PPE Standardization Priorities

For a Resilient Public Health Supply Chain

Report from the Healthcare and Public Health Sector Joint Supply Chain Resilience Workgroup's PPE Standardization Task Group

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EXECUTIVE SUMMARY

The worldwide COVID-19 pandemic caused widespread disruption to the global public health supply chain affecting the availability of adequate personal protective equipment (PPE) to healthcare, public health, and other critical infrastructure occupations and the public. In response, in 2021 the White House issued an Executive Order and coordinated the interagency development of a National Strategy for a Resilient Public Health Supply Chain.

A key component of this strategy was establishment of a PPE Standardization Task Group, charged with developing plans to improve the efficacy, effectiveness, safety, supply stability, and accessibility of PPE to reduce infectious disease exposure in workplaces and community settings. Recognizing the importance of standards and conformity assessment to ensure the performance, quality, and reliability of PPE, the Task Group launched a multi-year program to address gaps and needs in government and voluntary standards for PPE.

The Task Group developed a two-phase program to identify standardization gaps and needs, categorize them, and propose standards actions to reduce or eliminate them to provide improved safety and health outcomes.

The first phase involved information collection, literature review, and input from experts and stakeholders to identify and understand the standardization gaps. Throughout 2022, the Task Group conducted a series of virtual meetings in which public officials, private sector stakeholders, and subject matter experts explored the whole range of PPE standardization issues and activities. Topics in these discussions included federal regulatory and national consensus standards activities, workplace and public PPE performance and availability, PPE selection, and user training and guidance. The Task Group explored how PPE standards are affected by market dynamics, government regulations and policies, engagement of public and private partners, and international synergies. Additional phase 1 activities included a NIOSH-sponsored Workshop on Equitable PPE Protections and a meeting of the National Academies of Sciences, Engineering and Medicine (NASEM) Standing Committee on Personal Protective Equipment.

Summaries of all these meetings were published in a 2022 Annual Report, which also included a set of tables showing the standardization gaps and needs reported in the information gathering phase. The final step in phase 1 was a two-day workshop conducted by NASEM, where experts from government, academia, industry, and advocacy organizations examined the gaps with the goal of identifying near- and long-term actions to address them.

The second phase involved organizing the information from phase 1 into a plan to address the gaps. The Task Group authorized a volunteer Ad Hoc Subgroup of experts, led by the Task Group chair, to conduct this activity. This Subgroup took the information produced in phase 1 and the NASEM workshop and designed a framework for categorizing the gaps and identifying and prioritizing standards actions to resolve them.

The Ad Hoc Group developed a system that categorized gaps by hazard, by PPE attribute, and by standards type, and the group revised and reformatted the tables from the 2022 Annual Report. The group then identified standards actions that could reduce or eliminate each gap and annotated the tables to explain these actions. The group also developed a set of general principles that are broadly applicable to PPE standards and standardization, detailed in Table 2 of this report.

The final step was to prioritize these standards actions. The Ad Hoc Group collectively evaluated each gap for its burden on safety and health outcomes and the impact of a potential standards action to address the needs and eliminate or reduce the gap. Then for each Priority 1 gap, the group made an additional evaluation of the time likely to be required for necessary standards actions. The priority designations are summarized below.

Priority 1A	Gaps requiring standards actions that will provide maximum health and safety outcomes and eliminate a substantial gap when fully implemented, and that can be completed within 1 year
Priority 1B	Gaps requiring standards actions that will provide maximum health and safety outcomes and eliminate a substantial gap when fully implemented, and that can be completed within 1 to 3 years
Priority 1C	Gaps requiring standards actions that will provide maximum health and safety outcomes and eliminate a substantial gap when fully implemented, and that will require more than 3 years to complete
Priority 2	Gaps requiring standards actions that will provide a significant level of health and safety outcomes and significantly reduce important gaps when fully implemented
Priority 3	Gaps requiring standards actions that will provide a minimal improvement to health and safety outcomes and reduce some standards gaps when fully implemented

Appendix A of this report includes tables showing 74 gaps and needs, organized by hazard type. Each table is further organized by attribute and shows the priority assigned to each gap, the type of standards action required, the applicable existing standards, and a rationale for selecting the priority and standards actions.

Findings of the tables are summarized by attribute, and recommended standards actions are shown by priority and hazard type.

This report also includes recommendations for implementation of the recommendations, including organization and infrastructure and systems for initiating and revising standards, tracking progress, and periodic updating of the tables as standards actions are completed.

INTRODUCTION AND BACKGROUND

The COVID-19 pandemic highlighted the need for personal protective equipment (PPE) for healthcare and other essential workers involved in public health. Even though there are some control measures needed, PPE frequently worn by healthcare personnel—gowns, gloves, goggles, face shields, head covers, respirators, shoe covers, and surgical masks—plays a vital role in preventing the transmission of infectious diseases. Workers in public health and other critical infrastructure occupations where there is a risk of exposure to infectious diseases need this PPE, as do members of the public.

The pandemic also exposed limitations and choke points in the global public health supply chain, which includes PPE as well as medicines and medical devices. Panic purchasing led some healthcare facilities and others who support public health to hoard PPE, while others were caught short-handed without enough PPE to meet their needs and suppliers were not able to keep up with the sudden spike in demand. The market was flooded with substandard products and stockpiles were quickly exhausted. There was also unpredictable demand due to a lack of worker protection standards that spur production of specific PPE, lack of policies on what "effective" PPE is, and domestic reliance on competitive global supply chains. Therefore, limited resources had to be redirected to combat counterfeit PPE market, and public health authorities at all levels of government struggled to establish timely and effective policies and provide clear messaging.

In January 2021 the White House responded by issuing Executive Order 14001, *A Sustainable Public Health Supply Chain*,[1] directing federal agencies to develop "a strategy to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats." This led to the creation of the *National Strategy for a Resilient Public Health Supply Chain*[2] (hereafter, National Strategy), coordinated by the White House and developed by the Departments of Defense, Health and Human Services, Homeland Security, and Veterans Affairs. This strategy outlines national efforts to support preparedness and response to public health emergencies. It explicitly recognizes the importance of PPE and PPE standards. In a section of the National Strategy document titled "Ensuring Quality of PPE and Effective Coordination through the Supply Chain Life Cycle," the strategy describes the state of the PPE supply chain during the pandemic emergency as follows:

> During the early stages of the COVID-19 response, the federal government faced immense challenges in effectively coordinating sufficient supply—and effective distribution—of consumer-ready PPE such as respirators, gowns, and gloves.

[1] Available from https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-a-sustainable-public-health-supply-chain/

[2] Available from https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf

> Federal and SLTT [State, Local, Tribal and Territorial] acquisition organizations struggled to successfully procure PPE in an efficient or effective manner—in part because of reliance on intuition, lack of situational awareness, entrenched purchasing habits, and over-prioritization for immediate responses. In many cases, the acquisition process failed to identify the appropriate standards; or, in some cases, the appropriate standard did not exist. Moreover, in the rush to procure supplies from a supply-limited market, many purchasing decisions were made based on the PPE available for purchase, rather than on performance and quality standards. This rushed purchasing resulted in delivery of sometimes substandard, mislabeled, and counterfeit products.

Among the conclusions in the National Strategy was a clear statement of the importance of standards and conformity assessment:

> An effective supply chain starts with designating the required standards to which products must conform, coupled with a reliable means for demonstrating conformance. These standards inform the supply chain by identifying the performance, quality, and reliability of qualified products.

PPE STANDARDIZATION TASK GROUP

Purpose and Organization

As part of the government's implementation of the strategy, the Healthcare and Public Health Sector Partnership through the Critical Infrastructure Partnership Advisory Council established a Joint Supply Chain Resilience Working Group (SCRWG)[3] consisting of representatives of 27 federal agencies as well as experts from private industry, academia, and safety and health organizations. The Product Standardization Plan of Action and Milestones (POAM) 23, launched by the White House as one of over 30 POAMs developed to respond to the National Strategy, was identified as a priority by the Joint SCRWG leadership, and the PPE Standardization Task Group was established. The Joint SCRWG structure is provided in Figure 1.

[3] The Joint Supply Chain Resilience Working Group (SCRWG) consists of 179 experts from private industry and academia and representing twenty-seven federal agencies. Healthcare and Public Health (HPH) Sector-wide Private Sector Coordinating Council (SCC) identified the private sector experts through their long-standing involvement. SCC member supply chain owners and operators join the Joint SCRWG to provide expert insight into private and public sector-led sub-working groups. The Joint SCRWG falls under the Critical Infrastructure Partnership Advisory Council (CIPAC) framework. The U.S. Department of Homeland Security (DHS) established CIPAC to facilitate interaction between governmental entities and representatives from the community of critical infrastructure owners and operators. CIPAC facilitates consensus advice and information sharing on critical infrastructure security, resilience, and protection to flow bi-directionally between the government and industry.

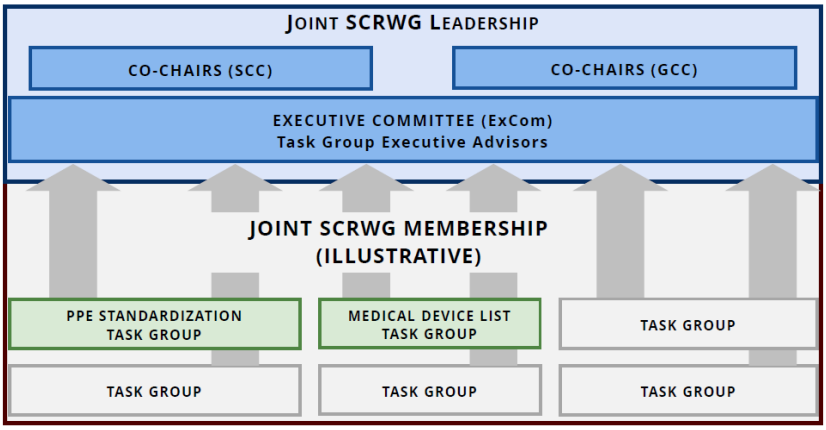

Figure 1 Joint SCRWG Leadership and Task Groups

The goal of this Task Group is to improve the efficacy, usage effectiveness, safety, supply stability, and accessibility of PPE designed for use in U.S. healthcare settings, critical infrastructure occupations and other occupations supporting public health, and to protect the public by reducing infectious disease exposures in workplaces and community settings. The Task Group comprises representation from the federal government, small and large businesses, industry, professional associations, procurement organizations, clinical healthcare organizations, and trade unions (see Appendix C for a list of Task Group participating organizations). It is chaired by Dr. Maryann D'Alessandro, Director of the National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) within the Centers for Disease Control and Prevention (CDC).

The objective of the Task Group is to "promote innovative approaches and technologies to streamline personal protective equipment and personal protective technology availability and use by cataloguing, prioritizing and addressing the standardization gaps." If successful, achieving this objective will overcome issues associated with PPE demand outpacing supply, provide greater assurance of PPE fit, and contribute to improved protection for workers and the public.

The PPE Standardization Task Group, working through the Joint SCRWG, brought together federal experts and the private sector to (1) foster information sharing, (2) collaborate to identify supply chain resilience priorities, and (3) ensure that public and private industry partners jointly establish the path to a more resilient healthcare and public health supply chain to achieve the Task Group's objectives.

PPE Standards and Standardization

Standards are essential throughout the PPE supply chain. The use of PPE depends on standards to define acceptable levels of product performance; enable selection of appropriate products; provide instructions for use, training, maintenance, or disposal; and any combination of these elements. Standards provide a shorthand by which producers, specifiers, regulators, and users

can understand the capabilities and limitations of PPE. They serve as the basis for conformity assessment, to provide a level of assurance of performance. They can be voluntary or mandatory, depending on whether they are embedded in regulation.

PPE product standards can include design requirements such as dimensions and materials, minimum requirements for performance, classifications, labeling, instructions for selection, use, maintenance, and disposal, or any combination of these elements. Standards commonly include test methods to be used to demonstrate conformity and may specify other conformity assessment requirements such as testing interval, lab accreditation, quality management, documentation of post-market surveillance, and recall.

Standards can apply to processes as well as products. Selection, use, maintenance, and disposal requirements for PPE fall under this category and apply to the purchaser and user rather than the producer or seller. These standards are often established as regulations, although they may also provide guidance for meeting regulatory requirements or establish practices not included in regulations.

Standards Development and Regulation

In the U.S., standards applicable to PPE are a combination of government regulations and voluntary consensus standards.

A standard enacted or adopted by a government agency is a regulation, carrying a legal requirement for compliance. In the U.S., respirator product standards are established by NIOSH under 42 CFR 84. These standards govern the NIOSH Respiratory Approval Program and can be used by manufacturers as they design respiratory protective devices (RPDs) for workplace use.

Regulations covering the use of PPE in the workplace are established by the Occupational Safety and Health Administration (OSHA) for most industries, by the Mine Safety and Health Administration (MSHA) for mining, by the Food and Drug Administration (FDA) for some healthcare PPE, and by other agencies of federal, state, and local governments. In many cases, PPE standards established by voluntary consensus organizations are incorporated by reference in these regulations, enabling the agency to enforce the use of products that comply with these standards.

Voluntary consensus standards are developed through a process that involves a broad and balanced range of interests, including product designers and manufacturers, testing and evaluation organizations, subject matter experts, government regulators, and user groups. Standards developing organizations (SDOs) establish rigid rules and requirements to ensure balance, fairness, and a diversity of views as well as technical accuracy and relevance.

A variety of SDOs in the United States develop standards for PPE. These organizations may be professional societies such as the National Fire Protection Association (NFPA), the American Society of Safety Professionals (ASSP—formerly ASSE), the Association for the Advancement of Medical Instrumentation (AAMI), and the Acoustical Society of America (ASA); trade associations such as the International Safety Equipment Association (ISEA); and SDOs such as ASTM International.

These SDOs are accredited by the American National Standards Institute (ANSI), a federation of standards developers and users that is recognized as the coordinator of voluntary standards activities in the U.S. ANSI coordinates recognition of standards committees and establishment of new standards projects, maintains rules and procedures for standards developers, and oversees a process leading to recognition of American National Standards. It is also the official U.S. member body of international standards organizations including the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

TASK GROUP ACTIVITIES

The PPE Standardization Task Group developed a two-phase program to prepare recommended actions to the Joint SCRWG. The first phase involved information collection, literature review, and input from experts and stakeholders to understand and identify gaps in PPE and Personal Protective Technology (PPT) standardization. The second phase used the information collected in phase 1 to produce consensus advice for the federal government, as well as standards developing organizations, on standardization gaps and needs.

Phase One

Information Collection

The Task Group held eight two-hour virtual meetings during March-October 2022. In these meetings, subject matter experts made presentations and led discussion on topics including federal regulatory and national consensus standards activities, workplace and public PPE gaps, PPE performance, research and development, PPE access, PPE training, and PPE education. Other topics included how marketing dynamics, government regulations and policies, engagement of public and private partners, international synergies, and barriers all impact PPE standards. Each of these meetings is summarized in a 2022 Annual Report[4], along with summaries of a NIOSH-sponsored workshop conducted in November 2022,[5] and a meeting of

[4]Annual Report of the National Strategy for a Resilient Public Health Supply Chain Product Standardization Task Force—2022. Available on the ASPR TRACIE website https://asprtracie.hhs.gov (registration required)

[5] NIOSH [2024]. Proceedings of the 2022 Equitable PPE Protections Workshop: A National Strategy for Equitable PPE Protections for All U.S. Workers. By Wehring J, Linkov F, Dempsey PG, Schall J, McCleery T, Yoon K, Moore S, D'Alessandro M (editors). Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No 2024-106. https://doi.org/10.26616/NIOSHPUB2024106

the National Academies of Sciences, Engineering and Medicine (NASEM) Standing Committee on Personal Protective Equipment (COPPE) in December 2022[6].

Tabulation of Standards Gaps

The 2022 Annual Report identified gaps in PPE standardization in four general categories as shown in Table 1.

Table 1. Categories of PPE Standardization from the 2022 POAM 23 Annual Report

Type of Gap	Characteristics of Gap
Protection from specific hazards	Protection hazard area not addressed; insufficient or incorrect protection; protection level(s) not matched to needs
Technology related to protection, testing, capability, environmental factors, ruggedness, and service life	Missing, unavailable, outdated, or incorrect technology
Selection, use, maintenance, and care information	Missing, outdated, or inaccurate information
Conformity assessment	Conformity assessment is not present or lacking in substance

Based on the Task Group's examination of existing standards and standards development programs and standardization gaps reported in the information gathering process, a set of tables was prepared. These tables were organized by types of PPE: respirators, medical face masks, barrier face coverings, eye and face protective devices, gloves, gowns, and other apparel.

Each table listed existing standards and regulations, current standards development work items and activities, and other areas where no standard exists. For each standard or issue, the tables showed the status and availability of the current standard or revision, as well as gaps in coverage and needs for improvement identified by members of the Task Group. Accompanying these tables were general descriptions of the applicable U.S. standards and regulations and lists of corresponding international and European PPE standards.

General Recommendations for Improvement of PPE through Standards

The 2022 Annual Report concluded with a set of general recommendations:

1. Improvements in standards should be sought for all types of PPE for workers and the public regarding the protection and up-to-date, relevant test methodology and requirements. Both evaluation procedures and criteria must be validated to demonstrate

[6] The agenda for this meeting is available from https://www.nationalacademies.org/event/12-08-2022/committee-on-personal-protective-equipment-for-workplace-safety-and-health-virtual-fall-2022-meeting

appropriate levels of protection and reliability.

2. A large proportion of PPE is not adequately sized or made available in the correct size to fit the increasingly diverse end user (including workers and the public) populations.

3. Approaches to conformity assessment vary significantly for PPE products ranging from robust government testing and approval requirements (e.g., NIOSH Approved® respirators) to no requirements (e.g., cloth masks used by the public). For many products, the value of current oversight processes for ensuring that healthcare, vital workers, and the public's needs are met has not been demonstrated for different types of PPE. The specific regulation of some PPE as medical devices is inconsistent with consensus-based standards on some products.

4. Several aspects related to the selection, use, and care of many PPE products are not clearly defined, often leading to a proliferation of different practices that may or may not be valid. There is a lack of specific guidance for end users for all forms of relevant PPE. There are specific shortcomings in areas such as distinguishing the adequacy of PPE with different performance ratings, the impact and effectiveness of cleaning or disinfectants on PPE, and self-contamination during doffing.

5. Greater efforts are needed to obtain more feedback on standards, including the participation of more end users in the review of standards, particularly in the early stages to establish product protection and information needs. In addition, feedback is needed on surveillance efforts that determine the overall effectiveness of standards in providing required levels of protection and access to PPE.

NASEM Workshop

The final step in phase 1 was a two-day workshop conducted by the National Academies of Science, Engineering and Medicine in March 2023[7]. During this workshop, experts from government, healthcare, academia, industry, and advocacy organizations examined the gaps identified in the 2022 Task Group report, with the goal of identifying near- and long-term actions that the nation can take to fill these gaps.

Participants in the workshop discussed the role of standards in creating and maintaining a resilient PPE supply chain, how standards affect product design and manufacturing capacity, the role of conformity assessment in evaluating and assuring product performance, stockpiling and distribution, and the need for clear and consistent communication to workers and the public. While the workshop

[7] National Academies of Sciences, Engineering, and Medicine. 2023. *Personal protective equipment and personal protective technology product standardization for a resilient public health supply chain: Proceedings of a workshop*. Washington, DC: The National Academies Press. https://doi. org/10.17226/27094.

format does not provide for development of consensus recommendations, participants discussed various approaches for categorizing standardization gaps and prioritizing standards actions to address them. The workshop proceedings served as an input to phase 2 of the process.

Phase Two

Framework

In the second phase, an ad hoc group of experts in PPE standardization, conformity assessment, and regulation was drawn from Task Group members. This group designed and implemented a process to categorize the standards gaps and prioritize efforts to address them, to provide a pathway to development of standards, guidance, and regulations to enhance the resilience of the PPE supply chain.

Categorization

The first step in phase 2 was to solicit input from the Joint SCRWG PPE Standardization Task Group on developing a framework for categorizing the standards gaps and needs. Volunteers were solicited from the Task Group to participate in an Ad Hoc Subgroup for this purpose. Led by the Task Group chair, the Ad Hoc Subgroup took an iterative process through a series of virtual meetings to establish a prioritization process and build on information presented at the NASEM Workshop to identify attributes common to PPE standards that could be used to evaluate their effectiveness in preventing or moderating injuries or illness. The prioritization process is shown in Figure 2.

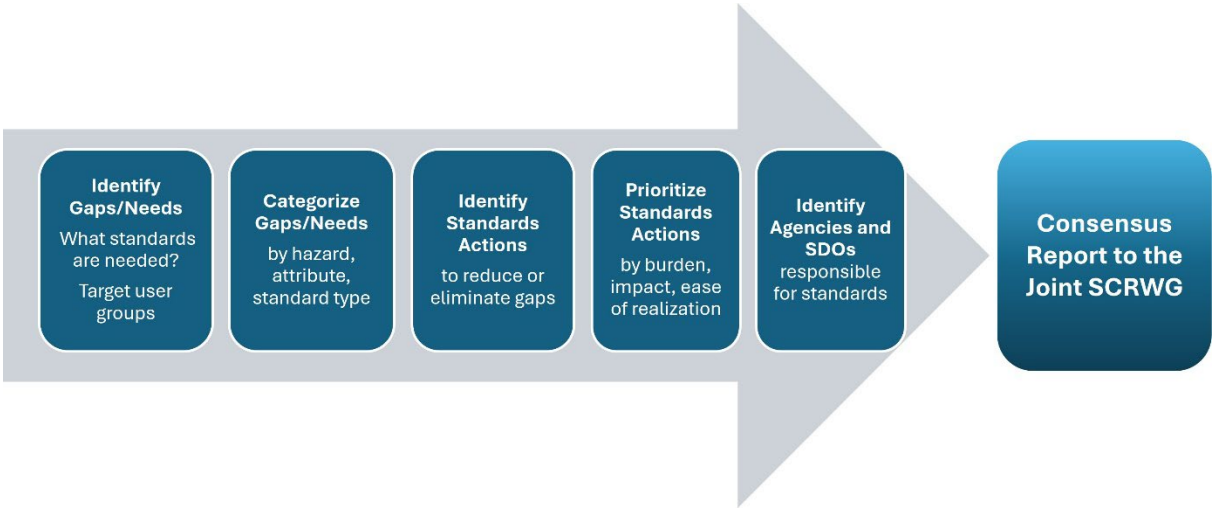

Figure 2. Process Used to Establish Priorities

The Ad Hoc Subgroup identified four ways of looking at standards gaps: by hazard, by PPE attribute or factor, by supply chain impact, and by guidance. Hazards were classified by exposure (e.g. inhalation, dermal, eye, and face) and PPE type applicable to each (e.g. respirators, gloves/gowns, goggles/face shields). PPE attributes included factors that could be addressed in

standards: fit and sizing; comfort and usability; interoperability and interface; decontamination, instructions for cleaning, reuse, extended use and care; selection and use; real-time performance, and labeling. Supply chain factors included design, manufacturing, distribution, stockpiling, and last mile access. Information and guidance are important to PPE wearers to ensure that the level of protection intended by the standards is afforded the wearer.

Guided by these criteria, the tables from the 2022 Annual Report were reformatted to focus on the gaps and needs, which eliminated duplicate entries where common gaps were found in multiple standards. The tables went through several rounds of review by NPPTL staff and the experts on the Ad Hoc Subgroup, producing a comprehensive set of identified gaps and needs that could be used in the prioritization process.

In the revised tables (see Appendix A), gaps and needs are organized by attribute (i.e., size/fit, comfort/wearability, selection/use, etc.), enabling identification of standardization gaps both in existing standards and areas where new standards are needed. Each table is associated with a hazard category, with an additional table A5 showing gaps that are not specifically product related but address issues important to the supply chain.

Table	Hazard/Protection Category
A1	Respiratory Protection (respirators, medical masks, BFCs, public safety masks)
A2	Eye/Face Protection (goggles, face shields, spectacles)
A3	Hand Protection
A4	Protective Apparel (gowns, drapes, coveralls, other apparel)
A5	Supply Chain Gaps

Within each hazard category, the tables are organized by attribute:

Attribute
Design/Performance for Healthcare
Fit/Sizing
Comfort/Wearability
Compatibility/Interface
Selection, Use, and Care
Shelf Life
Packaging and Labeling
Purchasing, Inventory
PPE Availability

For each identified gap and need, there is a column listing applicable standards or regulations and a "Type" column containing a numerical code indicating the type of standard, guidance, or regulation to which the identified gap or need applies.

Code	Standard Type
1	Product Standards (worker or public)
2	Program/Process Standards (hazard identification and PPE selection, use, training, care, maintenance, disposal)
3	Information and Guidance (education of workers and the public—may not be standards)
4	Conformity Assessment Standards and Requirements
5	Regulations and codes

The tables include a "Rationale" column to further explain the gap or need, and they identify potential standards actions to fill, eliminate, or reduce that gap or need. For the purpose of this analysis, the following definitions apply:

- A *standards action* is defined as the process to complete the development of a new standard, revise an existing standard, or rescind a standard that is obsolete or no longer needed.
- A PPE standard can be a product standard, a program or process standard covering any aspect of selection and use, a test method to be used on its own or as part of a product standard, or a standard defining methods of conformity assessment.
- A standard as defined here can be a voluntary consensus standard or a government regulation. The federal government requires that agencies give preference to standards developed through consensus standards organizations rather than unique standards established by an agency.

General Principles for PPE Standardization

Some of the identified gaps and needs were found to be broadly applicable to all PPE standards. These have been extracted and stated as a set of general principles for PPE standards and standardization. These principles include factors identified by the Task Group discussions and include protection, fit/sizing, comfort/wearability, interoperability/interface, selection/use/care, shelf life, conformity assessment, population considerations, as well as an open and inclusive process for standards development and regulation. All standards actions evaluated in the prioritization process are expected to meet the applicable general principles.

Table 2. General Principles for PPE Standardization

General	Standards developing organizations should have procedures in place to ensure understanding, effective navigation of and broad-based participation in processes for creation, revision, and maintenance of standards related to PPE. Coordination among regulatory agencies at all levels is essential to eliminate overlapping and conflicting requirements. Input from the full range of contributors, including producers, users, industrial hygiene, medical professions, public health, employers, workers, government agencies, standards developers, and others in the supply chain, is essential to produce effective standards and guidance to workers and the public on personal protection.
Protection	PPE product standards should be risk-based, addressing specific hazards expected to be encountered in a workplace or other hazardous environment, and may include design specifications, performance, quality, and reliability requirements and test methods to assess performance. PPE program standards address the proper use of PPE, including hazard assessment, selection, donning and wear, training, maintenance, and disposal.
Fit/Sizing	Where appropriate, standards should include uniform sizing guidelines for intended users based on anthropometric measurements that accurately and adequately represent the user, including users with special needs. Proper sizing helps to ensure better fit, which affects performance as well as comfort and wearability.
Comfort/Wearability	Where appropriate, standards should incorporate methods to objectively test and evaluate comfort and wearability for all environments where the PPE would be expected to be used. Design requirements should not constrain the wearability of PPE by people with physical impairment, nor should they constrain the ability to communicate with others (e.g., patients, other workers). Effective communication is essential to worker protection.
Interoperability/ Interface	Where ensembles or multiple types of PPE are required to ensure wearer protection (e.g., goggles, gloves, respirators, gowns, hoods, footwear), standards should address compatibility and interoperability.

Selection, Use, and Care	PPE standards should address hazard assessment, selection, use, care, and maintenance specific to the PPE type, wearer, and environment in which it is used, including training or user instructions on how to use and care for PPE. Where appropriate, standards should define methods for manufacturers to show the efficacy of cleaning, disinfecting, and decontamination recommendations in product standards for routine or extended use.
Shelf Life, Useful Life, and Storage	Where appropriate, PPE standards should include guidelines for determining shelf life, expiration date labeling, and specifications for storage conditions. Where appropriate, standards should specify methods to perform accelerated aging tests, identify potential failures, and analyze causes and effects.
Conformity Assessment and Surveillance	Conformity assessment standards should define methods and levels of conformity assessment and provide uniform guidance for determining the appropriate level of conformity assessment for any type of PPE based on risks of non-conformance. These standards may include: ● requirements for inspection, evaluation, testing, and quality assurance ● uniform criteria for supplier qualifications, manufacturer inspection and acceptance of components, and ongoing audits of supplier qualification ● systems of ongoing surveillance of product performance and conformity to standards once a product is on the market ● consistent ways to authenticate and track compliant PPE
Population Considerations	Standards should consider all expected wearer populations and unique issues they may face. This could include occupation, age (e.g. children or elderly adults), gender, ethnicity, and special physical or cognitive needs.

Prioritization

The Ad Hoc Subgroup followed a multi-step process in setting priorities for standards actions to fill, eliminate, or reduce each gap or need.

First, the subgroup collectively evaluated each identified gap/need using the criteria of **burden** and **impact**, where:

- **Burden** is the indication of the potential for serious injury or illness or death because of the identified gap/need.
- **Impact** is an estimate of the potential to eliminate/significantly reduce the identified gap/need and improve health and safety outcomes.

During this evaluation, reviewers assigned a priority rating of 1, 2, or 3 based on their collective view of the potential effect on burden and impact by successfully addressing the identified gap/need, where:

- **Priority 1** reflects a standards action that will provide *maximum health and safety outcomes* and eliminate a substantial gap when fully implemented.
- **Priority 2** reflects a standards action that will provide *a significant level of health and safety outcomes* and significantly reduce important gaps when fully implemented.
- **Priority 3** reflects a standards action that will provide *only a minimal improvement to health and safety outcomes* and reduce some standards gaps when fully implemented.

Next, the Ad Hoc Subgroup collectively evaluated each Priority 1 identified gap or need using the criterion of **ease of realization**, where:

> **Ease of Realization** is the estimated relative time for any ongoing standards development effort, reflecting the existence of capable and available infrastructure, including SDOs, knowledge, and expertise, to develop the new/improved standard. These factors affect the time needed to develop the new/improved standard. Another factor in the effectiveness of a standards action is the time to realize beneficial outcomes from market acceptance of PPE meeting new or revised standards. This is driven by factors such as cost, consumer demand, incentives, and regulatory mandates, and it is difficult to anticipate or estimate.

During this evaluation, the reviewers assigned a priority rating of 1A, 1B, or 1C based on their individual view of the estimated time for the standards action to be taken and the resources available, where:

- **Priority 1A** reflects a standards action that can be completed in 1 year or less. This assumes the knowledge and technology are available and there is an SDO capable of undertaking the task.
- **Priority 1B** reflects a standards action that can be completed in 1–3 years. Some additional research may be required, and an SDO may have to be identified.
- **Priority 1C** reflects a standards action that can be completed in more than 3 years. Additional research will likely be needed and an SDO may have to be identified.

These numbers appear in the Priority column of each table. During this process, the text in the Rationale column was reviewed and amended as necessary to explain the assignment of a priority.

TASK GROUP FINDINGS AND RECOMMENDATIONS

Priorities by Protection Category

There are 74 gaps or needs identified by the Task Group. Of these, respiratory protection and protective apparel account for two-thirds of all gaps and more than 90% of those were rated as Priority1, as shown in Table 3.

These numbers are influenced by the different types of devices in the respirator category, including various types of respirators, surgical and medical masks, and a new category of public respirator for which there are currently no definitive standards. Priority 1 standards actions would better define and upgrade requirements in product standards and standards for selection and use, as well as spur development of respiratory protection for members of the public who may be exposed to infectious disease or other airborne hazards.

Priority 1 standards actions for protective apparel focus on improvements in test procedures for materials used in the construction of healthcare garments, providing better user guidance and updating OSHA regulations for bloodborne pathogens and other exposures.

Table 3. Priorities by Protection Category

Protection Category	1A	1B	1C	2	3	total
Respiratory Protection	2	9	8	3	4	26
Eye/Face Protection	1			7	1	9
Hand Protection				9	3	12
Protective Apparel	2	4	3	10	4	23
Supply Chain			2		2	4
Totals	5	13	13	29	14	74

Priorities by Attribute

The Task group's prioritization of gaps by attribute reflects the importance of factors beyond product performance, as repeatedly expressed throughout the information-gathering phase. These include assessing fit and proper sizing, improving comfort and wearability, and providing guidance for users as well as regulations covering PPE selection, use, and care.

Table 4. Priorities by Attribute

Attribute	1A	1B	1C	2	3	total
Design/Performance for Healthcare	3	4	2	15	8	32
Fit/Sizing	1	2	3	2		8
Comfort/Wearability		2	2	3	2	9
Compatibility/Interface				1		1
Selection, Use, and Care	1	3	4	5	2	15
Shelf Life			1	2		3
Packaging and Labeling		1			1	2
Purchasing, Inventory			2			2
PPE Availability					2	2
Totals	5	12	14	28	15	74

Priorities by Standards Type

Five types of standards actions were identified in the categorization process:

1. **Product standards** contain design and performance specifications for PPE. They may include product descriptions, minimum performance requirements, product classifications, test methods, labeling, user instructions, and other requirements. Standards in this category are developed through regulatory or consensus processes, maintained by an agency or SDO, and recognized by appropriate authorities.
2. **Program/process standards** provide instructions on the proper use of PPE that meets product standards. This may include hazard assessment, product selection, user training, care, maintenance, disposal, and other requirements. These standards are developed in the same way as product standards.
3. **Information and guidance** includes information provided for users, including workers and the public, on selection, use, and care of PPE. This guidance may be developed and provided by a government agency or non-government organization, but is neither a regulation nor a consensus standard.
4. **Conformity assessment standards** provide a process for evaluating whether a product or program meets the requirements of a standard or regulation. Conformity assessment may be included as part of product standards, or they may be included as separate standards and requirements issued by an authority or accrediting body. They apply to product manufacturers and testing and certification organizations.
5. **Regulations** are mandatory government standards and requirements for PPE, issued by government agencies. They may be product design and performance requirements, program/process requirements, or conformity assessment requirements, and they have the force of law. When regulations incorporate or make reference to consensus standards, these consensus standards become mandatory.

Note in Table 5 that the totals are different from the previous categorizations. This is because multiple standard types may apply to an individual gap entry; for example, standards actions for an identified gap or need might include development of a product standard, development of a standard for the product's selection and use, and a regulation incorporating one or more of these standards.

Table 5. Priorities by Standard Type

Standard Type	1A	1B	1C	2	3	total
Product Standards	3	10	7	25	8	53
Program/Process Standards	1	4	7	5	2	19
Information and Guidance		4	3	3	1	11
Conformity Assessment Standards	1		1	1	5	8
Regulations	1	4	3	5	7	20
Totals	6	22	21	39	23	111

Summary of Findings

The report of the PPE Standardization Task Group is the culmination of a multi-year effort to define how standards for personal protective equipment and technologies protect the health and safety of workers in healthcare, in critical infrastructure occupations and other occupations supporting public health, and members of the public exposed to similar hazards.

The Task Group approach was to identify critical gaps and needs in these standards, how these gaps and needs could be eliminated or reduced, and where new standards need to be developed. In a series of virtual meetings and workshops, the group heard from a broad spectrum of PPE users, producers, and regulators, as well as experts in public health, emergency management, marketing, communications, standards, and conformity assessment. The group heard about breakdowns in the supply chain during the COVID-19 pandemic, inconsistent communication on what PPE is needed and how to use it, and workers' frustration about protection, fit, comfort, and wearability.

All this input was assembled into a framework that categorizes the standards gaps and needs, identifies standards actions to address them, and prioritizes these actions by their potential to improve safety and health outcomes.

Design/Performance for Healthcare

The fundamental purpose of PPE is protection. It provides a barrier or filter so that wearers will not come in contact with hazards that result in injury or illness. PPE is designed to meet standards that establish a level of performance that provides adequate protection against designated hazards at specific exposure levels. The levels and performance parameters are set by experts; few users will fully understand the technologies involved in respiratory filtration,

resistance to viral penetration, or the design of test procedures. Standards actions to address gaps in this category for all types of PPE are directed to product designers, manufacturers, test labs, and other professionals in health sciences and industrial hygiene. User input into the standards development process is important in order to ensure that the full range of applications has been considered, and this gives users confidence that their needs have been addressed.

Fit and Sizing

Fit and sizing are closely tied to protection. If a respirator does not provide a proper seal, it is not protective. If a garment is too small, it may expose areas of skin or tear—too large and it may snag equipment or impede movement. Users understand fit in a general way, but they need tools to help them find properly fitting PPE. Standards actions include developing standardized sizes for all types of PPE and new methods by which users can assess fit, which can be incorporated into program standards, guidance, and regulation.

Comfort and Wearability

No PPE is inherently comfortable. But minimizing the level of discomfort is essential to users who have to wear PPE. Although comfort is largely a subjective assessment, there are measures that can be taken to reduce the burden of wearing PPE. Standards actions in this category include product performance requirements that impose fewer physical burdens, developing methods for objectively assessing comfort, and reducing wearability restrictions such as fogging of goggle lenses.

Compatibility, Interface, and Interoperability

Often PPE is worn in ensembles—e.g., respirators and face shields, gloves and gowns, coveralls, and hoods. It is essential that these areas of interface do not allow exposure and that wearing one type of PPE does not affect the performance of another. Standards actions for ensembles are especially important in healthcare, where the hazards may be airborne and exposure may be sudden and unanticipated.

Selection, Use, and Care

The best PPE will not provide adequate protection unless it is matched to the hazard and exposure, worn and used properly, and maintained in a clean and workable condition. Supervisors and workers must be trained in PPE capabilities and limitations. Users must have instructions that are clear, readable, and understandable. Standards actions for all types of PPE are proposed for hazard identification, selection, use, care, cleaning and disinfecting, storage, and disposal. These may be part of product standards or separate program standards and guidance.

Shelf Life, Packaging, and Labeling

Some PPE standards include guidance on inspecting PPE and discarding it at the end of its useful life. But there are few guidelines for establishing the shelf life of PPE that may be stored for years before use. Recommended standards actions include development of tests to determine the useful life of a product, along with labeling and storage requirements, for inclusion in product standards.

Purchasing, Inventory, PPE Availability

The standards actions in this category apply directly to the supply chain. They propose adoption of standardized systems of monitoring PPE use to ensure that facilities have enough on hand to respond to emergency demand and developing the standardized terminology and data formats necessary for such systems to operate. They also propose mapping global PPE standards and approvals and establishing paths to mutual acceptance, along with examining whether there can be a pathway to approval for PPE produced by additive manufacturing.

Recommended Standards Actions to Eliminate or Reduce Gaps in PPE Standards

The standards actions covered in the tables in Appendix A were developed in a process that incorporated the views of experts in PPE design, manufacturing, and use as well as applicable standards and regulations. The priority assigned to each item represents their consensus on the criticality of eliminating or reducing standards gaps and needs, along with their estimate of the time required to complete the necessary standards actions. Decisions on what specific standards actions to take will be made by applicable regulatory authorities and SDOs.

Priority 1A Gaps and Needs

These require standards actions that will provide maximum health and safety outcomes and eliminate a substantial gap when fully implemented. The Task Group believes they should be addressed immediately and completed within 1 year.

Respiratory Protection
Standard to define levels of medical mask performance and limitations in wearing these products (i.e., source control devices vs RPD)
Fit capability requirement in the NIOSH Respirator Approval Program for half facepiece respirators
Eye and Face Protection
Existing OSHA standards include outdated references to Z87.1 and no reference to Z87.62
Protective Apparel
Standard test methods for water resistance do not consider other test fluids
The OSHA bloodborne pathogen standard does not reference PPE standards for disease transmission modes (i.e., contact, droplet, and aerosol)—PPE is considered acceptable if it prevents exposure to blood and other potentially infectious fluids

Respiratory Protection. Development of a standard for medical mask performance could be accomplished by updating ASTM F2100 to make it a product performance standard rather than a materials standard. This could include requirements for total outward leakage, clarifying the purpose of masks in various medical settings, and using existing research to define levels of performance.

There is an existing standard for fit capability[8] for half facepiece respirators (ASTM F3407) which could be incorporated into the NIOSH Respiratory Approval Program, with acceptable levels of performance for approval.

Eye and Face Protection. The OSHA standards for eye and face protection (29 CFR 1910.133 and related standards) reference versions of ANSI/ISEA Z87.1 that are ten years out of date, and they do not reference the ANSI/ISEA Z87.62 standard that was developed specifically for protection from blood and bodily fluids. OSHA could update these standards using direct final rulemaking.

Protective Apparel. Test methods used to evaluate fluid resistance of medical garment materials (AATCC 42 and AATCC 127) could be updated to use fluid challenges that more accurately predict the performance of the garment in resisting bodily fluids.

Healthcare worker dermal exposures to infectious disease hazards are not adequately covered in the OSHA bloodborne pathogens standard (29 CFR 1910.1030). OSHA could complete an infectious disease standard or develop a healthcare worker standard that references applicable PPE standards.

Priority 1B Gaps and Needs

These require standards actions that will provide maximum health and safety outcomes and eliminate a substantial gap when fully implemented and that can be completed in 1 to 3 years

Respiratory Protection
Fluid resistance requirement for air-purifying respirators and masks used in healthcare (policy)
Method for measuring outward leakage of respirators and masks
Test methods to specify head attachment strap tension and durability for respirators and masks
New respirator designs or methods to allow for use by wearers with facial hair, especially for healthcare
Reduced breathing resistance requirements for inhalation and exhalation for some work environments and tasks, such as healthcare and occupations requiring extended wear times

[8] Importantly, inclusion in POAM 23 does not presuppose that a respiratory protection fit test requirement will be published as a final rule, nor does it diminish the value of comments submitted to the docket when this issue is addressed through publication as a proposed rule.

	Requirements for demonstrating the efficacy of manufacturer instructions for cleaning, disinfection, and decontamination
	Standard for hazard assessment, selection, use, care, and maintenance of respirators to protect against infectious agents in the workplace
	Guidance for inhalation hazard assessment, selection, use, care, and maintenance of masks and/or respirators for the public including children and those with physical and cognitive disabilities
	Respirator and mask standards in some cases lack requirements to provide expiration date and methods to perform accelerated aging tests to evaluate shelf life
Protective Apparel	
	Specifications for apparel other than gowns, including coveralls, aprons, and partial body clothing
	Standard test methods using synthetic blood may not model all body fluids of interest
	Evaluation of the adequacy of sample sizes used in standard tests
	Minimum size requirements for critical zones and prominent labeling to indicate critical zone of protection

Respiratory Protection. The respiratory protection standards actions in this category include regulatory actions, consensus standard revisions, policy decisions and standards, and guidance for users.

A policy decision is needed to establish where and when respirators meeting current fluid resistance requirements should be used. Currently, only surgical N95® filtering facepiece respirators (FFRs) require testing for fluid resistance. Exposure assessment in the healthcare environment should guide the decision on where other approved FFRs can be used in healthcare applications. Policy decisions are also needed to determine what action should be taken when stockpiled respirators are past their expiration date.

Improvements to 42 CFR 84 proposed by the Task Group include measuring outward leakage of respirators, specifying head strap tension, evaluating innovative respirator designs allowing use by wearers with facial hair, and requirements for documenting the efficacy of manufacturer instructions for cleaning and disinfection. Some proposals, such as the outward leakage tests and amendments to breathing resistance requirements, could result in joint action by NIOSH and consensus standards organizations. An OSHA infectious diseases standard could fill a gap related to selection and use of respirators to protect against a wide range of infectious diseases in healthcare and in other occupations related to public health.

The Task Group also proposed development of new guidance for hazard assessment, selection, and use, care, and maintenance of respirators or masks for the public, which could also be used in defining requirements for public respirators and masks in a new standard.

Protective Apparel. In the protective apparel category, the Task Group recommended additional test method improvements, as well as development of standards for apparel other than gowns and establishment of minimum size requirements and labeling to identify the critical zone of protection.

Priority 1C Gaps and Needs

These require standards actions that will provide maximum health and safety outcomes and eliminate a substantial gap when fully implemented and can be completed in 3 to 5 years.

Respiratory Protection
Product standard for a mask and/or respirator for the public including children and those with physical or cognitive disabilities
More practical fit-testing methods, taking advantage of technologies such as facial recognition and AI, to ensure exposure reductions during respirator use
Method for assessing fit of masks and/or respirators for individuals without respiratory protection programs and the public including children and those with physical and cognitive disabilities
Sizing guidelines for respirators and masks
Requirements and methods to objectively evaluate the comfort of respirators and guidelines for their use
Test methods to evaluate verbal communications when wearing respirators or masks
Guidance for hazard assessment, selection, use, and care of respirators used for protection against wildfire smoke and other hazards such as mold and air pollution
Standard for hazard assessment, selection, use, and care of respirators used by workers not covered by an OSHA-compliant respiratory protection program
Protective Apparel
Standard test method that requires overnight development of cultures that are not suitable for rapid evaluations
Surveillance to assess the protection effectiveness of protective apparel products and the standards to which they are made
User guidance for inspection to identify tears, rips, seam failure, and worn-out product
Supply Chain Gaps/Needs
Standardized surveillance and monitoring system for sustainable PPE inventory management
Standardized terminology and data format for PPE

Respiratory Protection. This category includes the recommended development of a standard for a respirator or mask for public use, as well as enhancement to standards for fit, sizing, comfort, and wearability for all users. This is consistent with Recommendation 7-4 from the NASEM 2022 consensus report that the Department of Health and Human Services (HHS) should "establish and adequately resource a laboratory responsible for overseeing standards development, conformity assessment and approval for respiratory protective devices intended for use by the public..."[9]

The public mask standard would fill a critical need for an approved product for use by the public, including children and users with disabilities. A new standard would address appropriate sizing

[9] National Academies of Sciences, Engineering, and Medicine. (2022) Frameworks for Protecting Workers and the Public from Inhalation Hazards. Washington, DC: The National Academies Press. https://doi.org/10.17226/26372.

for a diverse population, methods for users to assess fit, comfort, and wearability. This effort will also involve identifying an organization that would recognize and promote such a standard.

Public wearers and workers not covered by OSHA-compliant respiratory protection programs would benefit from development of methods to assess fit that do not require specialized knowledge or equipment to perform. Sizing guidelines for respirators or masks, based on revised anthropomorphic data that accurately reflects the population of potential users, would enhance the process of respirators selection. Methods to objectively measure respirator comfort and evaluate voice communication are also needed.

Guidance for hazard assessment, selection, use, and care of respirators to protect against wildfire smoke and other non-infectious airborne hazards, as well to protect workers not covered by an OSHA-compliant respiratory protection program, could be developed by OSHA, the Environmental Protection Agency (EPA), or other relevant agencies. The 2022 NASEM consensus report recommended that OSHA should "establish and regularly update science-based, comprehensive workplace exposure standards for particulate matter indicators (e.g., from wildfire smoke), as well as airborne infectious disease agents, that would trigger respiratory protection program requirements, including for those workplaces in which respirators would not otherwise be required."

Protective Apparel. Along with additional test method improvements, this category includes a recommendation to develop user guidance to evaluate the continuing protective capabilities of as-worn garments and a surveillance program to assess how products in the field maintain their performance throughout their useful life.

Supply Chain. This category also includes a recommendation that the healthcare industry develop and adopt standard systems to determine the industry's PPE needs in normal operations and emergency situations, to ensure that products are available in the supply chain to meet spikes in demand. This would require development of common formats for terminology and data to be used in such a system which could be adopted by users and suppliers.

Priority 2 Gaps and Needs

These require standards actions that will provide a significant level of health and safety outcomes and significantly reduce important gaps when fully implemented. No time frame is included in this category; the schedule for completion of a standards action will be determined by the applicable agency or SDO.

Respiratory Protection
Evaluate the need for anti-counterfeiting programs and/or technology in healthcare respirators and develop standards
Determine the viability and applicability of the ASTM Barrier Face Covering as a separate category of respiratory protective device, including its intended use and regulator status
Eye and Face Protection
Improved definition of characteristics needed for glasses, goggles, and face shields used in healthcare
Criteria for assessing protection against aerosols and infectious agents other than blood and bodily fluids
Surveillance to assess the protection effectiveness of glasses, goggles, and face shields used in healthcare and the standards to which they are made
Methods to assess comfort and wearability
Method to evaluate fogging while in use
Guidance for cleaning and disinfecting for product reuse
OSHA standards do not address hazard assessment, selection, use, and care of eye and face protective devices used to prevent exposure via different disease transmission modes
Hand Protection
Material and testing specifications for medical gloves do not address whole glove evaluation
Physical property criteria (tensile strength and modulus) in surgical glove specification that accommodate nitrile rubber gloves as well as latex rubber
Durability requirement for single-use gloves
Material and testing specifications do not address viral penetration
Glove material and testing specifications do not address detection for puncture resistance by sharp objects such as needles, lances, and scalpels
Sizing criteria in specifications may not provide proper fit for all wearers
Specifications do not specify testing or labeling for shelf life or storage conditions
Standardized procedures to evaluate the effects of different disinfectants and cleaning agents on medical gloves (sterile and non-sterile)
General guidance for selection of gloves to prevent exposure via contact disease transmission mode that references available standards
Protective Apparel
Critical zone of garment is not adequately addressed but excludes cuffs, hems, and bindings
Standard test methods for penetration resistance of materials may not correlate to real-world exposures
Test methods to simulate physical stresses and pressures that might occur on protective clothing during clinical care and situations of exposure (some test methods are based primarily on visual detection of synthetic blood)

Standard test method for penetration resistance of materials using bacteriophage does not consider other surrogates to evaluate impact of virus morphology size and other factors, low viral counts in samples, or changing pressure levels
Assessment of specification for clothing for protection against chemotherapy drugs in practices involving mixing/compounding drugs, chemical sterilant and cleaning agents, contamination, and spills
Test methods to address minimum strength, tear strength, seam strength, reuse, and coverage per workplace requirements
Design specifications for neck closure, waist closure, stitching and adhesion to close easily and properly during donning, stay closed while worn, and easily and safely removing garment
Standards for healthcare ensembles to ensure protection at interface areas especially between garments (e.g., glove/gown, hood/coverall interface)
Requirement for testing after thermal, chemical, or physical stresses (e.g., exposures, laundering, sterilization)
Means to determine garment shelf life and labeling as appropriate (Note: AAMI PB70:2022 requires expiration date label)

Respiratory Protection. Respiratory protection actions in this category include research on authentication that could be built into a respirator to deter counterfeiting and deciding the status of the Barrier Face Covering (BFC) as a separate category of respiratory protective device. The BFC standard (ASTM F3502) was developed by ASTM in response to the COVID-19 emergency as a device for use by workers and the public but is not an approved NIOSH respirator. The Task Group recommended evaluation of whether an enhanced BFC could be incorporated into occupational respiratory protection or provide a template for a device for the public, and what level of government acceptance is appropriate.

Eye and Face Protection. There are numerous recommendations for updates to the ANSI eye and face protection standards. ANSI/ISEA Z87.1 is the standard occupational and educational eye and face protection, and ANSI/ISEA Z87.62 was developed as a standard for protection against exposure to blood and bodily fluids. The Task Group recommended addition of criteria assessing protection against other body fluids, methods to assess comfort and wearability, a test to evaluate fogging while in use, and improved definition of characteristics needed for eye and face protective devices used in healthcare. Guidelines for cleaning and disinfection as well as guidelines for hazard assessment, use, and care to prevent infection from different disease transmission modes are appropriate for development as OSHA standards.

Hand Protection. Numerous issues regarding gloves were identified in phase 1 and most are addressed in this category. One issue pertinent to standards development is that many standards and tests for glove materials do not address the whole glove. There are existing ASTM, ANSI, NFPA, and ISO standards and test methods for gloves, so this issue may be addressed by revising existing standards or developing new ones. Other recommendations address test methods for physical properties, durability, viral penetration, and puncture resistance.

Standardized sizing criteria are recommended to help ensure better fit. Testing and labeling for shelf life and storage conditions may require more research to test aging of materials and construction. The effect of disinfectant and cleaning agents on medical glove performance could be addressed in guidance or incorporated into standards. The Task Group acknowledged that new guidance on selection of gloves that references standards cannot be completed until product standards for gloves are available.

Protective Apparel. Protective apparel standards actions in Priority 2 include additional test method improvements as well as revisions to product standards to enhance usability and reliability. Recommended test method revisions would seek to evaluate performance of garments in real-world exposures to virus, chemotherapy drugs and bodily fluids, as well as tests for tear and seam strength and testing of garments after exposure, laundering, or sterilization. Design criteria could address critical protection zones, closures, and dermal exposure including protection at interface areas between different items of apparel. Labeling requirements could include garment shelf life determined by aging tests.

Priority 3 Gaps and Needs

These require either standards actions that will provide a minimal improvement to health and safety outcomes and reduce some standards gaps when fully implemented or changes in policy. No time frame is included in this category; the schedule for completion will be determined by the applicable agency or SDO.

Respiratory Protection
Decision on whether flammability testing is necessary and appropriate for respirators used in healthcare
Determine whether any NIOSH Approved air-purifying respirator is appropriate for use in healthcare settings
Determine whether FDA clearance should involve more robust conformity assessment
Biocompatibility testing for all FFRs and masks
Eye and Face Protection
Criteria that relate to disposable products
Hand Protection
Testing standard for resistance to chemotherapy only allows for evaluation of seven chemotherapy drugs
Specifications do not address breathability and moisture absorption of glove materials
OSHA standards for hand protection provide very general criteria, with no requirements specific to healthcare gloves
Protective Apparel
Test methods that can test thick materials or materials with inner linings
Standards for protection against bloodborne pathogens specifically address HBV, HCV, and HIV but are unclear as to their protection from other types of pathogens

Determination of whether FDA clearance should require more rigorous conformity assessment
Packaging instructions so that barrier performance level and size are visible; garments are easy to unpack and unfold without tearing
Supply Chain Gaps
Acceptability of products meeting non-U.S. standards
Pathway to approval and acceptance of PPE manufactured by 3D printing

Respiratory Protection. In this category, respiratory protection actions are mostly recommendations for research and policy decisions. Flammability testing is required for surgical N95s, but current NIOSH Approved respirators all meet Consumer Product Safety Commission (CPSC) flammability requirements. Determining whether to eliminate the requirement for this testing would hinge on research on the flammability risk in healthcare settings. Similarly, biocompatibility testing is required for surgical N95s, and research would determine if this testing is necessary for other classes of respirators.

OSHA accepts the use of any NIOSH Approved air-purifying respirator (APR) in healthcare workplaces, but only surgical N95 FFRs are acceptable to FDA. However, FDA, NIOSH, and OSHA believe that improving clarity in the marketplace concerning the use of NIOSH Approved APRs (that will not require new or revised/updated existing standards) would have a major positive impact on improving the protection of healthcare workers from airborne hazards including infectious diseases, while not compromising worker or patient safety.

Eye and Face Protection. The gap identifying a need for criteria that apply to disposable eye and face protection devices applies only to products such as face shields that do not meet ANSI standards. OSHA could include these criteria in 29 CFR 1910.130 or a healthcare standard.

Hand Protection. Recommendations for glove standards actions in this category include determining the efficacy of the testing standard for chemotherapy drugs against a broader range of drugs, specifications for breathability and moisture absorption, and revision of OSHA glove standards (29 CFR 1910.138) to include requirements specific to healthcare gloves. This could also be covered in an OSHA infectious disease or healthcare standard.

Protective Apparel. Actions recommended for protective apparel include test procedures that can test thick materials or materials with inner linings and assurance that test procedures to measure protection against bloodborne pathogens can be used for a broad range of viral hazards. Packaging instructions for garments should clearly show the barrier performance level and size, and provide for easy unpacking without risk of tearing.

Supply Chain. This priority category includes two additional supply chain gaps that will require research and policy decisions. The first is whether PPE that meets non-U.S. standards can be acceptable to OSHA. Mapping PPE standards and approvals globally to determine equivalence to U.S. requirements could ease pressure on the supply chain in emergencies.

During the COVID-19 emergency, a community of makers emerged, designing respiratory protection products and producing them using 3D printers. Conformity assessment for PPE is based on evaluation of design and manufacturing processes that ensure consistent production and quality. Research is needed to determine if there is a path to approval for respirators or other PPE produced by additive manufacturing or other innovative processes.

While national efforts associated with maintaining a domestic manufacturing capacity are outside the scope of the PPE Standardization Task Group, the Task Group discussed the importance of maintaining the domestic manufacturing capacity that the federal government funded during the COVID-19 pandemic to combat continued reliance on imported PPE. These efforts should be prioritized through the HHS Supply Chain Resilience and Shortage Coordinator.

Task Group Recommendations for Implementation

The actions envisioned in this report to address PPE standardization gaps and needs will require a national concerted effort involving the private sector, standards organizations, and government. Standards priorities will not be accomplished by a single entity, nor by multiple entities working independently. Each entity has a specific role to play, and coordination among them is critical. Government agencies can encourage, provide expertise, incentivize, and coordinate as necessary the development of consensus standards that meet public needs; consensus standards developers can encourage government acceptance and use of their standards to ensure widespread adoption; and consumers (i.e., users) of PPE must participate in the development process to ensure that the standards developed address protection needs in a manner that enable effective use.

Participation in standards development by all affected parties including product suppliers, users, public officials, and subject matter experts is essential to ensure the standards' use and effectiveness. Government can and should support, encourage, and incentivize development priorities. The government should provide resources such as member representation, leadership, research, scientific expertise, and support for the validation of respective standards and test methods, as deemed appropriate by the agency or agencies involved. Guidance for Federal departments and agencies can be found in a memorandum "Principles of Federal Engagement in Standards Activities to Address National Priorities," issued jointly by the White House Office of Science and Technology Policy, the Office of Management and Budget, and the United States Trade Representative in 2012.[10]

Throughout the task detailed herein, the Task Group recognized the need for effective national leadership, resources, and coordination to ensure that standards priorities are addressed systematically and in a timely fashion. Approaches for this coordination varied from the creation of a single government coordinating agency with effective oversight in the development,

[10] https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf

approval, and use of PPE to reliance on marketplace-driven approaches. Agencies with occupational safety and health expertise, including NIOSH and OSHA, must play a key role in inter-agency decision making on PPE development, approval, and use. Resources are required to initiate and sustain development enterprise on priorities, and effective coordination among key standards development participants is essential for priorities to be addressed.

The PPE Standardization Task Group believes the federal government can take a leading role in achieving the standardization goals of the National Strategy. To this end, it is recommended that HHS works with relevant federal and non-governmental partners to develop a strategy to support the recommendations presented in this report. Implementation of these recommendations will require leadership, resources, expertise and incentives, and where necessary coordination of the highest priority developments in a national effort involving the following:

- Government entities at all levels with responsibility for:
    - health and safety research and regulation
    - standards and conformity assessment
    - public health communications
    - emergency preparedness and response
    - production, stockpiling, and distribution
- Standards developing organizations for healthcare PPE
- Hospital administrators
- Healthcare professionals
- PPE manufacturers and distributors
- Test labs and conformity assessment bodies
- Labor unions and worker advocacy groups
- Occupational health and safety organizations
- Medical, nursing, and public health schools

HHS, with support from partners, can take a leading role in achieving the standardization goals of the National Strategy by identifying and establishing a national coordinating entity charged with the following:

- Holding public meetings to socialize the prioritized standards actions;
- Coordinating the activities of government and private sector entities addressing the standards actions;
- Establishing the timetables for the standards actions including the milestones and criteria for success; and
- Defining a mechanism for the continuous monitoring of the progress on the standards actions.

Progress reports should be reviewed annually, and the gaps and tables should be amended as necessary.

The Task Group recommends that all SDOs developing standards for PPE be encouraged to adopt the General Principles for Development of PPE Standards and Standardization found in Table 2 of this report.

Regarding national healthcare, consistent support and engagement from the healthcare community—technical, organizational, and financial—are essential to ensure that the standards emerging from this effort are adopted and put to use.

To this end, the Task Group encourages the healthcare industry to consider establishing a Standards Board to coordinate PPE standardization for healthcare workers. This could be a membership body or a consortium of industry associations, professional societies, government agencies at all levels, labor and worker advocates, and standards organizations. The Standards Board could identify appropriate product standards, specifications, and test methods for various types of PPE based on the hazard, risk, and protection needed. It could analyze existing standards as well as areas in which new standards are needed and communicate its findings to SDOs. It could inform the industry of opportunities to participate in standards development. Ultimately, the Standards Board could support the development of a comprehensive Healthcare Worker Protection Code incorporating these standards. Committee members expressed the importance of labor unions and other end users providing an equal, representative part of such a decision body to be consistent with other organizations in this space.

The Task Group encourages the healthcare industry to consider developing a Healthcare Worker Protection Code, incorporating existing and new standards, and addressing work practices and PPE. This could be a voluntary code suitable for adoption by OSHA, state OSHAs, licensing boards, insurers, and other entities having authority over healthcare workplaces. This would require identifying an appropriate SDO to develop the code.

The Task Group recognizes that there are potential barriers and obstacles to achieving the goals outlined in this report. For government entities, these include securing funding for multi-year projects, regulatory restrictions and limitations, and structural barriers to interagency actions. In light of the U.S. Supreme Court decision reversing the Chevron doctrine[11], Federal government departments and agencies may have to ensure that actions are explicitly supported by legislative authorization or seek Congressional approval for additional actions. Further, SDOs and other private sector participants must ensure that their organizational structures and financial and human resources are adequate and able to take on new projects. Suppliers, users, and regulators must adopt the standards developed so that products meeting these standards will penetrate the markets for PPE.

[11] *Loper Bright Enterprises et al. v. Raimondo, Secretary of Commerce, et al.,* accessed at https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf

Whether it is another pandemic, an extreme wildfire season, or some other unforeseen emergency, the nation must be able to protect its essential workers and members of the public from threats to their health and safety. A reliable, sufficient, and accessible supply of adequate personal protective equipment is essential to success in meeting this goal.

Funding and implementing the PPE standards actions identified in this report are fundamental to achieving a resilient supply chain for these products.

APPENDIX A. PRIORITY ACTIONS TO ADDRESS PPE STANDARDS GAPS AND NEEDS

This appendix contains tables showing all the standardization gaps and needs identified by the PPE Standardization Task Group. They are organized by type of PPE and hazard:

Table A1	Respiratory Protection (respirators, medical masks and respirators or masks for the public)
Table A2	Eye and Face Protection (goggles, face shields, spectacles)
Table A3	Hand Protection
Table A4	Protective Apparel (including gowns, drapes, coveralls, and other apparel)
Table A5	PPE Supply Chain Gaps and Needs

Within each table the gaps/needs are sorted by attribute and by priority within each attribute. Not all attributes are applicable to every table.

Design/performance for healthcare or public use

Fit and sizing

Comfort and wearability

Compatibility and interface

Selection, use, and care

Shelf life

Packaging and labeling

PPE purchasing and inventory management

PPE availability

Key to the Tables

Gap/Need. These are the gaps and needs identified by the PPE Standardization Task Group. They do not recommend specific standards actions.

Standard. This column shows existing standards applicable to the identified gap/need. It may also indicate the need for new standards or guidance.

Type. This column shows a numeric code to indicate the type of standards action or actions that could fill the identified gap. The following codes are used:

1 Product standard (worker or public). This can be a whole product standard, a specification, or a test method used in a standard.

2 Program/process standard (hazard identification and PPE selection, use, training, care, maintenance, and disposal).

3 Information and guidance, education of workers or the public (may not be standards).

4 Conformity assessment standards and requirements.

5 Regulations, codes, or policy decisions.

Priority. This is the priority number assigned by the task group to standards actions to fill each gap/need. The following numbers are used:

1A Standards actions that will provide maximum health and safety outcomes and eliminate a substantial gap when fully implemented and can be completed in 1 year or less. This assumes the knowledge and technology are available and there is an SDO capable of undertaking the task.

1B Standards actions that will provide maximum health and safety outcomes and eliminate a substantial gap when fully implemented and can be completed in 1to 3 years. Some additional research may be required, and an SDO may have to be identified.

1C Standards actions that will provide maximum health and safety outcomes and eliminate a substantial gap when fully implemented and will require more than 3 years for completion. Additional research will likely be needed and an SDO may have to be identified.

2 Standards actions that will provide a significant level of health and safety outcomes and significantly reduce important gaps when fully implemented.

3 Standards actions that will provide only a minimal improvement to health and safety outcomes and reduce some standards gaps when fully implemented.

Rationale. This column contains text with additional information about the gap/need, and potential standards actions were identified by the Task Group.

Table A1. Respiratory Protection Gaps and Needs

Gap/Need	Standard	Type	Priority	Rationale
Design/Performance for Healthcare or Public Use				
Standard to define levels of medical mask performance and limitations in wearing these products (i.e., source control devices vs RPD)	New standard or revision of ASTM 2100	1	1A	A new or updated standard is necessary to determine how well medical masks worn by healthcare workers protect patients against aerosols. The necessary research is sufficient to produce a standard. There are many reasons improved medical mask standards are needed. A few are: (1) Current standards do not assess total outward leakage (through the filter and around the facepiece); (2) While a standard exists, there is a significant lack of clarity and scientific understanding about their purpose in a range of medical settings; (3) There is confusion about their ability to protect the wearer from splashes and sprays. Scientific studies of mask efficacy do not support their original purpose for preventing surgical wound infection rates. ASTM plans to update ASTM F2100 to make it a performance standard for medical masks. ASTM 2100 will be leveraged when updated. Current medical masks can protect the wearer against droplets, and a standard exists.

Gap/Need	Standard	Type	Priority	Rationale
Fluid resistance requirement for air-purifying respirators and masks used in healthcare	42 CFR 84 FDA requirements ASTM 1862	1,2,3	1B (policy)	OSHA requires face shields be worn if fluid resistance is required. Some NIOSH Approved respirators offer splash protection because they include a full facepiece or hood. Further research and policy decisions are needed to determine if N95 FFRs that do not meet the current ASTM fluid resistance requirements can be used in non-surgical healthcare applications. Only surgical N95s are required to meet the current fluid resistance requirements. A fluid resistance requirement should be based on the hazard and requires further investigation since design changes to masks and FFRs to provide fluid resistance may impact breathing resistance and comfort. This is more of a policy decision regarding where certain products can be used rather than the need for a new standard. The importance of this policy needs to be revisited and determined in the context of healthcare settings. Once the policy decision is made, the test rigor could be assessed. (Development of a standard to improve test rigor would be Priority 2). If a user is worried about fluid resistance it is the face that should be protected, so a faceshield should be used.
Product standard for a mask and/or respirator for the public including children and those with physical or cognitive disabilities	New standard or ASTM F3407	1	1C	There is a need for a standard along with an organization that would recognize and promote such a standard. Other than NIOSH Approved FFRs and medical masks, there is nothing else. There is sufficient information to create a standard without much if any research. Comfort will be a critical element of any standard. Research may be needed to determine if anthropometric data used to represent target populations is adequate and appropriate, especially considering minorities and children. Research is underway to better characterize facial dimensions and shapes. This research is aimed at producing data that can be adopted in ASTM F3407 and other standards. (There is an ASTM Work Item for a General Public Respirator that includes children.) See also discussion of sizing guidelines.

Gap/Need	Standard	Type	Priority	Rationale
Evaluate the need for anti-counterfeiting technology in healthcare respirators and develop standards	42 CFR or new standard	1,5	2	There is a need to prevent counterfeiting as experienced during the COVID-19 pandemic. A standard method for evaluating anti-counterfeiting technology would be useful. Questions include what type of authentication can be built into a respirator, whether manufacturers can incorporate this technology into their products and whether NIOSH should require this technology in 42 CFR 84.
Determine the viability and applicability of the ASTM Barrier Face Covering as a separate category of respiratory protective device, including its intended use and regulatory status	ASTM 3502, OSHA, CDC/NIOSH, FDA, EPA	1,3,5	2	The BFC is its own category with a standard. It could be part of NIOSH approval as a separate device, it could be cleared by FDA for healthcare use if it meets current requirements, or it could remain a product evaluated to a consensus standard. The current BFC standard was not developed for the purpose of respiratory protection. An enhanced performance BFC might be appropriate in some workplace settings during some scenarios but would involve updating the ASTM BFC standard to require respirator fit capability testing and/or total outward leakage assessment on a panel of human subjects. This needs more discussion, however—what would be the purpose for such BFCs, who would wear them, what else would be required to ensure the wearer (or those around the wearer) is protected? There are no standards for public masks/respirators but if there becomes one, it might meet the standard. Clarifying the value of BFCs as public masks and within regulatory frameworks is important preparation for future pandemics.
Design and performance specifications for new respirators rugged enough for extended use in EMS or healthcare	42 CFR 84 NFPA standard	1	3	Elastomeric respirators can provide protection for extended use and are sufficiently rugged for EMS and healthcare use as noted in the 2019 NASEM report on elastomeric respirators in healthcare. If a new type of respirator is needed for extended use and rugged environments, additional research may be needed. Current standards to evaluate communications could be used as well as existing decontamination procedures.

Gap/Need	Standard	Type	Priority	Rationale
Decision on whether flammability testing is necessary and appropriate for respirators used in healthcare	42 CFR 84 FDA requirements 14 CFR 1610	1,2,5	3	Research has shown that current NIOSH Approved FFRs meet CPSC flammability requirements, even though flammability testing is only required for surgical N95s. The policy decision on whether to add or eliminate flammability testing for FFRs in the future would depend on whether different materials and filter media are used in constructing FFRs, research on whether there is a flammability risk in healthcare other than certain surgical procedures, and OSHA regulations and guidance. Note: Surgical 95 respirators per an FDA/NIOSH MOU are required to meet flammability requirements.
Determine whether any NIOSH Approved air-purifying respirator is appropriate for use in healthcare settings	FDA, CDC/NIOSH, OSHA	4,5	3	Existing NIOSH APRs are acceptable to OSHA for use in healthcare settings when used in compliance with 29 CFR 1910.134. This includes PAPRs as well as FFRs and elastomerics. However, only surgical N95 FFRs have been acceptable to FDA in the absence of the EUA as they have the fluid resistance, flammability, and biocompatibility requirements. There is no need for a separate set of standards for approval or use of respirators in healthcare settings. However, FDA, NIOSH, and OSHA believe that providing clarity in the marketplace concerning the use of NIOSH Approved APRs (that will not require new or revised/updated existing standards) would have a major positive impact on improving the protection of healthcare workers from airborne hazards, including infectious diseases, while not compromising patient or worker safety. It may be worth exploring exhalation valve outward leakage and further clarification on the acceptable use of PAPRs.
Determine whether FDA clearance should involve more robust conformity assessment	FDA	4,5	3	Respirators with fluid resistance, flammability, and biocompatibility requirements are approved by NIOSH and have robust CA. Unless there is a determination that medical masks protect wearer or patients from aerosols (not droplets), there is no need for conformity assessment beyond NIOSH approval.

Gap/Need	Standard	Type	Priority	Rationale
Fit/Sizing				
Fit capability requirement in the NIOSH respirator approval program for half facepiece respirators	42 CFR 84, ASTM 3407	1,4	1A	The ASTM 3407 Test Method was developed to demonstrate that a respirator will fit a proportion of the population prior to approval. Incorporating this test method into the NIOSH respirator approval process as is or with a statement of differences could improve the likelihood that a respirator will fit a proportion of the population. However, the current ASTM standard may not lead to a maximum health and safety outcome. Additional evaluation (e.g., interlaboratory comparison) could improve the utility of fit capability. The levels of acceptable performance achieved when tested in accordance with a half facepiece fit test standard need to be clearly identified. For example, consideration could be given to an elastomeric half facepiece achieving a high level of performance being approved to a different level than a non-elastomeric with a significantly lower level of performance.
Method for measuring outward leakage of respirators and masks	42 CFR 84, ASTM standards	1	1B	Currently no standard exists to evaluate the outward leakage of masks and respirators. This is a critically important issue especially regarding respirators with exhalation valves for healthcare and the protection to patients that masks offer. An ASTM standard is in development.
Test methods to specify head attachment strap tension and durability for respirators and masks	42 CFR 84 new mask test method	1	1B	Test methods exist in other countries (e.g. CSA Z94.4.1, EN 140) for tension and would impact comfort and fit. The crown arrangement for head straps has been a major improvement for keeping straps in place during use. These methods should accommodate future design innovations. Durability performance requirements should be established prior to developing test methods.

Gap/Need	Standard	Type	Priority	Rationale
More practical fit-testing methods, taking advantage of technologies such as facial recognition and AI, to ensure exposure reductions during respirator use	OSHA 29 CFR 1910.134 new consensus standard	2	1C	Technology may not be advanced enough to develop more practical and simple solutions (e.g., table-top fit testing unit). "Practical" is interpreted to mean an objective test that does not require expensive equipment. Even if the research were robust, finding an SDO and developing a consensus standard that can be adopted by OSHA within 3 years is an aggressive goal. New fit-testing methods and assessment methods may go hand in hand with new respirator designs as well as the potential for additive manufacturing to produce personalized respirators.
Method for assessing fit of masks and/or respirators for individuals without respiratory protection programs and the public including children and those with physical and cognitive disabilities	New standard or ASTM F3407	1	1C	Same issue as above only for the public, which allows more flexibility in developing methods. The NIOSH Fit Challenge and development of a mobile app could lead to innovative fit assessment solutions. The NIOSH Respirator Fit Challenge is expected to yield data important to assess fit.
Sizing guidelines for respirators and masks	42 CFR 84 ASTM mask standards new standard	1,5	1C	Sizing guidelines would be helpful to the public and workers when initially selecting respirators. This guidance might more easily allow users to find alternative respirators when currently used devices are unavailable. This is dependent on the development of additional anthropometric data. It should be noted, however, that sizing can be impacted by design. Equitable protection is key to ensuring everyone's safety. BLS data representing gender, race, and ethnicity in the working population underscore the importance of these guidelines.

Gap/Need	Standard	Type	Priority	Rationale
Comfort/Wearability				
New respirator designs or methods to allow for use by wearers with facial hair, especially for healthcare	42 CFR 84	1,3	1B	There are innovative designs that could preclude fit testing and allow for facial hair. These should be encouraged. "Beard bands" have been used to sustain a seal between the respirator and the wearer. Assessments need to be conducted to validate the performance of beard bands.
Reduced breathing resistance requirements for inhalation and exhalation for some work environments and tasks, such as healthcare and occupations requiring extended wear times	42 CFR 84 OSHA standards	1,2,5	1B	Filter technology and respirator design already can greatly reduce breathing resistance and standards should be substantially lower for comfort and to help those with breathing issues. ISO and CSA have addressed this issue in standards. Breathing resistance requirements and levels could be incorporated in a consensus standard or guidance practices.
Requirements and methods to objectively evaluate the comfort of respirators and guidelines for their use	new test method 42 CFR 84	1,2,3	1C	The physiological issues are probably known but linking other issues such as head straps and sealing surfaces to comfort is not well-established. ISO has produced extensive data on comfort factors. A comfort assessment tool (e.g.; R-COMFI) is available and could be used as the basis for a standard.
Test methods to evaluate verbal communications when wearing respirators or masks	42 CFR 84 ASTM mask standards	1	1C	Communications while wearing a respirator is highly important. An interruption in respiratory protection to enable talking (taking off the respirator) is a serious compromise in worker health and safety. There appear to be several approaches for determining speech intelligibility. This issue would benefit from a work group with expertise to review methods and propose a standard method. Speech intelligibility is a requirement for some respirators, but not EHMRs and FFRs. Additional research could determine the appropriateness of the current test method.

Gap/Need	Standard	Type	Priority	Rationale
Biocompatibility testing for all FFRs and masks	42 CFR 84 ASTM mask standards	1	3	Test methods already exist, and testing is a requirement of FDA for surgical N95s. Further research is required to determine if it is necessary for all classes of FFRs and other types of respirators. NIOSH general construction requirements are applicable to all NIOSH approved respirators. There have been no reports to NIOSH regarding negative experiences of wearing respirators. The reports associated with long-term wear of FFRs have not been linked to biocompatibility, but the impacts of long-term wear.
Selection, use, and care				
Requirements for demonstrating the efficacy of manufacturer instructions for cleaning, disinfection, and decontamination	All standards	1,3	1B	These requirements exist for other medical devices. Currently the manufacturer determines the requirements for cleaning and decontaminating its models. The level of detail provided by manufacturers for cleaning varies greatly. Determination regarding the approach to meeting decontamination and cleaning requirements is needed.
Standard for hazard assessment, selection, use, care, and maintenance of respirators to protect against infectious agents in the workplace	New standards, regulation	2,3,5	1B	There is already a standard in California for infectious agents that partially addresses this need. OSHA has had an infectious disease standard on the agenda for several years. Such a standard fills this gap. In many workplace settings there may not be a respiratory protection program in place.

Gap/Need	Standard	Type	Priority	Rationale
Guidance for inhalation hazard assessment, selection, use, care, and maintenance of masks and/or respirators for the public including children and those with physical and cognitive disabilities	New guidance	2,3,5	1B	The hazard assessment for inhalation hazards for workers and the public outside of healthcare was published by CDC for COVID-19 during the pandemic. CDC has current guidance posted on the website which can serve as a starting point. The guidance can be revised as new information becomes available and new technology for the public is developed (1C).
Guidance for hazard assessment, selection, use, and care of respirators used for protection against wildfire smoke and other hazards such as mold and air pollution	New OSHA standard, regulation, guidance	2,3,5	1C	EPA has a Wildfire Smoke Guide and risk assessment method. There are needs for workers with RPPs, workers without RPPs, and the public including children and those with disabilities. CDC has current general guidance posted on the website which can serve as a starting point. The guidance can be revised as new information becomes available.
Standard for hazard assessment, selection, use, and care of respirators used by workers not covered by an OSHA-compliant respiratory protection program	New standard, regulation	2,5	1C	The care and use of respirators can be the same for other workers covered by OSHA. However, the hazard assessment and risk assessment are difficult. Control banding should be considered. The recent NASEM report on workers not covered by OSHA can inform the development of this standard.

Gap/Need	Standard	Type	Priority	Rationale
Shelf Life				
Respirator and mask standards in some cases lack requirements to provide expiration date and methods to perform accelerated aging tests to evaluate shelf life	42 CFR 84 New test method	1	1C	This is an important issue if stockpiling products long-term rather than vendor-managed inventory that is routinely rotated. There are methods for determining aging for other products. Policies on how decision making in government and the private sector should transpire when stockpiles are past expiration dates but a pandemic still rages are critically important. Additionally, alternative approaches to managing stockpiles should be considered. (1C)

Table A2. Eye and Face Protection Gaps and Needs

Gap/Need	Standard	Type	Priority	Rationale
Design/Performance for Healthcare				
Existing OSHA standards include outdated references to Z87.1 and no reference to Z87.62	29 CFR 1910.133	5	1A	OSHA periodically updates its standards using direct final rulemaking to update consensus standards incorporated by reference into the regulation. This is a needed update given the ANSI standards referenced in 1910.133 are from 1989, 2003, and 2010.
Improved definition of characteristics needed for glasses, goggles and face shields used in healthcare	ANSI standards	1	2	ANSI Z87.62 is up for revision in 2026. May be more appropriate for an OSHA standard. This need may take more than 3 years to fill, but is important and must include consideration of the entire range of healthcare workers from the surgical suite to nursing homes and home healthcare workers.
Criteria for assessing protection against aerosols and infectious agents other than blood and bodily fluids	ANST standards	1	2	The Z87 committee acknowledges that this is an unresolved issue and may be considered in revisions to ANSI/ISEA Z87.62. This should be a major priority because it has not gotten the attention that protection from fluids has received, yet airborne infectious agents can be a greater hazard. Criteria for how protection against aerosols and infectious agents should be measured can and should be developed. The standard is up for revision in 2026.
Surveillance to assess the protection effectiveness of glasses, goggles and face shields used in healthcare and the standards to which they are made	conformity assessment	4	2	This gap implies the need for field work in healthcare facilities to assess effectiveness of eye protection as it is being used. This is important because efficacy testing is often done under laboratory and ideal conditions, not field conditions. This surveillance should extend to all types of healthcare, not just hospitals. Nursing home workers had markedly different experiences with availability and type of eye protection than hospital workers during the pandemic. Manufacturers conduct market surveillance on their products, and certification organizations may provide ongoing surveillance of certified products, but there is no requirement for third-party certification of eyewear in OSHA or other standards.

Gap/Need	Standard	Type	Priority	Rationale
Comfort/Wearability				
Methods to assess comfort and wearability	New criteria and test methods	1,2,5	2	ANSI Z87.62 includes a requirement that eyewear not have projections, sharp edges or defects that could cause discomfort or injury in use. Standard up for revision in 2026. In healthcare environments, eye protection may be required for extended periods, may be cumbersome and may interfere with other PPE so new criteria and concomitant test methods are needed. This is also a concern for public use of eye protection.
Method to evaluate fogging while in use	new test method	1	2	There is a test in the Z87 standards to evaluate the ability of a lens to resist fogging, but no tests for evaluating eyewear in use. Fogging is exacerbated by wearing respiratory protection, but this may be a function of improper respirator fit. Any new test method needs to replicate what is experienced in the field. This is especially important in healthcare settings.
Selection, use, and care				
Guidance for cleaning and disinfecting for product reuse	ANSI standards	1	2	ANSI standards reference using manufacturers' instructions for cleaning and disinfecting, with Z87.62 also referencing HICPAC guidelines. There is no use and care standard. This requirement is most appropriate for an OSHA healthcare or PPE standard.
OSHA standards do not address hazard assessment, selection, use, and care of eye and face protective devices used to prevent exposure via different disease transmission modes	New standard OSHA standard	2,5	2	The OSHA standard 1910.133 for eye and face protection is for "hazards from flying particles, molten metal, liquid chemicals, acids or caustic liquids, chemical gases or vapors, or potentially injurious light radiation." The standard could be revised to address disease transmission modes, but it is an OSHA decision on whether to develop these standards as part of a healthcare worker protection standard or as part of the PPE standards.
Criteria that relate to disposable products	OSHA standard	2,5	3	Disposable products are most likely face shields and probably do not meet the Z87 requirements. Again, this could be part of an OSHA healthcare standard or the PPE standard.

Table A3. Hand Protection Gaps and Needs

Gap/Need	Standard	Type	Priority	Rationale
Design/Performance for Healthcare				
Material and testing specifications for medical gloves do not address whole glove evaluation	New or revised standards	1	2	Not clear whether this suggests new standards or revisions to test methods in existing standards to test the glove rather than a sample of material. There are numerous ASTM standards for gloves and materials, NFPA standards for gloves for emergency medical operations, and an ANSI standard that provides performance ratings for gloves tested to ASTM and ISO standards.
Physical property criteria (tensile strength and modulus) in surgical glove specification that accommodate nitrile rubber gloves as well as latex rubber	ASTM D3577 ASTM D3578	1	2	Latex allergies are a major issue, and standards should recognize nitrile rubber gloves. Currently, users specify "latex free" in their acquisitions.
Durability requirement for single-use gloves	ASTM specifications	1	2	Determination of whether glove standards adequately address stretching and material integrity over time.
Material and testing specifications do not address viral penetration	ASTM specifications and test methods	1	2	ASTM 1671 provides a test method for evaluating viral penetration resistance. NFPA 1999 includes viral resistance testing for EMT whole gloves. If these standards are not sufficient, additional research will have to be performed to identify challenge agents for testing.
Glove material and testing specifications do not address detection for puncture resistance by sharp objects such as needles, lances, scalpels	ASTM specifications ANSI/ISEA 105	1	2	There is a needle puncture test (ASTM F2878). ANSI/ISEA 105 includes a puncture rating scale using that test. Detection of punctures is more appropriate for a selection, use, and care standard than material and testing specifications.

Gap/Need	Standard	Type	Priority	Rationale
Testing standard for resistance to chemotherapy only allows for evaluation of seven chemotherapy drugs	ASTM D6978	1	3	ASTM D6978 includes tests to evaluate permeation of nine chemotherapy drugs, which are considered worst-case and applicable to a broad range of drugs. If these gloves are being worn for protection against other drugs (e.g., law enforcement handling of illegal drugs), their efficacy should be determined.
Fit/Sizing				
Sizing criteria in specifications may not provide proper fit for all wearers	ASTM specifications ANSI/ISEA 105	1	2	Some manufacturers offer sizing charts for their gloves, but there are no standardized uniform sizing guidelines. This could be part of a whole-glove standard.
Comfort/Wearability				
Specifications do not address breathability and moisture absorption of glove materials	ASTM specifications	1	3	Gloves used in healthcare must provide a barrier. Moisture absorption and breathability must be evaluated for whether they degrade glove performance.
Shelf Life				
Specifications do not specify testing or labeling for shelf life or storage conditions	ASTM specifications ANSI/ISEA 105	1	2	Additional research may be needed to test aging of glove materials and construction. The current glove standards for heat aging should be evaluated for their ability to predict shelf life.
Selection, use, and care				
Standardized procedures to evaluate the effects of different disinfectants and cleaning agents on medical gloves (sterile and non-sterile)	New test methods	1	2	This could be provided as guidance or incorporated in product standards.

Gap/Need	Standard	Type	Priority	Rationale
General guidance for selection of gloves to prevent exposure via contact disease transmission mode that references available standards	New standards, guidance	2,3	2	Cannot develop this guidance until product standards are available
OSHA standards for hand protection provide very general criteria, no requirements specific to healthcare gloves	29 CFR 1910.138 New OSHA standard	2,5	3	OSHA standards for gloves could be revised to include reference to existing consensus standards, and glove performance could be part of an OSHA healthcare worker standard.

Table A4. Protective Apparel Gaps and Needs

Gap/Need	Standard	Type	Priority	Rationale
Design/Performance for Healthcare				
Standard test methods for water resistance do not consider other test fluids	AATCC 42, 127	1	1A	The AATCC 127 and AATCC 42 test methods, or variants thereof, should permit and specify additional types of fluids relevant to healthcare settings. It is possible that AATCC 127 could serve as a predictive test method for quality control purposes by employing various fluid challenges that accurately represent bodily fluids.
Specifications for apparel other than gowns, including coveralls, aprons, and partial body clothing	New standards NFPA 1999	1	1B	NFPA 1999 defines barrier and physical performance specifications for some of the protective apparel items for EMS. AAMI PB70-2022 also defines liquid barrier resistance requirements for certain protective apparel items but it does not clearly address all other apparel. There is no standard that defines both barrier and (physical performance criteria physical durability, seams, etc.) for all the items including coveralls and partial body clothing.
Standard test methods using synthetic blood may not model all body fluids of interest	ASTM 1670, F1819	1	1B	Some current standards use synthetic blood, which may not represent all types of body fluids for healthcare and may be of interest depending on the types of diseases (Ebola, etc.). It may be necessary to have additional specific fluids developed to mimic the different characteristics of a variety of body fluid types. Research is being conducted to develop fluids that better represent different properties of synthetic blood (surface tension, viscosity) to replace the current synthetic blood formulation in the testing standards (ASTM F1862, ASTM F1670, ASTM F1819).

Gap/Need	Standard	Type	Priority	Rationale
Evaluation of the adequacy of sample sizes used in standard tests	Test methods	1	1B	The existing standard test methods, such as AATCC 127, AATCC 42, and ASTM F1671, typically require a very limited number of samples (only three samples) for testing. However, this may not be adequate given the variability observed in test results for protective apparel used in healthcare settings. It is essential to address this issue in the sampling requirements of specific standard specifications (such as AAMI PB70, ASTM F3352, ASTM F2407, ASTM F3267) and as part of the conformity assessment requirements.
Standard test method that requires overnight development of cultures is not suitable for rapid evaluations	ASTM F1671	1	1C	ASTM F1671 is a complex and time-consuming method, which has several elements that may impact the test results and access to testing. A long test time in combination with few qualified labs impacts the use of the test for quality control purposes. A predictive short-term test may be needed. In addition, the ASTM F1671 is expensive, can produce false failures or passes depending on the certain testing parameters (e.g., screen type).
Critical zone of garment is not adequately addressed but excludes cuffs, hems, bindings	AAMI PB70	1	2	The critical zone is loosely defined for gowns in AAMI PB70 but is not described for non-gown apparel. AAMI PB70 also does not address the testing of interfaces and interoperability issues. This need will be mostly addressed for related need in the entry addressing NFPA 1999.
Standard test methods for penetration resistance of materials may not correlate to real-world exposures	ASTM F1670, F1819, F1671	1	2	The current standards available to assess the penetration of body fluids through protective apparel items may not correlate to the range of real-world exposure scenarios.

Gap/Need	Standard	Type	Priority	Rationale
Test methods to simulate physical stresses and pressures that might occur on protective clothing during clinical care and situations of exposure (some test methods are based primarily on visual detection of synthetic blood)	Test methods	1	2	Same as related gaps/needs above. Research studies are required to investigate the physical stresses and pressures experienced by protective clothing during clinical care and exposure situations. There is a need for standards that simulate these exposure scenarios to test the penetration.
Standard test method for penetration resistance of materials using bacteriophage does not consider other surrogates to evaluate impact of virus morphology size and other factors, low viral counts in samples, or changing pressure levels	ASTM F1671	1	2	This need is related to the gap/need in the previous row. ASTM F1671 uses a bacteriophage—Phi-X174—that has nearly spherical morphology similar to HIV, Hepatitis B, and Hepatitis C. At 27 nm in diameter, it is similar in size and shape to Hepatitis C (30 nm in diameter), which is the smallest-known bloodborne viral pathogen. Further, testing as performed at a single pressure of 2 psi in ASTM F1671. However, it is not known how virus morphology size and other factors, low viral counts in samples, or changing pressure levels affect the penetration.
Assessment of specification for clothing for protection against chemotherapy drugs in practices involving mixing/compounding drugs, chemical sterilant and cleaning agents, contamination, and spills	ASTM F3267	1	2	ASTM F3267 tests material and seams for resistance to permeation by chemotherapy and other hazardous drugs, but does not address all conditions of exposure. Setting a priority requires knowing applicable products for this standard. A determination may also be needed whether other test methods, such as ASTM F739, may be relevant to non-drug material testing.

Gap/Need	Standard	Type	Priority	Rationale
Test methods that can test thick materials or materials with inner linings	Test methods	1	3	Certain reusable products and especially seamed areas are challenging to test using current standard test methods. This testing issue is not a product engineering issue, but rather a test cell design and method specification problem. There has been ongoing effort to improve the current testing cells that are currently being balloted for certain standard test methods.
Standards for protection against bloodborne pathogens specifically address HBV, HCV, and HIV but are unclear as to their protection from other types of pathogens	Standards and test methods	1	3	There is a need for research studies to understand the impact of the virus size, shape, and other characteristics on the penetration properties. Then this research needs to translate into testing standards and standard specifications. It is unclear if current test methods can be universally used as a surrogate for the range of actual hazards.
Determination of whether FDA clearance should involve more robust conformity assessment	FDA	4,5	3	Very few apparel products, other than NFPA compliant garments, hoods, and footwear covers have highly defined conformity assessment criteria. ASTM F2407 and F3352 offer a low-level, principally manufacturer declaration form of conformity assessment. An investigation is needed to incorporate commensurate levels of conformity assessment for protective apparel.
Fit/Sizing				
Test methods to address minimum strength, tear strength, seam strength, reuse, and coverage per workplace requirements	All standards	1	2	ASTM F3352 and ASTM F2407 address these minimum durability, reuse, and coverage requirements for surgical and isolation gowns. However, there is a need to develop these requirements for other protective apparel items used in healthcare. Adequately addressing this gap may also require development of test methods to evaluate use of garments in simulated work environments.

Gap/Need	Standard	Type	Priority	Rationale
Comfort/Wearability				
Design specifications for neck closure, waist closure, stitching and adhesion to close easily and properly during donning, stay closed while worn, and easily and safely remove garment	AAMI PB70	1	2	Current standards do not include design specifications for closures. Self-contamination while doffing is a challenge, especially with the desire to increase the use of reusable HCTs for PPE.
Interface/interoperability				
Standards for healthcare ensembles to ensure protection at interface areas especially between garments—e.g. glove/gown, hood/coverall interface	New standard NFPA 1999	1	2	Research has been conducted at NIOSH. A standard test method that assesses the fluid leakage at the glove and protective clothing interface could probably be completed within 3 years. There is also the potential for applying the NFPA 1999 procedures for evaluating overall integrity of ensembles or garments using ASTM F1359 with or without modifications.
Selection, use, and care				
OSHA bloodborne pathogen standard does not reference PPE standards for disease transmission modes (i.e., contact, droplet, and aerosol)—PPE is considered acceptable if it prevents exposure to blood and other potentially infectious fluids	29 CFR 1910.1030	2,5	1A	Other disease transmission modes could be outside the scope of the bloodborne pathogen standard but still need to be accounted for in the development of clothing specifications where healthcare workers can still be exposed to pathogens in droplet and aerosol transmission modes. An OSHA healthcare worker protection standard or infectious diseases standard should reference applicable PPE standards.

Gap/Need	Standard	Type	Priority	Rationale
User guidance for inspection to identify tears, rips, seam failure, worn-out product	New standard, guidance	2,3	1C	Standard or guidelines are needed to provide basic steps for inspection and/or testing as may be applied to reusable items of protective apparel. Manufacturer instructions may not be sufficiently detailed in providing this information to end users. With the increasing focus on the use of reusable healthcare textiles for PPE in healthcare, it is important to address this gap to ensure the safety of the healthcare workers and the patient when the PPE is laundered and reused.
Surveillance to assess the protection effectiveness of protective apparel products and the standards to which they are made	conformity assessment	4	1C	This gap implies the need for field work in healthcare facilities to assess effectiveness of apparel as it is being used. This is important because efficacy testing is often done under laboratory and ideal conditions, not field conditions. This surveillance should extend to all types of healthcare, not just hospitals. Nursing home workers had markedly different experiences with availability and type of eye protection than hospital workers during the pandemic. Manufacturers conduct market surveillance on their products, and certification organizations may provide ongoing surveillance of certified products, but there is no requirement for third-party certification of any apparel other than protective garments meeting the NFPA 1999 standard. As of the end of March 2024, CMS has established a statute for enhanced barrier requirements in long term care facilities. As with the User Guidance Gap, this is important with the increasing focus on the use of reusable healthcare textiles for PPE in healthcare. When the reusables are laundered, their protective effectiveness must be assessed before they are put back into circulation for issue.
Requirement for testing after thermal, chemical, or physical stresses (e.g., exposures, laundering, sterilization)	New standard, guidance	2,3	2	Many test methods indicate the potential to apply different preconditions prior to evaluating barrier and other properties of protective apparel but do not offer specific recommendations on what preconditions to use. There is a need to evaluate whether existing standards include such tests.

Gap/Need	Standard	Type	Priority	Rationale
Shelf Life				
Means to determine garment shelf life and labeling as appropriate (Note: AAMI PB70:2022 requires expiration date label)	Test methods, standards	1	2	There is a need to develop accelerated aging test methods and conditions for protective apparel. Currently, the determination of shelf life is left to the discretion of manufacturers, resulting in potential variations between different manufacturers.
Packaging/labeling				
Minimum size requirements for critical zones and prominent labeling to indicate critical zone of protection	AAMI PB70	1	1B	At present, there are no minimum size requirements specified for the critical zones of protective apparel, allowing each manufacturer to determine these zones for their products. This lack of standardization makes it difficult for end users to discern the tested critical zone area. AAMI PB70 should establish minimum critical zone requirements for various types of protective apparel, and labeling should clearly indicate these critical zones.
Packaging instructions so that barrier performance level and size are visible; garments are easy to unpack and unfold without tearing	Standards	1	3	Currently, ASTM F3352 and ASTM F2407 outline specific packaging and labeling requirements, which should also be addressed in AAMI PB70. Additionally, there is a requirement for specifications facilitating the easy unpacking and unfolding of garments without tearing. Often labeling, which includes product instructions, or indications of conformance may not be on protective apparel item, making it impossible for user to determine compliance of item with standard.

Table A5. PPE Supply Chain Gaps and Needs

Gap/Need	Standard	Type	Priority	Rationale
PPE Purchasing and Inventory Management				
Standardized surveillance and monitoring system for sustainable PPE inventory management	New standard, HL7, HIPAC	2	1C	The healthcare industry could develop and adopt uniform systems that a facility could use to determine its PPE use in normal operations and emergency situations. NIOSH has sponsored research in this area with hospitals around the country. Such systems could enable establishment of baseline inventory requirements for various types of healthcare facilities and businesses to provide a cushion of PPE available in an emergency, allowing suppliers time to ramp up production to meet increased demand. It is important to have a real-time nationwide "PPE Needs and Available Inventory" Heatmap to ensure that the right protection is delivered to the right place at the right time. The need for such a system became very clear during the COVID-19 pandemic. The necessary information technology / infrastructure exists today (e.g., Uber Eats can tell us where our order is and when it will be delivered).
Standardized terminology and data format for PPE	New standard	2	1C	Common terminology and data formats are key requirements for surveillance and inventory systems. The technology and standards organizations are available. Associations of healthcare businesses at various levels (e.g. hospitals, clinics, long term care) could work with suppliers to adopt common data formats and terminology.
PPE Availability				
Acceptability of products meeting non-US standards	OSHA	1,4,5	3	PPE meeting standards from different countries may provide equivalent protection, but there is no federal surveillance or determination of the equivalency of non-U.S. standards or the adequacy of their conformity assessment. OSHA will accept the use of PPE meeting non-U.S. standards, but it is up to the employer to show that it is equivalent to the protection provided by PPE meeting standards that are referenced in the regulations. International trade agreements include provisions barring technical barriers to trade, but national health and safety standards are generally excluded, enabling countries to maintain preferences for domestic products. Mapping PPE standards and approvals globally and establishing paths to mutual acceptance could ease pressure on supply chains in emergencies.

Gap/Need	Standard	Type	Priority	Rationale
Pathway to approval and acceptance of PPE manufactured by 3D printing	New standards, guidance, and regulations	1,3,4,5	3	During the early phase of the COVID-19 pandemic, numerous designs for 3D-printed respirators were being produced and used to address shortages. While some were tested and found to perform to NIOSH specifications, the basics of quality assurance cannot be applied. Current PPE conformity assessment requires evaluation of the production process to ensure that product designs and specifications are being correctly and consistently applied. Regardless of the quality of the design, at this time there is no way to ensure that different printers, material, and process settings will produce the same results. Permitting the use of 3D-printed PPE would require new approaches to conformity assessment. More research is needed.

APPENDIX B. PPE STANDARDS AND REGULATIONS

Table B1. Standards Related to PPE Conformity Assessment

42 CFR Part 84	Respiratory Protection (NIOSH)
ANSI/ISEA 125-2021	American national standard for conformity assessment for safety and personal protective equipment
ASTM F3050-22A	Standard guide for conformity assessment of personal protective clothing and equipment
DHHS (NIOSH) Publication 2018–102	National framework for personal protective equipment conformity assessment—infrastructure

Table B2. Standards Related to Respirators and Masks

42 CFR Part 84	Approval of Respiratory Protective Devices (NIOSH)
29 CFR Part 1910.134	Respiratory Protection (OSHA)
ANSI/NFPA 1984	Respirators for wildland fire-fighting operations and wildland urban interface operations
ASTM F3387	Standard practice for respiratory protection. (This standard superseded ANSI Z88.2)
ASTM 3407	Standard test method for respirator fit capability for negative-pressure half-facepiece particulate respirators
ASTM F3502	Standard specification for barrier face coverings
ASTM F2100	Standard specification for performance of materials used in medical face masks
ASTM F2299	Test method on sub-micron particulate filtration efficiency
ASTM F1862	Test method for synthetic blood penetration of protective clothing materials

Related International/European Respirator Standards for Air-Filtering Respirators

ISO 16900—Respiratory Protective Devices—Methods of test and test equipment	
ISO 16900-1:2019	Part 1: Determination of inward leakage
ISO 16900-2:2017	Part 2: Determination of breathing resistance
ISO 16900-3:2012	Part 3: Determination of particle filter penetration
ISO 16900-7:2020	Part 7: Practical performance test methods
ISO 1600-10: 2015	Part 10: Resistance of ignition, flame, radiant heat and heat
ISO 16975—Respiratory protective devices—Selection, use and maintenance	
ISO/TS 16975-1:2016	Part 1: Establishing and implementing a respiratory protective device programme
ISO 16975-3:2017	Part 3: Fit-testing procedures
ISO/TS 16975-4:2022	Part 4: Selection and usage guideline for respiratory protective devices under pandemic/epidemic/outbreak of infectious respiratory disease
ISO 16976—Respiratory protective devices—Human factors	
ISO 16976-1:2022	Part 1: Metabolic rates and respiratory flow rates
ISO 16976-2:2022	Part 2: Anthropometrics

ISO 16976-4:2023	Part 4: Work of breathing and breathing resistance: Physiologically based limits
ISO 16976-5:2023	Part 5: Thermal effects
ISO 16976-6:2023	Part 6: Psycho-physiological effects
ISO 16976-7:2023	Part 7: Hearing and speech
ISO 16976-8:2023	Part 8: Ergonomic factors
ISO 17420-1:2021	Respiratory protective devices—Performance requirements—Part 1: General.
ISO 17420-2:2021	Respiratory protective devices—Performance requirements—Part 2: Requirements for filtering RPD
EN 140:1998/ AC:1999	Respiratory protective devices—Half masks and quarter masks—Requirements, testing, marking (revision underway)
EN 143:2021	Respiratory protective devices—Particle filters—Requirements, testing, marking
EN 149:2001 +A1:2009	Respiratory protective devices—Filtering half-masks to protect against particles—Requirements, testing, marking
EN 12941:2023	Respiratory protective devices—Powered filtering devices incorporating a loose fitting respiratory interface—Requirements, testing, marking
EN 12942:2023	Respiratory protective devices—Powered filtering devices incorporating full face masks, half masks or quarter masks—Requirements, testing, marking
EN 13274-1:2001	Respiratory protective devices—Methods of test—Part 1: Determination of inward leakage and total inward leakage (revision underway)
EN 13274-2:2019	Respiratory protective devices—Methods of test—Part 2: Practical performance tests
EN 13274-3:2001	Respiratory protective devices—Methods of test—Part 3: Determination of breathing resistance

Related International/European Medical Mask Standards

ISO 22609:2004	Clothing for protection against infectious agents—Medical face masks—Test method for resistance against penetration by synthetic blood
EN 14683:2019	Medical face masks—requirements and test methods

Related International/European Face Covering Standards

PD CEN/TS 17553:2022	Textiles and textile products—Community face coverings—Minimum requirements testing methods and use
BSI FLEX 5555	Community face coverings—specification (UK)
AFNOR SPEC S76-001	Barrier masks—Guide to minimum requirements, methods of testing making and use (France)

Table B3. Standards Related to Eye and Face Protection

29 CFR 1910.133	Eye and Face Protection (OSHA)
ANSI/ISEA Z87.1	American national standard for occupational and educational personal eye and face protection devices
ANSI/ISEA Z87.62	American national standard for occupational and educational eye and face protection devices for preventing exposures caused by sprays or spurts of blood or body fluids

Related International/European Eye and Face Protection Device Standards

ISO 16321-1:2021/ Amd 1:2024	Eye and face protection for occupational use—Part 1: General requirements—Amendment 1
ISO 19734:2021	Eye and face protection—Guidance on selection, use and maintenance
prEN ISO 16321-4	Eye and face protection for occupational use—Part 4: Additional requirements for protection against biological hazards (draft standard)

Table B4. Standards Related to Gloves

29 CFR 1910.1030	Bloodborne pathogen standard (OSHA)
29 CFR 1910.138	Hand Protection (OSHA)
ANSI/ISEA 105	American national standard for hand protection classification
ANSI/NFPA 1999	Protective clothing for emergency medical operations
ASTM D3577	Standard specification for rubber surgical gloves
ASTM D3578	Standard specification for rubber examination gloves
ASTM D5151	Standard test method for detection of holes in medical gloves
ASTM D5250	Standard specification for polyvinyl chloride gloves for medical application
ASTM D5712	Standard test method for analysis of aqueous extractable protein in natural rubber and its products using the Modified Lowe Method
ASTM D6124	Standard test method for residual powder on medical gloves
ASTM D6319	Standard specification for nitril examination gloves for medical application
ASTM D6355	Standard test method for human repeat insult testing of medical gloves
ASTM D6499	Standard test method for immunological measurement of antigenic protein in hevea natural rubber (HNR) and its products
ASTM D6977	Standard specification for polychloroprene examination gloves for medical application
ASTM D6978	Standard practice for assessment of resistance of medical gloves by permeation by chemotherapy drugs
ASTM D7102	Standard guide for determination of endotoxin on sterile medical gloves
ASTM D7103	Standard guide for assessment of medical gloves
ASTM D7160	Standard practice for determination of expiration dating on medical gloves
ASTM D7161	Standard practice for determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions

ASTM D7558	Standard test method for colorimetric/spectrophotometric procedure to quantify extractable chemical dialkyldithiocarbamate, thiuram, and mercaptobenzothiazole accelerators in natural rubber latex and nitrile gloves
ASTM D7907	Standard test methods for determination of bactericidal efficacy on the surface of medical examination gloves
ASTM F2010	Standard test method for evaluation of glove effects on wearer finger dexterity using a modified pegboard test
ASTM F2878	Standard test method for protective clothing material resistance to hypodermic needle puncture

Related International/European Glove Standards

ISO 374-2:2019	Protective gloves against dangerous chemicals and micro-organisms—Part 2: Determination of resistance to penetration
ISO 374-5:2024	Protective gloves against dangerous chemicals and micro-organisms—Part 5: Terminology and performance requirements for micro-organisms risks
ISO/TR 8546:2022	Hand protection—Guidance for selection and use
ISO 10282:2023	Single-use sterile rubber surgical gloves—Specification.
ISO 11193-1:2020	Single-use medical examination gloves—Part 1: Specification for gloves made from rubber latex or rubber solution
ISO 11193-2:2006	Single-use medical examination gloves—Part 2: Specification for gloves made from poly(vinyl chloride)
ISO 21420:2020/ Amd 1:2022	Protective gloves—General requirements and test methods—Amendment 1
EN 455 series (Medical gloves for single use).	
EN 455-1: 2020	Part 1: Requirements and testing for freedom from holes
EN 455-2: 2015	Part 2: Requirements and testing for physical properties
EN 455-3: 2015	Part 3: Requirements and testing for biological evaluation
EN 455-4: 2009	Part 4: Requirements and testing for shelf-life determination

Table B5. Standards Related to Protective Apparel

29 CFR 1910.1030	Bloodborne Pathogens (OSHA)
AAMI PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities
AAMI TIR11	Selection and use of protective apparel and surgical drapes in healthcare facilities
AATCC 42	Test method for water resistance: Impact penetration
AATCC 127	Test method for water resistance: hydrostatic pressure
ANSI/ISEA 101	American national standard for limited-use and disposable coveralls—size and labeling requirements
ANSI/NFPA 1999	Standard on protective clothing for emergency medical operations
ASTM F1154	Standard practices for evaluating the comfort, fit, function and durability of protective ensembles, ensemble elements and other components

ASTM F1670	Test method for resistance of materials used in protective clothing to penetration by synthetic blood
ASTM F1671	Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system
ASTM F1819	Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using a mechanical pressure technique
ASTM F2407	Standard specification for surgical gowns intended for use in healthcare facilities
ASTM F3267	Standard specification for protective clothing for use against liquid chemotherapy and other liquid hazardous drugs
ASTM F3352	Standard specification for isolation gowns intended to use in healthcare facilities

Related International/European Protective Apparel Standards

ISO 13688:2013/ Amd 1:2021	Protective clothing — General requirements — Amendment 1
ISO 13995:2000	Protective clothing — Mechanical properties — Test method for the determination of the resistance to puncture and dynamic tearing of materials
ISO 13996:1999	Protective clothing — Mechanical properties — Determination of resistance to puncture
ISO 13997:2023	Protective clothing — Mechanical properties — Determination of resistance to cutting by sharp objects
ISO 16603:2004	Clothing for protection against contact with blood and body fluids— Determination of the resistance of protective clothing materials to penetration by blood and body fluids—Test method using synthetic blood
ISO 16604:2004	Clothing for protection against contact with blood and body fluids— Determination of resistance of protective clothing materials to penetration by bloodborne pathogens—Test method using Phi-X 174 bacteriophage
ISO/WD 20384	Medical gowns surgical drapes, and protective apparel—Performance requirements performance levels and test methods (under development)
ISO 22610:2018	Surgical drapes, gowns, and clean air suits used as medical devices for patients, clinical staff and equipment—Test method to determine the resistance to wet bacterial penetration
ISO 22612:2005	Clothing for protection against infectious agents—Test method for resistance to dry microbial penetration
EN 13795-1:2019	Surgical clothing and drapes—requirements and test methods—Part 1: Surgical drapes and gowns
EN 13795-2:2019	Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment—Part 2: Test methods
EN 14126:2003/ AC:2004	Protective clothing—performance requirements and tests methods for protective clothing against infective agents

APPENDIX C. PPE STANDARDIZATION TASK GROUP ORGANIZATIONS

POAM 23 Government

Department of Health and Human Services (HHS)

- Administration for Strategic Preparedness and Response (ASPR)
- Biomedical Advanced Research and Development Authority (BARDA)
- Centers for Disease Control and Prevention (CDC)
    - Division of Healthcare Quality Promotion (DHQP)
    - National Institute for Occupational Safety and Health (NIOSH)
- Food and Drug Administration (FDA)

Defense Logistics Agency
Federal Emergency Management Agency (FEMA)
Environmental Protection Agency (EPA))
Occupational Safety and Health Administration (OSHA)
National Institute of Standards and Technology (NIST)
Department of Veterans Affairs (VA)
Department of State
Indian Health Service (IHS) National Supply Service Center (NSSC)

POAM 23 Nongovernment

Standards Development

- ASTM International committee representatives
- National Fire Protection Association (NFPA) representatives
- Association for the Advancement of Medical Instrumentation (AAMI) representatives

Healthcare System

- Sutter Health

Group Purchasing Organizations

- National Association of State Procurement Officials (NASPO)

Academia

- Georgia Institute of Technology
- University of Maryland
- University of North Carolina
- Yale University

Labor Unions

- American Federation of Labor & Congress of Industrial Organizations (AFL-CIO)
- International Association of Fire Fighters (IAFF)

Industry Representatives

- American Medical Manufacturers Association (AMMA)
- Health Industry Distributors Association (HIDA)
- International Safety Equipment Association (ISEA)

Marketplace Entities

- Amazon
- Google

Clinical Organizations and Professional Societies

- Association for Professionals in Infection Control & Epidemiology (APIC)
- Association of Perioperative Registered Nurses (AORN)
- American Industrial Hygiene Association (AIHA)

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APPENDIX E. ACRONYMS AND ABBREVIATIONS

AAMI	Association for the Advancement of Medical Instrumentation
AATCC	American Association of Textile Chemists and Colorists
ANSI	American National Standards Institute
APR	Air-purifying respirator
ASA	Acoustical Society of America
ASPR	Administration for Strategic Preparedness and Response (HHS)
ASSP	American Society of Safety Professionals
ASTM	American Society for Testing and Materials
BFC	barrier face covering
CA	conformity assessment
CDC	Centers for Disease Control and Prevention (HHS)
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CIPAC	Critical Infrastructure Partnership Advisory Council (DHS)
COPPE	Committee on Personal Protective Equipment (NASEM)
COVID	2019 novel coronavirus SARS-CoV-2
CPSC	Consumer Product Safety Commission
CSA	Canadian Standards Association
DHQP	Division of Healthcare Quality Promotion
DHS	Department of Homeland Security
DOL	Department of Labor
EMS	emergency medical services
EPA	Environmental Protection Agency
FDA	Food and Drug Administration (HHS)
FFR	filtering facepiece respirator
HHS	Department of Health and Human Services

ISEA	International Safety Equipment Association
ISO	International Organization for Standardization
MOU	memorandum of understanding
MSHA	Mine Safety and Health Administration (DOL)
NASEM	National Academies of Sciences, Engineering and Medicine
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPPTL	National Personal Protective Technology Laboratory (NIOSH)
OSHA	Occupational Safety and Health Administration (DOL)
PAPR	powered air-purifying respirator
PM	particulate matter
PPE	personal protective equipment
PPT	personal protective technologies
RPD	respiratory protective device
RPP	Respiratory protection program (OSHA-compliant)
SCRWG	Supply Chain Resiliency Working Group
SDO	standards developing organization
SLTT	state, local, tribal, and territorial
TRACIE	ASPR Healthcare Emergency Preparedness Information Gateway

APPENDIX F. LIMITATIONS

The report design has the following limitations:

The Task Group was established with representatives from major government and non-government stakeholder groups with equities in personal protective equipment matters to improve supply chain resiliency. Participants represented diverse perspectives and interests, embodying the broad spectrum of PPE standards gaps and needs. The individuals volunteering to participate on the Task Group may not represent the opinions of all individuals and organizations within those stakeholder groups.

In reviewing the identified standards gaps and priorities, Task Group members had the opportunity to provide comment and input, ask questions about specific PPE standards gaps characterizations, and comment on the draft report content; however, not all members participated in all meetings or opportunities to contribute and comment.