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Current Issues in the Assessment of Respiratory Protective Devices for Occupational and Non-Occupational Uses

PROCEEDINGS OF A WORKSHOP

Anna Nicholson, Olivia Yost, and Claire Giammaria, *Rapporteurs*

Board on Health Sciences Policy

Health and Medicine Division

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PLANNING COMMITTEE ON CURRENT ISSUES IN THE ASSESSMENT OF RESPIRATORY PROTECTIVE DEVICES: A WORKSHOP[1]

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[1] The National Academies of Sciences, Engineering, and Medicine's planning committees are solely responsible for organizing the workshop, identifying topics, and choosing speakers. The responsibility for the published Proceedings of a Workshop rests with the workshop rapporteurs and the institution.

Reviewers

This Proceedings of a Workshop 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 proceedings as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the charge. The review comments and draft manuscript remain confidential to protect the integrity of the process.

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

SUNDARESAN JAYARAMAN, Georgia Institute of Technology
JIM JOHNSON, JSJ & Associates
JULIE SCHUCK, National Academies of Sciences, Engineering, and Medicine

Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations of this proceedings, nor did they see the final draft before its release. The review of this proceedings was overseen by **HUGH H. TILSON,** University of North Carolina. He was 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 rapporteurs and the National Academies.

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Acronyms and Abbreviations

ANSI	American National Standards Institute
AQI	Air Quality Index
ASTM 73471	ASTM Work Item 73471–Standard Specification for Barrier Face Coverings
CA	conformity assessment
Cal/OSHA	California Occupational Safety and Health Administration
CDC	Centers for Disease Control and Prevention
CEN	European Committee for Standardization
CO_2	carbon dioxide
COVID-19	coronavirus disease 2019
DOE	Department of Energy
DOJ	Department of Justice
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFR	filtering facepiece respirator
HFE	human factors and ergonomics
ISEA	International Safety Equipment Association
ISO	International Standards Organization

LOSH	Labor Occupational Safety & Health program
MSHA	Mine Safety and Health Administration
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPPTL	National Personal Protective Technology Laboratory
NRC	National Research Council
OSH Act	Occupational Safety and Health Act
OSHA	Occupational Safety and Health Administration
PAPR	powered air-purifying respirator
PM	particulate matter
PPE	personal protective equipment
ppm	parts per million
PPT	personal protective technology
RPD	respiratory protective device
USBM	United States Bureau of Mines
VA	Department of Veterans Affairs

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Introduction

For more than 100 years the U.S. federal government has worked to improve respiratory safety and protection through research and certification programs. Beginning in 1911 with a program in the Department of the Interior's United States Bureau of Mines, these efforts have expanded to include multiple federal agencies and to provide protections to many types of workers and their environments.[1] As part of these efforts, since 2005 the National Institute for Occupational Safety and Health's (NIOSH's) National Personal Protective Technology Laboratory (NPPTL) has sponsored the National Academies of Sciences, Engineering, and Medicine's (the National Academies') Standing Committee on Personal Protective Equipment for Workplace Safety and Health.[2,3] Recently, new concerns for respiratory health and safety have emerged that are not readily addressed by the exist-

[1] More information about the federal government's history with respiratory protection is available at https://www.cdc.gov/niosh/npptl/Respiratory-Protection-history.html (accessed October 8, 2020).

[2] The Standing Committee on Personal Protective Equipment for Workplace Safety and Health at the National Academies of Sciences, Engineering, and Medicine provides a forum for discussing scientific and technical issues relevant to the development, certification, deployment, and use of personal protective equipment (PPE), PPE standards, and related systems used to ensure workplace safety and health.

[3] The planning committee's role was limited to planning the workshop, and the Proceedings of a Workshop was prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop. Statements, recommendations, and opinions expressed are those of individual presenters and participants, and are not necessarily endorsed or verified by the National Academies of Sciences, Engineering, and Medicine, and they should not be construed as reflecting any group consensus.

ing systems and processes for ensuring respiratory protection for certain user groups. For instance, wildland fires, air pollution, and infectious diseases are growing threats to the respiratory safety of many nontraditional workers[4] and members of the general public. Numerous challenges are at play with respect to the use of respiratory protective devices (RPDs) in these new environments, their conformity assessment (CA), and the processes used to evaluate them. Additionally, unanswered research questions and the need to communicate effectively about these concerns to nontraditional workers, their employers, and the general public are emerging as these groups need to increasingly use RPDs. On August 4–5, 2020, the National Academies convened a virtual workshop, Current Issues in the Assessment of Respiratory Protective Devices: Nontraditional Workers and Public Use. The workshop was sponsored by NPPTL to address approaches to the respirator approval process in the current landscape for both occupational and non-occupational use of respirators. Additionally, the workshop was tasked with considering gaps in respiratory protection for outdoor workers and the general public. (See Appendix A for the workshop Statement of Task.)

WORKSHOP OBJECTIVES

The workshop had six sessions held virtually over 2 days and featured invited presentations and discussions that focused on:

- Reviewing lessons learned over the past 100 years of respiratory protection and how these can be applied to the assessment of RPDs moving forward;
- Exploring current respiratory protection needs and risks for nontraditional worker groups and the public;
- Reviewing current practices of the NIOSH respirator approval program and CA processes for respirators and identifying opportunities and gaps;
- Exploring conformity assessment approaches used in other countries, by third-party organizations, and in private industry and discussing the risks and benefits of these approaches in the context of respiratory protective device use by nontraditional workers and the public;

[4] The planning committee and some workshop participants used the term "nontraditional workers" to describe those occupational users who perform their job functions outside of a formal respiratory protection program. The term "nontraditional worker" is used throughout the proceedings, but in some instances presenters may use other terms to refer to this or similar occupational user groups, such as contingent workers, informal workers, nontraditional employees, etc.

- Examining whether the respiratory protection needs of underserved groups, such as nontraditional workers and the public, are served by current standards and assessment programs and identifying opportunities and research gaps; and
- Exploring research gaps in understanding the respiratory protection needs of nontraditional workers as well as opportunities to enhance the communication of respiratory protection guidance to users and other stakeholders.

Because the workshop focused on two distinct types of potential occupational and non-occupational users of respiratory protective devices—nontraditional workers and the general public—the individual workshop sessions and presentations were targeted to the particular needs and requirements of these two different user groups. Sessions specific to each group were identified as such, and presenters were asked to tailor their remarks to the user group of focus.

In accordance with the policies of the National Academies, the workshop did not attempt to establish any conclusions or develop recommendations about needs and future directions, focusing instead on issues identified by the speakers and workshop participants. In addition, the organizing committee's role was limited to planning and convening the workshop. In accordance with institutional guidelines, the proceedings of the workshop were prepared by a designated rapporteur as a factual summary of what occurred at the workshop. The views captured in the proceedings are those of individual workshop participants and do not necessarily represent the views held by the workshop participants, planning committee, or the National Academies.[5]

TERMINOLOGY

The planning committee and some workshop participants used the term "nontraditional workers" to describe those occupational users who perform their job functions outside of a formal respiratory protection program. The term "nontraditional worker" is used throughout the proceedings but in some instances, presenters may use other terms to refer to this or similar

[5] In order to clarify terminology in this publication: masks, face coverings, facial coverings, and respirators are distinct terms with distinct meanings but their use in this proceedings depends on the speaker's choices. Every attempt has been made to limit the term respirators to a tight fitting device that protects the user from inhaling airborne contaminants and masks to mean coverings that are loose, unfitted devices that cover the nose and the mouth of the user and provide protection for the environment from the user's cough and exhaled secretions. Respirator protective devices (RPDs) include respirators as well as masks, face coverings, and facial coverings (Johnson, 2020; NASEM, 2019).

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ORGANIZATION OF THE PROCEEDINGS

The proceedings of this workshop are organized into seven chapters. Chapter 2 summarizes the discussion of the workshop's opening panel, which explored how the assessment and approval of RPDs have evolved over the past century to meet the needs of occupational users. Chapter 3 focuses on respiratory risks and user requirements for nontraditional workers, while Chapter 4 focuses on respiratory risks and user requirements for the public. Chapters 5 and 6 examine assessment pathways for RPDs for occupational use by nontraditional workers and non-occupational use, respectively. Chapter 6 also provides more background on devices, fabrics, and standards. Chapter 7 explores gaps in research and communication that relate to the assessment of respiratory protection devices for nontraditional workers and public use.

OPENING REMARKS

Maryann D'Alessandro, the director of NPPTL at NIOSH, explained that NIOSH and NPPTL got the idea for the workshop in 2019 after working for several years with the Department of State, the Environmental Protection Agency, and public safety stakeholders on the use of respiratory protection to ward off hazards associated with smoke exposures from wildland fire. Smoke exposures are one of multiple respiratory hazards confronted by contingent workers and the public. However, there is currently no well-defined approach for protecting against the respiratory hazards faced by these populations. There are clearly established responsibilities and pathways related to the testing and approval of respiratory protective devices for occupational uses, but clarity is needed concerning which parties should hold responsibilities related to the assessment and approval of RPDs and other face coverings for use by nontraditional workers and the general public. In requesting the National Academies to develop this workshop,

NIOSH and NPPTL sought to identify key concepts that could help to better inform respiratory protection policy and identify science gaps for the contingent workforce and the general public. The workshop also served as an information-gathering source for a soon-to-be-launched consensus study that will explore similar issues over the next 12–18 months, with the aim of providing recommendations on a path forward for the nation.

Melissa McDiarmid, the chair of the workshop planning committee and a professor at the University of Maryland School of Medicine, said that the planning for this workshop began before the beginning of the coronavirus disease 2019 (COVID-19) pandemic. As such, the COVID-19 pandemic was not intended to be a focus of the workshop, nor was it included as a defined topic in the workshop agenda. However, McDiarmid noted that COVID-19 would be discussed throughout the workshop sessions as it is a current issue of great relevance to the workshop's objectives, particularly in terms of the use of face coverings by workers and the public and in addressing research and communication gaps in the field of respiratory protection.

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Lessons Learned from 100 Years of Respiratory Protection

In the opening session of the workshop, Richard Metzler, a retired senior scientist at the National Personal Protective Technology Laboratory (NPPTL) at the National Institute for Occupational Safety and Health (NIOSH), explored how the assessment and approval of respiratory protective devices (RPDs) have evolved over the past century to meet the needs of occupational users. He discussed how lessons learned from that use can inform planning for imminent and future needs regarding the occupational and public use of respirators. The session was moderated by workshop planning committee member Melissa McDiarmid, a professor of medicine, epidemiology, and public health, University of Maryland School of Medicine.

CONFORMITY ASSESSMENT

Conformity assessment (CA) activities are the vital link between standards and products, services, processes, systems, personnel qualifications, and organizations, Metzler said.[1] He defined CA as "the demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled."[2] CA can include the supplier's declarations of conformity and independent certifications. Supplier's declarations of conformity

[1] More information about conformity assessment activities is available from https://www.standardsportal.org/usa_en/conformity_assessment/conformity_assessment.aspx (accessed September 16, 2020).

[2] See https://www.nist.gov/topics/conformity-assessment (accessed September 16, 2020).

are first-party statements of the ability to conform to specified standards. Certifications are always independent, third-party declarations of conformance, and they can include sampling and testing, inspections, management system assessment, and product quality control. Additional components of CA include accreditation of the competencies of those performing the certification activities and recognition of the accreditation program's capability.

Metzler explained that these CA activities are outlined in the National Technology Transfer and Advancement Act.[3] Signed into law in 1996, this legislation was designed to promote economic, environmental, and social well-being and to bring technology and industrial innovation to the marketplace. The National Institute of Standards and Technology is responsible for coordinating federal, state, and local standards and CAs. The American National Standards Institute (ANSI), a private, not-for-profit organization, coordinates the U.S. voluntary standards and CA system. ANSI facilitates the development of American national standards by accrediting more than 240 standards development organizations, such as ASTM International, the National Fire Protection Association, and the International Symposium on Computer Architecture.

Effective Conformity Assessment for Respiratory Protective Devices

RPD requirements are typically defined in American national standards developed by ANSI-accredited standards development organizations, Metzler said, but they may also be included in contracts and purchase agreements. Requirements for RPDs include design, performance, quality assurance and control, reliability, labeling, caution limitations and restrictions of use, and user instructions. Metzler said that the risk of hazardous exposure from use of nonconforming products is critical for driving CA activities for personal protective technologies; the specified standards should be effective in reducing the risk of exposure to safe levels. The National Academies of Sciences, Engineering, and Medicine (the National Academies) has studied and made recommendations for effective CA for personal protective equipment (PPE) and RPDs, Metzler said. In 1995, the National Research Council (NRC) recommended that government agencies retain oversight responsibility for critical regulatory and procurement standards in the area of public health, safety, environment, and national security (NRC, 1995). The same publication also recommended that the private sector perform assessment activities for conformance to standards, with the government acting only in an oversight capacity. In 2008, in a review

[3] More information about the National Technology Transfer and Advancement Act is available from https://www.nist.gov/standardsgov/national-technology-transfer-and-advancement-act-1995 (accessed September 16, 2020).

of research programs at NIOSH, an NRC and Institute of Medicine (IOM) committee recommended that NIOSH, in collaboration with a variety of organizations, should assess the certification mechanisms needed to ensure the efficacy of all types of personal protective technologies (NRC and IOM, 2008). Additionally, in 2011 the IOM recommended that NIOSH's NPPTL lead an effort to develop and implement a comprehensive, tiered risk-based framework for the classification and CA of personal protective technologies for specific applications (IOM, 2011a). From this work and in collaboration with private-sector organizations, NIOSH published a national CA framework for PPE in 2018 (NIOSH, 2017).

Metzler said that the CA infrastructure in the United States is sufficiently robust to support risk-based CA for PPE. To accomplish this he suggested using private-sector CA programs with centralized oversight, with the NIOSH-developed national framework for PPE CA applied to ensure the effectiveness of the CA program. He noted that the current infrastructure is market-driven and decentralized, having been shaped over the past century by major events including two world wars. As it evolved over time, the CA infrastructure has focused on appropriate standards and conformance for the acquisition of military equipment and on industries such as railroads, electrical power, fire service and prevention, and insurance. Global trade has also been a major factor in CA infrastructure, he added. Today, there are thousands of CA programs with different types of activities and varying levels of independence, and robustness that depend upon the particular program's objectives. Metzler said that the regulatory system for PPE is decentralized—for example, the range of PPE approved by NIOSH includes respirators used for occupational use, body armor for the Department of Justice (DOJ), fire service products for the National Fire Protection Association (NFPA), personal flotation devices for the U.S. Coast Guard, and helmets for the Snell Foundation but does not include cloth masks or face coverings. As NIOSH already provides oversight for respirator approvals, Metzler suggested that the current infrastructure could support an update to NIOSH's existing program for respiratory protective devices and additional PPE. However, he added that the current infrastructure lacks a centralized authority to provide oversight of nontraditional and public uses of RPDs.

APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

Metzler briefly traced the history of the approval process for RPDs (Spelce et al., 2019). Approval programs were established in the early 1900s, with the United States Bureau of Mines (USBM) making the first respirator certification program in 1919. In establishing a CA program, USBM indicated that certificates of approval should be based on the con-

cept of permissibility, meaning that the product is safe for the intended use. This concept of permissibility was extended beyond respirators and applied to all mining products, including equipment such as explosion-proof enclosures, explosives, and fire-resistant conveyor belts. USBM subsequently established the basic health and safety standards for all approved respirators: They must give adequate protection for intended use, be reasonably comfortable and convenient to wear, provide acceptable protection for a suitable period, and be constructed of durable materials. These approval requirements were linked to hazard classification and uses, with varying requirements for different respirator types. Metzler said that this approach is challenging in situations where the knowledge of a hazard is evolving or the technologies are advancing.

"Conformity assessment is necessary to safeguard personal protection, but it's not sufficient to ensure intended protection," Metzler emphasized. He offered four considerations related to ensuring adequate protections for users. First, a respiratory protection program is vital to assure proper product selection, use, and maintenance of RPDs. Respiratory protection program standards were revised by different organizations a total of seven times between 1938 and 2019, he said. The Occupational Safety and Health Administration (OSHA) implemented Respiratory Protection Standard 1910.134[4] in 1971, and NIOSH began administering respirator quality control provisions in 1972 via the federal regulation 30 CFR 11.[5] A major lesson learned from the past century, Metzler said, is that a respiratory protection program is necessary and should not be "short-circuited" for public protection.

The second consideration, Metzler said, is that for RPDs "a certification does not necessarily equal an approval." Private-sector accredited certification organizations make independent third-party declarations of conformance to specified standards. However, they do not assure that the specified standards are appropriate to meet the intended uses and exposures to specific hazards. Furthermore, the standards used in the private sector might not adequately describe the hazards or the limitations of use for conforming products. Until these aspects are integrated into the process, Metzler said, private-sector certification will not be not equivalent to NIOSH approval. Metzler's third point was that U.S. law requires NIOSH, when developing new mandatory regulations or standards for respirators, to not reduce the protection of existing standards. This is a

[4] More information about Respiratory Protection Standard 1910.134 is available from https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134 (accessed September 16, 2020).

[5] More information about federal regulation 30 CFR 11 is available from https://www.govinfo.gov/content/pkg/FR-1995-06-08/html/95-13286.htm (accessed September 16, 2020).

challenging requirement that necessitates substantial consideration from NIOSH every time new regulations are developed. Additionally, NIOSH must meet the obligations outlined in the Regulatory Flexibility Act,[6] which include assessing the need for the regulation, identifying alternatives, and determining if the regulation is designed to achieve the agency's objectives in the most cost-effective manner. NIOSH also facilitates the use of performance standards. Metzler suggested that these standards could also be applied to CA programs for protecting the private sector.

Finally, a fourth consideration for protecting users is centralized CA program oversight to help assure effectiveness, Metzler said. This would address issues such as evolving hazards, technological advancements, and updating requirements or revising standards. It would also make determinations regarding "grandfather periods," or periods of transition from previous standards to a new standards. A centralized program could resolve issues regarding non-conforming or counterfeit products and ensure that CA process evaluations are effective, he added.

A NATIONAL STRATEGY FOR CONFORMITY ASSESSMENT

Metzler explained that CA of RPDs is a component of a broader integrated system of requirements to ensure protections in the United States; this broader system includes national laws and regulations, the industrial hygiene infrastructure, the standardization infrastructure, the broader CA infrastructure, and federal and private research. Metzler suggested that a national strategy is needed for nontraditional RPD users, including the general public, a population for which there is no centralized, recognized authority currently providing oversight. In contrast, he said, centralized oversight of RPD conformance with standards for various occupations is provided by OSHA, the Mine Safety and Health Administration (MSHA), and the Department of Energy (DOE). For nontraditional RPD users, there are multiple agencies that have some form of jurisdiction, including NIOSH, the Food and Drug Administration (FDA), the Consumer Product Safety Commission, and now the Department of Homeland Security. The absence of centralized, secure, and clearly identified leadership can lead to inconsistencies, he said, adding that this is now evident in issues related to the national implementation of face coverings as a form of source control during the coronavirus disease 2019 (COVID-19) pandemic.[7]

[6] More information about the Regulatory Flexibility Act is available from https://www.govinfo.gov/content/pkg/STATUTE-94/pdf/STATUTE-94-Pg1164.pdf (accessed September 16, 2020).

[7] Source control is a term used to describe measures (e.g., cloth face coverings or face shields) intended to prevent people with COVID-19 from spreading the disease to others (CDC, 2020).

Metzler emphasized that a public protection system with recognized administrative authorities—mirroring the system in place for occupational safety and health—could integrate safety and health and CA risk-based requirements to ensure that PPE wearers are properly protected. This could be accomplished by integrating the safety and health requirements for these users with CA risk-based requirements, he suggested. Specifically, a nationally recognized authority could:

- Establish and maintain protection requirements based on hazards and risks;
- Investigate nonconformance and fraudulent CA declarations and remove nonconforming products;
- Inform and provide public with critical guidance when new or evolving hazards arise; and
- Update processes and requirements to address new or evolving hazards, advances in technologies, and revised or new national consensus standards.

Metzler concluded that the absence of these oversight functions weakens protection and reduces confidence in PPE conformance declarations; he said that Congress is best suited to act to fill this gap by identifying a centralized authority.

DISCUSSION

Contrasting Certifications and Approvals

Planning committee member Robert Harrison of the University of California, San Francisco, asked for clarification about the differences among CA, certification, and approval. Metzler said that CA involves a large number of varied activities and that the supplier of the product can perform these. When it is the supplier conducting CA activities and declaring that the standards are met, the user must decide (1) if this first-party declaration of conformity is an effective declaration and (2) if the appropriate standards have indeed been met. Certification, which is one of many types of CA activities, requires a declaration from an independent third party that a product conforms to the standard. Metzler added that an evaluation conducted by an independent group allows for greater user confidence. There are a number of private-sector organizations that issue third-party certifications for a variety of products, such as the Safety Equipment Institute and UL (Underwriters Laboratories Inc.).

Metzler explained that approval is a process that begins with the identification of a hazard, followed by a determination of the appropriate stan-

dards to address that hazard and then an evaluation of the product to assure that the product conforms to standards. The approval contains clearly identified hazards the product protects against, the product's intended use, and a variety of standards that the product would have to meet to ensure the wearer of that equipment is safe. In contrast, certifications do not necessary identify the hazard a product protects against. While a certification declares that a product conforms to a specified standard, it does not necessary link back to the hazard—a step that is required for approvals. Furthermore, approvals are a regulatory issue. For example, OSHA rules and regulations require a NIOSH-approved respirator for occupational uses, and NIOSH controls the certificate of approval. If NIOSH finds that a product is not conforming and the manufacturer's system cannot produce conforming products, then NIOSH can take away the certificate of approval and void the approval that it previously granted. Metzler said that NIOSH currently issues approvals for occupational-use respirators, but respirators used in mine emergency applications require joint approval from NIOSH and MSHA. For all other occupationally used respirators, NIOSH conducts CA activities and issues approvals independently. NIOSH does not currently use accredited third-party certifiers or laboratories in conducting its approval program, Metzler said.

Challenges to Nontraditional User Respirator Approval

McDiarmid asked about the barriers that might be encountered in extending the "traditional"[8] NIOSH approval process for occupational use products to products for nontraditional users. For example, there may be insufficient information about risk assessment for nontraditional users, including risks from the very hazards the products are designed to protect against. One barrier, Metzler answered, is the constant tension in the United States between personal freedom and community protection. He predicted that there would be resistance to any additional federal coordination or oversight over broad CA for respirators that might be used by the public. Thus, he suggested adding oversight to provide coordination rather than directly performing approval activities for products used by the public. He added that work should be carried out by the private-sector CA system, as NRC recommended in 1995 (NRC, 1995). Metzler emphasize the need for a central federal organization with recognized authority to analyze data and ensure that both decentralized certification programs and self-declaration-type programs are achieving their objectives. When objectives are not met,

[8] A participant commented that the National Institute of Standards and Technology no longer uses the word "traditional" in its communication or publications.

he said, NIOSH could perform assessments and identify proper corrective action to warn the public of concerns.

McDiarmid asked Metzler to comment on the difference between nontraditional occupational users and public users. Metzler said that the lessons learned from first half of the 20th century illustrate the negative ramifications of operating without a respiratory protection program that includes the elements of hazard identification, respirator selection, training, and respirator certification or approval. During that period, researchers found that mineworkers were overexposed to some hazards despite using USBM-approved respirators. Metzler said that even though the respirators were conformed to standards set by USBM, they did not deliver the intended protection because they were used improperly. He added that it is unfortunate that some people believe that using conforming respirators makes a respiratory protection program for the public unnecessary, because history indicates otherwise.

Planning committee member Howard Cohen of the Yale School of Medicine said that he gained an understanding from the opening session of the workshop that first a hazard should be identified, then the identified hazard should result in a standard, and finally, CA should be developed for that standard. However, he said, the traditional understanding is that standards relate to products, rather than to the hazard. Furthermore, he proposed that Metzler put forward two standards: a standard of care for using the device and a standard for the device itself. Cohen suggested that the standard of care for using the device should be clarified for nontraditional workers and the public. A nontraditional user might assume that because a respirator is an N95 NIOSH-approved respirator, a person is sufficiently protected when using it. However, protection may depend on how the device is used. Cohen asked Metzler if a central authority should be responsible for communicating to nontraditional users that a device will not necessarily offer protection unless it is used correctly.

Metzler suggested that a centralized authority could help eliminate inconsistencies in implementation in the United States; he also clarified his use of the word "authority." He explained that multiple authorities can provide needed recommendations and continuity within a program (e.g., DOJ's involvement with body armor approval and NFPA's oversight of fire service equipment). Metzler said he was involved in developing 42 CFR 84 (the current standard for respiratory protective devices) and that during that process the 1972 requirement in 30 CFR 11 that called for a respiratory protection program was removed. The requirement was removed because OSHA, MSHA, DOE, and other agencies were already using established national consensus-based respiratory protection program requirements or regulations. Metzler expressed some regret about that decision in hindsight, explaining that having a central respiratory protection program connected

with approval could help reinforce the idea that protection is not conferred simply by conformance but rather that the protection program coupled with the RPD CA confers protection.

Role of Agencies and Organizations in Imposing Additional Requirements for RPDs

A participant asked Metzler to comment on NIOSH's statement that the NIOSH RPD approval does not apply to nuclear and radiologic hazards. Metzler replied that he would let the representatives of NIOSH address specific questions about approvals and instead commented on the general process for respirator approvals in the United States. Typically, he said, NIOSH has basic requirements for respirator approval, and federal agencies may impose additional requirements for respirator use within their jurisdictions. For example, DOE may have additional requirements on equipment used at chemical waste storage sites that extend beyond NIOSH requirements. Metzler said he is not under the impression that NIOSH has eliminated respirator use against radiologic hazards from its program. The current 42 CFR 84 requirement for particulate respirators applies to all particulates; NIOSH uses a worst-case aerosol test under extreme conditions to approve the particulate filtering component of the respirator. Metzler said that he would not eliminate that step and noted that federal agencies can add further requirements. He also pointed out that organizations need not be federal agencies to add requirements—for example, NFPA outlines requirements for self-contained breathing apparatus for specific uses in the fire service. Metzler added that, typically, NIOSH would approve a self-contained breathing apparatus and then NFPA also would have the product certified by a certification organization to ensure that the specific NFPA requirements are met.

Role of Federal Agencies in Public Respiratory Protection

Planning committee member John Balmes of the University of California, San Francisco, noted NIOSH's central role in CA, certification, and approval of respirators for occupational users and remarked that multiple agencies are currently involved in respiratory protection for the public, including FDA, the Environmental Protection Agency, and the Centers for Disease Control and Prevention. Balmes asked Metzler to comment on the involvement of multiple agencies that may not be coordinating with one another. Metzler responded, "It's always difficult to have large organizations on exactly the same page" due to differences of opinion regarding a hazard or about the effective use of a product. Until a sufficient amount of research and data are available to clearly identify the appropriate direction, legitimate differences among orga-

nizations can make it difficult to coordinate, he added. For example, in the case of facial coverings or respirators being worn in response to COVID-19 outbreaks, the public was first told that these devices and coverings should not be worn and later told that they should be worn. He cited discussions about how much respiratory protection face coverings offer. In the case of the COVID-19 pandemic, information about the hazard is evolving, and recommendations are changing to appropriately respond to new information. In addition, the lack of a central authority to provide single answers also plays a role. Metzler said it is extremely important that any approved or certified product—and even any product self-declared to meet a standard—provides cautions, limitations, and restrictions of use, which are as important as the product's intended use.

Role of NIOSH in Approving Respirators for Use in Health Care Settings

A participant asked about FDA's role in the approval processes described by Metzler. Maryann D'Alessandro, the director of the NPPTL at NIOSH, explained that NIOSH approves all respirators that are used in occupational settings. In addition to NIOSH's approval requirements, FDA requires that N95 respirators used in health care settings meet standards for fluid resistance, biocompatibility, and flammability. Prior to 2018, FDA cleared NIOSH-approved respirators for these additional protections. However, in 2018 a memorandum of understanding between NIOSH and FDA established a coordinated effort between NIOSH and FDA and resulted in NIOSH assuming the role of approving N95 respirators for use in health care per FDA requirements.[9]

On KN95 Respirators

A participant asked about KN95 respirators. D'Alessandro said that NIOSH has evaluated numerous KN95 respirators, but approximately half of the respirators evaluated have not met the requirements of the purported standard. FDA has an emergency use authorization for KN95 respirators that identifies those KN95 respirators that do perform to filtration requirements that are similar to the NIOSH requirements.

[9] More information about this memorandum of understanding is available from https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006 (accessed September 10, 2020).

3

Respiratory Risks and User Requirements for Nontraditional Workers

Nontraditional respirator user populations—that is, workers who perform duties outside of a formal respiratory protection program or users from the general public—face situation-specific risks and need respiratory protection despite the absence of a formal respiratory protection program. In a session moderated by planning committee member Robert Harrison of the University of California, San Francisco, three workshop speakers discussed the risks encountered by workers across these user groups and examined how the situation-specific needs of these workers and respiratory risks align with existing recommendations, guidance, and standards.

RESPIRATORY RISKS AND RESPIRATORY PROTECTION IN SCHOOLS AND MEATPACKING FACILITIES

Bill Kojola, a retired industrial hygienist, discussed the respiratory risks faced by nontraditional workers who work in indoor environments where exposure risks often exist. In the context of respiratory risk and protection for indoor workers, the designation of "nontraditional" workers applies to worker populations in fields that are not typically associated with inhalation risks. These populations include those working in restaurants, bars, hotels, retail stores, conventional office environments, correctional facilities, grocery stores, schools, and meatpacking facilities. Workers in these settings often encounter exposure risks that could warrant respiratory protection (e.g., through exposure to cleaning products, asbestos, lead, solvents, or infectious disease). In some settings respiratory protection is neither worn by employees nor provided by employers. In other settings workers may

be provided with respirators in response to known exposure risks, but no respiratory protection program has been established. Kojola explained that in any work-related situation where employers require workers to wear respiratory protection, there must be a respiratory protection program in place that is compliant with Occupational Safety and Health Administration (OSHA) regulations. Thus, it is a violation of OSHA policies for employers to merely hand out respirators to workers without also establishing a respiratory protection program. Kojola discussed exposure risks in two settings where workers are not conventionally thought of as needing respiratory protection: kindergarten through 12th grade (K–12) schools and meatpacking facilities.

School Settings

K–12 schools are complex environments, Kojola said. In addition to teachers, schools employ custodians, food services workers, special educators who care for students with disabilities, maintenance personnel, school nurses, administrative staff, and a host of workers in other occupations. Traditionally, most workers in K–12 school settings are not required to wear a respirator, although some workers in schools (e.g., vocational teachers teaching carpentry and masonry) may wear respiratory protective devices. In some schools, nurses and health aides may occasionally wear respirators, especially during influenza season or during an outbreak of tuberculosis, measles, or pertussis. Similarly, some custodians and maintenance workers in schools may wear respirators when using solvents to remove graffiti or when they could potentially be exposed to asbestos. Kojola observed that in those relatively uncommon situations where workers in K–12 schools are using respiratory protective devices, these devices are often not fit tested or evaluated, workers are not educated in how to use them, and the schools do not have the comprehensive respiratory protection programs required to ensure that the respirators used are providing their employees with the intended protection.

Kojola commented on the changing respiratory risks in schools during the coronavirus disease 2019 (COVID-19) pandemic, noting that (as of August 2020) the Centers for Disease Control and Prevention (CDC) had recommended that all teachers and students wear cloth facial coverings to prevent droplet-based transmission of SARS-CoV-2[1] to others.[2]

[1] The virus is known as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease it causes is called coronavirus disease 2019 (COVID-19).

[2] More information on CDC's guidance for K–12 school administrators is available from https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/cloth-face-cover.html (accessed August 13, 2020).

However, he said that cloth facial coverings do not offer sufficient protection against airborne transmission, so schools may need to provide certain school employees with respiratory protection based on assessments of their specific risks. Workers at higher risk in these settings might include, for example, nurses caring for sick children, special educators working in close contact with their students. These issues are a critical part of the discussion regarding school policies amid the ongoing COVID-19 pandemic.

Meatpacking Facilities

As in school settings, line workers in meatpacking facilities do not typically use respirators and work in settings that generally do not have a respiratory protection program established or provide respiratory protection, Kojola said. These workers usually work in close proximity to their colleagues, often standing just 2–3 feet apart side to side and 4 feet across from each other on the processing lines. Although these workers have not been traditionally thought of as needing respiratory protection, meatpacking facilities were identified as hotspots of transmission during the COVID-19 pandemic. According to Kojola, in the United States as of July 27, 2020, there had been around 37,000 reported COVID-19 cases and at least 168 of these were among meatpacking facility workers.[3] One study found that COVID-19 was transmitted from as far away as 26 feet in a meatpacking plant in Germany where workers were wearing single-layer cloth masks (Guenther et al., 2020). Kojola said this finding suggests that CDC's guidance recommending the use of cloth masks is likely not adequate to prevent transmission in meatpacking facilities, and strategies for respiratory protection will need to be considered to protect meatpacking facility workers as the COVID-19 pandemic continues.

SMOKE EXPOSURE AMONG WILDLAND FIREFIGHTERS

In his remarks, Joseph Domitrovich, an exercise physiologist at the U.S. Forest Service, discussed the job demands and respiratory protection needs of wildland firefighters. Injuries related to smoke and heat are two of the primary physiological hazards of a wildland firefighter's job. The work of wildland firefighters involves a mixture of sedentary, light-, moderate-, and high-physical activities (West et al., 2020).[4] Hiking, which accounts for

[3] More information about COVID-19 outbreaks in the U.S. food system is available from https://thefern.org/2020/04/mapping-covid-19-in-meat-and-food-processing-plants (accessed August 13, 2020).

[4] In the Wildland Firefighter Heat Related Illness study carried out in the western United States during 2013–2016, wildland firefighter job tasks were categorized into four groups based on activity level and percentage of total person-task observations. Sedentary activity

almost 20 percent of the wildland firefighting job, is a demanding physical activity. Wildland firefighters routinely must trek through mountainous terrain while carrying packs that typically weigh around 50 pounds. A study of the metabolic demands of hiking in wildland firefighting found that wildland firefighters often had an average oxygen consumption above 22.5 mL/kg and a heart rate of more than 135 beats per minute (Sol et al., 2018). Furthermore, during their shifts, wildland firefighters maintain an average core body temperature of approximately 100 degrees Fahrenheit (Domitrovich, 2020). In addition to the great physical demands of the work, wildland firefighters must carry all the tools needed on their backs and may be transported by a range of different vehicles throughout their firefighting shifts. Domitrovich emphasized that "ounces matter" for wildland firefighters, which limits the size of respirators that they can use and requires balancing the risks of smoke exposure with the intense physical demands of their job and the risks of heat-related injury.

Exposure Profile, Health Risk, and Respiratory Protection for Wildland Firefighters

Between 5 and 15 percent of the time they are working, wildland firefighters are exposed to various contaminants at levels above occupational exposure limits, Domitrovich said (Reinhardt and Broyles, 2019). Although wildland firefighters typically have average levels of carbon monoxide exposure that are relatively low, they often encounter short bursts of high levels of exposure to carbon monoxide, which can vary widely in maximum intensity (Domitrovich, 2020). These workers face such a diversity of exposures that developing a standard for respiratory protection is difficult, Domitrovich said, as exposure to any given contaminant can vary greatly from one fire assignment to another. Furthermore, respirators are typically designed for high concentrations of exposure, but in the wildland firefighting context, protection is needed against low concentrations for long durations. Typical wildland firefighting shifts last approximately 14 hours, but can often exceed 24 hours depending on the fire. Domitrovich added that the short-duration exposures to high concentrations of contaminants have been linked to elevated risks of lung cancer and cardiovascular disease for both short-season and long-season wildland firefighters (Navarro et al., 2019).[5]

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accounted for 43.2 percent of all activity, light physical activity accounted for 9.4 percent, moderate physical activity for 19 percent, and high physical activity accounted for 28.4 percent of all activity (West et al., 2020).

[5] Short seasons typically last approximately 50 days during the summer months, and long seasons typically last approximately 100 days.

Studies conducted over the past several decades have sought to address the unique challenges associated with ensuring respiratory protection for wildland firefighters, Domitrovich said (NFPA, 2016). In 1984, the National Fire Protection Association (NFPA) published the first edition of its standard on respirators for wildland firefighting operations. These standards have been periodically updated, with the most recent edition published in 2016. Some respirators have failed to meet the unique needs of wildland firefighters, which include the ability to quickly don and remove the device while maintaining ease of communication and the ability to manage and use other firefighting equipment. Certain types of respirators were notably ill-suited to the needs of firefighters because they interfered with their ability to use radios for remote communication. Until recently, some wildland firefighters resorted to using conventional cloth bandanas as facial coverings in lieu of a respiratory device that meets their unique needs. Domitrovich said that education on respiratory exposure has largely, but not completely, eliminated the use of bandanas in lieu of respirators in the field. Domitrovich said that despite technological advancements in respiratory devices since the initial creation of the NFPA standards, no respirators have been tested to meet the current wildland fire respirator standard, which was first created in 1984 and most recently updated in 2010. The forthcoming new edition of the NFPA standards is expected to divide wildland firefighting respirators into three tiers: (1) particulate only; (2) particulate, vapors, and gases; and (3) particulate, vapors, gases, and additional vapors and gases not protected by the second tier. This approach was developed based on the observation that closer proximity to a wildland fire's combustion source is closely related to the presence and higher proportions of carbon monoxide, vapors, gases, and particulates in the air. Domitrovich suggested that this approach to developing wildland firefighting respirators may provide a broader range of options to help to ensure the respiratory protection of wildland firefighters in their dynamic working conditions.

RESPIRATORY PROTECTION FOR NONTRADITIONAL WORKERS

Kevin Riley, the director of research and evaluation at the Labor Occupational Safety & Health (LOSH) program at the University of California, Los Angeles (UCLA), discussed concerns related to respiratory protection for agricultural and residential workers, particularly those working in close proximity to wildfires. LOSH is an outreach program affiliated with the UCLA Fielding School of Public Health. The program conducts trainings and offers technical assistance and support in addressing health and safety issues affecting workers in various industries. Riley said that as wildfires have become an increasingly common concern in California, LOSH has received queries from workers concerned about respiratory issues related to

poor air quality and exposure to smoke and ash. Generally, he said, these concerns are not about immediate proximity to the wildfires themselves, but about their employers' expectations that they continue working despite significant exposures to smoke, ash, and poor air quality from regional wildfires. These concerns have been compounded by the emergence of the COVID-19 pandemic.

California Occupational Health and Safety Administration's Emergency Regulation on Protection from Wildfire Smoke

To address concerns regarding workers' exposure to smoke, ash, and poor air quality, in 2019 the California Occupational Safety and Health Administration (Cal/OSHA) established an emergency regulation on protection from wildfire smoke.[6] This temporary standard extends beyond the concerns of agricultural workers, covering any workers in the vicinity of wildfires where the Air Quality Index (AQI) for particulate matter $(PM)_{2.5}$[7] is 151 or greater due to smoke and ash. The standard does not apply to wildland firefighters, and employers are exempt if workers remain in buildings or structures with mechanical ventilation or filtered air or if exposure to unfiltered air with an AQI for $PM_{2.5}$ of 151 or greater occurs less than 1 hour per shift. This standard requires employers to monitor air quality, modify work practices to reduce workers' exposure to $PM_{2.5}$ during wildfire events, and enact respiratory protection measures as necessary. Under the standard, if the AQI for $PM_{2.5}$ exceeds 150, employers are required to allow for voluntary respiratory protection, following all applicable Cal/OSHA guidelines. If the AQI for $PM_{2.5}$ exceeds 500 and employees are expected to continue working, then employers must institute mandatory respiratory protection in accordance with all Cal/OSHA guidelines, which includes providing respiratory safety information to workers and establishing a respiratory protection program. Riley added that respiratory protection standards have not traditionally extended to the agricultural industry and that it is atypical for agricultural employers to have respiratory protection programs. Therefore, implementing and enacting these new emergency standards has required a novel approach that had not yet been tested because the standard had only been in place for roughly 1 year.

[6] More information about Cal/OSHA's emergency regulation on protection from wildfire smoke is available from https://www.dir.ca.gov/dosh/doshreg/Protection-from-Wildfire-Smoke/Wildfire-smoke-emergency-standard.html (accessed August 14, 2020).

[7] The Environmental Protection Agency has developed ambient air quality trends for particle pollution, also called particulate matter (PM). $PM_{2.5}$ describes fine inhalable particles, with diameters that are generally 2.5 micrometers and smaller. More information about $PM_{2.5}$ trends is available from https://www.epa.gov/air-trends/particulate-matter-pm25-trends (accessed September 15, 2020).

Education and Outreach to the Agricultural, Day Laborer, and Domestic Worker Sectors

Riley said that LOSH has efforts under way to educate both workers and employers about the new standards set by the emergency regulation on protection from wildfire smoke, with a particular focus on ensuring that adequate protections are in place before wildfires occur. He said that day laborers and domestic workers are not typically considered to be in need of respiratory protection, but concerns about this sector—which is largely composed of informal workers—have increased as wildfires in California have become more intense. Many people in this sector work in residential areas that have been developed on the boundaries of wildfire-prone areas. By virtue of their location, such residential areas are often in wealthy communities where day laborers are hired to care for properties and families. As wildfires have occurred with increasing frequency, workers on these properties are often expected to continue working even as fires approach their residential work sites (Cotsirilos, 2019; Mejia, 2019).[8] Riley noted that this work is often physically strenuous, and in some cases laborers are asked to attempt to defend the home from wildfires using garden hoses, trenches, and other means. Day laborers are also frequently called into these areas soon after a wildfire subsides to clean up the remnants of destroyed property or to remove soot and ash. Respirators could help protect these workers from exposure to fine particles during these types of cleanup efforts. However, given the informal nature of this work, formal respiratory programs are not in place for day laborers. More thought will be required to fully grapple with these complex issues, he said.

Riley emphasized the importance of educating both employers and employees about respiratory risks and protection. LOSH has conducted trainings on the emergency regulation on protection from wildfire smoke for agricultural workers, which covers various kinds of respiratory hazards and types of respiratory protection, including how to wear and test an N95 mask. Many of the workers who receive LOSH's training are Spanish speaking—and in some cases, workers from Mexico and Central America may only speak indigenous languages—so training mechanisms have been developed to better reach these workers. Riley added that beyond being educated about how to properly use an N95 mask, the workers also need to understand what an N95 mask can and cannot protect against. For instance, N95 masks are often used by agricultural workers, day laborers, and domestic workers under the presumption that they will protect against

[8] To demonstrate this point, Riley shared a video clip depicting a group of laborers working at a residential site just beside a cliff's edge in the Pacific Palisades. The cliffside was engulfed in smoke from a nearby wildfire. This video is available at https://youtu.be/bLkDH_9jVj8?t=899 (accessed August 17, 2020).

pesticides, paint fumes, or toxic chemicals. To address this issue, LOSH offers training focused on proper use cases for N95 masks and helping people to understand that "a mask is not a mask," Riley said. Training and education efforts also focus on the differences between the acute impacts of exposure to respiratory hazards and the potential long-term impacts of respiratory exposures.

Challenges and Potential Ways Forward

Respiratory protection issues intersect with many other factors. Incentive structures drive the pace of work—particularly agricultural work—and these structures may disincentivize workers from prioritizing their own safety. Agricultural workers are often paid per piece, so they are disincentivized from stepping away from work if they feel overheated or from wearing a respirator that may slow their work or add a physical burden. In the case of day laborers in temporary employment who have informal relationships with their employer, it may be challenging to ensure that (1) workers have the appropriate types of respiratory protective devices they need and (2) the use of these devices does not put them at additional risk. Riley suggested focusing on forms of exposure control that, to the extent possible, do not rely on personal protective equipment (PPE).

LOSH has also found that partnering and engaging with worker organizations and community organizations reaches these workforces most effectively. Riley added that as wildfires remain an escalating concern for people in California, the emergency regulation on protection from wildfire smoke can serve as a type of natural experiment. He said that employers, employees, and regulators in sectors where this new regulation applies are all starting from square one. Moving forward, Riley said, it will be critical to evaluate and monitor the implementation of this emergency regulation, especially across the agricultural, domestic work, and day labor sectors.

DISCUSSION

Regulation of Respiratory Protection Programs for Nontraditional Users

Harrison opened the discussion by noting that several questions had been submitted in regard to the role of OSHA and regulation for nontraditional respirator wearers. He asked about the connection between OSHA-required respiratory protection programs and the nontraditional user, particularly in workplaces that historically have not considered themselves as being in need of OSHA-mandated respiratory protection programs.

U.S. Forest Service and Department of Veterans Affairs

Noting that wildland firefighters shifted away from using bandanas due to the inadequate respiratory protection they provide, Harrison asked whether OSHA covers the U.S. Forest Service. Domitrovich replied that the U.S. Forest Service has been cited by OSHA for incidents not related to respirators. However, he said that citations issued by OSHA may not carry the weight they would with other employers and contractors because the U.S. Forest Service is itself a federal agency. He added that the complexity of having multiple organizations responding to the same wildfire can cause various regulatory issues. A participant from the Department of Veterans Affairs (VA) said that OSHA does apply to the VA, but that the VA cannot be fined.

Nontraditional Private-Sector Workplaces and Schools

Kojola said that many nontraditional workplaces do have some exposure hazards that warrant the use of respirators and the establishment of respiratory protection programs. He continued that OSHA regulations apply to private-sector workplaces and that if a private-sector employer requires a worker to wear a respirator due to inhalation hazards, then the OSHA respiratory protection standard applies. However, in his experience, he said, many nontraditional workplaces are doing little or nothing to protect their workers from respiratory hazards. In workplaces that do address respiratory protection issues, efforts are generally limited to a small subset of the requirements of a complete respiratory protection program, he said. For example, an employer might hand out respirators to workers without providing any training or fit testing. Thus, workers may not be receiving the full protection that the respirator is designed to provide. In other cases, the workers might be provided with inappropriate types of respiratory protective devices for the hazard of concern. Harrison provided the example that schools traditionally do not carry out respirator fit-testing programs. Kojola said that as public institutions, public schools differ from private-sector employers. Twenty-four states have a state program that places public schools under OSHA regulations. However, the other 26 states have no requirements for public schools to adhere to respiratory protection standards, Kojola said.

Informal Employment

Harrison gave the example of an informal worker who wears an N95 on top of facial hair to ask how OSHA standards can be applied to workers in such informal employment relationships. Riley replied that OSHA stan-

dards do not apply to informal work arrangements, particularly in residential settings. He added that an effort is ongoing in California to extend OSHA protection to domestic workers hired informally at residential properties, which is gaining some traction. Riley noted that logistical questions arise when consideration is given to applying OSHA standards to informal employment (e.g., whether this would involve OSHA inspectors going into private homes and issuing citations). Riley said there are some efforts to grapple with issues stemming from the current lack of protection in informal sectors.

Harrison shared a participant's comment regarding the issues of fitting the needs of a nontraditional workplace into the structure of a traditional respiratory protection program, which requires the management of worker training, fit testing, and medical clearance for workers who use respirators. Harrison wondered where the responsibility for these programs would lie and about the logistics of complying with the full respirator protection program, including the medical aspect.

Education and Training

Harrison said that there had been a number of participant comments regarding the need for education and training to facilitate understanding of the difference between a respirator and a facial covering. Riley emphasized that although workers need to be trained, employers require training as well. In particular, employers need to understand that respiratory protection is more than handing out a respirator—it is an entire program that includes standards, requirements, and employer responsibilities. Employers also need to understand the potential risks of providing a worker with an N95 in the absence of proper testing and medical evaluation, he continued. Furthermore, homeowners also require education. As wildfires in residential areas become more and more prominent, Riley said, many homeowners are relying on a response and cleanup workforce of day laborers. Homeowners need to understand the potential risks for these workers and assume some responsibility for hiring them, he said.

Integrating Respiratory Protection into Broader Safety Programs

Harrison shared a participant comment regarding the need for a respiratory protection program for the nontraditional user to be integrated with an overall occupational safety and health program that also includes skin and hearing protection. Harrison asked how a respiratory protection program for wildland firefighters integrates with overall occupational safety and health efforts. Domitrovich agreed that a holistic approach is needed to improve wildland firefighter health and safety. Over the past decade,

he said, federal agencies have transitioned to considering more health and safety factors. For example, in recent years the U.S. Forest Service has put hearing conservation efforts in place, especially as pertains to aircraft noise exposure. Additionally, the U.S. Forest Service is in the initial stages of examining firefighters' dermal exposures to potential carcinogens. This represents efforts to go beyond hazard-specific PPE or mitigation measures to create holistic, complete worker health, Domitrovich said.

Hazard Assessment

Saying that a number of participant comments and questions regarded hazard assessment, Harrison asked how hazard assessments can effectively determine the type of PPE necessary for nontraditional wearers, who should perform such assessments, and what kinds of respiratory protection programs should be created. He also relayed a question about whether NIOSH would be performing workplace health hazard evaluations to gather research to inform appropriate PPE determinations. Harrison reported that some hazard assessment questions pertained to COVID-19, airborne transmission, and fine particles.

Kojola replied that in regard to recommendations for respiratory protection for COVID-19, an N95 filtering facepiece respirator is the baseline. For high-level exposures, such as those that are encountered with aerosol-generating procedures, the recommendation is typically to use a powered air purifying respirator. He added that there is no current exposure level or standard for traditional industrial hygiene sampling for SARS-CoV-2 but, from the perspective of worker protection, it is critical to move away from devices that do not offer respiratory protection. Workers who have the potential for risk and exposure should receive respiratory protection, he said, especially with evidence mounting that airborne transmission of COVID-19 exists. Kojola added that cloth face coverings are insufficient for providing protection for the user and "we owe it to ourselves to ensure that those workers are as adequately protected as possible."

Standards Expectations for Nontraditional Users

Harrison shared a participant comment that traditional workplace regulation favors engineering controls and allows PPE to serve as an effort of last resort. Within the traditional hierarchy of controls,[9] engineering controls are more effective than PPE, which is the least effective level of the hierarchal model. The participant noted that respiratory protections stan-

[9] More information about the hierarchy of controls is available from https://www.cdc.gov/niosh/topics/hierarchy/default.html (accessed September 15, 2020).

dards can be fairly restrictive for nontraditional users and asked whether this highly protective approach—involving penetrating particles sizes and fit factor—is appropriate for nontraditional users and nontraditional workplaces. Harrison added that this question arose in California with the standard on wildfire smoke for nontraditional users and asked whether an N95, even if it is not fit tested, is better than no protection at all. Harrison asked whether OSHA regulations regarding assigned protection factors, fit testing, and compliance with the OSHA respiratory standard should ever be relaxed. Finally, Harrison asked whether nontraditional users should be required to conform to the same levels of compliance and standards used for traditional users.

Kojola said that the same provision should apply to all workers who have exposure risks, which means full compliance with respiratory protection standards. He said that while "better than nothing" is a step in the right direction, it is insufficient. Efforts to protect workers in fields where there are known and extensive exposures to inhalation hazards, such as construction and manufacturing, should extend to industries and environments that typically lack respiratory protection programs, he contended. Additionally, Kojola emphasized the need to look beyond respirators to address exposures at the other stages of the hierarchy of controls. For example, a recent paper that examined airborne transmission of COVID-19 in a German meatpacking plant focused on ventilation controls (Guenther et al., 2020). Air is recirculated in this cold environment, and ventilation is thereby a major focus in protecting workers beyond the single-layer face coverings that German workers wear. Kojola maintained that engineering controls should be implemented before resorting to giving everyone respirators.

In addressing the issue of whether standards should be relaxed for nontraditional workers, Domitrovich described the respirators used by wildland firefighters in the 1990s. This apparatus resembled a snorkel, consisting of a nose clip and a small, lightweight mouthpiece that filtered out particulates. He said that these respirators would not meet the fit-test requirement. In addition, facial hair is an issue, as most federal fires are in remote locations where daily hygiene with shaving is not practical. He spoke about the facial hair he grew while fighting wildfires, not wanting to reduce any time spent sleeping in the hotel by taking time to shave. Many firefighters in these areas have long beards and handlebar mustaches, he continued, so meeting the respiratory protection needs for this environment requires some creativity to maintain protection while also being appropriate for their nonstandard working environment. He said he would not use the word "relax" in regard to protection, but rather the fact that these workers are working in an outdoor environment that has good ventilation should be "taken into account."

Riley said that it is important not to relax OSHA standards from a protective point of view and that it is important to set expectations for employers. He maintained that even if a state OSHA program is not sufficiently enforcing standards, the framework informs employers of their responsibilities, including respiratory protection and higher levels of protection on the hierarchy controls. Riley asserted there should not be separate expectations for nontraditional workers.

John Balmes of the University of California, San Francisco, commented on the importance of assessing the risks, in order to avoid letting the perfect be the enemy of the good. For example, he contended that the risks from wildfire smoke to agricultural workers and gardeners who are healthy and do not have pre-existing heart or lung disease is not sufficiently high to require a fit-tested N95. In trying to protect a large population of workers at some risk, he said, a practical approach can provide some protection even if it is not perfect according to an OSHA respiratory protection program.

Howard Cohen of the Yale School of Medicine commented on the need for new types of respirators. Referring to Domitrovich's remarks about facial hair, Cohen said that many issues of nontraditional users apply to the public as well. Although OSHA respirator programs are needed whenever possible, he said, there inevitably will be situations that call for different types of respirators that are not yet commercially available.

4

Respiratory Risks and User Requirements for the Public

Nontraditional respirator user populations—that is, workers who perform duties outside of a formal respiratory protection program or members of the public—face situation-specific risks that may require respiratory protection despite the absence of a formal respiratory protection program. In a session moderated by planning committee member John Balmes of the University of California, San Francisco, three workshop speakers discussed the risks encountered by members of the public among these user groups and examined how situation-specific needs and respiratory risks align with existing recommendations, guidance, and standards.

NON-OCCUPATIONAL RESPIRATOR USE AT U.S. EMBASSIES AND CONSULATES

Claire Huson, an industrial hygienist at the Department of State, said that the Department of State has more than 270 diplomatic posts around the world. The Department of State promotes peace and stability in areas of vital national interest and provides services for U.S. citizens and government employees traveling abroad, including providing passports and visas to foreigners seeking to visit the United States. When abroad, U.S. government employees and their families living in areas with high levels of air pollution often require respiratory protection outside of their workplaces—for example, when commuting to work or school. This population's use of respiratory protection is voluntary, but the decision whether to use respiratory protection is often made with input from the Department of State. Because members of this population may influence others through their

decisions and practices regarding respirator protection use, Huson said, it is important to the Department of State that members of this population set a good example in terms of using respiratory protective devices. For instance, U.S. employees and their families may influence the behaviors of locally engaged staff at embassies and consulates, locally employed staff and their family members, and residents of host nations.

Respiratory Protection Use Scenarios

Severe air pollution is the primary reason that families overseas choose to wear some form of respiratory protection, Huson said. Severe pollution affects more than half of the Department of State posts around the world. The average $PM_{2.5}$[1] level in those settings is worse than the areas with the worst pollution in the United States, and in some settings the average $PM_{2.5}$ level is as much as three times higher than the most polluted areas of the United States. Additionally, families may choose to use respiratory protection due to vegetative fires, volcanic eruptions, and pandemic influenza. For instance, Huson said that in 2019 wildfires in Australia had an impact on the air quality at the Department of State posts in that country, sharing two photographs of a city landscape to illustrate the severity of pollution in certain settings. In the first image air pollution has made it impossible to see the city landscape in the photograph. At the time the photograph was taken, the Air Quality Index (AQI) was 370, which falls under the Environmental Protection Agency's (EPA's) designation of hazardous. In the second photograph, which was taken on the following day, the city landscape is visible, and the air appears to be much clearer. However, at the time the second photograph was taken, the AQI was 154, which falls under EPA's designation of unhealthy. Huson said that Department of State employees often report that while they were aware of air quality issues in their host countries prior to moving, they were surprised by the amount of air pollution once they arrived. Some U.S. government employees have become extremely concerned and are eager to find ways to protect themselves and their families. For example, many people overseas use a variety of negative-pressure-type air purifying respirators for particulate filtration is common. Huson said that the Department of State discourages purchasing cloth facial coverings from sidewalk vendors. If travelers decide to seek out a respiratory protective device, then the Department of State advises them on

[1] The Environmental Protection Agency has developed ambient air quality trends for particle pollution, also called particulate matter (PM). $PM_{2.5}$ describes fine inhalable particles, with diameters that are generally 2.5 micrometers and smaller. More information about $PM_{2.5}$ trends is available from https://www.epa.gov/air-trends/particulate-matter-pm25-trends (accessed September 15, 2020).

which respiratory protections might work best. They also advise people to consider whether they may be putting themselves at risk by wearing respirators (e.g., through risks associated with pre-existing medical conditions).

The Department of State's Considerations for Recommending Respiratory Protective Devices

Ideally, air-purifying particulate respiratory devices should offer consistent and effective protection, Huson said. She explained that, in addition to guidance on whether the use of a facial covering is medically acceptable for individuals, the Department of State offers guidance on filtration quality, fit, and proper use. Other considerations for air pollution respiratory devices include comfort, portability, availability in sizes that fit children, the use of ear loops versus head straps, cleanability, and cost. She added that many aspects of the currently available information about respiratory devices can cause confusion, such as devices marked as "not for industrial use," "HEPA [high-efficiency particulate air]-type," or "shows conformance to U.S. standards in testing." Additionally, there may be confusion about persons with beards wearing respiratory devices. The Department of State recommends that travelers find reusable respirators approved by the National Institute for Occupational Safety and Health (NIOSH). If none are available, it advises travelers to seek other hallmarks of quality. Huson said that travelers often find lightweight, portable cloth facial coverings, which Huson and her colleagues refer to as "air pollution masks." These facial coverings are desirable for many travelers because they are lightweight, low profile, reusable and somewhat cleanable. However, none of these air pollution masks are NIOSH-approved. Huson added that should such a pollution mask attain NIOSH approval, it would be encouraging for those deployed overseas seeking protection from air pollution. She explained that her office is only comfortable recommending NIOSH-certified respiratory protective devices (RPDs). She reported that one of her colleagues has located an elastomeric, low-profile N95 respirator and has encouraged travelers to use it; however, they have not yet gotten feedback on this device.

Health Indications, Pre-Existing Conditions, and Respirator Use

Huson said that for the Department of State, the first considerations for respirator use are an individual's health indications and pre-existing conditions, including physiological effects such as pulmonary concerns, cardiac issues, claustrophobia, anxiety, hyperventilation, and heat stress risks, which can be exacerbated when using a respirator. Potential contraindications that make wearing a mask inadvisable include severe pulmonary disease, severe cardiac disease, uncontrolled hypertension, claustrophobia,

and facial abnormalities that prevent good fit. There are additional concerns regarding respiratory protection for children. Children are not merely "little adults," she noted. Children may benefit from respirators, but they may also face greater risks associated with them. For example, sensitive individuals—such as children with asthma—may have the greatest need for respiratory protection, but use of a respirator may pose the biggest challenge with respect to medical provider concurrence.

Huson said the Department of State's medical staff need clear, consistent, evidence-based guidance to inform their decisions and assist them in making recommendations to medical professionals and parents. She specifically mentioned a need for more research to address liability concerns and to create a risk-benefit analysis of respirator use. Furthermore, the department requires guidance for identifying the appropriate respirator types for various challenging situations (e.g., lower-resistance models, carbon dioxide) and for offering specific advice for populations that are especially sensitive to air pollution. Differentiated approaches may be required for routine use and emergency situations. Where individuals are entering settings with chronic air pollution, Huson said, they need to be prepared in advance. People need to be able to distinguish between the warning signs of problems caused by respirators and those caused by exposure hazards. Finally, Huson emphasized the need to highlight and prioritize other exposure reduction strategies.

Leak Checking Air Pollution Masks

Huson said that to address issues regarding the fit of employees' air pollution masks, the Department of State conducts "leak checks" by having people put on their chosen device and performing a leak challenge test. She said that this procedure is not as rigorous of a fit test as those conducted according to the standards of the Occupational Safety and Health Administration (OSHA). However, the Department of State has found high device failure rates when using this leak-check method, even for devices that people considered to be of high quality (see Figure 4-1). She noted that this can be upsetting for people who believed they had been wearing a high-quality device in outdoor environments with severe air pollution but found out that it had not afforded them the protection they expected.

Respiratory Protection Devices: Considerations and Potential Ways Forward

Huson formatted her presentation around the use of RPDs among Department of State employees and their families who are posted abroad. The major considerations are whether respiratory protection is even needed

	Respirator	Unit Cost	NIOSH Approved?	Pass/Fail
1	FFR 1 (disposable)	~$2.25	Yes	Fail
2	Anti-pollution mask 1 (reusable)	~$30	No (KF94[a])	Fail
3	Anti-pollution mask 1 (reusable)	~$30	No (KF94[a])	Pass
4	FFR 2 (disposable)	$2	No [b]	1st Fail 2nd Pass
5	Anti-pollution mask 1 (reusable)	~$30	No (KF94[a])	Fail
	FFR 3 (disposable N99)	$9	Yes	Pass
6	Anti-pollution mask 1 (reusable)	~$30	No (KF94[a])	Fail

FIGURE 4-1 Results from the Department of State "leak checks" for adults and their air pollution masks.
NOTE: FFR = filtering facepiece respirator; NIOSH = National Institute for Occupational Safety and Health.
[a] Korean standard, 94% efficient.
[b] U.S. brand.
SOURCE: Huson presentation, August 5, 2020.

for this population and, if so, when it is needed and what the mechanism should be for triggering the use of RPDs.

Regarding the first consideration, Huson suggested that RPDs will likely be necessary in light of the 2019 decision by the California Occupational Safety and Health Administration (Cal/OSHA) to establish an emergency regulation on protection from wildfire smoke to address the concerns regarding workers' exposure to smoke, ash, and poor air quality. Huson said that conditions abroad are often worse than California's established threshold AQI for $PM_{2.5}$ of 151 for 1 hour or longer.[2] Further needs include a more detailed understanding of medical indications and contraindications for using RPDs and for a more consistent vocabulary for

[2] Under Cal/OSHA's emergency regulation on protection from wildfire smoke, if the AQI for $PM_{2.5}$ exceeds 151, employers are required to allow for voluntary respiratory protection, following all applicable OSHA guidelines. More information about Cal/OSHA's emergency regulation on protection from wildfire smoke is available from https://www.dir.ca.gov/dosh/doshreg/Protection-from-Wildfire-Smoke/Wildfire-smoke-emergency-standard.html (accessed August 14, 2020) and in Chapter 3.

explaining the issues around RPD selection and use. Additionally, a greater variety of sizes or an improvement in universal fit of RPDs is needed; the affordability and availability of the devices are key concerns as well. Huson said out that air pollution masks are somewhat expensive—costing approximately $50 per year—and that any necessary replacement parts must be readily available. To improve the clarity and detail of information provided to consumers about RPDs and other devices like air pollution masks, she suggested adopting a protection-factor system and conveying information about breathing resistance from the RPD itself. User acceptance, Huson said, is determined by factors such as aesthetics, comfort, and convenience; these considerations are critical for developing persuasive messaging that convinces people to use RPDs. The devices should feature an adequate filter, Huson said, with appropriate fit and seal every time they are worn, and would benefit from an easy-to-conduct seal check procedure. Huson specified that these devices must be available in sizes that also fit children and various facial features, with sizes that are consistent to accommodate online ordering. These devices, she added, should be also be cleanable and last for at least 6 months of regular use. Huson said all of these design and use considerations contribute to preventing the false sense of protection that many of these overseas employees have regarding the effectiveness of their devices. Huson closed by remarking that the ideal scenario would be to entirely eliminate the use of RPDs by eradicating the exposure hazards that make them necessary.

RESPIRATORY PROTECTION IN CHILDREN AND ADULTS

In her presentation, Stephanie Holm, the co-director of the Western States Pediatric Environmental Health Specialty Unit, explored considerations related to respiratory protection in children. She opened by explaining why protecting the respiratory health of children should be at the forefront of the discussion of respiratory protection for the general public. Children tend to be more vulnerable to respiratory hazards than adults because children often spend more time outdoors and more time exercising, which increases their breathing rate and can cause them to take in more airborne pollutants. Even when children are not exercising, their physiological characteristics make them more vulnerable to respiratory hazards. For instance, due to their higher rate of ventilation per kilogram of body weight, children breathe in a greater volume of air and thus a greater volume of airborne irritants than adults. Additionally, Holm said, changes that occur during developmental windows in early childhood can have lifelong effects. For example, evidence suggests that children with lower lung function become adolescents and adults with lower lung function.

Mask Filtration and Leakage

Discussions about the use of masks and respirators for individual respiratory protection, such as during wildfire smoke events, should focus on protection for the wearer, Holm said. Filtration and leakage are two primary considerations. Filtration refers to the proportion of particles that pass through the material of the mask or respirator and the decrease in particles after moving through the material. Leakage refers to the number of particles that can pass around the mask or respirator. Holm provided an overview of some of the characteristics of and evidence for cloth and medical masks.

Cloth Masks

Cloth masks have increasingly become a topic of interest because of their potential to decrease transmission of infectious droplets. However, Holm said, when they have been tested for use against particulate pollution, studies have found them to have a broad range of filtration properties depending on the category and type of fabric. Thus, the original source or application of a fabric (i.e., a t-shirt, hijab, scarf, or sweatshirt) is not indicative of the filtration characteristics of that material because most fabrics are not designed to optimize filtration characteristics, Holm said. Notably, cloth masks made with certain fabrics have been found to "pool particles" in such a way that it creates higher $PM_{2.5}$ concentrations inside the mask (Shakya et al., 2017). In other cases—for example, for bandanas and some commercially available cloth masks—the decrease in exposure is as low as 10 percent due to poor filtration and leakage, which is a small and highly unpredictable decrease (Bowen, 2010; Davies et al., 2013; Oberg and Brosseau, 2008; Rengasamy et al., 2010; Shakya et al., 2017). For that reason, even though cloth masks are currently recommended for decreasing the droplet transmission of viruses, they should not be relied on to decrease exposure in the case of particulate pollution, Holm said.

Medical Masks

Medical masks, or surgical masks, are designed to prevent surgeons from contaminating the surgical field with droplets, not specifically for respiratory protection, Holm said. However, because these masks are somewhat regulated, they may offer some degree of respiratory protection. Multiple studies have tested medical and surgical masks specifically for filtration by looking at the characteristics of the materials, which have been found to filter 60–80 percent of particles (Jung et al., 2014; Langrish et al., 2009; Oberg and Brosseau, 2008). That range is wide because filtration is

not the intended purpose of these materials, she explained. Because medical masks do not fit tightly over the face like a respirator, these masks allow for substantial leakage around the mask perimeter. In NIOSH testing, the mean decreases in particulate exposure were between 15 and 40 percent (Oberg and Brosseau, 2008). Other groups have found average decreases in exposure of between 33 and 60 percent (Bowen, 2010; Duling et al., 2007; Grinshpun et al., 2009). Holm said, the only study that has tested medical masks specifically in children (a small sample of 11) found that medical masks decreased children's exposure by 66 percent or more, which is similar to the findings for adults (van der Sande et al., 2008). Notably, the researchers in that study helped the children secure their masks tightly to their faces, which likely helped to ensure a good seal. This suggests that children could be expected to get roughly similar protection from medical masks as adults as long as the mask is well fitting, Holm said.

Filtering Facepiece Respirator Use by the General Public

Next, Holm discussed the general public's use of filtering facepiece respirators (FFRs). A major consideration is that when these respirators are used by the general public—unlike in an occupational setting—they are not fit tested. No regulatory body is currently tasked with making decisions or certifications of respirators for the general public. In 2007 a NIOSH study found that without fit testing, the 95th percentile value for the class of FFR was a reduction in exposure of 70 percent or more (Duling et al., 2007). Holm said that some products would meet the criterion for occupational use even without fit testing (meaning that they achieve a protection factor of 10, or a 90 percent reduction in exposure in 95 percent of users). This suggests that in the future, Holm said, there could be products certified for the general public that have more stringent requirements for how much reduction of an exposure is required in the absence of fit testing.

Furthermore, Holm said, data suggest that some respiratory protection for the public user is possible when using respirators without the implementation of a respiratory protection program. Historically, respiratory protection programs have been key for ensuring respiratory protection in occupational settings. Holm said that although it is difficult to envision how a respiratory protection program could be implemented for the general public, it is important to acknowledge that some protection is still available to the public even in the absence of such programs. Several studies have found beneficial health effects for adults who wear N95 respirators in the presence of particulate pollution. These effects include having less airway inflammation (Guan et al., 2018), lower systolic blood pressure (Langrish et al., 2009), and fewer symptoms and improved short-term indicators of cardiovascular health among adults with cardiovascular disease (Langrish

et al., 2012). Holm said, only two studies have evaluated the use of N95 respirators among children. The aforementioned study evaluated the use of N95[3] respirators among 11 Dutch children ages 5–11 and found a decrease in exposure of 92–97 percent (van der Sande et al., 2008). Holm reiterated that children were given assistance in donning and securing their respirators in this study. Another study of 106 children in Singapore found that it was possible to achieve a quantitative mask fit with an N95 respirator designed for children (Goh et al., 2019). Additionally, Holm said, 3M has reported that it has propriety data on the use of N95 respirators among children. It has reported that (1) many children fall on the NIOSH adult grid for face size, (2) when using an adult small respirator most children's exposure is reduced by more than 80 percent, and (3) potential further reductions in exposure will be possible with a respirator designed specifically for children. While these claims are based on unpublished proprietary data, Holm suggested that regulatory standards for respirators for children could facilitate further reductions in exposure.

Public Concerns About Mask and Respirator Use

Holm highlighted some common concerns raised about the use of masks and respirators among the general public. Many people are concerned that the use of respiratory protection by the general public, specifically by children, could create a false sense of security and promote riskier behavioral choices. Holm said this concern highlights the need for clear communication to help people understand that (1) masks and respirators reduce—but do not eliminate—pollution or particulate exposure, (2) devices provide the best protection when they are used correctly, and (3) these devices should only be considered in the context of other preparedness options. For example, Holm said, preparation for wildfires should include plans to improve the quality of indoor air.

Safety is another area of concern related to the use of masks and respirators by the general public. Holm said that most safety research has evaluated the use of these devices among adults and generally has found subjective physical changes, including the experiences of discomfort, heat around the face, and anxiety. However, physiological parameters such as heart rate, respiratory rate, and blood pressure change only slightly, if at all, and typically stay within normal ranges for healthy adults. One study of 10 young men found a slight increase in facial temperature and a slight increase in respiratory rate (Jones, 1991). Another study of adults found no physiological changes after adults spent 1 hour on a treadmill wearing

[3] In this study, researchers used NFP2 respirators, which are the European equivalent of N95 respirators.

respirators with different pressure drops (Roberge et al., 2013). A study that evaluated 10 health care workers found no physiologic changes after 1 hour on a treadmill in subjects wearing an N95 respirator versus subjects not wearing one (Roberge et al., 2010). A study evaluating 10 nurses found no change in blood pressure or SpO_2[4] after wearing an N95 respirator for 12 hours, although PCO_2[5] did increase slightly (Rebmann et al., 2013). In an evaluation of the use of respirators in a general population cohort that included individuals with mild respiratory disease, some subjects reported mild discomfort, but heart rate, respiratory rate, and spirometry were found to be within normal adult ranges (Bansal et al., 2009; Harber et al., 2009). Another study assessed the effects of respirator use among children while reading and while exercising on a treadmill for 3 minutes (Goh et al., 2019). The only difference found when children wore N95 respirators compared to when they did not is that they had slightly higher end-tidal carbon dioxide (CO_2), which is used as a marker of metabolic work. While the end-tidal CO_2 among those wearing N95 respirators was slightly higher, the ranges of those wearing N95 respirators overlapped with those not wearing N95 respirators. Holm added that data on the effects of respirators on pregnant people are mixed but that the use of an N95 respirator by pregnant women has not been found to have an effect on fetal heartrate (Roberge et al., 2014).

Holm said that these data suggest that respirator use is safe, both for the general public and for children. However, she cautioned that certain children should not use face coverings. These include young children under the age of 2,[6] children who are unable to remove a face covering on their own, children who have difficulty breathing while wearing a face covering, and children for whom the only available face covering is a possible choking or strangulation hazard. Additionally, Holm said, respirators should generally be used only by individuals who would be able to effectively communicate if they experience a problem while wearing a respirator. Holm said that while feeling hot or uncomfortable is normal, if an individual wearing a respirator has trouble breathing, he or she should take off the respirator. Holm reiterated that there are benefits that can be realized by

[4] SpO_2 is a measurement of how much oxygen your blood is carrying as a percentage of the maximum it could carry.

[5] PCO_2 is the partial pressure of carbon dioxide that is the measure of carbon dioxide within arterial or venous blood.

[6] Centers for Disease Control and Prevention (CDC) recommendations advise against the use of masks by children under the age of 2 or anyone who has trouble breathing, is unconscious, incapacitated, or otherwise unable to remove the mask without assistance. More information about CDC recommendations for wearing masks is available from https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html (accessed August 20, 2020).

the use of respiratory protective devices by the general public, even in the absence of a respiratory protective program, and that the perfect should not be the enemy of the good. She maintained that the public should be offered available devices with clarity about the amount of protection the devices provide so that individuals can make their own decisions.

IMPROVING MASKS WORN BY THE GENERAL PUBLIC

Mark Nicas, an emeritus adjunct professor at the University of California, Berkeley, focused on ways to improve the masks worn by the general public and offered four recommendations to do so. He explained that any face covering worn for the purpose of reducing the wearer's pollutant exposure—including NIOSH-approved N95 FFRs, surgical masks, cloth masks, or bandanas—is a form of respiratory protection. However, certain face coverings—including bandanas, cloth masks, and most surgical masks—do not qualify as "respirators" within the domain of occupational hygiene and in terms of compliance with OSHA standards because those face coverings permit excessive pollutant penetration and are not tested and certified by NIOSH. Nicas compared the appearance and function of NIOSH-approved N95 FFRs with that of a conventional cloth mask. NIOSH-approved N95 FFRs have two straps that wrap around the user's head to secure the device, while cloth masks typically rely on ear loops, which provide a less snug fit. He said that these two devices also offer very different levels of protection for the wearer. A well-fitting N95 FFR might allow 5 percent particle penetration, while a cloth mask may permit 50 percent particle penetration. Bandanas permit nearly 100 percent particle penetration. He remarked that during his presentation he would primarily focus on the use of cloth masks by the public, but that the ideas discussed pertain to other RPDs as well.

Increasing the Production of N95 Filtering Facepiece Respirators

Nicas's first suggestion was to substantially increase the manufacturing of N95 FFRs so that these devices will be available to the general public without causing shortages in workplace settings. The rationale is that N95 FFRs are far superior to cloth masks in terms of respiratory protection for the wearer. Particulate pollutants are a key concern for the public and are related both to wildfire smoke and infectious viruses, as are concerns related to exposure to gaseous pollutants. Cloth masks can only remove some particulates; by contrast, FFRs more efficiently remove these particulate pollutants, and some FFRs incorporate sorbents that can remove certain gases and vapors. Small wildfire smoke particles are less than 2.5 microns in diameter, and a virus carried by particles emitted from the respiratory tract

are may be up to 10 microns in diameter. Particles smaller than 10 microns can penetrate down to the end air sacs in the lungs. Nicas explained that the penetration of pollutant particles into a mask without an exhalation valve may occur in two ways: through the filter itself and through gaps around the mask perimeter. Masks with exhalation valves (see Chapter 6 for image reference) may provide a third route for particle penetration through a poorly sealed exhalation valve. Different filter materials allow particles to penetrate to different degrees—that is, different filter materials remove particles with different efficiencies. The various materials used to make cloth masks have varying filtering capacities, he added. For instance, some cloth filter materials may be more than 99 percent efficient in removing 10-micron particles but only 25 percent efficient in removing 1-micron particles. Such a filter material would be suitable for filtering pollen grains, but not for filtering wildfire smoke.

For any mask, determining overall filter efficiency requires testing the filter against a range of particle sizes, Nicas said. However, this type of testing has been conducted for only a few cloth masks. Furthermore, different masks will fit the same individual's face differently, and the same mask will fit different individuals' faces differently. Nicas said achieving a good mask fit is comparable to finding a well-fitting shoe. Nicas explained that an individual who wears a size 9 shoe cannot expect all size 9 shoes to fit equally well, and the shoe that best fits such an individual will not necessarily be the shoe that best fits all individuals who wear size 9 shoes. Furthermore, the looser the fit of any mask, the more gaps exist around the mask perimeter. In turn, more unfiltered air will enter that mask through these gaps. Nicas said that whenever large openings can be seen on the sides of a cloth mask, the wearer is likely experiencing significant inward air leakage. A mask with two head straps is likely to fit more snugly than a mask with ear loops. The fit of a mask to a person's face can be quantitatively measured by quantifying the filter penetration, which involves measuring the degree of unfiltered inward air leakage permitted by a cloth mask while simultaneously accounting for the degree of test particle penetration through the filter. Again, he added, this type of testing has seldom been conducted on cloth masks.

Formulating Standard Protocols for Cloth Mask Testing

Nicas's second recommendation to improve masks worn by the general public was for a government agency or a professional or academic group to oversee the formulation of standard protocols for testing filter efficiency and fit, including exhalation valve leakage, of cloth masks. If a government agency tested the masks—or funded a group to do the testing—then the results could be posted publicly so that consumers could compare mask

performance, he said. While NIOSH might be the government agency with the most appropriate technical expertise, the evaluation of masks for the general public is outside of NIOSH's mandate. The Food and Drug Administration (FDA) may be the appropriate agency to carry out such testing in terms of agency purview, he suggested.

Nicas explained that, according to OSHA standards, workers must first pass a "fit test" to ensure that the fit of the respirator is adequate before they are assigned an N95 FFR for use. In fit testing, the N95 FFR wearer is exposed to a challenge aerosol. The N95 FFR filter is very efficient in removing the challenge particles, so if too much of the challenge aerosol is detected inside the N95 FFR, it is concluded that the mask perimeter leakage is excessive. Nicas said that most cloth masks would not pass the fit tests that are used to test the fit of N95 FFRs due to both the looser fit of typical cloth masks and the lower filter efficiency against challenge particles of most cloth masks. In addition to fit testing, OSHA standards require a seal check whenever a successfully fitted N95 FFR is donned. Upon donning an N95 FFR, the wearer is supposed to do a quick seal check of the N95 FFR for excessive air leakage around the perimeter. Nicas expressed concern that the current method of conducting seal checks of FFRs is not reliable and said that it would be useful to offer wearers a more reliable method.

Devising Fit- and Seal-Checking Procedures for Snugly Fitting Cloth Masks

Nicas's third recommendation was for a government agency or professional or academic group to devise both fit-testing and seal-checking procedures specific for use with snugly fitting cloth masks for use by the public, such as those equipped with head straps. The materials and equipment involved in such procedures would need to be both easy to use and inexpensive so that the procedures could be employed by the general public.

Studying Levels of Carbon Dioxide Gas Inhaled with Different Types of Masks

Nicas's final recommendation addressed the concern of some wearers of cloth masks, surgical masks, and N95 FFRs regarding their exposure to exhaled CO_2 gas. Exhaled air contains between 40,000 parts per million (ppm) and 50,000 ppm of CO_2 gas. Because exhaled gas can be trapped in the air volume between a mask and the wearer's face (i.e., "dead space"), it may be pulled back into the lungs upon the next inhalation. CO_2 concentrations between 40,000 ppm and 50,000 ppm can cause dizziness, headache, and breathing difficulty, but the air inhaled by mask wearers is

likely to have much lower CO_2 levels than this, Nicas said—typically about 10-fold lower than the 40,000–50,000 ppm range. Generally speaking, the amount of CO_2 gas inhaled by a mask wearer will depend on the volume of the mask's dead space and the air volume inhaled per breath, which in turn depends on the wearer's work rate.

Nicas offered rough estimates of typical amounts of CO_2 gas inhaled by wearers of cloth masks. A cloth mask's dead space has a volume of roughly 100 mL, and the volume inhaled per breath during light exercise, such as walking, is roughly 1,200 mL. For an ambient concentration of CO_2 gas of 400 ppm and a CO_2 gas concentration of 45,000 ppm in exhaled air, the CO_2 gas level would be 4,100 ppm in the inhaled air volume. A concentration of CO_2 gas of 4,100 ppm in inhaled air is not dangerous, he said, although such levels of CO_2 gas could cause some physiological effects and a decrease in cognitive performance. He added that the final determination of such effects would need to be made by qualified medical physiology experts. However, he noted that tens of millions of people across southeast Asia, China, Japan, and Korea have routinely worn cloth masks and surgical masks for years and that millions of workers in the United States have routinely worn respirators for the past several decades. Thus, he suggested that side effects would probably already have been observed in those populations if inhaling 4,100 ppm of CO_2 gas caused serious side effects for the wearer.

Given these considerations, Nicas's final recommendation was for a government agency or professional or academic group to conduct a laboratory study to measure the CO_2 gas levels inhaled when wearing various types of cloth masks and inhaling various volumes per breath. Such tests could be conducted in a test chamber by placing a mask on a breathing mannequin, he suggested. The CO_2 gas levels could be controlled at a range of 40,000–50,000 ppm for exhaled air and 400 ppm for the chamber air. A measure of CO_2 gas levels in the total inhaled air volume could then be evaluated by medical experts to determine whether the inhaled CO_2 gas would result in health effects of concern.

DISCUSSION

Leak Testing

Balmes said that several participants asked for additional information on the Department of State's leak test. Huson replied many people were using the Bitrex fit test kit for N95 masks or testing for air and smoke on N99 respirators. The Department of State offers the choice of which challenge agent they would like to use. A challenge agent or scent is used to determine whether a respirator is leaking or improperly fitting. If the

individual wearing the respirator can smell the released agent, then that respirator is leaking, she said.[7]

Wildfire Smoke

Balmes shared a participant's question regarding wildfire smoke and asked whether gases are a concern in addition to fine particulate matter (PM). Balmes responded that according to the presentation by Joe Domitrovich of the U.S. Forest Service, wildland firefighters do have a risk of gas exposure. However, the primary concern in areas downwind of a fire is $PM_{2.5}$ and not gases.

Public Fit Testing

A participant commented that the public will not have access to fit testing unless the municipality pays for it and suggested that the public should have access to a central stock of respiratory protective devices at the local level. Balmes said that even if the municipality pays for public fit testing, it is doubtful whether it would take place. This underscores the need to increase the production of N95s and possibly surgical medical masks to make them more broadly available to the public, rather than making them exclusively available to frontline workers.

Improving the Fit of Disposable Masks for Public Wearers

Balmes asked whether medical tape should be used to secure disposable masks for a better fit and reduced leakage. Holm said, "Anything you can do to improve the fit is going to be helpful." She noted that problems arise when the filtration characteristics of the mask material are unknown. For instance, the filtration properties of an N95 or a surgical mask are relatively well known, and securing these will likely decrease one's particulate exposure. However, it is much more difficult to predict the impact of securing a cloth mask with medical tape because the filtration characteristics of the cloth are unknown. Holm also said that any action that could potentially irritate the skin is difficult to maintain for long periods of time; for instance, some health care workers experience skin irritation from the pressure of an N95 worn day after day. Holm said that better solutions are needed for the general public if they are to avoid resorting to ad hoc measures such as securing cloth masks with medical tape.

[7] More information about challenge fit tests can be found at https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA (accessed October 9, 2020).

A participant asked whether FFRs that are designed to be attached to the face via adhesive may be a viable option for members of the public to use as a barrier face covering. Another participant, who works for the National Personal Protective Technology Laboratory (NPPTL), said that NIOSH has approved respirators with adhesive seals but that these types of devices do not necessarily provide a better fit than those with straps.

N95s with Exhalation Valves

Balmes reported several questions regarding whether N95s with exhalation valves provide adequate protection. Nicas said that N95s with exhalation valves are not supposed to leak for the wearer. There is always a little leakage, but the exhalation valve leakage is assessed during NIOSH-approval testing and must be below a specified level. He added that the main issue is whether N95s with exhalation valves act as effective source control in reducing the amount of coronavirus disease 2019 (COVID-19) exhaled by an infected wearer. Nicas listed three potential pathways for the release of exhaled air from the wearer: (1) unfiltered air coming from around the edges of cloth masks, (2) filtered air coming through the mask media itself, and (3) unfiltered air coming out an exhalation valve. He said he was not aware of any quantitative studies that have apportioned the percentage or volume of air coming from each of those pathways, however. Nicas added that during a NIOSH study of a fit test on an N95 used during light exercise, there was an observation that the exhalation valve was not activated, at least according to a visual inspection. This suggested that there is not much air coming through the exhalation valve during light exercise and that substantial force would have to be exerted to activate the exhalation valve. Nicas said that his impression is that the amount of unfiltered air coming out of an N95 respirator exhalation valve is not substantial enough to merit not using the device. However, he said that if individuals are concerned about N95 facepieces with exhalation valves, they should not use them. Importantly, a participant said, more complete data are still needed regarding the infectious dose of COVID-19 and the size of particles that people need to be protected from. Access to such data would allow for a greater understanding of how source control strategies, such as masks or face shields, can best be used to protect the public.

KN95 Standards

Balmes relayed a participant question about whether the widely available ear-loop KN95s are effective or if these offer a false sense of security for the wearer. Holm replied that it is difficult to know, but more certainty is possible with regulated devices, and she is, therefore, more confident

in recommending NIOSH-certified devices. She added that many of these devices are currently entering the United States through atypical routes. For instance, people are ordering devices online from many different countries and manufacturers. She said that in theory the KN95 certification standard is a good standard, but when devices enter the country through atypical pathways it is more difficult to ascertain the true level of protection that these devices offer the wearer.

Maryann D'Alessandro, the director of NPPTL at NIOSH, said that NIOSH has evaluated many KN95s and found that about half of those tested have not met the requirements to the KN95 standard. FDA issued an emergency use authorization for KN95s, which identifies those KN95s that do perform to filtration efficiency requirements that are similar to the NIOSH requirements for use in health care settings. NIOSH has published results from respirator assessments that have been performed as part of its COVID-19 response, she added.[8] Richard Metzler, a retired senior scientist at NPPTL at NIOSH, said that a couple of years ago he researched the Chinese GB-2626 standard and found that it was essentially a combination of European standards and NIOSH standards. He noted that, per the data D'Alessandro presented, there may be issues with the conformity assessment (CA) program, or distributors may be counterfeiting or inappropriately labeling those respirators that do not actually meet the standards.

Nicas added that all the KN95s he has seen have had ear loops and that the use of ear loops implies that these KN95s would likely have more face perimeter leakage than a NIOSH-approved N95 face filtered respirator with head straps. He acknowledged that he has not seen quantitative fit testing data comparing the face perimeter leakage of these two devices, but he said that he presumes KN95s with ear loops are not the equivalent of NIOSH-approved N95s. Kojola said that KN95s have been used in many health care facilities in New York state and New Jersey and that reports from representatives and staff from the health care unions indicate that these have been provided without fit testing. He stated that devices with ear loops generally do not pass fit testing requirements and that needed fit testing is not taking place. Jim Johnson, a consultant for JSJ & Associates, said that preliminary data indicate that a device with ear loops could have a measured fit factor level between 6 and 10, which does not approach the 100 needed to receive OSHA approval for the strap requirement.

[8] More information about respirator assessments to support the COVID-19 response is available from https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html (accessed September 16, 2020).

User Seal Checks

Balmes suggested that it would be helpful to have data on the efficacy of using only a seal check to fit test a respirator. He noted that during the H1N1 influenza pandemic, FDA required manufacturers to conduct a study before marketing respirators for influenza to the public, which involved an anthropometric balanced group of people who had never worn a respirator before. Participants were asked to perform a seal check and then were quantitative fit tested. Balmes, who performed this study for a manufacturer, said the respirator "failed miserably." However, he said, 3M also did the study, and their respirator passed. Balmes suggested that manufacturers require encouragement to design respirators with a user seal check that would provide assurance that the respirator actually provides an effective fit. Nicas asked about the pass fit factor used in the seal check studies conducted during the 2009 H1N1 influenza pandemic. He said that the only 3M study of which he is aware was published in the mid-1990s and used a pass fit factor of 10 for the quantitative fit testing to indicate a good fit, as opposed to the OSHA standard, which requires a criterion of 100. Nicas said that in that study, the seal check seemed effective because the criterion for adequacy was lowered.

Use of N95 Respirators by the Public

A participant commented that the N95 respirator requires fit testing to be effective and asked whether individuals wearing non-fit-tested N95s might have a false sense of security that could result in reduced social distancing. Nicas replied there is only a false sense of security when a person does not understand the limitations of a device, which underscores the importance of clearly communicating and providing information about a device's capabilities. Referring to Holm's data showing that non-fit-tested N95s can still reduce particulate exposure, Nicas said a non-fit-tested N95 filtering face respirator reduces a wearer's exposure by approximately 75 percent. While this may not be the 95–99 percent reduction in exposure that a fit-tested N95 respirator is meant to provide, Nicas contended that a 75 percent reduction is likely of benefit.

Fit-Test Adapter Equipment

A participant asked whether NIOSH approves fit-test adapter equipment as part of its approval process or whether any approving agency approves fit-test adapters. The participant reported that the fit-test adapter for a particular elastomeric mask, which is marketed for use while welding, is attached on the sides of the mask near the user's cheeks. Typically, the fit-test adapter is centered on the mask. A representative from NPPTL explained that NIOSH does not approve the fit-testing adapter because the

requirement to complete individual fit testing is an OSHA requirement, and OSHA-accepted methods must be employed in the testing. The representative added that fit testing should always be conducted using all required personal protective equipment (PPE) that a worker is required to wear because the equipment may interface with the performance of the respirator.

Cloth Masks

Balmes relayed a participant question regarding the efficacy of the three-layer cloth masks that were recommended by the Centers for Disease Control and Prevention. Holm was unable to address the question because of a lack of data but noted that the limited number of studies assessing different types of cloth masks suggest that the filtration characteristics of fabric vary widely. However, Holm continued, without knowing the specifics about the fabric being used, it is nearly impossible to predict how much protection such a cloth mask actually provides. Balmes added that additional layers are likely to improve filtration but are also likely to increase resistance to breathing and thus decrease comfort.

Counterfeit Respirators

Planning committee member Robert Harrison of the University of California, San Francisco, asked about laws prohibiting the sale of counterfeit respirators in the United States and whether that would fall within the purview of FDA's Consumer Product Safety Commission or other regulatory agencies. D'Alessandro answered that with the current COVID-19 response there are indeed rules in place across many federal agencies. Agencies including the Department of Homeland Security and FDA's Office of Criminal Investigations are involved in looking into counterfeit respirators and are working to get these products off the market. Metzler added that years ago NIOSH contacted the Federal Bureau of Investigation and the Department of State regarding a nonconforming product that the supplier was making false declarations about. At the time the issue was not pertinent enough for those agencies to address, but, given the current COVID-19 pandemic, that is no longer the case. A participant asked how those seeking to purchase NIOSH-approved products can avoid counterfeit products. An NPPTL representative answered that NIOSH works hard to remove counterfeit and substandard products from the market.[9]

[9] More information about NIOSH's assessment of counterfeit and substandard products is available from https://www.cdc.gov/niosh/npptl/respirators/testing/default.html (accessed September 14, 2020) and https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html (accessed September 14, 2020).

Balmes asked D'Alessandro to comment on manufacturer labeling of devices as N95s even if they have not been NIOSH-approved. D'Alessandro said that the term "N95" currently has no regulation associated with it and is not currently trademarked, although NIOSH is in the process of doing so. In terms of meeting requirements for filtration and breathing resistance, the term "N95" can be meaningless if a device has not been NIOSH approved, she added.

REFLECTIONS FROM DAY 1

On the Need for a National Strategy for Respiratory Protection

Balmes said that in any given situation it is necessary to identify the respiratory hazards and risks at hand and to ensure that respiratory protective gear is up to the task of protecting against the hazards and risks identified via a CA process. Balmes said that a national strategy that is able to address emerging risks, such as COVID-19, would help to ensure respiratory protection for the public. Such a strategy should include clear and simple messaging to improve awareness and educate the public about respiratory protection. While offering RPDs to the public outside of a respiratory protection program may be beneficial, Balmes said, it is antithetical to the current regulatory frameworks used to ensure respiratory protection for occupational users. Issues related to RPD sizing (e.g., child sizes), fit testing, and a lack of training on fit testing and use will further complicate the necessary considerations related to providing RPDs outside of respiratory protection programs. Harrison added that it appears that innovative research will be needed to improve our understanding of hazard assessment and respiratory protection to nontraditional users of RPDs. These populations, Harrison said, are in urgent need of new and innovative forms of PPE that are adaptive to their unique needs. Nontraditional users of RPDs may not be familiar with the terminologies used within the respiratory health disciplines. Thus, Harrison added, it must be ensured that clear guidance can be successfully delivered to the end user of RPDs. Additionally, it may be necessary to consider in advance how the various regulations of agencies, such as NIOSH, OSHA, and FDA, will apply to the use of RPDs by these nontraditional user populations.

On Addressing the Needs and Concerns of Nontraditional Workers and Their Employers

Workshop planning committee member Melissa McDiarmid, professor of medicine, epidemiology, and public health at the University of Maryland School of Medicine, said that the COVID-19 pandemic has highlighted

the need to offer respiratory protection in settings where workers typically do not wear respirators (e.g., long-term care). Even employers that have a comprehensive health and safety program may be unaware that respiratory protection needs to be included. Regarding this concern, Harrison suggested research that engages with employers and frontline workers—and particularly workers who are not in formal employment relationships—will help to better understand their perceptions, needs, and recommendations, whether it is under the auspices of "research to practice" or applied research. In his opinion, he said, this responsibility could fall within the purview of a federal agency like NIOSH in partnership with academic researchers, frontline groups, worker education programs, unions, worker centers, and community-based organizations. Balmes added that less representation by unions in the labor force in the United States, has led, in part, to a devaluation of occupational health and safety as a component of public health, and in that respect, it may be helpful if an agency focused on occupational safety and health, like NIOSH, had greater visibility among employers.

Planning committee member Daniel Shipp, who is retired from the International Safety Equipment Association, remarked that NIOSH is not a regulatory agency and so there are limitations to its scope and authority. NIOSH can set standards for respiratory protection, for example, and it can approve respirators. However, it is up to other agencies to determine when NIOSH-approved respirators should be used, when hazard assessments should be conducted, the need for fit testing, and other related issues. He added that currently no overarching health and safety agency in the United States has regulatory authority that can be extended to the public or to the multiple uses of cloth masks; even OSHA's scope is limited to certain workplaces. McDiarmid remarked that employers have some obligation to recognize respiratory hazards, even in segments of the worker population that have not traditionally been thought of as needing a formal respiratory protection program. She suggested that part of a research agenda could prioritize the examination of both employer and employee hazard recognition. McDiarmid wondered how to translate that research into practice—for example, with some type of pre-regulatory or regulatory structures. Johnson added that the COVID-19 pandemic has shifted the prioritization of PPE and RPDs as defenses against respiratory hazards and that going forward it may be necessary to reevaluate the role of, research on, and training for the use of PPE.

Harmonizing Regulation with the Needs of Nontraditional Workers and the Public

Balmes said that the rigor of an OSHA-compliant respiratory protection program cannot be reproduced for the general public. For instance, it

will not be feasible to offer fit testing to the public, and the education about respiratory protection provided to the public will differ from that provided within occupational settings. McDiarmid added that while misinformation about respirators may pose a hazard to the public, especially during the COVID-19 pandemic, there is likely a greater hazard in the unavailability of RPDs. To address future respiratory protection needs of the public, she added, new kinds of respirators may be needed. Such respirators may include large sealing surfaces so that fit testing may not be required. Harrison pointed out that the authority to make recommendations related to respiratory protection for the public generally rests with state and local governments. This was true in California until Cal/OSHA established the emergency regulation on protection from wildfire smoke. He raised the question of whether the mission and responsibility of an agency like NIOSH could be expanded to cover the public use of PPE. Balmes added that in California, the public is bombarded with various messages about wildfire smoke and respiratory protection and that there are efforts under way to harmonize the messaging from county public health officials, the Department of State, NIOSH, and EPA representatives.

5

Assessment Pathways for Respiratory Protective Devices for Occupational Use by Nontraditional Workers

Like other health devices, respiratory protective devices (RPDs) are assessed and approved through various regulatory pathways. Most RPD regulations are administered through workplace-specific policies. In a session moderated by planning committee member Howard Cohen of the Yale School of Medicine, three speakers explored how existing conformity assessment (CA) processes align with the health and safety requirements of nontraditional user groups. This session focused on opportunities to develop or support CA processes for RPDs or alternative devices for these user groups and evaluated lessons learned from CA models used outside the United States, by third-party organizations, and in private industry.

RESPIRATORY PROTECTION AND CONFORMITY ASSESSMENT IN OCCUPATIONAL SETTINGS

Maryann D'Alessandro, the director of the National Personal Protective Technology Laboratory (NPPTL) at the National Institute for Occupational Safety and Health (NIOSH), discussed the role that NPPTL plays in the approval and CA processes for respiratory protective devices for occupational use. She said that the mission of NPPTL is to prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technologies and that this is achieved by efforts focused on personal protective equipment (PPE) research, surveillance, CA, outreach, and interventions. The cornerstone of the work done by NPPTL is the NIOSH Respirator Approval Program, which approves all respirators used in workplaces across the United States (see Box 5-1). While NIOSH approves

BOX 5-1
Types of Respirators Certified by the National Personal Protective Technology Laboratory

The National Personal Protective Technology Laboratory (NPPTL) approves a variety of types of respirators. In addition to the N95 filtering facepiece respirators used in health care settings, NPPTL approves various air purifying respirators and atmosphere-supplying respirators. These respirators are used for protection from various hazards in many settings, including firefighting, tunneling, mining, and flight air systems.

Air-purifying respirators:

- Powered or non-powered
- Particulate
- Gas and vapor
- Gas masks
- Combination respirators

Atmosphere-supplying respirators:

- Self-contained breathing apparatus
- Supplied-air (airline)
- Combination atmosphere-suppling respirators

SOURCE: D'Alessandro and Peterson presentation, August 5, 2020.

these respirators for occupational use, the Occupational Safety and Health Administration (OSHA) maintains responsibility for overseeing respiratory protection programs for workplaces that require the use of respirators and worker compliance in accordance with OSHA's respiratory protection standard, 29 CFR 1910.134.[1] In addition, NIOSH approves respirators for use in health care settings by working closely with the Food and Drug Administration (FDA) under a memorandum of agreement published in 2018. NIOSH currently executes these FDA requirements for respirators used in health care settings—fluid resistance, flammability, and biocompatibility—through NIOSH's respirator approval process. However, she said, manufacturers must still list and register their products as per FDA regulations.

D'Alessandro explained that the responsibilities of NPPTL vary depending on which of its three strategic goals—reducing inhalation hazards, reduc-

[1] More information about 29 CFR 1910.134 is available from https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134 (accessed September 16, 2020).

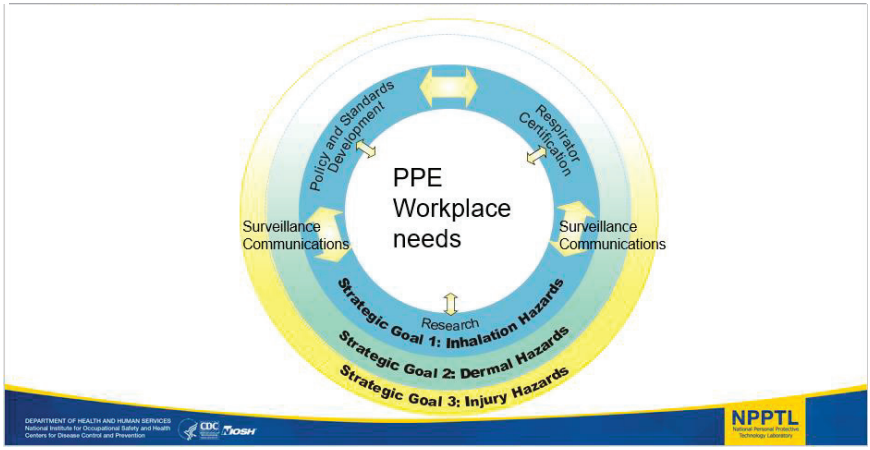

FIGURE 5-1 NPPTL's three strategic goals.
NOTE: PPE = personal protective equipment.
SOURCE: D'Alessandro and Peterson presentation, August 5, 2020.

ing dermal hazards, and reducing injury hazards—is in play and that the work of the agency touches on all aspects of respiratory protection in the workplace (see Figure 5-1). NPPTL's role in reducing inhalation hazards involves leading research and surveillance activities that serve as the basis for the development of both consensus and federal standards as well as serving in a leadership role in the development of these consensus standards and the federal respiratory protection standard, 42 CFR 84.[2] Additionally, NIOSH is responsible for leading respiratory protection CA in the United States, including respirator pre-approval and post-approval activities.

Conformity Assessment for Personal Protective Equipment

CA is critical for addressing worker health and safety, D'Alessandro said. CA is defined as the "demonstration that specified requirements relating to a product, process, person, or body are fulfilled." As described above, NIOSH is responsible for CA for respirators used in occupation settings as enforced by OSHA, and it also approves respirators for use in health care settings. D'Alessandro said that a robust CA program helps to ensure that workers' health and safety issues are addressed, provides consumers with added confidence in product performance, and gives companies a competitive edge.

[2] More information about 42 CFR 84 is available from https://www.cdc.gov/niosh/npptl/topics/respirators/pt84abs2.html (accessed October 9, 2020).

Conformity Assessment Framework

D'Alessandro explained that NPPTL led the development of the National Framework for Personal Protective Equipment Conformity Assessment, which can be applied when identifying the specific exposure hazards in a workplace and determining whether respirators that conform to existing standards can be applied to address the hazard of concern (see Figure 5-2). While this framework is well-suited to occupational uses of respirators, she said that complexities may arise with respect to the unique needs of contingent workers and the general public, for whom respiratory hazards may be less clear. D'Alessandro acknowledged the sentiment expressed during John Balmes's presentation and others in earlier sessions that "the perfect must not be the enemy of the good," but she said that "the good" must be good enough to actually provide protection from the hazards in question. She suggested that NIOSH's scientific and deliberate approach of aligning hazards with an approved product for use in an occupational setting could also ensure that the public and contingent workers are advised to use devices that address the hazards of concern and are safe when used as intended. In cases where there are no existing standards that are appropriate for addressing the hazard of concern, then NIOSH can determine whether a standard should be developed to address that hazard through either the establishment of a new federal standard under 42 CFR 84 or through a consensus standard process. She said that NIOSH aims to ensure that all standards are informed by science and that all hazards are well understood.

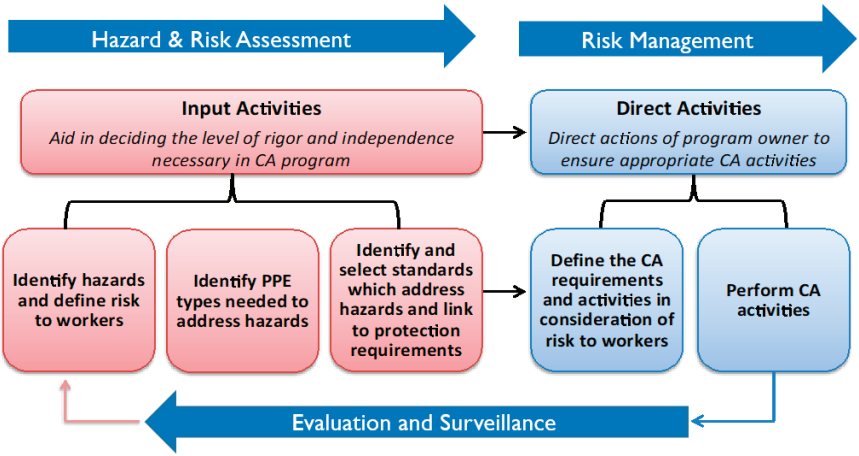

FIGURE 5-2 Personal protective equipment conformity assessment framework.
NOTE: CA = conformity assessment; PPE = personal protective equipment.
SOURCES: D'Alessandro and Peterson presentation, August 5, 2020; NIOSH, 2017.

Once a standard approach is selected, NIOSH collaborates with its partners to identify a CA method that should be used to execute that standard. In the workplace, D'Alessandro said, this is typically ensured through 42 CFR 84, although there are exceptions. For instance, respiratory protective devices used by the fire services are approved by NIOSH through 42 CFR 84, but are also required to meet additional requirements identified through consensus standards developed by the National Fire Protection Association (NFPA). Once the CA approach has been determined, a post-market approach is then established to ensure the products continue to conform to the standards under which they were originally approved and certified.

In conclusion, D'Alessandro said that the changing nature of work has resulted in gaps that directly affect certain workers, such as those who perform their roles outside of a formal respiratory protection program, and this raises questions regarding how other conformity assessment approaches could be applied to address these needs. D'Alessandro emphasized that some type of CA is necessary for devices that are used by the public and that NIOSH's current CA framework (see Figure 5-2) is broadly applicable for understanding how the needs of these new user populations should be aligned with potential processes and approaches. Additionally, it will be essential that key partners are identified and engaged in this evaluative process.

RESPIRATOR APPROVAL FOR USE IN WORKPLACES

Jeffrey Peterson, the branch chief at NPPTL, described the process and approach used by NIOSH and NPPTL to approve respirators for use in occupational settings, including health care settings. He explained that NPPTL executes NIOSH's authority to approve respirators under 42 CFR 84 and that two regulatory agencies require the use of NIOSH-approved respirators: OSHA and the Mine Safety and Health Administration. Since its inception, NIOSH has issued more than 9,000 approvals for a variety of types of respirators (see Box 5-1) and currently has 101 approval holders in 15 countries who are manufacturing NIOSH-approved products in 192 manufacturing sites in 26 different countries. He said that NPPTL has improved the quality of the U.S. inventory of respiratory protection for workers in all industry sectors by making 552 respirator approval decisions and completing 254 respirator audit activities in 2019, adding that NPPTL activity has increased in 2020 in response to the coronavirus disease 2019 (COVID-19) pandemic. Between January 2020 and August 2020, NPPTL issued 498 decisions and completed 538 audit activities.

National Institute for Occupational Safety and Health Respirator Approval Process

Peterson described the NIOSH approval process, which begins with the submission of a request for approval that is processed by the receiving/records room. The submission package includes a standard application form, a document package documenting the specifications of the product, fees, and sample hardware needed for evaluation (see Figure 5-3). NIOSH conducts all evaluations—including testing for NIOSH approval—internally. No third-party activities or laboratories are used for the NIOSH evaluation process. Next, an initial engineering review is conducted to (1) confirm the reason for application, (2) review the application content, (3) verify whether the hardware is a new or revised configuration, (4) issue fee estimate, and (5) assign appropriate tests. The product then moves into the dual stages of testing and quality assurance. In these stages, NPPTL (1) conducts the assigned testing, (2) assesses quality management system for conformance to requirements within 42 CFR 84, (3) reviews inspection procedures and ensures that the classifications of defects are consistent with the regulation, and (4) reviews documentation for proper revision level.

The NIOSH approval process concludes with a final engineering review, Peterson said. During this stage, NPPTL reviews test data, updates the NIOSH parts database, reviews and finalizes labeling, and finalizes the approval or denial package. The NIOSH respirator approval process is robust and involves many stakeholders, he said. Figure 5-4 depicts the workflow of the approval process. Nested within each block of the workflow are numerous

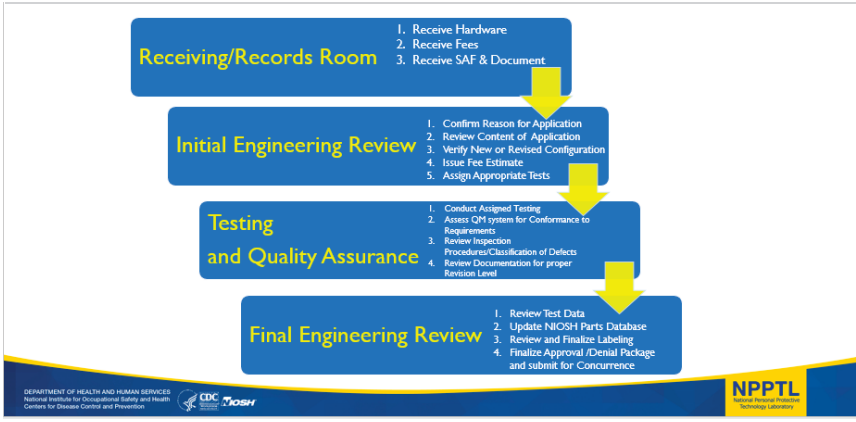

FIGURE 5-3 NIOSH approval process overview.
NOTE: NIOSH = National Institute for Occupational Safety and Health; QM = quality management; SAF = standard application form.
SOURCE: D'Alessandro and Peterson presentation, August 5, 2020.

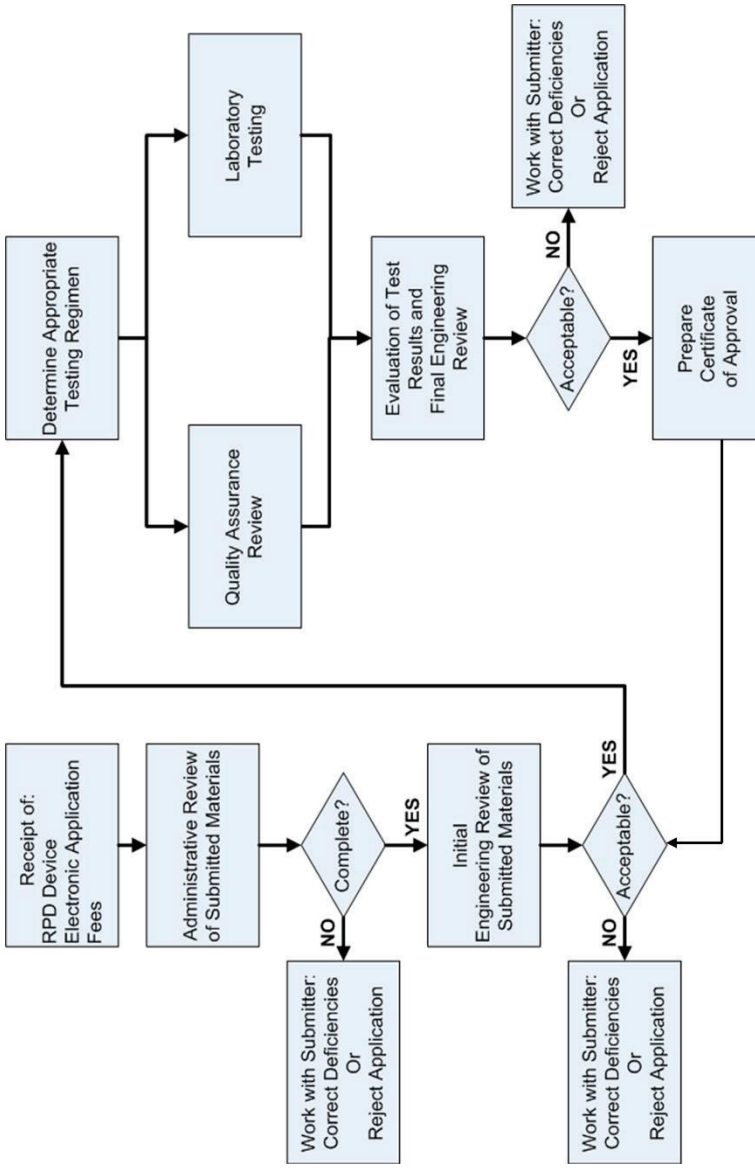

FIGURE 5-4 Example of the NIOSH respirator approval process workflow.
NOTE: RPD = respiratory protective device.
SOURCE: D'Alessandro and Peterson presentation, August 5, 2020.

additional workflows and decision points. All of these workflows and decision points are intended to maintain the consistency of NIOSH decisions and evaluations throughout the respirator approval process.

National Institute for Occupational Safety and Health Post-Approval Processes

Peterson explained that in addition to pre-approval and issuance of approval, NIOSH is engaged in post-approval activities such as post-approval product audits, post-market evaluation activities, and the Site Audit Program.

Post-Approval Product Audits and Post-Market Evaluation Activities

Peterson described the approach that was used to conduct these post-approval product audits until 2015, when NIOSH's regulation changed and allowed it to expand the product audit program. Each year, 40 to 50 products were selected for auditing, and each was purchased on the open market. Products might be selected for auditing for a range of different reasons—to investigate a product about which questions or reports had been made, for example, or to determine whether issues had been resolved for a product that had undergone a certified product investigation. After the expansion of the program in 2015, NIOSH developed a decision logic based on the number of product approvals that a company holds. Products are chosen from the certified equipment list for audit using criteria such as respirator type, time since that respirator was last tested, and product problem history. One product per type of respirator product approved is audited each year. Peterson added that the revised audit process has allowed NIOSH to expand its auditing capacity to conduct 140 to 150 product audits each year, with any test failures resolved through the certified product investigation process. In recent years, purchased products have focused on filtering facepiece respirators. Peterson described NIOSH's post-market evaluation activities as providing for effective product conformity and use assessments, noting that NIOSH has the regulatory authority to conduct evaluations of the requirements that must be met to maintain product approval.

Site Audit Program

In addition to its product audits, NIOSH's site audit program ensures manufacturer compliance with approved quality system plans and the respirator performance requirements of 42 CFR 84.[3] Peterson said that site

[3] Peterson clarified that N95 manufacturing sites are inspected as part of the NIOSH NPPTL approval process.

audits of production facilities are conducted every 2 years and site audits of corporate offices are conducted every 4 years. Audits are typically conducted over 1–2 days, with the length of the audit based on facility size, the number of approvals held by the company operating the site, language barriers, the complexity of respirators being produced, and the audit and field problem history. Peterson outlined three typical outcomes of a site audit: (1) the site is deemed to be acceptable, (2) the site is deemed to be provisionally acceptable, or (3) the site is deemed to be unacceptable. An acceptable site requires no further action, but sites that are deemed provisionally acceptable are required to implement corrective actions. Through NIOSH's evaluation and testing branches, these corrective actions are followed up. Sites are asked to submit effective evidence that problems have been addressed. In some cases, the implementation of these corrective actions requires the submission of a modification to approval. Thus, the site audit process feeds back into the larger CA program for respirators, and any changes must be evaluated and documented as part of the formal approval record. These site audits help NIOSH ensure that approval holders' quality, systems, and products continue to meet standards, Peterson said. Additionally, they help approval holders assure the quality and reliability of respirators and give workers stronger assurance of respirator functionality. Peterson concluded by saying that NIOSH stands apart from other CA processes through NPPTL and the robust respirator approval process.

ALTERNATIVE CONFORMITY ASSESSMENT APPROACHES

Jeff Stull, the president of International Personnel Protection, Inc., acknowledged the relatively robust and comprehensive program used by NIOSH to certify and approve respirators. However, he suggested that it is worthwhile to consider other CA approaches that exist to address the needs of nontraditional workers who are using RPDs or workers who are using products that fall outside of existing government regulations on RPDs.

Ideal Personal Protective Equipment Conformity Assessment Approach

Stull reviewed the ideal PPE CA approach that had been described by D'Alessandro earlier in the session (NIOSH, 2017) (see Figure 5-2). Broadly, the ideal conformity assessment process consists of input activities, direct activities, and a cycle of evaluation and surveillance to continually improve the program. The steps of an ideal CA process include (1) identifying the hazards and risk to workers, (2) evaluating what devices are needed to address these hazards, (3) identifying what standards should be used, (4) defining what processes are needed to ensure that the required level of protection has been met, and (5) performing these CA activities.

Alternative Conformity Assessment Approaches

Stull noted that CA is a large-scale process that includes not only product-based standards, but also standards related to the selection, use, and care of these devices. He provided an overview of four different CA approaches.

European Committee for Standardization Conformity Assessment

The European Committee for Standardization (CEN) is a CA program operating in Europe that establishes basic requirements for directives and regulations related to PPE as well as evaluation for multiple types of respirators.[4] Stull said that the European Union has a relatively robust system of standardization across its member nations. In terms of PPE, part of that standardization falls under a key regulation for establishing how CA of PPE is undertaken: 2016/425 (PPE CE Marking).[5] The European Union also has a counterpart regulation for the use of PPE that meets the directives of regulations: 2019/1832 (use of PPE), which he described as similar to OSHA requirements for using approved (certified) respirators.[6] Stull said that part of the process of establishing CA is to set basic safety and health requirements for different types of PPE. He added that these are very general requirements as part of the hazard needs assessment conducted during the initial stages of the standards development process. Then, as part of CEN's process of developing standards, specific requirements are established for unique products in terms of the general hazard protection needs. Part of this process includes the classification of risk into three distinct categories associated with different types of PPE. Category 1 includes products with a simple design and lower risk (e.g., gardening gloves). Category 3—which includes most PPE products—includes devices with more complex design and the highest associated risks or consequences for use. As such, Category 3 PPE products also have more stringent requirements for technical documentation, testing, quality control, oversight, and how the declaration of conformity is ultimately provided. Examples of European norms include EN 136 (full facepieces), EN 140 (half and quarter masks), EN 143 (particulate filters), EN 149 (FFRs), and EN 12941 (powered hood/helmet respirators). There is a separate but parallel effort by the International

[4] More information about CEN is available from https://standards.cen.eu (accessed September 16, 2020).

[5] More information about EU 2016/425 is available from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0425&rid=4 (accessed October 9, 2020).

[6] More information about EU 2019/1832 is available from https://op.europa.eu/en/publication-detail/-/publication/4edc1256-fbd2-11e9-8c1f-01aa75ed71a1/language-en/format-PDF/source-126627073 (accessed October 9, 2020).

Standards Organization (ISO) TC94/SC15 on RPDs, he noted. However, typically ISO does not write any type of CA or certification requirements, as it leaves these processes to the independent bodies and nation members of the ISO organization set their own in-country requirements.

National Fire Protection Association Conformity Assessment

NFPA has a CA program that addresses multiple respirators used by first responders and offers a third-party certification that is mandatory in certain settings.[7] NFPA has one of the most robust nongovernmental CA processes, Stull said. Like NIOSH, NFPA establishes standards based on an understanding of specific hazards, protection needs, and defined requirements (NFPA, 2016).[8] He explained that while NFPA's standards are typically built on existing NIOSH requirements for respirators, as per 42 CFR 84, NFPA still requires certification above and beyond that offered by NPPTL. One unique aspect of NFPA is its requirement for robust third-party certification conducted through certified accredited organizations and laboratories which assess product quality requirements, conduct initial and annual testing, and conduct some post-market surveillance of certified products. Stull expressed his concern that these NFPA standards may have been written with relatively strict or overreaching requirements. He pointed out that it was nearly 10 years ago—in 2011—that NFPA established a standard for wildland respirators, yet so far no products have been certified that meet that standard. Similarly, in 1999 NFPA established a standard for hooded powered air-purifying respirators (PAPRs), but no product has been qualified against that standard. Stull added that NFPA and NIOSH plan to jointly create a combination self-contained breathing apparatus air purifying respirator standard, which will be supplemental to what NIOSH already offers.

ASTM International Conformity Assessment

Stull explained that ASTM International is a standards organization that addresses various products and services but is fairly new to the RPD standards space.[9] ASTM International has developed several standards that are relevant

[7] More information about NFPA is available from https://www.nfpa.org (accessed September 16, 2020).

[8] Stull listed several relevant NFPA standards, including the NFPA 1981 fire service self-contained breathing apparatus standard, the 1984 wildland respirator standard, the NFPA 1986 tactical self-contained breathing apparatus standard, the NFPA 1987 combination respirator standard, and the NFPA 1999 hooded PAPR standard.

[9] More information about ASTM International is available from https://www.astm.org (accessed September 16, 2020).

to PPE, including standards for emergency escape devices (E2952-17), as well as forthcoming standards for the Test Method for Respirator Fit Capability Conformance Test for Half-Mask Air-Purifying Particulate Respirators, which has nearly been adopted, and the Specification for Barrier Face Coverings, which has been proposed. Additionally, ASTM International has a newly formed F23.65 subcommittee on respiratory protection that has been working on a standard for barrier face coverings, which is intended to aid in the response to the COVID-19 pandemic but has proven challenging to write due to the rapid timeframe for development. ASTM International also has a Standard Guide for Conformity Assessment of Personal Protective Clothing and Equipment.[10] This guide provides four models of CA based on (1) attestation, (2) testing and inspection levels, (3) quality management systems, and (4) ongoing conformity through the duration of the product's life in the marketplace. Stull described ASTM International as a nimble organization that is able to include broad representation from stakeholders while still being proactive in moving forward with standards to address immediate needs, such as those associated with the ongoing COVID-19 pandemic.

International Safety Equipment Association Conformity Assessment

Stull said that the International Safety Equipment Association (ISEA) is a trade organization that primarily represents PPE manufacturers in the interests of U.S. consumers.[11] It has developed a separate CA standard and a respirator product group that represents the manufacturers of respirators and other interests. ISEA's conformity standard establishes three levels of conformity with respect to the type of quality management system, the laboratory in which CA testing was conducted, who determines re-testing, the testing interval, corrective or preventive action, record keeping, and declaration of conformity. This process has not always been specified, he added, but it is available for specification by organizations seeking to implement some form of CA.

Comparison of Conformity Assessment Approaches and Recommendations

Stull compared the CA approaches he described above and maintained that the only approach that addresses the full range of the CA processes—

[10] More information about ASTM International's Standard Guide for Conformity Assessment of Personal Protective Clothing and Equipment is available from https://www.astm.org/Standards/F3050.htm (accessed September 16, 2020).

[11] More information about ISEA is available from https://safetyequipment.org (accessed September 16, 2020).

i.e., the only ideal approach—is that that of NPPTL (see Table 5-1). The ideal approach addresses the identification of hazards, the identification of PPE types, the selection or development of standards, the definition of CA approach, the performance of conformity assessment, and post-market surveillance. Each of the organizations described in the previous section implements various parts of this process, he said, but none of them actually qualifiy products. Third-party organizations perform CA for NPPTL and NFPA standards, while NPPTL qualifies third-party organizations to perform CA. He added that there are gaps in the CA approaches used across these organizations.

Given this conclusion, Stull recommended using U.S. standards development organizations to allow for the expansion of product types and for CA assessment that addresses the respiratory protection needs of nontraditional workers. He noted that there are specific CA requirements for NIOSH addressed within 42 CFR 84. However, Stull added, a broader range of products that address the needs of nontraditional users of RPDs should be pursued. He suggested that standards development organizations within the United States have the capacity to reach these user groups and to address their specific needs by involving otherwise unrepresented private or government interests and that they can work with these unrepresented groups to create robust standards. These organizations can build on existing government regulations for additional criteria, including the development of appropriate CA approaches for both standards development and verification of product conformance, and can create other standards for the selection, care, and maintenance of these devices.

Stull also recommended that NIOSH take a centralized role for coordinating the CA process to address the diversity of organizations involved in this space. In this capacity, NIOSH would recognize standards, conduct supportive research for requirements, qualify CA bodies, and provide surveillance support. Stull argued for this recommendation on the basis that the four organizations he discussed in his presentation are uncoordinated, with each addressing specific product needs for various workplaces and products. While the American National Standards Institute has the role of coordinating standards, in practice there is a "free-for-all" in determining which organization performs which roles, Stull said. Thus, he suggested that benefits could be realized if a single agency like NIOSH could take on the role of centralized coordinator of CA activities for products that are not covered by governmental regulations. Through this coordination, broader CA activity would be more likely to reach nontraditional workers. Stull added that this type of coordinated effort could be used to establish standard practices, guides, and other information that end user groups could use to support their respiratory protection.

TABLE 5-1 Comparison of Conformity Assessment Approaches

Organization	Identification of Hazards	Identification of PPE Types	Selection or Development of Standards	Define CA Approach	Perform Conformity Assessment
NIOSH NPPTL	Pre-market surveillance	U.S. government	U.S. government	U.S. government	U.S. government (third party)
CEN	Basic health and safety requirements in EU PPE regulations	By technical committee	By technical committee	By EU PPE regulations	Member recognized notified bodies
NFPA	By technical committee	By technical committee	By technical committee	By technical committee	Qualified third-party organization
ASTM International*	By workgroup or subcommittee	By workgroup or subcommittee	By workgroup or subcommittee	Not yet implemented	Not yet defined
ISEA*	By product group	By product group	By product group	By product group	Qualified as per standard

* No defined process for post-market surveillance.

NOTE: CA = conformity assessment; CEN = European Committee for Standardization; EU = European Union; ISEA = International Safety Equipment Association; NFPA = National Fire Protection Association; NIOSH = National Institute for Occupational Safety and Health; NPPTL = National Personal Protective Technology Laboratory; PPE = personal protective equipment.

SOURCE: Stull presentation, August 5, 2020.

DISCUSSION

Occupational Safety and Health Administration and the Nontraditional Workforce

Cohen opened the discussion by highlighting the unique needs of the nontraditional or contingent workforce. Discussant Andrew Levinson, the deputy director of the Directorate of Standards and Guidance at OSHA, said his agency has been dealing with issues related to temporary workers, joint employment, and "gig workers" for the past decade and that this is an area of increasing concern. Levinson said there is an associated issue where workers are misclassified as independent contractors so they are not covered by the Occupational Safety and Health Act of 1970 (OSH Act) in order to avoid complying with OSHA regulations. Levinson said that one of OSHA's foundational principles is that any employee who is covered by the OSH Act is entitled to the same protection under the OSH Act, OSHA standards, and OSHA whistleblower protections as traditional employees.

In 2013, Levinson said, OSHA started the Temporary Worker Initiative,[12] which produced a set of guidance documents developed to better address the complicated nature of nontraditional employer–employee relationships. The OSHA website includes guidance on PPE[13] for temporary workers and on respiratory protection programs[14] for temporary workers in joint-employment, nontraditional work settings. By 2016 this area had become a significant OSHA concern, he said, and when OSHA revised its guidance for employer programs to address overall safety and health management, a seventh core element was added: communication and coordination for employers, contractors, and staffing agencies.

Levinson said that OSHA approaches the issue of nontraditional employment with a focus on how employers effectively handle communication and coordinate occupational safety and health responsibilities in the work environment of nontraditional employees. As the employer controls the workplace and has the best understanding of the hazards and controls that are necessary to protect their employees, much of the responsibility rests on the employer. OSHA examines how contractors or temporary staffing agencies handle the assignment of OSHA responsi-

[12] More information about OSHA's guidance on protecting temporary workers is available from https://www.osha.gov/temporaryworkers (accessed September 16, 2020).

[13] More information about OSHA's guidance on PPE from the Temporary Worker Initiative is available from https://www.osha.gov/Publications/OSHA3780.pdf (accessed September 16, 2020).

[14] More information about OSHA's guidance on respiratory protection from the Temporary Worker Initiative is available from https://www.osha.gov/Publications/OSHA3952.pdf (accessed September 16, 2020).

bilities. He said that there is often some forethought reflected in contracts, agreements, and communication between the host employers and workers on topics such as training, injury, and illness recording and reporting.

Levinson emphasized that OSHA standards in this area are performance-oriented, which allows for a "tremendous amount of flexibility" in how employers implement the requirements, provided that these requirements are accomplished. This flexibility is reflected in respiratory protection standard enforcement memorandums and enforcement interpretations that propose somewhat more complicated, but ultimately effective, methods of ensuring that workers get the necessary components of respiratory protection, Levinson said. For example, labor unions, temporary staffing agencies, contractor associations, trade associations, professional associations, and licensed medical providers may handle different aspects of the respiratory protection program by way of contract or agreement with the employer. These groups may conduct fit testing, medical evaluation, or the training component, while the employers handle only the aspects necessary for on-site work. In this way host employers and temporary staffing agencies can coordinate with service providers to ensure that workers' protection needs are met. Ultimately, Levinson said, regardless of the avenue that employers use, OSHA is focused on ensuring that workers are afforded all aspects of the respiratory protection standard.

Using the Conformity Assessment Framework to Address Unmet Standards

Cohen asked the panel how having groups of people who are not meeting the standards for respiratory protection programs affects CA. D'Alessandro said the PPE CA framework ultimately guides this process and that when requirements are not being met, the starting point is to look at requirements that the group is able to meet. She suggested that there needs to be a balanced approach in having science-based standards that are also practical. In examining hazards, D'Alessandro said, one determines whether there are existing standards that could address those hazards or whether standards could be modified to address those hazards. Then, the type of PPE that could be used based on those standards can be determined. Therefore, the PPE CA framework can provide a flexible path forward in these cases, as it provides a general process, outlines needs, and offers distinct steps to address these needs.

Stull agreed that the PPE CA framework described earlier is important. He gave an example from a workgroup tasked with determining how to develop standards for "barrier face coverings," which is the term that the group selected for describing the cloth face coverings that many in the public simply refer to as "masks." Because both workers and the general public

are wearing these barrier face coverings, a standard for this product could encompass nearly every person in the United States. As such, Stull said, the group wants to avoid creating a standard so lofty that it eliminates every product from the marketplace. However, given the large number of products that have emerged in response to the COVID-19 pandemic, requirements need to be grounded in science, to pragmatic, and to be practical so as to reach all of these diverse user groups, he suggested. Determining fundamental requirements that should apply under the variety of different circumstances in which these barrier face covering will be used has been a "tremendous challenge," he added. Ultimately, the group's work in writing this new consensus standard follows the flow of the PPE CA framework in that they are seeking to (1) define hazards, (2) examine which types of products are being used to address them, (3) write appropriate requirements, and (4) determine how manufacturers demonstrate to buyers that their products are appropriate. Concerning the products, Stull said, user instructions, the limitations of the product, and the types of claims that can be made also need to be considered.

Fit Testing and Requests for the New Devices

Cohen said that the fit-testing requirement is one aspect of the OSHA-defined respiratory protection programs that contingent groups are having difficulty meeting. Cleaning and disinfecting are generally not difficult for filtering facepiece respirators—at least outside of the COVID-19 pandemic—but fit testing appears to be on ongoing challenge. Cohen suggested that developing a respirator standard that requires an effective user seal check instead of fit testing could address this ongoing challenge. However, Cohen pointed out that because OSHA requires fit testing of a tight-fitting respirator, potential complications include coordination with a certifying body (presumably NIOSH) and locating a respirator manufacturer with the vision to create such a product.

Additionally, Cohen said, although there is an NFPA standard for wildland firefighting, no manufacturers make a respirator that meets that standard. Cohen suggested that having an additional group focused on the development of respirators that are specifically designed to meet the unique needs of contingent workforces, such as wildland firefighters, could be of value. Levinson replied that the OSHA fit-test requirement should not be an impediment. He characterized the no-fit-test, tight-fitting respirator as somewhat of a "mythical creature" that may exist but has not yet been found. The current OSHA fit-test requirement for tight-fitting respirators is based on evidence that the fit test is necessary to ensure that (1) the respirator fits properly and (2) the worker receives the expected level of protection. Levinson suggested that if there were widespread confidence

that an alternate standard for a no-fit-test, tight-fitting respirator would ensure an effective fit for the user, OSHA would be open to considering this as a new class of device that could be exempted from the fit-test requirement. However, Levinson said, OSHA has not yet seen evidence that such a product exists, nor are there sufficient data to support eliminating the fit test. However, he added, "OSHA standards are always modifiable if the evidence suggests that they should be."

Cohen replied that there are accounts of some respirator models that appear to do well with a user seal check in predicting a fit test, although verifying this would require further research to be performed by NIOSH and by manufacturers. Stull added that the working group involved in the development of the draft consensus standard for barrier face coverings is taking a hybrid approach in that they are suggesting the use of a "leakage test" as opposed to a traditional fit test. In this scenario it would be the responsibility of the manufacturer to utilize a small panel that can demonstrate the relative fit of the product. As more manufacturers add the test method, they will learn more about good fit and how to build products with better fit, Stull said. Such an approach might move the process in the right direction, he suggested.

Health Status in the Contingent Workforce

Cohen remarked that air-purifying respirators have inhalation-exhalation resistance requirements so that healthy individuals can be confident they will be able to breathe while using the respirator. However, he added, workers in the contingent workforce do not always have medical testing and medical clearance, so there is a question of whether there is the same level of confidence in the use of these products by these worker groups. D'Alessandro confirmed that NIOSH evaluations are performed according to specific worker criteria that are based on healthy workers.

Clarifying "Nontraditional" Terminology

In the first day's discussion about nontraditional workers, these worker groups were defined by this committee as workers who perform their duties outside of a formal respiratory protection program. However, the current panel focused on nontraditional employment. Bill Kojola, a retired industrial hygienist, cautioned against conflating the two, explaining that nontraditional employment relates to temporary and contingent workers. Nontraditional workers, by contrast, are typically full-time employees working in an industry without a formal respiratory protection program despite exposure to risk and the associated need for such a program. Cohen added that nontraditional employment could also refer to employees who

are using respiratory protection in the absence of a complete respiratory protection program, regardless of the type of work. This includes workers who are provided respirators by employers who require them to be worn for certain tasks but without a full respirator program, he added.

Expedition of Standards

Cohen relayed a participant's question about whether there are ways for federal agencies to fast-track the development, approval, and publishing of standards when public health emergencies such as COVID-19 arise and, if so, what the typical timeframe for rolling out such a standard might be. D'Alessandro provided the example of a PAPR standard that was published during the COVID-19 response. Although NIOSH had been working on this standard for years, it likely would have taken an additional year for it to be published. Due to the COVID-19 pandemic, however, NIOSH was able to finalize everything within 1 month and publish it as an interim final rule within several weeks. This indicates that it is possible to expedite such standards, D'Alessandro commented. Peterson remarked that with the success of the PAPR standard rollout and the knowledge gained in the COVID-19 response effort, other activities could be pursued if sufficient resources were in place. Peterson said one of NIOSH's challenges is ensuring the throughput of equipment into the field while maintaining continuity, making corrections, and pushing out new standards. NIOSH has also been able to effectively convey feedback to consensus standards agencies, Peterson added.

Stull commented that of the alternative CA processes he described in his presentation, ASTM International has an expedited process. If a first draft of an ASTM standard came out perfectly, it would be possible to roll it out within a couple of weeks or months. However, because approving a standard is a consensus process with rules to ensure it is balanced and fair, it is difficult to get a standard through that quickly, he said. On the other hand, the processes can be flexible, and as long as the rules for the consensus process are followed and balance is maintained, these standards can be put out relatively quickly. Stull said noted that, generally, this process takes a minimum of 3 months—with 6 months still considered a quick turnaround—but the process often takes much longer. He added that NFPA has a substantially longer process.

Levinson noted that OSHA addresses needs related to a health crisis through enforcement flexibility or interpretation. Also, under the general duty clause, OSHA has the ability to impose some requirements. Furthermore, there is a mechanism for an emergency temporary standard, but Levinson said this is very rarely used and may not have been used in the past two decades.

Occupational Safety and Health Administration Standards and Voluntary Use Provision

Cohen shared a comment from a participant who pointed out that nursing homes and dentists' offices are places where respirators are being used, but not under the auspices of traditional respiratory protection programs. Levinson explained that if there is a hazard that employees are being protected from, the employer is required to have a respiratory protection program. If an employer is not complying with the standard, that does not mean the employer is not *required* to comply with the standard. For instance, if OSHA investigated a complaint, it could cite an employer for not using a traditional respiratory program standard. He noted that OSHA has a voluntary use provision under its respiratory protection standard, which is in place for workplaces where an employer has not formally determined that respirators are necessary, but employees are allowed to use these devices for personal comfort reasons (e.g., an employee stirring up incidental dust while cleaning out a storeroom and choosing to wear a respirator for comfort).

Availability of Fit Test Results

Cohen answered a question from a participant about whether results on respirators tested by a fit test panel are available for others to use in comparing the results of various models. Cohen said that results are not made available for filtering facepiece respirators, but that this does happen under the standards, certification, and approval for other respirators. Peterson confirmed that there is not a requirement within rule 42 CFR for particulate-only type devices.[15] Therefore, a fit test is not performed as part of the approval. For other types of respirators there are requirements for collective fit among an identified population rather than individual fit, he said. The NIOSH panel is used to ensure that fit can be achieved across different populations via the variety of sizes or models offered under an approval, he continued. Therefore, Cohen said, the fit requirement is not for individual fit; rather, a fit requirement ensures that a product meets some established criteria for a population. Therefore, fit test data are not shared because they are considered proprietary information, Cohen added.

Mark Nicas, an emeritus adjunct professor at the University of California, Berkeley, contended that fit results generated by NIOSH testing should not be proprietary information. He suggested that it would benefit program administrators if they could access the results of a fit-panel testing

[15] More information about 42 CFR 84 is available from https://www.cdc.gov/niosh/npptl/topics/respirators/pt84abs2.html (accessed September 16, 2020).

for different respirators. This would allow them to assess the fit capability of various products and reduce the time spent fit testing those products for their workforce. He added that fit testing results would also be helpful information for the public. However, manufacturers are often reluctant to release their results to the general public due to the potential for competitive disadvantage with other manufacturers. Nicas maintained that this government testing should be public information and not held as proprietary by NIOSH. Kojola added that NIOSH has long attempted to establish minimum requirements for the fit of filtering facepiece respirators, but their approval process currently does not include fit requirements. D'Alessandro added that for several years, NIOSH has been participating on an ASTM Committee helping to develop a respiratory fit capability. When this standard is completed it could lead to the assessment of fit capability at some level and they are considering whether manufacturers would report this as part of their product certification or have it be incorporated by reference in 42 CFR 84.

Final Reflections on the Session

Planning committee member Howard Cohen of the Yale School of Medicine offered his reflections on the presentations and discussions of Session 4A: Assessment Pathways for Respiratory Protective Devices for Nontraditional Workers. Cohen said standards are the foundation of CA processes, and these standards typically presume a certain degree of sophistication in the respiratory protection programs they support. In the case of nontraditional workers, he said, these presumptions are not well-supported because respiratory protection programs do not exist. Thus, he proposed that it is necessary that either (1) these populations are made to adhere to the presumptions of existing standards, or (2) new standards be developed that are appropriate for nontraditional workers. He said that more research is needed to address the challenges of ensuring respiratory protection for nontraditional workers, as respiratory protection is more sophisticated that other forms of PPE, such as earplugs and safety glasses. He concluded that this sophistication—and the persistent gaps in knowledge—may best be addressed through standards and engagement with employers by OSHA and other public health agencies.

6

Assessment Pathways for Respiratory Protective Devices for the Public

Respiratory protective devices (RPDs) are assessed and approved through various pathways, but there are large gaps in regulation where certain populations are using devices that have not been subjected to any assessment. In this session, moderated by planning committee member Daniel Shipp, retired from the International Safety Equipment Association, three speakers explored how existing conformity assessment (CA) processes may be used to provide respiratory protection for non-occupational use, specifically the use of these devices by the general public. They also discussed classifications and testing requirements for general-purpose face coverings and described extant opportunities to develop or support CA processes that address the requirements of nontraditional users. Before beginning the session, Shipp commented that current events have rapidly changed our perception concerning the use of RPDs and cloth masks by the public. As such, he said, it is critical to understand how mask performance can be assessed against requirements and who should regulate this.[1] These topics would be explored by the expert panelists in their presentations and during the discussion period.

[1] In order to clarify terminology in this publication, masks, face coverings, facial coverings and respirators are distinct terms with distinct meanings, but their use in this report depends on the speaker's choices. Every attempt has been made to limit the term "respirator" to a tight-fitting device that protects the user from inhaling airborne contaminants and "masks" to mean coverings that are loose, unfitted devices that cover the nose and the mouth of the user and provide protection for the environment from the user's cough and exhaled secretions. Respiratory protective devices (RPDs) include respirators as well as masks, face coverings, and facial coverings (Johnson, 2020; NASEM, 2019).

CHALLENGES IN PROVIDING RESPIRATORY PROTECTION TO THE PUBLIC

Jim Johnson, the principal for JSJ & Associates, discussed the critical questions and challenges associated with providing non-occupational respiratory protection to the public. He highlighted several critical issues, including (1) to whom should this protection be provided, (2) the hazards from which protection is needed, and (3) how protection will be provided. RPDs have typically been designed for use in occupational settings by healthy workers, he said, but the need is growing for respiratory protection among the general public, children, and at-risk populations (e.g., elderly, physically challenged, immunocompromised). Unique issues may arise in offering respiratory protection to members of each of these groups, he said.

Defining the hazards to be addressed by RPDs has long been challenging due to the broad range of potentially hazardous chemicals (e.g., chemical spills, pesticide spray, leaded gasoline), air pollution (e.g., smog, ozone particulates, smoke from wildfires), and biological agents (e.g., mold, coronavirus disease 2019 [COVID-19]). He said that in addition to the nature of the hazard, the source of the hazard is also an issue that must be considered. In the context of the COVID-19 pandemic, for example, the major source of the hazard is the presence of other infected people.

Some of the mechanisms through which respiratory protection can be provided include engineering controls, administrative controls, and the use of personal protective equipment (PPE), Johnson said. For instance, protection may be provided through ventilation systems, high-efficiency particulate air filters, electrostatic filters, increasing the frequency of air changes, or using large air volumes to help control or dilute the hazard source. An example of administrative control would be using social distancing to reduce the hazards of COVID-19 transmission. Johnson said that PPE has typically been regarded as the last line of defense or the last resort to protect against hazards that cannot be avoided through other controls. However, he said, during the COVID-19 pandemic, PPE has emerged as a major focus of the pandemic response, underscoring the need for better education about the appropriate use of RPDs to reduce the spread of disease.

Defining Respiratory Protective Devices

Johnson explained that RPDs are devices that have been designed to provide the wearer with a specified level of respiratory protection against a defined hazard. RPDs can be divided into three types based on design and performance: (1) respirators, which are a recognized type of PPE; (2) masks, like surgical masks, which can be a type of PPE; and (3) facial coverings, which are not a type of PPE. For respirators, the National Institute for Occu-

pational Safety and Health (NIOSH) and the Food and Drug Administration (FDA) define the CA process, and the Occupational Safety and Health Administration (OSHA) defines the elements of the respiratory protection program for use by management. For masks, FDA defines the performance of surgical and non-surgical face masks, but face masks for non-medical use by the general public have no FDA requirements. "Facial covering" is a new designation that is currently being defined, with specific performance requirements being identified and developed. Johnson shared images of three common examples of NIOSH-approved half-facepiece respirators, including elastomeric half facepieces, filtering half facepieces, and surgical N95s, that would pass fit-test requirements. One of the filtering half facepieces pictured featured an exhalation valve. Johnson commented that exhalation valves are a type of impactor, which when opened can remove some of the particulate, especially large droplets, from an individual's exhaled airstream. He also presented images of various types of masks and facial coverings, including a surgical face mask, non-surgical procedure face mask, comfort mask, and several types of facial coverings (see Figure 6-1). FDA has some oversight over the two types of face mask and sets performance criteria for the protection these provide the wearer. Johnson reiterated that work is under way to develop a standard for facial coverings.

Ensuring the Effective Use of Respiratory Protective Devices by the Public

Johnson discussed several strategies to support the effective use of RPDs—specifically, facial coverings—by the public. The first strategy was to assign the responsibility for the overall program to a single organization with the authority to delegate responsibilities as appropriate. This organization could be a government or private-sector entity; Johnson suggested that NIOSH could be a good candidate for this role because it has the history, skills, and knowledge that could help expedite this effort. The second strategy was to develop an education program for the general public that could help to clarify the distinctions between respirators, masks, and facial coverings and the levels of protection they provide. A third strategy would be to evaluate, quantify, and communicate information about the hazards and risks clearly and accurately (e.g., whether droplets or particles are the major COVID-19 inhalation hazard). Finally, Johnson suggested implementing consensus standards that define RPD performance and include a CA program. He noted that multiple publications from the Institute of Medicine and the National Academies of Sciences, Engineering, and Medicine provide a wealth of information about RPDs and other topics related to the use of PPE (IOM, 2006, 2011a,b; NASEM, 2019).

To conclude, Johnson emphasized that the development of a CA program for RPDs and other PPE for civilian use needs to be assigned to a

FIGURE 6-1 Examples of respiratory protective devices, masks, and facial coverings. Top: NIOSH-approved half facepiece respirators. Bottom: Masks and facial coverings.
NOTE: FDA = Food and Drug Administration.
SOURCES: Johnson presentation, August 5, 2020; Moldex, 2020; Sundström, 2020.

single organization with the authority to delegate as appropriate. He suggested that this CA program could follow the successful models currently used by NIOSH and OSHA. Finally, he underlined the major challenge of developing systems to identify and characterize hazards and quantify the risks encountered by the public when they use RPDs or other PPE.

CLASSIFICATIONS AND TESTING REQUIREMENTS FOR GENERAL-PURPOSE FACE COVERINGS

Emiel DenHartog, an associate professor and an associate director of the Textile Protection and Comfort Center at North Carolina State University, provided an overview of classifications and testing requirements for general-purpose face coverings. He said that during the early stages of the COVID-19 pandemic, he and his colleagues at the North Carolina State University's Wilson College of Textiles received numerous requests from textile manufacturers who wanted to begin producing general-purpose face coverings and wanted a better understanding of surgical masks and N95 respirators; however, at that time only limited guidance and standards were available for general-purpose masks. This catalyzed a group of volunteers from the American Association of Textile Chemists and Colorists and other institutes and organizations to help guide the textile industry in developing a voluntary standard.[2] Their efforts, DenHartog said, focused on helping manufacturers understand what they would need to do to help serve the public by making general-purpose face coverings, a category that is distinct from N95 respirators and surgical/medical masks.

Because of the nature of existing requirements for PPE for occupational use, DenHartog said, general-purpose masks need a separate requirement. The extant RPD certifications primarily target occupational use (3M, 2020), and most, if not all, standards for protective masks are focused on occupational health settings and protecting people while they work. In contrast, few standards or requirements exist for general-purpose masks, although several voluntary guidance documents are available, especially from Europe (e.g., AFNOR, BSI, CE, NEN).[3] As a PPE scientist, he said, he is concerned about the common adage "Anything is better than nothing" when it comes to respiratory protection because he knows of many examples in which inappropriate use of a protection product worsened the user's exposure or risk. This can result in a false sense of security associated with the use of respiratory protection, he said, and poorly designed RPDs may be made with materials that actually contribute to the risk of exposure.

Monograph Specifications for General-Purpose Face Coverings

The collaborative efforts described by DenHartog led to the development of a voluntary draft monograph[4] for the textile industry that offers

[2] The voluntary standard is available at https://www.aatcc.org/guidance-for-making-a-better-face-covering (accessed October 9, 2020).

[3] AFNOR = French Standardization Association; BSI = British Standards Institution; CE = Conformitè Europëenne; NEN = Royal Netherlands Standardization Institute.

[4] The voluntary standard is available at https://www.aatcc.org/guidance-for-making-a-better-face-covering (accessed October 9, 2020).

basic design guidance and construction suggestions.[5] DenHartog highlighted two of the technical specifications provided in the monograph: particle filtration and air permeability. The monograph attempts to offer some guidance regarding fit, but there is no available standard, so the document provides general guidance about what indicators should be considered to address the fit of a face covering. He noted that the monograph is now being further developed by ASTM International to provide more technical detail, background, and guidance.

Particle Filtration Efficiency

The voluntary draft suggests that for particle filtration efficiency,[6] face coverings shall demonstrate a particle filtration efficiency of greater than 70 percent with maximum 3-micron particle size at a velocity of 10.4 cm/s. Testing is to be performed on "as-received" samples after a specified number of washes. DenHartog characterized this target filtration efficiency as a low bar that would primarily guarantee only the filtration of larger droplets. In the future, he said, a target filtration efficiency of 70 percent with maximum particle size of 2.5 microns may be suitable for protecting against smoke or pollution. The filtration efficiency of 70 percent was chosen based on European standards (ASTM F2299 or technical equivalent).

Breathing Resistance: Air Permeability

Ensuring the appropriate technical specifications for breathing resistance is important for ensuring that people can actually breath through the face covering, DenHartog said. The three international standards for air permeability—EN 14683,[7] ASTM D737,[8] and ISO 9327[9]—are each associated with basic air permeability tests to assess how air flow will pass through a fabric or a fabric assembly at a certain pressure. The monograph provides guidance on how manufacturers can test their materials and understand how their results correspond with the various standards, including the EN standards and the requirements for NIOSH-certified products. DenHartog suggested that if these requirements can be fulfilled by those

[5] DenHartog emphasized that while the monograph was not intended for the general public, education is needed among the public to ensure that RPDs are used correctly.

[6] Specification is per ASTM F2299 or technical equivalent.

[7] Using 8 L/min air flow, with standard diameter of 25 mm. Should exhibit a maximum of 36.7 Pa/cm^2.

[8] Using a standard 125 Pa pressure drop. Use the standard 38.3 cm^2 test area. Should exhibit a minimum of a minimum of 37.5 ft^3/min/ft^2.

[9] Using a standard 100 Pa pressure differential. Should exhibit a minimum of 0.91 L/min/cm^2 (or 15 cm/s).

manufacturing face coverings, it might be appropriate to say that "anything is better than nothing" with respect to the risk–benefit ratio.

Variation in Fabrics Used in General-Purpose Masks

DenHartog said that the fabric used to manufacture non-medical, general-purpose masks for use by the general public varies widely and affects the filtration properties of the masks. The fabric used in general-purpose cloth masks differs in important ways from the fabric used in N95s, he said. N95s are manufactured with non-woven, technical-filtration fabrics that have a different structure than woven fabrics and have additional electrostatic functionality to enhance filtration efficiency. The structure of non-woven, technical-filtration fabric is made of a random fiber net that is created by the intersection of fine, rod-like segments of fibers. Because of the distribution of these fine fibers and other features of technical-filtration fabrics, they work well as effective yet inexpensive filter materials. In contrast, DenHartog said, woven fabrics and knit fabrics have a structure that is less random, so they must be designed carefully to provide any degree of filtration. In fact, he added, due to its standardized and patterned structure, woven cloth may function more like a sieve than a filter. Furthermore, the same basic structure can provide different filtration properties depending on the type of yarn that is used. Yarn can be made of different types of fibers that can be spun in various ways and thus affect a textile material's filtration efficiency (Ghosh et al., 2008). Fabric finishing techniques such as brushing, pilling, or raising can also affect surface hairiness and roughness, in turn influencing filtration efficiency.

General-purpose mask manufacturers must understand that "one cloth does not equal another" in terms of filtration efficiency, DenHartog said. Given the wide variation in textile materials, it is not yet possible to provide manufacturers with clear, simple guidance regarding fabric structure. Filtration efficiency should be measured, but it cannot yet be predicted, he said. For instance, the description of a fabric (e.g., "one-layer knit," "layer jersey knit," "two-layer jersey knit") can capture some of a fabric's physical properties, but descriptions of a fabric's property are not sufficient to predict its filtration efficiency. He said that the textile industry is generally receptive to shifting production toward the materials best suited for filtration, but there is not yet sufficient evidence to make specific recommendations to manufacturers. In part, this is because the focus has been on understanding the filtration properties of non-woven fabric rather than of woven or knit fabrics. Although filtration efficiency can be improved by adding layers of fabric, this improvement comes at the expense of breathing resistance. DenHartog added that various woven and knit fabrics will need to be tested for any evidence-based claims to be made about their filtration efficiency.

Particulate Filtration Efficiency of Different Materials

DenHartog presented findings about the particulate filtration efficiency of materials assessed through North Carolina State University's Textile Protection and Comfort Center's newly developed material-level evaluation (see Figure 6-2). For most filtering materials, particulate filtration efficiency was relatively low for particles ≤3 microns in size; only N95 mask material performed consistently when filtering such particles. Filtering very small particles and aerosols is a great challenge for most fabrics, he said, and this is a major issue when using fabrics for filtration. These findings suggest that general-purpose face masks are best suited to protect against large droplets that are ≥3 microns in size, which may not travel as far or be suspended as long as smaller particles.[10] He added that cloth fabrics have poor filtration efficiency in the aerosol particle range; however, depending on the hazard, these face coverings may not require a highly protective level.

Considerations for General-Purpose Face Coverings

DenHartog said that the protection offered by PPE is not merely about the fabric used, but about the final product and how it fits an individual. Mask fit is a major consideration because air follows the path of least resistance. Air that escapes from the mask perimeter is not passing through the mask. For instance, if a person's eyeglasses fog up while wearing a mask, it indicates that the mask is not appropriately fitted and that air is escaping around the mask perimeter. This effect is compounded by the fact that smaller particles (i.e., aerosols) are more likely to follow the flow of air. He noted that masks with transparent "plastic windows" to make the mask wearer's mouth visible will necessarily divert airflow, including aerosols, away from the impermeable plastic section and, as a result, they may not reduce the spread of a virus such as SARS-CoV-2.

To conclude, DenHartog explained that face coverings are not PPE, but they may help reduce the aerosol-exposure of the wearer to some degree, and, in the case of infectious diseases, they may help to reduce the spread of infectious droplets from the wearer. PPE scientists who are accustomed to dealing with filtration efficiencies of 95–99.9 percent may be concerned by the low filtration efficiencies of cloth masks, he said. However, the high filtration standards for extant PPE devices are designed to protect individuals who are entering known hazardous environments (e.g., first responders, chemical crews). From a public health perspective,

[10] DenHartog clarified that technically it is small droplets rather than aerosols that would be suspended in air for a longer period of time and that assessment involves looking at the smaller micron particle size. NPPTL tests are in the range of 0.1–0.5 microns because 0.3 microns is the most challenging size for technical media to filter.

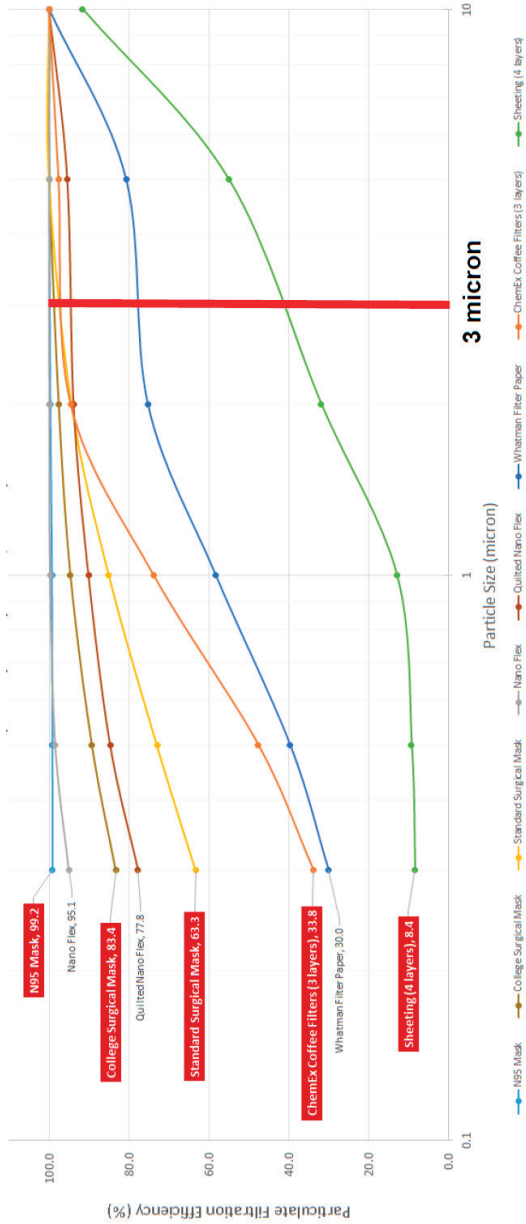

FIGURE 6-2 Particulate filtration efficiency of materials assessed through North Carolina State University's Textile Protection and Comfort Center's newly developed material-level evaluation.
NOTE: Tests conducted using FLUKE 985 particle counter–0.1 cfm (2.8 L/min)–1 minute duration–3 cycles.
SOURCE: DenHartog presentation, August 5, 2020.

however, there may be value in using less efficient filtering materials even though the minimal effective level is not yet known, DenHartog said. For example, he suggested that using a face covering with 20 percent filtration efficiency could represent a significant reduction that contributes to improved public health outcomes, even if that level of efficiency would be insufficient for use as occupational PPE. For instance, if 10 million individuals are exposed, then the use of a face covering with 20 percent filtration efficiency could potentially avoid exposing 2 million people. In a scenario with a 0.2 percent mortality rate associated with exposure, this device could save as many as 4,000 lives. DenHartog emphasized "not PPE" does not mean "not effective" from a public health perspective. This is because the objective of face coverings is to improve public health, not to protect individuals in hazardous environments. He suggested that in the context of the COVID-19 pandemic, this argument could help in public messaging about the potential benefits of using face coverings in addition to physical distancing.

DEVELOPING A STANDARD SPECIFICATION FOR BARRIER FACE COVERINGS

Jonathan Szalajda, the deputy director of the National Personal Protective Technology Laboratory (NPPTL) at NIOSH, discussed opportunities to develop or support CA processes for RPDs and for source control strategies, such as cloth face coverings, that are responsive to the specific requirements of nontraditional user groups. He focused specifically on the ASTM Work Item 73471–Standard Specification for Barrier Face Coverings (ASTM 73471).

ASTM Work Item 73471–Standard Specification for Barrier Face Coverings

Szalajda described how the development of ASTM 73471 began in summer 2020, when a fabrics industry association initiated a discussion about developing a "get back to work" product in response to the COVID-19 pandemic. A committee of more than 45 representatives from industry, academia, and government was then convened to develop ASTM 73471. The "get back to work" product is not a respirator or a surgical mask, nor is it intended to replace those commodities. Instead, Szalajda said, the basic idea was to create a device that is superior to a simple cloth face covering—perhaps closer in caliber to an N95 or surgical mask—but that also addresses the issues of scalability associated with true respirators. One scalability issue relates to the amount of non-woven fabric required to produce respirators. To address this issue, Szalajda suggested identifying commonly

available materials that would be accessible in larger quantities to create different designs for use as barrier face coverings.

Scope and Performance of ASTM 73471

The scope of the ASTM 73471 standard includes source control and the provision of some degree of inhalation protection. Emerging evidence suggest that face coverings may help to reduce transmission through source control, Szalajda said, and there is growing awareness that the types of face coverings currently being used vary in terms of effectiveness. The efficacy of face coverings for reducing transmission is dependent on how reliably individuals actually wear them, he said. Face coverings are not effective if they are not worn consistently or if individuals refuse to wear them. Citing historical accounts of non-compliance with policies regarding face covering during the 1918 influenza pandemic (Hauser, 2020), Szalajda said that neither face covering technology nor issues related to public compliance with face coverings have evolved substantially over the past century.

Szalajda recognized that the new ASTM 73471 standard could not be developed through the existing occupational approval or CA processes of NIOSH or NPPTL. Thus, ASTM International was engaged to initiate the work item and to develop a specification for barrier face coverings. The specification was intended to identify some minimum level of performance requirements, along with a standard that would provide improved source control while also preventing particles from being inhaled. Szalajda said the idea behind this approach was to afford the wearers of these face coverings greater control over their own safety, a greater incentive to wear their face coverings, and a higher degree of confidence in resuming normal activities.

ASTM 73471 has three main performance elements of concern: (1) if the covering has filtration capability, (2) if the covering "fits," and (3) whether wearers can breathe while wearing the covering. "Fit," Szalaida said, refers to a combination of factors, including how well a covering seals to the user's face and how well the covering prevents particles from entering the covering via its perimeter. Szalaida further explained that comfort is another aspect of performance that will be critical for public use, as face coverings must be comfortable enough to wear for long durations without requiring manipulation by the wearer to maintain comfort. Reusability is also an important feature of barrier face coverings, he added. The standard is intended to be flexible enough to address reusable products as long as those products still provide a degree of protection once laundered. For reusable barrier face coverings, Szalaida added, ASTM 73471 will require that the product will be tested after laundering.

Addressing Translational Gaps and Challenges

The committee developing the ASTM 73471 standard has been identifying performance-related research gaps, Szalajda said. He added that translating a process and procedure from well-defined occupational products to general use products is challenging. However, the committee is working to determine minimum performance criteria to be expanded on in the future following more comprehensive research efforts to fill critical knowledge gaps related to performance. He said that, thus far, the committee's focus has been on developing standards that use existing test methods for ASTM International or NIOSH processes. For instance, they are looking at filtration requirements using the ASTM F-2100 standard and the NIOSH test procedure for N95 filtering facepiece efficiency. They are also considering the forthcoming ASTM standard for measuring fit (expected to be released in late 2020) as well as the NIOSH breathing resistance test. Additionally, they are planning to reference the ASTM International CA method described by Jeff Stull, the president of International Personnel Protection, Inc., in Chapter 5 of this proceedings. Szalajda said that the committee has also considered a unique approach that involves looking at manufacturers' self-reported data about fit capability given that most of the users of these types of devices will not have the capability to fit test their own device. Szalajda suggested that integrating fit capability as part of the approval process could increase the probability that devices will appropriately fit users.

Next Steps After the Development of the Standard

Szalajda suggested several potential ways forward after the development of the ASTM 73471 standard. A major translational challenge will be that nuanced terminological distinctions (e.g., N95, surgical masks, face coverings) are not readily apparent to the public. "They are all a mask as far as the public is concerned," he said. Going forward, he added, how these concepts are introduced to the public will be critical. Szalajda went on to say it will also be necessary to identify the required protection for these types of products and technical experts are working to synthesize existing literature and research to develop a standard for the performance of face coverings, to establish a baseline for identifying research gaps, and to identify hazards and appropriate levels of performance.

Szalajda also remarked on considerations related to the oversight associated with this type of product (e.g., determining which governing bodies have authority over such products and how oversight will be implemented at the national level). CA will be another important aspect of the success of this new product, he said. CA can provide needed assurance that a product meets the declared performance standard and helps to eliminate products

from the market that do not offer any protection. He commented that this effect was demonstrated following the September 11, 2001, attacks, when many products came to the market that purported to provide users with protection from chemical, biological, radiological, and nuclear hazards. However, once a standard was established that identified the appropriate protections, many of these products disappeared from the market. Looking to the future, he raised the question of how performance can be presented to users in a way that helps individuals make informed decisions. He wondered if information about the performance of face coverings—or any other types of products that may evolve to public use from occupational use—will need to be presented in a manner that allows for informed decision making by the public.

DISCUSSION

Conformity Assessment for Barrier Masks

Shipp asked the panel about the most critical elements or factors for a CA program to examine in assessing the performance of barrier masks. Johnson spoke of the need to address the hazard that a barrier mask is to be used for as well as the expectations of the wearer. Additionally, Johnson said, there should be a background of approval, CA, and test methods that assure a certain level of protection and performance for an individual who decides to wear that barrier mask to reduce risk. DenHartog suggested developing some level of hazard assessment to determine appropriate standards and test methods, which would make it possible for certification to be conducted by private companies or through NPPTL. At that point public health and educational efforts could then support individuals in decision making related to the selection and use of products for different circumstances, he added.

Szalajda suggested that using an analysis of risk to identify the appropriate CA for face-covering products is an opportunity to apply the national framework developed by NIOSH. Face coverings, he said, should not be discussed as providing the same level of protection as a respirator or a surgical mask. However, these products do serve a role in providing a level of protection for the general public, he said, so he suggested that the development of a standard for barrier face coverings should determine and propose a CA level that is associated with the risks in the areas where these products are being used.

Shipp asked Szalajda whether he envisions (1) a set of standards or CA procedures for face coverings that are equivalent to what NIOSH currently has in place for respirators to assess different types of hazards, such as particulates, vapors, or gases, or (2) a broader set of requirements that would

define, in general terms, factors such as filtration efficiency, breathing resistance, and fit. Szalajda replied that a more general set of requirements will be needed for face coverings because they are source control devices and not respirators. Whether through a third-party evaluation or some other mechanism, source control should be addressed as part of the standards development process, he said. He went on to explain that in settings where there is less certainty regarding the risk and the protection associated with those risks, more flexibility could be allowed in terms of how information is presented. A standard would allow manufacturers to report their filtration efficiency against the NIOSH requirement.[11] Szalajda added that manufacturers will be allowed to present their "fit" or "leakage" for their products, depending on which term is ultimately agreed upon. The lingering issue, Szalajda said, will be determining how that information is translated to the public to assist decision making and it is unclear whether this would fall into the NIOSH framework or into a Safety Equipment Institute framework in association with ASTM International.

Barrier Face Coverings as Source Control

Shipp highlighted Szalajda's comments that barrier face coverings provide source control and, therefore, are only effective when everybody is wearing them. This differs from more typical respiratory protective devices, which are designed to protect the wearer. A participant asked whether a barrier face covering needs to perform similarly to a surgical N95—or perhaps at a lower protected factor—in providing protection to the wearer and providing source control as a barrier to outgoing pathogen flow. In addition, the participant asked whether a face covering should also protect from environmental hazards such as smoke and air pollution. Szalajda said he thinks the same requirement could be used for both the surgical mask and the face covering standard as the surgical mask standard has a national consensus already in place. Existing methods can be used to provide the source control element to ensure devices perform as they are intended to, he said.

Johnson contended that the growing evidence base about facial coverings will demonstrate that no single universal facial covering can be effective for protection against the full spectrum of exposure hazards (e.g., wildland smoke, SARS-CoV-2, pesticide applications), so the public will need to be educated about different types of hazards. He added that local public health departments will need to help ensure that the correct equipment is specified when there is a public health emergency. "We [cannot] fall in the trap that this current barrier mask is going to take care of everything," he cautioned.

[11] More information about the 0059 test is available from https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf (accessed September 16, 2020).

DenHartog raised the issue of air speed as it pertains to source control, noting that sneezing has been found to produce higher speeds and larger droplet sizes than coughing, talking, and breathing. In terms of source control, he said, the impact of droplet size on the effectiveness of cloth masks is still unknown. DenHartog said that the device needed for protection against smoke will be different than a device needed for protection against COVID-19. However, DenHartog added, it is becoming increasingly clear that there is at least some beneficial effect of well-designed cloth masks as source control.

N95 Exhalation Valves

Workshop planning committee member Melissa McDiarmid, professor of medicine, epidemiology, and public health at the University of Maryland School of Medicine, suggested that concerns about the use of N95s with exhalation valves have been minimized somewhat by the asymptomatic spread of COVID-19. She mentioned that there are other pathways through a mask through which transmission could occur from the mask wearer, such as through the face seal. She noted that 10 percent face seal leakage is allowable even for an N95, and she asked the panel to comment about exhalation valves on N95s as well as on elastomerics.

Johnson suggested creating a visualization to demonstrate the difference between coughing through an exhalation valve and coughing without an exhalation valve. He noted that different exhalation valve designs will remove different percentages of particles. The exhalation valve may not open very much when the wearer of a filtering face piece mask is in a sedentary state, because air is flowing out through the filter media and the pressure does not drop substantially. He added that the potential effects of exhalation valves come into play when the wearer has a higher breathing rate, which reduces breathing resistance. Elastomerics always open, he explained, as that is the mechanism for exhaled air to exit the elastomeric face piece.

Johnson gave the example of a medical center that put an embargo on any filtering face piece with an exhalation valve and instructed people to wear face coverings instead. He said that this decision does not reflect an understanding of aerosol physics or respiratory protection, which underscores the need for better communication about the scientific underpinnings of different types of RPDs. From his perspective, he said, the key questions are (1) how the exhalation valve affects source control, (2) how the exhalation valve works as an impactor,[12] and (3) how the covering on most

[12] Johnson clarified that exhalation valves are a type of impactor, which can remove particles when an airstream comes in contact with them earlier in the proceedings.

exhalation valves functions as another collector of droplets of any size that pass through the valve. He maintained that if the medical community determines that exhalation valves are not acceptable, then every person who wears a mask is a potential contaminated source. In that case, he said, all of the controls applied to respirators need to be applied in the same way to masks. Szalajda said that any respirator—including respirators with exhalation valves—is a source control device. He said that NPPTL is actively working to quantify anything that may be coming through the exhalation valve or through face seal leakage. He added that an exhalation valve is often misconstrued as a hose blowing air out, which is not the case.

Maryann D'Alessandro, the director of NPPTL, referred to preliminary data showing that the outward leakage from an exhalation valve is not significant under normal breathing situations. She added that NIOSH is conducting laboratory studies to compare elastomerics and N95s with exhalation valves as well as with surgical masks in order to produce quantitative data. D'Alessandro said that the current position of the Centers for Disease Control and Prevention is that the N95 respirator with an exhalation valve provides the same level of protection to the wearer as one without a valve, but the presence of the valve reduces exhalation resistance, making it easier to breathe. She suggested that wearers could opt to put a covering over the valve until more data are available. D'Alessandro added that NIOSH is also exploring how to work with manufacturers to develop devices to cover the exhalation valve, either to filter air or to serve as a covering to eliminate this issue.

DenHartog added that masks with exhalation valves likely work better than many of the face coverings that people are wearing, such as gaiters or single-layer cloth masks. He also noted that masks need to be assessed in different ways. For example, cloth masks featuring a transparent window or cloth face coverings with filter pocket inserts to provide filtration in the center of the product could potentially increase air resistance and drive air around the filter. Instead of looking at the exhalation valve or at the fabric filtration in isolation, he suggested examining the mask overall and developing guidelines to certify masks.

Reflections on the Session

Shipp offered his reflections on the presentations and discussions of workshop Session 4B: Assessment Pathways for Respiratory Protective Devices and Other Options for the Public. First, he said, existing knowledge and experience about respiratory protection in occupational settings could be used and translated into a public health approach to respiratory protection. Respiratory protection for the public, Shipp said, needs to be properly situated among other health, safety, and administrative controls.

For instance, Shipp added, in the response to the COVID-19 pandemic, administrative controls such as social distancing may have been incorporated into potential standards or guidance on the use of facial protection for the public. Given current circumstances, Shipp said, the typical process for standard development—which takes approximately 5 years—would need to be significantly accelerated to address the respiratory protection needs at hand. He highlighted the urgent need for information, both in terms of the public's need for information about how to best protect themselves and in terms of the need for information about how to measure and communicate measures of the performance of respiratory products among suppliers, distributers, and sellers of respiratory products (e.g., community masks). He concluded that although he agrees that "the perfect should not be the enemy of the good," particularly in terms of providing respiratory protection to the public, it is not necessarily the case that any protection is better than no protection.

7

Addressing Research and Communication Gaps

The challenges of ensuring respiratory protection for nontraditional workers and the public through regulation have been further complicated by gaps in research and communication. As mentioned in earlier chapters, a key component to getting individuals to use appropriate respiratory protective devices (RPDs) will be educating workers, employers, and the general public about the different types of RPDs available. In a session moderated by planning committee member Tener Veenema of the Johns Hopkins University School of Nursing, three speakers discussed the public understanding of respiratory protection, explored the human factors and systems engineering perspective on RPDs, and described concerns relating to the use of respirators by the general public.

PUBLIC COMMUNICATION ABOUT RESPIRATORY PROTECTION

Rachael Jones, an associate professor at The University of Utah, provided an overview of the types of public communication strategies that could help to educate the general public about the benefits of the proper use of respiratory protection. She remarked that the coronavirus disease 2019 (COVID-19) pandemic has highlighted a gap in knowledge about the perception and knowledge of respiratory protection among both the general public and among people who do not routinely wear respirators in occupational settings. Additionally, the contexts in which people are willing to wear respirators are not well understood. Jones said in certain areas of the United States, there have been high rates of compliance and interest in wearing face coverings in response to the COVID-19 pandemic, but the

experiences regarding respirator compliance in communities has varied. Much remains unknown about the motivating factors that have influenced people's attitudes about wearing face coverings and respirators. These motivating factors, Jones said, may be interpreted partly as a political response to the COVID-19 pandemic, but they may also be interpreted as a reflection of various personal values or perceptions. Many people are willing to wear face coverings and respirators in the context of wildfires or pandemics. However, she added, less is known about the general public's willingness to use face coverings and respirators while in their homes, working on projects, or in other non-occupational contexts. Jones suggested that better characterizing this user group would contribute substantially to addressing this research gap and advancing efforts to target messages and designs that facilitate the use of respiratory protection.

Research on respirator design could support efforts to effectively communicate and educate nontraditional users of RPDs about respiratory protection, Jones said. For instance, there has been public concern about the presence of and risks associated with exhalation valves on respirators amid the COVID-19 pandemic. Jones suggested this public concern could be addressed in a relatively straightforward way by conducting the necessary research and communicating the findings through clear public messaging.

Communication strategies are also needed to address misperceptions and misinformation about respiratory protection that have emerged in the context of the COVID-19 pandemic, Jones said. For example, videos that circulated online raised concerns among the public about trapping carbon dioxide in the facepieces of respirators. These concerns, Jones said, could be addressed relatively straightforwardly with evidence providing a reasonable explanation for the presence of carbon dioxide in facepieces. However, this explanation and the associated evidence would need to be communicated to the public in a clear and appropriate way. Similarly, news reports during the early stages of the pandemic raised concern about the chemical content of respirators that could potentially affect the wearer. Jones said that regardless of the validity of such claims, they can affect public perceptions and provide a reason to fear respirators.

Better public communication is also needed about respirator fit and the potential consequences of ill-fitting respirators, Jones said. However, research is ongoing into how to increase the number of individuals who will be able to achieve proper respirator fit, Jones added. Research will need to be complemented by effective communication strategies about the importance of a properly fit respirator, Jones explained. People also need to be aware of health conditions that can affect a person's ability to effectively and comfortably wear a respirator, she said.

Jones added that research- and evidence-informed communication strategies are needed to encourage the use of respirators and the adoption and

implementation of respiratory protection programs in the workplace, particularly among smaller organizations. The Occupational Safety and Health Administration (OSHA) standards for respiratory protection programs are complicated and may be challenging for small organizations to implement, particularly if they do not already have other kinds of occupational health and safety programs in place, Jones said. Research could be conducted to investigate how to best to communicate about respiratory protection programs, how to implement them efficiently, and how to evaluate them. This research, Jones said, could then be used to inform guidance on the effective use of workplace respiratory protection among small employers or employers that do not have established health and safety programs.

A HUMAN FACTORS AND SYSTEMS ENGINEERING PERSPECTIVE ON RESPIRATORY PROTECTIVE DEVICES

Ayse Gurses, a professor at Johns Hopkins University School of Medicine, offered a human factors and systems engineering perspective on issues related to the use of RPDs by nontraditional users. She described the role of human factors engineering in the design and use of RPDs, framed RPDs as a part of a larger sociotechnical safety-critical work system, and suggested avenues for future research on RPDs from a human factors engineering perspective. According to the International Ergonomics Association, human factors and ergonomics (HFE) is "the scientific discipline concerned with the understanding of interactions among humans and other elements of a system and the profession that applies theory, principles, data, and methods to design in order to optimize human well-being and overall system performance."[1] HFE can be applied to systems, technologies, or tools, such as N95 respirators. Some HFE scientists, Gurses said, are concerned with ensuring that patients and health care workers remain safe, as the safety of these groups is critical for optimization of system performance in health care settings. For instance, the Armstrong Institute for Patient Safety and Quality is dedicated to improving the way that people—health care professionals, patients and families—interact with care systems so that the systems are safer, high performing, and patient-centered.[2] Their projects include, for example, work done to address Ebola, she said.

Gurses identified three specializations in the field of HFE and described how they may relate to the issues of RPDs: (1) physiological ergonomics, (2) cognitive ergonomics, and (3) macroergonomics, also called organiza-

[1] More information about HFE and the International Ergonomics Association is available from https://iea.cc/what-is-ergonomics (accessed August 31, 2020).

[2] More information about the Armstrong Institute for Patient Safety and Quality is available from www.hopkinsmedicine.org/armstrong/humanfactors (accessed August 31, 2020).

tional ergonomics (Gurses et al., 2012). Physical ergonomics may help to address the issues of RPD fit, comfort, and ease of use. Cognitive ergonomics may help address the issues of RPD packaging and labeling, manufacturer instructions for use, colors and textures used in RPDs, and RPD training. Macroergonomics may help address issues related to the use of RPDs within a specific context or "work system," Gurses said. Macroergonomics addresses entire systems by considering the relevant timing constraints, safety climates, and teamwork. Macroergonomics also accounts for training and adaptive capacity—that is, whether workers' training encourages them to merely follow directions or empowers them to adapt to changes in the workplace to maintain their safety while completing their work. Macroergonomics also uses participatory ergonomics to design interventions in a manner that increases acceptance of those interventions.

Respiratory Protection Devices as a Component of the Sociotechnical Work System

Gurses said that nontraditional users of RPD vary in terms of physical characteristics, anthropometric characteristics, cognitive characteristics, knowledge, skills, attitudes, and user behaviors as well as in terms of age, preferences, degree of trust, culture, comfort, perceived workload, and perceived ease of use, usefulness, and feasibility. These factors, Gurses said, influence user behaviors that, in turn, affect compliance or non-compliance. As Jones noted in her presentation, little is known about these user populations or why some populations are more motivated to use face coverings or respirators than others. Research on these issues may help to elucidate the cultures, preferences, biases, and factors of comfort that contribute to the use behaviors of these different groups. This could contribute to better managing the respiratory health and improving the compliance of these groups within user populations, she said.

Gurses presented a model from a systems engineering initiative for patient safety (see Figure 7-1). This model was created to address patient safety, but it could also be used to consider the safety of health care work systems or even home safety. The work system component of the model represents individuals conducting tasks. This work system model indicates that there are many complex interactions occurring among technology and tools, persons, tasks, environments, and organizations. RPDs fit within the designation of technology and tools, and understanding their context among the other work system factors could inform strategies to design RPDs, develop instructions for their use, and develop training about RPDs.

In the field of respiratory protection, the term "hazard" is often used to refer to an exposure hazard, Gurses said. However, in HFE hazards include any factors that may lead to noncompliance. For instance, if a work system

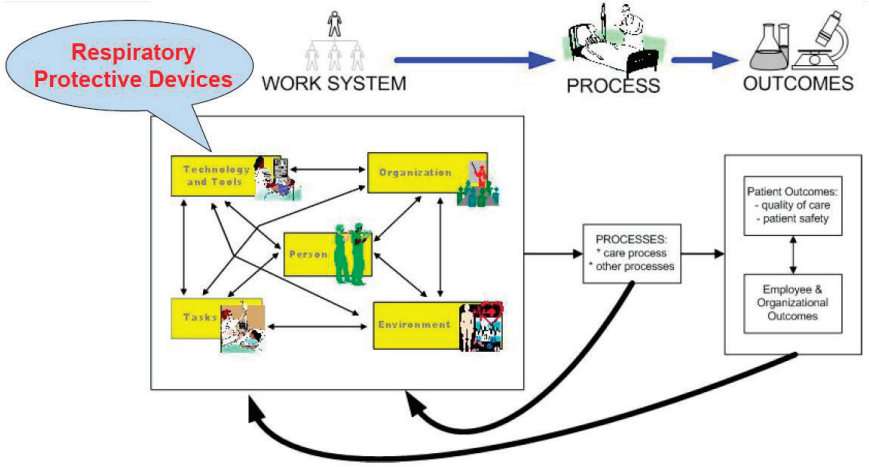

FIGURE 7-1 Systems engineering initiative for patient safety.
SOURCES: Gurses presentation, August 5, 2020; Carayon et al., 2006.

does not have N95s, then it will be impossible for workers to comply. Less extreme examples of "hazards" include poorly fitting RPDs or any other factor that is a hazard to compliance with a safety program. In addition to considering exposure hazards, Gurses said, it is necessary to consider hazards in the work, home, or public system that impede users from complying with intended use and protocols.

The sociotechnical work system is a highly dynamic system, Gurses said. This system exists in "safety critical" work or living environments. In HFE, task–technology fit is a key consideration for safety critical work or living environments. The safety-prone approach focuses on work as imagined. This approach sets out to design every factor of systems in the "correct" way to ensure safety among the system participants. In HFE, the safety-tool approach acknowledges that safety critical environments are highly dynamic, nonlinear, and unpredictable. This approach presumes that it is not possible to account for every possible hazard through design. For instance, face coverings or masks are designed to be worn in a particular way to ensure their proper function, yet "in the wild" masks are worn in myriad ways that diminish their function, Gurses said. The approaches in safety literature focus on work-as-done and educating system participants, thus providing them with tools to ensure their own safety. This approach is intended to ensure that when safety factors change unexpectedly, system participants will be resilient and able to develop solutions to preserve system safety. HFE methods and approaches must be used to study work and living environments and engineer resilience using a combination of the

safety-prone and safety-tool approaches, Gurses said. She emphasized that resilience is key in this model. When unexpected events occur, resilient systems empower individuals to react in a safe manner. For instance, Gurses and her colleagues published a paper on their findings that workers in a cardiovascular operating room had begun taping labels on their new smart intravenous pumps to clearly mark the names of the drugs being dispensed (Pennathur et al., 2013). This demonstrates an oversight on the part of engineers who did not fully consider the needs of the users of these products and also illustrates the resilience of workers who recognized a safety need and adapted. Similar types of studies and design approaches should be considered in the development of RPDs, she said.

Human Factors Engineering Approaches and Respiratory Protective Devices

Gurses said that there are many approaches of HFE that may be relevant to the use of RPDs. Conceptual approaches to HFE of relevance include systems approaches, naturalistic decision making, distributed cognition, reliance engineering, high reliability, organizational learning, and implementation science. Methodological approaches include task analysis and cognitive task analysis; work system analysis, including in-depth understanding of the context of use; human-centered design; usability evaluation, including formative and summative evaluations; proactive risk analysis, including failure mode and effects analyses and what-if analyses; and participatory ergonomics and design. Gurses said that naturalistic decision making has to do with how people make decisions in real settings. For example, researchers may study how people choose which personal protective equipment (PPE) or gowns or gloves to use when under time pressure in real settings and team environments. This approach was developed through the study of firefighting. She added that implementation science is a key approach for issues related to RPDs. Even if the perfect RPD could be developed, proper implementation would be necessary to account for the variation in tasks that require RPDs to be used and in the types of RPD users. Cognitive task analysis is used to evaluate why individuals make certain decisions, such as why a person may don a mask incorrectly, she said. This form of analysis may be used to investigate whether the person is unaware of the correct way to don the mask or perhaps has chosen to don it incorrectly for some reason. This kind of analysis is valuable for designing better training and instructional materials, Gurses said. Finally, she noted that numerous areas of study within the domain of human-centered design may be of value to those working on the challenges of RPDs.

Creating a Research Strategy to Improve Use and Safety of Respiratory Protective Devices

Gurses proposed that a comprehensive, interdisciplinary, multidimensional research strategy be deployed to improve RPD use and safety. Such a research strategy might include various forms of interdisciplinary scientific research. An evaluation of the different needs of different users could be conducted through ethnographic studies on work-as-imagined versus work-as-done. Safety risks and other problems, Gurses said, can be identified through failure mode and effects analyses and what-if analyses, while new human centered RPD designs can prioritize resilience whenever possible. Test solutions developed using human-centered design could be iteratively developed and piloted. Implementation science can be harnessed to tailor, implement, and disseminate those solutions, coupled with effective feedback mechanisms to inform public health systems about the real-world use and effectiveness of RPDs, Gurses said. Gurses also commented on the need for communication in addition to mere education. The existing focus on improving communication about RPDs—both to users and from users—should be maintained. The public's perceptions, problems, and needs must be heard and acknowledged so that they can be addressed, she added, noting that a top-down approach is not suitable for addressing the communication needs related to RPDs. Gurses said that there are feedback mechanisms in place to engage users of RPDs and assess the effectiveness of RPDs. To ensure the success of new national strategies to support the use of RPDs among the public, these mechanisms must be maintained as new systems and devices are developed, she added.

ON THE USE OF RESPIRATORS BY THE GENERAL PUBLIC

Barbara Materna, the chief of the Occupational Health Branch of the California Department of Public Health, explained that in her work as a certified industrial hygienist she has been involved with the use of respirators in health care under the California Occupational Safety and Health Administration (Cal/OSHA). She helped to develop Cal/OSHA's aerosol transmissible diseases standard and has collaborated with National Institute for Occupational Safety and Health (NIOSH) and the federal OSHA to develop a respiratory protection program toolkit for hospitals. She explained that during various emergency responses, when workers or members of the general public have been at risk for health effects from inhaled hazards, public health officials have recommended respirators as a necessary control measure outside of a formal respiratory protection program. When this has occurred, the events give rise to recurring questions, including (1) how much protection is provided by respirators that

have not been fit tested, (2) how should those with pre-existing heart or lung disease be advised, and (3) how to address individuals' improper use of respirators and consequent lack of protection. Materna explained that she has encountered such issues primarily in the context of responding to California wildfire emergencies where the respiratory hazards in question are particulates in smoke or ash. She has also worked on developing guidance for the Environmental Protection Agency's updated wildfire smoke guide regarding the use of respirators by the public or outdoor workers who have not been fit tested. Other emergencies where particulate hazards become an issue include volcanic ash from eruptions, mold exposure after floods, and infectious disease pandemics, such as the COVID-19 pandemic. She suggested that the public would benefit from better use of respirators in certain non-emergency situations if they had access to clear and accurate information about the technical details as well as access to equipment designed with their ease of use in mind.

Regarding the use of respirators among nontraditional workers, Materna suggested focusing on providing the same level of protection to these workers as is provided to all workers who rely on respirators. She said she would concentrate her remarks on the use of respirators by the public. In consideration of this aim, she raised three questions: (1) What is needed to provide the best protection for the public who use respirators without the benefit of fit testing? (2) Can N95s or other filtering facepiece respirators (FFRs) be used by those with heart or lung conditions? and (3) What is needed to better communicate to the public about proper respirator use?

Providing the Best Respiratory Protection Without Fit Testing

Materna said that communication to the public often conveys the importance of achieving a seal close to the face in order to provide adequate protection. However, one drawback of the N95 and other FFRs is that, unlike other elastomeric half mask respirators, it is difficult, or impossible, to conduct an effective user seal check to assess their fit, Materna said. If filtering facepiece models were put on the market in multiple sizes that had been proven to fit a variety of facial shapes and sizes well, then the public would be better served in situations where fit testing is not feasible, she added. She suggested that RPD manufacturers ought to be required to meet a minimum fit criteria before being allowed to market their products. In some cases, stockpiles of RPDs have contained poorly fitting devices which, upon being deployed during an emergency, failed fit testing among a high proportion of users. NIOSH has recognized the need to add a fit standard to the NIOSH certification process, Materna said. The issue of fit is urgent and must be addressed as soon as possible, she added. There may be a role for innovation and development of new products in addressing these

concerns. The flexibility and stickiness of facepiece materials in elastomeric half-mask respirators make them easier for most people to achieve a good seal and conduct user seal checks with these devices, she added. However, Materna said, existing reusable elastomeric respirators are often perceived as too industrial in appearance or too expensive to be acceptable. Newer, more lightweight devices that afford a good seal and easy user seal checking for a wide range of users would be beneficial, she added. As has been discussed, user acceptance testing would be critical to assess how useful such new devices would be for addressing the needs of various groups.

Use of Respirators by Those with Heart or Lung Conditions

Materna next considered the question of whether N95s or other FFRs can be safely worn by people with heart or lung conditions, including during physical exertion. She explained that during wildfire emergencies some jurisdictions broadcast messages warning against the use of respirators by those with pre-existing heart or lung conditions. However, during wildfire emergencies, those with heart or lung conditions may be the most in need of respiratory protection should they be outdoors in the presence of smoke or ash. This has also been a concern for outdoor workers in the vicinity of smoke and ash from wildland fires, who frequently have been advised to wear a respirator despite never having been medically cleared to use a respirator. A similar situation emerged during the COVID-19 pandemic, which raised questions about whether older people with heart or lung conditions—who are at higher risk—should wear N95s when in public. Materna said the most common guidance on these questions has been that individuals should speak with their physicians before using a respirator, but the majority of physicians know little about respirators and the risk they may pose to users with various kinds of pre-existing conditions. Thus, evidence-based guidance on the potential risks of respirator use would be helpful, she added. This may require that additional research be conducted, or it may require better translation of existing research on respirator use and potential risk. Additionally, she said, physician education about respiratory protection would make physicians better prepared to provide accurate information to patients about these questions.

Improving Public Communication About the Proper Use of Respirators

Materna emphasized the need for better communication to educate the public on how to use respirators properly, pointing out that depictions in the media often show respirators being used incorrectly. Proper respirator use needs to be better conveyed, she said, using clear visuals and messaging developed by experts in advertising and media campaigns. These messages

could be piloted and evaluated for effectiveness, then distributed via channels such as social media and short YouTube videos, Materna added. The persistent use of the term "mask" is another challenge that can be addressed through improved communication, she said. This term means different things to different people, and the use of the term causes confusion among both members of the public and public officials. This confusion has become widespread in the response to the COVID-19 pandemic, she added. Individuals frequently confuse devices worn as source control with respirators that are designed to protect the wearer from inhaling hazardous particles, Materna said. As a result, she added, it has been necessary to develop guidance to differentiate respirators, surgical masks, and cloth face coverings. The technical details related to respirator use have complicated this guidance, as these details are not widely understood. She emphasized that the general public must be made more comfortable using the term "respirator" when the device being discussed is, in fact, a respirator. The public understanding of respirators needs to be improved so that individuals understand what respirators are, how they work, their limitations, and where to obtain accurate information about respirators from experts. Research evaluating the knowledge and perceptions about respiratory protection among the public may help to create effective messaging on this subject. Materna said that because NIOSH is the most respected source of information about respirators, it has an important role to play in addressing the need for messaging even though its typical audience is groups of workers rather than the public.

DISCUSSION

Veenema listed several reoccurring needs discussed during the session's presentations, including public awareness, user acceptance, and human factors that affect decision making. She reviewed the comments made by Jim Johnson, a consultant for JSJ & Associates, in an earlier session about the need to (1) understand the hazard, (2) identify options for protection from that hazard and educate people about their options, (3) explore how people internalize the perception of risk, and (4) examine how that may affect people's willingness to use RPDs and to learn how to use these devices properly and consistently.

User-Centered Compliance Programs

Veenema highlighted Jones's comments regarding the need for social and behavioral research to better understand the context in which people will wear devices, noting an intersection between Jones's comment about making programs more acceptable and easier to implement in smaller

businesses and Gurses's comment about organizational ergonomics. Jones commented that user needs must be understood in order to create a user-centered design and that this pertains not only to the design of the technology, but also to the design of communications. Jones explained that communications may take the form of labeling, public-facing advertising, or communicating through the workplace as a way to reach more people. Additionally, Jones said, workplace education can influence how people engage with these devices in their personal lives. This underscores the need to understand why people behave as they do, whether approaching this via occupational health, a human factors approach, or an advertising/marketing perspective. Questions to explore include why some people are successful in using devices and some are not as well as why some people are engaging in actions that are not easy to understand. She asked how all of those perspectives can be brought together to tailor messaging, technologies, and programs.

Gurses said she agreed with Jones's point about exploring the needs of small organizations. In her research, both in this context and in patient safety, she has found that one organization will have various differences from another. Community health centers differ from academic centers, and the workflow and available resources vary from one organization to the next. Therefore, Gurses said, it is important to tailor implementation approaches to the organization. Gurses emphasized the role that an organization's culture plays in implementation, and she mentioned research that she conducted with workers providing environmental care services at Johns Hopkins via room cleaning. While these environmental service associates are not nontraditional workers, they are also not nurses or physicians, and Gurses said she found that they did not think of themselves as part of the team. The rooms were not being cleaned as well as the organization wanted, which Gurses attributed to the safety climate and to relations between environmental service associates and nurses. The feeling of being part of the team can affect workers' behavior, which in turn affects safety climate and follow-through on guidelines provided by the respiratory protection program, she said.

Respirator Public Awareness

Veenema referred to the comments made by Materna regarding challenges with educating the public on the selection and use of RPDs. Public education topics include knowing what a respirator is, understanding the use of the device known by the blanket-term "mask," and identifying the type of respirator or covering one should use in the workplace or for the COVID-19 response. Veenema said that misinformation and myths related to respiratory devices have been at play in 2020 and asked whether any

progress has been made with respect to bolstering the public understanding of what a respirator is. She also asked how key stakeholders can be educated to enable them to advise the public.

Materna said that progress has been made, citing the example of the response to wildfire smoke. Wildfire smoke is a hazard affecting many different parts of the country, and because people can see and smell smoke, it is a hazard that is perhaps easier for people to understand than COVID-19, she suggested. Through media coverage of wildfire events, people have become familiar with the use of the Air Quality Index to assess the degree of hazard they are facing People can smell the smoke, and they understand it is not healthy to have the smoke in their lungs; therefore, Materna said, at least a certain proportion of the public is motivated to protect themselves. Another sign of progress is that more people have respirators on hand as part of emergency preparedness. Materna said that where she lives, many people had filtering facepiece respirators in their emergency kits, and they began using them on visits to the grocery store before face coverings were rolled out as part of the COVID-19 response. She said that older people who understood they were at higher risk for COVID-19 seemed especially aware of the need to protect themselves. Materna concluded that there is slow and steady progress and that much more remains to be done.

Physician Respirator Knowledge and Medical Clearance

Veenema relayed a question from a participant regarding the standards that physicians are using to clear workers in respiratory protection programs if those physicians know little about respirators. Furthermore, she asked whether these physicians are instructed on follow-up testing that would assure the safe use of a respirator. Materna, emphasizing that she is not a medical doctor and is not speaking for all doctors, said she had noted a difference between primary care providers and the occupational medicine physicians and nurse practitioners who typically perform respirator medical clearances. The latter group, Materna said, seems to be better informed on what to look for, as they typically know what to do when a person indicates on an initial screening questionnaire having asthma or other indicators of breathing issues, she noted. For instance, those practitioners may perform pulmonary function testing to assess the true degree of impairment. Materna said that primary care providers are typically less informed and this can lead to problems when members of the public are told not use a respirator until cleared by one's doctor and then the doctors are unsure of how to proceed. Materna said that this lack of knowledge regarding medical clearance leads some public officials who are physicians to recommend that people use filtering facepiece respirators that have low breathing resistance

and advise users that, if they experience problems, they should immediately take the respirator off, leave the area, and pursue other options. She added that some people have expressed concerns that they will be held liable in the event of respirator-related issues.

Human Factors Engineering

Veenema repeated the suggestion made by Gurses that the concepts of work imagined versus work done could be considered in addition to robust interdisciplinary science on RPDs. Using the example of workers in agriculture and landscaping who are exposed to hazards such as air pollution and wildfire smoke, Veenema asked how human factors engineering can enhance successful respiratory protective device performance and programs for nontraditional workers. Gurses replied that there are multiple ways to improve work-as-done versus work-as-imagined. Some of the protocols being communicated via guidelines, protocols, or training materials may be perceived in the actual work setting as being impossible—or at least very difficult—to implement. There is a gap, Gurses said, between the protocol and the implementation and understanding these gaps requires not only perfecting the tool or technology, but also understanding its use in actual settings, whether it is a wildfire, agricultural, or meatpacking setting. The challenges to that particular environment and the strategies that people have developed can be identified and learned from, she added.

Human factors engineers have expertise in using in-depth ethnography and qualitative and quantitative studies to identify these gaps, Gurses said. Once gaps are identified, all stakeholders are brought together using a participatory ergonomics approach to develop solutions. Gurses added that a systemic engineering approach could benefit the development of training and education protocols. She noted that if a technology is easy to use, it will not require instructions or training. Labeling, instructions, and training are developed to supplement device design limitations, and that training should be developed based on risk points and evaluated via systemic analysis of why people are perceiving communications differently than intended, Gurses said. At that point, she added, training can be altered to address sources of misunderstanding.

Oxygen Deficiency Myths

Veenema asked a participant's question about how to effectively address people's unfounded fear about oxygen deficiencies being caused by masks and barrier facial coverings. Materna said that a trusted spokesperson is needed to address this issue by way of mass media. Misconceptions and rumors are used as excuses not to pursue these control measures, and mis-

information needs to be addressed head on through the clear communication of the facts, she said.

Workshop planning committee member John Balmes of the University of California, San Francisco, said that a national strategy for respiratory protection is necessary, especially in the context of the COVID-19 pandemic. Recounting information presented by Stephanie Holm of the Western States Pediatric Environmental Health Specialty Unit, he said that the physiologic impacts of wearing almost any type of respiratory protection are not severe. Balmes added that improperly designed cloth masks may have higher air flow resistance and might not perform as well as N95s or surgical masks, but there is very little evidence to indicate that wearing these masks results in negative physiological consequences. Balmes emphasized the need to develop clear and simple messaging to counter misinformation and added that some county public health officers also have knowledge gaps. He offered the example of public health officers in California who have emphasized the harm that wearing N95s might cause people with pre-existing asthma, but Balmes said these are the very people who should be wearing N95s when going out during a wildfire air quality episode. Jones also noted that misperceptions extend beyond the general public. She has worked with manufacturers in Utah who have questions or concerns about the use of respirators in the context of COVID-19, despite being people who wear respirators with some regularity. She said that this represents an underlying gap in knowledge about how these devices work. COVID-19 has made this gap more prominent, but Jones contended that it was already there before the pandemic.

NIOSH Research and Funding

Jones said that NIOSH is a trusted source that could potentially expand its role in public communication and research. Balmes added that to do so, NIOSH would need more funding. Gurses pointed out that more funding also needs to be allocated to improve the collective understanding of the science of implementing the use of RPDs efficiently, consistently, and safely because this is an ongoing research gap. Gurses suggested NIOSH could collaborate on this research with the Agency for Healthcare Research and Quality because health care worker safety and patient safety are interrelated.

Final Reflections on the Session

Veenema offered her reflections on the presentations and discussions of Session 5: Research and Communication Gaps and Opportunities, noting that the research questions at hand are numerous and diverse, ranging from issues about the performance of particular RPDs to the exploration

of human factors on individual adoption and proper use of RPDs. Overall, the session speakers recognize that a systems perspective will be key for investigating why certain RPDs are used or not used and what can be done to increase their proper use and understanding. Additionally, Veenema recognized the time constraints at play, such as the urgent need to address the concerns related to the use of cloth face coverings by the public as soon as possible. Given the need to answer many of the questions raised by the workshop's speakers within the context of these time constraints, strategic prioritization and advocacy for targeted research will be the best path forward for optimizing public health impact, she added.

FINAL REFLECTIONS AND DISCUSSION

Training

Reflecting on comments made by Gurses, Johnson suggested that if an RPD requires extensive training (e.g., multiple workdays) it is a sign of a defective approach to respiratory protection. One design aim in respiratory safety could be to make equipment for which the proper use is self-evident. Gurses replied that this would be more aptly considered a design limitation than a defect; it is impossible to design a perfect tool or technology, and there will be some limitation to every type of product. Training needs to be developed systematically to address those limitations so that training, instructions, programs, and design make up an overall system with the best possible outcome, Gurses said. Shipp remarked that respiratory protection is so complex in occupational and industrial settings that training on RPDs will always be required because products will have to be designed specifically to protect workers against inhalation hazards that cannot be engineered out. Workers in particularly hazardous settings, Shipp added, will need more extensive training to ensure they are afforded enough protection. Gurses clarified that training should not be used as a means to overcome bad design. Training itself should be developed in accordance with the principles of good training, such as commander's intent (e.g., telling people why they are doing the training). Melissa McDiarmid of the University of Maryland School of Medicine commented that the shortcomings of RPDs are often linked to the shortcomings—or even total lack—of respiratory protection programs in which these RPDs are being used. For instance, she suggested that the defects in the use of respiratory protective devices and face coverings in response to the COVID-19 pandemic are linked to the historical failure of governments to invest in public health infrastructure and the inadequacy of national stockpiles of needed equipment for a pandemic response. Balmes said that there is clearly a role for well-designed training in occupational settings. For public use, this role must be fulfilled

through different types of messaging, as respiratory protection trainings for the general public is unlikely to be practical, Balmes said.

COVID-19 Pandemic and Future Opportunities

Balmes said that NIOSH's increasing visibility due to the COVID-19 pandemic could be used to promote a heightened awareness of occupational and respiratory health and safety in the public health discourse. In particular, NIOSH's special competence and expertise for occupational safety and health issues can be brought to bear in this discourse, Balmes said. Under normal (non-pandemic) circumstances, only a limited population needs or has any interest in RPDs. However, the COVID-19 pandemic has provided an opportunity to take advantage of public interest to increase investment in RPDs, Balmes said. The role of the National Personal Protective Technology Laboratory (NPPTL) could be expanded to act as the single source of messaging and training about RPDs, both for occupational settings and the public, Balmes added. Nicas commented that creating a new approval process for RPDs intended only for public use would not be feasible. He proposed using the Defense Production Act to force companies in the United States to make N95 FFRs, rather than creating a new structure for approving public use respirators.

Messaging and Awareness

Holm said that educating both the public and medical professionals about respiratory health is a key concern. While the amount of training on RPDs may vary among medical professionals, most general providers know little more about respiratory protection than any member of the general public. The COVID-19 pandemic has presented an opportunity to raise awareness about respiratory protection. Veenema suggested finding ways to clarify and harmonize risk messaging about RPDs, which would require additional funding for agencies involved in this area, such as NIOSH. Cohen said that there has been a lack of clarity in messaging to the public about the intended function and appropriate use of respirators versus face masks in the context of the COVID-19 pandemic. McDiarmid also highlighted the need for careful messaging and clear communication to different populations about the use of true respirators versus masks.

Developing Unifying Standards, Messaging, and Strategies

Emiel DenHartog, an associate professor and the associate director of the Textile Protection and Comfort Center at North Carolina State University, highlighted the importance of supporting individuals and small

companies who are designing and producing masks during the COVID-19 pandemic (e.g., by providing them with guidelines or creating an ASTM standard for general-purpose face masks). He suggested drawing a distinction between PPE for occupational safety and general-purpose masks for the public, with the latter having looser requirements but accurate labeling to clearly indicate its intended usage (e.g., wildfire, pesticide exposure). Jeff Stull, the president of International Personnel Protection, Inc., added that standards can apply not only to products but also to use, care, and creating awareness. Making standards and documentation more accessible to end users and leveraging more nimble organizations in concert with direction from NIOSH and NPPTL would help to make these standards more effective, Stull added.

Maryann D'Alessandro, the director of NPPTL, explained that NIOSH has been working to develop a comprehensive national strategy for respiratory protection that includes CA and research. While NIOSH has expertise in CA and certain areas of research, the people there are aware of their need for assistance. Thus, D'Alessandro said, the path forward likely includes the development of centers of excellence for personal protection technologies and equipment across the United States. She added that the expertise of these centers can be leveraged in areas such as human factors, behavioral issues, and other areas discussed in this workshop. Partnerships across federal agencies, universities, and manufacturers will also be invaluable, D'Alessandro said, for identifying and executing strategies to enhance domestic production of RPDs, despite a lack of funding for such production. D'Alessandro closed the meeting on a note of optimism, remarking that NIOSH and the occupational health community more broadly seem committed to expanding their mission to protect respiratory health in the workplace and beyond.

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Appendix A

Statement of Task

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will plan and conduct a 1- or 2-day public workshop to engage key stakeholders and relevant technical contributors in a discussion on approaches to the respirator approval process in the current landscape for both occupational and non-occupational use of respirators. Additionally, the workshop will consider gaps in respiratory protection for outdoor workers and the general public. Research and communications avenues to address those gaps will be discussed.

This workshop will explore the current state of practices related to conformity assessment and National Institute for Occupational Safety and Health (NIOSH) approval of respiratory protective devices (RPDs) in accordance with 42 Code of Federal Regulations, Part 84 (42 CFR 84). The workshop will discuss the NIOSH RPD systems-based approach for occupational applications and the current approaches in the United States and internationally for non-occupational use. The workshop would provide an opportunity to discuss the technical issues relevant to both approaches to conformity assessment with a focus on the associated workplace and public health and safety benefits and risks and related important and impactful topics. Situation-specific needs for respirators (e.g., forest fires, urban pollution) to protect different target populations (e.g., outdoor workers, international workers, and the general public) will also be explored, as well coordinated guidance to those communities regarding respirator use.

This workshop shall provide the opportunity to exchange knowledge and ideas between professionals, policy makers, manufacturers, and users involved in the field of personal protective equipment. The planning commit-

tee will plan and organize the workshop, select and invite workshop speakers and discussants, and moderate the discussions. The workshop topics could include

- Overview of the current NIOSH Respirator Approval Program (RAP) including factors influencing respirator approval input, output, and timelines;
- U.S. and international government and/or private industry conformity assessment models for respirator use by the public;
- Lessons learned from 100 years of respiratory protection in the United States (e.g., respiratory protection programs in occupational settings);
- Situation-specific needs (e.g., forest fires, urban pollution) to protect different target populations (e.g., firefighters, outdoor workers, diplomats, and the general public);
- Gaps in respiratory protection for outdoor workers and the general public along with potential research and communications avenues to address those gaps; and
- Current respiratory protection guidance and recommendations to outdoor workers and the general public dealing with natural disasters and accidents, as well as coordination of that guidance.

A summary, Proceedings of a Workshop, will be published to capture the presentations and discussions at the workshop. This summary will be prepared by a designated rapporteur in accordance with National Academies institutional guidelines.

Appendix B

Workshop Agenda

Current Issues in the Assessment of Respiratory Protective Devices: Nontraditional Workers and Public Use

August 4–5, 2020
National Academies Webinar

DAY 1
August 4, 2020, 10:30 a.m.–2:30 p.m.

10:30 a.m. Opening Remarks and Charge to Workshop Speakers and Participants

Melissa McDiarmid, M.D., M.P.H., DABT
University of Maryland School of Medicine
Planning Committee Chair

Maryann D'Alessandro, Ph.D., M.S.
Director
National Personal Protective Technology Laboratory
National Institute for Occupational Safety and Health (NIOSH)

Session 1 Objectives

- Describe the evolution in the assessment and approval of respiratory protective devices over the past century to respond to the needs of occupational users.
- Discuss how these lessons can inform planning for future needs, such as the approval and use of respiratory protective devices by the public and by occupations that do not currently use respirators as part of a formal respiratory protection program.

10:45 a.m. **SESSION 1: LESSONS LEARNED FROM THE LAST 100 YEARS OF RESPIRATORY PROTECTION**

Moderator: Melissa McDiarmid, M.D., M.P.H., DABT
Planning Committee Chair

Richard Metzler, MSIE
Senior Scientist, *Retired*
National Personal Protective Technology Laboratory, NIOSH

11:00 a.m. Discussion with Planning Committee and Speaker (15 minutes)

Session 2 Objectives

- Identify nontraditional respirator user populations[1] (i.e. workers who perform duties outside of a formal respiratory protection program or the public) and examine the respiratory risks for these groups.
- Describe the situation-specific needs of these populations, as well as current guidance regarding their use of respiratory protective devices and other respiratory protection strategies.
- Explore how these risks compare to those encountered in professions that currently use respirators in the context of formal respiratory protection programs.
- Examine how these situation-specific needs and respiratory risks align with existing recommendations, guidance, and standards.

[1] Target populations include outdoor workers in highly polluted environments (wildland fire fighters and agricultural workers); non–health care workers exposed to respiratory risks (workers in meatpacking plants and grocery stores); government employees and families deployed to high air pollution locales; and the general public.

11:15 a.m. SESSION 2A: RESPIRATORY RISKS AND USER REQUIREMENTS FOR NONTRADITIONAL WORKERS

Moderator: Robert Harrison, M.D., M.P.H.
University of California, San Francisco
Planning Committee Member

Bill Kojola, M.S.
Industrial Hygienist, *Retired*
American Federation of Labor and Congress of Industrial Organizations

Joseph Domitrovich, Ph.D.
Exercise Physiologist
U.S. Forest Service

Kevin Riley, Ph.D., M.P.H.
Director of Research and Evaluation
Labor Occupational Safety & Health Program
University of California, Los Angeles

11:45 a.m. Panel Discussion (30 Minutes)

12:15 p.m. Lunch Break (30 Minutes)

12:45 p.m. SESSION 2B: RESPIRATORY RISKS AND USER REQUIREMENTS FOR THE PUBLIC

Moderator: John Balmes, M.D.
University of California, San Francisco
Planning Committee Member

Claire Huson, CIH
Industrial Hygienist
Department of State

Stephanie Holm, M.D., M.P.H.
Co-Director
Western States Pediatric Environmental Health Specialty Unit

Mark Nicas, Ph.D., M.P.H., CIH
Emeritus Adjunct Professor
University of California, Berkeley

1:15 p.m. Panel Discussion (30 Minutes)

1:45 p.m. Break (15 Minutes)

Session 3 Objective

- Revisit the major themes and ideas of the day.

2:00 p.m. Rapporteurs:
John Balmes, M.D.
Planning Committee Member

Robert Harrison, M.D., M.P.H.
Planning Committee Member

2:15 p.m. Closing Remarks from Workshop Chair

2:30 p.m. Adjourn

DAY 2
August 5, 2020, 10:30 a.m.–3:30 p.m.

10:30 a.m. Highlights from Day 1

Melissa McDiarmid, M.D., M.P.H., DABT
University of Maryland School of Medicine
Planning Committee Chair

Session 4 Objectives

- Review the current NIOSH Respiratory Approval Program and conformity assessment process for the occupational use of respirators.
- Explore how existing conformity assessment processes and standards align with the health and safety requirements of nontraditional user groups and how these processes function to deliver technologies to the end user while balancing speed of delivery with safety.
- Discuss what opportunities exist to develop or support conformity assessment processes for respiratory protective devices and control strategies, such as cloth face coverings, that are responsive to the specific requirements of these user groups.
- Discuss conformity assessment models used in other countries, by third-party organizations, and in private industry for the occupational and non-occupational use of respirators and barrier masks.

10:45 a.m. SESSION 4A: ASSESSMENT PATHWAYS FOR RESPIRATORY PROTECTIVE DEVICES FOR NONTRADITIONAL WORKERS

Moderator: Howard Cohen, Ph.D., M.P.H.
Yale School of Medicine
Planning Committee Member

Maryann D'Alessandro, Ph.D., M.S.
Director
National Personal Protective Technology Laboratory
NIOSH

Jeffrey Peterson
Branch Chief
National Personal Protective Technology Laboratory
NIOSH

Jeff Stull, M.S.
President
International Personnel Protection, Inc.

11:15 a.m. Discussion with Panelists and Discussant (30 minutes)

Discussant
Andrew Levinson, M.P.H.
Deputy Director
Directorate of Standards and Guidance
Occupational Safety and Health Administration

11:45 a.m. Lunch Break (30 minutes)

12:15 p.m. SESSION 4B: ASSESSMENT PATHWAYS FOR RESPIRATORY PROTECTIVE DEVICES AND OTHER OPTIONS FOR THE PUBLIC

Moderator: Daniel Shipp
International Safety Equipment Association, *Retired*
Planning Committee Member

Jim Johnson, Ph.D., CIH, QEP
Consultant
JSJ & Associates

Emiel DenHartog, Ph.D., M.Sc.
Associate Professor
Associate Director Textile Protection and Comfort Center
North Carolina State University

Jonathan Szalajda, M.S.I.E., M.Eng.
Deputy Director
National Personal Protective Technology Laboratory, NIOSH

12:45 p.m. Panel Discussion (30 Minutes)

1:15 p.m. Break (15 Minutes)

Session 5 Objectives

- Identify research gaps related to the assessment of respiratory risks and needs of different user groups.
- Explore research priorities related to human factors engineering and psychology around the use of respiratory protective devices outside of a formal respiratory protection program.
- Discuss challenges related to user acceptance and approaches for developing and communicating guidance on the effective use of respiratory protective devices and barrier masks to nontraditional workers and the public.

1:30 p.m. SESSION 5: RESEARCH AND COMMUNICATION GAPS AND OPPORTUNITIES

Moderator: Tener Veenema, Ph.D., M.P.H., M.S., RN
Johns Hopkins School of Nursing
Planning Committee Member

Rachael Jones, Ph.D., M.P.H.
Associate Professor
The University of Utah

Ayse Gurses, Ph.D., M.S., M.P.H.
Professor
Johns Hopkins School of Medicine

Barbara Materna, Ph.D., CIH
Chief, Occupational Health Branch
California Department of Public Health

2:00 p.m. Panel Discussion (30 Minutes)

2:30 p.m. Break (15 Minutes)

Session 6 Objectives

- Revisit the major themes and highlights of the workshop.
- Discuss what additional research is required to deliver the appropriate respiratory protection to these groups.
- Discuss future directions for conformity assessment and approval of respiratory protective devices for nontraditional workers and public use.

2:45 p.m. SESSION 6: REFLECTIONS FROM THE WORKSHOP

Moderator: Melissa McDiarmid, M.D., M.P.H., DABT
Planning Committee Chair

Howard Cohen, Ph.D., M.P.H.
Planning Committee Member

Daniel Shipp
Planning Committee Member

Tener Veenema, Ph.D., M.P.H., M.S., RN
Planning Committee Member

John Balmes, M.D.
Planning Committee Member

Robert Harrison, M.D., M.P.H.
Planning Committee Member

3:15 p.m. Closing Remarks from Workshop Chair

3:30 p.m. Adjourn

Appendix C

Biographical Sketches of Workshop Speakers, Moderators, and Staff

WORKSHOP SPEAKERS

Maryann D'Alessandro, Ph.D., M.S. (*Chair*), has served as the director of the National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) since March 2012. She also served as the associate director for science for NPPTL from 2003 to 2012. Dr. D'Alessandro provides leadership to the NIOSH Personal Protective Technology (PPT) Core and Specialty Program and the Public Safety Program, where she serves as the manager leading the effort to align PPT initiatives with user needs across all workplace industry sectors. Within the PPT program, Dr. D'Alessandro has served as the catalyst for aligning surveillance, research, standards, certification, outreach, and intervention activities to improve workplace safety and health. Prior to joining NIOSH in 2003, she had a short academic career at the University of Pennsylvania's Department of Bioengineering and served in various U.S. Army research and development organizations for 15 years. Dr. D'Alessandro holds electrical engineering degrees from the Florida Institute of Technology (B.S.), Fairleigh Dickinson University (M.S.), and the Georgia Institute of Technology (Ph.D.).

John R. Balmes, M.D., received his M.D. from Mount Sinai School of Medicine in 1976. After internal medicine training at Mount Sinai and pulmonary subspecialty, occupational medicine, and research training at Yale, he joined the faculty of the University of Southern California in 1982. He joined the faculty at the University of California, San Francisco

(UCSF), in 1986 and is currently a professor in the divisions of occupational and environmental medicine and pulmonary and critical care medicine at Zuckerberg San Francisco General Hospital and Trauma Center. His major academic activities include several collaborative epidemiological research projects, various advisory and editorial committees, director of the University of California (UC) Berkeley–UCSF Joint Medical Program, and director of the Northern California Center for Occupational and Environmental Health (a consortium of programs at UC Berkeley, UC Davis, and UCSF). Since 2008 he has been the physician member of the California Air Resources Board.

Howard J. Cohen, Ph.D., M.P.H., is a professor of occupational safety and health management at the University of New Haven and 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. Prior to joining the University of New Haven faculty in 1994, Dr. Cohen spent 16 years as the corporate manager of industrial hygiene at Olin Corporation, a Fortune 200 company with nearly 20,000 employees. Among the most recognized industrial hygienists in the United States, Dr. Cohen was the editor-in-chief of the *American Industrial Hygiene Association Journal* from 1991 to 2003 and currently serves as a member of the editorial board of *Journal of Occupational and Environmental Hygiene*. He is the current chair of the ANSI Z88.2 Committee on Respiratory Protection and the chair of the American Industrial Hygiene Association Committee on Respiratory Protection. A member of the Industrial Hygiene Roundtable, he has served as the treasurer of the American Board of Industrial Hygiene. Dr. Cohen has received numerous professional awards, including the 1989 Warren A. Cook Award for outstanding scholarship from the University of Michigan and the 1990, 1992, and 2002 John M. White Award for excellence in respiratory protection from the American Industrial Hygiene Association. He shared the 2003 Adolf G. Kammer Award for Authorship from the American College of Occupational and Environmental Medicine and the 2004 President's Award from the American Industrial Hygiene Association. His published writings address the assessment of workplace respiratory hazards, the characterization of specific airborne particulates, and the development and implementation of respiratory protection programs.

Emiel DenHartog, Ph.D., M.Sc., has a master's degree in experimental physics from the University of Utrecht in the Netherlands and a Ph.D. in medical

physics from the Erasmus University in Rotterdam in the Netherlands. After his Ph.D. he went to work for more than 15 years in defense research on the evaluation and innovation of military protective clothing systems where he studied modeling human heat exchange in extreme environments. Over time he moved towards the impact of protective clothing on the human body (e.g., chemical, biological, ballistics, camouflage, flame retardance) and became program manager of the protective clothing research for the Ministry of Defense in the Netherlands, also actively collaborating within the European Union on research projects as well as contributing to NATO activities around protective clothing. In 2013 he moved to North Carolina State University; since then he has been the associate director of the Textile Protection and Comfort Center and an associate professor in the textile engineering, chemistry, and science department in the Wilson College of Textiles at North Carolina State University. In his research he studies the interaction between clothing and the human body to optimize protection, performance, and comfort. Recently his work has developed on the local interaction of fabrics and materials with the skin and the effects of the local microclimate on skin health. The focus of the work is on using and developing test and evaluation methods for functional textiles to demonstrate and quantify the protection, performance, health, and comfort of clothing and textiles. He actively collaborates with a wide range of scientists providing measurement and evaluation support on anything related to improvements on human health, performance and comfort. In 2019 he received the North Carolina State award as university faculty scholar for his contributions to research and education in this field. He teaches classes on clothing biophysics and textile testing and publishes on comfort and protection evaluations of textiles and clothing. Since 2015 he has been a member of the National Academy of Medicine Standing Committee on Personal Protective Equipment for Workplace Safety and Health, advising the National Personal Protective Technology Laboratory on its testing and research agenda. Since 2019 he has been the director of graduate programs at the Wilson College of Textiles and the associate head of the Department of Textiles Engineering, Chemistry, and Science.

Joseph Domitrovich, Ph.D., is a wildland firefighter and an exercise physiologist for the U.S. Forest Service National Technology and Development Program based in Missoula, Montana. He started with the forest service 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 also from the University of Montana and his bachelor's degree from Cal Poly San Luis Obispo in California. Dr. Domitrovich's work at the National Technology and Development Program includes hydration, nutrition, health effects of smoke, heat-related illnesses,

stress, and fitness. He is an advisor to the National Wildfire Coordinating Group Risk Management Committee and the Forest Service Fire Risk Management Council. Dr. Domitrovich is the forest service representative to the National Fire Protection Agency (NFPA) committee on respiratory protection and the task group chair for NFPA 1984 (Wildland and Urban Interface Respiratory Protection). He teaches wildland fire training courses at the local and national level.

Ayse 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. She is an industrial and systems engineer (with subspecialization 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, she 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. She serves as the scientific editor of *Applied Ergonomics*, a top-level journal in the field of human factors engineering. Her work has been recognized with numerous awards. Most recently she was awarded with 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., has been with the California Department of Public Health and on the faculty at the University of California, San Francisco (UCSF), in the Division of Occupational and Environmental Medicine since 1984. He established the UCSF Occupational Health Services where he has diagnosed and treated thousands of work and environmental injuries and illnesses. He has designed and implemented numerous medical monitoring programs for workplace exposures, and he has consulted widely with employers, health care professionals, and labor organiza-

tions on the prevention of work-related injuries and illnesses. Dr. Harrison has led many work and environmental investigations of disease outbreaks. He has served as a technical and scientific consultant to the Occupational Safety and Health Administration, the Centers for Disease Control and Prevention, and the National Institute for Occupational Safety and Health (NIOSH), and he was a member of the California Occupational Safety and Health Standards Board. He is currently the director of the NIOSH-funded Occupational Health Internship Program and the associate director of the UCSF occupational and environmental medicine residency program. His research interests include the collection and analyses of California and national data on the incidence of work-related injuries and illnesses. Dr. Harrison has authored or co-authored more than 50 peer-reviewed journal articles and more than 40 book chapters/contributed articles/letters to the editor. He is the co-editor of the most recent edition of the textbook *Occupational and Environmental Medicine* (McGraw-Hill Education, 2014).

Stephanie Holm, M.D., M.P.H., is the co-director of the Western States Pediatric Environmental Health Specialty Unit (PEHSU). 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 the Children's Hospital and Research Center Oakland before leaving to further pursue her interests in pediatric research and pediatric environmental medicine. She was the principal investigator on the AQUA 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 PEHSU, she reviewed literature relevant to disinfectant use and toxicities in early care and education environments. Dr. Holm completed an M.P.H. in epidemiology at the University of California, Berkeley, in 2017 and is currently pursuing a Ph.D. in epidemiology while continuing her research activities.

Claire Huson, CIH, is a certified industrial hygienist with 35 years of experience in occupational health and safety in a variety of industries and settings. She is the director of the Safety, Health and Environmental Management (SHEM) Office's Policy and Special Studies Division, which is located in the Bureau of Overseas Buildings Operations within the Department of State. SHEM's focus is the safety of employees at U.S. embassies and consulates around the world and the American families who accompany them. Ms. Huson joined SHEM more than 20 years ago, and in that

time severe air pollution at overseas locations has become widespread and the source of great health concerns particularly for the families. These concerns may even affect the ability to staff postings and perform important overseas work. In 2013 she teamed with medical staff responding on site to an extended period of extreme air pollution in Beijing, China. Shortly thereafter, they formed the department's air pollution working group to promote a multifaceted approach to this complex problem. SHEM continues to develop guidance on air pollution exposure reduction measures and evaluate their effectiveness.

Jim Johnson, Ph.D., CIH, QEP, is a certified industrial hygienist and qualified environmental professional who has operated JSJ & Associates on a part-time basis since 1978. JSJ & Associates is a small consulting firm specializing in occupational safety and health and hazardous material issues. Many of the firm's projects since 1978 have involved a variety of personal protective equipment work activities, with tasks on firefighter respiratory protective equipment routinely addressed. Dr. Johnson worked at the Lawrence Livermore National Laboratory (LLNL) from1972 through 2006. His position from November 2000 to 2006 was 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 personal protective equipment as a respiratory program administrator, a research scientist, and a division and section manager. He is an American Industrial Hygiene Association fellow, a past member of the National Fire Protection Association (NFPA) Technical Correlating Committee on Fire and Emergency Services Protective Clothing and Equipment, a past member of the NFPA Respiratory Protection Equipment Committee, a past chair of the International Society for Respiratory Protection (ISRP), a past ISRP Americas section chair, and a past editor of the *International Society for Respiratory Protection Journal*. Currently, Dr. Johnson is the subcommittee chair of the ASTM International subcommittee F23.65 on respiratory protection. The recent relocation of the ANSI Z88 Secretariat from the American Society of Safety Professionals to ASTM International has expanded the visibility and participation in respiratory standards development. New work items initiated to support the coronavirus disease 2019 pandemic will address facial covering performance, emergency responder elastomeric respirator performance, and elastomeric respirator decontamination test methods. He also continues to provide his expertise on respiratory program improvements, Hanford Tank Farm, use of toxic materials, and beryllium as well as providing expert witness consultation on respiratory protection. He has co-authored a number of respirator articles as well as authored several chapters on respiratory protection in the past several years. Dr. Johnson continues to be a strong

advocate for the inclusion of elastomeric half-facepiece respirators in the Strategic National Stockpile as well as routine use in health care.

Rachael M. Jones, Ph.D., M.P.H., is interested in research questions about how people—workers and communities—come into contact with stressors in their environment and how those stressors can be mitigated or eliminated if they pose a threat to health. A lot of her work has used mathematical models to describe these contacts or exposures, but in recent years she has expanded her research methodologies to include (1) statistical methods to characterize exposures and their determinants, such as for epidemiologic studies; (2) qualitative methods; (3) simulation experiments; and (4) field-based studies. One of the stressors of great interest to her is infectious agents, such as encountered by health care workers providing care to patients with infectious diseases. She has sought to explore the processes by which infectious diseases are transmitted from person to person, the risk of infection (including the burden of occupationally acquired infections among health care workers), and strategies for managing and preventing disease transmission. In addition, she is increasingly interested in structural problems that create and sustain unhealthy work, particularly among low-wage workers. She is always interested in building research collaborations to explore questions and areas that are new to her.

Bill Kojola, M.S., is formerly the industrial hygienist for the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) Department of Occupational Health and Safety. His experience in health and safety spans more than 30 years. During that time, Mr. Kojola has been the director of the Occupational Safety and Health Division of the Laborers Health and Safety Fund of North America, an occupational safety and health specialist for the International Brotherhood of Boilermakers, and director of safety and health for the United Cement, Lime, Gypsum and Allied Workers International Union. Prior to this he was a health research scientist at the University of Illinois School of Public Health, studying the human health effects of air and water pollutants. With the AFL-CIO, Mr. Kojola was responsible for developing strategies for securing new safety and health protections through federal and state regulations, coordinated with affiliates on leading a unified labor response to proposed Occupational Safety and Health Administration regulations, and represented the AFL-CIO before government regulatory agencies, on federal advisory committees, and in consensus standard setting efforts. He also worked with affiliate unions to address emerging workplace hazards and issues. Mr. Kojola holds a B.S. in biology and an M.S. in genetics from the University of Minnesota, and he studied toxicology and industrial hygiene at the University of Illinois School of Public Health.

Andrew Levinson, M.P.H., is the deputy director for the Directorate of Standards and Guidance at the Occupational Safety and Health Administration (OSHA). Prior to that he was the director of OSHA's Office of Biological Hazards. Mr. Levinson works on safety and health management systems, emergency response and preparedness, infectious disease, and protective clothing and equipment issues. Prior to joining OSHA he worked on emergency responder health and safety matters at the International Association of Fire Fighters and on safety and environmental compliance at Anheuser-Busch's brewery in Cartersville, Georgia. Mr. Levinson received his master of public health from the Emory University's Rollins School of Public Health and is a graduate of the University of Michigan, Ann Arbor.

Barbara Materna, Ph.D., CIH, is the chief of the Occupational Health Branch in the California Department of Public Health, a position she has held for the past 18 years. Dr. Materna is a certified industrial hygienist whose career in occupational health has primarily been in state and local government public health programs. Some of the worker health topics she has studied include perchloroethylene in dry cleaning, exposures to wildland firefighters, occupational lead poisoning, lung disease in flavor manufacturing workers, aerosol transmissible diseases, respiratory protection for health care workers, and Valley fever. She has a Ph.D. in environmental health sciences from the University of California, Berkeley.

Melissa A. McDiarmid, M.D., M.P.H., DABT, is a professor of medicine and the director of the University of Maryland School of Medicine's Occupational Health Program. She received her B.A. in 1975 from the University of Maryland, Baltimore County, in biological sciences, her M.D. from the University of Maryland, Baltimore, in 1979, and her M.P.H. from the Johns Hopkins Bloomberg School of Public Health in 1986, where she also completed fellowship training in occupational medicine. She is board-certified in internal medicine, occupational medicine, and toxicology. She maintains professional society affiliations as a fellow of the Collegium Ramazzini, the American College of Physicians, the American College of Occupational and Environmental Medicine, and the American College of Preventive Medicine and as a member of the American Public Health Association and the Society of Occupational and Environmental Health. Dr. McDiarmid was the director of the Office of Occupational Medicine for the Occupational Safety and Health Administration (OSHA) in Washington, DC, a position she held from 1991 until 1996. A principal career focus for Dr. McDiarmid has been that of environmental reproductive and developmental hazards. While at OSHA she guided the reproductive health effects aspects of several standards including those for cadmium, butadiene, and methylene chloride. She has co-chaired the National Institute for Occupational Safety and

Health National Occupational Research Agenda work group on reproductive health. Dr. McDiarmid has authored numerous journal articles and book chapters on occupational and environmental medicine topics related to health care workers, medical surveillance and management, reproductive hazards, and occupational cancers.

Richard Metzler, M.S.I.E., has more than 44 years of experience in federal safety and health product approval programs. He is a respiratory protection consultant and the past director of the National Personal Protective Technology Laboratory at the National Institute for Occupational Safety and Health (NIOSH). His experience includes managing laboratories and establishing federal regulations and national and international respiratory protective equipment standards. Mr. Metzler holds a bachelor of science degree in systems engineering from Wright State University in Dayton, Ohio, and a master's degree in industrial engineering from the University of Pittsburgh. He is an honorary member, past director, and past president of the International Society for Respiratory Protection; is a member of the American National Standards Institute (ANSI)/ASTM International F23.65 Practices for Respiratory Protection Committee; served as the chairman of ANSI/American Society of Safety Engineers/Z88.2 Practices for Respiratory Protection Subcommittee; is a member and past chairman of the American Industrial Hygiene Respiratory Protection Committee; a past administrator of US ANSI ISO, TC 94/SC 15 TAG - Respiratory Protective Devices; and a past chairman of the air-purifying respirator standards project group. Mr. Metzler led regulatory reform efforts at NIOSH promulgating 42 CFR 84 respirator approval regulations and standards for chemical, biological, radiological, and nuclear respiratory protective devices.

Mark Nicas, Ph.D., M.P.H., CIH, is an emeritus adjunct professor at the School of Public Health at the University of California, Berkeley. He has a Ph.D. and an M.P.H. in environmental health sciences from the University of California, Berkeley, an M.S. in genetics from the University of Wisconsin, and a B.S. in biology and chemistry from the City College of New York. He has been a professional industrial hygienist for more than 40 years and is a certified industrial hygienist. His academic research has been in three areas: (1) exposure and risk assessment for pathogens including *M. tuberculosis*, *C. immitis*, and the influenza virus, (2) the mathematical modeling of exposure intensity to airborne chemical toxicants, and (3) variability in the efficacy of respiratory protection.

Jeff Peterson has more than 29 years of technical expertise in the area of respiratory protection. He began his career with the National Institute of Occupational Safety and Health (NIOSH) in 1991 where he per-

formed testing and research in support of standards development efforts for Title 42, Code of Federal Regulation, Part 84 (42 CFR 84). After the implementation of 42 CFR 84 in 1995, Mr. Peterson remained with the respirator certification program as a general engineer where he used his knowledge and skills to address and resolve technical issues and customer concerns related to approving and testing respiratory protection equipment. He became the team lead for respirator certification in 2006, coordinating technical and policy reviews for certification projects. In 2010, Mr. Peterson became the deputy branch chief for the branch that administers the NIOSH Respirator Approval Program and he currently serves as the branch chief, providing technical leadership, project management, and administrative support for all projects related to respirator certification activities mandated by 42 CFR 84.

Kevin Riley, Ph.D., M.P.H., is the director of research and evaluation at the University of California, Los Angeles (UCLA), Labor Occupational Safety and Health Program, 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 had 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. He 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 the evaluation of various worker training initiatives. Dr. Riley received his Ph.D. in sociology from UCLA and his M.P.H. from the UCLA Fielding School of Public Health. He is an active member of the Occupational Health Section of the American Public Health Association.

Daniel K. Shipp was president of the International Safety Equipment Association (ISEA), the association for personal protective equipment and cloth-

ing, from 1993 until his retirement in 2017. ISEA represents manufacturers and distributors of the full range of personal protective equipment (PPE) for workers in manufacturing, construction, utilities, health care, and other industries, and it is accredited by the American National Standards Institute as a standards-developing organization. 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 National Academies Committee on Personal Protective Equipment, the board of the Americas section of the International Society for Respiratory Protection, and the board of directors of the National Safety Council, as well as the National Institute of Occupational Health and Safety's National Personal Protective Technology Laboratory PPE Conformity Assessment Working Group.

Jeff Stull, M.S., is the president of International Personnel Protection, Inc. He is a member of several National Fire Protection Agency committees on personal protective equipment (PPE) as well as the ASTM International committee on protective clothing. Mr. Stull was formerly the convener for international work groups on heat/thermal protection and hazardous materials PPE as well as the lead U.S. delegate for International Standards Organization Technical Committee 94/Subcommittees on Protective Clothing and Firefighter PPE. He participates in the Interagency Board for Equipment Standardization and Interoperability and co-authored the book *PPE Made Easy*.

Jonathan Szalajda, SIE, M.Eng., is the deputy director of the National Personal Protective Technology Laboratory at the National Institute of Occupational Safety and Health.

Tener G. Veenema, Ph.D., M.P.H., M.S., RN, is an internationally recognized expert in disaster nursing and public health emergency preparedness. As the president and the chief executive officer of the Tener Consulting Group, LLC, Dr. Veenema served as a senior consultant to the U.S. government, including the Departments of Health and Human Services, Homeland Security, and Veterans Affairs; the Administration for Children and Families; and, most recently, the Federal Emergency Management Agency. Her decision-support software and information technology applications for disaster response have been presented at conferences around the globe. Her scholarship includes the leading international text in the field, *Disaster Nursing: Disaster Nursing and Emergency Preparedness for Chemical, Biological and Radiological Terrorism and Other Hazards* (Springer, 3rd edition, 2013), and two nationally award-winning disaster e-learning courses, Red Cross ReadyRN Disaster and Emergency Preparedness for Health Ser-

vices (American Red Cross, 2007) and ReadyRN (Elsevier, MC Strategies, 2008). Dr. Veenema received master's degrees in nursing administration (1992), pediatrics (1993), and public health (1999) and a Ph.D. in health services research and policy (2001) from the University of Rochester School of Medicine and Dentistry. She is a member of the American Red Cross National Scientific Advisory Board and is an elected fellow in both the National Academies of Practice and the American Academy of Nursing. Dr. Veenema was awarded the Florence Nightingale Medal of Honor from the International Red Crescent (Geneva, Switzerland), the highest international award a nurse can receive. Her areas of expertise include disaster nursing, public health emergency preparedness, children and disasters, public policy and environmental health, health policy, leadership and decision making, and clinical decision support systems.

STAFF

Olivia 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 in 2015, Ms. Yost worked as a research officer for ARCHIVE Global, a global health organization based in New York City, 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, low-cost testing methodologies to identify failing wastewater infrastructure. She received her B.A. in history and communications from Franklin University Switzerland.

Rebecca English, M.P.H., is a senior program officer on the Board on Health Sciences Policy at the National Academies and serves as the project director for the Planning Committee on Current Issues in the Assessment of Respiratory Protective Devices. Since 2009 Ms. English has staffed and directed projects reflecting the range of challenges brought to the National Academies from sponsors. Most recently these efforts have included *Temporomandibular Disorders: Priorities for Research and Care* (2020); *Necessity, Use, and Care of Laboratory Dogs at the U.S. Department of Veterans Affairs* (2020); and *Physician-Assisted Death: Scanning the Landscape: Proceedings of a Workshop* (2018). As of late 2020, Ms. English is direct-

ing a congressionally mandated study on increasing fairness and equity in the deceased donor organ transplant system and a study sponsored by the National Aeronautics and Space Administration on managing cancer risks associated with radiation exposure during crewed space missions. Ms. English has received multiple internal awards at the National Academies for promoting a positive work atmosphere by helping to bring together people throughout the organization and for approaching her work and any associated challenges with determination and philosophical resolve. Prior to joining the National Academies, Ms. English was a legislative assistant at the National Active and Retired Federal Employees Association as well as a legislative assistant for health policy for U.S. Congressman Porter J. Goss (FL-14). She received her M.P.H. from the University of Michigan in 2009 and her B.A. in political science from the University of Notre Dame in 2002.

Kendall Logan is a senior program assistant for the Board on Health Sciences Policy. She joined the National Academies in 2018 and staffed two consensus study reports: *Social Isolation and Loneliness in Older Adults: Opportunities for the Health Care System* and *Temporomandibular Disorders: Priorities for Research and Care*. She also supports the Standing Committee on Medical and Epidemiological Aspects of Air Pollution on U.S. Government Employees and Their Families. Ms. Logan received her B.A. in anthropology with a public health minor from Haverford College and is currently pursuing a master of public health from Columbia University.

Claire Giammaria, M.P.H., is an associate program officer on the Board on Health Sciences Policy. Prior to coming to the National Academies, Ms. Giammaria was the 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.

Andrew M. Pope, Ph.D., is the director of the Board on Health Sciences Policy. He has a Ph.D. in physiology and biochemistry from the University of Maryland and has been a member of the National Academies staff since 1982 and of the Health and Medicine Division staff since 1989. His primary interests are science policy, biomedical ethics, and environmental and occupational influences on human health. During his tenure at the National Academies, Dr. Pope has directed numerous studies on topics that range from injury control, disability prevention, and biologic markers to the protection of human subjects of research, National Institutes of

Health priority-setting processes, organ procurement and transplantation policy, and the role of science and technology in countering terrorism. Since 1998 Dr. Pope has served as the director of the Board on Health Sciences Policy, which oversees and guides a program of activities that is intended to encourage and sustain the continuous vigor of the basic biomedical and clinical research enterprises needed to ensure and improve the health and resilience of the public. Ongoing activities include forums on neuroscience, genomics, drug discovery and development, and medical and public health preparedness for catastrophic events. Dr. Pope is the recipient of the Health and Medicine Division's Cecil Award and the National Academy of Sciences' President's Special Achievement Award.