. Nongovernmental organizations may be involved in conformity assessment, including standards development and device testing. Regarding the use of respiratory protective devices, private businesses (e.g., grocery stores) may require and enforce their use by members of the public using their facilities. Nongovernmental and community organizations, as well as health care professionals, play critical roles in the "last-mile" reach of information, and in some cases, supplies, to community members and are often leveraged by local public health and other local government agencies.

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mechanism to ensure coordination of their activities; that is, it serves as the coordinating entity. Different configurations for the hub are potentially suitable, as described below.

The committee eliminated from further consideration the two models at the extremes of the spectrum. The distributed model is in fact a version of the status quo. Multiple federal agencies, including the Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA), currently act independently with regard to different kinds of inhalation hazards. While there have been laudable examples of effective coordination, as with the development of *Wildfire Smoke: A Guide for Public Health Officials*, such coordination is dependent on relationships rather than being built into an ongoing and established system. Without structure and designated responsibilities, gaps might not be addressed, particularly in the face of changing circumstances and new scientific evidence, and efforts would likely be focused on single threats at particular moments (e.g., SARS-CoV-2). Experience with the COVID-19 pandemic has highlighted the many ways in which this model is inadequate. While a stopgap interagency task force could be established (either by executive action or self-organized) to increase coordination among stakeholders with minimal requirements for resources, this approach would not respond to the committee's charge to provide a framework that constitutes a unified and authoritative source of information and effective oversight in the development, approval, and use of respiratory protective devices across all of the functions involved.

The fully centralized model, whereby a centralized entity would replace the existing fragmented authority of multiple agencies, provides a useful contrast. This model could support a unified and authoritative source of information and effective oversight, but as discussed in Chapter 5, restructuring several federal agencies and reassigning responsibilities and authorities now held by current stakeholders would present enormous organizational, operational, and legislative challenges. Such a model might be more feasible if the required authorities were missing and needed to be created and given a federal home. In the present circumstances, however, many of the required authorities exist within agencies currently responsible for some of the functions laid out in the committee's framework. Moreover, such a model could isolate respiratory protective devices from more upstream primary prevention efforts and create an additional barrier to exchange, integration, and communication.

The committee therefore views the hub-and-spoke model as the preferable path forward to address the need for a coordinating entity within a broader structure designed to ensure adequate and effective respiratory protection for the public. This model would allow the domain-specific expertise and infrastructure of existing stakeholders to be leveraged while providing mechanisms for coordinating efforts toward a shared objective.

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Thus in this model, the hub represents a coordinating entity serving as the unified and authoritative source of information and effective oversight in the development, approval, and use of respiratory protective devices, while the spokes represent stakeholder agencies with domain-specific expertise and infrastructure related to one or more framework functions (see Figure 7-1). Designating a coordinating entity to serve as a central hub also has the advantage of creating a single locus of accountability for congressional and executive oversight. This model differs from the existing situation wherein an empowered and accountable hub is lacking.

This is not to say that the hub-and-spoke model is without challenges. In particular, there are missing authorities that need to be addressed,

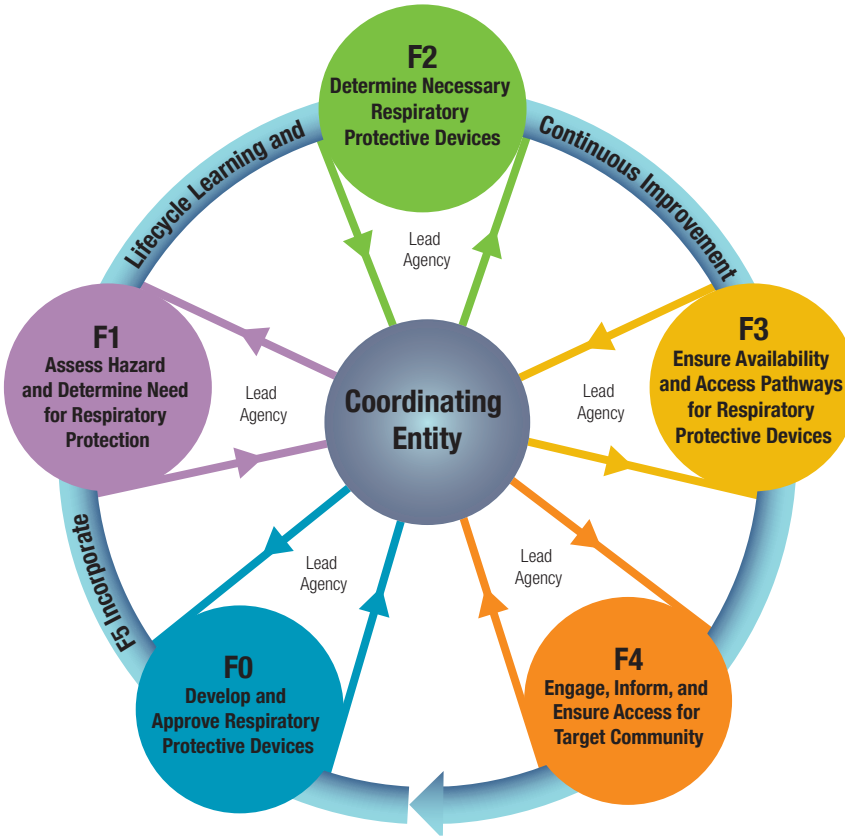


FIGURE 7-1 A hub-and-spoke model for coordination related to respiratory protection for the public. This model shows the formalized, central role of the coordinating entity as it relates to the seven functions of the committee's framework, which could be distributed across multiple stakeholder entities.

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particularly for conformity assessment for respiratory protective devices for the public. Additionally, issues could arise in which the authority of the hub could potentially overlap with an authority already granted to an individual spoke. The potential for such overlap would necessitate ongoing cooperation between the coordinating entity and the agencies that already provide hazard-specific or other expertise, and it would remain important for the coordinating entity to be guided by the expertise of the spokes, with feedback being sought from all levels, including those responsible for on-the-ground implementation. In addition, overlapping authority can impede decision making in the absence of consensus and create tensions among existing stakeholders over questions of authority. In the absence of a hierarchical authority structure, requirements for participation and coordination might need to come from the White House or Congress (as codified in legislation). There is no simple solution to the effective management of cross-cutting issues that require the engagement of multiple federal agencies.

The coordinating entity (the hub) could be designated from among existing stakeholders—those that could potentially serve as spokes—or a new agency could be created to fill this role. To the extent that a coordinating entity displaced authority currently allocated to another agency, implementation of the hub might require some restructuring of government agencies (organization and authorities), thereby entailing some of the disadvantages of the fully centralized model, although to a lesser extent. As noted above, the creation of a new federal agency would carry the risk of limiting integration of its function into a larger system of controls aimed at primary prevention. Alternatively, housing the hub in an existing agency could leverage the infrastructure and expertise of that agency.

The committee's analysis of existing authorities and responsibilities presented in Chapter 2 points to two federal agencies with public health missions that could potentially house the coordinating entity—the Department of Health and Human Services (HHS) and EPA. Within HHS, the coordinating entity might best reside at the level of the Office of the Secretary, but alternatively, it could be housed within an operating division, such as CDC or the Food and Drug Administration (FDA), with implications related to oversight as discussed below. Other potential agencies that might be considered include the Federal Emergency Management Agency (FEMA) within the Department of Homeland Security (DHS) and the Consumer Product Safety Commission (CPSC), but both have lesser responsibilities and expertise related to inhalation hazards and respiratory protection relative to HHS and EPA.

EPA has substantial regulatory authorities related to environmental hazards, but a far less prominent role when inhalation hazards are infectious agents, excepting the guidance it develops for indoor exposure to

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mold or its approval of disinfectants for airborne agents such as tuberculosis or SARS-CoV-2. HHS has lesser regulatory authority regarding environmental hazards relative to EPA, but its component agencies would bring a depth of expertise in both environmental hazards and infectious agents, as well as conformity assessment (i.e., FDA and NIOSH's National Personal Protective Technology Laboratory [NPPTL]). Moreover, the secretary of HHS has oversight over CDC, FDA, the National Institutes of Health (NIH), and the Office of the Assistant Secretary for Preparedness and Response (ASPR), four key federal stakeholders with regard to respiratory protection. Therefore, housing the coordinating entity within HHS would enable a more hierarchical authority structure than would be possible were the coordinating entity to be housed within EPA.

As the nation's preeminent public health agency, CDC is also reasonable to consider as the locus of the coordinating entity. It would certainly be expected to have a prominent role in a framework of responsibilities and authorities related to oversight and guidance for respiratory protection for the public, and indeed has had such a role with SARS-CoV-2. Multiple centers within CDC provide expertise related to hazards both environmental (e.g., the National Center for Environmental Health) and infectious (e.g., the National Center for Immunization and Respiratory Diseases and the National Center for Emerging and Zoonotic Infectious Diseases). Additionally, CDC has established channels for coordination with state, local, tribal, and territorial public health agencies, which are necessary partners in providing respiratory protection for the public. However, coordination within HHS and with stakeholders outside of HHS (e.g., EPA, DHS) could be impeded if the coordinating entity were placed at the level of an operating division. Moreover, the coordinating entity would have to be able to respond to hazards at a pace that reflects the urgency of the need for respiratory protection. During the COVID-19 pandemic, CDC has been slow to respond to rapid advances in scientific evidence (Tanne, 2020), including the evidence clearly documenting airborne transmission of SARS-CoV-2 by aerosols (NASEM, 2020; Samet et al., 2021). These factors are important considerations in determining whether the coordinating entity should reside within the Office of the Secretary of HHS or alternative locations within the department.

Regardless of the location in which it resided, to ensure the successful functioning of the hub-and-spoke model, the coordinating entity would need to have

- sufficient authority to coordinate across multiple agencies effectively and enforceably;

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- sufficient resources to generate new research and data where needed, to respond to emerging circumstances with meaningful action, and to enforce requirements placed on stakeholders; and
- systems for accountability to ensure that the coordinating entity would act expeditiously and effectively in addressing the respiratory protection needs of the public.

No stakeholder agency is currently empowered to take on this broad scope of responsibility. A long-term unified solution to fill this gap will require a clear congressional mandate, codified in legislation, and supported by additional resources via congressional action. In the interim, however, urgently needed coordination could be provided through mandates arising from executive action. Ensuring that the agency designated as the coordinating entity was empowered to carry out this coordination function might necessitate one or more mechanisms for facilitating interagency collaboration, such as memorandums of understanding and joint budgeting, and these mechanisms would need to be considered by Congress. Requirements for annual reports to Congress could be considered as one mechanism for accountability.

Recommendation 7-1: ***Establish a Coordinating Entity to Oversee the Framework for Respiratory Protection for the Public***
Congress should expeditiously establish a coordinating entity within the Department of Health and Human Services (HHS) with the necessary responsibility, authority, and resources (financial, personnel, and infrastructure) to provide a unified and authoritative source of information and effective oversight in the development, approval, and use of respiratory protective devices that can meet the needs of the public and protect the public health. Given the urgent need for action, the Secretary of HHS should immediately establish an interim office to take on priority near-term tasks of the coordinating entity until Congress acts to establish the coordinating entity. Pending such congressional action, the White House should establish an interagency task force focused on respiratory protection for the public to ensure that the activities of the interim HHS office are coordinated with other stakeholder federal agencies.

Of note, while this coordinating entity should be focused on the respiratory protection needs of the public, coordination with OSHA on respiratory protection issues that overlap with the needs of workers is critical to reducing the potential for conflicting messages and confusion and ensuring a seamless system for the nation. Given the inherent overlap in the activities of the groups tasked with carrying out these functions, the science guiding

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those activities, and the populations themselves—outside of the work setting, workers make up a substantial proportion of the general population—harmonization between the two frameworks is vital. Issues requiring collaboration with OSHA may include carrying out communication and messaging, assuring the supply chain, and conducting coordinated research on respiratory protection. The committee recognizes that this collaboration may present some challenges; in the recent past, there have been strong disagreements between HHS agencies and external occupational health professionals on the controls needed to protect workers against airborne infectious diseases (Tanne, 2020). Successful collaboration will require that these coordinating agencies overseeing respiratory protection for the public and for workers view each other as partners, each acknowledging the other's expertise in the realm over which it has responsibility. Including ongoing evaluation of harmonization of the two frameworks among the requirements for regular assessment and reporting, as noted in Recommendation 7-9, will serve to ensure that objectives related to collaboration and coordination are met.

Recommendation 7-2: ***Ensure Collaboration and Cooperation Between the Coordinating Entities for the Worker and Public Frameworks***
As the two frameworks are implemented, the heads of the two agencies housing them—the Department of Labor (in which the Occupational Safety and Health Administration resides) and the Department of Health and Human Services—should ensure that mechanisms are established to support collaboration and cooperation between them.

In this section, the committee has laid out options for a coordinating entity structure. It should be emphasized, however, that this proposal represents a starting point for a new system, one that would need to evolve over time through a process of ongoing evaluation. The specific coordination role for this entity for each of the functions in the committee's framework is described in the sections that follow and compiled at the end of the chapter.

DEFINING RESPONSIBILITIES AND ADDRESSING GAPS IN AUTHORITIES RELATED TO THE FRAMEWORK FUNCTIONS

As discussed in Chapter 2, the regulatory and legal landscape with respect to oversight of nonoccupational use of respiratory protection is extraordinarily complex, with both gaps and overlaps in the authorities related to the key functions of the committee's framework (described in Chapter 5). The review and assessment presented in Chapters 2 and 4, respectively, document a patchwork of entities currently involved with

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the functions and abundant gaps that must be filled if the framework is to be realized. While a coordinating entity is necessary to harness the authorities, resources, and domain-specific expertise of all stakeholders to that end, each function may require one or more leads with the necessary domain-specific expertise, resources, and authority to serve in an oversight role for that function. One critical task as the framework for the public is implemented will be identifying the various entities and stakeholders that are active in relation to these functions and those that could be engaged to serve as leads for each. Consequently, the committee offers the following recommendation.

Recommendation 7-3: ***Assign and Coordinate Roles and Responsibilities for the Framework Functions***
The coordinating entity proposed in Recommendation 7-1 should assign and organize roles and responsibilities of federal and other stakeholders through a structured process that matches their capabilities to the committee's framework functions. Where gaps in authorities are identified, Congress should address them to ensure the necessary oversight for each of the framework functions. This process should build on the committee's work to identify the necessary capabilities and oversight authorities of stakeholders for each function and to consider potential stakeholders to fill current gaps.

For each framework function, it will be necessary to consider the role of the coordinating entity and where gaps in responsibilities may need to be filled by a lead agency that has been granted the necessary authorities. In some cases, the lead agency for a function might be the coordinating entity. The committee's assessment of the necessary capabilities and oversight authorities of stakeholders for each function and its consideration of potential stakeholders that might fill current gaps are discussed in the following sections.

Function F0: Develop and Approve Respiratory Protective Devices

Massive wildland fires in the western United States and the COVID-19 pandemic have underscored the public's need for access to appropriate respiratory protection. Current devices used by the public with the intent of reducing exposure to inhalation hazards are a mix of NIOSH-approved industrial respirators, medical and nuisance dust masks, and a variety of other commercial and homemade face coverings (see Chapter 4). The current knowledge and technical base for respiratory protection is derived largely from OSHA regulation (i.e., from requirements for workplace respiratory protection programs) and NIOSH research on worker needs. No

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comprehensive study has characterized the public as users of respiratory protection or assessed their equipment needs, although as discussed in Chapter 4, such research is now under way as a result of COVID-19.

The workforce is made up largely of healthy individuals from aged 15–64, although changes in Social Security retirement benefits encourage working to age 70 (Leonesio et al., 2012), and the Americans with Disabilities Act[11] promotes employment among persons with disabilities. The public, by comparison, represents a broader age range, from infants to senior citizens, as well as individuals with a variety of health issues and special needs. As a result, the numerous factors that affect the design and appropriate use of respiratory protection (e.g., facial characteristics, fit in the absence of fit testing, acceptable breathing resistance, wearability, the need for an end-of-service-life indicator) are not well understood in the context of public use (Chughtai et al., 2019; Fischer et al., 2020; Regli et al., 2021; van der Sande et al., 2008).

No federal entity comparable to NIOSH/NPPTL is responsible for overseeing the development, approval, marketing, or postmarketing surveillance of all respiratory protective devices for the public, or for generating or overseeing a conformity assessment program for managing these processes. The lack of an appropriate management system and user information could result in multiple failures of a device worn by the public, resulting in inadequate respiratory protection and the potential for unacceptable risks.

To address these major shortfalls, a robust research and approval program is needed to evaluate the needs of users and device requirements and guide the development of comprehensive performance standards and innovative respiratory protective devices specifically designed for public use, including those that would not require fit testing. The needs and requirements should be informed by ongoing scenario planning, a function that itself suffers from lack of coordination within the federal government. As with the development of workplace regulations and consensus standards, private-sector manufacturers and other businesses need to be active participants in these efforts, providing input on technology for future product development and considerations related to manufacturing and supply chain processes. The conformity assessment component of this program will need to ensure the quality, effectiveness when used outside of a respiratory protection program, and appropriate labeling of respiratory protective devices to be used by the public.

[11] Americans with Disabilities Act of 1990 as amended by the ADA Amendments Act of 2008 (Public Law 110-325).

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Addressing Gaps in Responsibilities and Authorities

In addressing how best to meet the need for a robust research and approval program focused on nonoccupational use of respiratory protection, the committee considered the respective responsibilities of the coordinating entity and a federal-level organization that would have the authority to oversee standards development for and approval of respiratory protective devices intended for use by the public (i.e., the scheme owner). These respective roles and different potential approaches to addressing current gaps in oversight authorities are described in Box 7-1.

As laid out in Box 7-1, there are two potential approaches for establishing the necessary capability; each has pros and cons, and the committee did not identify a preferred approach. One model is to expand NIOSH/NPPTL's research portfolio and respirator approval program to encompass respiratory protection for the public, including a wide range of potential public exposure scenarios and user needs. Advantages of this approach include harnessing its unique capabilities in respiratory protection (e.g., conformity assessment and respirator research) built within NPPTL over the past two decades. Doing so might address the public's needs more quickly relative to establishing a new organization. However, expansion of NPPTL's mandate beyond workers could pose challenges given its location within NIOSH, as well as have unanticipated impacts on its occupational oversight functions. Another risk is that inadequate additional funds could be provided to NPPTL for this expansion on the assumption that this is work similar to what it currently performs. In actuality, this work related to the public is likely to be quite different from the work done for workers. Furthermore, such expansion would require congressional action, which could delay the implementation of this approach and NPPTL's ability to address the public's needs expeditiously.

An alternative would be to develop a parallel system for nonoccupational contexts with a laboratory analagous to NPPTL as the lead for research on and approval of respiratory protective devices for the public. The advantages of establishing a new laboratory include a dedicated focus on meeting the unique needs of the many members of the public for whom currently available respirators are problematic—including infants, young children, and the frail elderly—and the ability to house the new laboratory in an organization with a broader primary prevention mission than that of NIOSH. This approach could require some duplication of infrastructure and would need to be explored in close collaboration with NPPTL to build on the best practices and lessons learned over its two decades of experience. This collaboration would likely help advance the development of the new organization while avoiding duplication of resources.

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BOX 7-1
Necessary Stakeholder Capabilities and Oversight Authority Options for Function F0

Overall coordinating entity role: Ensure that information from ongoing scenario planning and research on user needs informs design requirements that feed into standards development and guides the development of new respiratory protective devices.

Role of lead agency(ies) with oversight for this function: Ensure and oversee the development of device standards, set requirements for testing, oversee testing organizations (if not internal), approve devices that meet standards, maintain and make available an approved equipment list, and conduct postmarket surveillance (i.e., serve as scheme owner, as described in Chapter 2).

Necessary characteristics of a lead oversight agency: Expertise in respiratory protection, including standards development, conformity assessment processes, and certification models, as well as market forces and incentives related to product development; access to testing laboratories and standards development organizations; regulatory authority for device approval and for enforcement mechanisms that enable taking corrective action for nonconforming products (including recall authority).

Current agencies with some oversight authorities related to this function:

- Food and Drug Administration (FDA)—General authorities related to devices are derived from Section 201(h) of the Federal Food, Drug, and Cosmetic Act and the Medical Device Amendments of 1976, and are intended to ensure devices' "safety and effectiveness." However, authorities for respiratory protective devices are limited to those devices used for medical purposes, including for the prevention of disease (see, for example, 21 C.F.R. § 880.6260). Authorities include premarket approval and seizure and other penalties for adulterated or misbranded devices (postmarket surveillance is limited to Class II/III devices, including surgical masks and respirators, but not face coverings).
- Consumer Product Safety Commission (CPSC)—Authorities under the Consumer Product Safety Act and Federal Hazardous Substances Act include issuing performance requirements, warnings, instructions, and product bans. CPSC considers consumers' and children's face masks to be apparel that is subject to flammability testing requirements, but has disclaimed the authority to regulate masks that qualify as "medical devices" or N95 filtering facepiece respirators (FFRs) and P100 respirators.

Addressing gaps in oversight authorities (options with considerations for each):

Approach 1: Designate an existing agency as lead with expanded resources. Potential oversight agencies include:

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- National Institute for Occupational Safety and Health (NIOSH)/National Personal Protective Technology Laboratory (NPPTL)—Has necessary expertise related to respirators used in workplace settings but less expertise in other respiratory protective devices that may be used by the broader general population. NIOSH standards are often referenced in other agency guidance to the public, but the scope of its authority pertaining to oversight and approval of respirators is limited to occupational settings. NPPTL would require significant expansion (of authority and resources) and possible reorganization (movement out of NIOSH) to oversee standards development for and approval of respiratory protective devices for nonoccupational use. Such expansion of the NIOSH/NPPTL mandate could overload the agency.
- FDA—Has experience with clearance of surgical respirators for use in health care settings and the authority to clear devices intended for public use when such use is for medical purposes. FDA authorities could be expanded to all respiratory protective devices intended for use by the public if such use were interpreted as having a medical purpose. FDA may not have the necessary expertise related to standards development, however.
- CPSC—Has established processes for ensuring that consumer products meet standards and has enforcement authorities, but lacks expertise in respiratory protection.

Approach 2: Establish a new entity with the necessary resources:

- A laboratory analogous to NPPTL could be established with the mandate to oversee standards development and approval for devices intended for public use. This approach would require a significant startup effort and could create redundancy in infrastructure. The relationship of the new laboratory to NPPTL would need to be clarified, and the new agency would need to coordinate with NPPTL and build on its expertise.

Subfunctions (to be overseen by the lead agency and/or coordinated) and examples of key/potential partners:

- Scenario planning and research (characterizing hazards and populations)—The Department of Homeland Security; the Assistant Secretary for Preparedness and Response; CDC; the Department of Defense; the Environmental Protection Agency; state, local, tribal, and territorial public health agencies; academic researchers
- Standards development (for devices and testing methods)—Consensus standards development organizations (e.g., ASTM International, International Organization for Standardization [ISO])
- Development of respiratory protective devices—Manufacturers, academic researchers
- Conformity assessment (including testing) and certification—Third-party organizations (e.g., those that are ISO accredited), manufacturers (if conducting their own testing)

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Recommendation 7-4: ***Establish a Capability to Oversee Standards Development for and Approval of Respiratory Protective Devices Used by the Public***

Congress should mandate that the Department of Health and Human Services establish and adequately resource a laboratory responsible for overseeing standards development, conformity assessment, and approval for respiratory protective devices intended for use by the public, as described for Function F0.

Considerations that should guide the choice between expanding the capacity and funding for NPPTL and establishing a new laboratory include the differences between the user populations to be covered (i.e., the general population versus workers) and the implications for the necessary capabilities of the laboratory, the comparative efficiencies of the two approaches, and the administrative infrastructure that would have to be created around providing respiratory protection for the public. Assessment of the two approaches would logically be one of the first tasks in the effort to assign and organize the roles and responsibilities described in Recommendation 7-3. Regardless of which approach is chosen, significant additional funding will be necessary to carry out these major new tasks.

Function F1: Assess Hazard and Determine Need for Respiratory Protection

Protecting the public from such diverse inhalation hazards as wildfire smoke, dust storms, infectious aerosols (e.g., SARS-CoV-2), and mold from flooding events, among others, will require a system for identifying and assessing hazards, evaluating exposure and risk, and determining the need for respiratory protection. This core function is complex because of the diversity of inhalation hazards faced by the public and the potential need for a range of scientific expertise to assess them.

CDC has various systems and a formalized process for identifying new infectious disease outbreaks, but its process for evaluating risk for the public and generating specific public health recommendations regarding the need for public use of respiratory protection is fragmented and ad hoc. While experts in infectious diseases are dispersed across multiple centers within CDC, expertise in respiratory protection is limited to those program units focused on occupational safety and health. In the absence of a permanent locus within CDC focused on respiratory protection for the public, relevant experts from NIOSH and CDC's Division of Healthcare Quality Promotion make decisions about the public's need for respiratory protection through an emergency management structure (i.e., incident command) that is activated with each new public health emergency (Delaney,

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2021). Such structures have been used to negotiate recommendations on respiratory protection for the public during the H1N1 influenza and COVID-19 pandemics, and the unprecedented duration of the latter pandemic has enabled enhanced functionality as the response has matured. However, incident command structures are inherently temporary and hazard specific, and therefore not well suited to the development of forward-thinking and formalized processes for considering inhalation hazards faced by the public or the public's respiratory protection needs. Moreover, reliance on CDC's occupational safety and health experts for the substantial task of addressing the public's respiratory protection needs could distract from the important focus of such groups on the needs of workers. Occupational safety and health experts also may have limited expertise regarding the full range of subpopulations for whom respiratory protection poses unique challenges, including young children, the frail elderly, and people with certain medical conditions.

The incident command structure at CDC includes mechanisms and pathways for assembling evidence on infectious inhalation hazards to guide recommendations on respiratory protection for the public (and workers). A chief science officer is responsible for ensuring that those recommendations are guided by the best available evidence; the evidence supporting the recommendations is distilled into science briefs (de Perio, 2021), providing some measure of transparency. Multistakeholder meetings are held to facilitate discussions on how the latest science might inform policy considerations, although there is no formalized process for determining the need for interagency engagement. Notable challenges include the lack of data to inform risk evaluations and reliance on systems built for academic publication of data (Bell, 2021). While preprint servers have increased access to recently generated data that have not yet been peer-reviewed, the timeframe for publication still poses barriers to rapid reviews of quickly evolving evidence. As a component of a response structure, these processes for compiling evidence are hazard-specific and do not represent a long-term solution for the ongoing evaluation of inhalation hazards faced by the public and its respiratory protection needs.

A useful example of an ongoing standardized, rigorous process for monitoring hazards and translating the available science to public health policy is EPA's process for setting National Ambient Air Quality Standards (NAAQS). The Clean Air Act Amendments of 1977[22] mandates that the agency repeat this process every 5 years for the major criteria air pollutants. The process begins with a science policy workshop held to gather input from the scientific community, followed by the creation of an Integrated Review Plan designed to move the process forward (EPA, 2020). The review

[22] Clean Air Act Amendments of 1977, Public Law 95-95.

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contains three parts in order: an Integrated Science Assessment (ISA), a formal, structured review and synthesis of the current policy-relevant science; (2) a Risk/Exposure Assessment that both characterizes the uncertainty in the estimates described by the ISA and uses those estimates to characterize risk to humans and the environment; and (3) a Policy Assessment that provides the scientific basis for different policy options. Based on this formal review, EPA makes final recommendations for specific air quality standards for such pollutants as $PM_{2.5}$, ozone, and nitrogen dioxide, which are finalized following a period of public comment and public hearings. These standards are also translated into EPA's Air Quality Index, a color-coded metric used to communicate relative risk to the public.[33] It should be noted, however, that EPA does not currently conduct such ongoing assessments for other environmental inhalation hazards that pose risks to the public, such as wildfire smoke and volcanic ash.

Addressing Gaps in Responsibilities and Authorities

To protect the public health from the diverse inhalation hazards of concern, a coordinating entity is needed to oversee the compilation of existing knowledge on exposure and risk; gather input from experts; and guide the public, including specific subgroups, on the need for respiratory protection, accounting for alternative strategies (e.g., other control methods, such as social distancing and vaccination) and potential health risks of using respiratory protective devices. This core function will require coordination across multiple agencies, based on the relevant scientific and administrative expertise of each agency and the nature of the inhalation hazard in question (Shaffer, 2021). The respective roles of the coordinating entity and the agencies with the relevant expertise for different inhalation hazards faced by the public are considered in Box 7-2.

Decisions about the public's need to use respiratory protection have broad policy, operational, and societal implications. Such decisions need to be based on the best available science, but also informed by a breadth of perspectives so that the full ramifications of such determinations are thoroughly considered. Consequently, the committee favors Approach 1 in Box 7-2, whereby recommendations on public use of respiratory protective devices are made through a collaborative, interagency effort mediated by the coordinating entity rather than by a single agency.

To ensure that determinations regarding the public's need to use respiratory protection are science based, they need to be informed by a structured scientific review and risk evaluation process led by the agency with

[33] For more information on the Air Quality Index, see https://www.airnow.gov/aqi/aqi-basics (accessed October 5, 2021).

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the relevant expertise for the hazard at hand (e.g., EPA for environmental hazards, CDC for infectious hazards). While EPA's NAAQS process can serve as a useful example of formalizing the steps of hazard identification, exposure monitoring, and risk evaluation to inform recommendations on the public's need for respiratory protection, such a process does not necessarily require a congressional mandate. In some cases (such as novel infectious agents), a formal evaluation may require an accelerated timeline for the scientific review of the evidence. Thus, in addition to the creation of a standardized process similar to that used for the NAAQS, it could be helpful to create a supplemental process that uses rapid reviews (e.g., following the Cochrane rapid review guidelines) (Garritty et al., 2021) as a starting point, followed by more comprehensive reviews.

Any system broadly addressing respiratory protection for the public would differ from EPA's process for establishing the NAAQS in other important ways. Whereas the NAAQS process is limited to specific air pollutants, the coordinating entity for respiratory protection for the public would need to regularly survey existing and emerging hazards that might trigger that need. Thus, a novel system would be needed. Such a surveillance system would have to be transparent to the public and to include opportunities for public comment and stakeholder engagement. One factor that complicates implementing such a system, however, is that population exposure data and quantitative risk assessment are currently lacking for hundreds of potential inhalation hazards. In contrast to EPA's national monitoring network for criteria air pollutants, for example, the United States currently has a very limited ability to measure or forecast public exposure to such hazards as wildfire smoke (Rice et al., 2021) and volatile chemical compounds from industrial accidents. In the case of infectious agents, information on transmissibility or virulence may not exist, especially in the early stages of disease outbreaks.

Another key distinction is that the NAAQS process began at a time when a large, published literature of cohort studies, mechanistic animal research, and controlled human studies had already demonstrated adverse health effects of exposure to criteria air pollutants, which could be used to estimate risk (i.e., exposure-response relationships). For new hazards, the task of estimating exposure-response, quantifying transmission risks (for infectious agents), or identifying higher-risk/vulnerable populations may begin with a very sparse scientific literature. Thus, coordinating and integrating new scientific knowledge on exposure and risk is crucial. A major advantage of a rigorous scientific review process is that knowledge gaps are identified in a timely fashion, so that research to address such gaps can be prioritized.

Lastly, while the NAAQS process leads to ambient air quality standards, any recommendations regarding the public's use of respiratory protection

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BOX 7-2
Necessary Stakeholder Capabilities and Oversight Authority Options for Function F1

Overall coordinating entity role: Provide a mechanism for stakeholders to collaborate on the development of a structured process for assessing the need for respiratory protection based on an evaluation of the evidence regarding the inhalation hazard(s) of interest, exposures and risks to the public, and ability to mitigate those risks through alternative control measures. Provide a forum for stakeholders to discuss and prioritize hazards for which this evaluation process should be conducted and to discuss policy considerations regarding recommendations on the public's respiratory protection needs resulting from the process.

Role of lead agency(ies) with oversight for this function: Conduct ongoing hazard monitoring and exposure forecasting. Lead the aggregation and review of the scientific evidence regarding the inhalation hazards of interest, the identification of knowledge gaps, the evaluation of risk to the public, and the likely effectiveness of other control measures for adequately mitigating the risk, and potentially (depending on the approach taken [see below]) generate recommendations for consideration by the coordinating entity regarding the public's need to use respiratory protective devices.

Necessary characteristics of a lead oversight agency: Expertise in hazard monitoring, hazard and exposure assessment, risk evaluation and hazard control options, including respiratory protection; access to hazard monitoring infrastructure and a multidisciplinary group to monitor hazards, conduct hazard assessments, and judge acceptability of risks.

Current agencies with some oversight authorities related to this function:

- Environmental Protection Agency (EPA)—Has authorities under the Clean Air Act and Toxic Substances Control Act to regulate a variety of environmental inhalation hazards facing the public, but there is no clear EPA authority to manage the majority of those hazards through respiratory protective devices. EPA does provide guidance to the public on respiratory protection against some environmental hazards (e.g., wildfire smoke, indoor mold).
- Centers for Disease Control and Prevention (CDC)—Current authorities include those regarding inhalation hazards posed by infectious diseases (including hazard monitoring) and may include requirements for public use of respiratory protective devices (such as requiring the use of medical masks or face coverings on public transportation conveyances). For environmental hazards, the National Center for Environmental Health (NCEH) has a research and communication/education role.

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Addressing gaps in oversight authorities (options with considerations for each):

Approach 1: The coordinating entity makes decisions on the public's need to use respiratory protective devices based on consideration of the evidence from those agencies conducting the hazard/risk evaluation and the feasibility of other controls. The lead agencies only perform hazard/risk evaluations (allowing for different lead agencies for different types of hazards—e.g., environmental or infectious), and are not charged with making recommendations to the coordinating entity on the public's use of respiratory protective devices.

- With this approach, CDC could be designated as lead for assessing hazards/risk for infectious hazards and EPA as lead for assessing hazards/risk for such environmental hazards as wildland fires, volcanic ash fall, or industrial releases. This approach could require greater coordination effort but could reduce duplication in requirements for in-house expertise related to respiratory protection.

Approach 2: Each lead agency performs hazard/risk evaluations and makes recommendations to the coordinating entity on the public's need to use respiratory protective devices within the context of the full range of possible interventions.

- This approach would require agencies conducting assessments to also have expertise in respiratory protection but could make it easier to link guidance on respiratory protection to hazard/risk evaluations (e.g., using the Air Quality Index for EPA).

Subfunctions (to be overseen by lead agency and/or coordinated) and examples of key/potential partners:

- Hazard monitoring and exposure assessment/forecasting (for incidents resulting in inhalation threats to the public)—Department of Homeland Security; CDC; Department of Defense; EPA; state, local, tribal, and territorial public health agencies
- Hazard characterization research (to generate the evidence reviewed by the lead agency)—Academic researchers, national laboratories and other federal agency laboratories, NCEH
- Risk characterization—EPA, CDC
- Guidance on need for respiratory protection—National Personal Protective Technology Laboratory (in an advisory role unless its mandate were expanded)

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involve an intervention at the level of the individual, with potential health risks that remain poorly described. Therefore, as part of the core function of assessing hazards and making recommendations for the use of respiratory protection, the coordinating entity will need a clear understanding of the safety of respiratory protective devices across different population subgroups. The coordinating entity will then need to compare the anticipated benefits of respiratory protection against any (known) risks of use among members of the public and consider alternative strategies for reducing their exposure.

Recommendation 7-5: ***Establish and Use a Standardized Process for Determining the Public's Need for Respiratory Protection***
The coordinating entity should work with the Centers for Disease Control and Prevention, the Environmental Protection Agency, and other relevant federal stakeholders to establish a timely, responsive, and standardized process for expert scientific review of inhalation hazards and evaluation of risk to the public (including susceptible subgroups of the population) so as to identify those hazards that warrant the public's use of respiratory protection. The coordinating entity should oversee each of the steps in this process and engage stakeholders with the relevant expertise to perform the scientific review and risk evaluation, and use this information to inform evidence-based decisions on the need for public use of respiratory protective devices.

Function F2: Determine the Necessary Respiratory Protective Devices

Once it has been determined that an inhalation hazard faced by the public warrants the use of respiratory protection, recommendations on specific devices will need to be matched to the nature of the hazard and guidelines developed regarding their use. For example, widely available FFRs (e.g., N95 FFRs) are appropriate for particulate hazards, including infectious microorganisms (OSHA, 2011). Many inhalation threats faced by the public are particulate in nature, including particulate matter components of wildfire smoke, respiratory viruses, and mold spores. For other potential hazards, including such gases as chlorine, appropriate respirators, such as elastomeric half-mask respirators, may not be widely available to the public. Additionally, any device-specific risks to the wearer (Kyung et al., 2020) will need to be considered in developing recommendations for the selection of respiratory protective devices. Risk-benefit considerations for respiratory protection more generally are discussed under Function F1, but they play a crucial role in making those recommendations.

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Ideally, recommended devices will be approved for public use following a conformity assessment process (Function F0) and selected from some form of approved equipment list, analogous to the NIOSH Certified Equipment List.[44] As yet, however, the government has approved no respiratory protective devices for public use in the United States. During the COVID-19 pandemic, wildfires, and air pollution events, members of the public have found themselves using devices not designed for them or improvising devices that provide an unknown level of protection. The absence of approved devices will remain an impediment for the public until the necessary systems and infrastructure can be established to fill this gap (Recommendation 7-3), and industry can manufacture and scale up the design of appropriate respiratory protective devices. In the interim, emergency use authorization (EUA) could be granted for existing devices, a step taken by FDA during the COVID-19 pandemic (CRS, 2021), with authorized devices being listed in a central database.

Current market-driven approaches for the development, manufacture, and marketing of respiratory protective devices rely heavily on the regulatory model for occupational respiratory protection in that devices are manufactured with the knowledge that their use will be required in certain industries to perform certain tasks. Thus, manufacturers have a guaranteed market. However, respiratory protective devices for the public would likely not carry such requirements, and their manufacture would therefore be a riskier proposition for industry. Indeed, two 3M respirators that had received regulatory approval for use by the public during public health emergencies were made available during the H1N1 pandemic. However, few were ever purchased because the pandemic was over by the time the products were marketed, and they were then discontinued in 2013 (FDA, 2009; McCullough, 2021). Accordingly, both consumer demand (e.g., as a result of public education and preparedness campaigns) and incentives for manufacturers to develop and produce these devices are necessary to ensure an ongoing market for public use.

The provision of such incentives would likely entail government work to develop relationships with manufacturers for the new devices, as well as federal government purchase guarantees (e.g., for inclusion in the Strategic National Stockpile [SNS]) (Robinson, 2021; Watney and Stapp, 2020). Within ASPR, the Biomedical Advanced Research and Development Authority (BARDA) supports advanced development and scale-up of manufacturing capacity for medical countermeasures, such as personal protective equipment (PPE), and promotes partnerships with developers

[44] NIOSH's CEL is available at https://wwwn.cdc.gov/niosh-cel (accessed September 28, 2021).

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and manufacturers. Inclusion in a database of approved devices for use by the public would likely help drive the consumer market to those products.

Addressing Gaps in Responsibilities and Authorities

Current processes for generating recommendations on devices meeting the public's needs for respiratory protection are ad hoc and often rely on collaborative relationships among multiple federal stakeholders. Needed is a formalized and enduring process and structure with a clear

BOX 7-3
Necessary Stakeholder Capabilities and Oversight Authority Options for Function F2

Overall coordinating entity role: Provide a mechanism for ensuring that hazard assessments conducted by agencies with the appropriate hazard-specific expertise (see Function F1) inform the identification of appropriate respiratory protective devices for the public. Facilitate coordination among agencies responsible for recommendations on respiratory protective devices and those responsible for supporting innovation in products when gaps in approved devices are identified (if there are different lead agencies for these two roles).

Role of lead agency(ies) with oversight for this function: Consider respiratory protection needs based on existing hazard assessments and considerations regarding risks from use of respiratory protective devices by the public, review the technical specifications and capabilities of existing respiratory protective devices, and determine which existing devices best meet the identified needs, as well as which needs are unmet and could be met by future products. Ensure that recommendations for respiratory protective devices are updated as new information becomes available and hazard assessments are updated. Develop approaches for manufacturers to fill gaps in respiratory protective devices meeting the public's protection needs.

Necessary characteristics of a lead oversight agency: Expertise in the variety of respiratory protective devices needed by the public (especially other than respirators) and the ability to match performance specifications of existing devices to identified needs for respiratory protection; expertise in product development, including knowledge of market forces and incentives; relationships with manufacturers; access to a certified equipment list (or equivalent).

Current agencies with some oversight authorities related to this function: As discussed for Function F1, there are few clear federal authorities to recommend/require public use of respiratory protective devices (although the Centers for Disease Control and Prevention [CDC] and the Environmental Protection Agency currently make recommendations to the public on respiratory protective devices related to some specific inhalation hazards).The Food and Drug Administration

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lead organization responsible for determining which existing respiratory protective devices best meet those needs based on evaluation of the hazard and risks at hand (Function F2) and review of the technical specifications and capabilities of existing devices. This lead organization also will need to develop rubrics for use at the state and local levels to provide recommendations on respiratory protection that accord with local environmental conditions. Stakeholder roles and different potential approaches to addressing current gaps in oversight authorities for Function F2 are described in Box 7-3.

(FDA) has issued guidance to manufacturers on special controls related to filtering facepiece respirators marketed for use by the public during public health emergencies, and under the Federal Food, Drug, and Cosmetic Act, can issue emergency use authorizations (EUAs) for specific devices that can be used by the public for medical purposes when no devices meeting standards are available and the Department of Health and Human Services (HHS) secretary determines that an EUA is appropriate. The Biomedical Advanced Research and Development Authority (BARDA) authorities under the Pandemic and All-Hazards Preparedness Act include directing and coordinating HHS's activities related to countermeasures and product advanced research and development and supporting innovation through strategic initiatives and investments.

Addressing gaps in oversight authorities (options with considerations for each):

Approach 1: Designate an existing agency as lead to make recommendations to the coordinating entity on the respiratory protective device best meeting the needs of the public based on the hazard and risk evaluation, with potential leads and considerations being the same as those identified for Function F0 (i.e., the National Personal Protective Technology Laboratory [NPPTL], the Consumer Product Safety Commission, or FDA).

Approach 2: Establish a new entity as lead to make recommendations to the coordinating entity on the respiratory protective device best meeting the needs of the public based on the hazard and risk evaluation (with the same considerations as identified for function F0).

Subfunctions (to be overseen by lead agency and/or coordinated) and examples of key/potential partners:

- Identify and recommend existing devices best meeting protection requirements. Depending on who is lead, partners could include NPPTL (in an advisory role unless its mandate were expanded) and FDA.
- Initiate new product development in the event that no existing device meets protection needs—manufacturers; the Assistant Secretary for Preparedness and Response/BARDA; standards development organizations, such as ASTM International, the International Organization for Standardization, and the National Fire Protection Association.

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As indicated in Box 7-3, the characteristics of a lead organization for Function F2 overlap with those for Function F0. Thus, the laboratory called for in Recommendation 7-3 is also well suited to lead the process for determining which existing respiratory protective devices best meet the needs of the public and developing guidelines for their use to inform targeted and tailored guidance for specific audiences (Function F4). To ensure that such specific device recommendations are grounded in an understanding of the hazards and risks of concern, the coordinating entity will need to ensure that the laboratory can access the hazard and risk evaluation conducted in the context of Function F1.

Recommendation 7-6: ***Use Hazard and Risk Evaluations to Determine the Necessary Respiratory Protective Devices for the Public***
The laboratory called for in Recommendation 7-4 should use the hazard and risk evaluations generated through the standardized process described in Recommendation 7-5 to identify and make recommendations to the coordinating entity on approved respiratory protective devices that best meet the respiratory protection requirements of the public. When no approved device exists that meets the identified requirements, the laboratory should oversee efforts to address this gap, consistent with its role in Function F0.

Function F3: Ensure Availability and Access Pathways for Respiratory Protective Devices

Supply chain failures during the COVID-19 pandemic disrupted the supply of respiratory protective devices for occupational settings (particularly for health care) (CRS, 2020; Mason and Friese, 2020), a problem exacerbated when those same devices became sought by the public. Countries established export restrictions on various respiratory protective devices and source materials (e.g., meltblown fabric) they deemed necessary for their own nation's needs (Cohen and Rodgers, 2020; Gruley and Clough, 2020). Given the future likelihood of these types of global supply chain disruptions, differentiating manufacturers' domestic and global capabilities would provide a more complete picture of availability during a global crisis.

To address the kinds of shortfalls in domestic production capability and capacity for a variety of respiratory protective devices experienced during the COVID-19 pandemic and other past emergency events, the development of such products for the public—particularly those that do not rely heavily on the model of the occupational respiratory protection program, including fit testing, needs to be encouraged. As discussed above, doing so will require building strong relationships with and providing incentives for manufacturers (Patel et al., 2017) to produce and innovate in the development of such

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devices. Moreover, the SNS and other stockpiles cannot be static depots of supplies that are used only when needed. Rather, they need to be integrated into the national supply chain such that there is turnover in inventory and ongoing evaluation of the performance of stockpiled devices. This would reduce the likelihood of stockpiled devices not being properly maintained or reaching their expiration dates without having been used, as well as yield greater understanding of which devices were being used in practice. To this end, the SNS requires a sophisticated product tracking system.

ASPR, which leads the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), oversees the procurement of medical countermeasures, including PPE such as respirators, and their associated inventory management, including stockpiling (CDC, 2014; Gerstein, 2020; NASEM, 2016). Both ASPR and its component agency, BARDA, have lead roles in procuring medical countermeasures for stockpiling. The Department of Defense (DoD) and the Department of Veterans Affairs may also serve as needed in planning or executing stockpiling options (ASPR, 2015). The SNS provides for significant purchasing power on the part of the federal government by establishing and guaranteeing a marketplace for respiratory protective devices (CDC, 2014). This governmental marketplace will be needed until the concept of respiratory protection for the public is embraced, and the public actively seeks out such devices and includes them in disaster supply kits for use during infectious disease, wildfire, and air pollution events. Such purchasing power can also drive innovation in respiratory protective devices through the establishment of requirements for products that will be stockpiled (Robinson, 2021).

During emergencies necessitating respiratory protection for the public, the federal government will likely need to serve as the gatekeeper of purchasing and distribution operations. Carrying out this function will require knowledge of the various distribution mechanisms and understanding of equity issues and relationships between the SNS and state, local, tribal, and territorial governments. In the event of wildfires or other pollution events in one region of the country, for example, the federal government will need to be able to divert more devices to affected areas from areas with either less need or less utilization, by, for example, developing and updating (in real time) a "heat map" of available and needed devices nationwide (NASEM, 2019).

During the COVID-19 pandemic, there were clear disparities in who had access to respiratory protective devices, leading to a widening of the COVID-19 risk differences across some groups. Diverse pathways for distribution of respiratory protective devices are needed in response to the heterogeneity of the population and the accessibility challenges for many of its subgroups. Design of access pathways needs to be prospectively considered. Given the importance of community trust in respiratory protective

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devices to people's willingness to use them, it will be important to consider issues of health equity in the procurement and distribution process (e.g., having minority-owned businesses as part of the procurement chain). Federal agencies overseeing the supply chain have historically not had the infrastructure to prioritize elimination and prevention of disparities among different population groups. Consideration should be given to opportunities to partner with other agencies that have this focus, including those at the subfederal level that are able to solicit feedback directly from community partners to guide the creation of a more equitable system.

The National Strategy for a Resilient Public Health Supply Chain, released in July 2021, calls for a strategy for improving the coordination and distribution of PPE, including respiratory protective devices, in public health emergencies (HHS et al., 2021). In the development of such a strategy, it will be important to attend to, among other issues,

- a process for ensuring that stockpiled products continue to meet performance requirements and for rotating out and replacing stock nearing its shelf life;
- inventory and distribution systems, including processes for coordinating with and leveraging state, local, tribal, and territorial agencies to ensure access for underserved groups; and
- a means of guiding appropriate use of the Defense Production Act (DPA) (see Chapter 2) to address shortages.

Addressing Gaps in Responsibilities and Authorities

The supply chain related to PPE, including respiratory protective devices, has received inadequate attention, with consequences that were apparent during the COVID-19 pandemic. Remedying this gap will require a responsible party with the authority to serve as the interface between manufacturers and existing federal authorities related to supply chain. As described in Box 7-4, this function could be filled by the coordinating entity or another lead agency. Given that this is a clear coordination function, the committee favors the former option.

The coordinating entity would be tasked with monitoring and guiding federal efforts to manage the supply chain so as to ensure adequate supplies of respiratory protective devices to meet public needs (e.g., providing input to those with the authority to invoke the DPA or working with manufacturers to incentivize production). Coordination with OSHA will be important to ensure that such efforts are not siloed. The coordinating entity would need to maintain the expertise to understand and engineer the market forces involved in the manufacture of these devices. The entity would also need to establish and sustain relationships with manufacturers both to ensure

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production capability and to trigger innovation within the industry (e.g., devices with improved fitting characteristics, devices suitable for children of a variety of ages), similar to the way DoD and BARDA work with their respective manufacturing bases. These relationships enable the entity to work nimbly with manufacturers to shift production between different types of respiratory protective devices, if possible, to address immediate needs.

Recommendation 7-7: *Ensure Availability of and Access to Respiratory Protective Devices*

The coordinating entity should organize efforts to make respiratory protective devices available and accessible to the public. It should interface with relevant stakeholders, including the Office of the Assistant Secretary for Preparedness and Response and the Occupational Safety and Health Administration, to guide stockpiling decisions regarding respiratory protective devices, including necessary quantities and characteristics (e.g., fit, reusability). To prepare for the occurrence of a large-scale incident involving inhalation hazards and ensure an adequate supply of respiratory protective devices in the event of such an incident, the entity should also work with the White House and the Federal Emergency Management Agency, as well as manufacturers, regarding the need to trigger the Defense Production Act and to provide incentives for manufacturing the necessary devices, especially during public health emergencies.

Function F4: Engage, Inform, and Ensure Access for the Target Community

Mitigating inhalation hazards outside of occupational settings is challenging because the public does not know where, which, how, and when respiratory protective devices should be used (see Chapter 4). People need clear, consistent, and timely guidance on the selection, acquisition, and effective use of appropriate respiratory protective devices for specific hazards that addresses their risk perceptions, preferences, and beliefs for that hazard (see Figure 7-2).

Given that respiratory protection is effective only if used correctly, education and training, ideally incorporating some means of feedback, are critical. A core function of public health agencies is health education. As discussed in Chapter 4, health information originating from CDC is typically passed through state health departments to local health departments, which then disseminate the information to health care providers and the public after ensuring that it is understandable and linguistically and culturally appropriate.

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BOX 7-4
Necessary Stakeholder Capabilities and Oversight Authority Options for Function F3

Overall coordinating entity role: Depends on the approach taken (see below), but may include monitoring the availability of respiratory protective devices and facilitating interfaces among existing authorities related to the supply chain, manufacturers, and the lead agency responsible for access pathways by which the public acquires these devices.

Role of lead agency(ies) with oversight for this function: Depends on the approach taken (see below), but includes oversight for establishing access pathways.

Necessary characteristics of a lead oversight agency: Access to information on and authorities related to the Strategic National Stockpile (SNS), including purchasing and distribution; relationships with manufacturers and with state, local, tribal, and territorial authorities that may be responsible for distributing respiratory protective devices; expertise in supply chain management and understanding of diverse population needs related to device access.

Current agencies with some oversight authorities related to this function: The Department of Health and Human Services (HHS) secretary and the Assistant Secretary for Preparedness and Response (ASPR) hold authorities related to stockpiling and rapid purchasing under the Public Health Services Act, as amended by the Pandemic and All-Hazards Preparedness Act. The U.S. president has Defense Production Act (DPA) authorities, as does the administrator of the Federal Emergency Management Agency (FEMA), who chairs the Defense Production Act Committee and advises on effective use of the DPA.

Education is most successful in reaching all segments of the nation's increasingly diverse communities when public health agencies engage with other organizations that routinely connect with and communicate health information to broader populations. While guidance can and should be provided directly to the public, its acceptability and use are amplified when it is conveyed through such trusted sources as health care providers and systems, faith leaders, community leaders, and other community-based organizations that serve specific population subgroups (Stout et al., 2019; Udow-Phillips and Lantz, 2020). Individuals who are from the target community, such as community health workers and *promotoras*, can be particularly effective at facilitating communication and education in local contexts. Effective communication is achieved when repeated and consistent messages in the audience's preferred language are delivered through multiple channels, through trusted individuals and organizations. Formatting guidance as

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Addressing gaps in oversight authorities (options with considerations for each):

Approach 1: Coordinating entity interfaces with ASPR/Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to guide stockpiling decisions regarding respiratory protective devices and continuously monitor supply and demand, and also interfaces with the White House/FEMA regarding the need to trigger the DPA for manufacturing of respiratory protective devices. Lead agency(ies) (e.g., Centers for Disease Control and Prevention [CDC], Environmental Protection Agency) are charged with working with partners, including those on the ground, to establish access pathways. In this approach, lead agency(ies) responsible for ensuring access pathways could have reduced visibility on the supply chain as compared to approach 2, requiring close coordination with the coordinating entity.

Approach 2: Lead agency interfaces with ASPR/PHEMCE regarding the supply chain for respiratory protective devices and ensures access pathways. This approach could result in duplication/overlap in a coordination function.

Subfunctions (to be overseen by lead agency and/or coordinated) and examples of key/potential partners:

- Monitoring the availability of respiratory protective devices—manufacturers, ASPR/SNS
- Triggering increased manufacturing volume—FEMA/White House (for DPA), manufacturers, the Department of Defense
- Establishing a reliable manufacturing base and stockpile to meet surge needs—manufacturers, ASPR/SNS
- Establishing access pathways—ASPR/SNS; FEMA; CDC; state, local, tribal, and territorial public health and air quality agencies

talking points that can easily be tailored to specific audiences and communication needs facilitates its dissemination (see Chapter 4). During the COVID-19 pandemic, agencies at the state and local levels have leveraged their community partners and staff in educational efforts designed to promote prevention measures that limit community transmission, including safe isolation and quarantine, increased testing, and vaccination (Buchner et al., 2021). Such community partnerships are critical to equity such that all groups have access to key information and resources. Additionally, these community partners can play a critical role in helping public health stakeholders understand perceived barriers impeding adherence to the guidance provided, such as the reasons behind the hesitancy toward the COVID-19 vaccine.

Health care providers also have traditionally played a critical role in health education because of the high level of trust their patients have in

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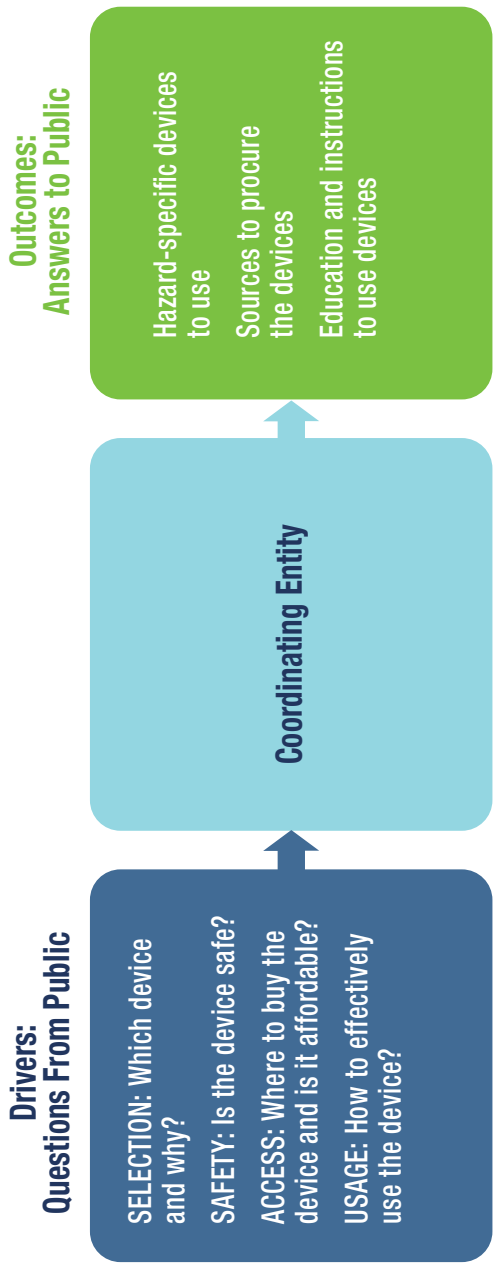


FIGURE 7-2 Drivers and outcomes of a framework for the public. The public's needs for clear and timely guidance are addressed by the functions of the coordinating entity and result in outcomes that support the public's effective use of respiratory protective devices.

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them when making difficult health-related decisions. They have the added benefit of knowing the medical histories of their patients, enabling them to offer personal guidance that can increase effective use of respiratory protective devices and compliance with public health guidance.

In the absence of a formal respiratory protection program for the public then, public health professionals and health care providers are left with the critical responsibility of providing guidance to the public on the medical indications for and use of respiratory protection (Harber et al., 1996). However, many lack adequate training and the tools and resources needed to perform this function well (Alfano-Sobsey et al., 2006; Barratt et al., 2020; John et al., 2017). To be effective in this role, they need to be better equipped to do so. Thus a critical gap is the lack of formal requirements or mechanisms for public health agencies and health care providers to be trained in respiratory protection so they can be confident in evaluating resources to which they can direct their patients.

In addition to communication pathways, the form and content of health messages influence their effectiveness. As discussed in Chapter 4, however, messages about respiratory protection have not been adequately tested, and the most effective strategies for ensuring appropriate selection and use of these products by the diverse communities that make up the U.S. public are unknown. Instructions on appropriate use of respiratory protective devices need to be clear (Clayman et al., 2010) and to take account of health literacy principles, such as those espoused in the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (Think Cultural Health, 2018). The National CLAS Standards are a set of action steps intended to advance health equity, improve quality, and help eliminate health care disparities by providing a blueprint for individuals, public health agencies, and health care organizations to provide culturally and linguistically appropriate services (Think Cultural Health, 2018). It is especially critical that messages be developed with the input of relevant experts to ensure their accuracy and tested with members of the target audiences to ensure that they have the intended effect in different population groups. Reliance on "common sense" strategies will not necessarily lead to effective messaging (Council of Canadian Academies, 2015; NASEM, 2017).

Individually focused strategies for promoting the use of respiratory protective devices during a public health emergency such as COVID-19, when the hazard is invisible, may not be as successful as would be the case with a visible hazard such as smoke during a wildfire (Lakhina and Lebeda, 2021; Santana et al., 2021). Recognizing that risk perception varies, risk should be communicated in a relatable way and described by comparison with commonly known inhalation hazards—the approach taken with air quality

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warnings and COVID-19 with seasonal influenza and chickenpox being used as analogies to communicate transmissibility (Buchner et al., 2021).

Messaging to the public needs to address not only what should be done in the midst of an incident or emergency resulting in exposure to inhalation hazards but also what preparedness steps should be taken before such an event occurs. Recognizing that the SNS is often not immediately available to a locality at the outset of a public health emergency, state and local emergency response plans include stockpiling of PPE and other critical supplies, which also may not be readily available to the public for hours. Therefore, local preparedness plans often include community engagement designed to promote individual and family preparedness and convey the importance of having a disaster supply kit. In response to the COVID-19 pandemic, CDC has expanded the list of items that should be in a disaster kit, which include masks for everyone aged 2 and above (Ready.gov, 2021). It will be important for this new guidance to be reflected in local emergency preparedness communications directed at the public to increase their awareness and early use of respiratory protective devices during events related to infectious diseases, wildfires, and air pollution.

Beyond the significant issues related to education and communication, it is equally important to address issues related to access to information and protective products. The coordinating entity needs to ensure that issues of equity and access, including product cost, availability, and acceptability to a broad range of groups, are considered throughout the entire lifecycle process. It is particularly important to consider access issues among the most vulnerable, and to devote resources to ensuring that inequities in access are prevented or eliminated. Depending on cost, it may be critical for subsidies to be provided so that those who are most vulnerable do not end up receiving information and education but not the protective devices they need.

Addressing Gaps in Responsibilities and Authorities

Multiple federal agencies develop and disseminate guidance for the public on the selection and use of respiratory protection based on the nature of the inhalation hazard at hand. For example, EPA, which regulates environmental pollutants and provides air monitoring data, has produced guidance for public health officials on protecting the public from wildfire smoke, which includes the use of respiratory protective devices (EPA et al., 2019), while CDC has published a multitude of guidance on the public's use of masks and face coverings (and respirators to a lesser degree) during the COVID-19 pandemic (CDC, 2021). This lack of a central, coordinated body to provide guidance on respiratory protective devices for the public has led to a decentralized and fragmented process for public health recommendations and education, which in turn has resulted in considerable

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confusion around selection and use of the devices by the public. The coordinating entity could fill this gap by facilitating a collaborative process for the development of such guidance or harmonizing independently developed guidance. The role of the coordinating entity in ensuring consistent guidance and different potential approaches to structuring stakeholder responsibilities in that effort are described in Box 7-5.

Of the approaches presented in Box 7-5, the committee favors proactive collaborative development of guidance and training over post hoc efforts to harmonize independently developed materials. Given the scale of the undertaking, this task is not well suited to the coordinating entity and would distract from the core functions of the laboratory charged with oversight of standards development and approval for respiratory protective devices intended for public use (Recommendation 7-3). A lead agency with the requisite expertise and communication infrastructure is needed. As the nation's public health agency, CDC has deep expertise in health communication, as well as in environmental and infectious inhalation hazards. The agency also has the necessary infrastructure and established channels for dissemination, including to state, local, tribal, and territorial public health agencies. Consequently, the committee believes CDC is best positioned to lead the development of guidance and training related to public's use of respiratory protection.

Recommendation 7-8: ***Develop Culturally Appropriate Guidance and Training on the Use of Respiratory Protective Devices by the Public***
The Centers for Disease Control and Prevention should lead the development of culturally appropriate guidance and training related to the use of respiratory protective devices by the public. This guidance and training should address which respiratory protective devices should be used, when they should be used, and how they should be worn to reduce harm from inhalation hazards. The coordinating entity should facilitate the engagement of and gathering of input from key stakeholders to advance these efforts, and ensure that the approaches developed consider the needs, cultural and socioeconomic factors, and local contexts of vulnerable groups and those facing persistent health burdens.

Specifically, the committee suggests the following considerations:

- CDC should serve as the focal point for assurance that guidance materials are accessible to and appropriate for the general population and its many subgroups. While other federal agencies (e.g., EPA, the Federal Emergency Management Agency) will be involved in developing the guidance, harmonization will be necessary to avoid conflicting information. CDC should develop formalized mechanisms for that purpose.

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BOX 7-5
Necessary Stakeholder Capabilities and Oversight Authority Options for Function F4

Overall coordinating entity role: Provide a focal point for policy discussions on guidance related to the public's use of respiratory protective devices and a mechanism for stakeholders to harmonize guidance intended for the public, as well as guidance and training for public health and medical professionals. Ensure coordination among federal, state, local, tribal, and territorial public health agencies. Interface with the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) regarding harmonization with guidance on use of respiratory protective devices to mitigate workplace exposures during emergencies.

Role of lead agency(ies) with oversight for this function: Expeditiously develop culturally appropriate guidance and training on respiratory protective devices for the public that addresses where, which, how, and when such devices should be used and how they should be worn to provide reduction of harm. Ensure that inequities in guidance, training, and access to protective products are prevented or eliminated.

Necessary characteristics of a lead oversight agency: Expertise in public health messaging and risk communication, sociobehavioral science, health equity, and guidance development; networks to reach target audiences; authority to approve guidance.

Current agencies with some oversight authorities related to this function: Environmental Protection Agency (EPA) authorities related to public engagement and communication stem from responsibilities related to monitoring and reporting air quality under the Clean Air Act and indoor air issues under title IV of the Superfund Amendments and Reauthorization Act (SARA) and the Radon and Indoor Air Quality Research Act. EPA provides guidance to the public on respiratory protection (particularly for wildfire smoke). The mission of the Centers for Disease Control and Prevention (CDC), which is derived from the public health goals set out in the Public Health Service Act, is focused on disease prevention and control, environmental health, and health promotion and health education activities.

Addressing gaps in oversight authorities (options with considerations for each):

Approach 1: A single lead organization develops guidance and training in coordination with experts from partner agencies, which is then distributed through

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those partners using their existing networks and channels. Options for lead organizations include:

- The coordinating entity, which could develop the guidance and training but leverage the networks of other stakeholders for dissemination. This would require significant investment in infrastructure and expertise within the coordinating entity.
- An existing agency (CDC) develops the guidance and training. This approach would utilize existing infrastructure, including expertise in communication with the public and networks with state, local, tribal, and territorial government authorities.
- The laboratory proposed in Recommendation 7-3, which would be charged with oversight of standards development for and approval of respiratory protective devices for the public, develops the guidance and training. This approach could create redundancy in infrastructure and lack of clarity regarding roles and responsibilities.

Approach 2: Different lead agencies develop guidance and training for different hazard types (e.g., EPA for environmental hazards, CDC for infectious diseases), with coordination and harmonization occurring through the coordinating entity.

- This approach could result in redundancy in communication expertise across agencies and duplication of effort in generating the guidance separately.

Subfunctions (to be overseen by lead agency and/or coordinated) and examples of key/potential partners:

- Develop and test guidance—CDC and EPA (if not lead[s]); the Federal Emergency Management Agency (FEMA); state, local, tribal, and territorial public health agencies (and their associated community partners); public health and medical associations and societies (e.g., the American Thoracic Society); the Department of State (for overseas staff and families)
- Disseminate guidance during events—CDC and EPA (if not lead[s]); FEMA; state, local, tribal, and territorial public health agencies (and their associated community partners); public health and medical associations and societies (e.g., the American Thoracic Society); the Department of State (for overseas staff and families)
- Develop, test, and disseminate training modules designed for public health and medical professionals—CDC and EPA (if not lead[s]); state, local, tribal, and territorial public health agencies; public health and medical associations and societies

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- In addition to partner federal agencies, CDC should gather input from other key stakeholders, such as local, state, and tribal partners and nongovernmental groups, including medical care providers and health systems, faith leaders, community leaders, and community-based organizations with reach to specific population groups.
- CDC should test the guidance as part of ongoing preparedness activities and periodically following its dissemination to ensure that it is appropriate for diverse population groups and determine whether it needs to be refined as information and contexts change.
- CDC should ensure that mechanisms for reaching critical partners for dissemination, including local, state, territorial, and tribal agencies, as well as community organizations, have been explored and tested, along with routes for direct dissemination to individuals. CDC should map the reach of its communications to ensure that they can reach all segments of the population.
- CDC should partner with medical and public health professionals and societies, as well as device manufacturers and retailers, to develop, test, and disseminate training modules and guidance appropriate for health care and public health professionals and community health workers so they will be prepared to provide guidance to and respond to questions from the public about health risks associated with inhalation hazards and respiratory protective devices.
- If CDC is made aware of the spread of misinformation, it should develop and disseminate improved versions of the guidance to counter such misinformation.

To support the efforts of public health agencies on the ground in responding to the needs of their diverse communities, guidance from CDC should

- be sufficient for incorporation into emergency response plans at the local, state, tribal, territorial, and federal levels;
- be easily tailored for specific populations by local, state, territorial, and tribal agencies and usable by community organizations;
- be tested with diverse end-user groups and periodically over time to determine whether the guidance needs further refinement, particularly as environmental and political contexts change;
- take into account health literacy principles embodied in the National CLAS Standards to increase the information's acceptability and usability; and
- apply principles in CDC's Clear Communication Index and the National Academies publication *Communicating Science Effectively: A Research Agenda* (NASEM, 2017).

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To ensure effective and adequate dissemination and implementation, trainings for public health and medical professionals should

- provide continuing education credits;
- be free and easily accessible;
- acknowledge the diverse needs of the American public and potential inequities in the public's access to health care and respiratory protection; and
- be incorporated into the medical and public health education system where feasible so that future generations have this training as part of their foundational skill set.

Function F5: Incorporate Lifecycle Learning and Continuous Improvement

Function F5 is responsible for ongoing learning and continuous improvement that are critical to catalyzing advances in each of the core functions (F0 through F4) and ensuring the continued robustness of the framework over time to anticipate, prepare for, and respond to evolving needs for respiratory protection for the public. Just as learning and continuous improvement is the underlying operational paradigm for the various steps in the product lifecycle depicted in Figure 5-1 in Chapter 5, Function F5 is responsible for executing the activities associated with lifelong learning and continuous improvement of the framework. Function F5 also serves as the pathway to activating Function F0 (e.g., product design, standards development, conformity assessment, and manufacturing) when the need for a respiratory protective device to protect the public against an inhalation hazard has been identified. The various feedback loops that make up Function F5 and drive continuous improvement are critical because the framework must evolve continuously while anticipating and preparing for future changes. Thus, the ultimate objective of Function F5 is to create a "learning organization" (Garvin, 1993; Senge, 1990) that will address present needs while creating a robust system to anticipate and continuously enhance national preparedness in respiratory protection for the public.

Addressing Gaps in Responsibilities and Authorities

The major activities associated with Function F5 for the public are as follows:

- Promote collaboration among stakeholders in the framework by developing and utilizing appropriate channels of communication in a coordinated and timely manner.

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- Define and implement streamlined processes with milestones to monitor the activities in the framework, track progress, and modify the functions as necessary to ensure that their goals are being met.
- Institute a process for capturing learning and experience over time to create a rich knowledge base that can be harnessed by all stakeholders.
- Track and analyze technological advances related to respiratory protection, and work with relevant stakeholders in using these advances to improve existing and create new respiratory protective devices for the public.
- Create a roadmap for the future of respiratory protection for the public, and institute processes for ongoing updating of the roadmap to keep it robust and responsive to evolving inhalation hazards and technological advances.
- Use the roadmap to develop a strategic research agenda for both filling identified gaps and laying the foundation for meeting respiratory protection needs in the future.

Execution of these activities will need to be purposefully driven and reinforced by mechanisms for accountability. No single agency or other federal entity currently holds this responsibility. Addressing this gap will require oversight by the coordinating entity and implementation by those stakeholders with lead roles across the other framework functions, as described in Box 7-6.

Development of the nascent knowledge base related to public use of respiratory protective devices will have to be a focused, expansive science- and policy-driven effort guided by a coordinated research agenda. Research activities related to respiratory protection for the public are currently fragmented, with CDC and EPA leading intra- and extramural research. Other stakeholders include NIH, particularly the National Institute for Environmental Health Sciences (NIEHS), and DHS. NIOSH's National Occupational Research Agenda (NORA)[55] provides a useful model that could be considered in the efforts to establish a research agenda.

Recommendation 7-9: *Continuously Evaluate Progress Toward Goals, and Enhance the Framework's Operations*
Based on ongoing monitoring and evaluation, the coordinating entity should

[55] Information on NORA is available at https://www.cdc.gov/nora/default.html (accessed December 12, 2021).

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- develop and update plans with objective and transparent milestones, and ensure that changes needed to continuously enhance the framework are made;
- regularly assess and publicly report on progress;
- ensure that available funding and its allocation enable goals to be achieved;
- coordinate linkages across partners in government, academia, nonprofits, and industry;
- conduct periodic exercises to evaluate national preparedness for respiratory protection for the public; and
- lead the development of a coordinated, strategic research agenda to develop the knowledge base and address knowledge gaps in respiratory protection for the public.

BOX 7-6
Necessary Stakeholder Capabilities and Oversight Authority Options for Function F5

Overall coordinating entity role: Establish formal mechanisms for continuous evaluation and feedback for each of the framework functions, and coordinate research to address identified gaps through the development and ongoing refinement of a coordinated, strategic research agenda.

Role of lead agency(ies): All lead agencies for previously discussed functions would be responsible for conducting continuous improvement activities related to those specific functions for which they had oversight authority, ensuring that feedback was systematically solicited from those on the ground. Those with relevant research programs would be responsible for conducting research to address knowledge gaps regarding respiratory protection as related to users (the public), hazards, devices, and systems.

Necessary characteristics of a lead oversight agency: Infrastructure for research, as well as for monitoring and evaluation for ongoing improvement purposes; expertise in specific hazards of interest, respiratory protection, sociobehavioral science, implementation science, and continuous improvement

Current agencies with some oversight authorities related to this function: The Environmental Protection Agency, the Centers for Disease Control and Prevention, the National Institutes of Health (e.g., the National Institute of Environmental Health Sciences), and the Department of Homeland Security all have relevant research programs.

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Function F6: Coordination

The coordinating entity for the public framework will be charged with integrating the efforts of all stakeholders to ensure that the six preceding functions are carried out seamlessly. To this end, the coordinating entity will have an oversight role for each function, as described in Box 7-7.

BOX 7-7
Consolidated Roles for the Coordinating Entity Across Functions

Function F0 (Develop and approve respiratory protective devices): Ensure that information from ongoing scenario planning and research on user needs informs design requirements that feed into standards development and guides the development of new respiratory protective devices.

Function F1 (Assess hazard and determine need for respiratory protection): Provide a mechanism for stakeholders to collaborate on the development of a structured process for assessing the need for respiratory protection based on an evaluation of the evidence regarding the inhalation hazard(s) of interest, exposures and risks to the public, and ability to mitigate those risks through alternative control measures. Provide a forum for stakeholders to discuss and prioritize hazards for which this evaluation process should be conducted and to discuss policy considerations regarding recommendations on the public's respiratory protection needs resulting from the process.

Function F2 (Determine the necessary respiratory protective devices): Provide a mechanism for ensuring that hazard assessments conducted by agencies with the appropriate hazard-specific expertise (see Function F1) inform the identification of appropriate respiratory protective devices for the public. Facilitate coordination among agencies responsible for recommendations on respiratory protective devices and those responsible for supporting innovation in products

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when gaps in approved devices are identified (if there are different lead agencies for these two roles).

Function F3 (Ensure availability and access pathways for respiratory protective devices): Monitor the availability of respiratory protective devices and facilitate interfaces among existing authorities related to the supply chain, manufacturers, and the lead agency responsible for access pathways by which the public acquires these devices.

Function F4 (Engage, inform, and ensure access for the target community): Provide a focal point for policy discussions on guidance related to the public's use of respiratory protective devices and a mechanism for stakeholders to harmonize guidance intended for the public, as well as guidance and training for public health and medical professionals. Ensure coordination among federal, state, local, tribal, and territorial public health agencies. Interface with the Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health regarding harmonization with guidance on use of respiratory protective devices to mitigate workplace exposures during emergencies.

Function F5 (Incorporate lifecycle learning and continuous improvement): Establish formal mechanisms for continuous evaluation and feedback for each of the framework functions, and coordinate research to address identified gaps through the development and ongoing refinement of a coordinated, strategic research agenda.

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Appendix A

Study Approach and Methods

In response to a request by the National Institute for Occupational Safety and Health (NIOSH), the Environmental Protection Agency, and the Department of State, the National Academies of Sciences, Engineering, and Medicine convened the Committee on Respiratory Protection for the Public and Workers Without Respiratory Protection Programs at Their Workplaces. This committee was charged with making recommendations for a framework of responsibilities and authorities that would provide a unified and authoritative source of information and effective oversight for the development, approval, and use of respiratory protection. The committee's report presents an overview of considerations and needs for use of respiratory protective devices by the public and certain worker groups, along with conclusions and recommendations to address the need for oversight and guidance related to respiratory protection.

STAKEHOLDER ENGAGEMENT AND INFORMATION GATHERING

The committee deliberated from November 2020 to October 2021 and held eight virtual meetings (two meetings in November 2020, followed by meetings in January, April, June, July, August, and October 2021). The two November 2020 meetings and the meetings in January, July, and October 2021 included portions that were open to the public (see the section on Public Session Agendas below). The remainder of the committee meetings were held in closed session.

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To inform its deliberations, the committee used several mechanisms to gather information: (1) a 2-day workshop in January 2021 with open public sessions to hear from federal agencies, public health and air quality agencies, worker-oriented nonprofit organizations and research institutions, labor unions, manufacturers, and others; (2) public meetings with sessions on third-party testing and certification of respiratory protective devices, models for federal agency roles and structures for coordinating cross-agency activities, and processes and systems for evaluating infectious agents transmissible by inhalation routes and determining the need for public use of respiratory protection; (3) a request to NIOSH for information on considerations regarding use of third-party testing laboratories and voluntary consensus standards; (4) a series of comprehensive and targeted reviews of factors that influence the effectiveness of respiratory protective devices for their intended use (see the section on Research Methods and Appendix B); and (5) an assessment of authoritative guidance (e.g., from governmental, national labor union, and other prominent worker organization sources) on the use of respiratory protective devices by the public and selected worker groups to identify gaps.

PUBLIC SESSION AGENDAS

First Committee Meeting
Public Session Agenda

Thursday, November 5, 2020
12:30–3:40 p.m. ET
Zoom

OPEN SESSION

SESSION I	Presentation of the Committee's Charge

Session Objective: To present and clarify as needed the charge to the committee.

12:30 p.m. **Welcome and Introductions**

JONATHAN SAMET, *Committee Chair*
Dean and Professor
Colorado School of Public Health

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12:40 p.m. **Overview of the Statement of Task**

MARYANN D'ALESSANDRO
Director
National Personal Protective Technology Laboratory
National Institute for Occupational Safety and Health

12:45 p.m. **Clarifying Questions on the Statement of Task**

SESSION II	Context for the Study and Discussion of Study Scope

Session Objective: To provide additional context for the study, including an overview of the current regulatory environment for respiratory protective devices, with a focus on variable processes for conformity assessment and diversity of key stakeholders.

1:00 p.m. **Context for the Study: State Department Perspective**

CLAIRE HUSON
Industrial Hygienist
Bureau of Overseas Buildings Operations
Department of State

SHANNA SURENDRA
Foreign Service
Department of State

MOLINI PATEL
Chief Air Pollution Advisor
Bureau of Medical Services
Department of State

1:15 p.m. **Discussion with Committee**

1:30 p.m. **Context for the Study: The Complex Regulatory Environment**

SUSAN MOORE
Associate Director for Science
National Personal Protective Technology Laboratory
National Institute for Occupational Safety and Health

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1:35 p.m. **U.S. and International Approaches to Conformity Assessment of Respiratory Protective Devices**

Colleen Miller
National Personal Protective Technology Laboratory
National Institute for Occupational Safety and Health

2:05 p.m. **Conformity Assessment for Non-Respiratory Personal Protective Equipment in the United States**

Jeffrey Stull
President
International Personnel Protection, Inc.

2:20 p.m. **Role of Respiratory Protection Programs in Effective Respirator Use**

Andrew Levinson
Deputy Director
Directorate of Standards and Guidance
Occupational Safety and Health Administration

2:35 p.m. **Break** (5 min)

2:40 p.m. **Discussion of the Study Scope**

3:40 p.m. **Adjourn Open Session**

Second Committee Meeting
Public Session Agenda

Tuesday, November 24, 2020
12:45–1:45 p.m. ET

OPEN SESSION

12:45 p.m. **Methods for Literature Review and Evidence Evaluation**

Karen Robinson
Evidence-Based Practice Center
The Johns Hopkins University

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Anne Marie Houppert
Research Center
National Academies of Sciences, Engineering, and Medicine

1:45 p.m. **Adjourn Open Session**

Third Committee Meeting
Public Session Agenda

Day 1: Monday, January 25, 2021
10:30 a.m.–4:30 p.m. ET

OPEN SESSION

10:30 a.m. **Welcome and Introductions**

Jonathan Samet, *Committee Chair*
Dean and Professor
Colorado School of Public Health

SESSION I | Revisiting the Scope and Context of the Study Charge

10:40 a.m. **Perspectives from the Environmental Protection Agency**

Wayne Cascio
Director, Center for Public Health and Environmental Assessment
Environmental Protection Agency

10:55 a.m. **Respiratory Protection Needs During a Radiological Emergency**

Armin Ansari
Radiological Assessment Team Lead, Radiation and Chemical Branch
National Center for Environmental Health
Centers for Disease Control and Prevention

11:05 a.m. **Committee Discussion on Study Scope and Context**

11:25 a.m. **Break**

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SESSION II	Understanding Respiratory Protection Needs, Current Practices, and Barriers to Use by the General Public

Moderator: Stephanie Holm, Committee Member

11:30 a.m. **Perspectives from Public Health Officials**

Georges Benjamin
Executive Director
American Public Health Association

John Douglas
Executive Director
Tri-County Health Department, Colorado

George Conway
Director
Deschutes County Health Services Department, Oregon

Kris Ray
Air Quality Program Manager
Confederated Tribes of the Colville Reservation

12:10 p.m. **Discussion with the Committee**

12:45 p.m. **Moderated Panel Discussion: Communicating with Diverse Populations**

Fairfax County Health Department's Outreach Team
Kirsten Buchner
Jennifer Chuong
Carla Paredes-Gomez
Zubair Saeed
Nikkia Wilkens
Binbin Yang

1:20 p.m. **Moderator's Reflections**

1:25 p.m. **Break**

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SESSION III	Understanding Respiratory Protection Needs, Current Practices, and Barriers to Use by Workers Without Respiratory Protection Programs

Moderator: Robert Harrison, Committee Member

1:45 p.m. **Understanding Gaps in Respiratory Protection for Workers**

Gregory Wagner
Adjunct Professor
Harvard T.H. Chan School of Public Health

1:55 p.m. **Understanding the Needs of Specific Worker Populations**

Kathleen Navarro
Research Industrial Hygienist
National Institute for Occupational Safety and Health

Julie Sorensen
Director
Northeast Center for Occupational Health and Safety

Nancy Zuniga
Workers Health Program Manager
Institute of Popular Education of Southern California

Robyn Robbins
Director, Occupational Safety and Health Office
United Food and Commercial Workers International Union

Mark Catlin
Industrial Hygienist
MDC Consulting and Training

Jonathan Rosen
Principal Consultant
AJ Rosen & Associates

2:30 p.m. **Discussion with the Committee**

3:05 p.m. **Moderator's Reflections**

3:10 p.m. **Break**

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SESSION IV	Understanding Current Responsibilities and Authorities for Oversight and Guidance Related to Public Use of Respiratory Protective Devices

3:15 p.m. **Federal Perspectives on the Regulatory Landscape and Guidance for Public Use of Respiratory Protection**

Susan Stone
Senior Environmental Health Scientist
Office of Air Quality Planning and Standards
Environmental Protection Agency

Laura Kolb
Director, Center for Scientific Analysis, Indoor Environments Division
Office of Radiation and Indoor Air
Environmental Protection Agency

Patrick Breysse
Director, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention

BiFeng Qian
Scientific Reviewer
Center for Devices and Radiological Health
Food and Drug Administration

4:00 p.m. **Discussion with the Committee**

4:30 p.m. **ADJOURN**

Day 2: Tuesday, January 26, 2021
11:00 a.m.–12:45 p.m. ET

OPEN SESSION

11:00 a.m. **Welcome and Introductions**

Jonathan Samet, *Committee Chair*
Dean and Professor
Colorado School of Public Health

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SESSION V	Respiratory Protective Devices: Technologies, Gaps/ Challenges, and Opportunities to Meet Needs

11:10 a.m. **Perspectives from Respiratory Protective Device Manufacturers**

Nicole McCullough
Global Technical Service and Regulatory Manager, Personal Safety Division
3M

Zane Frund
Executive Director and Global Leader
Product Research and Development, Materials and Chemical Research
MSA Innovation, LLC

John Schwind
President
Global Safety First, LLC

12:00 p.m. **Discussion with the Committee**

Richard Stein (Discussant)
Consultant

12:45 p.m. **ADJOURN PUBLIC SESSION**

Sixth Committee Meeting
Public Agenda

Friday, July 9, 2021
11:30 a.m.–2:00 p.m. ET

OPEN SESSION

11:30 a.m. **Welcome and Introductory Comments**

Jonathan Samet, *Committee Chair*
Dean and Professor
Colorado School of Public Health

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SESSION I	Third-Party Certification and Conformity Assessment

Session Objective: To gather information on the considerations related to third-party certification in the conformity assessment process for respiratory protection.

11:40 a.m. **Potential Roles of Third-Party Certification in Conformity Assessment for Respiratory Protection**

Tricia Hock
Director, Certification Operations
Safety Equipment Institute

Ganesh Rao
Global Director
UL LLC

11:55 a.m. **Committee Discussion**

SESSION II	Establishing New Federal Entities: Experiences and Lessons Learned

Session Objective: To explore considerations and lessons learned related to the establishment of new federal organizations.

12:10 p.m. **Establishing Regulatory Agencies: Lessons from the Center for Tobacco Products**

David Ashley
Professor, School of Public Health
Georgia State University

12:20 p.m. **Committee Discussion**

12:30 p.m. **Break**

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SESSION III	Federal Agency Roles and Structures in a Framework to Ensure Access to and Effective Use of Respiratory Protection

Session Objective: To explore federal agency roles and coordination mechanisms in a framework to ensure access to and effective use of respiratory protection.

12:35 p.m. **Perspectives from Former and Current Federal Agency Leadership**

Former Federal Agency Leadership Panel
THOMAS BURKE
Jacob I. and Irene B. Fabrikant Professor and Chair
Department of Health Policy and Management
Johns Hopkins Bloomberg School of Public Health

ROBIN ROBINSON
Vice President
Scientific Affairs
RenovaCare, Inc.

JOSHUA SHARFSTEIN
Vice Dean for Public Health Practice and Community Engagement
Department of Health Policy and Management
Johns Hopkins Bloomberg School of Public Health

RICHARD SERINO
Distinguished Senior Fellow
Harvard T.H. Chan School of Public Health

Current Federal Agency Leadership Panel
MARYANN D'ALESSANDRO
Director
National Personal Protective Technology Laboratory
National Institute for Occupational Safety and Health

ERIKA SASSER
Director
Health and Environmental Impacts Division
Office of Air Quality Planning and Standards
Environmental Protection Agency

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PATRICK BREYSSE
Director, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention

1:55 p.m. **Closing Remarks**

2:00 p.m. **ADJOURN**

Eighth Committee Meeting
Public Session Agenda

Wednesday, October 6, 2021
3:00–4:00 p.m. ET

3:00 p.m. **Welcome and Introductory Comments**

JONATHAN SAMET, *Committee Chair*
Dean and Professor
Colorado School of Public Health

3:05 p.m. **Current Processes for Determining the Need for Public Use of Respiratory Protective Devices for Infectious Inhalation Hazards**

MICHAEL BELL
Deputy Director, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

CAPT LISA DELANEY
Associate Director, Emergency Preparedness and Response Program
National Institute for Occupational Safety and Health

CAPT MARIE DE PERIO
Senior Medical Advisor, Office of the Director
National Institute for Occupational Safety and Health

3:55 p.m. **Closing Remarks**

4:00 p.m. **Adjourn Public Session**

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RESEARCH METHODS

To address the charge, the committee, guided by input from the study sponsors, identified nine high-priority use scenarios (see Table 1-1) for respiratory protective devices and, for each scenario, conducted a comprehensive or targeted literature review to assess what is currently known regarding the factors that influence the effectiveness of respiratory protective devices. Six of these use scenarios were selected as the focus of comprehensive reviews of the literature, while three were explored via targeted reviews. The methods of the comprehensive reviews are described below. Although literature searches and data extraction were conducted separately for each of the review topics, findings were combined into a single narrative synthesis that describes cross-cutting and unique findings across the use scenarios (see Appendix B). The committee uses the term *comprehensive review* to address the "deep dives" requested by the sponsors, and notes that the reviews were not systematic reviews, using, for example, Cochrane or other established methods. With the constraints of time and available resources, formal systematic reviews were not feasible.

Additionally, other targeted searches of peer-reviewed and gray literature were carried out to address information needs and support the committee's conclusions and recommendations. This review effort included the collection of highly cited, foundational articles related to filtration efficiency, breathing resistance, fit, comfort, and usability of respiratory protective devices to provide contextual information for the discussion of findings from the comprehensive reviews. Targeted research also included nonexhaustive collection of public- and worker-oriented guidance from authoritative sources (e.g., federal agencies, national-level unions, and prominent workers organizations) on the selection and use of respiratory protective devices, as well as research on the scope and effectiveness of respiratory protection programs in the United States. Additionally, an analysis of citation data from the Occupational Safety and Health Administration (OSHA) related to the Respiratory Protection Standard (1910.134) was undertaken to inform challenges related to compliance with the standard (methods and data tables included below).

High-Priority Topics for the Comprehensive Reviews

Use Scenario Topics for Comprehensive Review

The selection of the six high-priority use scenario topics for comprehensive review, listed below, was guided by the priority populations and hazards identified by the study sponsors (see Table 1-1). The committee conducted literature searches for air pollution separately from wildfire

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smoke, and communicable biological agents separately from noncommunicable biological agents, resulting in 10 separate literature reviews, which were synthesized with a narrative approach.

Comprehensive review topics included:

- Wildland firefighters
  - Wildfire smoke
  - *No review conducted on ambient air pollution due to the specific interest in wildfire smoke for this worker population.*
- Outdoor workers
  - Air pollution
  - Wildfire smoke
- Outdoor workers
  - Noncommunicable biological agents
- Indoor workers
  - Noncommunicable biological agents
  - Communicable biological agents
- Public
  - Air pollution
  - Wildfire smoke
  - Noncommunicable biological agents
  - Communicable biological agents

The differentiation of indoor workers and outdoor workers for the purposes of the literature searches was driven by the matrix of priority populations and hazards (see Table 1-1), but the committee acknowledges that these distinctions are not always relevant and that many workers perform job functions (and are exposed to inhalation hazards) both indoors and outdoors. The findings presented in the synthesis describe occupation type and location of work, when possible, rather than referring to the broad categories of indoor versus outdoor workers.

Targeted Review Use Scenario Topics

Certain use scenarios were selected for targeted rather than comprehensive review because search terminology overlapped with some of the use scenario topics covered by comprehensive reviews (e.g., search terminology for outdoor workers included some search terms oriented to emergency responders). Targeted reviews were conducted for the use scenarios involving paid and volunteer emergency responders. Findings from these targeted reviews were integrated into Chapter 3 and into the narrative synthesis (see Appendix B).

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Comprehensive Review Protocol

Research Question

What is known about the factors that influence the effectiveness of respiratory protection for TARGET POPULATIONS exposed to HAZARDS OF INTEREST? Target populations and hazards of interest are captured in the bulleted list above.

Research Goal and Factors of Interest

The purpose of the 10 individual literature reviews was not to assess the evidence of the effectiveness of respiratory protective devices as measured by distal health outcomes, but rather to review the state of the evidence on the spectrum of factors within the system of respiratory protection (see Figure 1-4 in Chapter 1) that influence the effectiveness of such devices for their intended use. Factors of interest include filtration efficiency; breathing resistance; fit; antimicrobial properties, cleaning, and disinfection; comfort and usability; knowledge, attitudes, beliefs, and perceptions; sociodemographic characteristics of users; communication, education, and training; accessibility; cultural norms; and oversight and enforcement.

Search Strategy and Article Selection Method

Literature searches for each of the 10 review topics were conducted for articles published in English between 1980 and April 2021 in PubMed, Scopus, and EMBASE using the search terms listed below. The literature searches on factors of interest were broken into three overlapping search categories—device, user, and system factors. These delineations, however, are not reflected in the final narrative synthesis, which is organized by factor type (see Appendix B). Records were extracted to EndNote. Article titles and abstracts were screened for further full-text assessment based on the criteria of interest (population and hazard) described above. Additional articles were identified for inclusion for full-text review through reference mining, targeted searches, and committee input. During full-text review, studies that did not address factors affecting the use of respiratory protective devices by the population for the hazard of interest were excluded. Studies that used surrogates rather than the specific hazard of interest (e.g., viable viral particles) to assess such factors as filtration efficiency and fit were not excluded. Table A-1 shows the numbers of articles captured in the searches and remaining after screening for each review. Following the initial screening based on the criteria of interest, committee members applied judgment in selecting articles for ultimate inclusion in the synthesis

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TABLE A-1 Articles Captured and Remaining After Screening for Relevance to the Review Topics

USE SCENARIO	ARTICLES CAPTURED DURING LITERATURE SEARCH	ARTICLES REMAINING AFTER SCREENING
Public and Wildfire Smoke	Device Factors: 6 User Factors: 13 System Factors: 17	Device Factors: 0 User Factors: 5 System Factors: 15
Public and Air Pollution	Device Factors: 133 User Factors: 165 System Factors: 140	Device Factors: 7 User Factors: 6 System Factors: 5
Public and Communicable Biological Agents	Device Factors: 1,500 User Factors: 2,744 System Factors: 2,940	Device Factors: 35 User Factors: 72 System Factors: 54
Public and Noncommunicable Biological Agents	Device Factors: 53 User Factors: 82 System Factors: 71	Device Factors: 0 User Factors: 2 System Factors: 1
Indoor Workers and Communicable Biological Agents	Device Factors: 280 User Factors: 679 System Factors: 667	Device Factors: 1 User Factors: 15 System Factors: 5
Indoor Workers and Noncommunicable Biological Agents	Device Factors: 26 User Factors: 27 System Factors: 34	Device Factors: 3 User Factors: 1 System Factors: 1
Outdoor Workers and Noncommunicable Biological Agents	Device Factors: 20 User Factors: 24 System Factors: 17	Device Factors: 3 User Factors: 0 System Factors: 0
Outdoor Workers and Wildfire Smoke	Device Factors: 4 User Factors: 10 System Factors: 6	Device Factors: 0 User Factors: 2 System Factors: 1
Outdoor Workers and Air Pollution	Device Factors: 233 User Factors: 169 System Factors: 139	Device Factors: 7 User Factors: 7 System Factors: 12
Wildland Firefighters and Wildfire Smoke	Device Factors: 5 User Factors: 5 System Factors: 2	Device Factors: 8 User Factors: 6 System Factors: 5

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and excluded those that had limited relevance or applicability to the U.S. context, as well as those for which there were concerns regarding major methodological limitations (e.g., failure to use reproducible test methods and controls).

Of note, a large body of research on particle and respiratory protection science exists, which includes studies that are not specific to the hazards and populations identified by the high-priority hazard use scenarios. This body of literature was not captured in the committee's narrowly targeted searches but was reviewed separately (see the section below on targeted reviews of fit, filtration, and other factors). In some cases, key articles were discussed in the introductory section for a given factor to provide context for the findings from the committee's literature reviews.

Search Terms

Respiratory protective devices: "Respiratory protection", respirator, facemask, mask, face cover*, filtering facepiece, FFR, N95, N-95, KN95, respiratory protective device, respiratory protective equipment, RPD, elastomeric respirator, particulate respirator, P2, P3, FFP2, FFP3, DS1 and respirator, DS2 and respirator, "community mask", "barrier mask", cloth mask, PAPR, APR, air purifying respirator, "breathing apparatus", SCBA

Populations of interest:

- Public: Public, general public, resident, citizen, non-occupational, pregnan*, child*, communit*, elderly, immunocompromised
- Wildland firefighters: Wildland/wildfire/bush/forest firefight*, wildland fire fight*, firefight*/fire fight*, hotshot crew, hotshot and wildfire
- Indoor workers: Grocery, worker/employee; supermarket, worker/employee; domestic worker; housekeep*; "domestic labor"; "home healthcare"; "home health care"; home care workers; home, aide; factory worker; warehouse worker; meatpacking; confined feeding operation, poultry worker/processing, food manufacturing; food processing; retail worker; residential care workers; food service; shift worker; transit workers; bus drivers; corrections workers; personal care aides; emergency medical technicians; subway workers; ambulance drivers; flight attendants; sanitation workers; security guards; day care workers; social workers; restaurant workers; teachers; janitors; environmental services; building and grounds maintenance and cleaning; emergency responders
- Outdoor workers: "Day laborers"; laborers, outdoor; workers, outdoor; "outdoor work"; agricultural workers (mesh); migrant worker (mesh); undocumented worker (mesh); "seasonal worker";

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farmworker, farm worker, farmer; forestry, worker; fishery, worker; fruit sorting and packing; crop production; "construction workers", outdoor, worksite; construction AND jobsite; outdoor, workplace, tradespersons; "construction trades"; asphalt AND workers; highway AND crew; road workers paving contractors; masons; roofer; police (mesh); traffic enforcement; trash/waste/garbage collectors; landscapers; utility workers; postal AND worker; school personnel (i.e., maintenance staff working outdoors)

Hazards of interest:

- Air pollution: Air pollution, dust, particulate matter, particulate air pollution, $PM_{2.5}$, air quality (outdoor)
- Wildfire smoke: wildfire smoke, smoke and wildfire/bushfire/forest fire, bushfire smoke, wildland fire smoke
- Communicable biological agents: Virus; influenza; MERS; SARS (SARS-CoV-1, SARS-CoV-2); H1N1; COVID-19; infectious aerosols; viral aerosols; viral droplets; bioaerosol; respiratory infection; TB, tuberculosis, Mycobacterium tuberculosis
- Noncommunicable biological agents: mold; anthrax; aspergill*; fungal bioaerosol; Stachybotrys chartarum, black mold

Respiratory protection factors:

- Device factors: Performance, penetration, leakage, leak, resistance, protection factor, filter, loading, work rate, fit, "fit factor", pass rate, fit test panel, "fit capability", airflow, faceseal, face-seal, seal, strap, fabric, material, efficiency, filtration, stability, exertion, dead space, characteristics, features, anthropometr*, breathability, pressure drop
- User factors: Thermal, temperature, heat, moisture, warmth, sweat*, aesthetics, physiological impacts/effects/responses, psychological impact/effects/response, subjective, cleaning, disinfection/decontamination/laundering, glasses, eyewear, fogging, shortness of breath/out of breath, limitations, barriers, reuse/disposal/replacement, communication, interference, intelligibility, weight, age, seal check, fit check, usability, wearability, comfort, discomfort, ease of use, don*, doff*, facial hair, beard, risk perception, heart/cardiovascular, oxygen deficiency, headache, claustrophobic, anxiety, stress, distress, skin irritation, dermatitis, acne, adherence, compliance, acceptability, steriliz*, perception, expression, storage, movement, instructions, access*, knowledge, attitudes, practices
- System factors: Policy, education, training, communication, messaging, cost, supply, instruction, label*, sizing, guidance, risk perception, knowledge, attitude, behavior, production and manufacturing, access/accessibility, availability, belief, trust, distrust, fit testing,

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capacity, compliance, adherence, safety culture, culture, safety and practices, respiratory protection program (RPP), implementation, enforcement, medical screening/clearance

Data Extraction and Narrative Synthesis

For each review, the following baseline information was extracted from included articles to aid in the synthesis of the material: author, title, year, country, setting, study type, data collection method, population, exposure, exposure detail (e.g., particle size, duration of exposure), device factors detailed, user factors detailed, system factors detailed, and qualitative themes (where applicable). The extracted data were used in the development of the narrative synthesis, which summarizes the evidence and describes patterns and themes across the selected literature. Key findings were identified for each of the syntheses and were incorporated into the relevant report chapters to support the committee's conclusions and recommendations.

Collection of Standards and Authoritative Guidance

As noted above, the committee carried out a separate assessment of the landscape of standards and authoritative guidance on respiratory protection for selected use scenarios to determine where gaps may exist. Guidance included written, visual, or auditory information provided directly to the user or to other stakeholders with roles in disseminating guidance (e.g., employers, public health agencies, clinicians) for the purpose of supporting the selection, proper use, care, and disposal of respiratory protection for the hazard of interest. Standards and guidance were collected through a search of the gray literature, including PPE-info, consensus standards organizations, and reports and webpages of federal agencies, labor unions, professional associations, and academic and nonprofit institutions.

Additionally, a small, nonrandom sample of guidance was also collected from webpages of local, state, tribal, and territorial public health agencies and regional air quality agencies. The sampling process used four dimensions (Federal Emergency Management Agency [FEMA] region, jurisdiction type, jurisdiction demographic, and agency type) to guide the selective sampling of publicly available guidance from the webpages of 10 public health and air quality agencies in a manner that reflects the organizational heterogeneity and regional and demographic diversity in which these agencies operate throughout the United States. This guidance was evaluated to describe the variability of public-focused guidance on respiratory protection, including the hazards addressed, messages used, and recommendations provided. A discussion of the guidance landscape, gaps, and variability can be found in Chapters 3 and 4.

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Targeted Review of Fit, Filtration, and Other Factors

A targeted literature review of articles describing fit, filtration, breathing resistance, comfort, and other factors related to usability was conducted to provide context for the committee's comprehensive reviews. This review focused on highly cited articles that were not restricted in the search by user type or exposure. These searches were conducted in PubMed with no date restrictions. Selected device and user search terms from the comprehensive reviews were used for targeted searches. Within each subject matter search, the top 10 most published authors on the topic were selected and then the relevant titles from the top 50 most cited articles were saved to Endnote for review. Additional articles were included based on committee member input.

Analysis of OSHA Citation Data

As part of its efforts to understand the effectiveness and limitations of workplace respiratory protection programs (see Chapter 3), and specifically, challenges related to compliance with the Respiratory Protection Standard, the committee initiated an analysis of OSHA data on violations issued between January 1, 2015, and December 31, 2020, citing any provision of 1910.134(c)(1) of OSHA's Respiratory Protection Standard. Data were requested from and provided by OSHA in April 2021, in the form of Excel spreadsheets.[1] Data elements included the name of the cited establishment, site address, date of the citation, North American Industry Classification System (NAICS) code for the cited establishment, inspection type (e.g., whether the inspection was programmed or complaint driven), the violation description, the gravity of the violation, and the penalty amount, among others. Frequency tables (see Tables A-2 through A-4) were generated by a committee consultant from the California Department of Public Health for industry type (NAICS code), gravity, and inspection type data fields for federal OSHA violations.[2] Mean and median values were generated for the penalty data element (see Table A-5).

[1] Original data files are available by request through the National Academies' Public Access Records Office.

[2] The analysis did not include violations of state OSHA requirements.

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TABLE A-2 Frequency of OSHA Respiratory Protection Standard Citations by Industry Type (NAICS Code)

NAICS CODE	FREQUENCY	PERCENT
Accommodation and Food Services	21	0.7
Administrative and Support and Waste Management and Remediation Services	92	3.06
Agriculture, Forestry, Fishing and Hunting	15	0.5
Arts, Entertainment, and Recreation	50	1.67
Construction	538	17.92
Educational Services	6	0.2
Health Care and Social Assistance	144	4.8
Information	1	0.03
Manufacturing	1,428	47.55
Mining, Quarrying, and Oil and Gas Extraction	33	1.1
Other Services (except Public Administration)	315	10.49
Professional, Scientific, and Technical Services	29	0.97
Public Administration	17	0.57
Real Estate and Rental and Leasing	20	0.67
Retail Trade	98	3.26
Transportation and Warehousing	55	1.83
Utilities	6	0.2
Wholesale Trade	135	4.5
Total	3,003	100

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TABLE A-3 Frequency of OSHA Respiratory Protection Standard Citations by Gravity

GRAVITY	FREQUENCY	PERCENT
High	327	14.12
Moderate	1,061	445.81
Low	928	40.07
Total	2,316*	100

* There were 687 missing fields for the gravity variable.

TABLE A-4 Frequency of OSHA Respiratory Protection Standard Citations by Inspection Type

INSPECTION TYPE	FREQUENCY	PERCENT
Complaint	1536	51.15
Fatality/Catastrophe	149	4.96
Follow Up	54	1.8
Monitoring	4	0.13
Program Planned	641	21.35
Programmed Other	5	0.17
Programmed Related	54	1.8
Referral	420	13.99
Referral-Employer Reported	39	1.3
Unprogrammed Other	9	0.3
Unprogrammed Related	92	3.06
Total	3,003	100

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TABLE A-5 Summary Statistics on Penalties for OSHA Respiratory Protection Standard Citations

PENALTY	MEAN	MEDIAN	MINIMUM	MAXIMUM
Initial penalty	$3,169.51	$2273.00	$0	$84,000
Current penalty	$2119.60	$1485.00	$0	$34,691

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Appendix B

Review of Factors Necessary to Ensure Respiratory Protection is Effective for its Intended Use

While the science of respiratory protection is supported by an established body of literature on device-related factors, such as fit and filtration, comparatively less is known about other factors that impact the effectiveness of devices during real-world use. A narrative review synthesis was developed from the series of comprehensive literature reviews on the high-priority respiratory protection use scenarios described in Appendix A—four reviews related to the public and five related to workers. This synthesis presents findings from included articles on factors that influence the effective use of respiratory protective devices by the public and workers for exposures to biological agents, air pollution, and wildfire smoke. The findings from this narrative review synthesis were used to inform gaps and challenges discussed in Chapters 3 and 4, and to identify research and implementation needs addressed in Chapters 6 and 7. Of note, a narrative review synthesis is not a formal systematic review with defined inclusion/exclusion criteria and a formal risk-of-bias assessment, nor is it a meta-analysis. The committee used its judgment in selecting articles to include in this synthesis, excluding those that had limited relevance or applicability to the U.S. context, as well as those for which there were concerns regarding major methodological limitations (e.g., failure to use reproducible test methods and controls).

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NARRATIVE SYNTHESIS OVERVIEW

Organization of the Findings by Factor of Interest

As discussed in Appendix A, the literature searches and data extraction were carried out using the committee-developed categories of device, user, and system factors to capture information about the breadth of factors that influence the effectiveness of respiratory protective devices for their intended use (see Figure 1-4 in Chapter 1). However, the extensive overlap of literature and findings across these three categories necessitated a more topical structure for the written layout of the synthesis. This narrative review synthesis presents the findings from the committee's review of the literature for the following factors:

- Filtration Efficiency
- Breathing Resistance
- Fit
- Antimicrobial Properties, Cleaning, and Disinfection
- Comfort and Usability
- Knowledge, Attitudes, Beliefs, and Perceptions
- Sociodemographic Characteristics
- Communication, Education, and Training
- Accessibility
- Cultural Norms
- Oversight and Enforcement

Variation in the structure of the factor-specific sections below reflects the key findings that the committee felt most warranted emphasis. For some factors, notable differences in findings across different hazards merited highlighting, while for others, organizing the material by population was most logical given differences in findings for the public and workers.

Respiratory Protection Terminology

In this narrative synthesis, device terminology generally reflects the term used in the cited article. In cases in which the term *mask* or *face mask* is used in the source article with no other identifying information, this will be indicated in the text for the reader's awareness. Where cited studies refer to both masks and face coverings, this is indicated with "masks/face coverings." Some articles discussed in this appendix use the terms *mask mandate* and *mask-wearing behavior*. The committee also uses these terms, as they are common in the public vernacular, but acknowledges that they are not specific to medical/surgical masks and may be used also in reference to face coverings and even respirators.

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FILTRATION EFFICIENCY

Filtration efficiency (FE) is a measure of how well the material of a respiratory protective device prevents particles from penetrating through the filter medium. The performance of a respiratory protective device is closely tied to FE because the penetration of particles through the filter contributes to the inhaled dose—a key determinant of risk. FE is affected by multiple factors, including, for example, filter type, flow rate (i.e., velocity of the air through the filter), and particle aerodynamic properties (including size, shape, and density) (Brown, 1989; He et al., 2013; Huang et al., 2013; Rengasamy et al., 2010). These factors and how they relate to performance are well understood for respirator use in occupational settings, but less so for nonoccupational hazards and other types of respiratory protective devices (e.g., masks and face coverings).

Particle size[1] is an especially important parameter for FE. Aerosol filtration mechanisms include impaction, diffusion, gravitational settling, interception, and electrostatic attraction (Hinds, 1999). These mechanisms act nonlinearly across the aerosol-size range of interest (from ~0.01 μm to 100 μm). As a result, filters often exhibit a U-shaped relationship between FE and particle size, with maximal FE occurring at very small (i.e., 0.01–0.05 μm) and very large (i.e., 10–100 μm) sizes, and minimal FE occurring in the range of 0.05 μm to 0.3 μm, depending on the filter properties.

The National Institute for Occupational Safety and Health (NIOSH) uses standard test methods for evaluating respirator FE (see, e.g., NIOSH, 2019a). These tests are designed to evaluate FE conservatively (i.e., to approximate a worst-case condition) by specifying a highly penetrating aerosol size distribution in the submicron range (i.e., a mass median diameter between 0.2 μm and 0.3 μm) and a high flow rate (85 L/min) through the device, which minimizes particle residence time, and relevant filtration mechanisms (i.e., diffusion and electrostatic attraction) at the indicated size range. ASTM has also published standards for determining bacterial FE (ASTM, 2019) and particle FE (ASTM, 2017) for medical masks, and submicron FE for barrier face coverings (ASTM, 2021c)—the latter of which is derived from published NIOSH protocols.

The NIOSH test methods are rigorous, standardized, and reproducible, but they have limitations in their generalizability to members of the public (e.g., to children or nonoccupational settings) and in their extensibility to specific airborne hazards. For example, a mask that exhibits poor FE under standard NIOSH test conditions for N95 series filters (NIOSH, 2019a)

[1] For aerosol filtration, particle size is characterized by the aerodynamic diameter for inertial capture mechanisms (i.e., impaction and settling), by the thermodynamic diameter for diffusive and interception mechanisms, and by the electrical mobility diameter for electrostatic mechanisms. For spherical particles of standard density, these diameters are all equivalent.

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may exhibit acceptable FE for larger particle sizes relevant to other hazards, such as for airborne fungal spores (Górny et al., 1999). And whereas NIOSH test protocols operate at 85 L/min of flow through the device (to simulate human respiration under moderate exercise), most members of the public breathe at resting inhalation rates of approximately 10–30 L/min. Although a high flow rate (85 L/min) will minimize collection of submicron aerosol, it will enhance collection of supermicron aerosol (i.e., particle sizes >1 μm) within a given filter medium (Leith et al., 2021). To date, there are no standard methods for evaluating the outward leakage of respiratory protective devices (i.e., to act as a form of source control for respiratory aerosol emissions from the wearer). For these reasons, the committee considered a wide range of published literature on mask performance, beyond those that only used NIOSH or ASTM test methods.

Filtration Efficiency for Communicable Biological Agents

In response to the COVID-19 pandemic, a growing body of research has focused on the ability of different respiratory protective devices to filter biological agents for nonoccupational users as source control and, in some instances, respiratory protection for the wearer. This research encompasses traditional filter materials, such as N95 filters; commercial products, such as surgical masks; and household materials that could be used to create face coverings, such as vacuum bags or knit cotton. This body of literature complements a long history of published research on the FE of masks, respirators, and face coverings. Most of these studies are laboratory based and designed to simulate respiratory emissions (and/or inhalation) during breathing, talking, coughing, or sneezing.

Both classical filtration theory and published research suggest that the filtration mechanisms for biologically derived aerosols are largely identical to those for industrial aerosols (Gardner et al., 2013; Hinds, 1999; Rengasamy et al., 2004; Willeke et al., 1996) and that FE is primarily a function of particle size, regardless of the particle's origin or composition (only highly nonuniform particles, such as rod-shaped bacteria, have different collection efficiency from their spherical aerodynamic counterparts, and those elongated shapes appear to be collected more efficiently). Thus, from a filtration standpoint, a biologically derived particle will behave similarly to an inert particle, such as sodium chloride (NaCl)[2] (Brosseau et al., 1997; Eninger et al., 2008; Harnish et al., 2013; Rengasamy et al., 2004). Thus, particle surrogates such as NaCl and monodisperse latex spheres are commonly used in studies evaluating FE in the context of potential respiratory protective

[2] NIOSH test methods specify the use of NaCl and oil droplet aerosols; ASTM methods specify the use of NaCl aerosol and monodisperse latex spheres.

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devices for communicable biological agents. One of the challenges, however, for assessing FE of respiratory aerosols (and their associated exposure risks) is that the size range of particles emitted from breathing, talking, singing, coughing, or sneezing spans the full aerosol size distribution and beyond (from ~0.01 μm to >1,000 μm in diameter) (Duguid, 1946; Good et al., 2021; Holmgren et al., 2010; Johnson et al., 2011).

Findings from this review indicate that FE varies substantially across different types of respiratory protective devices and, as expected, as a function of particle size. Highlighted below are several key findings:

- Devices made from common cloth/fabric materials (i.e., those that lack high-efficiency particulate air [HEPA] filtration media or electret fibers[3]) tend to exhibit lower FE (e.g., <25 percent) at submicron particle sizes and higher FE (>75 percent) as particle sizes approach 10 μm (Davies et al., 2013; Leith et al., 2021; Lindsley et al., 2021b). This finding is consistent with classic filtration theory (Brown, 1989; Hinds, 1999) and reinforces the belief that most respiratory protective devices, regardless of material, are effective as source control for particles larger than 5–10 μm if worn properly over the nose and mouth (Johnson et al., 2009; Milton et al., 2013). Below 10 μm in diameter, FE varies widely depending on the device and its constituent filter material(s).
- Masks and face coverings made from common cloth or fabric materials rarely achieve 95 percent FE for submicron particle sizes, regardless of the test method employed (Joo, 2021; Jung et al., 2014; Leith et al., 2021; Lindsley et al., 2021b; Long et al., 2020; Pan et al., 2021; Rengasamy et al., 2010; Zhao et al., 2020), which suggests that such devices would fail to meet relevant NIOSH N95 filter requirements.
- Medical and surgical masks exhibit variable FEs (e.g., from approximately 25 percent to >95 percent) (Chen and Willeke, 1992; Davies et al., 2013; Rengasamy et al., 2009). Furthermore, these devices tend to suffer from poor fit (discussed below), which can reduce their overall effectiveness (Arumuru et al., 2021; Oberg and Brosseau, 2008).
- Laboratory studies suggest that N95 filtering facepiece respirators (FFRs) are effective as source control devices for respiratory aerosol

[3] Electret fibers are engineered to carry a stable electric charge at their surface. Such fibers, often made from melt-blown polymers, are the principal filtration material in most N95 filtering facepiece respirators (FFRs). Electrostatic charging is known to improve filtration efficiency of fibrous filters without adding mass or density to the material and, therefore, without adding resistance to airflow (i.e., preserving breathability) (Brown et al., 1988; Zhao et al., 2020).

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emissions of all sizes (Asadi et al., 2020; Lindsley et al., 2021a), more so than cloth face coverings (Lindsley et al., 2021b; Pan et al., 2021), provided they are properly fit to the face.
- FFRs offer good inhalation protection to the wearer when fitted properly (Ferguson et al., 2014; Lawrence et al., 2006; van der Sande, 2008).
- Fabric type (woven, nonwoven, knitted),[4] and fiber type (e.g., manmade or natural),[5] are not reliable indicators of FE, as the properties of textiles are determined by interactions between the design parameters (IOM, 2006). Changes in parameters—including number of layers, fiber diameter, and packing density—can cause dramatic shifts in FE (Leith et al., 2021). This finding reinforces the need for products that conform to established performance requirements for FE.
- Adding layers to cloth and other fabric masks increases FE, but also reduces breathability (Joo et al., 2021; Long et al., 2020).

Filtration Efficiency for Ambient Air Pollution

Comparatively few studies have assessed the importance of the FE of respiratory protective devices specifically for ambient air pollution exposures. However, as the FE of respiratory protective devices depends primarily on particle size (as opposed to particle source/type), many of the findings from the communicable disease literature are relevant and will not be repeated here. Instead, we highlight findings from studies that examine FE in relation to specific forms of ambient air pollution. Like respiratory particle emissions, sources of particulate matter air pollution produce particles that span a wide range of sizes (from <0.01 μm to 100 μm in diameter) (Seinfeld and Pandis, 2016).

- For many types of ambient air pollution, cloth and synthetic fiber face coverings have low FE (typically less than 50 percent), surgical masks have intermediate FE (typically between 50 percent and 90 percent), and N95 FFRs offer relatively high FE (95–99 percent).

[4] Woven and knitted fabrics are two-dimensional structures made from yarns, which, in turn, are produced from fibers through the process of spinning. Woven fabrics are made by interlacing warp and filling yarns together, while knitted fabrics are made by interlooping the individual yarns. Nonwoven materials are created by using mechanical, thermal, or chemical bonding processes to entangle fibers into a three-dimensional structure (Varallyay et al., 2020).

[5] Natural fibers refer to cotton, wool, silk, bamboo, and similar materials that occur in nature. Manmade fibers encompass synthetic fibers (e.g., polyester, nylon) and regenerated fibers (e.g., rayon).

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This finding was consistent across studies of urban fine particulate air pollution (particulate matter $[PM]_{2.5}$) (Kodros et al., 2021), diesel exhaust (Shakya et al., 2017), urban dust from roadways and windblown sources (PM_{10}) (Kodros et al., 2021; Patel et al., 2016), volcanic ash (Mueller et al., 2018), and wildfire smoke (Kodros et al., 2021).

- For combustion-derived air pollution, respirators with particulate filters are effective at removing particles but not harmful vapors (e.g., formaldehyde and acrolein) (De Vos et al., 2006, 2009).
- Bandanas are widely used as face coverings intended to protect against wildfire smoke, but like other forms of cloth masks, they offer little to no protection because of their poor FE for submicron particle sizes (Foote, 1994).

BREATHING RESISTANCE

The *breathability* of a respiratory protective device is characterized by a breathing resistance measurement (i.e., the pressure drop of airflow through the device at a specific rate, typically denoted by ΔP). Breathing resistance is a key performance metric because devices with poor breathability may be uncomfortable to wear (Manninen et al., 1988; Popendorf et al., 1995), more prone to leak (Campbell, 1984; Nelson and Colton, 2000; Vaughan et al., 1994), and may require more physical effort (by the wearer) to achieve a desired ventilatory rate (Caretti et al., 2001, 2006; Coyne et al., 2006; Harber et al., 1982; Johnson, 2016). NIOSH has established breathing resistance requirements for air-purifying respirators used by workers (NIOSH, 2019b), and the Food and Drug Administration (FDA) has requirements for breathing resistance of medical masks that follow ASTM standards (ASTM, 2021a). ASTM's recently published standard for barrier face coverings also includes performance requirements for airflow resistance (ASTM, 2021c). Most of the important breathability characteristics of respiratory protective devices can be described from a review of basic fluid dynamic theory.

Darcy's Law states that the pressure gradient required to move a fluid (such as air) through a porous medium (such as a mask or face covering) is directly related to the velocity of air within the medium (Bear, 1988; Jonas et al., 1972), when the flow within the medium is laminar (which is generally satisfied for a range of human breathing rates through most respiratory protective devices). This theory suggests that mask breathability (in terms of pressure drop, ΔP) is specific to a given flow rate (Q) and increases in direct proportion to flow rate. NIOSH specifies a test flow rate of 85 L/min for breathability; however, breathability measurements made at other flow rates are easily compared by reporting *flow resistance* (i.e., pressure drop

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per unit flow, $\Delta P/Q$), assuming the entire device is tested.[6] For a given material type, an increase in thickness (e.g., by adding an additional layer) will bring about a proportional decrease in breathability (i.e., by increasing ΔP). Increasing the cross-sectional area (or decreasing the material permeability) of a device will bring about a proportional increase in breathability (i.e., a reduction in ΔP)—an important consideration for device design. In addition to these relationships, the committee's review of the extant literature found several additional highlights worth noting:

- The use of a respirator can alter the timing and effort of breathing when greater energy is needed for inhalation and exhalation of air through the filter medium (Caretti et al., 2001, 2006; Coyne et al., 2006; Harber et al., 1982; Johnson, 2016; Lee and Wang, 2011), although in some cases these changes are imperceptible to the wearer (Roberge et al., 2010a).
- Most cloth and other fabric face coverings intended for public use during the COVID-19 pandemic meet the NIOSH breathability requirement[7] for workplace respiratory protection (Leith et al., 2021; Lindsley et al., 2021a) (though they do not meet the FE requirement, as mentioned above).
- Respiratory protective devices that meet NIOSH breathability requirements likely do not pose a physical hazard to the worker (in terms of increased respiratory workload) (Bansal et al., 2009; Harber et al., 2009; Roberge et al., 2010b, 2013), but whether low-breathability of respiratory protective devices poses a risk to at-risk members of the public (e.g., elderly populations or those with acute or chronic respiratory diseases) remains an active area of research (Kyung et al., 2020; Salles-Rojas et al., 2021).
- Devices made from electret filter media tend to provide improved breathability for a desired level of FE because electret filters have enhanced particle capture when compared to uncharged filter media (Brown, 1989; Huang et al., 2013; Romay et al., 1998).

[6] NIOSH method TEB-APR-STP-0007 specifies the entire mask area be tested for breathability at 85 L/min of flow; ASTM method F2100-19 (by virtue of standard EN 14683:2019, Annex C) specifies a measurement of pressure drop per unit area of material (4.9 cm^2) at 8 L/min of flow. Conversion between these measures requires one to know the effective surface area (A) of the device.

[7] NIOSH sets maximum breathing resistance levels for respirators (35 μm water column height pressure for inhalation and 25 μm water column height pressure for exhalation) (42 C.F.R. § 84).

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FIT

Any respiratory protective device designed with a facepiece (i.e., designed to form a physical seal around the user's nose and mouth) must achieve a proper fit to function properly. A proper fit means that the respiratory protective device seals to the face during use, which prevents inward particle leakage or, in the case of respiratory protective devices being used as source control, outward leakage of particles from around the edges of the device. Even when the FE of a tightly fitting respirator (e.g., FFR) is appropriate for the hazard of concern, if the device is not well-sealed to the face, leakage around its edges will become a route of entry for the hazardous particles (Cho et al., 2010; Grinshpun et al., 2009; He et al., 2013; Rengasamy and Eimer, 2011). Particle leakage through and around a respiratory protective device is sometimes expressed as *total inward leakage*, a measurement combining particles that leak around the face seal, through the filter media, and by any other means (He et al., 2014; Rengasamy and Eimer, 2012; Rengasamy et al., 2014).

The fit characteristics of some respirators may be tested during the NIOSH respirator approval process. A fit capability test is not currently required as part of the approval process for FFRs (Coffey and Miller, 2019), but ASTM recently published a standard for evaluating fit for negative-pressure half-facepiece particulate respirators (ASTM, 2021b) that enables respirator manufacturers to develop better-fitting respirators. The Occupational Safety and Health Administration (OSHA) also has published methods for respirator fit testing,[8] which is required annually for any employee enrolled in a workplace respiratory protection program and ensures that the respirator selected is capable of fitting the specific worker. At the individual level, a *fit factor*[9] is often used to define respirator fit following a quantitative fit test. At the population level, respirators are selected to provide an *assigned protection factor*, which is a conservative estimate of the protection that a properly functioning respirator would be expected to provide to a population of properly fitted and trained users. For example, an assigned protection factor of 100 implies that a user would inhale no more than 1/100th (or 1 percent) of the concentration of a given hazard during exposure. Both fit factors and assigned protection factors are estimates of actual protection afforded by a respirator. In real-world environments, a

[8] 29 C.F.R. § 1910.134. Final rule. Fed. Reg. 63:1152–1300 Respiratory Protection. See also Appendix A to § 1910.134 Fit Testing Procedures (Mandatory).

[9] A respirator fit factor is a quantitative estimate of the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn (29 C.F.R. § 1910.134). Fit factors are used to estimate the level of personal protection provided by a respirator to an individual.

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workplace protection factor study may be conducted (or simulated in a laboratory and referred to as a *simulated workplace protection factor study*), which estimates performance of the respirator during regular workplace tasks. Workplace protection factors often may be lower than fit factors due to unique challenges of specific work tasks (OSHA, 2009).

A large body of published literature exists describing the fit of respirators in the workplace. This research demonstrates the following salient points:

- Respirator fit varies across respirator classes and across models within the same class (Campbell et al., 2001; Coffey et al., 2004, 2006; Oestenstad, 2007; Zhuang et al., 2005) and also across multiple donning events by a given user (Bergman et al., 2012; Vuma et al., 2019). This variation in fit produces variation of the level of protection factors provided by different devices (Coffey et al., 2004; Janssen et al., 2007; Nicas and Neuhaus, 2004; Vo et al., 2015).
- Many user variables can affect fit, such as face shape (Brazile et al., 2011; Han and Choi, 2003; Oestenstad and Perkins, 1992; Oestenstad et al., 1990), sex and age (McMahon et al., 2008), the presence of facial hair (Floyd et al., 2018; Stobbe et al., 1988), one's training level (Harber et al., 2013; Kim et al., 2019), and even one's level of perspiration (Kim et al., 2016).
- Elastomeric facepiece respirators tend to provide improved fit when compared to N95 FFRs (Chew et al., 2006; Lawrence et al., 2006; NASEM, 2019).
- Periodic reuse of an FFR may eventually reduce the fit as the material loses integrity over time (Bergman et al., 2012; Degesys et al., 2020).

Literature on the fit of nonrespirator devices (e.g., masks and face coverings) and nonoccupational users is less abundant but has grown rapidly since the emergence of SARS-CoV-2, from which the committee found several important findings:

- Cloth face coverings, medical and surgical masks, and other non-NIOSH-approved devices (such as KN95s) tend to suffer from poor fit (in addition to poor FE), which can reduce their overall effectiveness (Arumuru et al., 2021; Davies et al., 2013; Lai et al., 2012; Leith et al., 2021; Lindsley et al., 2021a; Oberg and Brossau, 2008; O'Kelly et al., 2021; Steinle et al., 2018) as both source control and personal protective devices.

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- The fit of medical/surgical masks may be improved with the use of additional close-fitting layers or technologies[10] designed to press the mask against the face (Brooks et al., 2021; Runde et al., 2021; Sickbert-Bennett et al., 2021).

ANTIMICROBIAL PROPERTIES AND IMPACT OF CLEANING AND DISINFECTION ON FUNCTION

Antimicrobial Properties

Microorganism survival on filter media is dependent on multiple factors, including the type of microorganism in question, the length of exposure, humidity, and the presence of biocides (Jachowitz et al., 2019). While interest in antimicrobial treatments for respiratory protective devices preceded the emergence of SARS-CoV-2 (Tseng et al., 2016), the ongoing COVID-19 pandemic has spurred new research efforts on the treatment of filtering materials with a variety of antimicrobial properties to deactivate viruses through contact (as reviewed by Balachandar et al., 2020; Pullangott et al., 2021). This nonexhaustive review of the literature shows that questions exist regarding the potential need for antimicrobial properties, given that (1) particles captured on filter media are likely to stay captured; (2) that collected particles are more likely to be found on the exterior of the device (and not necessarily in contact with the wearer) or on the interior of the device (when the wearer is the source); and (3) that particle migration through the filter media over time is likely negligible. As the antimicrobial properties or treatments have the potential to place additional risk on the wearer (via inhalation and/or ingestion), more research is needed to develop and evaluate existing and novel coatings and properties, and to assess potential risks and benefits to the wearer (Pullangott et al., 2021). FDA requires manufacturers that make antiviral claims to provide to the agency supporting evidence demonstrating the effectiveness and safety of their products.

Cleaning and Disinfection

The impact of cleaning, washing, disinfecting, and other manners of reprocessing on the fit and FE of respiratory protective devices (both those intended for single use and those intended for multiple use) over time is not well understood. While this nonexhaustive review identified several studies assessing the impact of various reprocessing methods on fit and FE, the

[10] These technologies are commonly called "mask fitters" or "braces." They are worn over the mask and then secured with head ties or elastic ear loops.

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findings indicate that more research is needed to understand how function is impacted by the cleaning and disinfection of various types of respiratory protective devices. Several studies found that various techniques studied for the washing of different types of cloth masks either slightly improve fit and FE or do not greatly negatively affect it (Clapp et al., 2021; Sankhyan et al., 2021; Varallyay et al., 2020). Multiple studies have also found various technologies (microwave steam bags, heat, ultraviolet light, vaporous hydrogen peroxide) effective at decontaminating microorganisms from respiratory protective devices, including N95 FFRs, cloth face coverings, and surgical masks, without extensive degradation of the FE (Fisher et al., 2011; Liao et al., 2020; Wigginton et al., 2020). However, decontamination of N95 FFRs using gamma sterilization (Kumar et al., 2020) and other technologies for decontamination, such as use of ethanol, chlorine, or hydrogen peroxide gas plasma, have been shown to have a more significant negative impact on FE (Liao et al., 2020; Wigginton et al., 2020).

COMFORT AND USABILITY

Filtration efficiency, breathing resistance, and fit—which, as explained above, determine the level of protection that a respiratory protective device may be able to provide under ideal conditions of use—can be measured objectively. However, issues related to comfort and usability exist at the interface of the device and the user, and are complex in that these factors relate not only to the design and function of the device (size, weight, breathing resistance) but also to the user's perception of how these characteristics impact them (e.g., claustrophobia, anxiety), actual physiological impacts (e.g., increased heart rate, changes in respiration), and the context in which the device is used. Respirators, specifically FFRs, have a number of issues related to comfort and usability that are well documented in occupational settings—particularly in health care—and can impact whether a device is used and used correctly. While much of the body of research on the comfort and usability of respiratory protective devices is derived from studies of respirator use in occupational settings, increasing interest in the use of devices for inhalation hazards impacting broader populations, such as exposure to particulate matter and biological agents (e.g., SARS-CoV-2), has led to research on use by more diverse populations—both the public and certain worker groups. The research identified in this review suggests that user concerns associated with comfort and usability of devices are generally similar across both public and occupational users, although certain groups (e.g., children, wildland firefighters) present unique needs that will need to be addressed in device designs.

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Comfort

Among the populations of interest for the committee's review, issues with comfort centered on difficulty breathing, temperature, and humidity regardless of the inhalation hazard of concern, although much of the research was conducted in the context of the COVID-19 pandemic. Concerns about discomfort have been noted by researchers as potential barriers to effective use and spanned a variety of types of respiratory protective devices across a diverse population of public and occupational users (Al Naam et al., 2021; Ali et al., 2021; Cheok et al., 2021; Cramer et al., 2017; Ferng et al., 2011; Liu et al., 2020; Vereen et al., 2021). Specifically, compounding issues with heat, humidity, and breathing challenges (Allison et al., 2010; Chao, 2020; Cheok et al., 2021; Gershon et al., 2010; Liu et al., 2020; Mojtahedzadeh et al., 2021; Mpofu et al., 2002; Riden et al., 2020; Smart et al., 2020); dermatological concerns or pain (Al Naam et al., 2021; Allison et al., 2010; Cheok et al., 2021; Riden et al., 2020; Szepietowski et al., 2020); and issues with sizing (Allison et al., 2010) were among the most frequently reported causes of discomfort. These findings are generally consistent with experiences of discomfort during the use of FFRs by occupational users, with discomfort levels increasing dramatically when users perceive or experience increased levels of facial or total body heat, such as during physical exertion or in warm, humid environments (Baig et al., 2010; Foster et al., 2020; Roberge et al., 2012). Different types of respiratory protective devices, including surgical masks, N95 FFRs (Toprak et al., 2021), and KN95 respirators (Liu et al., 2020), were associated with different levels of discomfort.

Device designs that incorporate exhalation valves into air-purifying respirators can help decrease discomfort by dissipating humidity and reducing temperature within the facepiece (Roberge, 2012). However, due to concerns about exposure to respiratory secretions in the exhaled air discharged from the wearer's exhalation valve, the Centers for Disease Control and Prevention does not recommend the use of a respirator with an exhalation valve as a source control device by the public or in certain health care settings (NPPTL, 2020). FDA does not clear surgical and medical masks with exhalation valves for the same reasons.

Physiological response to the use of respiratory protection and experience of comfort are interrelated in many respects, and the impact of this relationship can range from insignificant to incompatible with use. For example, ventilation and cardiopulmonary-exercise capacity can be reduced during the use of surgical masks but more substantially impaired during the use of FFRs; these variables are also affected by the user's activities while wearing the device (Fikenzer et al., 2020). For some user populations, such as wildland firefighters, unique needs can directly impact whether a

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device can be worn comfortably and safely during exposure to the inhalation hazard of concern. The most common challenge reported by wildland firefighters related to the comfort and usability of respirators was the reduction in work intensity or performance as a result of increases in the work of breathing during use (Beason et al., 1996; Sharkey, 1997). Studies comparing identical respirators equipped with different cartridges (HEPA versus HEPA + OV/AG [organic vapor/acid gas]) observed that the decline in performance while using a respirator was proportional to the breathing resistance, with a doubling in breathing resistance resulting in a doubling in the decline in work performance. Additionally, the material used to remove carbon monoxide, a major hazard of wildfire smoke exposure beyond particulate matter, adds breathing resistance and causes an even greater decline in user performance (Sharkey, 1997).

In cases where the user is not performing metabolically demanding tasks, some evidence suggests that respirator use can be associated with minor increases in such measures as heart rate and transcutaneous carbon dioxide, although these changes are tolerable in healthy individuals (Kim et al., 2013), while other studies have found no significant differences in physiological responses (Roberge et al., 2010b, 2013). Despite this reported variability in physiological responses, studies of occupational users report such physical sensations as shortness of breath (Hopkins et al., 2021; Rebmann et al., 2013), breathing discomfort (Kim et al., 2016), headache, and lightheadedness (Rebmann et al., 2013), as well as such psychological responses as anxiety, distress, and feelings of claustrophobia (Johnson, 2016; Wu et al., 2011). Some types of devices may trigger greater psychological responses relative to other types (Wu et al., 2011).

Very few studies have examined the physiological impacts of respirators on user comfort when these devices are used by the public, including among vulnerable populations (e.g., children and people with chronic obstructive pulmonary disease [COPD]) when exposed to particulate matter and communicable biological agents. Among children wearing a specially designed N95 FFR, breathing parameters (end-tidal carbon dioxide [$ETCO_2$], fractional concentration of inspired carbon dioxide [$FICO_2$], respiration rate, heart rate, and oxygen saturation [SpO_2]) remained within normal range, and over 90 percent of children reported no issues with breathing while wearing the device, indicating good comfort and safety levels (Goh et al., 2019). However, among individuals with severe COPD and airflow limitations who wore an N95 FFR during a 6-minute walking test, certain physiological variables (e.g., forced expiratory volume [FEV] of <30 percent) were found to be associated with an increased likelihood of respirator removal due to dyspnea, breathing discomfort, decreased blood oxygen saturation, and increased partial pressure of end-tidal CO_2 ($PETCO_2$). Even among those participants who continued using the N95 FFR during

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the walking test, their breathing frequency, blood oxygen saturation, and $PETCO_2$ differed significantly before and after use for 10 minutes while in a resting state, indicating that N95 FFRs may not be well adapted to COPD patients (Kyung et al., 2020).

Studies conducted during the COVID-19 pandemic found that while cloth face coverings/masks were associated with discomfort, participants in the United States were not deterred from use (Shelus et al., 2020). Efforts to make devices more breathable, "cooler," and better fitting may have an impact on comfort and overall wearability (Galea et al., 2018; Smart et al., 2020).

Usability

The usability of respiratory protective devices of all types may impact proper use and thereby the effectiveness of devices for their intended use. The literature related to the usability of respiratory protective devices for the public and the worker groups of interest to this review identified a number of factors that impact the usability of devices (generally, respirators for workers, and masks and face coverings for the public), including the following:

- issues with visual and verbal communications, facial recognition, or visual acuity (Al Naam et al., 2021; Carragher et al., 2020; Freud et al., 2020; Johnson, 2016; Palmiero et al., 2016; Shelus et al., 2020);
- challenges associated with physical user characteristics impeding use (e.g., eyeglasses) (Al Naam et al., 2021; Cheok et al., 2021; Shelus et al., 2020);
- negative perceptions of aesthetics, attractiveness, or acceptability (Al Naam et al., 2021; Allison et al., 2010; Ferng et al., 2011; MacIntyre et al., 2009);
- challenges with correct donning, wearing, or doffing (Deschanvers et al., 2021; Jabbari et al., 2020; Kellerer et al., 2021; Lee et al., 2020; Machida et al., 2020; Mueller et al., 2021; Tam et al., 2021);
- barriers related to storage and reuse (Chao, 2020; Doung et al., 2021; Scalvenzi et al., 2020); and
- interference with tasks (Johnson, 2016; Mojtahedzadeh et al., 2021).

The majority of available research focuses on the use of respiratory protective devices, primarily face coverings and surgical and other masks, during the COVID-19 pandemic. Generally, these common usability issues may lead to a lack of user compliance (e.g., pulling a device away from the mouth to communicate, improperly placing the device on the face, or

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storing the device in an unsafe manner) and increase the likelihood that the intended level of respiratory protection is not being attained.

Communication and Vision Impediments

The ability to communicate clearly is essential to a safe work environment, as well as to interpersonal interactions within and outside the work setting. The use of respiratory protective devices of any type by both workers and members of the public may impact the intelligibility and transmissibility of speech, although the degree to which speech intelligibility is reduced is debated, and may depend on device type, ambient noise, and the context of use (Muzzi et al., 2021; Palmiero et al., 2016; Radonovich et al., 2010). Even when speech intelligibility is not impacted, users may feel as though they are not communicating clearly, and the reading of facial expressions may be affected (Allison et al., 2010). Such impediments to communication may have far-reaching implications in schools (Allison et al., 2010; Caniato et al., 2021) and other work settings where communication is a critical part of workers' job functions. For example, a study of German home care professionals reported that the use of devices while providing personal and nursing care in patient homes during the COVID-19 pandemic significantly impeded their ability to communicate and interact and, by extension, to build close relationships with their patients (Mojtahedzadeh et al., 2021).

Additionally, the weight, bulk, and other physical characteristics of respirators can impede users' activities and performance. Obscured vision may occur when a respirator interferes with vision (i.e., downward gaze or visual acuity) or through fogging of the lens of a full facepiece respirator (Johnson, 2016). Fogging is often the result of an ill-fitting or improperly placed respirator and may be addressed by using a tightly fitting device and performing a user seal check to ensure that the device is correctly placed and outward leakage is reduced.

For such occupations as wildland firefighting, devices that impede communication and visual acuity are incompatible with many job tasks and have been described as a significant barrier to use (Beason et al., 1996; Sharkey, 1997).

Donning and Doffing

Correctly donning and doffing a respiratory protective device is essential for effective use. Research conducted during the COVID-19 pandemic has suggested that while the majority of study participants from the public

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were able to correctly position a respiratory protective device, typically masks or face coverings, on the face, incorrect placement exposing the nose or mouth and other incorrect practices were prevalent (Deschanvers et al., 2021; Jabbari et al., 2020; Machida et al., 2020; Mueller et al., 2021; Rahimi et al., 2021; Tam et al., 2021). Improper practices commonly observed in public users in the donning, wearing, and doffing of respiratory protective devices included inadequate hand hygiene and failure to avoid touching the surface of the device after placement (Kellerer et al., 2021; Lee et al., 2020; Machida et al., 2020). Proper donning and doffing may pose particular challenges to some vulnerable groups, such as those with cognitive disorders. For example, in one study conducted during the COVID-19 pandemic, nearly three quarters of patients living with dementia were unable to independently don and wear a mask, but the majority were able to successfully don a device with the assistance of a caretaker (Kobayashi et al., 2020).

Reuse and Storage

As discussed above, steps taken to enable reuse of respiratory protective devices, including cleaning or disinfection and storage, may impact the effectiveness of the device for its intended use. Relatively few studies have explored how devices are cleaned and reused by the public. Findings from studies conducted during the COVID-19 pandemic suggest that, among the public using devices for communicable biological agents, practices for cleaning and reuse vary and often depend on the device type. This variation may be the result of a lack of knowledge, lack of standard processes for reuse for specific devices like face coverings (Doung et al., 2021; Matusiak et al., 2020; Scalvenzi et al., 2020), or a function of risk perception (Yu et al., 2021). For example, in one study respondents were more likely to change their surgical mask if it was used in a location that was perceived as high risk (i.e., a hospital, public transportation, and gathering places) (Yu et al., 2021).

Similarly, methods for device storage while not in use were found to vary widely in studies conducted with participants from the public during the COVID-19 pandemic, although research is limited. Respiratory protective devices, largely face coverings and surgical masks, were most commonly stored in pockets and designated bags (Chao, 2020; Scalvenzi et al., 2020), on desk tops (Chao, 2020), or on the wrist/arm (Scalvenzi et al., 2020). The lack of a defined place for safe storage could impact the risk of fomite transmission.

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KNOWLEDGE, ATTITUDES, BELIEFS, AND PERCEPTIONS

Knowledge

Research identified in this review suggests that user knowledge of the role of respiratory protection, the inhalation hazard of concern, and the proper use of respiratory protective devices is likely to be associated with greater awareness of the value of respiratory protective devices and/or improved performance of effective use practices (Al Naam et al., 2021; Ali et al., 2021; Cummings et al., 2006; Domiati et al., 2020; Ferng et al., 2011; Horwell et al., 2019; Kelly, 2020; Kuo et al., 2011; Lei et al., 2019; Riden et al., 2020; Sikakulya et al., 2021; Xiong et al., 2018; Yang and Wu, 2020). However, this finding is not universal. Several studies included in this review illustrated that knowledge was not always a predictor of practice (Cowling et al., 2010; Cummings et al., 2006; Kamau et al., 2019; Lambrou et al., 2020; Tenzin et al., 2017; Zierold et al., 2016), and knowledge levels vary considerably from study to study, with some populations showing low respiratory protection knowledge (Cummings et al., 2006; Gershon et al., 2010; Shelus et al., 2020). These findings held true across hazards and across worker and public populations.

Attitudes, Perceptions, and Beliefs

A body of available research describes how user attitudes, perceptions, and beliefs impact whether and how respiratory protective devices are used to prevent inhalation of infectious hazards, air pollution, and wildfire smoke (personal protection), as well as transmission of infectious respiratory hazards (source control). The findings of these studies cover a range of different populations (i.e., nationalities, cultural groups, demographics) and indicate that these user factors are varied and are tied to sociocultural and structural forces within the broader system. Findings from these studies have been roughly categorized into subgroups of motivators and barriers to practice: risk perception, perceived effectiveness of respiratory protective devices, perceived self-efficacy, and perceived acceptability. Of note, results of these studies show conflicting conclusions across hazards and populations. Depending on the study, risk perception and perceived effectiveness of respiratory protection were both predictors of respiratory protection use and uncoupled from user behavior.

Risk Perception

Studies examining risk perception were limited to the public's use of respiratory protective devices in the context of communicable diseases. The

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available literature suggests some relationship between a user's perception of risk of the infectious inhalation hazard and use of respiratory protective devices. Generally, members of the public are more likely to use respiratory protective devices to prevent transmission if the perceived risk of the disease outbreak or pandemic is sufficiently high (Barceló and Sheen, 2020). This relationship between risk perception—including fear about illness or fatality and severity of illness—and face covering/mask use was generally present regardless of user population (Cowling et al., 2010; Ferng et al., 2011; Kwan et al., 2021; Lau et al., 2010; MacIntyre et al., 2009; Ozdemir et al., 2020; Tang and Wong, 2004). Of note, perception of risk can decline over time and impact preventive behaviors (Fielding et al., 2014; Lau et al., 2011).

Perceived Efficacy of Respiratory Protective Devices

Like perception of risk, available research indicates that there may be a relationship between the perceived effectiveness or perceived efficacy of masks/face coverings in the context of communicable disease and the use of these devices by the public (Chan et al., 2020; Lau et al., 2007; Tang and Wang, 2004; Vereen et al., 2021). Similarly, limited research suggests that the use of respiratory protective devices for wildfire smoke provides members of the public with a sense of protection, regardless of the actual level of protection provided (Mott et al., 2002). However, for communicable diseases, as was found with perceived risk, beliefs in the effectiveness of masks/face coverings can deteriorate over time (Lau et al., 2010), and not all studies described a positive connection between perceived effectiveness and adherence to the use of devices (Chan et al., 2015; Ferng et al., 2011).

Conclusions from studies examining workers' perceptions regarding the effectiveness of respiratory protective devices varied based on worker population and hazard. Studies of agricultural workers found knowledge of air pollution hazards and perceived usefulness of respirators did not translate into use of respiratory protective devices (Cramer et al., 2017; Kearney et al., 2014). Indeed, despite studies showing that while most farmers suggest and believe that they engage in actions to protect themselves from respiratory disease, among those studied, very few wear respiratory protective devices of any type (<10 percent), and importantly, most remain ambivalent about the usefulness of these devices for dust exposure (Carruth et al., 2008). When the respirator or dust mask (terminology used in the study) was used, higher usage continued to be associated with higher levels of user knowledge about occupational exposure and the risks associated with dust (and bacterial exposure) from grain and animal handling, as well as knowledge about the importance of NIOSH approval, seal, and fit-testing processes (Cramer et al., 2017).

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Despite the lack of an appropriate "wildland respirator," wildland firefighters have noted their belief that respiratory protection is needed in their line of work. In a 1997 analysis, Sharkey reported that of 300 state and federal respondents involved with wildland firefighting 82.2 percent felt that the smoke hazards that they encountered warranted the use of a respirator. In the few studies that assessed user perceptions of respirators during use in wildland firefighting, respirator use was generally viewed positively, but results were mixed (Beason et al., 1996; De Vos et al., 2006; Sharkey, 1997), and the literature is notably outdated.

Self-Efficacy and Use of Respiratory Protective Devices

Self-efficacy, defined for this purpose as the perceived ability to perform risk-reducing behaviors during a threat to protect oneself, is likely to play a role in how the public adheres to the use of respiratory protective devices to reduce exposure risk (Avery et al., 2021). Limited research in this area suggests that the public's perception of their own knowledge may, in turn, enhance their confidence in their own ability to effectively employ practices to protect themselves from communicable diseases (Tam et al., 2021). However, feelings of self-efficacy do not universally translate into effective protective practices. A study of the Chinese public did not identify any significant predictors between participants' self-efficacy and the practice of protective behaviors, despite the fact that participants who perceived COVID-19 infection as more severe exhibited a greater likelihood of wearing a face covering/mask (Rui et al., 2021).

Social Acceptability and Use of Respiratory Protective Devices

Studies examining social acceptability were limited to the public's use of respiratory protective devices in the context of communicable diseases. Social acceptability of respiratory protective devices is a broad category that, for the purposes of this review, encompasses attitudes, beliefs, and feelings that act as motivators or barriers at an individual level as to whether and how respiratory protective devices are used. Several studies have noted issues with perceived social barriers that impact use of respiratory protective devices. While overall compliance with and knowledge of the use of respiratory protective devices may be high during a pandemic or major outbreak, embarrassment about wearing a respiratory protective device of any type could act as a barrier to use (Al Naam et al., 2021; Ferng et al., 2011; Seale et al., 2012). Another barrier related to social acceptability and the effective use of masks/face coverings, as noted by Shelus and colleagues (2020), was the tendency of individuals to reduce their use when close to family or

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friends, even among populations that report a high level of compliance with the use of these devices in general (Shelus et al., 2020).

User Anxiety and Mental Health

Studies examining user anxiety and mental health were limited to use of respiratory protection by Chinese workers during the COVID-19 pandemic and suggest that user anxiety may influence the effective use of respiratory protective devices. A survey of 67,357 teachers in China indicated that anxiety and the use of respiratory protective devices impact one another in several defined ways. For example, teachers who did not know how to properly use masks (terminology used in the study) during the COVID-19 pandemic had higher odds of anxiety than users who did have knowledge of proper use practices, and failure to adhere to proper mask use resulted in a 39 percent increase in odds of anxiety (Li et al., 2021). A study among factory workers in China during the COVID-19 pandemic found that depressive symptoms were associated with consistent face mask use (Pan et al., 2020a).

SOCIODEMOGRAPHIC ASSOCIATIONS

Sociodemographic factors may be associated with differences in the use of respiratory protective devices among members of the public and workers exposed to inhalation hazards, although the nature of these associations vary by population and exposure type. In the United States, limited evidence suggests that gender, concern about health effects, and higher education level are associated with greater mask use in the setting of wildfire smoke and communicable disease (e.g., COVID-19) outbreaks.

Findings for the Public

Data is mixed across the literature but suggest that sociodemographic characteristics, such as gender, age, and education level, may influence the likelihood of the use of respiratory protective devices by the general public. Women are consistently more likely to believe in or adhere to the use of respiratory protective devices, as demonstrated in the United States (Cowling et al., 2010; Haischer et al., 2020; Lu et al., 2021; Sugerman et al., 2012) and in multiple international settings (Cheok et al., 2021; Lee et al., 2020; Machida et al., 2020; Takahashi et al., 2017).

Evidence of a relationship between older age and greater likelihood or odds of using respiratory protective devices has been noted in several studies (Barceló and Sheen, 2020; Lau et al., 2010; Lu et al., 2021; Rahimi et al., 2021), including studies in the United States during the COVID-19

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pandemic (Haischer et al., 2020) and during wildfire smoke conditions (Sugerman et al., 2012). During wildfire smoke conditions in California, having a history of chronic lung disease has been associated with compliance with messaging regarding use of respiratory protective devices (N95 FFRS and other devices), likely due to concern about personal health risks (Sugerman et al., 2012).

Higher levels of education have been associated with higher likelihood of use of respiratory protective devices of all types in multiple U.S. studies, both for infectious disease outbreaks and wildfire smoke exposure (Anderson et al., 2021; Clements, 2020; Sugerman et al., 2012). In the cleanup of New Orleans after Hurricane Katrina, residents with higher education were more likely to identify respirators as appropriate devices to reduce exposure to mold, while knowledge of respiratory protection did not differ on the basis of sex, age, race, or previous experiences with flooding and mold (Cummings et al., 2006). There is limited evidence that higher income may be a predictor of the use of respiratory protective devices in the United States for protection against COVID-19 (Anderson et al., 2021) and wildfire smoke (Sugerman et al., 2012), although very low income has also been associated with greater compliance (Anderson et al., 2021).

In addition to cultural and societal forces that impact social stigma around mask use, residing in an urban or rural area may impact the likelihood or actual use of respiratory protective devices. In the United States, most studies suggest greater likelihood of preventive behaviors, including mask use, among those living in urban or suburban locations as compared to rural locations (Callaghan et al., 2021; Haischer et al., 2020; Lu et al., 2021), although not all studies have found this pattern (Anderson et al., 2021).

Findings for Worker Groups

Several studies have evaluated use of respiratory protective devices among farmworkers who are exposed to agricultural dusts, and these studies have consistently found that younger farmers are more likely than older farmers to report wearing a form of respiratory protection, typically respirators (Donham et al., 2011; Mitchell and Schenker, 2008; Mpofu et al., 2002; Syamlal et al., 2013; Virolainen et al., 1987). In addition, differences have been found by smoking status, with greater use of respiratory protection against dust while working among ex-smokers and a lower likelihood of use among current smokers. As in the general public exposed to ambient pollution, higher education attainment, concerns about respiratory problems, and a prior history of respiratory disease have been associated with a higher likelihood of wearing a respirator of any type to prevent exposure to dust in the farm setting (Schlenker et al., 1990; Virolainen et

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al., 1987). The size and earnings of the farm are also an important determinant of use of respiratory protection, with greater likelihood of availability of respirators for farmworkers at larger or higher-earning farms (Cramer et al., 2017; Kearney et al., 2014; Syamlal et al., 2013; Virolainen et al., 1987). Although studies of the use of mask/face coverings in the workplace during the COVID-19 pandemic are still emerging, studies of market and poultry workers conducted in Asia have consistently found that education level, older age, and longer work experience were associated with preventive practices, including the use of such devices to reduce transmission of infectious disease (Lei et al., 2019).

COMMUNICATION, EDUCATION, AND TRAINING

Factors and Attributes That Influence Adherence to Recommendations on the Use of Respiratory Protective Devices

Public health messaging, education, and training can influence user knowledge (Cummings et al., 2006), attitudes, and practices (Kelly, 2020) regarding use of respiratory protective devices of all types. However, relatively little is known about factors impacting decision making about such device use and how public health messaging and educational interventions could be more effective (Shelus et al., 2020).

Much of the research conducted during the COVID-19 pandemic on the use of respirators, face coverings, and surgical masks by the public sought to describe these complex cultural, behavioral, and sociodemographic factors. Findings from these studies identify key factors and attributes associated with mask wearing that can be used to tailor messages, risk communication, and programs to specific, targeted segments of the population to enhance uptake among vulnerable groups (Barceló and Sheen, 2020; Casola et al., 2021; Chan et al., 2015; Fisher et al., 2020; Siu et al., 2016; Zhang et al., 2019).

These findings, many of which are discussed in earlier sections of this appendix, include the following:

- sociodemographic and health factors (Azlan et al., 2020; Islam et al., 2021);
- location of residence (e.g., urban, rural, region) (Azlan et al., 2020; Betsch et al., 2021);
- user knowledge (Duong et al., 2021), attitudes, and beliefs (Gray et al., 2020);
- self-efficacy (Berg and Lin, 2020; Betsch et al., 2021; Ozdemir et al., 2020);

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- perceptions of risk or severity of illness (Berg and Lin, 2020; Shelus et al., 2020), or of risk of infection (Betsch et al., 2021);
- perceptions of mask effectiveness (Kamate et al., 2010; Ozdemir et al. 2020);
- trust in institutions (Betsch et al., 2021; Fielding et al., 2014); and
- fatigue, both with constant messaging and with mask use itself (Lee et al., 2020).

Of note, behaviors and risk perception can change over time (Fielding et al., 2014), which emphasizes the importance of understanding the population's barriers and motivations, and developing strategies based on this understanding for responsive communication and messaging for the public on the use of respiratory protective devices (Teasdale et al., 2014).

Information Seeking

Research conducted in the context of the COVID-19 pandemic found that online information-seeking behaviors and search themes provide valuable information about what the community needs at a given time (Bento et al., 2020; Galido et al., 2021). These findings are likely to be broadly applicable to other inhalation hazards. Importantly, these search patterns will evolve over time and require adjustments to public health messaging and communication of guidance.

Best Practices in Public Health Communication and Messaging

Appropriately designed and targeted communications can improve the public's adherence to recommendations regarding the use of respiratory protective devices and positively impact health outcomes. The literature review identified the following best practices, primarily from the review of the public's use of respiratory protective devices to protect against communicable biological agents. The studies largely focused on the use of face coverings and masks, although some studies specific to wildfire smoke also examined communication and messaging around respirator use. These best practices are expanded on in sections below.

- Target Messaging to Specific Audiences
- Tailor Materials and Ensure Cultural Appropriateness
- Use Positive Framing and Avoid Stigma
- Convey Clear Simple Messages That Address User Needs and Questions
- Leverage Trusted Partners and Diverse Information Sources
- Update Messaging Based on Continuous Evaluation

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Targeted and Tailored Messaging

Targeting groups with low adherence The evaluation of factors impacting the willingness of the public to comply with recommendations on the use of respiratory protective devices for respiratory infection prevention is critical because it allows for the identification of key groups that are less likely to comply and may benefit from targeted and tailored risk communication strategies or health education (Barceló and Sheen, 2020; Fisher et al., 2020; Ozdemir et al., 2020; Taylor et al., 2009). Mediators and barriers that predict adherence to the correct use of respiratory protective devices of any type require in-depth and ongoing evaluation, as these factors and attributes mediating perception and use are not static. Key population groups can include those demonstrating resistance to mask use (Barceló and Sheen, 2020; Majam et al., 2021), specific demographic groups (Daoust, 2020), and individuals demonstrating personality characteristics associated with reticence toward mask wearing (Barceló and Sheen, 2020). Ultimately this tailoring of education campaigns and guidance to particular population segments or predictors of adherence will require large population studies to identify these underlying determinants (Majam et al., 2021). The complexities of mask/face covering use during the ongoing COVID-19 pandemic demonstrate the need for research to develop more complete understandings of behavioral predictors and other motivators and barriers to use of respiratory protective devices by the public.

Tailoring materials and ensuring cultural appropriateness Public health messaging and communication activities should be tailored to address the key needs, barriers, and motivators specific to the population of interest (Riden et al., 2020; Sim et al., 2014) and should be culturally appropriate (Ferng et al., 2011; Vereen et al., 2021). Language should resonate with the intended audience (Shelus et al., 2020), and materials should be developed and disseminated in collaboration with the community of interest.

Message/Guidance Content

Using positive framing and avoiding stigma For the U.S. public, studies show public health communications to encourage mask wearing may be improved by the use of short, clear requests paired with examples of direct and positive benefits, such as protecting one's community, saving lives, and reducing transmission (Fisher et al., 2020; Shelus et al., 2020; Vereen et al., 2021). Additionally, positively framed and toned messages are more impactful on behavior than fear-based messaging (Vereen et al., 2021). It is important to avoid the use of images or wording that may draw

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unintentional or damaging associations between a disease and particular groups (Batova, 2021).

Using clear, simple messaging to guide effective use of respiratory protective devices To address challenges related to adherence with public health recommendations on use of respiratory protective devices, as well as improper use, which may be an issue even in communities with high levels of adherence to the use of such devices (Tam et al., 2021), public health communications need to clearly convey the risks from the inhalation hazard (i.e., why use of the device is recommended) (Kelly, 2020); benefits and risks of the type of device used, including uncertainties (McDonald et al., 2020); and guidance regarding when and how to properly use the devices and where they can be accessed (Kellerer et al., 2021; Scalvenzi et al., 2020; Vereen et al., 2021). It is also important to address misinformation about correct use (Azlan et al., 2020; Scalvenzi et al., 2020) to avoid a false sense of protection.

Differences have been noted in the emphasis on respiratory protective devices in public health messaging regarding protective measures for communicable infectious agents, such as SARS-CoV-2, and wildfire smoke. Cook (2020) found that the majority of public health materials pertaining to wildfire smoke did not focus on the use of a respirator or other type of respiratory protective device, and instead included such recommendations as remaining indoors or reducing outdoor activities. These findings indicate that attention should be paid to increasing the balance (between detail and simplicity) of messaging and to providing more information about how and when different protective measures should be employed.

Public health communications would benefit from providing clear information about who can and cannot safely use respiratory protective devices (Vereen et al., 2021). For example, messaging around the use of respiratory protective devices by children, who are also highly susceptible to the negative health effects of wildfire smoke exposure, has been noted to lack clarity. Cook's (2020) evaluation of public health materials on wildfire smoke exposure found that, while materials noted that children should not use adult-sized masks when exposed to wildfire smoke, no alternative options were offered nor was information offered about why an adult mask would not function properly, leading to potential confusion about whether effective masks for children exist and why adult masks cannot be used by children (Cook, 2020). Furthermore, public health materials for wildfire smoke included contradictory information about the use of N95 FFRs by the public during the 2018 Camp fire and caused confusion by creating the impression that those with respiratory and cardiac conditions should not use the respirators, although they are in fact the group most in need of protection from exposure.

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In crafting messages, technical language and jargon should be avoided. Sugerman and colleagues (2012) found that public health messages about wildfire smoke that included technical terminology, such as "use respirators during clean up [of ash following wildfires]," were less easily remembered than messages with nontechnical terminology, such as "stay indoors" or "keep windows and doors closed." It is important to confirm that messages are accessible and understandable and address misinformation (Pan et al., 2020b). Additionally, individuals from different socioeconomic levels access information about mitigation measures differently and will view the clarity of messaging differently (Aburto et al., 2010).

A lack of clarity in messaging can have long-term consequences for the use of respiratory protective devices, as illustrated by the struggle over communication of guidance on mask use early in the COVID-19 pandemic when recommendations were changing regularly and information sources presented conflicting information (Casola et al., 2021; Erikainen and Stewart, 2020; Shelus et al., 2020). Shelus and colleagues (2020) concluded that mixed messages contributed to significant confusion and concerns over the efficacy of masks and face coverings for the public.

Leverage Trusted Partners and Diverse Information Sources

Effective behavior change in the public to expand adherence and proper use of respiratory protective devices will require the coordinated efforts of a variety of stakeholders (Sim et al., 2014). Trust is an important component of public health messaging during a pandemic, but preferences for and trust in designated information sources can change over time (Fielding et al., 2014; Lau et al., 2011). Logistical and cultural challenges in adopting preventive practices are more easily overcome when local public health departments prioritize building ongoing, trusted relationships within communities. This improved relationship can in turn improve the distribution and cultural acceptability of public health messaging and adherence of the population to essential preventive measures (Ali et al., 2020). Clear communication, up-to-date scientific information, and transparency in government decision making may be effective in improving adherence to preventive measures. A communication platform created in collaboration with government and academic institutions could address these needs and act as a unified source for disseminating information to the public (Lau et al., 2009).

Role of the media Mass media (radio, television, newspapers, and websites) plays a significant role in the dissemination of information about inhalation hazards and preventive measures, including the use of respiratory protective devices, to the public. This has been the case with communicable biological agents, such as COVID-19 (Anwar et al., 2020) and H1N1 influenza

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(Aburto et al., 2010); air pollution (Zhang and Mu, 2017); and mold (Cummings et al., 2006).

During the COVID-19 pandemic, social media has also been used as a key communication platform for information exchange, and the evaluation of interactions on social media can allow for greater understanding of how messages can spread and impact attitudes and practices for mask use over time (Ahmed et al., 2020). Social media analysis can be used to identify themes and attitudes shared by the population to inform the content and dissemination of outreach to the public.

Role of government and public health experts Information presented by experts may impact adherence to mask wearing and other preventive behaviors (Rui et al., 2021). In addition, governmental or professional association guidance for workers was indicated in two articles as important to the effective use of respiratory protective devices and other preventive practices during the COVID-19 pandemic (Homer et al., 2021; Jones et al., 2021). Health departments, followed by the Federal Emergency Management Agency and other government agencies, were viewed as most appropriate for educating the public about mold remediation practices requiring the use of respirators (Cummings et al., 2006).

Role of employers For workers, employers have a critical role in communication and education regarding the use of respiratory protective devices to protect employees against inhalation hazards. In one study, when asked what entities bear the responsibility for educating workers about prevention of mold exposure using respirators, surveyed workers performing mold remediation reported that employers (70 percent) followed by OSHA or another government agency (34 percent) were best suited for this responsibility. However, these perceptions varied by employment status (self-employed versus employed by a company), level of education, and prior work experience with mold remediation in flooded structures (Cummings et al., 2006).

Role of manufacturers Manufacturers can play a role in educating the public on correct use of respiratory protective devices, although little research exists that explores these opportunities in the context of public use. Manufacturers can address some of the user errors that lead to improper use of respiratory protective devices by providing accessible and clear instructions on packaging, and engineering certain design features to reduce errors in donning (such as the common error of wearing the device inside out) (Tam et al., 2021). Of note, Kelly (2020) found that N95 FFR manufacturer instructions, which did not include health risk messaging, did not significantly

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change participants' responses on knowledge, attitudes, and practices in the context of donning a respirator for protection against wildfire smoke (Kelly, 2020).

Update Messaging Based on Continuous Evaluation

Ongoing evaluation of factors and attributes impacting adherence to recommendations on use of respiratory protective devices, as well as monitoring of public perceptions of policies on preventive measures would facilitate regular assessments of risk communication and other public health outreach (Lau et al., 2011).

Specific Training Needs for Workers

Few captured studies relevant to workers without respiratory protection programs provided information on their specific training needs. Discussed below are the findings related to training for agricultural workers and wildland firefighters.

Agricultural Workers

The studies reviewed for agricultural workers exposed to air pollution emphasized the importance of providing training and guidance for farmworkers in order to effectively support behavior change aimed at reducing farmwork-related risk of exposure to dust and other air pollutants. A Canadian study by Mpofu and colleagues (2002) noted that less than half of the respondents reported having had previous training or instructions on how to use respirators, which could explain the overall low prevalence of respirator use in this outdoor worker population. However, evidence on the effectiveness of training has been mixed. Two studies demonstrated that farms or farmers in educational intervention groups saw an increase in the use of respirators as compared to the control groups (Donham et al., 2011; Virolainen et al., 1987). A third study found that farms (pig and dairy farms) that received an educational intervention (including provision of informational documents about farmer exposures, the associated risks, and advice on how to mitigate those risks) showed an overall significant decrease in dust exposure through behavioral changes compared to the control group. However, the authors did not observe a significant difference in respirator use between the intervention and control groups, and respirator use remained low in both groups (Basinas et al., 2016).

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Wildland Firefighters

For wildland firefighters, the development of a culture of safety will require a commitment to routine trainings of workers in both a classroom and a field setting (Reinhardt and Ottmar, 2000). Multiple articles included in the committee's review referenced the importance of training and education for the effective use of respirators by wildland firefighters. Issues that need to be addressed in training include hazard assessment, the limitations of respirators for wildfire smoke, proper donning and use, maintenance and service life (Reinhardt and Ottmar, 2000), and fit (Sharkey, 1997). Reinhardt and Ottmar (2000) wrote that hazard awareness training is critical for helping users understand why exposure to the components of wildfire smoke is of concern and how a respirator can and cannot reduce that exposure. This understanding of the limits of protection and when to don a respirator is of critical importance for avoiding exposure to carbon monoxide while wearing an air-purifying respirator with a particulate cartridge (as described by De Vos et al., 2009; Haston, 2007; and Reinhardt and Ottmar, 2000). Training could be provided for users during annual training and during recertification (Reh and Deitchman, 1992) and should be led by qualified personnel (Beason et al., 1996). Reinhardt and Ottmar (2000) noted that education about the hazards of wildfire smoke should begin before workers are deployed to the field and then routinely refreshed both in a traditional classroom setting and in the field.

ACCESSIBILITY

The use of respiratory protective devices requires users to be able to access the device and, in many cases, to be able to afford to purchase the correct device. As such, accessibility issues are an essential component to ensuring effective use of devices at a population level and in occupational settings. At this time, there is very limited research relating to supply, access, and affordability of respiratory protective devices for the populations covered in the committee's review.

Accessibility for the Public

Individual perception of cost and accessibility of respiratory protective devices may act as a barrier or motivator for use, although the number of studies identified in this review that point to cost and accessibility of devices as a barrier is extremely limited (Aburto et al., 2010; Anwar et al., 2020; Casola et al., 2021; Selby et al., 2020). Studies have suggested that public use could be encouraged by the government providing devices for free rather than requiring the public to pay out of pocket (Anwar et al., 2020;

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Casola et al., 2021; Selby et al., 2020). However, little is known about how distribution of free respiratory protective devices would affect actual use.

In the context of wildland fire smoke exposure, McDonald and colleagues (2020) noted that respirators, which more effectively filter out hazardous particles in air pollution (e.g., smoke) to protect the wearer, are more expensive than other types of nonrespirator devices, such as surgical masks. These authors also suggest that this additional cost may necessitate the mass distribution of respirators by public health agencies or by donation directly from the manufacturer for distribution to the population (McDonald et al., 2020).

Supply issues were a major challenge in the early months of the COVID-19 pandemic when public health authorities recommended the public use cloth face coverings to protect low supplies of surgical masks and respirators for frontline workers. This created a public demand for new types of products, like face coverings, which were not yet widely available. Within a very short period of time, new industries that produced these products emerged. One notable example is the wax fabric mask industry in Ghana that marketed to consumers via social media and messenger applications. The mask products created great public interest and resulted in a new government investment in the local production of masks (De-Graft Aikins and Akoi-Jackson, 2020). More research is needed to understand the interplay between sociocultural factors and market forces.

Controlled or optimized distribution of masks to those at greatest risk of adverse outcomes (such as the elderly) and, in scenarios where supply is extremely limited, could target resources toward prevention of the most severe or deadly infectious cases (Worby and Chang, 2020). Such an approach would preserve supply of respiratory protective devices in the setting of "panic buying," such as was seen early in the COVID-19 pandemic. When many parts of the world experienced severe supply chain shortages of personal protective equipment, South Korea and Taiwan both implemented centralized inventory management programs to improve the efficiency, reliability, and cost of masks for public use (Kim, 2021; Lin et al., 2020). A review of the actions taken by South Korea with regard to early attention to respiratory protective device supply and distribution in the COVID-19 pandemic demonstrates a centralized approach in managing supply, the value of an enterprise approach, and those qualities and actions that need to be leveraged to improve access to respiratory protective devices by the public in a timely manner via a mask inventory service. The success of South Korea in maintaining adequate supply and access to respiratory devices is attributed to (1) collaboration of stakeholders across the enterprise; (2) clearly defined roles and responsibilities, and communication pathways; (3) cooperation and buy-in from the population; and (4) information technology (IT) infrastructure and coordination of data sharing across institutions

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in real time (Kim, 2021). Taiwan carried out a coordinated mask dissemination and inventory management program through its pharmacy network, and rationed the number of masks that could be sold to an individual and on what days masks could be purchased by defined groups of individuals (Wang et al., 2020).

Accessibility for Worker Groups

Perceived or actual lack of access to respiratory protective devices is a barrier to effective use in the occupational setting (Duruk et al., 2020; Gershon et al., 2010; Homer et al., 2021; Jones et al., 2021). For example, the perception of lack of availability of respirators in the workplace was noted as a barrier to respirator use in a survey of 384 home health care workers in the United States (Gershon et al., 2010). A study comparing infection prevention and control practices within home health care agencies in the United States in December 2019 reported that, while almost all agencies (more than 99 percent) provided personal protective equipment (PPE) (including surgical masks) to staff prior to the COVID-19 pandemic, just 39.7 percent provided N95 FFRs (Shang et al., 2021). In other contexts, the provision of free masks and other PPE by authorities was identified as a tool for increasing compliance with the use of respiratory protective devices by both employees and customers of neighborhood businesses that supply essential goods to their communities, during the COVID-19 pandemic (Jones et al., 2021).

Among farmworkers, limited research suggests that use of respirators is low, although in one study this appeared to be related to lack of education, safety audits, and performance incentives rather than lack of access to respiratory protective devices onsite (Donham et al., 2011). On the other hand, in the setting of wildland fire smoke exposure, access to respirators has been found to be an important determinant of use (Amster et al., 2013).

CULTURAL NORMS

Cultural and social norms—shared belief systems within a social group that influence behavior and the management of relationships (Santana et al., 2020)—play a significant role in shaping user perceptions and practices regarding mask wearing among the public. Understanding these cultural nuances and establishing relationships with communities are critical to designing responsive public health programs (Barceló and Sheen, 2020; Santana et al., 2020; Siu et al., 2016) and disseminating culturally acceptable public health messaging (Ali et al., 2020).

Mask wearing is more acceptable in some countries with such cultural values as a strong sense of collectivism, and was common practice even

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before the COVID-19 pandemic. A sense of interdependence may motivate use of respiratory protective devices in countries with a greater sense of collective purpose and dissuade it in cultures that value self-expression (Casola et al., 2021). Unsurprisingly, members of the public are more likely to use respiratory protective devices if they live in a region or country where use is more prevalent and widely accepted (Barceló and Sheen, 2020; Zhao and Knobel, 2021). In some areas, past outbreaks and pandemics (e.g., SARS, H1N1) have resulted in the integration of mask use into the societal fabric (Siu et al., 2016).

Importantly, factors mediating the use of respiratory protective devices within a population are not static and can shift over time. Positive social influences, including feelings of solidarity, civic responsibility, and altruism, can be short lived and taper off as an epidemic wanes and the threat is no longer perceived as serious. This process can be followed by a shift into more negative feelings (Tsang and Probst et al., 2021). Public health communications, educational outreach, and guidance would benefit from responding to fluctuations in perceptions regarding the use of respiratory protective devices in future public health events.

In occupational settings, safety culture may shape norms related to respiratory protection at the organizational level (Beason et al., 1996). Limited research shows that employer and supervisor attitudes toward safety (Riden et al., 2020) and modeling behavior by management (Jones et al., 2021) are important drivers of effective use of respiratory protective devices by workers.

OVERSIGHT AND ENFORCEMENT

Oversight and Enforcement for Workers

In the occupational setting, employers are required by OSHA—or, in some cases, other regulatory agencies—to establish respiratory protection programs (RPPs) and supply employees with respirators when such devices are necessary to protect workers from inhalation hazards. Workers whose employers have instituted elements of an RPP (e.g., provision of respirators, fit testing, training) may be more likely to consistently use and be knowledgeable about respirators when facing inhalation hazards (Cummings et al., 2006; Gershon et al., 2010). In the case of home health care workers, implementing RPPs and providing access to respiratory protective devices, among other strategies, may also be important for ensuring employee willingness to continue performing their job functions in the context of a pandemic (Gershon et al., 2010). However, lack of employer compliance with RPP requirements is a barrier to effective use of respiratory protective devices. Lack of training and fit testing has been reported even among

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workers whose employers had provided respirators (Cummings et al., 2006; Gershon et al., 2010). As a result, access to respirators in the workplace does not necessarily translate to knowledge on or proper use of respiratory protective devices.

Some workers reported that a top-down approach featuring strong regulatory oversight and incentives for employers, including financial incentives (e.g., penalties for noncompliance), would be needed to ensure full compliance with worker safety and health measures, such as RPP requirements (Riden et al., 2020). However, a top-down approach may not be effective in all circumstances. For example, in the case of wildland firefighters, enforcement without worker buy-in may not lead to consistent use of respirators in the field, underscoring the importance of communication among regulatory agencies, unions, and employees (Reinhardt and Ottmar, 2000).

Tailoring RPPs to the needs of specific worker populations is critical for addressing the unique needs of that group (Earle-Richardson et al., 2014). For example, language barriers, lack of transportation, and lost work hours associated with fit testing and medical clearance were noted as disincentives for migrant farmworkers (Earle-Richardson et al., 2014) and would need to be considered in the development of an RPP. Pilot programs have been suggested as a mechanism for developing RPPs that effectively address the unique needs of wildland firefighters related to training, fit testing, and medical clearance (Sharkey, 1997).

Oversight and Enforcement for the Public

In the context of the use of respiratory protective devices by the public, there is no established equivalent to an OSHA-mandated RPP. Consequently, little research exists related to oversight and enforcement of the use of respiratory protective devices by the public, outside of some limited research on mask mandates.

During the COVID-19 pandemic, both mandatory and voluntary mask-use policies were instituted around the globe as a method for enforcing mask use by the public. The impact of these two policy types—mandatory versus voluntary—is just beginning to be assessed and the few articles identified by this review suggest that mandatory policies may be more effective than voluntary policies in effecting compliance (Schmelz, 2020; Sprengholz et al., 2020). One study suggests that mandatory policies may be perceived as more effective and fairer than voluntary policies (Sprengholz et al., 2020). Thus while some policies may be effective in encouraging mask use by the public (Fischer et al., 2021), more needs to be known about challenges and best practices for implementation.

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Appendix C

The Regulatory Landscape Regarding Respiratory Protection[1]

by Professor Arden Rowell, J.D.

Commissioned by the National Academies Committee on Respiratory Protection for the Public and Workers Without Respiratory Protection Programs at Their Workplaces

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[1] A white paper commissioned by the National Academies of Sciences, Engineering, and Medicine's Committee on Respiratory Protection for the Public and Workers Without Respiratory Protection Programs at Their Workplaces, written by Arden Rowell, J.D., Professor, University of Illinois College of Law. Special thanks to Todd Aagaard for review and commentary, to Karen Bradshaw and Adam Finkel for helpful background discussions, and to Stephanie Davidson and Becky Tzucker for their research assistance.

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EXECUTIVE SUMMARY

The regulatory landscape of respiratory protection in the United States is highly fragmented, involving multiple actors at the federal and subfederal levels, which have varying responsibilities and have authority regarding different aspects of different respiratory hazards.

Occupational Protection

A few regulatory authorities—notably the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH)—have substantial authority over the regulation of health and safety of many workplaces and over respiratory protection of workers in those workplaces. Many other authorities, including the Environmental Protection Agency (EPA), have authority over inhalation hazards in specific workplaces or against specific hazards.

- Most workers are not currently protected by a respiratory protection program (RPP) or by mandatory workplace safety standards addressing the use of respiratory protection. OSHA has the statutory authority to implement new or expanded RPPs if they find that the respiratory hazards workers are facing are a "significant risk," and so long as the workers are not part of a statutorily excepted group (e.g., state and local government workers or the self-employed).
- NIOSH, and its division the National Personal Protective Technology Laboratory (NPPTL), is the primary federal authority for researching and certifying respiratory protection for the workplace. While some other federal and state actors are involved in oversight for some workers in some industries or as against some hazards, these recommendations tend to be coordinated with NIOSH, and with NPPTL, which plays a critical role in centralizing evaluation of occupational respiratory protection. NIOSH also provides guidance for workers outside its programs, and in some cases has acted historically as a consultant on matters of respiratory oversight that touch on its expertise. That said, NIOSH's mandate, authority, and consequent testing protocols are directed toward workplace respiratory protection rather than toward more general public protection.

Protection of the Public

The regulation of respiratory protection for the public is more fragmented than occupational respiratory protection. There is no central authority responsible for respiratory protection of the public, and there is not even any centralized repository of information about which authorities are responsible for which hazards.

- There is no single federal entity responsible for regulating the use of respiratory protection by the public, though there are a number of federal agencies responsible for regulating specific types of respiratory hazards that might require or be addressed by respiratory protection. Among these agencies, EPA and the Centers for Disease Control and Prevention (CDC) have the broadest mandates, with the Federal

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Emergency Management Administration having special authority in the context of emergencies.

- There is no single federal entity responsible for overseeing the development, approval, marketing, or postmarketing surveillance of respiratory protection for the public, or for generating or overseeing a certification program for managing these processes. The Food and Drug Administration serves an oversight function for respiratory protection used for "medical purposes," and several other federal entities serve some oversight function against specific respiratory hazards. In the gap left by the lack of centralized federal authority, multiple agencies have issued nonbinding guidance to advise the public regarding respiratory protection. This guidance often relies upon oversight and certification provided by NIOSH for occupational contexts.

Regulatory Implications of Recommendations by the Committee

Recommendations for addressing the gaps and overlaps created by this complex regulatory landscape can be most effective when they are addressed to the institutional actor(s)—whether congress, the president, or agencies—with the authority to respond. As a general matter, the committee may be able to maximize the effectiveness of its recommendations by making specific (and in some cases differing) types of recommendations to congress, the president, and agencies. In particular, this may involve making recommendations specifically to agencies to address gaps and overlaps that come from regulatory interpretations, to congress to address any statutory gaps and/or matters of appropriations, and to the president to address problems of coordination and enforcement.

INTRODUCTION

The National Academies Committee on Respiratory Protection for the Public and Workers Without Respiratory Protection Programs at Their Workplaces ("the Committee") has commissioned a background paper as part of the context for its study and to inform its recommendations. This document is the final draft of that background paper.

The Committee presented the following tasks to be addressed by the background paper:

1. *Describe the regulatory environment, including applicable laws, regulations, and guidance documents related to use of respiratory protection in occupational and non-occupational settings and regarding oversight of the development, approval, marketing, and post-market surveillance of respiratory protection; and*
2. *Analyze the implications of new or revised laws or regulations that may be considered to address current gaps in responsibilities and authorities related to respiratory protection for the public and workers without workplace respiratory protection programs.*

Accordingly, this paper (1) describes the existing regulatory landscape regarding respiratory protection, and (2) analyzes the potential regulatory landscape that might exist in response to recommendations by the Committee. In addition, the Committee has asked that the paper identify key authorities related to national stockpiling of respiratory protective gear.

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To answer these questions, the paper splits into two parts, with each part designed to answer one of the presented questions. Part I addresses the existing regulatory landscape regarding the use and oversight of respiratory protections for workers and the public. It begins by addressing the relatively centralized landscape regarding respiratory protection in the workplace (including a brief treatment of stockpiling), before then addressing the more fragmented regulatory landscape of respiratory protection for the public. Part II addresses the options and implications of potential Committee recommendations, including recommendations to Congress, agencies, and the President. It also includes a brief overview into the types of laws and regulations that make up the regulatory landscape of respiratory protection.

The goal of this paper is to provide the Committee with factual information about the regulatory landscape regarding respiratory hazards. The paper does not recommend or advocate for any particular course of action. Rather, it is intended to help the Committee as it navigates through a complex and often fragmented landscape, which involves multiple actors at the federal and subfederal levels, which have varying responsibilities and have authority regarding different aspects of different respiratory hazards. Thus, while the paper identifies important legal and regulatory implications that flow from making one kind of recommendation over another, it leaves the Committee to chart its own way through those recommendations. In this sense, the paper is meant to be a cartographic document that the Committee can use to help plan its journey from where we are now to where the Committee believes we should be in the future.

While this paper aims to provide the Committee with a meaningful map of the regulatory landscape regarding respiratory hazards, the landscape is too fragmented and the time scale for research is too short to have either found or included every detail regarding the regulation of respiratory protection. The paper has prioritized general topographic takeaways and characterizations over specific program descriptions or lists—and as the Committee will see, even this choice has generated a very long paper. The hope is that the outlines of the landscape will still prove helpful to the Committee as it develops recommendations to improve the respiratory protection both of workers without respiratory protection programs and of the general public. It should also provide a starting point for further research, including research to be undertaken by the National Academies staff, where such inquiries are deemed valuable.

PART I: THE EXISTING REGULATORY LANDSCAPE

This part of the paper describes the existing regulatory landscape regarding the use and oversight of respiratory protections. It provides an overview of the multiple legal actors and authorities that bear on how respiratory protection is used and overseen for both occupational and nonoccupational use. Existing authorities substantially distinguish between occupational and nonoccupational regulation of respiratory protection, so the paper addresses those categories separately.

As it discusses the various authorities and legal constraints on occupational and nonoccupational respiratory protection, this part seeks to identify where there are clear areas of authority, and at which agencies, so that the Committee can make its eventual technical, scientific, and medical recommendations directly to those authorities. It also identifies where there are potential problems of "overlap," where multiple actors have authority, and "gaps," where arguably no actors have authority. As is discussed further in Part II, distinguishing these situations may be helpful in informing the Committee's eventual recommendations and in tailoring those recommendations in light of the underlying regulatory structure.

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As a brief preview of the substance of this part, of the two contexts, the regulation of respiratory protection for occupational use is significantly more centralized—and less fragmented—than regulation of respiratory protection outside the workplace. This means that there are clearer authorities to which recommendations may be directed regarding the regulation of occupational respiratory protection than regarding the regulation of respiratory protection for the public.

A. Respiratory Protection in the Workplace

This section describes the existing regulatory landscape regarding respiratory protection in the workplace. It begins by describing the way that occupational respirator use is regulated, and then proceeds to a discussion of the regulatory oversight of respiratory protection (including development, approval, marketing, and postmarketing surveillance). The Committee has also requested that the paper include, where possible, a treatment of the authority to stockpile respiratory protective devices. To that end, this section also includes a brief treatment of the authorities involved in stockpiling respiratory protective devices for the public.

There is no single federal statute, executive plan, or agency that addresses respiratory protection in all workplaces as against all inhalation hazards. That said, two federal agencies—the Occupational Safety and Health Administration (OSHA), which is responsible for setting enforceable workplace safety standards, and the National Institute for Occupational Safety and Health (NIOSH), which is responsible for research, certification, and other forms of nonenforceable oversight—share primary authority for protecting most workplaces in the nation against most respiratory hazards.

The remainder of this section details the roles of OSHA and NIOSH, as well as the roles of other federal agencies that have authority that overlaps with, or in some cases displaces, the authority of OSHA and/or NIOSH. As a general matter, the section concludes that OSHA and NIOSH have significant federal authority regarding respiratory protection in the workplace, though the protection they offer is not comprehensive. OSHA regulates respiratory protection in the workplace primarily through requirements for respiratory protection programs (RPPs), which apply in circumstances where OSHA has determined that respiratory hazards present a substantial risk to workers.[2]

Most workplaces are unprotected by such plans.[3] Furthermore, the Occupational Safety and Health Act (OSH Act) limits OSHA's authority over significant categories of workers, including the self-employed, many state and local government workers, and workers who are imperiled by hazards outside OSHA's primary authority.[4] While these instances of overlapping authority between OSHA and other agencies add complexity to the regulatory landscape of occupational respiratory protection use, that complexity is addressed at least in part by a statutory provision that displaces OSHA authority where other agencies have regulated, and by the history of coordination between OSHA and other agencies regarding respiratory protection standards. Despite this coordination, some workers—including the self-employed—remain unprotected from respiratory hazards by any federal or state authority.[5]

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[2] *See* Part I.A.1.a.
[3] *See* Part I.A.1.a.iii (providing a rough estimate that 3.3 percent of American workers are protected by an RPP issued under OSHA standards).
[4] *See* Part I.A.1.a.ii.
[5] *See* Part I.A.1.e.(3).

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Although it is not empowered to issue enforceable workplace safety standards, NIOSH plays an important role in researching respiratory protection standards and in certifying respirators for occupational use through the National Personal Protective Technology Laboratory (NPPTL).[6] While some other actors are involved in oversight for some workers in some industries or as against some hazards, these recommendations tend to be coordinated with NIOSH, and with NPPTL, which plays a critical role in centralizing evaluation of occupational respiratory protection. NIOSH also provides guidance for workers outside its programs and in some cases has acted historically as a consultant on matters of respiratory oversight that touch on its expertise; as a result, NIOSH's expertise sometimes influences the management of inhalation hazards to the public. That said, NIOSH's mandate, authority, and consequent testing protocols are directed toward workplace respiratory protection rather than toward more general public protection.

1. Occupational Use and Regulation in the Workplace

This section addresses current agency authority to regulate use of respiratory protection in the workplace. The general purposes of the section are to provide both a general overview of the regulatory landscape regarding occupational use of respiratory protection and to help the Committee in distinguishing where recommendations can be addressed effectively to OSHA from situations where recommendations on occupational use of respiratory protection would need to address other authorities as well.

Although respirators were certified for occupational use in the United States as early as 1920 by the Bureau of Mines,[7] the use of respirators in workplaces was not federally regulated in the United States until 1969, with the passage of the Federal Coal Mine Health and Safety Act.[8] Amendments to that act created the Mine Safety and Health Administration (MSHA) and empowered it to set enforceable workplace standards in mines while simultaneously continuing the certification and oversight work of the Bureau of Mines.[9] The following year, Congress passed the OSH Act of 1970 to address workplace safety in (most) other workplaces.[10] In the OSH Act, however, Congress chose to bifurcate enforcement and research responsibilities, creating and empowering OSHA to issue and enforce enforceable safety standards,[11] and NIOSH for research, certification, and other oversight functions.[12] The OSH Act also called for establishment of the National Advisory Committee on Occupational Safety and Health (NACOSH), which serves an advisory role.[13]

Because of this allocation of authority, OSHA is the primary federal authority for issuing enforceable standards regarding respiratory hazards and the use of respiratory protection in the

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[6] *See* Part I.A.2.a.
[7] *See 100 Years of Respiratory Protection History*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 31, 2019), https://www.cdc.gov/niosh/npptl/Respiratory-Protection-history.html.
[8] *See* Federal Coal Mine Health and Safety Act of 1969, Pub. L. No. 91-173, 83 Stat. 742 (codified as amended in scattered sections of 30 U.S.C.); *see also 100 Years of Respiratory Protection History* (note 7).
[9] *See* 29 U.S.C. § 557a.
[10] *See* 29 U.S.C. §§ 651–678; *see* Part I.A.1.c–d (discussing workplaces that are regulated by other authorities, including other federal agencies and state and local governments).
[11] *See* 29 U.S.C. § 655.
[12] *See* 29 U.S.C. § 671 (establishing NIOSH).
[13] 29 U.S.C. § 656(a)(1). (NACOSH is a 12-member body "composed of representatives of management, labor, occupational safety and occupational health professions, and of the public.")

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workplace. The first portion of this section is therefore dedicated toward more fully describing the authority of OSHA, outlining the extent of OSHA's authority, and flagging where are there gaps where OSHA is precluded from regulating (e.g., in regards to state and local government workers). The section then expands on the federal, state, and local authorities that have authority over regulating respirator use in some workplaces, as against some hazards, and in some circumstances where OSHA's authority is limited.

a. The Occupational Safety and Health Administration (OSHA)

OSHA is the preeminent government authority for regulating workplace safety and health.[14] This subsection describes OSHA's general authority and its current approach to regulating the use of respiratory protection, and highlights where OSHA's existing approach is demanded by statute and where it appears to be a matter of agency discretion (that might be changed via a change in agency practice).

The subsection concludes that, while it has broad authority to set occupational safety and health standards for workers covered by the OSH Act, OSHA's authority is limited in several circumstances, including where the statute excepts classes of workers from OSHA regulation (as with state and local workers and the self-employed) and where other agencies have issued such standards pursuant to their own statutory authority; OSHA's authority is also limited by its own determinations about which workers are subject to substantial risk.

i. The general authority of OSHA under the OSH Act

OSHA derives its authority over workplace health and safety from the OSH Act, which was enacted "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources."[15] Under the OSH Act, employers have a general duty to furnish to their employees "employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to [their] employees."[16] The Act gives OSHA broad general authority in creating and enforcing "occupational safety and health standards,"[17] which it defines as "standards which require conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[18] When dealing with "toxic materials or harmful physical agents," OSHA is required to "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."[19]

Generally speaking, to promulgate an occupational safety and health standard, OSHA must go through notice-and-comment rulemaking and issue permanent standards.[20] That said, under the OSH Act, OSHA also has the rarely used authority to issue an Emergency Temporary

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[14] *See* OSH Act, 29 U.S.C. §§ 651–678.
[15] 29 U.S.C. § 651(b).
[16] 29 U.S.C. § 654(a)(1). This requirement is sometimes referred to as the "General Duty Clause."
[17] 29 U.S.C. § 655.
[18] 29 U.S.C. § 652.
[19] 29 U.S.C. § 655(b)(5).
[20] *See* 29 U.S.C. § 655(b).

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Standard (ETS) without notice and comment.[21] An ETS remains in effect for 6 months, and when published, serves as a proposed permanent standard.[22] An ETS must be directed toward a "grave danger" that can be protected against by the standard.[23] Courts have interpreted this to mean a life-threatening hazard that exists during the 6-month period the ETS is in effect.[24]

Any employer under the OSH Act is required to comply with the occupational safety and health standards promulgated by OSHA.[25] The Act covers most private sector employers and their workers, both in the 50 states and in territories and jurisdictions under federal authority.[26] As discussed below, however, the Act does not cover many other workers. Occupational safety and health standards can, and do, address inhalation hazards in the workplace[27]—though these standards are constrained by important limitations on OSHA's authority under the OSH Act.

ii. Limitations on OSHA's authority under the OSH Act

While OSHA has broad general authority in the regulation of workplace safety and health, its authority is constrained in important ways. Two types of constraints on OSHA's authority are particularly worth noting: limitations on the types of workplaces and hazards OSHA may regulate; and informational requirements that OSHA must meet prior to regulating.

(1) Limitations on the types of workplaces and hazards OSHA regulates

The first of these constraints flows from the fact that the OSH Act exempts several important categories of workplaces and hazards.

Under the OSH Act, a workplace is only protected if it is managed by a person or entity that qualifies as an "employer" under the Act, and that can therefore be obligated to satisfy occupational safety and health standards.[28] The definition of who qualifies as an employer thus plays an important role in determining which workers and workplaces are protected with OSHA's occupational safety and health standards, including respiratory standards.

The OSH Act defines an "employer" as "a person engaged in a business affecting commerce who has employees," excepting that this "does not include the United States (not

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[21] *See* 29 U.S.C. § 655(c).
[22] *See* 29 U.S.C. § 655(c)(3).
[23] *See* Int'l Union v. Donovan, 590 F. Supp. 747, 750 (D.D.C. 1984) (stating that an ETS must address grave danger, even though a permanent standard may address merely significant risk). Courts have interpreted this to mean a life-threatening hazard that exists during the 6-month period the ETS is in effect. *See* Fla. Peach Growers Ass'n v. Dep't of Lab., 489 F.2d 120, 132 (5th Cir. 1974) (defining "grave danger" as the potential for incurable, permanent, or fatal consequences); Asbestos Info. Ass'n v. OSHA, 727 F.2d 415, 422 (5th Cir. 1984) (emphasizing the importance of immediate threat).
[24] *See* Fla. Peach Growers Ass'n, 489 F.2d at 132; Asbestos Info. Ass'n, 727 F.2d at 422.
[25] 29 U.S.C. § 654(a) (requiring "each employer" to "comply with occupational safety and health standards promulgated under this Act"); 29 U.S.C. § 652(5) (defining "employer" as "a person engaged in a business affecting commerce who has employees, but does not include the United States [not including the United States Postal Service] or any State or political subdivision of a State").
[26] *See* 29 U.S.C. § 653(a).
[27] OSHA Respiratory Protection Standard, 29 C.F.R. § 1910.134(a)(2) (2020) (establishing that employers are responsible for establishing and maintaining a respiratory protection program for covered employees); 29 C.F.R. § 1910.134(c) (describing the requirements for respiratory protection programs). *See also* Part I.A.1.a.iii (describing OSHA's current approach to respiratory protection).
[28] 29 U.S.C. § 654(a) (requiring "each employer" to "comply with occupational safety and health standards promulgated under this Act").

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including the United States Postal Service) or any State or political subdivision of a State."[29] Under the explicit statutory language, Congress has clearly excluded federal, state, and local government workplaces (other than the Postal Service) from regulation by OSHA.[30] Other categories of potential covered employers are more ambiguous, however,[31] depending at least partially on the definition of who constitutes an "employee."

Unfortunately, the statutory definition of "employee" is similarly circular: under the statute, an "employee" is a person who is "an employee of an employer who is employed in a business of his employer which affects commerce."[32] This definition leaves substantial ambiguity over which workers qualify as employees, and thus which workers are subject to workplace protections by OSHA.

Generally speaking, agencies have substantial discretion in deciding how to interpret ambiguous terms in statutes they administer (as OSHA does with the OSH Act).[33] OSHA has long adopted a somewhat narrow interpretation of the OSH Act that determines whether a worker qualifies as an "employee"—and thus whether occupational safety and health standards apply—at least in part by reference to the (notoriously complex) system of judicial precedent that makes up the common law of agency.[34] To determine whether or not a worker is an employee or a self-employed "independent contractor" under common law, the hiring party is required to consider a number of factors, including the degree of control the hiring party asserts over the manner in which the work is done, and the degree of skill and independent judgment the hired party is expected to apply.[35] Because this test is multifactorial and fact-specific, it can be difficult to determine for many workers whether they are employees who qualify for protection under the OSH Act standards, or whether they are instead self-employed or independent contractors who

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[29] 29 U.S.C. § 652(5).

[30] *See* 29 U.S.C. § 652(5) (defining "employer" to exclude "any State or political subdivision of a State"); *see also* Part I.A.1.d. (discussing regulation of state and local government workplaces). Federal workplaces must comply with the statutory requirements of the Act, though the head of each agency is responsible for ensuring that standards are met. *See* 29 U.S.C. § 668 (requiring the head of each Federal agency other than the Postal Service to "establish and maintain an effective and comprehensive occupational safety and health program"); Executive Order 12196, 45 Fed. Reg. 12769, 3 C.F.R., 1980 Comp., p. 145 (directing agencies to comply with basic program elements identified by the Secretary of Labor).

[31] For a summary of some of the complexities in determining who constitutes an "employer" under this standard, and the outcomes of cases litigated on the point, see *Who is "employer" for purposes of Occupational Safety and Health Act (29 U.S.C. § 651 et seq.)*, 153 A.L.R. Fed. 303.

[32] 29 U.S.C. § 652(6); *see also* 29 U.S.C. § 652(4) (defining "person" as "one or more individuals, partnerships, associations, corporations, business trusts, legal representatives, or any organized group of persons").

[33] *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–843 (1984) (holding that agencies interpreting an ambiguous statute they administer may adopt any reasonable or "permissible" interpretation of a statute, so long as that interpretation has not been explicitly foreclosed by Congress).

[34] *See* Occupational Injury and Illness Recording and Reporting Requirements, 66 Fed. Reg. 5916, 6038 (Jan. 19, 2001) (to be codified at 29 C.F.R. pts. 1904, 1952) ("Whether an employment relationship exists under the Act is determined in accordance with established common law principles of agency"). The common law of agency is highly complex; the best-known synthesis of it is provided by the Restatement (Third) of Agency. *See also* STEPHEN M. BAINBRIDGE, AGENCY, PARTNERSHIPS & LLCS 116–117 (2004) ("In general, the single most influential source of legal rules in this area remains the American Law Institute's Restatement of Agency").

[35] *See* RESTATEMENT (THIRD) OF AGENCY § 7.07 (AM. L. INST. 2006); *see also* Occupational Injury and Illness Recording and Reporting Requirements, 29 C.F.R. pts. 1904, 1952 (2001) (citing Loomis Cabinet Co. v. OSHRC, 20 F.3d 938, 942 [9th Cir. 1994]). For further discussion of this interpretation, see Part I.A.1.e.3.

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are not protected by the Act.[36] OSHA has adopted somewhat narrow interpretations of the Act, however, which exclude unpaid volunteers, family members of farm employees, and domestic workers in a residential setting,[37] as well as the general category of the self-employed.[38]

Finally, the statute provides a third category of important exemptions from OSHA jurisdiction where occupational safety and health have been regulated by another federal agency. More specifically, § 4(b)(1) of the OSH Act excepts any context where other federal agencies "exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."[39] The purpose of this exception, which is articulated in § 4(b)(1) of the OSH Act, was to avoid wasteful duplication, such as might result where both OSHA and another federal agency are providing for the occupational safety of a class of workers.[40] While Congress could have managed such overlap in regulatory authority by preferencing OSHA's workplace safety standards, it instead chose to preference standards set by other agencies, when they are acting within their statutory authority, and when they have actually acted to regulate some workplace hazard under that authority.[41]

As a result, OSHA's authority to enforce occupational safety and health standards is sometimes limited by the actions of other agencies.[42] This includes activities and conditions regulated under the control of another dedicated federal agency, such as the conditions in "coal and other mines,"[43] as well as where other agencies are authorized to regulate particular hazards, as with occupational inhalation hazards from pesticides.[44] Although less obviously relevant in respiratory protection contexts, OSHA's authority is similarly limited over vessels regulated by

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[36] *See generally* 153 A.L.R. Fed. 303 (summarizing, e.g., Richard Johnstone, Claire Mayhew & Michael Quinlan, *Outsourcing Risk? The Regulation of Occupational Health and Safety Where Subcontractors Are Employed*, 22 COMP. LAB. L. & POL'Y J. 351 (2001) (characterizing U.S. occupational and safety protection of subcontractors, and comparing that protection to that offered by other jurisdictions).

[37] *See* 29 C.F.R. pts. 1904, 1952 (2020); *see also* 29 C.F.R. § 1975.4(b)(2) (2020) (excepting family members of farmworkers); 29 C.F.R. § 1975.6 (excepting domestic workers).

[38] *See, e.g.*, 29 C.F.R. § 1904.31(b)(1) (2020) (explaining that self-employed individuals are not covered by the OSH Act); *see also* Occupational Injury and Illness Recording and Reporting Requirements, 66 Fed. Reg. 5916, 6038 (Jan. 19, 2001) (29 C.F.R. pts. 1904, 1952) (explaining OSHA's reasoning in excepting self-employed individuals from the definition of "employer").

[39] *See* 29 U.S.C. § 653(b)(1).

[40] *See* Organized Migrants in Cmty. Action, Inc. v. Brennan, 520 F.2d 1161, 1167 (D.C. Cir. 1975) (discussing the legislative history of the exception).

[41] *See* Organized Migrants, 520 F.2d at 1161, 1167. When exactly such displacements have occurred is a complicated and fact-specific question, which has given rise to an extraordinarily long list of court decisions. For a summary of these decisions and the specific contexts in which courts have found OSHA's authority to displaced by other agencies' actions, see Daniel E. Feld, Annotation, *Construction and Application of § 4(b)(1) of Occupational Safety and Health Act, Providing That Act Does Not Apply to Working Conditions of Employees with Respect to Which Other Federal Agencies Exercise Statutory Authority to Prescribe or Enforce Standards or Regulations Affecting Occupational Safety or Health*, 40 A.L.R. Fed. 147 (2021) (providing a list of cases interpreting § 4[b][1]).

[42] *See* Feld (note 41).

[43] Under the Federal Mine Safety and Health Act of 1977, 30 U.S.C. §§ 801 *et seq.*, these are regulated by MSHA. *See* Part I.A.1.c.(ii).

[44] Under the Federal Insecticide, Fungicide, and Rodenticide Act, the Environmental Protection Agency (EPA) is responsible for setting workplace safety standards for farmworkers and pesticide applicators regarding pesticide safety, including pesticide inhalation. *See* Organized Migrants, 520 F.2d at 1166 (explaining that the Federal Environmental Pesticide Control Act encompasses regulation of farmworker exposure to pesticides, thus preempting OSHA's power to act); *see also* Part I.A.1.c.(i)(2)(a).

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the Coast Guard,[45] contractor-operated nuclear facilities,[46] and large segments of the railroad and airline industries.[47] Except in specific circumstances, as discussed further below, OSHA standards regarding respiratory protection do not apply in these contexts. OSHA manages these and other occupational health and safety relationships via a complex mosaic of interagency cooperation agreements, or memoranda of understanding.[48]

(2) Informational requirements that OSHA must meet prior to regulating

A second limitation on OSHA's authority to regulate workplace safety arises from the long-standing regulatory interpretation that holds that OSHA is only authorized to promulgate health and safety standards in the workplace after it has satisfied a threshold finding that "a significant risk" of material health impairment exists. This requirement flows from the plurality opinion in an influential Supreme Court case, *Industrial Union Department v. American Petroleum Institute* (generally called the "Benzene decision"), which overturned a workplace safety standard under the OSH Act on the grounds that the agency had failed to determine that benzene posed what the plurality of the Supreme Court called a "significant risk" in the workplace.[49] The plurality opinion is controversial among legal commentators,[50] who note both that the requirement of significant risk is not mentioned in the statute itself and that other portions of the OSH Act demand repeatedly that OSHA regulate to ensure that "no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience."[51] Nevertheless, the opinion has given rise to a long-standing agency practice at OSHA of demanding substantial information about the significance of a risk prior to issuing new workplace safety standards.[52] Because this is a long-standing agency practice, recommendations by the Committee to OSHA regarding respiratory protection would likely need to account for the agency's understanding of the significant risk requirement, and OSHA's current approach to regulating respiratory protection may be best understood in light of it.

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[45] *See* Feld (note 41); *see also* Clary v. Ocean Drilling & Exploration Co., 609 F.2d 1120 (5th Cir. 1980) (finding that OSHA regulations do not apply to vessels in navigation, since the Coast Guard has jurisdiction over the safety and health of seamen).
[46] *See* Feld (note 41). These are regulated by the Department of Defense.
[47] *See* Feld (note 41); *see, e.g.*, Northwest Airlines, 8 BNA OSHC 1982 (No. 13649, 1980) (holding that preemption applies to airline maintenance workers because they are within the class of persons intended to be protected under the Federal Aviation Act).
[48] *See* OSHA, *Memorandums of Understanding—By Agency*, https://www.osha.gov/laws-regs/mou/agency (last visited Apr. 29, 2021) (listing 48 memoranda of understanding with 25 other agencies).
[49] *See* Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607 (1980) (plurality opinion) (the "Benzene" decision); *see also* Amer. Textile Manufacturers Inst. v. Donovan (known as the "Cotton Dust case") (holding that it must be "technologically and economically feasible" for employers to comply with any OSHA-imposed standard).
[50] *See, e.g.*, Howard A. Latin, *The Feasibility of Occupational Health Standards: An Essay on Legal Decisionmaking Under Uncertainty*, 78 NW. U. L. REV. 583, 587–598 (1983) (describing conflicting treatments of uncertainty under the OSH Act, and arguing that the Benzene decision fails to provide meaningful guidance); Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1639–1640; 1663–1664 (1995) (characterizing Benzene as requiring OSHA to enact a "charade" by offering "strong and virtually inescapable incentives to conceal policy choices under the cover of scientific judgments and citations").
[51] *See* 29 U.S.C. §§ 651(b)(7), 655(b)(5), 669(a)(3).
[52] *See* Adam M. Finkel et al., *The NFL as a Workplace: The Prospect of Applying Occupational Health and Safety Law to Protect NFL Workers*, 60 ARIZ. L. REV. 291, 303-305 (2018) (providing a nuanced overview of the impact of the Benzene decision on OSHA standards).

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iii. OSHA's current approach to respiratory protection

This subsection discusses OSHA's existing approach to regulating the use of respiratory protection in the workplace. As it emphasizes, OSHA's existing approach to regulating workplace respiratory protection is dominated by a sharply bifurcated level of protection for different workplaces, depending upon whether OSHA has found that its Respiratory Protection Standard requires the workplace to have a respiratory protection program (RPP) or not. Workers at workplaces with RPPs are provided with substantial levels of respiratory protection: they must be provided with employer-provided respirators and are further protected with a series of checks to ensure that those respirators fit and remain functional. Employers at workplaces without RPPs, by contrast, need not provide respiratory protection. Counterintuitively, in some cases, workers in workplaces without RPPs may not even be permitted to provide their own respirators for use at the workplace (in cases where the wearing of respirators is determined by the employer to be a hazard). The result is stringent regulation of respiratory protection in the workplace for workers in workplaces with RPPs, and voluntary or even limited use of respiratory protection in workplaces without RPPs.

(1) The Respiratory Protection Standard and RPPs

Generally speaking, OSHA's primary approach to regulating the use of respiratory protection in the workplace is set out in its Respiratory Protection Standard,[53] a regulation that OSHA promulgated in 1998.[54] Under the Respiratory Protection Standard, employers must establish and implement an RPP "[i]n any workplace where respirators are necessary to protect the health of the employee."[55] When it issued its final standard in 1998, OSHA estimated that the rule would mandate respiratory protection for approximately 5 million workers.[56] If this estimate is still accurate, and given that the Bureau of Labor Statistics estimates that there are 148 million employed persons in the United States,[57] this suggests that approximately 3.3 percent of American workers are protected with RPPs under OSHA's Respiratory Protection Standard.

RPPs are highly specified, and workers in workplaces with an RPP must be provided with a NIOSH-certified respirator by the employer, as well as fit testing, medical evaluation, training, and ongoing recordkeeping.[58] Employers must provide respirators "which are applicable and suitable for the purpose intended,"[59] which involves using the NIOSH-certified respirator that is suited to the inhalation hazard presented.[60] Further specification of this complex set of requirements has been provided by National Academies staff. In general, the point for current purposes is that workers who are protected by RPPs are guaranteed significant protection that

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[53] 29 C.F.R. § 1910.134 (2020).
[54] The 1998 regulation replaced OSHA's original respiratory standard, which was promulgated in 1972.
[55] *See* 29 C.F.R. § 1910.134(c)(1).
[56] *See* Respiratory Protection, 63 Fed. Reg. 1152, 1152 (Jan. 8, 1998) (to be codified at 29 C.F.R. pts. 1910, 1926) (noting that "[t]he final respiratory protection standard covers an estimated 5 million respirator wearers working in an estimated 1.3 million workplaces").
[57] *See* U.S. BUREAU LAB. STAT., *Labor Force Statistics from the Current Population Survey* (January 22, 2021), https://www.bls.gov/cps/cpsaat11.htm (estimating number of workers).
[58] *See* 29 C.F.R. §§ 1910, 1926.
[59] *See* 29 C.F.R. § 1910.134(a)(2).
[60] *See* 29 C.F.R. § 1910.1001(g)(2)(ii).

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extends from the designation of the underlying product to be used through to requirements about fit testing and ongoing recordkeeping.

(2) OSHA regulations and guidance addressing respiratory hazards at workplaces without RPPs (including voluntary programs at OSHA)

This section identifies and describes OSHA's approach to regulating the safety of workers without existing RPPs. As a basic matter, at workplaces where OSHA does not regulate, or where it has not found respirators to be "necessary to protect the health of the employee," no RPP is required.[61] The Respiratory Protection Standard does allow for voluntary provision and use of respiratory protection in these workplaces[62]—though the standard imposes limitations on that voluntary use. First, before any employee may use respirators (whether self-provided or voluntarily provided by the employer),[63] the employer must determine that respirator use "will not in itself create a hazard."[64] If the employer finds that the respirator use is not a hazard, the employer is required to provide the employee with guidance developed by OSHA, "Information for Employees Using Respirators When Not Required Under the Standard."[65] Finally, the employer must "establish and implement those elements of a written respiratory protection program necessary to ensure that any employee using a respirator voluntarily is medically able to use that respirator, and that the respirator is cleaned, stored, and maintained so that its use does not present a health hazard to the user."[66] Workers in workplaces where the employer has determined that respirator use would create a hazard are therefore precluded from wearing respirators even voluntarily.[67] Where no hazard is presented by the respirator, workers can follow the guidance provided by OSHA in its "Information for Employees Using Respirators When Not Required Under the Standard."[68] This information, also drafted in 1998, is about one page long—a significant contrast to the detailed requirements that apply under RPPs. This brief guidance encourages employees to use respirators even below exposure limits, while taking

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[61] *See* 29 C.F.R. § 1910.134(c)(2) ("Where respirator use is not required: An employer may provide respirators at the request of employees or permit employees to use their own respirators, if the employer determines that such respirator use will not in itself create a hazard. If the employer determines that any voluntary respirator use is permissible, the employer shall provide the respirator users with the information contained in Appendix D to this section [""Information for Employees Using Respirators When Not Required Under the Standard"]". In addition, the employer must establish and implement those elements of a written respiratory protection program necessary to ensure that any employee using a respirator voluntarily is medically able to use that respirator, and that the respirator is cleaned, stored, and maintained so that its use does not present a health hazard to the user. Exception: Employers are not required to include in a written respiratory protection program those employees whose only use of respirators involves the voluntary use of filtering facepieces [dust masks]").

[62] *See* 29 C.F.R. § 1910.134(c)(2) ("Where respirator use is not required: An employer may provide respirators at the request of employees or permit employees to use their own respirators, if the employer determines that such respirator use will not in itself create a hazard").

[63] The limitations do not apply to "filtering facepieces" (dust masks). *See* 29 C.F.R. § 1910.134(c)(2) ("Exception: Employers are not required to include in a written respiratory protection program those employees whose only use of respirators involves the voluntary use of filtering facepieces [dust masks]").

[64] *See* 29 C.F.R. § 1910.134(c)(2).

[65] *See* 29 C.F.R. § 1910.134(c)(2); *see also* 29 C.F.R. § 1910.134 app. D (2020).

[66] *See* 29 C.F.R. § 1910.134(c)(2).

[67] *See* 29 C.F.R. § 1910.134(c)(2).

[68] *See* (Mandatory) Information for Employees Using Respirators When Not Required Under the Standard, 29 C.F.R. § 1910.134 app. D.

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actions (such as only using one's own respirator) to prevent respirators from becoming a hazard themselves.[69]

b. Other authorities under the OSH Act

The OSH Act of 1970 remains the primary statutory authority for regulation of workplace safety. As discussed above, under the OSH Act, OSHA is responsible for issuing enforceable workplace safety standards. As a result, it is the federal authority with the greatest responsibility for regulating the use of respiratory protection against respiratory hazards in the workplace. That said, the OSH Act also created and empowered two other authorities—NIOSH and NACOSH—which routinely coordinate with OSHA. Of these, NIOSH's role in researching and recommending workplace safety standards is particularly important, while NACOSH acts as a relatively minor advisory committee that nevertheless has the authority to advise OSHA regarding its workplace safety standards.

i. The National Institute for Occupational Safety and Health (NIOSH) in the Centers for Disease Control and Prevention (CDC)

NIOSH was created alongside OSHA in the OSH Act of 1970.[70] The primary statute empowering NIOSH for purposes of workplace use of respiratory protection remains the OSH Act, which allocates significant research authority to NIOSH, even as it tasks OSHA with standard setting and implementation.[71] While NIOSH does not directly regulate any use requirements for respiratory protection in the workplace,[72] as part of its research role, it is empowered to "develop and establish recommended occupational safety and health standards" on the basis of its research and analysis, which OSHA then has the authority to implement.[73] NIOSH also plays a critical role in oversight of the development and approval of respiratory protective gear in occupational settings, as described in Part I.A.2.

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[69] *See* 29 C.F.R. § 1910.134(c)(2) (providing 282 words of guidance, including, "Respirators are an effective method of protection against designated hazards when properly selected and worn. Respirator use is encouraged, even when exposures are below the exposure limit, to provide an additional level of comfort and protection for workers. However, if a respirator is used improperly or not kept clean, the respirator itself can become a hazard to the worker. Sometimes, workers may wear respirators to avoid exposures to hazards, even if the amount of hazardous substance does not exceed the limits set by OSHA standards. If your employer provides respirators for your voluntary use, or if you provide your own respirator, you need to take certain precautions to be sure that the respirator itself does not present a hazard. You should do the following: 1. Read and heed all instructions provided by the manufacturer on use, maintenance, cleaning and care, and warnings regarding the respirators limitations. 2. Choose respirators certified for use to protect against the contaminant of concern. NIOSH, the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services, certifies respirators. A label or statement of certification should appear on the respirator or respirator packaging. It will tell you what the respirator is designed for and how much it will protect you. 3. Do not wear your respirator into atmospheres containing contaminants for which your respirator is not designed to protect against. For example, a respirator designed to filter dust particles will not protect you against gases, vapors, or very small solid particles of fumes or smoke. 4. Keep track of your respirator so that you do not mistakenly use someone else's respirator").

[70] 29 U.S.C. § 671.

[71] *Compare* 29 U.S.C. § 671, *with* 29 U.S.C. § 655.

[72] *See generally* 29 U.S.C. § 671; *see also* CTRS. FOR DISEASE CONTROL & PREVENTION, *About NIOSH* (Mar. 28, 2018), https://www.cdc.gov/niosh/about/default.html.

[73] *See* 29 U.S.C. § 671(c)(1).

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In developing and issuing recommendations, the director of NIOSH is authorized to "conduct research and experimental programs" that he or she "determines are necessary for the development of criteria for new and improved occupational safety and health standards," and "after consideration of the results of such research and experimental programs make recommendations concerning new or improved occupational safety and health standards."[74] Research performed by NIOSH, or by divisions of NIOSH (such as NPPTL), can thus generate and support recommendations to OSHA regarding enforceable workplace safety standards, including the regulation of respirator use in the workplace.

Perhaps unsurprisingly given their concurrent creation in the same statute, OSHA and NIOSH have a long history of coordinating their activities.[75]

ii. National Advisory Committee on Occupational Safety and Health (NACOSH)

NACOSH serves an advisory role to the secretary of labor and the secretary of health and human services on matters related to administration of the OSH Act.[76] NACOSH is a 12-member body composed of representatives of management, labor, occupational safety and occupational health professions, and the public.[77] All support for NACOSH is provided by OSHA, and NACOSH submits reports and advice via OSHA.[78]

While NACOSH does not have either rulemaking or enforcement authority of its own, it provides input on workplace safety and health issues, and feedback on existing initiatives under the OSH Act to improve worker safety and health.[79] Periodically, NACOSH identifies subcommittees and work groups dedicated to particular issues.[80]

Most of NACOSH's past recommendations have been relatively minor—for example, recommending that OSHA and other agencies fund a symposium[81] or supporting OSHA's existing attempts at rulemaking.[82] Nevertheless, because it is a permanent, nondiscretionary advisory committee, with a close advisory connection to OSHA, NACOSH provides a durable

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[74] See 29 U.S.C. § 671(d).
[75] For example, NIOSH and OSHA have entered into memoranda of understanding to coordinate joint access to databases maintained by one another and to coordinate guidance for worker protection during hazardous waste cleanup. *See* OCCUPATIONAL SAFETY & HEALTH ADMIN., *Memorandum of Understanding Between the Centers for Disease Control National Institute for Occupational Safety and Health and the Department of Labor Occupational Safety and Health Administration* (Dec. 26, 1989), https://www.osha.gov/laws-regs/mou/1989-12-26; *Memorandum of Understanding, Guidance for Worker Protection During Hazardous Waste Site Investigations Cleanup and Hazardous Substance Emergencies* (Dec. 18, 1980), https://www.osha.gov/laws-regs/mou/1980-12-18.
[76] 29 U.S.C. § 656(a)(1).
[77] *See* OCCUPATIONAL SAFETY & HEALTH ADMIN. (note 75).
[78] *See* 29 U.S.C. § 656(a)(4); 29 C.F.R § 1912a.9 (2020); *see also* OCCUPATIONAL SAFETY & HEALTH ADMIN., *National Advisory Committee on Occupational Safety and Health Charter* (October 2, 2020), https://www.osha.gov/advisorycommittee/nacosh/charter.
[79] *See* NACOSH charter, 2020 (note 78).
[80] *See* NACOSH charter, 2020 (note 78).
[81] *See* OCCUPATIONAL SAFETY & HEALTH ADMIN., *Recommendations Approved at the June 20, 2012, National Advisory Committee on Occupational Safety and Health (NACOSH) Meeting*, https://www.osha.gov/advisorycommittee/nacosh_report_06202012.
[82] *See* OCCUPATIONAL SAFETY & HEALTH ADMIN., *NACOSH, Recommendations to the Secretaries of Labor and Health and Human Services December 14-15, 2011*, U.S. DEP'T LAB., https://www.osha.gov/advisorycommittee/nacosh_report_12142011 (encouraging OSHA's attempts to issue a rule addressing silica exposure).

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institutional locus for potential recommendations regarding the use of respiratory protection in the workplace.

c. Other federal agencies

This section provides a description of actors other than those empowered by the OSH Act that have the authority to regulate respiratory protection use in at least some workplaces, as against at least some hazards.

While OSHA has the primary authority to regulate workplace safety, the structure of the OSH Act—which prohibits OSHA from issuing workplace safety standards in any workplace where another federal agency creates or enforces workplace safety and health standards[83]—makes the regulatory landscape of actual protection complex. As a result of this statutory structure, many federal agencies have authority to issue workplace safety standards in some workplaces against some hazards or in some circumstances, and these displace OSHA standards.

The displacement of OSHA standards by occupational safety and health standards set by another agency generally arises in one of two ways.

The first is through federal agencies' general responsibility to regulate the safety of their own workplaces. Recall that federal agencies have the responsibility of managing their own occupational safety and health standards for their own workplaces.[84] These must generally meet the same standards as private employers.[85] Many agencies coordinate with OSHA and NIOSH for such standards, including regarding respiratory protection for their workers.[86]

The second way OSHA standards are displaced is via the issuance of federal occupational safety and health standards by an agency other than OSHA, regarding a hazard or workplace over which that agency has statutory authority.[87] Recall here that the OSH Act provides that agencies displace OSHA standards when they prescribe or enforce standards or regulations affecting occupational safety or health against hazards under their jurisdiction.[88] Whether or not particular occupational safety or health standards displace OSHA standards in any particular situation, as against any particular hazard, in any particular workplace, is a surprisingly opaque question, and is often litigated.[89] The resulting mosaic of occupational safety and health regulations is difficult, if not impossible, to describe in its entirety.

Nevertheless, agencies other than OSHA have authority to regulate respiratory protection outside their own workplaces at least some of the time. These include agencies—such as the Environmental Protection Agency (EPA)—that have authority to regulate against some inhalation hazards in ways that may require regulation of respirator use in the workplace, and agencies that have authority to regulate particular workplaces or types of workplaces other than

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[83] *See* 29 U.S.C. § 653(b)(1); for a collection of the cases where courts have found § 4(b)(1) of the Act to apply, see Feld (note 41).

[84] One exception is the U.S. Postal Service, the largest federal agency, which since 1998 has been covered directly by OSHA requirements. *See* Postal Employees Safety Enhancement Act, Pub. L. No. 105-241, 112 Stat. 1572 (1998).

[85] *See* Feld, 2021 (note 41).

[86] *See* 29 U.S.C. § 668 (making federal agency heads responsible for establishing safe and healthful working conditions); Exec. Order No. 12,196, 45 Fed. Reg. 12,769 (February 26, 1980) (requiring the head of each agency to establish an occupational safety and health program).

[87] *See* 29 U.S.C. § 653(b)(1).

[88] *See* 29 U.S.C. § 653(b)(1).

[89] *See* Feld, 2021 (note 41).

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their own, like MSHA. These two examples are discussed in more detail below. Notably, no other agency has OSHA's broad rulemaking authority or its broad mandate regarding multiple hazards in workplaces across multiple industries. That said, in some cases, other agencies' authority to regulate respiratory protection in the workplace extends over workers who would otherwise be unprotected by OSHA, such as state and local government workers.[90] In other cases, where other agencies have specific statutory authority to issue workplace safety and health standards—whether regarding specific hazards, specific workplaces, or under specific conditions—that authority displaces OSHA's under the OSH Act[91]—though OSHA may still be permitted and even required to regulate other hazards.

i. The Environmental Protection Agency (EPA)

EPA has substantial authority to regulate a number of environmental inhalation hazards, some of which arise in workplaces. When EPA issues occupational safety and health standards under its statutory authority, these standards displace OSHA protections that would otherwise apply.

This section addresses the authority of EPA regarding regulation of workplace inhalation hazards and the use of respiratory protection. It describes the general authority of EPA, gives a brief summary of its most important statutory mandates, and explains EPA's responsibilities regarding workplace exposures to respiratory hazards, emphasizing its history of coordination with OSHA/NIOSH regarding those exposures.

(1) EPA's general structure and authority

EPA is the nation's chief environmental agency. Created originally in 1970 via executive action, EPA administers a broad array of environmental statutes, including many that address exposure to pollutants and dangerous substances.[92] As discussed further in the subsequent section addressing respiratory risks to the public, these include the Clean Air Act[93] and the Toxic Substances Control Act (TSCA),[94] as well as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[95] the Emergency Planning and Community Right-to-Know Act (EPCRA),[96] the Resource Conservation and Recovery Act (RCRA),[97] and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[98] None of these statutes restrict EPA to only regulating environmental exposures that are occupational. However, because some

[90] For example, as discussed in Part I.A.1.c.i.(2)(b), EPA's asbestos regulations apply to state and local workers, who would otherwise not be reachable under the OSH Act, which excepts those workers from OSHA regulations.
[91] *See* 29 U.S.C. § 653(b)(1); *see also* Part I.A.1.c.i.(2)(a).
[92] *See* Reorganization Plan No. 3. of 1970, 35 Fed. Reg. 15,623 (July 9, 1970) (presenting President Nixon's plan to Congress to establish EPA, along with the National Oceanic and Atmospheric Administration). For further overview of EPA's authority and role within U.S. environmental regulation, see ARDEN ROWELL & JOSEPHINE VAN ZEBEN, *A Guide to U.S. Environmental Law* (Cal. Press, 2021).
[93] *See* Clean Air Act, 42 U.S.C. §§ 7401–7671q.
[94] *See* Toxic Substances Control Act, 15 U.S.C. §§ 2601–2695d.
[95] *See* Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y.
[96] *See* Resource Conservation and Recovery Act, 42 U.S.C. § 6901 *et seq*.
[97] *See* Emergency Planning and Community Right-to-Know Act, 42 U.S.C. §§ 11001–11050.
[98] *See* Comprehensive Environmental Compensation and Liability Act (CERCLA), 42 U.S.C. §§ 9601–9675.

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exposures to dangerous substances arise in occupational settings, EPA sometimes ends up addressing worker safety, including as against some inhalation hazards.[99]

(2) EPA's past coordination with OSHA

This section identifies the substance and past practice of jurisdictional overlaps between EPA and OSHA and gives examples of how these overlaps have been managed in the past to harmonize across agencies and to help fill what could otherwise have become gaps in the regulatory landscape.

Generally speaking, the regulation of *environmental* hazards in *occupational* contexts presents an area of regulatory overlap between OSHA/NIOSH and EPA: where there are occupational exposures to environmental hazards, as with asbestos or pesticides, either or both agencies may have the authority to regulate, depending upon the particular hazard being protected against and the particular statutory grant of authority for both agencies.[100]

In light of these frequent overlaps, OSHA/NIOSH and EPA have developed a long history of cross-agency coordination.[101] In some cases, as in the FIFRA example provided below, this coordination has helped to reduce the complexity that can otherwise arise from competing and overlapping regulations of the same workplace. In other cases, as with the asbestos example below, it has been used to fill in gaps where OSHA, working alone, would not have been able to fully regulate workplace safety.[102]

(a) Coordination through overlap with OSHA: The example of the pesticide Worker Protection Standard (WPS)

The regulation of respiratory protection against pesticides presents one example where coordination between EPA and OSHA helped to reduce regulatory complexity without reducing protection. Under FIFRA, EPA is authorized to regulate not just pesticides in general, but also specifically the exposures of pesticide handlers and farmworkers in the field.[103] Because the OSH Act prohibits OSHA from regulating working conditions or hazards when other federal agencies exercise statutory authority to issue occupational safety and health standards,[104] EPA's authority displaces OSHA's for this set of workplace hazards.

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[99] For additional treatment of where EPA's statutory authority extends to occupational hazards, see Todd Aagaard, *Regulatory Overlap, Overlapping Legal Fields, and Statutory Discontinuities*, 29 VA. ENV'T L.J. 237 (2011). For a general discussion of types of overlap and the functions overlap can serve, see Robert B. Ahdieh, *Dialectical Regulation*, 38 CONN. L. REV. 863, 882–83 (2006).

[100] While OSHA is prohibited from issuing workplace safety standards under § 4(b)(1) of the OSH Act when another agency, such as EPA, exercises statutory authority to prescribe or enforce standards for occupational safety and health, the fact that EPA's statutory authority is often specific to the hazard, and that OSHA's authority is subject to multiple exceptions, means that there remains substantial opportunity for overlap and—ideally—coordination. For further treatment of the challenges and opportunities presented by such overlaps, see Aagaard, 2011 (note 99).

[101] *See* Aagaard, 2011 (note 99, p. 240), providing an examination of six case studies where EPA and OSHA have managed jurisdictional overlap "to create regulatory synergy rather than dysfunction."

[102] *See* Aagaard, 2011 (note 99, pp. 254–256), discussing OSHA and EPA's coordination regarding asbestos.

[103] *See* Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y.

[104] *See* 29 U.S.C. § 653(b)(1).

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EPA's Office of Pesticide Programs implements its pesticide programs.[105] Occupational safety standards implemented under FIFRA include the pesticide applicator certification program,[106] as well as the Agricultural WPS[107] that satisfies EPA's statutory obligation to protect agricultural workers from pesticides.

The WPS protects 2 million agricultural workers and pesticide handlers.[108] With a few exceptions,[109] it requires employers to provide personal protective equipment (PPE), including respiratory protection.[110] For some years, the fact that EPA was responsible for farmworkers and pesticide handlers in the field, while OSHA retained authority in some indoor environments and over farmworkers when exposed to hazards other than pesticides, created a challenge of coordination between the agencies. This was particularly true while the safety standards differed significantly. In part in response to these concerns, EPA revised its WPS in 2015 to coordinate its respirator safety standards with OSHA's, adopting a set of requirements in the WPS that mirror those that attach to a workplace with an OSHA-implemented RPP.[111] Accordingly, as with workers with RPPs in place, farmworkers must be provided with adequate respiratory protection by their employers, who must also provide fit testing, training, and medical evaluation.[112] By incorporating OSHA standards in this way, EPA simplified a situation of overlapping authority that otherwise could have created significant additional complexity without improving levels of protection.

(b) Coordination across gaps: The example of workplace asbestos regulation

In some cases, the fact that EPA and OSHA are both empowered to regulate at least some workplace inhalation hazards has allowed the agencies to coordinate and thus to overcome gaps in regulatory protection for workers. The best example of this may be the coordination between EPA and OSHA/NIOSH on the regulation of asbestos in the workplace.[113]

In the case of asbestos, OSHA is authorized to set workplace safety standards under the OSH Act,[114] whereas EPA's authority arises under the Toxic Substances Control Act (TSCA),

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[105] Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y. Generally speaking, FIFRA provides for federal regulation of pesticide distribution, sale, and use. The Office of Pesticide Programs implements FIFRA, as well as a few other statutes addressing pesticide risk.

[106] *See* EPA Certification of Pesticide Applicators, 40 C.F.R. pt. 171 (2017). FIFRA requires any person who applies or supervises the use of "restricted use" pesticides (RUPs) to be certified, to establish that they know how to apply RUPs properly and effectively. *See* 7 U.S.C. §§ 136–136y; 40 C.F.R. pt. 171. The rule on certification of pesticide applicators provides a set of regulations that certify who may apply RUPs. It also requires that, to achieve and maintain certification, pesticide handlers must show themselves to be able to apply and use PPE, including respiratory protection. *See* 7 U.S.C. §§ 136–136y; 40 C.F.R. pt. 171.

[107] *See* EPA Worker Protection Standard, 40 C.F.R. § 170.305 (2015).

[108] *See* U.S. ENV'T PROT. AGENCY, *Agricultural Worker Protection Standard (WPS)* (Apr. 29, 2021), https://www.epa.gov/pesticide-worker-safety/agricultural-worker-protection-standard-wps.

[109] Owners and immediate family members of farm owners, as well as crop advisors, are excepted from the requirements of the standard. 40 C.F.R § 170.303(b).

[110] *See* 40 C.F.R. § 170.305; for an overview of requirements, see U.S. ENV'T PROT. AGENCY, *Personal Protective Equipment for Pesticide Handlers* (Oct. 27, 2020), https://www.epa.gov/pesticide-worker-safety/personal-protective-equipment-pesticide-handlers.

[111] *See Personal Protective Equipment for Pesticide Handlers* (note 110).

[112] *See Personal Protective Equipment for Pesticide Handlers* (note 110).

[113] *See* Aagaard, 2011, pp. 254–256 (note 99, discussing EPA/OSHA coordination in regulating asbestos).

[114] *See* 29 U.S.C. § 655(c); 29 C.F.R. pt. 1910 (2020); 29 C.F.R. § 1926., 1101.

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which grants EPA broad authority to regulate toxic substances.[115] As noted above, the OSH Act exempts state and local government workers, meaning that OSHA alone cannot create or enforce workplace safety standards that address state and local government workers—even if OSHA believes those workers to be at substantial risk from inhalation hazards.[116] To address this gap, since 1985, EPA has used its authority under TSCA to protect state and local government workers engaged in asbestos abatement activities.[117] This includes implementing a requirement for an RPP.[118] To eliminate the chance of duplication, EPA has harmonized its regulation with OSHA by cross-referencing them, thereby requiring state and local employers to comply with OSHA's asbestos regulations (and with any changes to those regulations that OSHA subsequently promulgates).[119] Coordination in this case serves as an example of agency cooperation in overcoming statutory gaps to provide respiratory protection from (at least some) workplace inhalation hazards.

ii. The Mine Safety and Health Administration (MSHA)

Other agencies have statutory authority that displaces OSHA in regards to particular workplaces, and the inhalation hazards presented at those workplaces. The chief example of this type is MSHA, the successor to the Bureau of Mines, whose responsibilities regarding respirator safety actually pre-date the OSH Act.[120] The primary statute empowering MSHA is the Federal Mine Safety and Health Act, which requires MSHA to establish mandatory health and safety standards for "coal and other mines."[121]

The purpose of the Act was to create a comprehensive regulatory scheme for preventing mine accidents and diseases caused by the occupation of mining.[122] To this end, the statute directs MSHA to set standards that are structurally quite similar to those set by OSHA—"to set standards which will most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life"[123]—but again, specifically for mines.

Unlike the OSH Act, which separates standard-setting and research-based functions between OSHA and NIOSH, MSHA is empowered by the Federal Mine Safety and Health Act

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[115] *See* Toxic Substances Control Act, 15 U.S.C. §§ 2601–2695d.
[116] *See* 29 U.S.C. § 652(5); *see also* Asbestos Abatement Projects, 50 Fed. Reg. 28,530, 28,531 (July 12, 1985) ("Currently, State and local employees in 27 States are not protected by the OSHA Asbestos Standard").
[117] *See* Aagaard, 2011, pp. 254–256 (note 99); *see also* Asbestos Abatement Project, 50 Fed. Reg. at 28,531.
[118] *See* 29 C.F.R. § 1910.1001(g)(2)(i) (requiring implementation of a respiratory protection program).
[119] *See* Aagaard, 2011, pp. 255–256 (note 99); *see also* Asbestos Worker Protection, 65 Fed. Reg. 69,210, 69,210 (Nov. 15, 2000) ("This final rule cross-references the OSHA Asbestos Standards for Construction and for General Industry, so that future amendments to these OSHA standards are directly and equally effective for employees covered by the WPR").
[120] Indeed, the Bureau of Mines was the first agency ever empowered to regulate respirator safety. *See 100 Years of Respiratory Protection History* (note 7). Other agencies with similar authority that displaces OSHA's authority include the Coast Guard (with authority over vessels) and the Federal Aviation Administration (with authority over air travel). See Part I.A.1.a.ii.1.
[121] *See* 30 U.S.C. § 3; Federal Mine Safety and Health Act of 1977, 30 U.S.C. §§ 801 *et seq*.
[122] *See 100 Years of Respiratory Protection History* (note 7).
[123] 30 U.S.C. § 811(a)(6)(A).

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for both developing and certifying respirators, and for enforcing safety standards.[124] MSHA thus has broad authority to regulate both use and oversight of respiratory protection, though this broad authority applies to the relatively limited set of workplaces that is made up of mines.

d. States and local authorities

Although this background paper focuses on the federal regulatory landscape, it is important to recognize that respiratory protection can also be affected by state and local law and authorities. Accordingly, this subsection provides an overview of the relationship between federal and state authority regarding workplace safety regulation, focusing on the regulation of use of respiratory protection in the workplace. As a general matter, it emphasizes that while the relationship between state and federal authority over workplace regulation is complex and still evolving, much of the time, federal standards preempt state standards on workplace safety. That said, the OSH Act establishes a complex system of "cooperative federalism" that leaves significant space for states to participate in governing workplace safety pursuant to federal constraints. As a result, many states administer their own occupational safety and health programs via OSHA-approved State Plans. State and local authorities also retain substantial authority over the regulation of several types of workplaces, including state and local government workplaces.

i. Federal preemption and state law

The relationship between state and federal workplace protections is complex. Congress is generally understood to have the authority to prevent states from regulating in areas where the federal government is empowered to act.[125] The principle that federal law overrides state law—often thought to derive from the Supremacy Clause of the U.S. Constitution—is known as preemption.[126] Conflicts between federal and state authority generate complexity in multiple areas of law.[127] That said, the law of preemption is particularly complex in areas of traditional state concern—including public health and safety—where the Supreme Court has adopted a general presumption against preemption that requires Congress to make its intent to supersede state law "clear and manifest."[128] It is further complicated where—as with workplace

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[124] *See* 30 U.S.C. § 811(a)(6)(A); *see also* Victor E. Schwartz, Cary Silverman & Christopher E. Appel, *Respirators to the Rescue: Why Tort Law Should Encourage, Not Deter, the Manufacture of Products that Make Us Safer*, 33 AM. J. TRIAL ADVOC. 13, 32–34 (2009) (comparing MSHA authority to that of NIOSH and OSHA).

[125] *See* Pacific Gas & Electric Co. v. State Energy Comm'n, 461 U.S. 190, 203 (1983) (characterizing it as "well-established" that Congress has the power to preempt state law); *see also* Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767 (1994) (providing a history of and orientation to preemption).

[126] *See* Gardbaum (note 125); *see also* U.S. Const. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof…shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding").

[127] *See generally* David P. Currie et al., *Conflict of Laws: Cases, Comments, Questions* (6th ed.) ("Law comes from many sources. In an ideal world, the authority of these sources would be clearly defined and demarcated, so that no event or occurrence was ever subject to control by more than one law maker or law enforcer. But such is not our world. The power of different bodies to make or administer law is often unclear and, even when clear, frequently overlaps"); *see also* Mary J. Davis, *On Preemption, Congressional Intent, and Conflict of Laws*, 66 U. PITT. L. REV. 181, 182-83 (2004) (providing an overview of preemption and conflict of laws).

[128] *See* Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947); Hines v. Davidowitz, 312 U.S. 52 (1941); *see generally* Gardbaum (note 125).

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regulation—the historical evolution of an issue involves an interweaving of federal and state action, expertise, and jurisdiction.[129]

Although complex, it is still possible to identify the general structure of authority as it is shared between federal regulators and state authorities. The OSH Act itself makes certain aspects of state authority relatively clear. Most notably, it declares that "nothing in this chapter shall prevent any State agency or court from asserting jurisdiction under State law over any occupational safety or health issue with respect to which no [federal] standard is in effect."[130] This provision preserves state authority in areas that have not been regulated by OSHA or that the OSH Act does not reach—though it is worth noting that the provision has also been interpreted by the Supreme Court to implicitly preempt state regulation where OSHA *has* promulgated standards.[131] This means that states are permitted to regulate regarding occupational safety and health where OSHA has not acted, but precluded from such regulation where OSHA is deemed to have issued a standard. Debate often surrounds the question of whether OSHA has regulated in a particular area of workplace safety or not.[132]

ii. State Plans and federal/state coordination

In some cases, debate over whether OSHA has regulated in a particular area of workplace safety or not is addressed via interactions between OSHA and state agencies. The OSH Act somewhat famously establishes a form of "cooperative federalism," a type of relationship between federal and state regulation where the federal government has the authority to regulate directly, but where it nevertheless chooses to leave states the option to regulate themselves—so long as they do so according to baseline federal standards.[133] In the context of OSHA, this structure is administered through the creation and approval of State Plans—OSHA-approved workplace safety and health programs, which are then operated by individual states or U.S.

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[129] *See* Henry Drummonds, *The Sister Sovereign States: Preemption and the Second Twentieth Century Revolution in the Law of the American Workplace*, 62 FORDHAM L. REV. 469 (1993) (describing the historical evolution of the modern regulatory landscape regarding workplace regulation); *see also* Richard C. Ausness, *The Welding Fume Case and the Disruptive Effect of OSHA's HazCom Standard on Common Law Failure-to-Warn Claims*, 54 BUFFALO L. REV. 103 (2006) (discussing federal preemption of state workplace safety laws under the OSH Act, and flagging ongoing debates about preemption in this area).

[130] *See* 29 U.S.C. § 667(a).

[131] *See* Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 100 (1992) (determining that the OSH Act's "preservation of state authority in the absence of a federal standard presupposes a background pre-emption of all state occupational safety and health standards whenever a federal standard governing the same issue is in effect").

[132] *See, e.g.*, Ausness, 2006 (note 129) (discussing OSHA preemption of state failure-to-warn claims); Victor E. Schwartz, Cary Silverman & Christopher E. Appel, *Respirators to the Rescue: Why Tort Law Should Encourage, Not Deter, the Manufacture of Products that Make Us Safer*, 33 AM. J. TRIAL ADVOC. 13 (2009) (discussing federal preemption of state tort claims regarding respirators).

[133] *See* New York v. U.S., 505 U.S. 144, 145 (1992) (describing cooperative federalism and citing the OSH Act as an example of a statute where it is used); *see also* Drummonds, 1993, pp. 477–478, 553–555 (note 129) (describing the OSH Act as "an intermediate preemption regime" where "[f]ederal administrative standards divest the states of authority over safety issues covered by the federal standards, but not over issues that fall outside the areas for which federal standards exist," and noting that "[e]ven within areas covered by federal standards, however, OSHA's cooperative federalism provision allows a kind of reverse preemption if the Secretary of Labor approves workplace safety plans that meet or exceed federal standards"); *see also* Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 105 (1992) (holding that the OSH Act preempted state regulation of workplace safety where the state had failed to obtain OSHA approval for its state-administered State Plan).

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territories, even as they implement OSHA safety standards.[134] OSHA limits its activities (such as site inspections) within states with approved State Plans and provides as much as 50 percent of the funding for administering those plans.[135]

To have its plan approved by OSHA, a state must meet several requirements. It must designate a state agency responsible for occupational safety and health, ensure that state inspectors can enter workplaces, provide adequate staff, and cover employees of the state and its subdivisions.[136] Furthermore, it must show that its standards are "at least as effective" as OSHA standards in protecting workers and in preventing work-related injuries, illnesses, and deaths.[137] Although states are precluded from implementing standards that are less effective than OSHA standards, they can request approval to go beyond what OSHA standards require to mandate even more stringent protections.[138] OSHA has significant discretion in granting or denying such requests.

iii. Other areas of state authority, including state and local government workers

The existence of (or lack thereof) a State Plan has special relevance for whether state and local government workers are protected by RPPs or an equivalent. The OSH Act explicitly exempts state and local government workers from OSHA standards,[139] so state and local government workers are not automatically covered by RPPs or other OSHA standards.[140] In places with State Plans, workers—including state and local government workers—have protections at least as effective as OSHA standards regarding respiratory hazards in the workplace.[141] There are currently 22 approved State Plans covering private and public state and local government workers, and 6 State Plans covering only state and local workers.[142] Third-

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[134] *See* Gade v. Nat'l Solid Wastes Mgmt. Ass'n*,* 505 U.S. 88, 105 (1992). OSHA maintains substantial resources on State Plans on the OSHA website. *See* OCCUPATIONAL SAFETY & HEALTH ADMIN., *State Plans*, https://www.osha.gov/stateplans.

[135] *See* Feld, 2021 (note 41); *see also See* OCCUPATIONAL SAFETY & HEALTH ADMIN., *State Plans*, U.S. DEP'T LAB. https://www.osha.gov/stateplans; Ausness, 2006 (note 129) (describing OSHA's inspection activities inside and outside states with approved plans).

[136] 29 U.S.C. § 667(c).

[137] 29 U.S.C. § 667(c).

[138] *See, e.g.*, 29 C.F.R. §§ 1904.37, 1902.7 (2020) (indicating that State Plans may promulgate injury and illness recording and reporting requirements that are more stringent than OSHA's after obtaining consent from OSHA); *State Plan Frequently Asked Questions*, U.S. DEP'T LAB., https://www.osha.gov/stateplans/faqs (explaining that State Plans can impose higher fines or stricter penalties than OSHA).

[139] *See* 29 U.S.C. § 652(5); *but see* OCCUPATIONAL SAFETY & HEALTH ADMIN., 3302-01R 2020, *All About OSHA* (2020), https://www.osha.gov/sites/default/files/publications/all_about_OSHA.pdf (describing OSHA's understanding that "[w]orkers at state and local government agencies are not covered by Federal OSHA, but have OSH Act protections if they work in those states that have an OSHA-approved state program").

[140] *See* OCCUPATIONAL SAFETY & HEALTH ADMIN. (note 139).

[141] *See* OCCUPATIONAL SAFETY & HEALTH ADMIN. (note 139).

[142] The following 22 states and territories have OSHA-approved State Plans that cover both private and state and local government workers: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. The relevant authority/authorities for each state are designated in this updated map, maintained by OSHA: https://www.osha.gov/contactus/bystate. The following 6 states/territories have OSHA-approved State Plans that apply to state and local government workers, but not private sector employers: Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands. In these jurisdictions, private sector workers are covered by federal OSHA, while state and local government workers are protected by (OSHA-approved) state programs. Notably, almost half (24) states do not have an OSHA-approved State Plan; OSHA

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party analysis of Census data suggests that there are 3.1 million state and local government workers in states without State Plans.[143] These workers are not covered either by OSHA standards or by OSHA-approved State Plans.

Finally, for workers or workplaces that the OSH Act does not reach or that OSHA has not regulated, as well as a few areas of state law that have been explicitly preserved, such as state workers' compensation laws,[144] state law has a more direct impact. For example, California's occupational safety and health agency—Cal/OSHA—recently issued updated guidance for employers on respiratory protection in the workplace that appear to go beyond OSHA requirements in several respects.[145] During the COVID-19 pandemic, some state agencies have also provided updated guidance to workers on the type of respiratory protection needed for specific workplaces.[146]

e. Characterizing occupational use

This section summarizes the regulatory landscape regarding occupational use of respiratory protection, focusing particularly on the protection of workers who are currently not addressed by RPPs. It focuses on distinguishing the categories of workers who are not protected by RPPs, and on identifying the reason those categories are unprotected.

Specifically, workers who are currently not protected by RPPs fall into three categories: (1) workers who OSHA is responsible for protecting, but for whom OSHA has chosen not to create an RPP; (2) workers who OSHA is not responsible for protecting, but who some other authority is responsible for protecting; (3) "gap workers," who no one is responsible for protecting. The regulatory landscape for each category is importantly different, in ways that may inform Committee recommendations. Where possible, this section identifies the source of any gap, overlap, or miscoordination, so that the Committee's eventual recommendations can be tailored to the legal basis underlying those challenges, and to the legal authority that can best remedy any problem. Potential recommendations are identified merely for illustration purposes and are not meant to advocate for any particular prescription or recommendation.

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reports that there are no State Plans in Alabama, Arkansas, Colorado, Delaware, Florida, Georgia, Idaho, Kansas, Louisiana, Massachusetts, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Texas, West Virginia, or Wisconsin. *See* OCCUPATIONAL SAFETY & HEALTH ADMIN, *OSHA Offices by State*, U.S. DEP'T LAB., https://www.osha.gov/contactus/bystate (last visited Apr. 13, 2021). These states' occupational safety and health is directly regulated by OSHA under the OSH Act and is subject to exemptions (such as those for state and local government workers) that exclude some workers from protection under RPPs.

[143] *See* Michael Maciag, *States with Most Government Employees: Totals and Per Capita Rates*, GOVERNING: THE FUTURE OF STATES AND LOCALITIES (Mar. 21, 2014), https://www.governing.com/archive/states-most-government-workers-public-employees-by-job-type.html (relying on U.S. Census Bureau Annual Survey of Public Employment and Payroll data).

[144] *See* 29 U.S.C. § 653 (stating that nothing in the OSH Act shall be construed to "supersede or in any manner affect any workman's compensation law or to enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment").

[145] *See* CAL. DEPT. OF INDUSTR. REL'NS, *Respiratory Protection in the Workplace – A Guide for Employers* (April 2021) (providing general guidance on respirator use in the workplace, as well as guidance about managing wildfire and aerosol transmissible disease risk in the workplace).

[146] *See, e.g.*, WASH. STATE DEPT. OF LABOR & INDUSTRIES, Division of Occupational Safety and Health, *Which Mask for Which Task? COVID-19 Prevention at Work: When to Use Face Coverings and Respirators* (September 9, 2020), https://www.lni.wa.gov/forms-publications/F414-168-000.pdf.

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i. Workers for whom OSHA has chosen not to create an RPP

Many workers who are subject to protection by OSHA are not protected by an RPP.[147] Potential protection of these workers varies according to the level of respiratory risk to which OSHA believes the workers are exposed at the workplace.

Some workers may be subject to significant respiratory risk in the workplace, despite their lack of current protection. For these workers, OSHA has the option of issuing a new RPP following its accustomed procedure, as outlined above. If the Committee believes that some worker types are exposed to significant risk in the workplace, for example as a result of the COVID-19 pandemic, and that these significant risks were not reflected in the protection offered by current RPPs, it could recommend issuance of RPPs by OSHA to other workers and/or other industries. For workers exposed to significant risk, whether protected by RPPs or not, OSHA also has the statutory authority to extend additional or alternative protections, other than those currently outlined in the RPP process, by issuing new regulatory rules or by amending existing rules.

As noted above, the RPP process is outlined by OSHA's Respiratory Protection Standard.[148] OSHA has the discretion to revisit this standard if it believes that a different standard would satisfy its statutory obligations. If the Committee believes that OSHA's current policy in addressing respiratory risk for workers facing significant risk is insufficient, it could recommend that OSHA change its policy by issuing an amended Respiratory Protection Standard. OSHA also has the authority to issue emergency rules more quickly under its ETS procedure.[149] Such a mechanism might be used to address immediate (and/or temporary) substantial respiratory risks to workers, such as those presented by the COVID-19 pandemic, who are otherwise covered under the OSH Act.

Other workers who are subject to protection by OSHA may not be protected by mandatory OSHA programs because they are not subject to what OSHA would consider to be significant risk. Creating mandatory standards to protect workers it believes are not at significant risk would require OSHA to revisit its long-standing interpretation of the Benzene decision, which it generally understands to mandate a finding of significant risk prior to issuing workplace standards. While OSHA may have the legal authority to reconsider its interpretation, this would be a substantial change in agency policy. Even absent changes in its interpretation of Benzene, however, OSHA has expansive authority to issue or amend existing voluntary guidance regarding respiratory protection.

ii. Workers protected by an authority other than OSHA

As noted above, the OSH Act exempts many workers from OSHA protection. Some of these workers are protected by other authorities, including other federal agencies. State and local authorities are specifically responsible for protecting state and local government workers, and while some states have adopted State Plans, others have not.

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[147] If approximately 3.3 percent of workers are protected by RPP programs under OSHA standards, *see* Part I.A.1.a.iii, then approximately 96.7 percent of workers are *not* protected under RPPs.

[148] 29 C.F.R. § 1910.134(a)(2) (2020) (establishing that employers are responsible for establishing and maintaining a respiratory protection program for covered employees); 29 C.F.R. § 1910.134(c) (describing the requirements for respiratory protection programs).

[149] *See* 29 U.S.C. § 655(b); *see also* 5 U.S.C. § 553 (allowing exceptions to notice-and-comment procedures for "good cause").

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To address the protection level of workers who are unprotected by RPPs, but who are protected by health and safety standards set by other federal or state authorities, the Committee would have to address authorities other than, or in addition to, OSHA.

Workers in federal agencies and state and local government workers in states with State Plans have very similar levels of protection to OSHA-covered workplaces, as do farmworkers under EPA's Worker Protection Standard (WPS) and state and local asbestos mitigation workers under EPA's TSCA rule. Standards in these workplaces have been purposefully harmonized with OSHA's requirements. While some of these rules have been harmonized via cross-referencing, however, as with EPA's asbestos rule, it is not clear that all such programs have utilized cross-referencing. In some cases, these authorities might need to take additional action to realign their policies and standards with OSHA's, particularly if OSHA were to update its Respiratory Protection Standard or its interpretation of when there are risks in the workplace significant enough to justify an RPP. As a result, if the Committee were to recommend that OSHA expand its RPP programs, either permanently or during the coronavirus emergency, it might be reasonable to also note for federal agencies, states with State Plans, and other agencies (such as EPA) that have harmonized with OSHA's regulations that the Committee is recommending expansion of the respiratory protections offered in the workplace.

If the Committee believed that employers in states without State Plans should provide additional respiratory protection to their workers, consistent with the types of protections otherwise provided under RPPs, it should make that recommendation to states. States have the authority either to then propose a State Plan to OSHA, or to increase their existing respiratory protections for their own workers. OSHA has significant discretion in deciding to approve or deny requests for approval for more stringent state protection, about which the Committee could advise. OSHA could also presumably issue a policy statement or other guidance encouraging more stringent state-level regulation of otherwise unprotected workers.

iii. Gap workers: Workers without any apparent statutory protection

Some workers appear to fall into gaps, such that there is no clear authority responsible for regulating their occupational respiratory protection. These include self-employed persons (including independent contractors),[150] unpaid volunteers,[151] family members of farm employees,[152] and domestic workers in a residential setting.[153] These categories of workers are

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[150] *See, e.g.*, 29 C.F.R. § 1904.31(b)(1) (indicating OSHA's current interpretation that "self-employed individuals are not covered by the OSH Act or this regulation").

[151] *See* OSHA Std. Interp. 1910.178(L) (Nov. 13, 2005), 2005 WL 3801505, https://www.osha.gov/laws-regs/standardinterpretations/2005-05-13 (explaining OSHA's interpretation that "volunteers who receive no monetary or other compensation…are not employees subject to coverage under the federal OSH Act"); *see also* Occupational Exposure to Tuberculosis, 62 Fed. Reg. 54160 (1997) 29 C.F.R. § 1910 (stating OSHA's position that "the OSH Act applies to employees, not bona fide volunteers").

[152] *See* 29 C.F.R. § 1975.4(b)(2) (2020) (explaining that "[a]ny person engaged in an agricultural activity employing one or more employees comes within the definition of an employer under the Act, and therefore, is covered by its provisions. However, members of the immediate family of the farm employer are not regarded as employees for the purposes of this definition").

[153] *See* 29 C.F.R. § 1975.6 (explaining that "[a]s a matter of policy, individuals who, in their own residences, privately employ persons for the purpose of performing for the benefit of such individuals what are commonly regarded as ordinary domestic household tasks, such as house cleaning, cooking, and caring for children, shall not be subject to the requirements of the Act with respect to such employment"); *see also* Chelsey Castro, *Dying to Work: OSHA's Exclusion of Health and Safety Standards for Domestic Workers*, 4 AM. U. MODERN AM. 3 (2008)

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exempted under OSHA's current interpretation of the OSH Act and do not appear to be protected by occupational safety and health standards issued by any other authority.

The situation regarding each of these categories of unprotected workers is complex. As a general matter, to protect workers who are explicitly exempted from OSHA protection under the language of the OSH Act, a new act of Congress would be necessary. Even then, Congress might face constitutional hurdles, depending upon the category of workers to whom they sought to extend statutory protection. If Congress attempted to regulate state and local government workers currently exempted by the OSH Act, for example, it might face challenges under the Tenth Amendment,[154] while if it sought to protect (entirely) unpaid volunteers under the OSH Act, it might face challenges under the Commerce Clause.[155]

Absent congressional action, OSHA clearly does not have the authority to extend protections to workers who are explicitly excluded by the statute, such as state and local government workers. OSHA, like Congress, is also constitutionally barred from regulating workers or workplaces that fall outside of the far boundaries of federal constitutional authority.

(explaining that OSHA interprets domestic workers as not being "employees" "employed in a business of [their] employer which affects commerce," as per the OSH Act, 29 U.S.C. § 652[6]).

[154] To legislate, Congress must be able to trace its actions to one of the enumerated powers of the federal government identified in the Constitution. *See* generally U.S. Const. art. II. Federal jurisdiction over state government workers is complicated by tension between the Supremacy Clause of the Constitution on the one hand, which prohibits states from interfering with the federal government's exercise of its constitutional powers, U.S. Const. art. VI, cl. 2, and the Tenth Amendment on the other, which provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserve to the States respectively, or to the people." U.S. Const. amend. X. Whether Congress has the constitutional authority to subject state activities to generally applicable requirements that it has enacted under its otherwise constitutional authority—such as occupational safety and health standards justified via the commerce power—thus remains a contentious issue. *See* Martha A. Field, *Comment: Garcia v. San Antonio Metropolitan Transit Authority: The Demise of a Misguided* Doctrine, 99 Harv. L. Rev. 84 (1985) (discussing the history of Supreme Court reversals in this area); *Cf., e.g.*, Garcia v. San Antonio Metropolitan Transit Authority, 469 U.S. 528 (1985) (overturning prior precedent to hold that the Tenth Amendment imposes practically no judicially enforceable limit on the application of generally applicable federal legislation, concluding that while "Congress's authority under the Commerce Clause must reflect [the] position … that the States occupy a special and specific position in our constitutional system," that the Fair Labor Standards Act's minimum wage and overtime provisions could be applied to state employees without exceeding constitutional limits), *with* National League of Cities v. Usery, 426 U.S. 833 (1976) (overturning federal legislation of wage and hours of some state and local government workers, and noting that "there are attributes of sovereignty attaching to every state government which may not be impaired by Congress, not because Congress may lack an affirmative grant of legislative authority to reach the matter, but because the Constitution prohibits it from exercising the authority in that manner").

[155] Legislative history, of which courts have taken note in the past, tie the far extent of Congress's authority in the Occupational Safety and Health Act to the Commerce Clause, which gives Congress the power "to regulate commerce with foreign nations, and among the several states, and with the Indian tribes," U.S. Const. art. I, § 8 cl. 3. *See* Brennan v. Occupational Safety and Health Review Commission, 492 F.2d 1027 (2d Cir. 1974) (discussing the legislative history of the OSH Act and noting that federal authority over occupational safety and health is as broad as the Commerce Clause). The OSH Act currently limits its key definitions—including of "employer" as "a person engaged in a business affecting commerce who has employees" and "employee" as an "employee of an employer who is employed in a business of his employer which affects commerce"—to relationships "affecting commerce," further emphasizing the perceived link between federal authority in this area and the Commerce Clause. Because of the more attenuated relationship to commerce, Congress could therefore face constitutional challenges if it sought to extend occupational safety and health protections to unpaid volunteers. Regulation of members of agricultural workers, currently excepted by OSHA's regulatory policy under 29 C.F.R. § 1975.4(b)(2), might face similar challenges if such persons' health and safety do not affect commerce.

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Some unpaid volunteers—those whose work falls outside of and does not affect interstate commerce—may fall into this category.

There are other categories of currently unprotected workers, however, who OSHA likely has the authority to protect even without an act of Congress. Where a statute is ambiguous, courts generally grant the agency that administers the statute broad discretion in choosing how to interpret the ambiguous term.[156] Agencies are even free to change their interpretations of the same term over time, and—so long as the agency's interpretation is reasonable—even to adopt different interpretations of the term than those that courts would adopt.[157] Because of their circularity, the definitions of both "employer" and "employee" in the OSH Act are notably ambiguous, affording OSHA substantial discretion in deciding who qualifies for protection under the Act.[158] In some cases, OSHA appears to have used this discretion to adopt a narrow interpretation that excludes some workers from protection. For example, OSHA's decision to exclude domestic workers from protection appears to be a product of its own interpretive choices; the OSH Act itself is silent regarding the status of domestic workers.[159] OSHA has also long excluded self-employed persons from the requirements of the Act,[160] apparently choosing to presume that self-employed persons are not "employers" because they have no "employees," rather than treating self-employed persons as employers of themselves. The statute itself does not explicitly mandate this interpretation. Theoretically, this may mean that the Committee could recommend that OSHA reconsider its exclusion of workers who fall outside its current interpretation of "employee," or that OSHA adopt the broadest interpretation of "employee" and/or "employer" permissible under the OSH Act.[161] However, the agency may feel itself to be bound to its existing interpretations, either because it believes them to be wisest, or because of settled expectations. In that case, if the Committee believes that respiratory protection of these workers should be regulated by OSHA or another authority, it would need to address either Congress (to amend the statute, as below) and/or the President (to direct reinterpretation of the statute). The Committee could also direct recommendations to OSHA that fall short of recommending reinterpretation of the statute on this critical issue and that instead urge OSHA to issue improved or alternative guidance for workers who do not qualify as "employees" under OSHA's interpretation.

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[156] *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984) (indicating that agencies interpreting an ambiguous statute they administer may adopt any reasonable or "permissible" interpretation of a statute, so long as that interpretation has not been explicitly foreclosed by Congress).

[157] *See* Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs., 545 U.S. 967 (2005) (applying deferential *Chevron* review to an agency's interpretation of a statute it administered, despite countervailing judicial precedent).

[158] *See* Nationwide Mut. Ins. Co. v. Darden, 503 U.S. 318, 323 (describing a similar definition of "employee" in another statute, as "any individual employed by an employer," as "completely circular" and stating that it "explains nothing").

[159] 29 C.F.R. § 1975.6 (explaining that "[a]s a matter of policy, individuals who, in their own residences, privately employ persons for the purpose of performing for the benefit of such individuals what are commonly regarded as ordinary domestic household tasks, such as house cleaning, cooking, and caring for children, shall not be subject to the requirements of the Act with respect to such employment"); see also Chelsey Castro, *Dying to Work: OSHA's Exclusion of Health and Safety Standards for Domestic Workers*, 4 Am. U. Modern Am. 3 (2008) (explaining that OSHA interprets domestic workers as not being "employees" "employed in a business of [their] employer which affects commerce" as per the OSH Act, 29 U.S.C. § 652[6])

[160] *See* 29 C.F.R. § 1904.31(b)(1).

[161] *See* Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs., 545 U.S. 967 (2005) (applying deferential *Chevron* review to an agency's interpretation of a statute it administered, despite countervailing judicial precedent).

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Finally, if the Committee believed that the multiplicity of workplace safety standards was overly complex or counterproductive, or that additional worker types should be incorporated into the statute, it could recommend to Congress that it amend the OSH Act. For example, the Committee could recommend that Congress reconsider the provision of the OSH Act that prohibits OSHA from passing workplace health and safety standards when authority to do so has been granted to another agency.[162] As further discussed in Part II, such amendments are time-consuming and unusual, as they require Congress to go through the process of legislation. Absent such a change, however, workplace respiratory standards may continue to be regulated by a patchwork of federal and state authorities, with OSHA standards playing a focal but not dominant role.

2. Occupational Oversight

This section identifies who has the authority to oversee development, approval, marketing, and postmarket surveillance of respiratory protection in the workplace. It focuses primarily on the regulatory role of NIOSH, though it will also discuss other authorities with more limited roles, including the Food and Drug Administration (FDA) and MSHA.

a. The National Institute for Occupational Safety and Health (NIOSH)

NIOSH is part of the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS).[163]

NIOSH has substantial responsibilities regarding occupational respiratory protection, though these responsibilities are driven by its role as a research and advisory institution. The section addresses the extent of NIOSH's authority and describes NIOSH's existing approach to oversight of respiratory protection. It also highlights the important role played by the National Personal Protective Technology Laboratory (NPPTL) within NIOSH in researching, evaluating, and certifying respirators.

i. The general authority of NIOSH under the OSH Act regarding development, approval, marketing, and postmarket surveillance

NIOSH was created under the OSH Act of 1970, which grants NIOSH the authority to "develop and establish recommended occupational safety and health hazards."[164] Such recommendations are made to OSHA, which then has the authority under the OSH Act to implement and enforce them. In furtherance of its research and advisory role, NIOSH is directed to engage in research, develop plans, establish criteria, promulgate regulations, and conduct educational programs about the use of occupational safety and health equipment.[165]

Because of its general statutory responsibility to research and recommend occupational safety and health standards, NIOSH is the primary authority for researching the effectiveness of respirators and other protective devices. Under this authority, NIOSH has established an approval process for respiratory protective devices, which it promulgated as a rule on

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[162] *See* 29 U.S.C. § 653§(b)(1).
[163] CTRS. FOR DISEASE CONTROL & PREVENTION, *About NPPTL* (Dec. 4, 2020), https://www.cdc.gov/niosh/npptl/about.html.
[164] 29 U.S.C. § 671.
[165] 29 U.S.C. §§ 669(a), 670(a).

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"Respiratory Protective Devices."[166] This rule forms the primary regulatory basis for NIOSH's management and control of respirator development, approval, marketing, and postmarket surveillance.

NIOSH is comprised of multiple divisions.[167] As discussed below, NIOSH's regulation of respiratory protective devices is supported and informed by general research and surveillance work performed within its Respiratory Health Division (RHD), which administers several hazard identification and surveillance programs regarding respiratory health. Another NIOSH division—NPPTL—acts as the primary authority responsible for conducting respirator evaluation and certification.

ii. The Respiratory Health Division (RHD), a division of NIOSH

RHD is a division within NIOSH dedicated to conducting research and administering service programs to prevent occupational respiratory diseases and improve workers' respiratory health.[168] RHD administers a series of programs that help in identifying workplace inhalation hazards and in surveilling worker health.

RHD's role in hazard identification is largely implemented through its Health Hazard Evaluation (HHE) Program, which helps workers and employers identify and evaluate potential inhalation hazards in their workplace.[169] Under the HHE Program, RHD visits workplaces and then makes recommendations regarding inhalation (and other) hazard mitigation, which can include recommendations for respirator use.

RHD also conducts public health surveillance and epidemiological studies to better understand and identify respiratory diseases from occupational exposures. Most of RHD's work is general and not specific to a single industry or inhalation hazard—the Work-Related Disease Surveillance System (eWoRLD), for example, presents data on multiple occupational respiratory diseases (including asbestosis, coal workers' pneumoconiosis, silicosis, asthma, and mesothelioma).[170] RHD also administers a program called the Coal Workers' Health Surveillance Program (CWHSP), which studies the causes and effects of respiratory diseases related to coal mine dust exposure and provides for health screenings and surveillance of coal miners.[171] To administer this program, RHD coordinates with MSHA, which as noted above has primary authority over workplace safety, including respiratory use, in mines.[172]

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[166] *See* 42 C.F.R. pt. 84 (2020).
[167] *See About NIOSH* (note 72) (describing NIOSH's mission, structure, and divisions, and providing fact sheets for those divisions summarizing their basic functions).
[168] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *Respiratory Health Division Factsheet*, Publication Number 2018-142 (July 2018), https://www.cdc.gov/niosh/docs/2018-142/pdfs/2018-142.pdf?id=10.26616/NIOSHPUB2018142.
[169] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *Health Hazard Evaluations*, https://www.cdc.gov/niosh/hhe.
[170] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *Work-Related Lung Diseases Surveillance System (eWoRLD)*, https://wwwn.cdc.gov/eworld.
[171] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *Coal Workers' Health Surveillance Program*, https://www.cdc.gov/niosh/topics/cwhsp/default.html. The CWHSP was established by the Federal Coal Mine Health and Safety Act of 1969 to address pneumoconiosis (black lung) risk from mining exposures; requirements for the surveillance program have been updated both by statute, under the Mine Safety and Health Act, and regulatory rulemaking, via the Mine Safety and Health Administration's rule for respirable coal mine dust exposure, Lowering Miners' Exposure to Respirable Coal Including Continuous Personal Dust Monitoring, 79 Fed. Reg. 24813 (May 1, 2014).
[172] *See* 30 U.S.C. § 3; Federal Mine Safety and Health Act of 1977, 30 U.S.C. §§ 801 *et seq.*

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iii. The National Personal Protective Technology Laboratory (NPPTL), a division of NIOSH

NPPTL within NIOSH plays a central role in researching, evaluating, and certifying respirators. In particular, its research and testing informs the respirator standards that NIOSH recommends and OSHA implements. This subsection describes the structure of the NPPTL, before describing NPPTL's current approach to respiratory protection, and reviewing NPPTL's periodic work regarding postmarket surveillance (including evaluation of the continued effectiveness of stockpiled respirators).

(1) History and structure of NPPTL

NPPTL is a division of NIOSH.[173] NPPTL was established in 2001 at the request of Congress, in response to a recognized need for improved personal protective equipment for workers and for focused research into personal protective technologies.[174] In passing the appropriations bill that recommended establishment of the NPPTL, the Senate Report on the bill noted "the need for design, testing and state-of-the-art equipment for this nation's … miners, firefighters, healthcare, agricultural and industrial workers," as a result of which it encouraged NIOSH "to carry out research, testing, and related activities aimed at protecting workers who respond to public health needs in the event of a terrorist incident," and CDC "to organize and implement a national personal protective equipment laboratory."[175]

NPPTL maintains offices and labs in Pittsburgh, Pennsylvania, and Morgantown, West Virginia.[176] As of July 2018, NPPTL had 73 full-time staff positions, with staff expertise covering the areas of science, engineering, occupational health, health communications, and quality assurance.

(2) Role and activities of NPPTL

While NIOSH as a whole is dedicated to generating and implementing new knowledge in the field of occupational safety and health, NPPTL is specifically tasked with addressing the safety and adequacy of personal protective technologies (PPTs) used by workers in their professional duties.[177] PPTs include respirators, clothing gowns, gloves, eye protection, and other types of protective gear.[178] To carry out its mission of protecting workers using PPT, NPPTL aims to develop and implement guidance for PPT, develop methods to test for PPT effectiveness for workers, create guidance to help employers and workers most effectively use PPT, and develop and evaluate PPT designs.[179]

NPPTL accomplishes its mission by conducting scientific research, developing guidance and authoritative recommendations, disseminating information, and responding to requests for

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[173] *About NPPTL* (note 163).
[174] *About NPPTL* (note 163).
[175] *See* S. REP. NO. 106-293, at 110 (2000).
[176] CTRS. FOR DISEASE CONTROL & PREVENTION, *Directory of NIOSH Offices and Key Personnel* (Mar. 28, 2018, 12:00 AM), https://www.cdc.gov/niosh/contact/officers.html; NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUB. NO. 2018-141, *National Personal Protective Technology Laboratory Factsheet* (July 2018), https://www.cdc.gov/niosh/docs/2018-141/pdfs/2018-141.pdf?id=10.26616/NIOSHPUB2018141.
[177] *See About NPPTL* (note 163).
[178] NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, Pub. No. 2018-141 (note 176).
[179] *See* NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUB. NO. 2018-141 (note 176).

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evaluations of workplace health hazards.[180] NPPTL also conducts surveillance, standards development, interventions, and conformity assessment activities.[181]

NPPTL's work in promoting occupational health and safety includes a respirator approval program as well as "post-market evaluations to increase the compliant use of PPT and improve its usability and effectiveness."[182] NPPTL also conducts worksite surveillance of hazards necessitating the use of PPT by workers, which complements the further surveillance work by RHD noted above.[183]

(3) NPPTL's respirator certification testing

NPPTL is the unit of NIOSH that conducts respirator certification testing.[184] NPPTL is responsible for conducting the examination, inspection, and testing of respirators used in occupational settings.[185] Following standard test procedures,[186] NPPTL evaluates and approves respirator models used in occupational settings to ensure conformity with construction, performance, and respiratory protection standards.[187] Respirators used in occupational settings must meet the minimum performance requirements defined in 42 C.F.R. Part 84 in order to receive approval. NPPTL also conducts site and product audits of respirators to ensure conformance with standards following approval.[188] Finally, NIOSH maintains a database of all respirators that have been approved by NPPTL, to help people determine if the respirator they are using or considering using is NIOSH-certified.[189]

(4) NPPTL's work and approach in the pandemic

During the COVID-19 pandemic, NPPTL has focused significant efforts on increasing the supply of respirators available to workers. Through these efforts, NPPTL has exhibited several ways in which it operates as an important reservoir of expertise on respiratory protection that extends beyond their responsibilities as the authority for occupational respirator certification.

To address respirator shortages associated with the COVID-19 pandemic, NPPTL is conducting a series of limited assessments for respirators in the following categories: (1) respirators that are stockpiled/beyond shelf life; (2) respirators that purport to meet an international certification standard but are not NIOSH approved; (3) respirators that have been

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[180] *About NPPTL* (note 163).
[181] NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUB. NO. 2018-141 (note 176).
[182] NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUB. NO. 2018-141 (note 176).
[183] *See* NAT' INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUB. NO. 2004-111, NIOSH'S NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY: PROVIDING PERSONAL PROTECTIVE TECHNOLOGY INNOVATIONS FOR THE 21ST CENTURY, AT 6 (May 2004), https://stacks.cdc.gov/view/cdc/5206/cdc_5206_DS1.pdf; *see also* CTRS. FOR DISEASE CONTROL & PREVENTION, Work-Related Lung Diseases Surveillance System (eWoRLD), https://wwwn.cdc.gov/eworld (note 170).
[184] *See* 42 C.F.R. § 84.2 (2020) ("NPPTL administers the NIOSH conformity assessment program for respiratory protective devices, replacing the former Certification and Quality Assurance Branch").
[185] 42 C.F.R. § 84.10(c) (2020).
[186] CTRS. FOR DISEASE CONTROL & PREVENTION, *Standard Respirator Testing Procedures* (Apr. 10, 2020), https://www.cdc.gov/niosh/npptl/stps/respirator_testing.html.
[187] NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUB. NO. 2018-141 (note 176).
[188] NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUB. NO. 2018-141 (note 176).
[189] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *Certified Equipment List* (Apr. 9, 2020), https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html.

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decontaminated; and 4) non-NIOSH-approved respirators produced by novel commercial equipment.[190] The purpose of these assessments is to "support the availability of respiratory protection to U.S. healthcare workers and other workers."[191] The results of the limited assessments are disseminated to the public via the NPPTL webpage.[192]

The type of assessment NPPTL is performing varies based on the approval process the respirators have undergone: for stockpiled respirators, respirators beyond shelf life, and respirators approved under international standards similar to NIOSH-approved N95s, NPPTL is solely assessing particulate filter efficiency;[193] for internationally approved (non-NIOSH-approved) respirators and N95 respirators following decontamination, NPPTL is assessing particulate filter efficiency and change in static fit;[194] while for innovative N95 respirators produced by novel commercial equipment, NPPTL is assessing particulate filter efficiency and pressure difference.[195]

As another step of the response to COVID-19, the NIOSH Respirator Approval Program (conducted by NPPTL) is accepting and prioritizing certain applications to increase the supply of NIOSH-approved respirators used by health care personnel and other workers.[196] Priority is given to domestic manufacturers already holding an approval.[197]

NPPTL has also been providing guidance to manufacturers, for example, clarifying FDA's emergency use authorizations (EUAs) as they relate to NIOSH-approved respirators.[198] Additionally, NPPTL has assisted in investigations of manufacturers that are charged with producing misbranded and defective masks during the COVID-19 pandemic.[199]

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[190] CTRS. FOR DISEASE CONTROL & PREVENTION, *NPPTL Respirator Assessments to Support the COVID-19 Response* (Mar. 8, 2021), https://www.cdc.gov/niosh/npptl/respirators/testing/default.html.
[191] CTRS. FOR DISEASE CONTROL & PREVENTION, *International Assessment Results – Not NIOSH-Approved* (Mar. 29, 2021), https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html.
[192] *See NPPTL Respirator Assessments to Support the COVID-19 Response* (note 190).
[193] NPPTL, *Assessment of Filter Penetration Performance for Respirators Beyond Designated Shelf Life and Stockpiled N95 Respirators 3* (Mar. 30, 2020), https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/ExpiredN95_TestPlan.pdf; NPPTL, *Assessment of Filter Penetration Performance for Non-NIOSH Approved Respirators 4* (Mar. 31, 2020), https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NonNIOSH_Filtration_TestPlan.pdf.
[194] NPPTL, *Assessment of Filtration Efficiency and Manikin Fit for Decontaminated International Respirators 3* (Oct. 16, 2020), https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NonNIOSH_DeconInternat_TestPlan-508.pdf.
[194] NPPTL, *Assessment of Filter Penetration Performance and Fit for Decontaminated N95 Respirators 3* (Apr. 16, 2020), https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NIOSHApproved_Decon_TestPlan10.pdf.
[195] NPPTL, *Assessment of Filter Penetration and Pressure Difference for Non-NIOSH Approved Innovative Filtering Facepiece Respirators 4* (June 22, 2020), https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/Non-NIOSHApproved-Innov-Respirator-TestPlan.pdf.
[196] NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, CA 2021-1032, *Conformity Assessment Letter to Manufacturers 3–5* (Feb. 2021), https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/pdfs/CA-2021-1032-P.pdf.
[197] *See* NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, CA 2021-1032.
[198] NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, CA 2020-1029, *Conformity Assessment Letter to Manufacturers* (June 2020), https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/pdfs/CA-2020-1029-P.pdf.
[199] *E.g.*, U.S. DEP'T OF JUST., Press Release 20-187, *Chinese Manufacturer Charged with Exporting Defective and Misbranded Masks Falsely Purporting to Be KN95 Respirators* (June 17, 2020), https://www.justice.gov/usao-nj/pr/chinese-manufacturer-charged-exporting-defective-and-misbranded-masks-falsely-purporting.

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b. Other authorities

This section identifies the roles of other key federal and state authorities in developing, approving, marketing, and performing postmarket surveillance on respiratory protection in the workplace.

i. Federal agencies

A variety of other federal agencies have authority over some aspects of oversight of the development, approval, marketing, or postmarket surveillance of occupational respiratory protection.

Some of these agencies have only partial or shared authority over one of these functions; others only have authority as it extends to inhalation hazards in particular workplaces (e.g., mines) or that arise in particular contexts (e.g., emergencies). This section will attempt to summarize the key agencies involved in various parts of each of these functions, including the occupational oversight functions served by other federal agencies, including FDA, MSHA, the Nuclear Regulatory Commission (NRC), and the Federal Emergency Management Agency (FEMA).

FDA is a consumer protection agency that is responsible for regulating the "safety and effectiveness" of food, drugs, and medical devices.[200] The subsequent section on respiratory protection for the public analyzes FDA's authority in regards to masks and respirators.[201] In general, however, these fall under FDA's jurisdiction when they are intended for a medical purpose.[202] Some masks and respirators are intended for the medical purpose of occupational use in a health care setting, and thus subject to FDA regulation.[203] In the past, this overlap has occasionally caused confusion: several years ago, for example, concerns arose that some medical workers were using NIOSH-approved respiratory protective devices that were not FDA cleared.[204] To address this concern, FDA and NIOSH have coordinated their overlapping authority for respirators used in medical care workplaces via a memorandum of understanding.[205] As a general matter, the memorandum prescribes that N95 respirators used in health care settings should be both certified by NIOSH and cleared by FDA.[206] While this is the way that overlapping authority between NIOSH and FDA is generally handled regarding medical workplaces, FDA has relaxed requirements during emergency conditions regarding specific

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[200] *See* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301–392; *see also* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified in scattered sections of 21 U.S.C. & 42 U.S.C.).
[201] *See* Part I.B.
[202] *See* Part I.B.
[203] *See* 21 C.F.R. § 878.4040 (2020) (covering surgical masks, pediatric/child face masks, face shields, and N95 respirators).
[204] *See* Respiratory Protective Devices Used in Healthcare, 79 Fed. Reg. 14,515 (March 14, 2014) (explaining the history of concern of use of non-FDA-cleared respiratory protective devices in health care settings, even where those devices were approved by NIOSH).
[205] *See* Memorandum of Understanding Between the Food and Drug Administration/Center for Devices & Radiological Health and the Centers for Disease Control & Prevention/National Institute for Occupational Safety & Health/National Personal Protective Technology Laboratory, MOU 225-18-006 (Dec. 18, 2017), https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006.
[206] *See* Memorandum of Understanding, 2017 (note 205).

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hazards. In particular, FDA has issued a series of EUAs for non-NIOSH-approved respirators during the COVID-19 pandemic.[207]

MSHA is empowered by the Federal Mine Safety and Health Act both for developing and certifying respirators, as well as for enforcing safety standards within U.S. mines.[208] By statute, MSHA is also required to take part in NIOSH's certification functions.[209] While MSHA technically has substantial authority over a wide range of standard-setting and oversight functions within in U.S. mines, it manages this authority via collaboration with OSHA and NIOSH for both functions. This coordination is particularly robust in regards to respirator oversight, where MSHA has established a memorandum of understanding with NIOSH whereby NIOSH has the lead role in respirator certification, while MSHA and NIOSH jointly review and approve the respirators used for mine emergencies and mine rescue.[210] That said, MSHA also retains primary responsibility for several testing and oversight requirements specific to the use of respirators in mines, including investigating complaints and potential deficiency of approved respirators that are used in mines, and for testing and approving electrical and electronic components of respirators for use in potentially explosive atmospheres (an unusual feature of some mining contexts that pose additional hazards beyond those presented in many other workplaces).[211] As a result of this arrangement, NIOSH remains the primary federal authority in certifying respirators, with MSHA continuing to play a role only in regards to respirators for use in mines.

The NRC is the coordinating agency for incidents at or caused by nuclear facilities.[212] In the event of a radiological release, the NRC is specifically responsible for providing recommendations for protective actions at nuclear facilities and for performing postincident surveillance and monitoring.[213]

FEMA has the authority to assert an expanded role over respiratory protection in workplaces during emergencies and natural disasters.[214] When emergencies present respiratory hazards—as with COVID-19, wildfires, and radiological disasters—FEMA has a coordinating role that can affect the oversight of respiratory protection in the workplace.[215] FEMA also has the authority to play a role in emergency distributions of respiratory protection to workers and the

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[207] *See, e.g.*, U.S. FOOD & DRUG ADMIN., *Emergency Use Authorization for Imported, Non-NIOSH Approved Disposable Filtering Facepiece Respirators* (Mar. 24, 2021), https://www.fda.gov/media/136403/download; FDA, *Emergency Use Authorization for Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China* (Oct. 15, 2020), https://www.fda.gov/media/136664/download.
[208] *See* 303 U.S.C. § 3.
[209] *See* 42 C.F.R. § 84.3 (2020).
[210] *See* 42 C.F.R. § 84.3 (2020) (providing for joint certification); Respirator Protective Devices, 60 Fed. Reg. 30,336, 30,339 (June 8, 1995) (explaining that MSHA has retained its role in approving respirators for mine emergencies because of its "expertise in identifying the special needs and considerations for respirators used in the mining environment").
[211] *See* Respirator Protective Devices, 60 Fed. Reg. at 30,338-39; 30,343; 30,349-51.
[212] *See* U.S. DEP'T OF HOMELAND SEC., *Nuclear/Radiological Incident Annex to the Response and Recovery Federal Interagency Operational Plans 33–34* (Oct. 2016) (describing NRC's role and responsibilities).
[213] *See* U.S. DEP'T OF HOMELAND SEC., 2016 (note 212).
[214] Most of FEMA's authority comes from the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("Stafford Act"), 42 U.S.C. § 4121 *et seq*.; *see* Disaster Mitigation Act of 2000, 42 U.S.C. § 5121 *et seq*. (amending the Stafford Act and providing incentives for states to develop their own predisaster mitigation plans). FEMA also has coordinating authority under the Defense Production Act of 1950 (DPA), 50 U.S.C. §§ 4501–4568. For further treatment of FEMA's authority in contexts of public emergency, see Part I.B.1.c.
[215] *See* Part I.B.1.c.

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public. During the early COVID-19 pandemic, for example, it established "Project Airbridge" for accelerating transportation of commercially distributed PPE from international manufacturers to the United States.[216] While these responsibilities do not conflict with NIOSH's authority of the oversight over respiratory protection, they may affect the availability and provision of PPE, including respiratory protection, in emergency circumstances.

ii. State and local authorities

State and local occupational safety and health agencies play an important role in enforcing many OSHA/NIOSH requirements.[217] In light of the substantial federal regulation of respirator certification at NIOSH, state and local authorities have traditionally played a relatively limited regulatory role in oversight of respiratory protection for workers who are not protected by RPPs. Even states with active state occupational safety agencies, such as California, routinely refer to NIOSH standards in setting requirements for occupational respiratory protection.[218]

c. Stockpiling

Generally speaking, questions of supply chains and national stockpiling strategy are outside the scope of this background paper. That said, questions of stockpiling can affect the availability of PPE, especially during emergencies, including PPE for critical workers. Accordingly, and by request of the Committee, this section briefly identifies the key authorities involved in identifying and maintaining the nation's stockpiles of respiratory protective gear for use by the public.

Federal stockpiling authority is largely governed by the Public Health Services Act, amended by the Pandemic and All-Hazards Preparedness Act (PAHPA).[219] Generally speaking, the secretary of HHS—in coordination with the secretary of the Department of Homeland Security, the director of CDC, and the assistant secretary for preparedness and response within HHS—is authorized to maintain the Strategic National Stockpile, a stockpile of drugs, vaccines, and other medical products and supplies, including respiratory protection.[220] The stockpile is meant to supplement state and local medical supplies and equipment during public health emergencies.[221]

The President has substantial authority regarding the management of national stockpiles, both as commander in chief and as the head of the executive branch. The President has the power to declare emergency, and expanded authority over stockpiling and supply chain issues in cases of emergency.[222] Under the Defense Production Act, the President can address matters of critical

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[216] *See FEMA Phasing out Project Airbridge*, FED. EMERGENCY MGMT. AGENCY (Mar. 18, 2021), https://www.fema.gov/press-release/20210318/fema-phasing-out-project-airbridge (announcing the ending of Project Airbridge).
[217] *See* Part I.A.1.d.
[218] *See, e.g.*, CAL/OSHA, *Respiratory Protection in the Workplace: A Guide for Employers* 12 (April 2021) ("Only select a NIOSH-certified respirator and only use it in compliance with the conditions of its certification"), https://www.dir.ca.gov/dosh/dosh_publications/respiratory-protection-employer-guide.pdf.
[219] *See* 42 U.S.C. § 247d–6b (addressing the Strategic National Stockpile and security countermeasure procurements).
[220] *See* 42 U.S.C. § 247d–6b.
[221] *See* 42 U.S.C. § 247d–6b.
[222] *See* Defense Production Act of 1950, 50 U.S.C. §§ 4501–4568.

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infrastructure, technology, national economic security, and national public health and safety, from manmade and natural disasters, as well as wartime concerns, via a series of mechanisms that mobilize national industrial capacity.[223] For many years, it was ambiguous under the DPA whether manufacturers could be liable in tort for the manufacture of products under the DPA, [224] though after passage of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, it is clear that at least some respiratory protective devices certified by NIOSH are protected from state and federal contract and tort liability.[225] At least in theory, FEMA is tasked with coordinating DPA activities.[226] In particular, the administrator of FEMA chairs the DPA Committee, which advises on effective use of the DPA and also reports to Congress.[227]

d. Characterizing occupational oversight regarding development, approval, marketing, and postmarket surveillance

This section summarizes the regulatory landscape regarding oversight of workplace respiratory protection, focusing particularly on the protection of workers who are currently not addressed by RPPs, and on oversight of development, approval, marketing, and postmarket surveillance. The paper attempts to identify the source of any gap, overlap, or miscoordination, so that the Committee's eventual recommendations can be tailored to the legal basis underlying those challenges.

Among the topics addressed by this background paper, the matter of oversight of occupational respiratory protection is the most centralized and least fragmented. The primary responsibility for overseeing development, approval, marketing, and postmarket surveillance of occupational respiratory protection clearly falls under the authority of NIOSH, and within NIOSH, within the purview of NPPTL. While other agencies, such as FDA, have authority over oversight of occupational respiratory protection for certain workers (in the case of FDA, medical workers), and other agencies, such as MSHA, have authority over occupational respiratory protection for certain workplaces (in the case of MSHA, mines), these agencies coordinate their requirements with NIOSH's—supplementing only where there are distinctive features of the work environment that present unusual risks (as with MSHA's management of explosive

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[223] *See generally* Defense Production Act of 1950, 50 U.S.C. §§ 4501–4568. For example, the President can prioritize Department of Defense contracts and can incentivize the production of goods that promote the national defense. For a discussion of the use of the DPA in the pandemic, see James E. Baker, *From Shortages to Stockpiles: How the Defense Production Act Can Be Used to Save Lives, Make America the Global Arsenal of Public Health, and Address the Security Challenges Ahead*, 11 J. NAT'L SEC.SECURITY L. & POL'Y 157 (2020).

[224] While the DPA clearly protects companies from contractual liability for prioritizing a DPA contract over existing commercial contracts (*see* 50 U.S.C. § 4557: "No person shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order issued pursuant to this chapter, notwithstanding that any such rule, regulation, or order shall thereafter be declared by judicial or other competent authority to be invalid"), its application to tort liability remains uncertain. *See* Baker, note 223 (noting ongoing manufacturer concern about tort liability prior to the passage of the CARES Act); *see also* 50 U.S.C. § 4557 (failing to address tort liability).

[225] *See* CARES Act, Pub. L. No. 116-136, § 3103, 134 Stat. 281, 361 (2020) § 4113 (exempting "respiratory protective device[s]" that are "approved by the National Institute for Occupational Safety and Health … and that the Secretary determines to be a priority for use during a public health emergency" from federal and state contract and tort liability); *see also* 42 U.S.C. § 247d–6d; Baker, 2020 (note 223) (discussing this amendment).

[226] *See* Defense Production Act of 1950 § 722, 50 U.S.C. § 4567. Some commentators have criticized some aspects of FEMA's implementation during the pandemic. *See, e.g.*, Baker, 2020 (note 223).

[227] *See* Defense Production Act of 1950 § 722.

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atmospheres) or where the agency's jurisdiction extends into additional oversight concerns (as with FDA's jurisdiction over respirator misbranding)—rather than displacing the NIOSH standards. Furthermore, because of the expansive federal role in this area, state authority appears limited.

Because the authority for managing oversight of occupational respiratory protection is so concentrated under the umbrella of NIOSH, most recommendations the Committee makes in this realm would need to address NIOSH's authority. This could be accomplished either by addressing NIOSH directly, addressing an agency that coordinates with NIOSH (such as FDA), by addressing Congress to expand NIOSH's authority, or by addressing the President to direct prioritization with NIOSH or coordination among agencies.

Matters addressed specifically to NIOSH should be targeted toward matters over which NIOSH has existing jurisdiction. For example, the Committee might make recommendations about the standards NPPTL applies to respirators, or the process it uses to certify them; or it might encourage NIOSH/NPPTL to develop additional guidance, for example highlighting the distinctions between public and occupational use of respiratory protection, or giving guidance for safe and effective respirator use outside an RPP.

Matters addressed to other agencies should be targeted toward matters over which they have authority, or where they have overlapping authority with NIOSH. For example, the Committee could support and/or encourage further coordination between FDA and NIOSH in the matter of managing oversight of occupational respiratory protection in medical workplaces, could encourage FDA to prioritize its enforcement actions against misbranded or adulterated respirators on particular aspects, or to continue and/or extend its EUAs in the COVID-19 pandemic.

If the Committee believed that existing statutory authority was insufficient or required some other change, it is Congress that would have the authority to respond. For example, if the Committee believed that responsibility over respiratory protection oversight should be reallocated, such that, for example, other agencies' certification or oversight regimes displaced NIOSH's, that is a change that would have to be implemented by Congress. Congress would also be the appropriate authority to which to direct recommendations for increased appropriations to NIOSH, NPPTL, or another authority.

Finally, if the Committee believed that the oversight of occupational respiratory protection demands even further levels or types of coordination than agencies currently exhibit, that is a matter that can be addressed to the President, as well as to the agencies themselves. Further possible actions over which relevant regulatory actors have authority, including the President, are discussed in Part II below.

B. Respiratory Protection for the Public

The organization of this section echoes the structure of the first part of this paper by distinguishing between regulations regarding nonoccupational *use* and those regarding nonoccupational *oversight* (of development, approval, marketing, and postmarket surveillance of respiratory protection).

No centralized authority is responsible for respiratory protection for the public as against all hazards. While occupational respiratory hazards have centralized authorities in the National Institute for Occupational Safety and Health (NIOSH) (for addressing occupational oversight), and to some extent in the Occupational Safety and Health Administration (OSHA) (for addressing occupational use), there is no corollary in the context of public protection. As a result,

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the landscape of respiratory protection for the public is substantially more complicated than that of occupational respiratory protection, with the authority for the use and oversight of respiratory protection for the public fragmented across multiple federal and state authorities, based upon the location and type of hazard. This complexity is increased by the fact that there is no centralized repository of information about which authorities are responsible for which hazards under which circumstances.

It is worth noting that these features of the regulatory landscape—the notable absence of both a centralized authority for coordinating respiratory protection for the public, and of a centralized repository for understanding the interconnections of multiple statutes, agencies, and branches in regards to public respiratory protection—present particular challenges for comprehensive treatment of public respiratory protection. Accordingly, while this paper attempts to identify and characterize key actors in the area of public respiratory protection, this section of the paper in particular cannot purport to be comprehensive. Given the fragmentation of authorities, understanding the full extent of the regulatory landscape regarding public respiratory protection could easily be a matter of full-time study.

1. Nonoccupational Use

This section addresses the question of who has the authority to regulate use of respiratory protection by the public—that is, use of respiratory protection by individuals outside their own workplaces. No single federal or state authority has the responsibility for managing all inhalation hazards or public exposures, much less for managing all use of respiratory protection by the public. However, some agencies do have authority over regulating some inhalation hazards that affect the public and over some aspects of the use of respiratory protection. This section will focus on identifying these authorities and articulating both the extent of their authority and where there appear to be existing gaps and overlaps in regulating the use of respiratory protection by the public. In particular, it explores the authority of the Environmental Protection Agency (EPA) in addressing use of respiratory protection against environmental hazards, the Centers for Disease Control and Prevention (CDC), and the Federal Emergency Management Administration (FEMA) for addressing public respiratory protection in emergency contexts. It then addresses the authority of other federal, state, and local actors.

a. The Environmental Protection Agency (EPA)

EPA is empowered by statute to regulate a variety of environmental inhalation hazards facing the public.[228] This subsection describes EPA's authority and current practice regarding the use of public respiratory protection under two of the most important of these statutes—the Clean Air Act and the Toxic Substances Control Act (TSCA)—and provides a briefer overview of EPA's authority under other statutes. It concludes that EPA has authority to regulate some inhalation hazards faced by the public, although its authority is largely limited to environmental hazards such as those that come from exposure to toxic chemicals or air pollution, and it is not always clear how much authority EPA has to manage those hazards via respiratory protection.

[228] For an overview of EPA's authority and role within environmental regulation, see ROWELL & VAN ZEBEN (note 92, pp. 22–26).

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i. The Clean Air Act

The Clean Air Act is the primary federal statute responsible for addressing the risks of air pollution. [229] It is administered by EPA. The Act includes a number of sections that authorize EPA to take action in regards to a variety of inhalation hazards, including those posed by wildfires and hazardous air pollutants emitted by industrial sources.

(1) EPA's general authority under the Clean Air Act

The gargantuan Clean Air Act of 1970, as substantially amended in 1977 and 1990, is the nation's most important law addressing the problem of air pollution.[230] EPA is responsible for administering the Clean Air Act and for overseeing a "cooperative federalist" structure that allows for cooperation between federal and state actors regarding the management of air quality.[231]

The Clean Air Act's multiple sections fit together in complex ways—indeed, the Act is so enormous and intricate that its complexity has been compared to that of the entire U.S. tax code.[232] In furtherance of its goals, the Act establishes separate approaches to regulating "criteria" pollutants that endanger public health or welfare and that come from multiple sources (including both mobile and stationary sources),[233] and "hazardous air pollutants" that present an even greater hazard and which may be generated by only one or a few sources (such as chemical plants or other industrial emitters).[234] EPA is tasked with different responsibilities and different authority regarding each of these types of pollutants. In this sense, the Clean Air Act requires a different regulatory approach for inhalation hazards posed by criteria pollutants and those posed by hazardous air pollutants.

(2) Criteria air pollutants

Criteria pollutants are those substances that "cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," which "are present in the air due to numerous or diverse mobile or stationary sources," and for which the administrator plans to issue air quality criteria, which are technical documents that identify the public health

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[229] *See* 42 U.S.C. §§ 7401 *et seq*.; *see also Summary of the Clean Air Act*, U.S. ENV'T PROT. AGENCY (Aug. 6, 2020), https://www.epa.gov/laws-regulations/summary-clean-air-act (providing a useful summary of the key parts of the Act and EPA's role in implementing them). EPA has also written an excellent, readable summary of the Act at U.S. ENV'T PROT. AGENCY, EPA-456/K-07-001, THE PLAIN ENGLISH GUIDE TO THE CLEAN AIR ACT (2007), https://www.epa.gov/sites/production/files/2015-08/documents/peg.pdf; *see also* ROWELL & VAN ZEBEN, 2021, pp. 104–116 (note 92) (providing a general overview of the U.S. approach to air pollution).

[230] *See supra* (note 229).

[231] *See generally* 42 U.S.C. §§ 7401 *et seq*.; *see also* Holly Doremus & W. Michael Hanemann, *Of Babies and Bathwater: Why the Clean Air Act's Cooperative Federalism Framework Is Useful for Addressing Global Warming*, 50 ARIZ. L. REV. 799 (2008) (discussing the history and cooperative federalist structure of the Clean Air Act); ROWELL & VAN ZEBEN, 2021, pp. 22–26, 93–115 (note 92) (providing an overview of the general U.S. approach to pollution regulation as administered by EPA and as characterized by cooperation between federal and state actors).

[232] *See, e.g.*, Richard Revesz, Michael Livermore, Caroline Cecot & Jayni Foley Hein, ENVIRONMENTAL LAW AND POLICY 353–613 (Foundation Press, 4th ed. 2019) (making the comparison to the tax code and providing a technical overview of key provisions of the Act).

[233] *See* 42 U.S.C. § 7408.

[234] *See* 42 U.S.C. § 7412; *see also* ROWELL & VAN ZEBEN, 2021, pp. 104–116 (note 92).

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and welfare effects of the pollutant.[235] The administrator of EPA is directed to issue National Ambient Air Quality Standards (NAAQS) to control pollutants listed as criteria pollutants at a level that is "requisite to protect the public health" and allows "an adequate margin of safety."[236] Currently, EPA has issued NAAQS for six criteria pollutants: carbon monoxide, lead, nitrogen dioxide, particulate matter (separately set for particulate matter smaller than 10 microns and fine particulate matter smaller than 2.5 microns), ozone, and sulfur oxides.[237] To implement the NAAQS, the Clean Air Act relies upon a cooperative federalist structure that assigns significant authority to states to develop State Implementation Plans (SIPs) for achieving the NAAQS that have been set by EPA.[238] SIPs are subject to review by EPA, which has the authority to replace them with Federal Implementation Plans (FIPs) if the SIPs fail to meet required standards.[239] States are also subject to more stringent federal regulation of new or modified sources of air pollution if they fail to attain the NAAQS (a status called "nonattainment") than if they achieve the NAAQS (a status called "attainment").[240] EPA administers a series of performance standards for new and modified stationary sources,[241] as well as permit systems that grant or deny permits to new and modified stationary sources of air pollution based upon the expected pollution created by the source, and the location in which the source is opening.[242] Mobile sources of criteria air pollution are regulated under a separate set of provisions.[243] These generally limit interstate variability by requiring mobile sources of criteria pollutants either to meet federal standards or to adopt California's more stringent air pollution standards.[244] As a result of these statutory choices, criteria pollutants are regulated via uniform, nationwide ambient air quality standards that address the sources of air pollution rather than exposures to that pollution.

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[235] 42 U.S.C. § 7408(a)(1).
[236] *See* 42 U.S.C. § 7409(b)(1).
[237] EPA maintains an updated table of the NAAQS for criteria pollutants at *NAAQS Table*, U.S. ENV'T PROT. AGENCY (Feb. 10, 2021), https://www.epa.gov/criteria-air-pollutants/naaqs-table.
[238] *See* 42 U.S.C. § 7410(a); *see also* ROWELL & VAN ZEBEN, 2021 (note 92).
[239] Required elements of SIPs include the creation of enforceable emissions limitations and other control measures to meet the NAAQS, air quality monitoring and reporting systems, enforcement mechanisms, and requirements that sources monitor and report to the state. *See* 42 U.S.C. § 7410(a)(2). States are permitted to go beyond these requirements to issue more stringent regulations of air quality, 42 U.S.C. § 7416, but they may not fall below what the Clean Air Act requires. If they do, they risk having their SIP rejected and an FIP issued in its place. *See* 42 U.S.C. § 7410(a)(2). Although a potent threat, EPA rarely exercises its authority to issue FIPs and indeed may only reject an SIP if it fails to meet a listed minimum requirement under § 7410(a)(2). EPA has no authority to review the feasibility of an SIP, and, for example, may not reject the SIP simply because it believes the SIP to be infeasible. *See* Union Elec. Co. v. EPA, 427 U.S. 246 (1976) (holding that EPA is required to review SIPs for the "minimum conditions" set by the Clean Air Act and that it "provides no basis for the EPA Administrator to object … on the ground of infeasibility").
[240] *Compare* 42 U.S.C. §§ 7470–7492 (addressing the standards for New Source Review in areas of attainment under the Prevention of Significant Deterioration regime) *with* 42 U.S.C. §§ 7501–7517 (addressing the standards for New Source Review in areas of nonattainment). *See generally* ROWELL & VAN ZEBEN, 2021 (note 92) (characterizing the difference in the regimes).
[241] *See* 42 U.S.C. § 7411.
[242] *See* 42 U.S.C. §§ 7470–7492 (Prevention of Significant Deterioration regime); 42 U.S.C. §§ 7501–7517 (Nonattainment regime).
[243] *See* 42 U.S.C. §§§ 7521–7590.
[244] *See* 42 U.S.C. § 7543(a) (preempting state standards for mobile sources that are both more and less stringent than federal requirements); 42 U.S.C. § 7543(b) (allowing waiver of preemption for California); 42 U.S.C. § 7507 (allowing states other than California to adopt California's standards under some circumstances).

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While EPA has broad discretion in interpreting ambiguous language within the Clean Air Act,[245] there does not appear to be language in the Clean Air Act that would allow EPA to substitute personal respiratory protection for source control. And indeed, neither EPA nor any state (via SIPs) appear to have ever incorporated public respiratory protection into standards for satisfying the NAAQS.

(3) Regulation of hazardous air pollutants (HAPs)

HAPs are pollutants that are "known or suspected to cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental effects."[246] Congress established an initial list of 189 pollutants, to which EPA has the authority to add; these include substances such as asbestos, benzene, vinyl chloride, and mercury when those substances are airborne.[247]

The approach used to control HAPs differs from the approach the Clean Air Act uses for criteria pollutants. While control of criteria air pollutants relies on the cooperative federalist partnership between the states and EPA, the HAP regime empowers EPA to directly regulate emissions sources of HAPs, on the theory that the dangers posed by inhalation of such pollutants are so severe that they justify more direct federal control.[248]

Under the 1990 Amendments to the Clean Air Act, EPA has two mechanisms for controlling HAP emissions: setting technology-based standards for controlling emissions from HAP sources and implementing a health-based standard as a backstop. The technology-based standard imposes control technology requirements on sources, varying the stringency and type of technology required according to the size and category of the source.[249] Once a floor standard of safety is achieved with these technology-based emissions standards, the administrator is empowered to consider whether "beyond-the-floor" standards are achievable in light of "the cost … and any non-air quality health and environmental impacts and energy requirements."[250]

Finally, and unusually, 8 years after the promulgation of technology-based emission standards, the administrator is required to consider promulgation of a health-based standard to address "residual risks" to address remaining health risks that exist even after the promulgation of the technology-based standard.[251] This health-based standard "shall provide an ample margin of safety to protect public health … unless the Administrator determines that a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect."[252]

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[245] Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–843 (1984).
[246] EPA maintains a wide variety of resources about HAPs at *Hazardous Air Pollutants*, U.S. ENV'T PROT. AGENCY (Apr. 14. 2021), www.epa.gov/haps.
[247] For the list of substances regulated as HAPs, see *Initial List of Hazardous Air Pollutants with Modifications*, U.S. ENV'T PROT. AGENCY (June 18, 2020), https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications.
[248] *See generally* 42 U.S.C. § 7412; *see also* John D. Graham, *The Failure of Agency-Forcing: The Regulation of Airborne Carcinogens Under Section 112 of the Clean Air Act*, 1985 DUKE L.J. 100, 107–08 (1985) (characterizing the HAP regime).
[249] *See* 42 U.S.C. § 7412(d) (setting out the requirements for establishing HAP emissions standards).
[250] *See* 42 U.S.C. § 7412(d)(2).
[251] *See* 42 U.S.C. § 7412(f).
[252] *See* 42 U.S.C. § 7412(f).

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The exact mechanisms through which these standards are supposed to operate is ambiguous, and EPA has struggled to find meaningful ways to enforce them.[253] One of Congress's primary goals in issuing the 1990 Amendments to the Act, in fact, was to encourage EPA to be more active in regulating HAPs.[254] Even after the 1990 Amendments, however, HAPs have generally received lower priority among air pollution policies,[255] and EPA has taken relatively few actions to regulate residual risks.[256] It is clear, however, that residual risk standards are supposed to work as a supplement to the technology-based standards that precede them. As a result, there may be some room for discretion for EPA in considering approaches to HAP control that are based on respiratory protection rather than source control. Indeed, such a program might help EPA as it continues to consider how residual risks of HAPs can be meaningfully managed after technology-based standards have failed to achieve an ample margin of safety to protect public health against HAPs.

(4) EPA's practice regarding the regulation of inhalation hazards from air pollution

The Office of Air and Radiation within EPA is the office responsible for implementing the Clean Air Act and thus the office with primary authority for managing inhalation hazards from air pollution.[257] Most of the Office of Air and Radiation's attention and resources are focused on source control. However, some of EPA's programs also include treatment of or guidance regarding respiratory protection. These include some aspects of EPA action regarding wildfires and indoor air quality. EPA also maintains databases and tools for public communication of hazards from air pollution, including the Air Quality Index (AQI), a tool designed and implemented to communicate air quality to members of the public.

EPA maintains substantial public resources regarding wildfire, including guidance for the public on how to address high levels of wildfire-related air pollution with respiratory protection.[258] For example, EPA has developed an infographic with information on reducing exposure to wildfire-related air pollution, highlighting that "[t]he right respirator and proper fit can reduce your exposure to wildfire smoke."[259] It notes that "[r]espirators are not designed to fit

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[253] For discussions of various controversies and of the initial structural difficulties that led Congress to amend the HAP regime in 1990, see Bradford C. Mank, *What Comes After Technology: Using an "Exceptions Process" to Improve Residual Risk Regulation of Hazardous Air Pollutants*, 13 STAN. ENV'T L.J. 263 (1994); Victor B. Flatt, *Gasping for Breath: The Administrative Flaws of Federal Hazardous Air Pollution Regulation and What We Can Learn from the States*, 34 ECOLOGY L.Q. 107 (2007).

[254] *See* Clean Air Act Amendments of 1990, Pub. L. No. 101-549, 104 Stat. 2399. For a discussion of the history leading up to these amendments, see Mank, 1994, p. 264 (note 253).

[255] *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-669, CLEAN AIR ACT: EPA SHOULD IMPROVE THE MANAGEMENT OF ITS AIR TOXICS PROGRAM (2006) (noting that EPA dedicated only a small portion of its air pollution funding to air toxics program).

[256] Some scholars have criticized both the structure of the residual risk provision, and the implementation of it, on these grounds. *See, e.g.*, Flatt, *2007* (note 253).

[257] *See About the Office of Air and Radiation (OAR)*, U.S. ENV'T PROT. AGENCY (May 20, 2021), https://www.epa.gov/aboutepa/about-office-air-and-radiation-oar.

[258] *See Wildfires*, U.S. ENV'T PROT. AGENCY (Mar. 31, 2021), https://www.epa.gov/natural-disasters/wildfires (collecting EPA's wildfire-related resources and guidance).

[259] *See How to Order the Infographic Card on "Reduce Health Risks in Areas with Wildfire Smoke,"* U.S. ENV'T PROT. AGENCY (Apr. 8, 2019), https://www.epa.gov/air-research/how-order-infographic-card-reduce-health-risks-areas-wildfire-smoke. The infographic advised using "a well-fitted N95 or P100 respirator if you go outside when it is smoky," and gives additional tips about finding an appropriate fit.

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children," and that "[f]acial hair prevents proper fit and reduces effectiveness"[260]—though it does not advise on how to address these challenges. EPA also maintains a downloadable app—the Smoke Sense app—to help members of the public learn about health risks from wildfire smoke in their area, and to advise them to take actions to reduce exposure, such as wearing a well-fitting N95 respirator.[261]

Although EPA has long interpreted its authority under the Clean Air Act to apply only to outdoor air,[262] it has adopted a number of voluntary programs addressing indoor air quality.[263] As part of these projects, EPA has provided consumer information on best practices for remodeling, reducing radon, and advice on adequate and proper ventilation, many of which include advice about public use of respiratory protection.[264] In the COVID-19 pandemic, it has also issued information to the public regarding coronavirus and indoor air.[265]

EPA also maintains the AQI, a color-coded, numerical index of air pollution levels.[266] The index characterizes the health hazards posed by exposure to outdoor air within bands running from "good" air quality (0–50 on the index; "Air quality is satisfactory, and air pollution poses little or no risk") to "hazardous" (301 and higher on the index; "Health warning of emergency conditions: everyone is more likely to be affected").[267] EPA routinely recommends behaviors to the public to reduce exposure based upon the AQI. For example, when air pollution levels are "moderate" (50–100 on the AQI) it recommends that "if you are unusually sensitive to particle pollution, consider reducing your activity level or shorten the amount of time you are active outdoors."[268] However, the AQI tool does not appear to attach respiratory protection

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[260] *See How to Order the Infographic Card* (note 259).
[261] *See Smoke Sense Study: A Citizen Science Project Using a Mobile App*, U.S. ENV'T PROT. AGENCY (May 5, 2021), https://www.epa.gov/air-research/smoke-sense-study-citizen-science-project-using-mobile-app. The app displays concentrations of fine particulate matter and ozone, both affected by wildfires, and includes recommendations about steps citizens can take to reduce their exposure, including wearing an N95 respirator. *See Smoke Sense Study Frequently Asked Questions*, U.S. ENV'T PROT. AGENCY (May 4, 2021), https://www.epa.gov/air-research/smoke-sense-study-frequently-asked-questions. *See also* U.S. ENV'T PROT. AGENCY, *Reduce health risks in areas with wildfire smoke: Follow these tips if someone in your family (including you!) has heart or breathing problems, is an older adult or child, or is pregnant* (advising members of the public "use a well-fitted N95 or P100 respirator if you go outside when it is smoky"), https://www.airnow.gov/sites/default/files/2020-02/reduce-health-risks-with-wildfire-smoke-508.pdf.
[262] *See, e.g.*, U.S. ENV'T PROT. AGENCY, EPA-600/8-87-031, EPA INDOOR AIR QUALITY IMPLEMENTATION PLAN 3 (1987) (noting that the Clean Air Act "gave EPA authority to control a wide variety of air emissions sources and air pollutants that contributed to the degradation of ambient air," which EPA has interpreted "to apply to outdoor air only," and that "the quality of indoor air was not addressed in the law"); 40 C.F.R. § 50.1(e) (2020) ("Ambient air means that portion of the atmosphere, external to buildings, to which the general public has access"). Although this is a long-standing interpretation, it is not clear that this interpretation is mandated by the statutory language. *See, e.g.*, Aagaard, 2011, pp. 269–270 (note 99) (summarizing commentary recommending EPA involvement in indoor air pollution in some circumstances); ARDEN ROWELL & KENWORTHEY BILZ, THE PSYCHOLOGY OF ENVIRONMENTAL LAW 173–74 (2021) (suggesting that psychological factors, rather than statutory mandate, may help to explain EPA's focus on outdoor environments).
[263] *See Indoor Air Quality (IAQ)*, U.S. ENV'T PROT. AGENCY (May 18, 2021), https://www.epa.gov/indoor-air-quality-iaq (summarizing programs and providing guidance).
[264] *See Indoor Air Quality*, 2021 (note 263).
[265] *See Indoor Air and Coronavirus (COVID-19)*, U.S. ENV'T PROT. AGENCY (Apr. 6, 2021), https://www.epa.gov/coronavirus/indoor-air-and-coronavirus-covid-19.
[266] *See Air Quality Index (AQI) Basics*, AIRNOW, https://www.airnow.gov/aqi/aqi-basics (last visited May 24, 2021).
[267] *See Air Quality Index (AQI) Basics*, 2021 (note 266).
[268] *See Air Quality Index (AQI) Basics*, 2021 (note 266).

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recommendations to various AQI levels or to distinguish between the need for respiratory protection for various groups.[269]

Finally, EPA maintains a National Air Toxics Assessment as an ongoing review of air toxics as a screening tool for state and local air agencies and stakeholders to help in identifying which pollutants, emissions sources, and places may generate risk to public health from air toxics.[270]

(5) Characterizing EPA's approach under the Clean Air Act

In one sense, all of the Clean Air Act is dedicated toward addressing inhalation hazards for the public, since the Act is dedicated toward controlling air pollution and is even more specifically dedicated toward addressing the human health and welfare effects of that pollution.[271] EPA generally protects health and welfare by controlling the source of air pollution, however, rather than relying on personal protective equipment. In some cases—as with regulation of sources of criteria pollutants—EPA appears to be locked into this focus on source control via the authority granted in the statute it administers. In other cases—as with residual risk regulation under the HAP regime—EPA could consider whether adding provision of personal protective gear could help it in satisfying some of its statutory obligations. Finally, in part because of its administration of the gargantuan Clean Air Act, EPA has substantial expertise about inhalation hazards, on which it is empowered to build to issue guidance and/or to provide public information.

ii. The Toxic Substances Control Act (TCSA)

TSCA, as amended by the Frank Lautenberg Chemical Safety Act for the 21st Century (Lautenberg Act), is the primary federal statute responsible for addressing the risks of exposure to toxic substances.[272] EPA has broad authority under TSCA to regulate inhalation hazards from public exposure to substances, so long as those substances qualify as "toxic substances" under TSCA. Understanding the extent of EPA's authority in this realm therefore requires both an understanding of EPA's authority under the statute, the general definition of toxic substances under TSCA, and the way that the statute exempts some substances from regulation under TSCA (specifically where those substances are sufficiently regulated under other statutory regimes).

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[269] EPA does provide additional guidance when there are "extremely high levels of PM2.5," which include among other recommendations that "[d]isposable respirators known as N-95 or P-100 respirators will help if you have to be outdoors for a period of time," noting that "[i]t's important that you wear the respirator correctly, however," and providing some resources on fit. *See Extremely High Levels of PM2.5: Steps to Reduce Your Exposure*, AIRNOW, https://www.airnow.gov/aqi/aqi-basics/extremely-high-levels-of-pm25.

[270] *See* U.S. ENV'T PROT. AGENCY, *NATA Overview-National* (Aug. 27, 2018), https://www.epa.gov/national-air-toxics-assessment/nata-overview (collecting past reports); *2014 NATA: Assessment Results*, U.S. ENV'T PROT. AGENCY (Jul. 23, 2020), https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results.

[271] *See, e.g.*, 42 U.S.C. § 7409(b)(1) (requiring NAAQS to be set at levels to "protect the public health"); see also ROWELL & VAN ZEBEN, 2021, pp. 104–116 (note 92).

[272] *See* Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq*., *amended by* the Frank Lautenberg Chemical Safety Act for the 21st Century, Pub. L. No. 114–182, 130 Stat. 448 (2016). For a quick overview of the U.S. approach to regulating toxic substances, see ROWELL & VAN ZEBEN, 2021, PP. 131–137 (note 92); for a more detailed overview of TSCA, see JERRY H. YEN & ALEXANDRA M. WYATT, CONGRESSIONAL RSCH. SERV. SERVICE, R45149, *Title I of the Toxic Substances Control Act (TSCA): A Summary of the Statute* (2018), https://fas.org/sgp/crs/misc/R45149.pdf.

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(1) EPA's authority under TSCA

TSCA is administered by EPA, and directs EPA to regulate chemicals that "present an unreasonable risk of injury to health or the environment,"[273] whether those risks are to workers or to the general public.[274] EPA's authority under TSCA was further expanded in 2016 with an important amendment to TSCA—the Lautenberg Act—which established new standards for identifying how and which substances must be tested for toxicity and which changed the trigger for EPA action under the statute.[275] The amended TSCA requires EPA to gather information regarding potential chemical risks, to prioritize chemicals for risk evaluation based upon the gathered information, and to regulate chemicals that present unreasonable risks to ensure they no longer do so.[276]

Under TSCA, EPA has broad authority to identify the mechanisms that are best-suited to address the risks from exposure to toxic substances.[277] This includes mandating use of respiratory protection, as evidenced by EPA's past use of TSCA to mandate use of respiratory protection against asbestos by workers.[278] As discussed above in the section addressing workplace protections, EPA has coordinated with OSHA in the past to create regulations mandating use of respiratory protection regarding asbestos. [279] While these regulations applied specifically to workplace exposures, TSCA itself does not limit EPA's authority to workplace environments.[280] Indeed, EPA's past coordination with OSHA to apply use protections to state and local workers helps illustrate the broader reach of EPA's authority under TSCA, particularly in comparison to OSHA's reach under the Occupational Safety and Health Act (OSH Act).[281]

(2) Exceptions to TSCA and overlaps with other federal authority

TSCA was originally passed with the intention of filling gaps in EPA's authority left by previous environmental statutes and was thus intended to confer significant authority on EPA to address substances that might otherwise be insufficiently regulated.[282] That said, in passing TSCA, Congress was aware of the possibility of overlap between TSCA and other federal

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[273] *See* 15 U.S.C. § 2605(b)(2)(B).
[274] *See* 15 U.S.C. § 2601 *et seq*.
[275] *See* Frank Lautenberg Chemical Safety Act for the 21st Century, Pub. L. No. 114-182, 130 Stat. 448 (2016); ROWELL & VAN ZEBEN (note 92, p. 133); *see also* Mitchell L. Guc, *Note & Comment: TSCA and the Lautenberg Act: Bloated Regulation, or Effective Legislation?*, 49 U. TOLEDO L. REV. 461 (2018) (comparing the changes of the Lautenberg Act to the prior structure under unamended TSCA).
[276] *See* 15 U.S.C. § 2601 *et seq*.; YEN & WYATT, 2018, p. 203 (note 272).
[277] *See* Part I.B.1.a.i.2.
[278] *See* Part I.B.1.a.i.2.
[279] *See* Part I.B.1.a.i.2.
[280] *See generally* 15 U.S.C. § 2601 *et seq.*
[281] *See* Aagaard, 2011, p. 241 (note 99) (emphasizing the greater expansiveness of EPA's authority in this realm and suggesting that EPA and OSHA's coordination regarding asbestos exposure provides an example of helpful statutory overlaps in authority that allow agencies to fill in what could otherwise be gaps in protection).
[282] *See* COUNCIL ON ENV'T QUALITY, TOXIC SUBSTANCES (1971), *as reprinted in* ENV'T & NAT. RES. POL'Y DIV., LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT 759–762 (1976) (providing the Council on Environmental Quality's conclusion that toxic substances were entering the environment, that then-existing legal authority was insufficient to handle the risks of toxic substances the risks of toxic substances justified direct regulation); *see also* David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 WASH U.J.L. & POL'Y 333 (2010); YEN & WYATT, 2018, p. 2 (note 272) (explaining that TSCA was passed by Congress after the Council on Environmental Quality's report).

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laws.[283] To balance this concern with the goal of protecting the public from the risks associated with toxic substances, the statute allows EPA to defer to another agency if the administrator of EPA believes that a law administered by the other agency could be used to prevent or sufficiently reduce an unreasonable risk to health or the environment presented by a chemical substance or mixture.[284] For example, in 1985, EPA referred 1,3-butadiene to OSHA when it found that exposure to the substance posed an unreasonable risk, but one that could be dealt with effectively within workplace safety standards.[285] In addition, substances that are already regulated by other federal authorities or under other statutes, such as food and pesticides, are excluded from regulation under TSCA.[286] Section 9 of TSCA also contains a number of exemptions for otherwise-toxic substances when those substances are managed under other regulatory schemes.[287]

(3) Other statutes administered by EPA

EPA administers a long list of environmental statutes,[288] including—in addition to the Clean Air Act and TSCA—the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA);[289] the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA);[290] and the Emergency Planning and Community Right-to-Know Act (EPCRA).[291] These statutes give EPA authority over a wide range of environmental issues, including regarding some environmental inhalation hazards.

EPA actions under these statutes may sometimes inform public use of respiratory protection. That said, the statutes generally rely on mechanisms other than respiratory protection—particularly source control—to address environmental (including inhalation) hazards. The EPCRA, for example, requires EPA to maintain a Toxics Release Inventory to inform the public about the emissions (including air emissions) of highly dangerous chemicals.[292] Members of the public might theoretically use this information to seek respiratory

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[283] *See* S. REP. NO. 94-698, at 13 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4513 ("SECTION 9 -- RELATIONSHIP TO OTHER LAWS. This section is intended to minimize overlap and duplication between this act and other Federal laws while assuring protection from environmental and health dangers"); *see also* 15 U.S.C. § 2608.

[284] *See* 15 U.S.C. § 2608.

[285] *See* 1,3-Butadiene; Decision to Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 41,393 (October 1, 1985). OSHA then regulated 1,3,-butadiene to address the unreasonable risks that EPA had identified and referred. Occupational Exposure to 1,3-Butadiene, 51 Fed. Reg. 35,003 (October 1, 1986) (to be codified at 29 C.F.R. pt. 1910).

[286] *See* 15 U.S.C. § §2602(2)(B) (excluding already regulated substances, even where otherwise toxic, including pesticides, tobacco, firearms, food, drugs, cosmetics, and medical devices). *See also* Aagaard, 2011 (note 99) (discussing EPA/OSHA coordination on 1,3-butadiene).

[287] *See generally* 15 U.S.C. § 2608 ("Relationship to Other Federal Laws"); MIRIAM V. GOLD & JEAN WARSHAW, Guide to the Toxic Substances Control Act § 2.04 (2020) (summarizing TSCA's relationship with other statutes, including the requirement to impose the least burden of duplicative environments, as well as a variety of exceptions that apply); *see also* 15 U.S.C. § 2602(2)(B).

[288] *See* EPA, *Laws and Executive Orders*, https://www.epa.gov/laws-regulations/laws-and-executive-orders.

[289] *See* Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y.

[290] *See* Comprehensive Environmental Compensation and Liability Act (CERCLA), 42 U.S.C. §§ 9601–9675.

[291] *See* Emergency Planning and Community Right-to-Know Act, 42 U.S.C. §§ 11001–11050.

[292] *See* Emergency Planning and Community Right-to-Know Act, 42 U.S.C. §§ 11001–11050; *see also* Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. § 9603 (requiring disclosure of emission of any reportable quantity of a hazardous substance, including into the ambient air); *see also* EPA,

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protection where needed, though it does not appear that EPA provides explicit guidance to that effect, either to individuals or to communities.[293]

Other connections between EPA authority and public respiratory protection seem somewhat tangential. For example, FIFRA allows EPA to determine which pesticides are beneficial enough (given the risks they pose) to be sold in U.S. commerce.[294] To determine whether or not a pesticide's risks outweigh its benefits, the agency may take account of public welfare and public exposures to the pesticide (which might theoretically be affected by personal protective equipment use, although no such consideration is mandated by the statute). In administering this statute, EPA is responsible for administering a worker protection program in regards to pesticides, which mandates respiratory protection, as discussed above, [295] though it does not appear to administer any similar system for respiratory protection for consumer users of pesticides.

(4) Characterizing EPA's approach under TSCA

EPA is the primary authority for regulating inhalation hazards from environmental sources and has collected substantial expertise regarding exposure and hazards presented by various air pollutants and toxic substances.

EPA's approach to regulating inhalation hazards facing the public has thus far varied under the differing statutes it administers. That said, there appears to be no centralized program within EPA for addressing public respiratory protection against environmental hazards. Instead, EPA has issued a variety of guidance under various statutory regimes, via several of its many divisions, regarding different respiratory hazards.

Recommendations to EPA regarding its regulation of inhalation hazards, and use of respiratory protection, are most likely to be effective where they target matters over which EPA has discretion. Such recommendations might address, for example, expanding guidelines for public respiratory protection, for example, those EPA makes as part of its AirNow/AQI program. In some cases, further consideration of the possibility of encouraging respiratory protection as a backstop to source control might even help EPA in addressing long-term statutory puzzles, such as how to best implement the requirements of the health-based residual risk backstop in the HAP regime.

Where the Committee believes that the statutes empowering EPA should be amended, it should direct its commentary toward Congress. For example, if the Committee believed that EPA should be permitted to consider respiratory protection as a backstop to source control of criteria

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CERCLA and EPCRA Continuous Release Reporting, https://www.epa.gov/epcra/cercla-and-epcra-continuous-release-reporting (describing the similarities and overlaps between CERCLA and EPCRA hazardous release reporting requirements).

[293] *See, e.g.*, *How to Better Prepare your Community for a Chemical Emergency: A Guide for State, Tribal and Local Agencies* (November 2017), https://www.epa.gov/sites/production/files/2015-07/documents/state_tribal_local_guide_factsheet_7-10-2015_2.pdf (providing updated guidance for communities performing emergency planning requirements under EPCRA, without mentioning personal protective equipment or respirators as mechanisms for emergency planning).

[294] *See generally* 7 U.S.C. §§ 135–136y. FIFRA requires that registered pesticides not cause "any unreasonable adverse effects on man or the environment," "taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

[295] *See* Part I.A.1.c.i.2.a.

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pollutants, such a change would need to be made to the underlying statute and could not be implemented via agency action alone.

b. The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS)

This section summarizes CDC's role in regulating the use of respiratory protection by the public. It identifies the general structure and authority of CDC, including divisions within CDC that serve important functions in regards to respiratory protection against some hazards, and summarizes CDC's current approach to regulating public use of respiratory protection.

i. CDC's statutory authority regarding inhalation hazards and public health

CDC is a national public health agency whose mission is to "serve[] as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States."[296] This mission is situated within the general public health goals set out in the Public Health Service Act, which authorizes the secretary of HHS—of which CDC is part—to "conduct in the [Public Health] Service … research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental disease and impairments of man."[297]

Although CDC is not restricted to dealing with public inhalation hazards, its authority bears on the regulation of those hazards in two important ways. First, CDC has a number of direct responsibilities relating to the control of infectious disease, as well as the authority to implement its recommendations regarding the spread of infectious disease. In some cases, such recommendations may bear on respiratory protection. Second, various agencies within CDC—including NIOSH, the National Center for Environmental Health (NCEH), and the Agency for Toxic Substances and Disease Registry (ATSDR)—play more specific roles in regulating public inhalation hazards.

(1) CDC's role in public respiratory protection

Over the years, CDC has issued a variety of guidance and public information designed to communicate with the public about its use of respiratory protection. For example, it has issued significant information for members of the public entering homes that have been flooded, to help in mitigating the hazards posed by mold inhalation.[298] This information includes recommendations about the use of respirators.[299]

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[296] CTRS. FOR DISEASE CONTROL & PREVENTION, *CDC Mission Statement,* https://www.cdc.gov/about/organization/cio-orgcharts/pdfs/CDCfs-508.pdf (May 25, 2021); *see also Mission, Role and Pledge*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 13, 2019), https://www.cdc.gov/about/organization/mission.htm.

[297] 42 U.S.C. § 241(a).

[298] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *Respiratory Protection for Residents Reentering and/or Cleaning Homes That Were Flooded* (Jan. 29, 2019), https://www.cdc.gov/disasters/disease/respiratory.html.

[299] *See, e.g.*, CTRS. FOR DISEASE CONTROL & PREVENTION, *What to Wear Before Entering a Home or Building with Mold Damage*, https://www.cdc.gov/mold/pdfs/What_to_Wear_Mold_Damage_Oct5_508c.pdf (recommending an "N-95 respirator or one that provides even more protection [check packaging for 'N-95']").

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In addition to its general responsibilities as a national public health agency, CDC has particular authority regarding inhalation hazards posed by infectious disease.[300] For example, CDC is authorized to take measures to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one state to another.[301] These activities address inhalation hazards from communicable respiratory diseases, such as the coronavirus pandemic.

CDC has taken a number of specific actions regarding the inhalation hazards posed by coronavirus during the pandemic. For example, pursuant to its statutory authority regarding control of infectious disease in interstate travel,[302] it issued an emergency action requiring the use of face masks on public transportation conveyances and at transportation hubs.[303]

(2) Role of agencies within CDC

A number of agencies exist within CDC that also take actions relevant to protection of the public from inhalation hazards. These include NIOSH, whose statutory responsibilities are directed toward occupational safety and health but which still takes some actions related to respiratory protection for the public, and NCEH/ATSDR, which plays a role in researching and coordinating response to environmental hazards.

a. The National Institute for Occupational Safety and Health (NIOSH)

NIOSH is an agency within CDC. While NIOSH operates within CDC, however, it is primarily empowered via the OSH Act, as discussed in more detail above.[304]

The statutory authority of NIOSH, which was created under the OSH Act, is directed toward workers rather than the public.[305] Indeed, NIOSH's mission, goals, and objectives are limited to occupational settings.[306] Notably, and consistently with this limitation, NIOSH's certification systems—such as those implemented by the National Personal Protective Laboratory (NPPTL)—are directed toward researching and evaluating respirator protection for workers, rather than toward researching and evaluating respiratory protection for the general public.[307]

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[300] *See, e.g.*, 42 U.S.C. §§ 300hh–32 (authorizing the director of CDC to enter into agreements with health departments to increase the prevention of and response to vector-borne diseases).
[301] *See* 42 U.S.C. § 264. The Act grants this authority to the secretary of the Department of Health and Human Services, which has delegated it to CDC. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *Legal Authorities for Isolation and Quarantine* (Feb. 24, 2020), https://www.cdc.gov/quarantine/aboutlawsregulationsquarantineisolation.html.
[302] *See* Public Health Service Act, 42 U.S.C. § 264; *see also* 42 C.F.R. § 70.2, 71.31(b); 71.32(b) (2020); Ctrs. For Disease Control & Prevention, Requirement for Persons to Wear Masks While on Conveyances and at Transportation Hubs, 86 Fed. Reg. 8,025 (Feb. 3, 2021).
[303] *See* Order Requiring Persons to Wear Masks, 86 Fed. Reg. at 8025, https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC_GMTF_01-29-21-p.pdf.
[304] *See* Part I.A.1.b.i.
[305] *See* 29 U.S.C. § 671(c) (authorizing NIOSH to recommend "occupational" safety and health standards, and imbuing NIOSH with research authority regarding occupational and employee education matters).
[306] *See* 29 U.S.C. § 671(c); *see also About NIOSH*, 2018 (note 72) (emphasizing NIOSH's occupational mission, goals, and objectives).
[307] *See* Part I.A.2.a.ii.

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Despite its general lack of statutory mandate regarding public safety and health, NIOSH and its division of NPPTL have taken a number of voluntary actions drawing upon their expertise and directed toward public protection from respiratory hazards.

Some of these actions are part of NIOSH's general research function and/or operate as an extension of NIOSH's occupational functions. For example, NIOSH maintains a list of which respirators are approved by NIOSH, how to get them, and how to use them;[308] this list is available to members of the public seeking respirators for personal use, as well as to employers and employees seeking them for occupational use.

Other actions have been undertaken during or in response to public emergencies. For example, NIOSH developed a program to respond to the respiratory hazards presented by the terrorist attacks of September 11, 2001, focusing on the respiratory hazards and needs of first responders regarding chemical, biological, radiological, and nuclear agents, and has been granted special statutory authority to provide special programs to support health and safety research for World Trade Center survivors (including members of the public).[309]

Finally, and as discussed further subsequently,[310] NIOSH/NPPTL's respirator certification program for occupational safety and health is routinely used as a touchstone for other agencies when they are making recommendations to the public about respiratory safety and health.

b. The National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry (NCEH/ATSDR)

NCEH and ATSDR are both agencies situated within CDC. Although each have specific roles to play in regards to protection from inhalation hazards, the two agencies often act together and in fact are currently headed by a single director.[311]

NCEH is a research agency within CDC that is responsible for researching, directing, and coordinating protection from environmental hazards.[312] It performs and coordinates applied research on a number of environmental hazards, including inhalation hazards; engages in public communication and education; and takes part in public health emergency training.[313]

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[308] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *Respirator Trusted-Source Information* (Apr. 9, 2020), https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/RespSource.html.

[309] *See* NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, No. 2018-143, *NIOSH, World Trade Center Health Program* (July 2018), https://www.cdc.gov/niosh/docs/2018-143/pdfs/2018-143.pdf?id=10.26616/NIOSHPUB2018143; *see also* James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, 124 Stat. 3623 (2011) (codified in scattered sections of 42 U.S.C.) (creating the World Trade Center Health Program as a division within NIOSH and directing it to address the health and safety of World Trade Center survivors).

[310] *See* Part I.B.2.c.

[311] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *National Center for Environmental Health/Agency for Toxic Substances and Disease Registry* (Apr. 1, 2019), https://www.cdc.gov/about/leadership/leaders/ncehatsdr.html.

[312] *See National Center for Environmental Health*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 10, 2021), https://www.cdc.gov/nceh.

[313] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *About NCEH* (Apr. 22, 2021), https://www.cdc.gov/nceh/information/about.htm.

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ATSDR was created to implement the health-related sections of laws that protect the public from hazardous wastes and environmental substances.[314] It is responsible for protecting communities from harmful health effects from exposure to toxic substances.[315]

NCEH/ATSDR often collaborate with other agencies, particularly EPA, in drafting guidance documents on respiratory protection,[316] as well as in evaluating and addressing the hazards posed by hazardous wastes and chemical substances. ATSDR in particular has a set of statutory responsibilities stemming from the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and the Resource Conservation and Recovery Act of 1976 (RCRA), both administered by EPA, which require ATSDR to assist EPA in determining which substances should be regulated and the levels at which substances (including inhaled substances) may pose a threat to human health.[317]

In combination, NCEH/ATSDR establish a significant reservoir of expertise regarding the health impacts of respiratory and other environmental hazards within CDC. Notably, these agencies—unlike NIOSH—are focused on health hazards to the public. Currently, there does not appear to be a division of NCEH/ATSDR that works as a corollary to NPPTL in NIOSH.

c. The Federal Emergency Management Agency (FEMA)

FEMA is the federal agency responsible for managing critical response to national emergencies. FEMA's authority is unusual among federal agencies because it is tied to emergencies, and thus tends to be both time- and subject-limited. That said, during emergencies, FEMA has substantial and broad-ranging authority that can apply to the approval, marketing, surveillance, and provision of respiratory protection. Emergencies that can trigger FEMA's authority include natural hazards—such as wildfires and floods—which can generate respiratory hazards (such as particulate matter and mold).[318] Other specific types of disaster—most notably radiological disaster[319]—trigger special responsibilities by other agencies.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) identifies FEMA's statutory authority for most federal disaster response activities, as well as establishing the presidential disaster declaration process.[320] Under the Stafford Act, FEMA is

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[314] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *ATSDR Background and Congressional Mandates* (July 5, 2018), https://www.atsdr.cdc.gov/about/congress.html; *see also* Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 U.S.C. §§ 9601–9675; RCRA of 1976, 42 U.S.C. §§ 6901–6992 (as amended).

[315] See *ATSDR Background and Congressional Mandates* (note 314).

[316] *See, e.g.*, U.S. ENV'TL PROT. AGENCY, EPA-452/R-19-901, *Wildfire Smoke: A Guide for Public Health Officials* (2019), https://www.airnow.gov/sites/default/files/2021-05/wildfire-smoke-guide-revised-2019.pdf.

[317] *See ATSDR Background and Congressional Mandates* (note 314).

[318] *See ATSDR Background and Congressional Mandates* (note 314); *see also* Post-Katrina Emergency Management Reform Act of 2006, Pub. L. No. 109-295, 120 Stat. 1394 (codified in scattered sections of 5, 6 & 42 U.S.C.) (expanding FEMA's authority in providing post-disaster support); Disaster Recovery Reform Act of 2018, Pub. L. No. 115-254, 132 Stat. 3438 (codified at 6 U.S.C. § 748 and scattered sections of 42 U.S.C.) (emphasizing FEMA's role in addressing wildfire and hurricane risk).

[319] *See* U.S. DEP'T OF HOMELAND SEC., 2016 (note 212) (describing the policies, situations, and responsibilities of federal agencies in response to incidents involving release of radioactive materials). As per that plan, the Department of Defense, Department of Energy, Department of Homeland Security, EPA, National Aeronautics and Space Administration, and Nuclear Regulatory Commission are designated a coordinating role.

[320] *See* Robert T. Stafford Disaster Relief and Emergency Assistance Act ("Stafford Act"), 42 U.S.C. § 4121 *et seq*.; Disaster Mitigation Act of 2000, 42 U.S.C. § 5121 *et seq*. (amending the Stafford Act and providing incentives for states to develop their own pre-disaster mitigation plans).

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empowered to coordinate national response and to assist state and local governments during "natural catastrophes." As noted below, FEMA also has responsibilities in the case of invocation of the Defense Production Act (DPA).[321]

FEMA has issued a series of temporary final rules attempting to manage the distribution and availability of personal protective gear during the COVID-19 pandemic.[322] These rules limit, for example, the export of health and medical resources, including respirators, without FEMA's consent.[323] As part of its response to the COVID-19 pandemic, FEMA has also issued an interim final rule to establish an "Emergency Management Priorities and Allocations System" (EMPAS), to establish procedures for FEMA to allocate materials, services, and facilities during emergencies, and for deciding which orders and contracts (e.g., of respirators) to prioritize over others.[324] For example, in May 2020, during the early coronavirus pandemic, FEMA sent personal protective equipment (PPE), including cloth masks, to nursing homes around the country.[325] In issuing the distribution order, FEMA cited "the critical need for PPE at nursing homes where some of our Nation's most vulnerable residents live"[326]; in this sense, FEMA's allocations were justified by concern over public, rather than (just) workplace, safety.

d. Other authorities

This section identifies the roles of other important authorities in regulating the use of respiratory protection by the public. It identifies additional federal agencies that participate in regulating respirator use, as well as state and local actors with important authority.

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[321] *See* Part I.B.3.

[322] *See* FED. EMERGENCY MGMT. AGENCY, Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, 85 Fed. Reg. 20,195 (April 10, 2020); *as amended at* 85 Fed. Reg. 22,021 (April 21, 2020) (providing several exceptions); 85 Fed. Reg. 48,113 (August 10, 2020) (modifying and extending the limitations on export); 85 Fed. Reg. 86,835 (December 31, 2020) (modifying and extending the limitations on export to June 30, 2021).

[323] *See* Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, 85 Fed. Reg. at 20,197 (banning unapproved export of N95 Filtering Facepiece Respirators and other filtering facepiece respirators, as well as surgical masks); Prioritization and Allocation of Certain Scarce and Critical Health and Medical Resources for Domestic Use, 85 Fed. Reg. 86,835, 86,839 (Dec. 31, 2020) (continuing ban on unapproved export of N95 respirators, as well as surgical masks). Currently that order holds through June 30, 2021, unless it is affirmatively modified by the administrator of FEMA. *See* Prioritization and Allocation of Certain Scarce and Critical Health and Medical Resources for Domestic Use, 85 Fed. Reg. at 86,836.

[324] *See* Emergency Management Priorities and Allocation System (EMPAS), 85 Fed. Reg. 28,500 (May 13, 2020).

[325] *See* Press Release, FED. EMERGENCY MGMT. AGENCY, Coronavirus Pandemic Response: PPE Packages for Nursing Homes (May 2, 2020), https://www.fema.gov/news-release/2020/05/02/coronavirus-pandemic-response-ppe-packages-nursing-homes. FEMA's response during this period was criticized along several parameters, *see, e.g.*, Andrew Jacobs, *FEMA Sends Faulty Protective Gear to Nursing Homes Battling Virus*, N.Y. TIMES (July 28, 2020), https://nyti.ms/3jCcb49 (suggesting that FEMA-provided gear was insufficient and faulty). Nevertheless, there was general consensus that FEMA had the authority to provide PPE, including masks and respirators, in emergency situations.

[326] *See* Press Release, FED. EMERGENCY MGMT. AGENCY, Coronavirus Pandemic Response: PPE Packages for Nursing Homes (May 2, 2020), https://www.fema.gov/news-release/2020/05/02/coronavirus-pandemic-response-ppe-packages-nursing-homes.

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i. Other federal authorities

As noted above, there appears to be no comprehensive accounting for all the federal agencies whose responsibilities extend to respiratory protection for the public against inhalation hazards. Agencies with at least some authority over some inhalation hazards would include agencies whose statutory authority extends to methods of public conveyance, including divisions of the Department of Transportation, such as the Federal Aviation Administration[327]; and agencies that have authority over particular inhalation hazards, such as the Nuclear Regulatory Commission's responsibilities regarding nuclear hazards.[328] Other agencies provide information that is used by the public in identifying which respiratory protection to use; OSHA's Safety and Health Information Bulletins on respiratory protection, for example, are sometimes recommended to members of the public seeking respiratory protection.[329] Still others recommend the use of respiratory protection under some circumstances; for example, the Consumer Product Safety Commission (CPSC) recommends respirator use to the public when using hazardous products, though it typically refers back to OSHA standards and NIOSH certification when making those recommendations.[330]

In addition, in the absence of legislation creating a comprehensive system for public respiratory protection, the executive branch has substantial authority to issue "gap-filling" enforcement and executive actions to require respiratory protection for the public in those areas where there is federal jurisdiction. During the recent pandemic, this authority has been used to create "mask mandates" on federal properties that apply to members of the public.[331]

ii. State and local authorities

Generally speaking, in the absence of a coherent federal regime addressing public respiratory protection, significant authority is left to the states to create and administer schemes for assuring adequate public protection. While the approach of states varies, two legal approaches to achieving such protection are particularly worth flagging: state regulations that attempt to proactively regulate and/or oversee respiratory protection for the public, and judicial liability regimes—particularly in tort—that affect liability of manufacturers and sellers of

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[327] *See, e.g.*, Northwest Airlines, 8 BNA OSHC 1982 (No. 13649, 1980) (holding that preemption applies to airline maintenance workers because they are within the class of persons intended to be protected under the Federal Aviation Act); *see also* U.S. DEP'T OF TRANSP., FED. AVIATION ADMIN., *COVID-19: Updated Interim Occupational Health and Safety Guidance for Air Carriers and Crews*, https://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo/all_safos/media/2020/SAFO20009.pdf.

[328] *See, e.g.*, U.S. DEP'T OF HOMELAND SEC., 2016 (note 212) (describing the Nuclear Regulatory Commission's role in relation to nuclear hazards).

[329] *See, e.g.*, *Respiratory Protection for Residents Reentering and/or Cleaning Homes That Were Flooded*, 2019 (note 298) (recommending members of the public refer to OSHA's general respiratory protection guidance to identify "more information about using respirators" in entering moldy homes).

[330] *See* U.S. CONSUMER PROD. SAFETY COMM'N, *Coronavirus Disease (COVID-19) Related Products Business Guidance*, https://www.cpsc.gov/COVID-19 (last visited May 26, 2021) (summarizing the CPSC's current regulation of respiratory protective devices, including face coverings, surgical masks, N95 respirators, face shields, and industrial face masks).

[331] *See* Exec. Order No. 13,991, 86 Fed. Reg. 7045 (Jan. 25, 2021); *see also* 5 U.S.C. § 7902(c) (explicitly authorizing the President to undertake measures s/he considers proper to prevent injuries and accidents to agency employees).

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respiratory protection, and which thus may influence the development and availability of respiratory protection for public use.

(1) Proactive regulatory regimes

States may choose to address respiratory protection for the public via proactive regulatory regimes, when those regimes have not been preempted by comprehensive federal action. Variation in state laws addressing public respiratory protection have been particularly salient during the coronavirus pandemic. While no state has issued public mandates for respirators—that is, respiratory protection that would protect wearers from airborne infection—many states have issued "mask mandates" requiring face covering.[332] The specific requirements, duration, and enforcement of these mandates has varied by state.[333] Generally speaking, however, management of source control through mask mandates is legally justified by states' "police power," which gives them authority over matters of general public safety,[334] and by states' authority to declare and enforce quarantine within their borders.[335] Such power is particularly broad where, as is the case with the coronavirus pandemic, no federal action (such as action by the surgeon general to "prevent the introduction, transmission, or spread of communicable diseases from … one State or possession into another State or possession"[336]) preempts state authority on communicable diseases.[337] And indeed, despite federal authority to intervene in quarantine matters where

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[332] *See* Gery P. Guy, Jr., *et al.*, *Association of State-Issued Mask Mandates and Allowing On-Premises Restaurant Dining with County-Level COVID-19 Case and Death Growth Rates—United States, March 1-December 31, 2020*, 70 MORBIDITY AND MORTALITY WEEKLY REPORT 350-354 (March 12, 2021) (reporting that 38 states and the District of Columbia issued mask mandates during 2020), https://www.cdc.gov/mmwr/volumes/70/wr/mm7010e3.htm.

[333] State mandates are changing daily at time of writing. *See* NBC News, *Mask tracker: Does your state still require face masks?*, https://www.nbcnews.com/news/us-news/map-mask-mandate-tracker-2021-n1269023 (indicating 31 states with some form of mask mandate as of June 5, 2021).

[334] *See* Edward P. Richards, *A Historical Review of the State Police Powers and Their Relevance to the COVID-19 Pandemic of 2020*, 11 J. NAT'L SECURITY L. & POL'Y 83 (discussing the constitutional basis for states' broad-ranging police powers in the context of a pandemic); *see also* Lawrence O. Gostin, *The Model State Emergency Health Powers Act: Public Health and Civil Liberties in a Time of Terrorism*, 13 HEALTH MATRIX 3, 24 (2003) ("The Supreme Court has made clear that states have a deep reservoir of public health powers, conceiving of state police powers as an 'immense mass of legislation in which inspection laws, quarantine laws, and health laws of every description … are components of this mass'") (quoting Gibbons v. Ogden, 22 U.S. 1, 203 [1824]); Stephanie Cooper Blum, *Federalism: Fault or Feature – An Analysis of Whether the United States Should Implement a Federal Pandemic Statute*, 60 WASHBURN L.J. 1, 22 (analyzing state authority to take action against communicable diseases, including via mask mandates); Emily Berman, *Who's in Charge? The Roles of the State and Federal Governments in a Pandemic*, 11 J. NAT'L SECURITY L. & POL'Y 61 (2020).

[335] States' authority in public health emergencies varies significantly with state law, but most states authorize the governor or other state officials to promulgate health orders designed to stop the spread of contagious diseases. *See* Blum, pp. 22–23 (note 334) (discussing varying state law); Jeff Thaler, *The Next Surges are Here: What Can American Governments Lawfully Do in Response to the Ongoing Covid-19 Pandemic?* 42 MITCHELL HAMLINE L.J. PUB. POL'Y & PRAC. 165 (2021) (analyzing the extent of federal and state authority in this realm); *see also* Public Health Service Act, 42 U.S.C. § 264 (describing federal and state authority in quarantine for communicable diseases).

[336] *See* 42 U.S.C. § 264(a) (authorizing the surgeon general, with the approval of the secretary of HHS, to "make and enforce such regulations as in his judgment are necessary" to prevent such spread); *see also* § 264(e) (indicating that, absent such federal action, State law applies).

[337] *See* Blum, pp. 22–28 (note 334) (discussing state authority in the coronavirus pandemic in light of federal [in]action).

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required to address spread of communicable disease, CDC has a history of deferring to state and local health authorities in their use of quarantine powers regarding communicable diseases.[338]

States and local authorities, such as counties and municipalities, also play an important role in emergency planning, including as required under the Emergency Planning and Community Right-to-Know Act,[339] though such requirements do not currently appear to extend to provision of or advice regarding respiratory protection.[340]

(2) Liability regimes

In addition to prospective regulatory frameworks above, an additional legal factor that may affect the use and availability of respirators for the public is retroactive liability in tort. Torts are civil wrongs, and can arise when a wrong by one person or company causes harm to another.[341] Torts generally arise out of state law, and are often adjudicated in state courts.[342] In some cases, specific rules in tort have been codified by state legislators via state statutes.[343] In most cases, however, tort law has been created via judge-made common law, which has developed over decades of case law and through the creation of judicial precedent.[344]

In environmental and public health contexts, tort law acts as a backstop for the types of proactive regulatory standards that this paper has discussed thus far.[345] It provides an additional set of incentives for manufacturers and sellers of respirators and other protective gear, and thus forms a part of the regulatory landscape that can affect what actions firms and individuals take in

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[338] *See* CDC, *Notice: Severe Acute Respiratory Syndrome* (January 20, 2004) (explaining CDC's general approach to managing the spread of Severe Acute Respiratory Syndrome [SARS], noting that "[i]n general, HHS defers to state and local health authorities in the primary use of their separate quarantine powers. Based on long experience and collaborative working relationships with our state and local partners, CDC anticipates that the need to use this federal authority to actually quarantine a person will occur only in rare situations, such as events at ports of entry or other time-sensitive settings"), https://www.cdc.gov/sars/quarantine/fs-isolation.pdf; *see also* Blum, pp. 22–25 (note 334) (discussing federal and state authority over quarantine and related actions).

[339] *See* Emergency Planning and Community Right-to-Know Act, 42 U.S.C. §§ 11001–11050.

[340] *See* Emergency Planning and Community Right-to-Know Act, 42 U.S.C. §§ 11001–11050; *see also* Part I.B.1.a.i.(3).

[341] *See Tort,* BLACK'S LAW DICTIONARY (9th ed. 2009) (defining "tort" as a civil wrong, other than breach of contract, for which a remedy may be obtained).

[342] *See, e.g.*, DAN B. DOBBS, THE LAW OF TORTS 39 (2000) ("The common law of torts is almost exclusively state law."); *see also* Barbara Kritchevsky, *Tort Law is State Law: Why Courts Should Distinguish State and Federal Law in Negligence-Per-Se Litigation*, 60 AM. U. L. REV. 71 (2010) (discussing the relationship between state and federal tort law).

[343] *See, e.g.*, Ind. Code Ann. §§ 34-6-2-29 to 34-20-9-1 (West 2011 & Supp. 2012) (specifying the rules governing all actions brought by a user against a manufacturer or seller for physical harm caused by a product); *see also* Mark A. Geistfeld, *Torts in the Age of Statutes*, 99 IOWA L. REV. 957 (2014) (discussing the relationships between tort law and statutory law).

[344] *See generally* OLIVER WENDELL HOLMES, THE COMMON LAW 77-163 (1881).

[345] *See* Thomas O. McGarity, *The Regulation-Common Law Feedback Loop in Nonpreemptive Regimes*, IN PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION 235 (William W. Buzbee ed. 2008) (describing common law liability as a potential "backstop" for regulatory regimes); *see also* Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357 (1984) (comparing the operation of proactive regulatory regimes with retroactive liability regimes); Mark Latham, Victor E. Schwartz & Christopher E. Appel, *The Intersection of Tort and Environmental Law: Where the Twains Should Meet and Depart*, 80 FORDHAM L. REV. 737 (examining the interactions of environmental regulation and tort law).

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regards to manufacturing, selling, and marketing respiratory protection to the public.[346]

Different kind of torts recognize different kinds of wrongs that people can do to one another. Two types of torts with potential impact on the design, manufacture, and sale of respirators to the public are products liability and fraud. Fraud is discussed in more detail in the subsequent subsection, as it bears particularly on state law oversight of respiratory protection.[347]

Products liability is an area of law that seeks to ensure that products are reasonably safe.[348] Products liability is "strict," in that product designs or manufacturing defects that cause people harm trigger liability for any damage that is caused.[349] As a result, in many cases, designers, manufacturers, and sellers of protective gear, including respirators, can be liable in products liability if their products cause harm to others—even if the product was designed and manufactured according to regulatory standards such as those set by NIOSH for N95 respirators.[350]

There is ongoing scholarly debate over whether stringent state liability regimes promote or deter the safe manufacture and sale of protective devices.[351] In some cases, scholars have suggested that robust state products liability regimes could stymie innovation and availability of public respiratory protection, and/or that existing judicial doctrines of preemption—which thus far have generally[352] allowed for state tort claims in products liability even where the product otherwise complies with product safety statutes or administrative regulations[353]—should be reconsidered in the case of respiratory protection.[354] Thus far, however, tort liability remains a

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[346] *See* note 345; *see also* Victor E. Schwartz, Cary Silverman and Christopher E. Appel, *Respirators to the Rescue: Why Tort Law Should Encourage, Not Deter, the Manufacture of Products that Make Us Safer*, 33 AM. J. TRIAL ADVOC. 13, 27-53 (2009) (reviewing tort liability regarding respirators and other personal protective gear).

[347] *See* Part I.B.2.d.(ii).

[348] *See generally* VICTOR E. SCHWARTZ ET AL., *Prosser, Wade and Schwartz's Torts* 737 (12th ed., 2010).

[349] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1998) (explaining that liability attaches to anyone "engaged in the business of selling or otherwise distributing products" for harm caused by "a defective product," and defining defective products as falling into one of three categories: (1) a "manufacturing defect" that occurs when the product "departs from its intended design"; (2) a design defect that results "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design … and the omission of the alternative design renders the product not reasonably safe"; or (3) a warning defect that occurs "because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings … and the omission of the instructions or warnings renders the product not reasonably safe").

[350] *See* Victor E. Schwartz, Cary Silverman and Christopher E. Appel, *Respirators to the Rescue: Why Tort Law Should Encourage, Not Deter, the Manufacture of Products that Make Us Safer*, 33 AM. J. TRIAL ADVOC. 13, 27-53 (2009) (reviewing tort liability regarding respirators and other personal protective gear).

[351] *See, e.g.*, Schwartz et al., 2009, pp. 53–68 (note 348) (arguing that existing federal oversight at NIOSH is sufficient to ensure that respirators are safe enough for public use).

[352] One particularly difficult puzzle relates to potential state products liability claims for respirators that qualify as "medical devices." Products that constitute medical devices are subject to broader claims of federal preemption than other consumer products. *See Federal Preemption of State Common-Law Products Liability Claims Pertaining to Medical Devices, Implants, and Other Health-Related Items*, 74 A.L.R. Fed. 2d 1. As a result, where respiratory protective gear constitutes a medical device—as discussed further in Part I.B.2.a—common law liability in products liability may be preempted.

[353] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 (b) (note 349). Note, however, that the question of how much and when federal law preempts state products liability remains somewhat ambiguous and a topic of scholarly debate. *See* Mark A. Geistfeld, *Torts in the Age of Statutes*, 99 IOWA L. REV. 957, 1004 (noting that "[o]ne area of the law in which the doctrine of preemption has been especially difficult to interpret has been tort law, and particularly products liability law").

[354] *See* Schwartz et al., 2009, pp. 59–68 (note 348).

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possible concern for product designers, manufacturers, and sellers, even where respirators sold comply with existing federal regulations.

e. Characterizing nonoccupational use

There is no single federal entity responsible for regulating the use of respiratory protection by the public, though there are a number of federal agencies responsible for regulating specific types of respiratory hazards that might require or be addressed by respiratory protection. Among these agencies, EPA and CDC have the broadest mandates. Notably, even agencies that have authority over some inhalation hazards, and that choose to encourage use of respiratory protection by the public, often refer to NIOSH standards—standards developed for occupational contexts, for a population of workers—when making recommendations to the public.[355] This practice is potentially problematic where the population NIOSH addresses—e.g., adults—is different than the public in important ways. The result is that some members of the public—notably, children—may not be served even by agencies' general recommendations about the type of respiratory protection to use against inhalation hazards. In the absence of comprehensive federal action on public respiratory protection, state and local law also plays a role in the use, provision, and availability of respiratory protection for the public, although this role varies by state and by hazard.

2. Nonoccupational Oversight

This section describes the regulatory landscape regarding the oversight of respiratory protection development, approval, marketing, and/or postmarket surveillance, when that oversight applies to respiratory protection for the public rather than for workers. While there is a clear authority for this type of oversight regarding occupational settings—where most authority rests clearly with NIOSH—there is no similar centralized authority for oversight of nonoccupational respiratory protection for the public. The agency with the broadest authority is likely the Food and Drug Administration (FDA), although even its authority is limited—in its case, to respiratory protection intended for medical purposes. The section describes FDA's authority, including the limits on that authority, as well as the limited roles of the CPSC and NIOSH. It then discusses the roles of other federal, state, local, and foreign actors.

a. The Food and Drug Administration (FDA) within HHS

FDA, a public health agency within HHS, is responsible for regulating food, drug products, and medical devices.[356] When respiratory protection is provided by a medical device that is intended for a medical purpose, such as preventing disease, it is subject to regulation by FDA, both via potential premarket approval processes, and through controlling device adulteration and misbranding. Respiratory protection that is not intended for a medical purpose is not subject to FDA oversight or control.

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[355] *See* Part II.B.2.c.
[356] *See* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301–392.

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i. The general authority of FDA under the FD&C Act regarding use of respiratory protection by the public

FDA's authority regarding respiratory protection traces to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Medical Device Amendments of 1976 (MDA). In addition to granting FDA a variety of consumer protection responsibilities related to the regulation of food and drugs, these statutes require FDA to regulate "adulterated" and "misbranded" devices, and to ensure devices' "safety and effectiveness."[357]

To qualify as a medical "device" under the FD&C Act, an item must be intended for a medical purpose.[358] Items are considered to be used for a medical purpose when they are "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[359] The FD&C Act is ambiguous as to what it means for items to be "intended" for a purpose, leaving FDA with substantial discretion in deciding when a device is intended for medical purposes and when it is not. Under FDA's current interpretation, in deciding whether any particular item is intended for a medical purpose, it will consider whether the item is labeled or otherwise intended for use by a health care worker; labeled or otherwise for use in a health care facility or environment; and/or includes any drugs, biologics, or antimicrobial/antiviral agents.[360] FDA retains discretion, however, to revisit or change this interpretation, so long as it remains within the bounds of the statute.

ii. FDA regulation of respirators

FDA has authority under Section 201(h) of the FD&C Act to regulate face masks and respirators when they meet the statutory definition of a medical "device."[361] Within FDA, the Center for Devices and Radiological Health is the division that implements rules and requirements regarding medical devices.[362]

FDA has long had special responsibilities regarding the regulation of adulterated or misbranded devices.[363] Generally speaking, devices are "adulterated" if they include filthy, putrid, or decomposing substances; if they are packed under unsanitary conditions; or if their manufacturer violates performance standards or good manufacturing practices. And they are misbranded if they are labeled in a false and misleading matter; if its packaging does not bear required labels, including directions for use; or if it is dangerous to health when used in the

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[357] *See* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301–392; *see also* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified in scattered sections of 21 U.S.C. and 42 U.S.C.) (broadening FDA's authority and charging them with ensuring that medical devices are safe and effective).
[358] 21 U.S.C. § 321(h).
[359] *See* 21 U.S.C. § 321(h).
[360] *See* 21 U.S.C. § 321(h); U.S. FOOD & DRUG ADMIN., *Enforcement Policy for Face Masks and Respirators during the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)* (May 2020), https://www.fda.gov/media/136449/download (hereinafter FDA ENFORCEMENT POLICY).
[361] 21 U.S.C. § 321(h); *see* FDA ENFORCEMENT POLICY (note 360).
[362] *See* 21 U.S.C. §§ 351–360fff-8.
[363] *See* 21 U.S.C. § 301 *et seq*. For a history of regulation in this realm, see Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99, 100–105 (1989).

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manner suggested on the labeling.[364] When adulterated or misbranded devices are in interstate commerce, they are subject to seizure and other penalties.[365] As a result, FDA has substantial authority in regards to the marketing and postmarketing surveillance of respirators that are intended for a medical purpose. It has no authority, however, over identical respirators that are not intended for a medical purpose.

Since passage of the Medical Device Amendments of 1976 (MDA), FDA has also had the authority to regulate premarket approval processes for new medical devices.[366] To satisfy its statutory mandate, FDA must evaluate all medical devices to "provide reasonable assurance of the safety and effectiveness of the device," and then classify them based on the level of risk that they present to consumers.[367] Class I devices are considered low risk and are minimally regulated; Class II are considered moderate risk and are subject to special controls, including performance standards, postmarket surveillance, and other actions FDA deems necessary; and Class III devices are high-risk and are additionally subject to a robust premarket approval process.[368] FDA designations of this type generally receive significant deference from courts,[369] and FDA retains the authority to redesignate among these classifications if it feels that it has misidentified the level of risk that a particular device poses to the public.

During the coronavirus pandemic, FDA has claimed authority under the FD&C Act to regulate all face masks, shields, and respirators that are used for a medical purpose, including N95 respirators used to prevent infection with the COVID-19 virus.[370] The same respirators are not considered "devices" when they are intended for a nonmedical purpose, such as for use in construction.[371]

Under current FDA classifications, face masks that are not surgical masks are regulated as Class I devices,[372] and thus are not subject to performance standards or postmarket

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[364] *See* 21 U.S.C. § 351; *see also General Controls for Medical Devices*, U.S. FOOD & DRUG ADMIN. (Mar. 22, 2018), https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices (summarizing the various statutory definitions of adulteration and misbranding).

[365] *See* 21 U.S.C. § 331(a) (prohibiting the "introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded"); 21 U.S.C. § 334(b). For example, a Chinese manufacturer was charged with importing half a million misbranded masks that claimed to be N95 respirators. *See* U.S. DEP'T OF JUST., Press Release 20-187, *Chinese Manufacturer Charged with Exporting Defective and Misbranded Masks Falsely Purporting to Be KN95 Respirators* (June 17, 2020), https://www.justice.gov/usao-nj/pr/chinese-manufacturer-charged-exporting-defective-and-misbranded-masks-falsely-purporting.

[366] *See* 21 U.S.C. § 360(e); *see also* Hutt, 1989 (note 363*)* (providing a history of FDA regulation).

[367] 21 U.S.C. § 360(c).

[368] *See* 21 C.F.R. § 860.3 (2021).

[369] *See* Stephanie P. Fekete, *Litigating Medical Device Premarket Classification Decisions for Small Businesses: Have the Courts Given the FDA Too Much Deference?*, 65 CATH. U.L. REV. 605 (2016) (reviewing case law giving FDA broad discretion in risk designations).

[370] *See* Fekete, 2016 (note 369); FDA has published a number of COVID-19-related guidance documents, and keeps updated links on its website at *Covid-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders*, U.S. FOOD & DRUG ADMIN. (May 25, 2021), https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders;https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders; *see also* FDA ENFORCEMENT POLICY (note 360).

[371] *See* FDA ENFORCEMENT POLICY, p. 5 (note 360).

[372] *See* 21 C.F.R. § 878.4040 (2021).

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surveillance, while surgical masks and respirators are regulated as Class II devices[373] and are subject to such standards and surveillance.

iii. Characterizing FDA's approach

FDA's authority over the development, approval, marketing, and postmarket surveillance of items used in respiratory protection is significant *when those items are used for a medical purpose*, including for the prevention of disease (such as the COVID-19 virus). In such cases, they have significant authority over development and approval, particularly of Class II medical devices such as N95s, which must meet FDA performance standards, as well as requirements of postmarket surveillance. FDA also has substantial authority over marketing and postmarket surveillance of other items that qualify as medical devices—including surgical masks when intended for medical purposes—via its authority to address adulterated and misbranded devices.

In some cases, FDA's governance of respirators (only) when they are used for a medical purpose, but not when they are intended for a different use, may lead to awkward overlap with other authorities. This is particularly true where the same device (such as an N95 respirator) is developed for multiple uses, only some of which are medical. FDA only claims jurisdiction over devices when their purpose is medical, as with the prevention of disease.[374] Many inhalation hazards—including environmental hazards—can produce diseases such as cancer; however, it can be difficult to determine just how far FDA's authority reaches. Thus far, FDA does not appear to have claimed authority to regulate all respiratory protection in all circumstances that protects against any inhalation hazard that can cause any disease, and it has specifically disclaimed authority, for instance, over N95s used in "construction"[375]—where, of course, N95s are used and often required (including, in occupational contexts, as part of OSHA-required respiratory protection programs) in part to protect against occupational and environmental exposures that can cause diseases such as silicosis, asbestosis, and cancer.

The question of just how far FDA's authority stretches over respirators as devices, and how it interacts with the authority of EPA, OSHA, and other authorities, thus remains ambiguous. And the case is made still more complex by the fact that while courts generally defer to statutory interpretations that involve an agency's own authority under a statute it administers, courts are significantly less deferential when it comes to interpretations of statutes administered by *other* agencies.[376] Thus while FDA might be able to interpret its own authority over medical devices broadly, it is not presumed to have any particular expertise in determining the countervailing authority of, for example, EPA in regulating toxic substances. In such areas of

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[373] *See* 21 C.F.R. § 878.4040 (2021) (covering surgical masks, pediatric/child face masks, face shields, and N95 respirators); 21 C.F.R. § 880.6260 (covering N95 Respirators "for Use by the General Public in Public Health Medical Emergencies").

[374] *See* FDA ENFORCEMENT POLICY, p. 5 (note 360).

[375] *See* FDA ENFORCEMENT POLICY, p. 5 (note 360) (explaining its interpretation as applying only to devices intended for a medical purpose and clarifying that FDA does not interpret itself to have authority over devices intended for other purposes: "Other face masks, face shields, and FFRs [filtering facepiece respirators] are marketed to the general public for general, non-medical purposes, such as use in construction and other industrial applications. Because they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, FDA device marketing authorization is not required, and all the other requirements of the FD&C Act do not apply to manufacturers, importers, and distributors of these products").

[376] Such interpretations generally receive less deference, under the stingier standard articulated in Skidmore v. Swift & Co., 323 U.S. 134, 139 (1944). For more discussion of judicial review of agency interpretations, see Part II.D.1.

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potential interagency overlap, it can be particularly helpful to have clarification of agencies' roles, either through interagency coordination (led by the agencies themselves, or as encouraged by the President), or to have Congress clarify the appropriate scope of the various agencies' responsibilities by passing new legislation addressing the area of overlap. Part II expands on the types of actions these different actors can take in regards to situations like this one, where the far extent of authority an agency (in this case FDA) has over a particular important issue (in this case the oversight of respiratory protective devices that are intended for use for a "medical purpose") remains unclear.

b. The Consumer Product Safety Commission (CPSC)

The CPSC oversees consumer products produced or distributed in the United States for sale to, or use by, consumers.[377] Its authority stems from the Consumer Product Safety Act (CPSA)[378] and the Federal Hazardous Substances Act (FHSA).[379] It is relevant to inhalation hazards that the public may face as the result of exposure to products, such as household cleaning agents. It also plays a limited role in regulating some forms of face coverings against flammability risk.

Under the FHSA, the CPSC has the authority to ban or regulate substances—such as cleaning agents[380]—that are hazardous and that may cause substantial injury or illness.[381] "Hazardous substances" include substances that are radioactive, toxic, corrosive, are an irritant or sensitizer, are flammable or combustible, or generate pressure through decomposition, heat, or other means, "if such substance … may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children."[382] "Toxic substances" includes substances that have the capacity to act as hazards via inhalation.[383] Under the CPSA, the CPSC can issue performance requirements, warnings, instruction, or product bans if it finds that the product would create an "unreasonable risk of injury" when "no feasible consumer product safety standard," including under the FHSA, can adequately address the risk.[384] When the CPSC identifies a product as containing a hazardous substance, as part of the plan for addressing the hazards of the product, it may issue guidance on how to handle the product in a safe way. In some cases, this has included giving the public guidance as to the use of respiratory protection.[385]

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[377] *See generally* U.S. CONSUMER PROD. SAFETY COMM'N, *About CPSC*, https://www.cpsc.gov/About-CPSC.
[378] *See* Consumer Product Safety Act, 15 U.S.C. § 2051.
[379] *See* Federal Hazardous Substances Act, 15 U.S.C. §§ 1261–1276.
[380] *See* 16 C.F.R. § 1500.83(a)(11) (2021).
[381] 15 U.S.C. § 1262.
[382] *See* 15 U.S.C. § 1261(f)(1).
[383] *See* 15 U.S.C. § 1261(g).
[384] *See* 15 U.S.C. § 2057. For products containing hazardous substances, the CPSC must find that the risk could not be regulated sufficiently under the FHSA or that it is in the public interest to proceed under the CPSA rather than the FHSA, before regulating under the CPSA. *See* Gulf S. Insulation v. U.S. Consumer Prod. Safety Comm'n, 701 F.2d 1137, 1149–1150 (5th Cir. 1983).
[385] *See, e.g.*, U.S. CONSUMER PROD. SAFETY COMM'N, *Consumer Alert: Proposed Instructions for Removing Non-Burning Artificial Fireplace Logs, Gas-Burning Fireplace Logs and Ashes Containing Asbestos* (Dec. 2, 1977), https://www.cpsc.gov/Newsroom/News-Releases/1978/Asbestos-Ban-Announced (recommending that to remove asbestos-laden products, consumers use "[a]" covering for the nose and mouth. [This could be a dust face mask, available at most drugstores, or a single-use respirator. Respirators may be purchased at most hardware stores]"). More recent CPSC guidance on respirators tends to be more detailed; *see, e.g.*, U.S. CONSUMER PROD. SAFETY

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The CPSC also has some authority regarding face masks and respirators when they qualify as "products" for regulation under the FHSA or the CPSA. For example, it applies labeling, testing, and certification requirements to consumer face masks, as well as flammability testing requirements.[386] That said, it has disclaimed the authority to regulate either face masks that qualify as "medical devices"[387] or N95 and P100 respirators.[388] The CPSC does, however, consider consumer and children's face masks to be apparel that is subject to flammability testing requirements.[389] As a result, during the coronavirus pandemic, the primary impact of CPSC regulations on the approval, marketing, and postmarketing surveillance of respiratory protective products for the public relates to its consideration of consumers' cloth face masks as apparel and (requiring compliance with flammability testing requirements of the Flammable Fabrics Act).

c. The National Institute for Occupational Safety and Health (NIOSH) within the Centers for Disease Control and Prevention (CDC)

NIOSH, within CDC, is empowered to "develop and establish recommended occupational safety and health standards."[390] As a result of their focus on occupational safety and health, NIOSH, and NPPTL nestled within it, have developed substantial research regarding PPE, and represent a substantial reservoir of expertise within the federal government regarding respiratory protection in particular.[391] That said, while NIOSH (and its associated agency OSHA) have sometimes partnered with other agencies (such as EPA) in addressing risks from inhalation hazards that apply both inside and outside workplaces,[392] neither NIOSH nor OSHA has the unilateral statutory authority to develop standards or to develop oversight programs for *nonoccupational* contexts.[393]

Though NIOSH/NPPTL's authority is constrained to occupational safety and health, its expertise is often leveraged by other actors and has occasionally been used by Congress in specific public health emergencies. For example, NIOSH been granted special statutory authority to provide special programs to support health and safety research for World Trade Center

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COMM'N, PUB. NO. 5015CPSC, ART AND CRAFT SAFETY GUIDE 8 (1998), https://www.cpsc.gov/s3fs-public/5015.pdf (referring arts and crafts hobbyists who might be exposed to hazardous products to "an occupational clinic for advice and training" on the use of respirators, and referring the hobbyists to OSHA and occupational health and safety standards and NIOSH certifications).

[386] *Coronavirus Disease (COVID-19) Related Products Business Guidance* (note 330) (summarizing the CPSC's current regulation of respiratory protective devices, including face coverings, surgical masks, N95 respirators, face shields, and industrial face masks).

[387] *See Coronavirus Disease (COVID-19) Related Products Business Guidance* (note 330) (referring readers to FDA guidance for further information).

[388] See *Coronavirus Disease (COVID-19) Related Products Business Guidance* (note 330) (referring readers to NIOSH).

[389] *See* Flammable Fabrics Act, 15 U.S.C. §§ 1191–1204. The CPSC has indicated that consumer face masks must be tested to either 16 C.F.R. part 1610 (Standard for the Flammability of Clothing Textiles) or part 1611 (Standard for the Flammability of Vinyl Plastic Film), depending upon the material used in construction. See *Coronavirus Disease (COVID-19) Related Products Business Guidance* (note 330).

[390] *See* 29 U.S.C. § 671(c)(1); *see also* Parts I.A.1.b.ii and I.A.2.

[391] *See* Part I.A.2.a.

[392] *See* Part I.A.c.i.(2).

[393] *See* 29 U.S.C. § 671(c) (authorizing NIOSH to recommend "occupational" safety and health standards, and imbuing NIOSH with research authority regarding occupational and employee education matters); *see also About NIOSH*, 2018 (note 72) (emphasizing NIOSH's occupational mission, goals, and objectives).

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survivors (including members of the public).[394] NIOSH/NPPTL expertise has also been used periodically for emergency-related tasks that benefit the public; for example, as described previously, during the pandemic, NPPTL staff conducted an assessment to determine the continued efficacy of respirators used beyond their designated shelf life.[395]

In addition, agencies with public health and safety authority routinely refer the public to NIOSH-set respirator standards, particularly NIOSH's N95 respirator standard, even for respirator uses that are nonoccupational. For example, the CPSC recommends members of the public using hazardous arts and crafts products (in nonoccupational settings) use respirators certified by NIOSH/NPPTL[396]; FDA uses NIOSH's N95 standards in its recommendations on respiratory protection for medical purposes[397]; CDC refers the public to NIOSH lists of approved respirators when giving guidance to members of the public about which respirators to wear[398]; and EPA recommends members of the public use a respirator certified as N95 by NIOSH/NPPTL against multiple hazards, including construction hazards,[399] flood cleanup,[400] and to protect against wildfire smoke.[401]

Notably, although NIOSH/NPPTL certification standards are used routinely by other federal agencies in nonoccupational contexts, it is almost universally unclear how those

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[394] *See* NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, NO. 2018-143, NIOSH, WORLD TRADE CENTER HEALTH PROGRAM (July 2018), https://www.cdc.gov/niosh/docs/2018-143/pdfs/2018-143.pdf?id=10.26616/NIOSHPUB2018143; *see also* James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, 124 Stat. 3623 (2011) (codified in scattered sections of 42 U.S.C.) (creating the World Trade Center Health Program as a division within NIOSH, and directing it to address the health and safety of World Trade Center survivors).

[395] *See NPPTL Respirator Assessments to Support the COVID-19 Response* (note 192).

[396] *See, e.g.*, U.S. CONSUMER PROD. SAFETY COMM'N, *Art and Craft Safety Guide*, Pub. No. 5015, 8 https://www.cpsc.gov/s3fs-public/5015.pdf (referring members of the public using arts and crafts materials that present exposure hazards to NPPTL publications, and suggesting that hobbyists "seek an occupational clinic for advice and training" for respirator use while otherwise ensuring that "the respirator [they] are using complies with recommendations made by [NIOSH]"); U.S. CONSUMER PROD. SAFETY COMM'N, *Products requiring special labeling under section 3(b) of the act*, 16 C.F.R. § 1500.14 (Oct. 9, 1992) 46671 (listing a series of precautionary statements for labeling hazardous art materials used by consumers, including "Wear NIOSH-certified mask for dusts/mists/fumes;" "Wear NIOSH-certified respirator with an appropriate cartridge for [specify]"; and "Wear NIOSH-certified supplied-air respirator," which are required by CPSC's interpretation of the FHSA). *See also* Part I.B.1.d.i.; *Coronavirus Disease (COVID-19) Related Products Business Guidance* (note 330) (referring to NIOSH's N95 certification standards).

[397] *See* Part I.B.2.c.

[398] *See, e.g.*, *Respiratory Protection for Residents Reentering and/or Cleaning Homes That Were Flooded*, 2019 (note 298) (recommending residents look for "more information about using respirators" at NIOSH's list of NIOSH-Approved Particulate Filtering Facepiece Respirators).

[399] *See, e.g.*, U.S. ENV'T PROT. AGENCY, *Brochure, Disaster Response: Attention: Homeowners, Contractors, and Volunteers* (2007) (indicating to homeowners and volunteers, as well as contractors, that "EPA recommends using N-95 respirator masks to protect your lungs" as "[t]he N-95 respirator provides better protection than regular dust masks against airborne health hazards like mold"), https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1008EK2.txt.

[400] *See* U.S. ENV'T PROT. AGENCY, *Flood Cleanup and the Air in Your Home* 13 (2017) (recommending that members of the public "[w]ear a respirator, an "N-95 respirator," mask", explaining that "[a] respirator that protects against mold is called an N-95 respirator" and warning that members of the public should "[o]nly use a respirator that says N-95 on the package"), https://www.epa.gov/sites/production/files/2017-08/documents/flood_cleanup_and_the_air_in_your_home_booklet_0.pdf.

[401] *See* U.S. ENV'T PROT. AGENCY, *Reduce health risks in areas with wildfire smoke: Follow these tips if someone in your family (including you!) has heart or breathing problems, is an older adult or child, or is pregnant* (advising members of the public "use a well-fitted N95 or P100 respirator if you go outside when it is smoky"), https://www.airnow.gov/sites/default/files/2020-02/reduce-health-risks-with-wildfire-smoke-508.pdf.

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occupational standards are supposed to be transferred to nonoccupational contexts. NIOSH/NPPTL does not, for example, give direction to other agencies about how to transfer their occupational standards to public use. Nor do public safety and health agencies have a common practice of explaining the key considerations in such a transfer; agencies do not, for example, give guidance about how NIOSH/NPPTL standards should be adjusted for children (for whom there is clearly no occupational standard and for whom there are obvious concerns of fit). As a result, although occupational respiratory certification is frequently used to make recommendations for public respiratory use, such recommendations have an ad hoc character, and are not subject either to the guidance of any centralized authority, or to any apparent agency practice that would help to ensure such recommendations address important differences between occupational and nonoccupational applications.

d. Other authorities

This section discusses the role of other authorities—including other federal agencies, state and local authorities, and foreign authorities—in addressing oversight of respiratory protection for the public.

i. Federal authorities

The agencies discussed above appear to comprise the most important federal authorities regarding federal oversight of the development, approval, marketing, and/or postmarket surveillance of respiratory protection for the public. That said, other federal agencies have partial or occasional authority over various aspects of oversight of development, approval, marketing, and/or postmarketing surveillance. For example, the U.S. Immigrations and Customs Enforcement (ICE) and U.S. Customs and Border Protection (CPB), both components of the Department of Homeland Security, have seized counterfeit respirators during the COVID-19 pandemic,[402] and ICE has established an initiative ("Operation Stolen Promise") to help keep counterfeit and substandard goods out of the medical and consumer supply chain.[403]

ii. State and local authorities

Generally speaking, states have authority to regulate development, approval, marketing, and/or postmarketing surveillance of public respiratory protection only where federal action has not precluded state action. States are precluded, for example, from engaging in oversight functions that would interfere with FDA's oversight over respiratory protective devices that are used for medical purposes.[404] Where there is no comprehensive federal scheme, however, states have substantial gap-filling authority.

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[402] *See, e.g.*, U.S. Customs & Border Protection, *CPB Seizes Counterfeit N95 Masks* (April 15, 2021), https://www.cbp.gov/newsroom/local-media-release/cbp-seizes-counterfeit-n95-masks.
[403] *See* Immigration and Customs Enforcement, *Operation Stolen Promise One-Year Anniversary*, https://www.ice.gov/topics/operation-stolen-promise. ICE reports that the first year of this operation led to 2,174 COVID-19 related seizures of over $52 million in illicit proceeds and 292 criminal arrests. *See CPB Seizes Counterfeit N95 Masks*, 2021 (note 402).
[404] *See Federal Preemption of State Common-Law Products Liability Claims Pertaining to Medical Devices, Implants, and Other Health-Related Items*, 74 A.L.R. Fed. 2d 1.

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As discussed above,[405] state law also has a potential role to play through products liability for defective products. Another arena in which state law plays an indirect role in the oversight of respiratory protection is through another tort: fraud. State laws generally prohibit fraud, or a "knowing misrepresentation of the truth or of a material fact to induce another to act to his or her detriment."[406] Potential liability for fraud may incentivize honest marketing of products, including respiratory protection products available to the public. For example, in Colorado, the state attorney general secured a settlement with a company that had made misleading claims about the masks and respirators it sold during the COVID-19 pandemic.[407]

iii. Foreign authorities

Some respiratory protection that is marketed to the public is certified by foreign regulators rather than by federal or state authorities in the United States. For example, KN95 respirators, which have been approved for emergency medical use by FDA during the pandemic,[408] are manufactured in China and are subject to Chinese regulatory control.[409] The emergency exception for these respirators is administered by FDA, which also maintains a list of specific respirators that it identifies as reaching a sufficient filtration efficiency level.[410] One point worth noting is that because of the use of imported respiratory protection devices, particularly during the pandemic, this is an area in which foreign authorities can have an impact on the protection of the U.S. public.

e. Characterizing nonoccupational oversight

In sum, there is no single federal entity responsible for overseeing the development, approval, marketing, or postmarketing surveillance of respiratory protection for the public, or for generating or overseeing a certification program for managing these processes. The agency with the most significant authority is FDA, although its oversight authority is limited to respiratory protection used for "medical purposes." Several other federal entities—including CDC and CPSC—serve some oversight function against specific respiratory hazards. Often, however, even these entities refer members of the public to NIOSH certifications, which were developed for occupational uses and for workers. Notably, there is no federal body—within CDC or elsewhere—responsible for creating respiratory protection certification programs for the public that would act as a corollary to the certification work done by NIOSH for occupational applications. This leaves substantial gaps in oversight for members of the public who seek to use

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[405] *See* Part I.B.1.d.ii.
[406] *Fraud*, BLACK'S LAW DICTIONARY (9th ed. 2009).
[407] *See* OFF. OF THE ATT'Y GENERAL, *Colorado business agrees to pay $70,000 to the State after misleading buyers about masks and respirators, price gouging during COVID-19 crisis* (January 25, 2021) (citing the Assurance of Discontinuance in the Matter of Nationwide Medical Supply Inc. [January 17, 2021], https://coag.gov/app/uploads/2021/01/Nationwide-Assurance.pdf), https://coag.gov/press-releases/1-25-21.
[408] *See* U.S. FOOD & DRUG ADMIN., Emergency Use Authorization for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (Oct. 15, 2020), https://www.fda.gov/media/136664/download, issued pursuant to FDA's authority under the FD&C Act. *See* 21 U.S.C. § 360bbb-3(b)(1)(c) (allowing authorization for devices for use in emergencies).
[409] *See* U.S. FOOD & DRUG ADMIN. (note 408).
[410] *See Appendix A: Authorized Surgical Masks*, U.S. FOOD & DRUG ADMIN. (May 24, 2021), https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixa.

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respirators outside of occupational-type contexts and for members of the public—most notably children—for whom there is no identifiable federal oversight at all.

PART II: POTENTIAL RECOMMENDATIONS AND THEIR IMPACTS ON THE REGULATORY LANDSCAPE

This part is intended to support the Committee as it crafts recommendations for new or revised laws or regulations regarding respiratory protection for the public and workers without respiratory protection programs (RPPs). In particular, it identifies possible actors and actions that the Committee could recommend to address gaps and help with managing overlaps, tailored to the reasons for those challenges in the regulatory landscape. The purposes of this section are to outline the range of potential recommendations and targets for recommendations by the Committee, and to support the Committee in addressing the institutional actors that have the legal authority to respond to the Committee's recommendations.

This part of the paper provides a number of examples of potential recommendations that the Committee might make. At no point does the paper intend to advocate for or against the substance of any of these examples. Rather, the examples are presented as illustrations, and the goal in providing them is merely to help the Committee in understanding the legal and regulatory implications of various types of recommendations they might make, and to help the Committee in tailoring its recommendations to the legal authorities that are most likely to be empowered to respond.

Even more than the prior part of the paper, this part focuses on the *federal* regulatory landscape. Perhaps needless to say, directions regarding state law should be directed toward states. From a federal perspective, as a very basic matter, this part emphasizes the usefulness of making recommendations specifically to Congress to address statutory gaps, to the President in addressing problems of coordination and enforcement, and to agencies in addressing gaps and overlaps that come from regulatory interpretations.

A. Identifying Key Actors and Actions

Like most other modern democracies, the federal government of the United States is made up of three branches: the legislature (in the form of Congress), the executive (headed by the President), and the judiciary. The purpose and authority of each of these branches—as well as the basic framework for the sharing of authority between the federal government and the states—is set out in the U.S. Constitution.[411]

In addition to these three branches of government, the United States also relies heavily upon the authority of administrative agencies.[412] Administrative agencies are units of government created by one of the branches of government—usually, though not always, Congress.[413] The powers of regulatory agencies are not set forth in the Constitution. Rather, agency authority is granted via statues enacted by Congress and/or executive actions taken by the

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[411] *See* U.S. CONST. art. I–III.

[412] For an overview of key actors in U.S. regulation, the role of administrative agencies, and a brief comparison to other systems, see Arden Rowell & Josephine van Zeben, *Key Actors*, *in* A GUIDE TO U.S. ENVIRONMENTAL LAW 11–35 (Calif. Press, 2021).

[413] *See* Part II.D.1.

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President, and constrained by review by the judiciary. The interconnected network created by administrative agencies, which are variously empowered to create, interpret, and enforce laws, and the branches that empower and constrain them, is commonly called the "regulatory state."[414]

As the Committee considers the implications of new or revised laws or regulations that may be considered to improve respiratory protection, it may be helpful to understand who has the authority to implement those recommendations, as well as how those recommendations are likely to operate within the regulatory state. Among the various actors to which the Committee may direct its recommendations, three—Congress, the President, and agencies—all have authority to choose to act in ways that affect the regulatory state and the ways in which the particular issue of respiratory protection is regulated. (Courts can also affect the operation of the regulatory state, though it is difficult to make meaningful recommendations directly to them, as their authority is limited to considering specific "cases" and "controversies" that come before them.[415] Their clearest role comes in reviewing the actions of agencies.[416] With this in mind, the remainder of this section outlines the authority of these key actors, describes the legal and regulatory tools that the Committee may choose to deploy in its final recommendations, and identifies some of the most important implications of selecting each tool. For a quick reference summarizing general areas of authority, key institutional strengths, and sample forms of action for Congress, the President, and agencies, please see Chart 1 below.

Chart 1: A Summary of Institutional Actors—Authority, Key Strengths, and Sample Forms of Action

Institution	Authority	Key Institutional Strength(s)	Sample Forms of Action
Congress	Legislative	➔ Able to expand (or constrain) agency authority via legislation. ➔ Able to fill in gaps where no agency is currently authorized to act. ➔ Significant power over appropriations.	• Passing a new statute (e.g., regarding inhalation hazards) giving authority to existing agencies • Amending existing statute(s) to clarify or expand the authority of existing agency/ies • Creating a new agency, empowered with new or existing authority • Adjusting appropriations to existing agencies
President	Executive	➔ Able to encourage (or discourage) agencies to act within their existing authority. ➔ Substantial power in prioritizing and	• Elaborating on or amending existing presidential plans, such as the COVID-19 response plan • Encouraging coordination across agencies • Issuing new executive orders

[414] *See, e.g.*, LISA SCHULTZ BRESSMAN, EDWARD L. RUBIN & KEVIN M. STACK, THE REGULATORY STATE (3d. ed. 2019).
[415] See U.S. CONST. art. III, § 2.
[416] See Part II.D.1.

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		coordinating overlapping authority from multiple agencies or statutes.	• Directing creation of a new agency • Repealing, expanding, or amending existing executive orders • Issuing emergency designations or funding
Agencies	Specific; determined by Congress (via statutes) and the President (via executive actions)	➔ Able to change regulatory decisions within the constraints of congressional and executive direction. ➔ Able to address overlaps via interagency coordination and to fill gaps when those gaps arise from their own policies. ➔ Able to build on existing expertise to issue nonbinding guidance and other information.	• Revisiting an existing interpretation of statutory authority, whether more expansively (to increase opportunity for requirements) or less expansively (to get out of the way of another agency) • Issuing new regulations under existing statutory interpretations • Providing additional guidance for voluntary recommendations, education, risk communication, etc. • Shifting resource allocation (e.g., by devoting additional resources to inhalation hazards or respiratory protection) • Coordinating with other agencies

B. Making Recommendations to Congress

This section addresses important types of recommendations that can be made to Congress. Such recommendations are particularly likely to be important where there are statutory gaps in authority or where the Committee believes that additional funding will be needed to implement its recommendations.

1. Features and Limitations of Congressional Action

This section presents a brief legal, procedural, and institutional orientation to congressional action and to legal constraints on Congress. The purpose of the section is to outline the basic procedures Congress uses to make law and the various functions Congress serves in empowering and controlling agency action.

The U.S. Congress is made up of two houses: the U.S. Senate and the House of Representatives. Congressional authority is set out in Article I of the Constitution.[417] Generally speaking, as the legislative branch of government, Congress is empowered to make law in the form of statutes. The legislative process for enacting statutes is long and relatively

[417] U.S. CONST. art. I. ("All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.")

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complicated.[418] First, a bill must be sponsored. Once it is sponsored—in either house of Congress—it is assigned to a committee of representatives or senators. The congressional committee may amend the bill if they choose. The committee then votes either to accept the bill (in which case it is sent to the House or Senate floor for debate), reject the bill (in which case the bill dies), or send it to a subcommittee for further research (in which case it comes back, eventually, to the committee to accept or reject). If a bill reaches the House or Senate floor, it is then debated and members of Congress may propose changes or amendments before voting. If the majority vote to pass the bill, it moves to the other house to go through a similar process, proceeding through committees, debate, and voting. Both houses must then agree to the same version of the final bill, in a process called reconciliation, before the bill is passed to the President. The President may then choose to sign the bill—in which case the bill becomes law—or to veto.[419] Amendments to existing statutes require essentially the same process.[420]

This process is time-consuming and of course may involve political controversy. As a result, most bills never become statutes.[421]

Another important aspect of congressional authority relates to appropriations. The responsibility for appropriations is technically shared between the President (who proposes an annual budget and has the opportunity to veto the final budget) and Congress.[422] In practice, however, Congress's role in appropriations is particularly intense, and recommendations to increase (or decrease) the appropriations granted to a particular agency or division within an agency are generally addressed within Congress's appropriations committees.[423]

2. Potential Types of Recommendations

This section identifies examples of the types of recommendations that would be most effectively directed toward Congress, rather than (only) agencies or the President. It identifies the types of recommendations that the Committee might make specifically to Congress, along with the basic procedural constraints and processes that would be required for each to occur, and gives several examples to illustrate the types of recommendations in which Congress would necessarily be involved. These examples are provided for purposes of clarification only and are not meant to advocate for or against any specific set of substantive recommendations by the Committee.

Generally, recommendations to Congress are a particularly good institutional fit when the remedy suggested would require a change to existing agencies or to those agencies' statutory authority, or to the appropriations and other resources assigned to specific agencies.

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[418] U.S. CONST. art. I, § 7. For an easy-to-follow infographic summarizing the steps involved in federal legislation, see *Infographic: How a Bill Becomes a Law*, USAGOV (Apr. 23, 2021), https://www.usa.gov/how-laws-are-made#item-213608.

[419] Congress can override the veto with 2/3 vote of those present in both the House and the Senate. *See* U.S. CONST. art. I, § 7.

[420] For a more detailed analysis of the amendment process, see RICHARD S. BETH, CONG. RSCH. SERV., RS20617 *How Bills Amend Statutes* (2008), https://www.everycrsreport.com/files/20080624_RS20617_f7ea9e9d45e2319fa60b474349887e764f1b44fe.pdf.

[421] E.g., for the 116th Congress (ended 1/3/21), only 1 out of every 50 bills and resolutions (2 percent) introduced were enacted into law.

[422] *See, e.g.*, 31 U.S.C. § 1105 (requiring the President to submit an annual budget to Congress).

[423] *See* Richard J. Lazarus, *Congressional Descent: The Demise of Deliberative Democracy in Environmental Law*, 94 GEO. L.J. 619, 649 (2006) (noting that legislative appropriations committee reports frequently include directives specifying how a certain agency should spend money).

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The types of potential action that would implicate Congress's authority, and which might therefore be best addressed to Congress, include:

- Passing a new statute giving authority to existing agencies
- Amending existing statute(s) to clarify or expand the authority of existing agency/ies
- Creating a new agency, empowered with new or existing authority
- Adjusting appropriations to existing agencies

For example, the current statutory landscape sharply distinguishes occupational and nonoccupational exposure to respiratory hazards. Under the Occupational Safety and Health Act (OSH Act), Congress has given specific authority to the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) regarding the regulation of workplace safety (including inhalation hazards),[424] without giving similar authority to either those agencies or other agencies regarding general public safety regarding inhalation hazards. While this distinction is currently a distinguishing feature of the regulatory landscape of respiratory protection, it is a feature that was created by Congress and which (only) Congress has the authority to change, whether by amending the OSH Act or passing a new statute. Similarly, only Congress has the authority to pass new legislation directed specifically toward the management of inhalation hazards.

Congress also has the authority to create a new agency via legislation. Most major agencies were created this way, although as noted in the subsequent section, a number of other agencies have been created unilaterally by the President.[425] Agencies created by Congress tend to be better-funded and to exist for longer than those made unilaterally by the President,[426] and to be less subject to presidential control.[427]

Smaller recommendations regarding the expansion or contraction of some agency's authority would also be appropriately directed toward Congress. For example, Congress could expand the responsibilities of the National Advisory Committee on Occupational Safety and Health (NACOSH), restrict or explicate the authority of the Food and Drug Administration (FDA) in regards to regulating respirators for public use, or amend the OSH Act to expand who is protected as a "worker."

Because of Congress's power over appropriations, advice to increase the funding of a particular agency, such as the National Personal Protective Technology Laboratory (NPPTL), would reasonably be directed to Congress as well.

C. Making Recommendations to the President

This section provides background regarding important types of recommendations that the Committee might choose to make to the President. Such recommendations may be particularly

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[424] *See* Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651–678.
[425] *See* William G. Howell & David E. Lewis, *Agencies by Presidential Design*, 64 J. POL. 1095, 1096 (2002) (finding that the total number of agencies created by Congress and the President are approximately equal).
[426] *See* Howell and Lewis, 2002, pp. 1098–1099 (note 425) (finding that agencies created by the President alone generally have smaller budgets and are less long-lived, and suggesting that presidentially created agencies are less "important").
[427] *See* Howell and Lewis, 2002 (note 425).

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helpful in encouraging coordination across agencies and/or in addressing statutory or regulatory gaps.

1. Features and Limitations of Executive Action

This section provides a brief legal, procedural, and institutional orientation on executive action, and a quick overview of legal constraints on executive action. The purpose of the section is to clarify the basic procedures and actions the President has available for managing agency decisions and working within statutory gaps.

The powers of the President are set out in Article II of the Constitution.[428] Generally speaking, the President is tasked with implementing and enforcing the law. As the head of the executive branch, the President has significant authority over the way that most agencies implement and enforce the statutes that they administer.[429] For agencies within the executive branch, presidential authority is particularly robust; the President may, for example, fire the heads of executive agencies for any reason at any time, including because the President dislikes the agency's implementation of the President's policy priorities.[430] Independent agencies, created by Congress outside the executive branch, have some insulation from presidential oversight—most notably, the heads of independent agencies are not removable by the President at will[431]—though they remain subject to some limited forms of executive authority.[432]

As chief executive, the President has a number of mechanisms for centralizing executive review of agency action[433] and for encouraging cross-agency cooperation, including by issuing executive orders directing cooperation and/or prioritizing management of respiratory hazards, creating interagency working groups, and/or elaborating or amending existing presidential plans, such as the COVID-19 response plan.[434] These functions can be used to coordinate multiple agencies, particularly where there are overlaps in existing authority of those agencies.

Presidents also have the authority to direct creation of a new agency, and in fact they have done so many times over the past decades.[435] Two limitations on this authority are worth noting, however. First, while Presidents have the authority to direct creation of executive agencies, which are then subject to direct executive control, Congress also has the power to restrict unilateral presidential action in this realm through their power over appropriations.[436] If the President were to create an agency that Congress disapproved of, Congress could use the power of the purse to starve the agency of public resources.[437] Second, actions that can be unilaterally performed by one President can be unilaterally reversed by a subsequent

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[428] U.S. CONST. art. II.
[429] *See generally* Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2246 (2001) (arguing that the President has primacy in "setting the direction and influencing the outcome of administrative process").
[430] *See* Myers v. United States, 272 U.S. 52, 122 (1926).
[431] *See* Humphrey's Ex'r v. United States, 295 U.S. 602, 626–29 (1935).
[432] *See* Bijal Shah, *Executive (Agency) Administration*, 72 STAN. L. REV. 641 (2020) (discussing executive impacts on independent agencies).
[433] *See* Cass R. Sunstein, *The Office of Information and Regulatory Affairs: Myths and Realities*, 126 HARV. L. REV. 1838 (2013) (discussing the coordination functions of centralized executive review).
[434] *See* Kagan, 2001 (note 429) (discussing the President's authority over agencies).
[435] *See* Howell and Lewis, 2002, p. 1096 (note 425) (finding that Presidents created over 240 administrative agencies during the latter half of the 20th century).
[436] *See* Howell and Lewis, 2002, p. 1100 (note 425).
[437] *See* Howell and Lewis, 2002, p. 1100 (note 425).

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President.[438] As a result, using executive power to create an agency leaves that agency vulnerable to executive abolishment.[439] Presidents have no such unilateral power to abolish agencies that are instead created by Congress.

As the head of the executive branch, the President has wide-ranging powers related to the execution of the law. Presidents implement their enforcement and executive authority with a variety of tools, including with executive orders and plans. These help articulate the policy preferences of the President and to direct the remainder of the executive branch in implementing those preferences. While Presidents do not have the authority to direct agencies or other actors to contravene the Constitution, and only rarely have the authority to direct them to violate existing statutes, this still leaves substantial executive discretion.[440]

2. Potential Types of Recommendations

This section will identify the types of recommendations that might be made to the President, along with the constraints and processes that would be required for each to occur. Recommendation types that might be considered include:

- Elaborating on or amending existing presidential plans, such as the COVID-19 response plan
- Encouraging coordination across agencies
- Issuing new executive orders
- Directing creation of a new agency
- Repealing, expanding, or amending existing executive orders
- Issuing emergency designations or funding

Where the Committee believes existing agencies already have sufficient authority to manage respiratory protection but believes that additional coordination would be valuable, it would be reasonable to direct recommendations on coordination to the President, rather than to (only) the individual agencies. The President has the authority to coordinate across agencies, to prioritize agency actions, and even to direct agencies to shift their interpretations of the statutes they administer (so long as those interpretations remain reasonable and within the bounds of what Congress has allowed).

General policy priorities can also be reasonably directed to the President, who has multiple mechanisms for executing those policies. Such priorities could be directed either toward improving respiratory protection in general, as with the creation of an interagency working group directed toward improving and coordinating provision and development of respiratory protection for the public, or could address particular respiratory hazards.

In regards to particular respiratory hazards, the President has significant authority in issuing specific plans and orders, particularly when directed toward emergencies such as the

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[438] *See* Howell and Lewis, 2002, p. 1103n.9 (note 425).
[439] *See* Howell and Lewis, 2002, p. 1099 (note 425). Indeed, Howell and Lewis found that the average agency created by statute exists for 17.6 years, while the average agency created by executive order lasts for just 8.8 years.
[440] *See* Howell and Lewis, 2002, p. 1100 (note 425) (noting President Kennedy's use of an executive order to bypass the legislative process and create the Peace Corps despite objections from Congress).

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COVID-19 pandemic.[441] The Committee could, for example, recommend amendments or details furthering the goals of the existing COVID-19 response plan by providing for additional respiratory protection for the public. The "National Strategy for the COVID-19 Response and Pandemic Preparedness" already includes, for instance, a goal to "[m]itigate spread through expanding masking, testing, treatment, data, workforce, and clear public health standards,"[442] and seeks "to implement a cohesive strategy to significantly reduce the spread of COVID-19 and release clear public health guidance to the public about what to do and when, including implementing mask mandates," as well as other methods.[443] Recommendations on how to further detail these recommendations to address respiratory protection as the Committee understands it would be reasonably addressed to the President, who obviously would have the authority to implement those recommendations under the plan if he or she so chose. Similarly, the Committee might make recommendations directly to the President about the best type of respiratory protection to require in instances where the executive has authority to mandate use of masks or respiratory protection. The President has, for example, required mask-wearing on modes of public transportation that are regulated by federal agencies, including airplanes, trains, and public maritime vessels,[444] and in federal workplaces.[445] The President has also directed multiple agencies to assess the availability of federal research grants "to study best practices for implementing, and innovations to better implement, effective mask-wearing and physical distancing policies, with respect to both the Federal workforce and the general public."[446] The Committee's recommendations may help to inform implementation of these existing orders—for example, by clarifying the type of mask-wearing and/or respiratory protection that is most effective. Any recommendations to change or amend existing executive orders would also need to be addressed to the President.

D. Making Recommendations to Agencies

This section provides background regarding important types of recommendations that the Committee may choose to make to agencies. Such recommendations may be particularly important where gaps or overlaps have arisen as a result of agency action and/or where there are gaps or overlaps that may be addressed by additional agency coordination.

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[441] *See* Amy L. Stein, *A Statutory National Security President*, 70 FLA. L. REV. 1183, 1193–97 (2018) (discussing statutorily delegated presidential authority in times of national security).
[442] *See* JOSEPH R. BIDEN, JR., NATIONAL STRATEGY FOR THE COVID-19 RESPONSE AND PANDEMIC PREPAREDNESS 11–14 (Jan. 21, 2021) (discussing this goal, which is one of seven priorities identified). Another priority provides for immediately expanding emergency relief and exercising the Defense Production Act, including by directing increased production of N95 respirators and surgical masks. *See* Biden, 2021, pp. 14–16. *See also* Exec. Order No. 14,001, 86 Fed. Reg. 7219 (Jan. 26, 2021) (directing agencies to fill supply shortfalls using all available legal authorities).
[443] *See* Exec. Order No. 14,0001, 86 Fed. Reg. 7219 (Jan. 26, 2021).
[444] *See* Exec. Order No. 13,998, 86 Fed. Reg. 7205 (Jan. 26, 2021).
[445] *See* Exec. Order No. 13,991, 86 Fed. Reg. 7045 (Jan. 25, 2021); *see also* 5 U.S.C. § 7902(c) (explicitly authorizing the President to undertake measures s/he considers proper to prevent injuries and accidents to agency employees).
[446] *See* Exec. Order No. 13,991, 86 Fed. Reg. 7045, 7047 (Jan. 25, 2021) (directing the directors of the Office of Science and Technology Policy, in consultation with the secretary of Health and Human Services [through the National Science and Technology Council], the Office of Management and Budget, the Centers for Disease Control and Prevention, the National Institutes of Health, the National Science Foundation, and "the heads of any other appropriate agencies" to perform this assessment).

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1. Features and Limitations of Agency Action

This section will include a brief legal, procedural, and institutional orientation on agency action and legal constraints on agency action. The purpose of the section is to clarify the basic procedures and actions agencies use to make, enforce, and interpret laws and regulations.

The powers of regulatory agencies are not set out in the Constitution. Rather, agency authority comes from the other branches—specifically, from Congress and the President. All three branches of the government have ways of checking (or changing) agency action. Congress has the power to change the statutory directions that empower the agency and thus to change the agency's obligations and room for discretion, and has significant control over agency appropriations.[447] Presidents affect agency decisions via executive orders and directions regarding the enforcement of an agency's duties, via centralized review and coordination of agency action, and in the case of executive agencies, via control over agency personnel (most notably, with the power to fire the heads of executive agencies for any reason, including disagreement over a particular regulation).[448] Courts affect agency actions via judicial review, which is most commonly directed toward ensuring that an agency has not exceeded its statutory authority, has used appropriate procedure, and/or that the agency has not acted arbitrarily.[449]

Agencies do not have Constitutional authority of their own and may never act beyond the authority that has been granted them by law.[450] Where statutes are ambiguous or leave gaps, however, agencies are typically granted broad discretion to interpret the statutes they administer, so long as their interpretations are reasonable and do not fly in the face of congressional direction.[451] Because of this—and despite the forms of control otherwise imposed by Congress, the President, and courts—agencies often have significant leeway in determining the policy choices that they believe to be best. Committee recommendations directed toward agencies can therefore have important power to persuade among varying permissible interpretations.

Agencies have several types of action they may take to further their statutory obligations and generally enjoy broad discretion in choosing between these forms.[452] Some of these types of action—namely, rulemaking and adjudication—create legally binding requirements and come along with procedural requirements that agencies must follow or risk having the action overturned in court.[453] Agencies also take a number of actions that do not create legally

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[447] *See* TODD GARVEY & DANIEL J. SHEFFNER, CONG. RSCH. SERV., R45442, CONGRESS'S AUTHORITY TO INFLUENCE AND CONTROL EXECUTIVE BRANCH AGENCIES (2018), https://fas.org/sgp/crs/misc/R45442.pdf.
[448] *See* Kagan, 2001, p. 2298 (note 429).
[449] *See* Kagan, 2001, p. 2269 (note 429).
[450] *See* Kagan, 2001, p. 2255 (note 429) ("[A]dministrative officials may exercise coercive powers only as authorized by and in conformity with legislative directives").
[451] *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984) (establishing agencies' broad discretion to interpret statutes that they administer, so long as the interpretation is permissible within the terms of the statute).
[452] *See* SEC v. Chenery Corp., 332 U.S. 194, 203 (1947) (providing the classic establishment of the principle that agencies generally have broad discretion in choosing the form of their action); M. Elizabeth Magill, *Agency Choice of Policymaking Form*, 71 U. CHI. L. REV. 1383 (2004) (analyzing the development of modern conceptions of agency discretion after *Chenery* and further discussing the extent of agencies' authority to choose the form of their action, including via guidance).
[453] The Administrative Procedure Act (APA) provides the general set of procedures that agencies are supposed to follow and which courts review. The APA provides separate procedural requirements for rulemaking, which involves issuing prospective rules that are published in the Federal Register, and adjudication, which involves fact-specific determinations such as those that come with specific considerations of licenses, enforcement orders, etc.

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enforceable requirements—but which the agency believes otherwise promote its statutory obligations. Agency actions that are not legally enforceable are generally characterized as "guidance," and includes things like interpretive rules, general statements of policy, memoranda, manuals, bulletins, and advisories.[454] They also include some forms of interagency cooperation, such as those imbedded in interagency memoranda of cooperation.[455] Because guidance is not legally enforceable, courts will often not review it[456]; when they do, however, they generally apply a less deferential standard of review.[457] As a result, while guidance is less likely to be reviewed by a court than are legally binding rulemaking or adjudication, any review by a court is somewhat more likely to overturn guidance that is reviewed.

Compare 5 U.S.C. § 553 (rulemaking), *with* 5 U.S.C. § 554 (adjudications). The APA also details—and agencies routinely use—some exceptions to these general procedural requirements, for example by relaxing some of the requirements for public notice and opportunity for comment for some forms of rulemaking. *See* 5 U.S.C. § 553(a)–(b). Agencies need not, for example, go through typical rulemaking procedures for matters "relating to agency management or personnel," for "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice," or where the agency finds "good cause" that the typical procedures are "impracticable, unnecessary, or contrary to the public interest" (5 U.S.C. § 553[a]–[b]).

[454] *See* Final Bulletin for Agency Good Guidance Practice, 72 Fed. Reg. 3,432, 3,434 (Jan. 25, 2007) (defining "guidance document" as "an agency statement of general applicability and future effect … that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue," and explaining that "[g]uidance documents often come in a variety of formats and names, including interpretive memoranda, policy statements, guidances, manuals, circulars, memoranda, bulletins, advisories, and the like. Guidance documents include, but are not limited to, agency interpretations or policies that relate to: the design, production, manufacturing, control, remediation, testing, analysis or assessment of products and substances, and the processing, content, and evaluation/approval of submissions or applications, as well as compliance guides"). For a recent evaluation by the Government Accountability Office of agencies' guidance practices, see U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-368, REGULATORY GUIDANCE PROCESSES: SELECTED DEPARTMENTS COULD STRENGTHEN INTERNAL CONTROL AND DISSEMINATION PRACTICES (Apr. 16, 2015).

[455] *See* Final Bulletin for Agency Good Guidance Practice, 72 Fed. Reg. 3,432, 3,434 (Jan. 25, 2007).

[456] *See generally* Melissa F. Wasserman, *Deference Asymmetries: Distortions in the Evolution of Regulatory Law*, 93 TEX. L. REV. 625, 651–52 (2015) (emphasizing the lesser likelihood that guidance documents will be found to be reviewable by a court). Substantive rules can typically be challenged immediately upon promulgation—even before the agency has brought an enforcement action against any noncomplying party. *See* Abbott Labs v. Gardner, 387 U.S. 136, 150 (1967). By contrast, courts are more likely to find guidance documents to be nonfinal or unripe—and thus nonreviewable—unless or until the agency takes some final action under the guidance. *See* Wasserman, 2015, pp. 654–655; Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 817–22 (2001). If a guidance document never leads to any final action by the agency, it may never become reviewable. *But see* Magill, 2004, p. 1441 (note 452) (noting that courts may treat guidance documents as final and ripe if it is likely to have a significant practical impact on regulated parties). Agency action is also not subject to judicial review when it is committed to agency discretion by law—as where a "statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." Heckler v. Chaney, 470 U.S. 821, 830 (1985).

[457] *See* Skidmore v. Swift & Co., 323 U.S. 134, 139 (1944); *see also* United States v. Mead Corp., 533 U.S. 218 (2001) (explaining that the *Skidmore* standard applies to agency actions that lack the "force of law"). *See* William Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from Chevron to Hamdan*, 96 GEO. L.J. 1083 (2008) (presenting an empirical analysis of how courts review agency statutory interpretations under various standards); *see also* Jud Mathews, *Deference Lotteries*, 91 TEX. L. REV. 1349, 1356–1372 (2013) (discussing evidence that agencies' actions have a higher "survival rate" when reviewed under the more deferential *Chevron* standard than when reviewed under the stingier *Skidmore* standard).

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As discussed further above, Presidents exert significant oversight of agency policy. This includes some executive oversight of guidance, particularly "significant" guidance,[458] and agencies are also subject to general executive-branch guidance meant to encourage good guidance policies, as well as to centralized executive review of guidance documents (and heightened review of "significant" guidance).[459]

Notably, recommendations to agencies by the National Academies can have particularly significant legal implications not only in potentially persuading an agency to use its discretion to act,[460] but also in the event that agency action is challenged in court.[461] Specifically, while agencies have substantial authority in setting their own priorities and in interpreting statutes they administer, courts will overturn agency actions if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[462] As the Supreme Court has explained, "[n]ormally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[463] National Academies recommendations can particularly affect whether courts view agencies as having failed to consider an important aspect of a problem or to have addressed the evidence before the agency.[464] In this sense, recommendations that comment on an important aspect of a problem that an agency needs to address, or that characterize existing evidence, can also be understood as particularly relevant to agency action and thus to the agencies that may read the Committee's report.

2. Potential Types of Recommendations

This section identifies examples of the types of recommendations that would be most effectively directed toward agencies, rather than (only) Congress or the President. It identifies the types of recommendations that the Committee might direct toward agencies, along with the basic procedural constraints and processes that would be required for each to occur. It also gives several examples to illustrate the types of recommendations in which agencies would presumably

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[458] *See generally* Catherine Y. Kim, *Presidential Control Across Policymaking Tools*, 43 FLA. ST. U.L. REV. 91 (2015) (discussing presidential control over agency policymaking, including as implemented via guidance).
[459] *See, e.g.*, Final Bulletin for Agency Good Guidance Practice, 72 Fed. Reg. 3,432, 3,434 (Jan. 25, 2007) (defining "significant guidance documents," e.g., including the relatively rare instance where a guidance document may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more).
[460] *See, e.g.*, Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2374 (2020) (reviewing the decision of the Health Resources and Services Administration to promulgate guidance based on recommendations from the National Academy of Medicine).
[461] *See, e.g.*, Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin., 538 F.3d 1172 (9th Cir. 2008) (relying heavily on a report by the National Academy of Sciences in reviewing actions by the National Highway Traffic Safety Administration regarding fuel economy standards in overturning the agency's rulemaking); *see also* Nuclear Energy Inst. v. EPA, 373 F.3d 1251 (D.C. Cir. 2004) (overturning regulations issued without following the recommendations of the National Academies, where the statute being administered—the Energy Policy Act—required the agency to issue standards based upon and consistent with National Academies' findings).
[462] *See* 5 U.S.C. § 706(2)(A); *see also* Center *for* Biological Diversity, 538 F.3d at 1207 (overturning the agency's action as arbitrary and capricious).
[463] *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42–43 (1983).
[464] *See, e.g.*, Ctr. for Biological Diversity, 538 F.3d at 1200–01 (holding that the agency's actions were arbitrary and capricious for, among other things, failing to address the National Academy of Sciences' factual findings).

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be involved. Once again, these examples are provided for purposes of clarification only and are not meant to advocate for or against any specific set of substantive recommendations by the Committee.

Generally, recommendations to agencies are a particularly good institutional fit when the remedy suggested falls within agency discretion. This includes matters that would require a change to an agency's existing interpretation of its own authority under a statute, or a change to the agency to issue a new regulation or guidance under its existing authority, or a shift in its own internal resource allocation.

Types of potential action that would implicate agency action, and that might therefore be best addressed to one or several agencies, include:

- Revisiting an existing interpretation of statutory authority, whether more expansively (to increase opportunity for requirements) or less expansively (to get out of the way of another agency)
- Issuing new regulations under existing statutory interpretations
- Providing additional guidance for voluntary recommendations, education, risk communication, etc.
- Shifting resource allocation (e.g., by devoting additional resources to inhalation hazards or respiratory protection)
- Coordinating with other agencies

For example, a recommendation that the Environmental Protection Agency (EPA) revisit its existing interpretations of statutes, such as the Toxic Substances Control Act and the Clean Air Act, to adopt the broadest permissible interpretations of its statutory authority to protect the public from inhalation hazards could be reasonably addressed to EPA rather than Congress. As noted above, EPA has substantial discretion in interpreting statutes it administers,[465] and so long as the agency's interpretations are not precluded by statute, this would be an example of a way in which agency discretion can substantially affect the regulatory landscape of respiratory protection. While Presidents may also make such recommendations—as noted in the prior section—agencies have substantial authority to adopt such interpretations of statutes they administer, even without specific presidential involvement.

Recommendations that agencies reconsider specific facts regarding inhalation hazards, and act under their existing regulations addressing those hazards, would also be reasonably addressed toward agencies. For example, a recommendation that the Occupational Safety and Health Administration (OSHA) revisit its presumption that workplaces without respiratory protection programs present no significant risk of workplace injury, either generally or specifically during a respiratory pandemic, could be addressed specifically to OSHA.

Agencies also have substantial discretion in setting their own priorities and to some extent in allocating resources within the agency. On this front, a recommendation that an agency or agencies, such as EPA, prioritize inhalation hazards as among its other statutory responsibilities, could also reasonably be addressed to the agency specifically.

By contrast, it is not helpful to make recommendations to agencies to expand their actions to address issues beyond their statutory authority. In some cases, the lack of statutory authority is clear. OSHA, for example, does not have the statutory authority to directly regulate

[465] *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984).

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state and local government workplaces, or to set safety standards outside the workplace. If the Committee believed that either of those limitations was inappropriate or unwise, it would have to address Congress to change the statute.

In some cases, it can be difficult to tell the far extent of an agency's statutory authority, and agencies may sometimes have adopted narrow interpretations without even recognizing that they have broader authority. EPA, for example, might believe that it is precluded under the Clean Air Act from regulating indoor respiratory hazards. If an agency believes (whether accurately or inaccurately) that it is statutorily precluded from an interpretation the Committee prefers, the Committee would do better to address its recommendations either to the President (who has the authority to direct executive agencies to take the preferred interpretation, so long as it is in fact permitted by statute) or to Congress (if the statute in fact precludes the preferred interpretation).

CONCLUSION

This background paper has described the current regulatory landscape of respiratory protection in the United States, looking at the way respiratory protection is regulated in the workplace (especially for workers without respiratory protection programs) and for the public. As it has detailed, the regulation of respiratory protection in the United States is highly fragmented, involving multiple actors at the federal and subfederal levels, which have varying responsibilities and authority regarding different aspects of different respiratory hazards.

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Appendix D

Biographical Sketches of Committee Members and Staff

COMMITTEE MEMBERS

Jonathan Samet, M.D., M.S. (*Chair*), a pulmonary physician and epidemiologist, is the dean of the Colorado School of Public Health. Previously, he was the distinguished professor and the Flora L. Thornton Chair for the Department of Preventive Medicine at the Keck School of Medicine at the University of Southern California. Dr. Samet's research has focused on the health risks of inhaled pollutants in outdoor air and also indoor pollutants, including secondhand smoke and radon. He has also investigated the occurrence and causes of cancer and respiratory diseases, emphasizing the risks of active and passive smoking. Dr. Samet has served on and chaired numerous committees of the National Research Council and the National Academies of Sciences, Engineering, and Medicine, including chairing the Board on Environmental Studies and Toxicology. For several decades, he has been involved in global health, focusing on tobacco control, air pollution, and chronic disease prevention. Dr. Samet has been the chair of the Clean Air Scientific Advisory Committee of the Environmental Protection Agency and the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration. He has served as an editor and the author for reports of the Surgeon General on smoking and health since 1984, receiving the Surgeon General's Medallion in 1990 and 2006 for these contributions. Dr. Samet received the 2004 Prince Mahidol Award for Global Health awarded by the King of Thailand, the Edward Livingston Trudeau Medal from the American Thoracic Society/American Lung Association, the Luther Terry Award for Distinguished Career from the American Cancer Society, and the Fries

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Prize for Health. He was elected to the National Academy of Medicine in 1997 and received the David Rall Medal in 2015.

Gloria Addo-Ayensu, M.D., M.P.H., is the director of health for Fairfax County, Virginia. In this capacity she provides overall leadership and direction for public health programs in the county and serves as the official health advisor to the Fairfax Board of Supervisors, the Health Care Advisory Board, and the Human Services Council. Dr. Addo-Ayensu is a visionary leader with a passion for promoting community resiliency and creating innovative, practical, and sustainable community-based approaches to public health challenges. She has led a number of regional and state public health initiatives in the areas of health literacy, emergency preparedness, obesity prevention, and health equity. She has served on a number of national committees, including the Public Health Preparedness Essential Services Committee of the National Association of County and City Health Officials and two Institute of Medicine committees on personal protective equipment for health care workers to prevent the transmission of pandemic influenza or other viral respiratory infections. In 2016, Dr. Addo-Ayensu received the A. Heath Onthank Memorial Award, the highest honor the county bestows on its employees.

Wändi Bruine de Bruin, Ph.D., is a provost professor of public policy, psychology, and behavioral science at the University of Southern California (USC), where she leads the initiative on Behavioral Science and Well-Being Policy and is affiliated with the Price School of Public Policy, the Dornsife School's Department of Psychology, the Schaeffer Center for Health Policy and Economics, the Center for Economic and Social Research, the Center for Sustainability Solutions, and the Center for Risk and Economic Analysis of Terrorism Events. She previously served on the faculty at Carnegie Mellon University's Department of Engineering and Public Policy and the Leeds University Business School (United Kingdom), and still holds affiliations with each. She holds a Ph.D. in behavioral decision research and psychology from Carnegie Mellon University. Dr. Bruine de Bruin's research is focused on understanding and informing how people make decisions about their health, well-being, and environmental impacts; she also studies age differences in decision-making competence. She has published more than 120 peer-reviewed papers on these topics in journals targeting psychology, public policy, health, and environmental science. Dr. Bruine de Bruin is a fellow of the Psychonomic Society; the United Kingdom's Academy of Social Sciences; and the Network for Studies on Pensions, Aging and Retirement (NETSPAR). She is a member of the editorial boards of the *Journal of Experimental Psychology: Applied*, the *Journal of Behavioral Decision Making*, *Decision*, *Medical Decision Making*, the *Journal of Risk Research*,

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and *Psychology and Aging*. Dr. Bruine de Bruin is co-leading a national USC survey that is tracking people's risk perceptions and experiences associated with COVID-19. She has previously served on expert panels for the National Academy of Sciences on communicating science effectively and for the Council of the Canadian Academies on Health Product Risk Communication.

Sarah Coefield, M.S., M.A., is an air quality specialist with the Missoula City-County Health Department. As a public health practitioner, she works to prepare the public for air pollution events through studies, communication, planning, and direct interventions. Ms. Coefield has lectured on the topic of wildfire smoke-ready communities at multiple conferences, workshops, and webinars in the United States and Canada, including a 2018 International Association of Wildland Fire conference, a 2018 Northwest Center for Public Health Practice Hot Topics in Practice webinar, the 2019 Health Effects Institute Annual Conference, a 2019 American Thoracic Society workshop, a 2019 Air & Waste Management Association conference, and a 2019 British Columbia Lung Association conference. Ms. Coefield has been part of the Air Quality Program at the Missoula Health Department since 2010, where she leads initiatives on smoke management, wildfire smoke response, and oxygenated fuels, and works on such projects as the PM10 Redesignation Request and the Carbon Monoxide Limited Maintenance Plan.

Howard J. Cohen, Ph.D., M.P.H., CIH, consults in areas of occupational exposure assessment and respiratory protection. He retired as a professor emeritus at the University of New Haven, where he chaired the Occupational Safety and Health Management program. Dr. Cohen has served as an adjunct professor and an instructor at Yale University's Schools of Public Health and Medicine, and as an adjunct professor of chemical engineering at the University of Rhode Island. He received his B.A. from Boston University and earned both his Ph.D. in industrial hygiene and his M.P.H. at the University of Michigan. He is board certified in the comprehensive practice of industrial hygiene by the American Board of Industrial Hygiene (ABIH). Prior to joining the University of New Haven faculty in 1994, Dr. Cohen spent 16 years as an industrial hygienist at Olin Corporation, where he last served as its corporate manager. He was the editor-in-chief of the *American Industrial Hygiene Association Journal* from 1991 to 2003, and then served as a member of the editorial board of the *Journal of Occupational and Environmental Hygiene* until 2017. He previously served as the chair of the American National Standards Institute (ANSI) Z88.2 Committee on Respiratory Protection and the chair of the American Industrial Hygiene Association Committee on Respiratory Protection. He also has served as the

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treasurer of ABIH. Dr. Cohen has received numerous professional awards, including the 1989 Warren A. Cook Award; the 1990, 1992, and 2002 John M. White Award for excellence in respiratory protection; the 2003 Alfred Kammer award; the 2007 Donald Cummings Award; and the 2011 Henry Smyth Jr. Award. His published writings address occupational exposure assessment, the characterization of specific airborne particulates, and the performance of respiratory protective devices. In August 2021, Dr. Cohen joined StoneTurn Consultants and, with 9 other subject-matter experts, is providing expertise to the National Institute for Occupational Safety and Health's National Personal Protective Technology Laboratory under a competitively awarded contract titled: "Transitioning PPE Conformity Assessment Practices to Align with the National Framework for Conformity Assessment."

Joseph Domitrovich, Ph.D., is a wildland firefighter and an exercise physiologist for the United States Forest Service's (USFS's) National Technology and Development Program (NTDP) based in Missoula, Montana. He started with USFS in 2007. He completed his Ph.D. at the University of Montana, Missoula, in interdisciplinary studies with an emphasis in exercise physiology. He received his master's degree at the University of Montana, and his bachelor's degree at Cal Poly San Luis Obispo in California. Dr. Domitrovich's work at NTDP includes hydration, nutrition, health effects of smoke, heat-related illnesses, stress, and fitness. Dr. Domitrovich is an advisor to the Risk Management Committee of the National Wildfire Coordinating Group and the Fire Risk Management Council of USFS. He is the USFS representative to the National Fire Protection Agency (NFPA) Committee on Respiratory Protection and the task group chair for the NFPA 1984 Standard on Wildland and Urban Interface Respiratory Protection. Dr. Domitrovich also teaches wildland fire training courses at the local and national level.

Karen Emmons, Ph.D., is a professor of social and behavioral science at the Harvard T.H. Chan School of Public Health. She is a behavioral scientist with a strong track record of funded research in community-based approaches to cancer prevention in a variety of settings that serve under-resourced communities, including low-income housing and community health centers. Dr. Emmons's work targets a range of cancer risk factors, including nutrition, physical activity, sun exposure, tobacco and secondhand smoke exposure, and cancer screening. Her research teams have included interdisciplinary perspectives on cancer risk reduction and health disparities, with a focus on multiple cancer risk behaviors. Dr. Emmons has a strong track record as a mentor, and is a past recipient of a mid-career K award focused on dissemination and implementation research to reduce cancer disparities.

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Her current work and writing focus heavily on implementation science, particularly in community health settings, and she has been actively involved in national efforts to develop implementation research and training programs. She currently serves as the faculty director of the Community Engagement Program for Harvard's Clinical Translational Science Award. Dr. Emmons is the past president of the Society of Behavioral Medicine and a member of the National Academy of Medicine.

Shawn Gibbs, Ph.D., M.B.A., CIH, joined Texas A&M University on May 1, 2020, as the dean of the School of Public Health. Dr. Gibbs is an industrial hygienist with expertise in the disruption of highly infectious diseases, such as COVID-19 and Ebola virus disease. His research has helped determine national policies, procedures, and best practices for responders and health care workers to safely treat patients with highly infectious diseases. Dr. Gibbs lends guidance to national and international organizations, serving on the Environmental Protection Agency's (EPA's) Board of Scientific Counselors Homeland Security Subcommittee, and working with the Department of State and the U.S. Air Force Air Mobility Command. He obtained a B.S. in biology at The Ohio State University. While working as a contractor for EPA, he attended the University of Cincinnati where he was awarded an M.S. in environmental engineering and a Ph.D. in environmental science. While serving as the associate dean at the University of Nebraska Medical Center (UNMC) he completed his M.B.A. in agribusiness from the University of Nebraska. His first tenure track position was with The University of Texas Health Science Center at Houston at its El Paso regional campus, where he was the co-director of two cores of the Hispanic Health Disparities Research Center. He also served as the director of master's programs and then the associate dean of student affairs at the College of Public Health at UNMC. There he worked with the Nebraska Biocontainment Unit as the director of research. Its team designed quarantine, isolation, personal protective equipment (PPE), other policies and procedures, and provided international training and evaluation to first responders, including the military, and others who have direct or indirect patient contact. It performed decontamination research to assist with shortages in PPE. Dr. Gibbs and the Nebraska Biocontainment Unit served the U.S. Ebola response, including treating patients with Ebola virus disease. Dr. Gibbs then served at Indiana University as the executive associate dean of the School of Public Health. While at Indiana University, he also held several interim roles, including the associate dean for research. He developed a National Institute of Environmental Health Sciences (NIEHS) training grant that resulted in the Biosafety and Infectious Disease Training Initiative, a partnership with several nationally recognized organizations, including The University of Texas School of Public Health,

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to deliver national trainings on infectious disease. This merged into a continuing partnership with the UTHealth-led Prevention, Preparedness, and Response (P2R) Consortium, a NIEHS-funded Worker Training Program, a relationship that has continued through his return to Texas. In his current role as the dean of Texas A&M's School of Public Health, his focus is on transforming health through interdisciplinary inquiry, innovative solutions, and development of leaders through the Aggie tradition of service to engage diverse communities worldwide. Dr. Gibbs and the Texas A&M School of Public Health have served the university, county, state and country through the response to COVID-19.

Ayse P. Gurses, Ph.D., M.S., M.P.H., is a professor in the Johns Hopkins University School of Medicine, Bloomberg School of Public Health, and Whiting School of Engineering. She is the founding director of the Armstrong Institute Center for Health Care Human Factors. Dr. Gurses is an industrial and systems engineer (with sub-specialization in human factors engineering), an implementation scientist, and a health services researcher. Her current research efforts focus on improving patient safety (medication safety, diagnostic safety, care transitions/handoffs in pediatric trauma, preventing health care acquired infections), health care worker safety (protecting health care workers from communicable diseases through engineering-based solutions, workload management, reducing clinician stress and burnout), and patient- and family-centeredness of care (improving communication and partnership with patients in primary care for safe medication management). Dr. Gurses earned her Ph.D. in industrial and systems engineering from the University of Wisconsin–Madison and completed her postdoctoral training at the University of Maryland, Baltimore. Before joining Johns Hopkins University, Dr. Gurses served as a faculty member at the University of Maryland, Baltimore, and the University of Minnesota. She is a member of the Human Factors and Ergonomics Society, where she was the chair of the Health Care Technical Group, and she serves as the scientific editor of *Applied Ergonomics*, a top-level journal in the field of human factors engineering. Dr. Gurses's work has been recognized with numerous awards, including, most recently, a Best Paper Award from the International Ergonomics Association and Liberty Mutual for research examining patient safety in the cardiovascular operating room, and an Early Career Investigator Award from the Federation of Associations in Behavioral and Brain Sciences Foundation.

Robert Harrison, M.D., M.P.H., is a clinical professor of medicine at the University of California, San Francisco (UCSF), having joined the faculty in 1984. He founded and, for more than 15 years, has directed UCSF's Occupational Health Services, and now is a senior attending physician.

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Dr. Harrison has diagnosed and treated thousands of patients with work- and environment-induced diseases and injuries. He also directs the worker tracking investigation program for the California Department of Public Health. Dr. Harrison received his B.A. from the University of Rochester and his M.D. from the Albert Einstein College of Medicine. He is board certified in both internal medicine and occupational medicine. He has served on the California Occupational Safety and Health Administration Standards Board. In addition, Dr. Harrison has authored numerous publications in the area of occupational medicine.

Stephanie Holm, M.D., M.P.H., Ph.D., is the co-director of the Western States Pediatric Environmental Health Specialty Unit and a public health medical officer at the Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency. Dr. Holm received her M.D. in 2011 from the University of Pittsburgh. She is board certified in both pediatrics and occupational/environmental medicine (trained at Children's Hospital and Research Center Oakland and University of California, San Francisco, respectively). She also completed 1 year of pediatric pulmonary training at Oakland before leaving to further pursue her interests in pediatric research and pediatric environmental medicine. Dr. Holm was the principal investigator on the Tobacco in the Home Environment and Air Quality Undermining Asthma Study, a dual cohort study of asthmatic children with and without cigarette exposure, which measured particulate matter levels in children's home environments in order to correlate these with features and behaviors of the household and its occupants. As part of her work with the Region 9 Pediatric Environmental Health Specialty Unit (PEHSU), she has reviewed literature relevant to the health effects of wildfire smoke and potential public health responses, including literature on the use of masks and respirators by the general public. Also at PEHSU, Dr. Holm has co-authored multiple fact sheets and infographics mentioning masks and respirators in the setting of wildfire smoke, which are based on her published work in the peer-reviewed literature. Dr. Holm completed an M.P.H. and a Ph.D. in epidemiology at the University of California, Berkeley.

Sundaresan Jayaraman, Ph.D., is a professor in the School of Materials Science and Engineering at the Georgia Institute of Technology, where he is also the founding director of the Kolon Center for Lifestyle Innovation. A pioneer in bringing about convergence between textiles and computing, Dr. Jayaraman's research has led to the paradigm of "Fabric Is the Computer." He is a leader in studying and defining the roles of engineering design, manufacturing, and materials technologies in public policy for the nation. Dr. Jayaraman has made significant contributions in the following

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areas: (1) smart textile-based wearable systems; (2) computer-aided manufacturing, automation, and enterprise architecture modeling; (3) engineering design and analysis of intelligent textile structures and processes; and (4) the design and development of knowledge based systems (KBS) for textiles and apparel. Dr. Jayaraman received the 1989 Presidential Young Investigator Award from the National Science Foundation (NSF) for his research in the area of computer-aided manufacturing and enterprise architecture. In September 1994, he was elected a fellow of the Textile Institute in the United Kingdom. His publications include a textbook on computer-aided problem solving and 10 U.S. patents. Dr. Jayaraman has received more than $16 million in research funding from such sources as NSF, the Department of Defense and its Defense Advanced Research Projects Agency, the National Institute of Standards and Technology, the Centers for Disease Control and Prevention, and industry. He served as the technical editor, information technology, for *ATI Magazine* (now *Textile World*) from 1995 to 2003. From May 2000 to October 2004, he was an editor of the *Journal of the Textile Institute* and is currently on the editorial advisory board. Dr. Jayaraman is a founding member of the National Academies of Sciences, Engineering, and Medicine's Standing Committee on Personal Protective Equipment for Workplace Safety and Health and has served on seven consensus study committees. From December 2008 to February 2011, he also served on the National Academies' Board on Manufacturing and Engineering Design, and in February 2011, he became a founding member of the National Materials and Manufacturing Board. Dr. Jayaraman is also a founding member of the IEEE Technical Committee on Biomedical Wearable Systems (2004–2008). In October 2000, he received the Georgia Technology Research Leader Award from the State of Georgia.

James S. Johnson, Ph.D., CIH, QEP, is a certified industrial hygienist and a qualified environmental professional who has operated JSJ and Associates, a small consulting firm specializing in occupational safety and health and hazardous material issues, since 1978. Many of the firm's projects have involved personal protective equipment (PPE) and firefighter respiratory protective equipment. Dr. Johnson worked at the Lawrence Livermore National Laboratory (LLNL) from 1972 through 2006. From November 2000 to 2006 he served as the section leader of the Chemical and Biological Safety Section of the Safety Programs Division. Throughout his career at LLNL, Dr. Johnson was involved with respiratory protection and PPE as a respiratory program administrator, research scientist, and division and section manager. He is a fellow of the American Industrial Hygiene Association, a past member of the Technical Correlating Committee on Fire and Emergency Services Protective Clothing and Equipment of the National Fire Protection Association (NFPA), a past member of the NFPA Respiratory

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Protection Equipment Committee, a past chair of the International Society for Respiratory Protection (ISRP), a past chair of the ISRP Americas Section, and a past editor of *ISRP Journal*. Currently, Dr. Johnson is the chair of the ASTM Subcommittee F23.65 on respiratory protection. The recent relocation of the ANSI Z88 Secretariat from the American Society of Safety Professionals (ASSP) to ASTM has expanded the visibility and participation in respiratory standards development. New work items initiated to support the COVID-19 pandemic will address facial covering performance, emergency responder elastomeric respirator performance, and elastomeric respirator decontamination test methods. Dr. Johnson also continues to provide his expertise on respiratory program improvements, Hanford Tank Farm, use of toxic materials, beryllium, as well as providing expert witness consultation on respiratory protection. He has co-authored a number of articles and authored several chapters on respiratory protection in the past several years. In August 2021, Dr. Johnson joined StoneTurn Consultants and, with nine other subject-matter experts, is providing expertise to the National Institute for Occupational Safety and Health's National Personal Protective Technology Laboratory under a competitively awarded contract titled: "Transitioning PPE Conformity Assessment Practices to Align with the National Framework for Conformity Assessment."

Bruce Lippy, Ph.D., CIH, CSP, FAIHA, is the director of nanomaterials research at CPWR (The Center for Construction Research and Training) and the president of The Lippy Group, LLC. Dr. Lippy started his career in industrial hygiene in 1978, working with Maryland Occupational Safety and Health. He has a Ph.D. in policy from the University of Maryland, Baltimore County. He is a certified industrial hygienist and a certified safety professional and was recently designated a fellow of the American Industrial Hygiene Association. As an associate at the Johns Hopkins Bloomberg School of Public Health, Dr. Lippy teaches a graduate course on occupational injury prevention. He is a member of the National Response Team and has supported the protection of responders during the attacks of September 11, 2001; the anthrax attacks; Hurricane Katrina; and the Gulf oil spill. Dr. Lippy has recently performed safety culture audits for large construction projects, including the first nuclear power unit to be built in the United States in decades. He served on the National Academies of Sciences, Engineering, and Medicine Committee on the Use of Elastomeric Respirators in Health Care. Dr. Lippy continues to advise management about proper respiratory protection for the workers at the Department of Energy's chemical waste storage facilities in Hanford, Washington. In August 2021, Dr. Lippy joined StoneTurn Consultants and, with nine other subject-matter experts, is providing expertise to the National Institute for Occupational Safety and Health's National Personal Protective Technology

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Laboratory under a competitively awarded contract titled: "Transitioning PPE Conformity Assessment Practices to Align with the National Framework for Conformity Assessment."

David Michaels, Ph.D., M.P.H., is an epidemiologist and a professor of environmental and occupational health at the Milken Institute School of Public Health of The George Washington University. He served as the assistant secretary of labor for the Occupational Safety and Health Administration from 2009 to 2017, the longest-serving in the agency's history. From 1998 to 2001, Dr. Michaels was the assistant secretary of energy for environment, safety, and health, charged with protecting the workers, community residents, and environment in and around the nation's nuclear weapons facilities. In that position, he was the chief architect of the historic initiative to compensate nuclear weapons workers who were sickened by radiation, beryllium, and other toxic exposures. Much of Dr. Michaels's work has focused on protecting the integrity of the science underpinning public health, safety, and environmental protections. On this topic, he is the author of *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health* (Oxford University Press, 2008) and *The Triumph of Doubt: Dark Money and the Science of Deception* (Oxford University Press, 2020). Dr. Michaels received the American Association for the Advancement of Science's Scientific Freedom and Responsibility Award; the American Public Health Association's David P. Rall Award for Advocacy in Public Health; and the John P. McGovern Science and Society Award given by Sigma Xi, the Scientific Research Society. He is a member of the Board of Scientific Counselors of the National Toxicology Program. He received his Ph.D. and M.P.H. from Columbia University and his B.A. from the City College of New York.

Mary Rice, M.D., M.P.H., is an assistant professor of medicine at Harvard Medical School, where her research focuses on preventable causes of chronic lung disease in children and adults, including such environmental exposures as air pollution, weather, allergens, and microbes, as well as behavioral and nutritional risk factors. Dr. Rice directs the Institute for Lung Health at Beth Israel Deaconess Medical Center (BIDMC), a clinical and translational research program in respiratory disease that applies advanced statistical and sampling methodologies, and leverages BIDMC clinical programs in chronic lung disease and multiple U.S.-based prospective cohort studies of children and adults. Her research is funded by the National Institute of Environmental Health Sciences (NIEHS). In 2020, Dr. Rice received an Outstanding New Environmental Scientist award from NIEHS to study the effect of home air purification for chronic obstructive pulmonary disease. She received the Jo Rae Wright award for outstanding

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science (2020) and the David Bates award (2016), both from the American Thoracic Society (ATS), for her contributions to the field of environmental, occupational, and population health. She was the vice chair (2015–2018) and is now the chair (2018–present) of the ATS Environmental Health Policy Committee, and is an active member of several ATS assembly committees. Dr. Rice is the co-editor of the section on environmental science and health of the *Annals of the American Thoracic Society.*

Kevin Riley, Ph.D., M.P.H., is the director of research and evaluation of the Labor Occupational Safety and Health (LOSH) Program at the University of California, Los Angeles (UCLA), which collaborates with workers, unions, community organizations, employers, academics, students, governmental representatives, and health professionals to improve health and safety conditions for workers in Southern California. Initiatives include health and safety training; education for low-income, minority, and immigrant workers; public advocacy; and participation in industry-wide research relating to policy issues in California. Dr. Riley serves as the principal investigator of the Western Region Universities Consortium (WRUC), a partnership of four university-based hazmat training programs funded by the National Institute of Environmental Health Sciences Worker Training Program and supporting hazmat-related worker training initiatives throughout Environmental Protection Agency Regions IX and X. He has led WRUC's training initiatives for health care workers on aerosol transmissible disease hazards and California's Aerosol Transmissible Diseases Standard—most recently with an emphasis on protections from SARS-CoV-2. Dr. Riley has also overseen training efforts for workers exposed to smoke and atmospheric particulate matter during wildfire events. Other areas of research have included heat illness among outdoor workers, occupational injuries and workers' compensation eligibility for residential day laborers and domestic workers, long work hours among long-haul truck drivers and live-in caregivers, and evaluation of various worker training initiatives. Dr. Riley received his Ph.D. in sociology from UCLA and his M.P.H. from the UCLA School of Public Health. He is an active member of the Occupational Health Section of the American Public Health Association.

Daniel K. Shipp is the past president of the International Safety Equipment Association (ISEA), the association for manufacturers and distributors of personal protective equipment and clothing, from 1993 until his retirement in 2017. As the chief staff officer of ISEA, Mr. Shipp represented U.S. safety equipment manufacturers before Congress and U.S. regulatory agencies, as well as global industry and government forums. He has served as a member of the Committee on Personal Protective Equipment for Workplace Safety and Health of the National Academies of Sciences, Engineering, and

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Medicine; the Board of the Americas Section of the International Society for Respiratory Protection; the Board of Directors of the National Safety Council; and the PPE Conformity Assessment Working Group of the National Institute for Occupational Safety and Health's (NIOSH's) National Personal Protective Technology Laboratory (NPPTL). Mr. Shipp was a member of the planning committee for the National Academies August 2020 workshop on current issues in assessment of respiratory protective devices. In August 2021, Dr. Lippy joined StoneTurn Consultants and, with nine other subject-matter experts, is providing expertise to NIOSH's NPPTL under a competitively awarded contract titled: "Transitioning PPE Conformity Assessment Practices to Align with the National Framework for Conformity Assessment."

Rosemary K. Sokas, M.D., M.O.H., M.Sc., is a professor of human science at the Georgetown University School of Nursing and Health Studies and a professor of family medicine at the Georgetown School of Medicine. An internist with more than 30 years of experience in the field of occupational and environmental medicine and public health, she has provided primary care in safety net health centers in Las Marias, Puerto Rico, and Bronx, New York. Subsequently, Dr. Sokas specialized in occupational health and public health, serving as the director of the Office of Occupational Medicine at the Occupational Safety and Health Administration and as the associate director for science at the National Institute for Occupational Safety and Health. She has held academic positions at the University of Pennsylvania Perelman School of Medicine, The George Washington University School of Medicine and Health Studies, and the University of Illinois at Chicago (UIC) School of Public Health. At UIC, Dr. Sokas conducted participatory action research and led educational programs engaging workers; community members; and practitioners and students in medicine, public health, nursing, and community peer education. Her research and career are focused on occupational and environmental health for high-risk, low-wage, vulnerable populations. Dr. Sokas's publications address the role primary care providers play in addressing the prevention needs of underserved working populations, and etiologic and intervention studies targeting hazards faced by construction workers, health care workers, and immigrant day labor and home care workers, including the impact of contingent work and the need for supply chain and other policy interventions. Her interests include transdisciplinary collaboration and mixed-method approaches to addressing social justice concerns in the workplace and in the community.

John Volckens, Ph.D., is a professor of mechanical engineering and the director of the Center for Energy Development and Health at Colorado State University (CSU). He holds affiliate appointments in environmental

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health, biomedical engineering, the Colorado School of Public Health, and the CSU Energy Institute. His research interests involve air quality, low-cost sensors, exposure science, and air pollution–related disease. His laboratory is currently testing respirators and other respiratory protective devices for effectiveness against COVID-19. Dr. Volckens is a founding member of the CSU Partnership for Air Quality, Climate, and Health—an organization that seeks to develop practical, science-vetted solutions to intertwined societal problems of air quality, climate, and health. He holds a B.S. in civil engineering from the University of Vermont and an M.S. and a Ph.D. in environmental engineering from the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill. He then went on to a postdoctoral position at the Environmental Protection Agency's (EPA's) National Exposure Research Laboratory in Research Triangle Park, North Carolina. At CSU, he has pioneered the development of several new pollution sensor technologies, which have been deployed for public health research in more than 30 countries and on the International Space Station. Dr. Volckens is the co-founder of Access Sensor Technologies, LLC, a company started through his research collaborations at CSU. He has published more than 100 manuscripts related to exposure science, aerosol technology, and air pollution–related disease, and has been the principal investigator for more than $20 million in funded research from EPA, the National Institutes of Health, the Centers for Disease Control and Prevention, and the National Aeronautics and Space Administration.

NATIONAL ACADEMIES STAFF

Autumn S. Downey, Ph.D. (*Study Director*), is a senior program officer with the Board on Health Sciences Policy. She joined the National Academies of Sciences, Engineering, and Medicine in 2012 and, in addition to the current study, she directs the Standing Committee on Personal Protective Equipment for Workplace Safety and Health. She was formerly the director of the Standing Committee on Medical and Epidemiological Aspects of Air Pollution on U.S. Government Employees and Their Families. Other National Academies studies she has worked on include Meeting the Challenge of Caring for Persons Living with Dementia and Their Care Partners and Caregivers; Evidence-Based Practice for Public Health Emergency Preparedness and Response; Return of Individual-Specific Research Results Generated in Research Laboratories; Preventing Cognitive Decline and Dementia; A National Trauma Care System; Healthy, Resilient, and Sustainable Communities After Disasters; BioWatch PCR Assays; and Advancing Workforce Health at the Department of Homeland Security. Dr. Downey received her Ph.D. in molecular microbiology and immunology from the Johns Hopkins Bloomberg School of Public Health, where she also completed a

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postdoctoral fellowship at the school's National Center for the Study of Preparedness and Catastrophic Event Response. Prior to joining the National Academies, she was a National Research Council postdoctoral fellow at the National Institute of Standards and Technology, where she worked on environmental sampling for biothreat agents and the indoor microbiome.

Olivia C. Yost, M.Sc., is a program officer with the Board on Health Sciences Policy. She has supported multiple consensus study and workshop committees related to the topics of respiratory protection, preparedness, and occupational health—most recently, the Committee on Best Practices for Assessing Mortality and Significant Morbidity Following Large-Scale Disasters, the Committee on Current Issues in the Assessment of Respiratory Protective Devices, and the Committee on the Use of Elastomeric Respirators in Health Care. Prior to joining the National Academies of Sciences, Engineering, and Medicine in 2015, Ms. Yost worked as a research officer for ARCHIVE Global, where she managed evaluation activities for disease control programs in the Caribbean, West Africa, and South Asia. Ms. Yost received her M.Sc. in the control of infectious diseases from the London School of Hygiene & Tropical Medicine, where her graduate research focused on developing rapid testing methodologies to identify failing wastewater infrastructure. She received her B.A. in history and communications from Franklin University Switzerland.

Aurelia Attal-Juncqua, M.Sc., is an associate program officer on the Board on Health Sciences Policy where she currently supports the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Prior to joining the National Academies of Sciences, Engineering, and Medicine, she worked for more than 3 years as a senior research associate at the Center for Global Health Science and Security at Georgetown University. Previously, Ms. Attal-Juncqua also briefly worked as a business analyst in the health care and pharmaceutical industry in London and as a research intern for the World Health Organization in Geneva. In addition to her role at the National Academies, Ms. Attal-Juncqua is a part-time doctoral student in health security at the Johns Hopkins Bloomberg School of Public Health. She received a B.Sc. with honors in biology and microbiology from Imperial College in London and an M.Sc. in control of infectious diseases from the London School of Hygiene & Tropical Medicine. Her main professional interests include biosecurity, capacity building for prevention and control of infectious diseases, and public health emergency preparedness and response.

Michael Berrios is a research associate currently working with the Forum on Medical and Public Health Preparedness for Disasters and Emergencies and the Committee on Respiratory Protection for the Public and Workers

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Without Respiratory Protection Programs at Their Workplaces. He has worked on numerous studies during his 6 years at the National Academies of Sciences, Engineering, and Medicine. He received a master's degree in Asian studies from The George Washington University.

Claire Giammaria, M.P.H., is a former associate program officer with the Board on Health Sciences Policy for the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine. She previously worked on the study on Assessment of Strategies for Managing Cancer Risks Associated with Radiation Exposure During Crewed Space Missions, the study on Respiratory Protection for the Public and Workers Without Respiratory Protection Programs at Their Workplaces, and the Decadal Survey on Biological and Physical Sciences Research in Space 2023–2032. Ms. Giammaria also helped to staff the Standing Committee on Medical and Epidemiological Aspects of Air Pollution on U.S. Government Employees and Their Families and the Standing Committees on Personal Protective Equipment for Workplace Safety and Health. Prior to coming to the National Academies, Ms. Giammaria was a research associate for the Technology and Liberty Project at the American Civil Liberties Union, where she primarily worked on genetics, health care, and privacy issues. She has an M.P.H. from the University of Michigan, where she studied public health policy and concentrated in public health genetics. Ms. Giammaria received her B.A. from Grinnell College where she majored in biology.

Lydia Teferra is a research assistant with the Board on Health Sciences Policy at the National Academies of Sciences, Engineering, and Medicine, serving as a staff member with the Roundtable on Genomics and Precision Health and the Forum on Regenerative Medicine. She graduated from Northwestern University in 2020 with a B.A. in psychology and global health, and has been working at the National Academies for more than 1 year. Prior to her time at the National Academies, Ms. Teferra interned and volunteered for local nonprofit organizations addressing a number of public health issues. She hopes to pursue a master's degree in public health in the near future.

Scott Wollek, M.P.A., is a senior program officer with the Board on Health Sciences Policy at the National Academies of Sciences, Engineering, and Medicine, where he serves as the director of the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. In his time at the National Academies, he has worked on a variety of projects focused on medical countermeasures, civilian biodefense, workforce resilience, health care capacity building, and other health security topics. Prior to joining the National Academies, Mr. Wollek served as the senior disaster program

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manager at the American Red Cross in the National Capital Region (NCR). In that role, he was responsible for the management of preparedness, response, and recovery programs throughout the NCR, including response to more than 500 local disasters each year. During his 11 years with the Red Cross, Mr. Wollek held a variety of paid and volunteer staff positions involving local disaster response, training, exercises, plans, and operations. He served in leadership positions during disasters and special events including the 2009 and 2013 presidential inaugurations; the 2010 blizzard; and the NCR response to Hurricane Irene, Tropical Storm Lee, the 2012 derecho, Hurricane Sandy, and the shootings at the Washington Navy Yard. Mr. Wollek holds a bachelor's degree in emergency health services from The George Washington University and a master's degree in public administration, with a concentration in homeland security and emergency management, from George Mason University.

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