



White Paper

Global Collaboration to Advance Personal Protective Equipment (PPE) Safety, Quality, and Innovation

February 2021

About This White Paper

Personal protective equipment (PPE) plays a crucial role in controlling infection and minimizing exposure to diseases. The ongoing COVID-19 pandemic has created new challenges surrounding the quality, availability, and use of infection control PPE—including face masks, gowns, medical-grade gloves, and respirators—across the globe. As part of its mission to respond to the pandemic and promote worldwide health, the World Health Organization has issued important guidance recommending that infection control PPE meet globally recognized standards from leading organizations such as ASTM International.¹

Many groups are gaining valuable insights from widespread use of PPE and are working to address emerging challenges and needs. The situation has highlighted the need for new and modified standards that can assist in preparing for and managing future outbreaks.

In September 2020, ASTM International held a workshop on fast-tracking standards development to address PPE shortages due to COVID-19. The focus of the workshop was to outline the current state of the industry, identify gaps in standardization, and encourage participants to get involved in modifying existing standards and creating new standards. Following the workshop, ASTM interviewed the workshop organizers to identify several key takeaways, including challenges and the opportunities for ASTM involvement and leadership.

This white paper discusses the current state of standards development for infection control PPE and the formation of an ASTM-led global collaboration platform to identify and address, in an ongoing capacity, key challenges and needs. The platform will leverage the capabilities of the global PPE community to more efficiently advance consensus PPE standards.

Current Landscape

WORKSHOP SUMMARY

The workshop on fast-tracking PPE standards development was jointly sponsored by ASTM Committees F04 (Medical and Surgical Materials and Devices) and F23 (Personal Protective Clothing and Equipment). The workshop provided a forum for engineers, scientists, and medical professionals worldwide to exchange ideas and identify areas for needed standards development. The workshop's two-day schedule consisted of 26 presentations from leading international experts, covering the following topics:

- Response to the pandemic
- Protective clothing and face shields
- Respirators and face masks
- Reprocessing and reuse of PPE
- Conformity assessments
- Modeling and additive manufacturing



Scope

Standards used in the PPE infection control supply chain including masks; respirators; gloves; gowns; face shields; barriers to biological agents; infrared thermometers; thermometer caps; test swabs and testing materials; laboratory supplies; cleaning, sanitizing, disinfecting, and sterilizing supplies; and related products and materials.

¹ World Health Organization, "COVID-19 Technical Specifications for personal protective equipment, list of standards and checklists," <https://www.who.int/publications/m/item/technical-specs-PPE-Covid19-07082020>.



Non-Traditional Manufacturing

Due to the severity of PPE shortages, healthcare systems have turned to non-traditional manufacturing options (e.g., additive manufacturing, cut and sew shops) to meet demand. These manufacturers need specific guidance to create high-quality products.

CHALLENGES FACING PPE QUALITY AND AVAILABILITY

The scope and magnitude of the COVID-19 pandemic quickly overwhelmed the PPE supply chain, leading to critical shortages. Alleviating these shortages is challenging due to several factors:

Lack of Standardization, Qualification, and Certification

While robust standards and requirements exist for many types of PPE, there are major gaps related to some high-demand equipment such as cloth face coverings and transparent face shields. This extends to qualification and certification as well.

Reuse of Single-Use PPE

Another option to address PPE shortages is the reprocessing and reuse of PPE units designed for single use. However, this solution comes with a host of challenges, including lack of tests and methods for washing and sanitizing single-use PPE.

New Environments and Uses

As PPE finds its way into everyday life, it is being used in new and unexpected ways and environments. For example, electrical workers need to consider the flammability of new face coverings.

CHALLENGES FACING STANDARDS DEVELOPMENT

Due to the wide-ranging impacts of the pandemic, there is urgent demand for developing PPE standards as quickly as possible. However, several challenges impede the standards development and adoption process:

Lack of Data

Many needed standards cover new areas that are not yet well understood. For nascent topics such as cloth face mask requirements and alternative manufacturing methods, the industry needs to gather more information from a wider set of stakeholders before developing a standard.

Coordination of Stakeholders

A multitude of stakeholders—including materials suppliers, manufacturers, users, and government agencies—impact the PPE supply chain. While participation from all stakeholders is encouraged, coordinating and ensuring that all relevant stakeholders understand and are engaged in the standards development process can be challenging.

Dissemination of Standards

The end users of PPE standards are diverse and geographically dispersed, making it difficult to not only reach them but also provide standards in a format they can effectively and efficiently use.

Timeframe for Standards Development

Because it takes approximately nine months² to develop a voluntary consensus standard using the ASTM process, new standards may only have limited impact during the current pandemic wave. To be more responsive, standards development needs to be forward-looking and anticipate future needs and challenges.

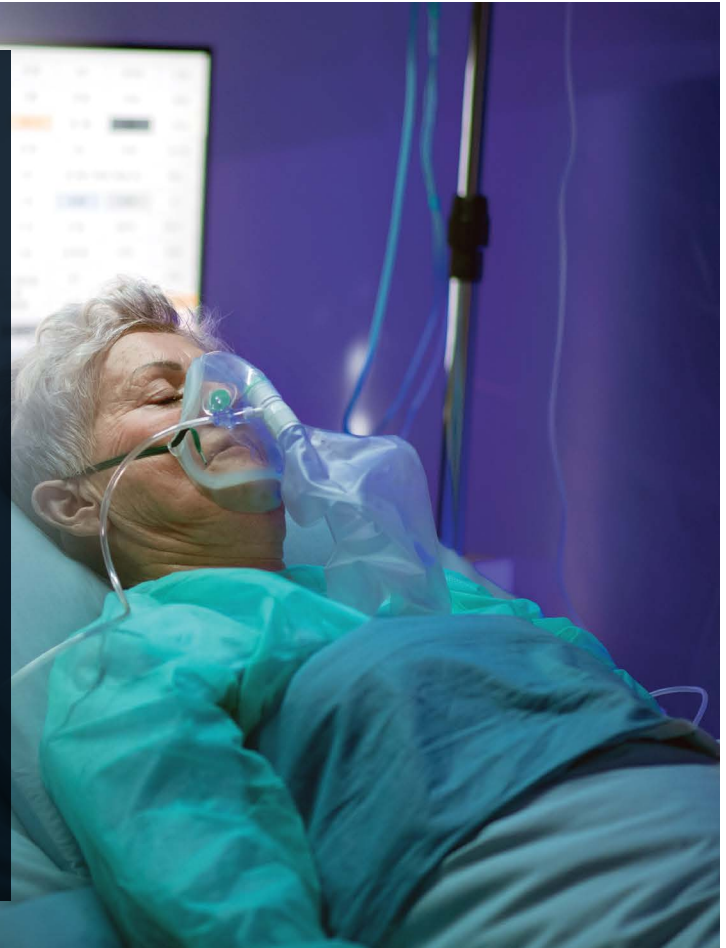
² For a demonstrated interest and need, ASTM may consider developing an alternative deliverable or technical report that can fill a gap or need until a full standard is developed.

Standards Needs

The workshop identified the need for new and modified standards across several categories of infection control PPE. These standards address high-priority gaps that ASTM and other standards developing organizations (SDOs) can pursue to support PPE quality and availability.

Respirators and Face Masks

- Respirator filtration testing per NIOSH³ mandatory standard—sampling methodology, mounting of respirators/masks methodology, handling of samples, pressure threshold limits
- Particle filtration efficiency testing
- Physical characterization, including pressure drop
- Specification of face velocities and neutralization in ASTM F2299
- Use of surfactant-free polystyrene latex (PSL) particles
- Optical particle counter (OPC) detector limits and alternative detection methods
- Specification of initial colony forming units (CFU) concentration in ASTM Standard F2101, including more details on culture conditions



Protective Clothing and Face Shields

- Guidance on manufacturing of isolation gowns
- Design guidance for face shields
- Basic requirements and definitions for face shields for healthcare use and material selection guidance (cleanability, disinfection)

Reprocessing and Reuse of PPE

- Standardization and guidance relevant to emergency re-use of PPE, and harmonization of test methods across agencies
- Overlying guidance document for testing of reprocessed PPE
- Standard reference materials and guidance on residuals
- Impact of disinfectants on filtering facepiece respirators (FFRs), with regulatory input
- Automated colony counting and specification of initial bacterial concentration in ASTM F2101
- Expanded single-use methods to include reusable devices with different requirements

Conformity Assessment

- Conformity testing for respirator fit capability
- Testing to identify counterfeit materials, kits, and devices
- Other “fit-for-purpose” methodologies

Modeling and Additive Manufacturing

- Verification check based on flow visualization for mask fit quality, or to validate another fit test
- Guidance document for computational modeling of aerosol leakage through 3D face masks (scope provided along with details of standard)
- Modeling and simulation standards to test PPE designs prior to 3D printing
- Computational test methods to augment physical testing
- Physical test methods



Other

- 01** Modifications to E1965 (infrared thermometers)
- 02** Field test methods to verify PPE function during PPE shortages
- 03** Testing methods/guidance development for PPE, decontamination of PPE, and best practices for using PPE

Global Collaboration Platform

To address the numerous challenges facing PPE and accelerate standards development, the community needs a global collaboration platform that unifies PPE standardization efforts by leveraging the collective capabilities of the PPE industry. At its core, the platform is a collaborative agreement—such as a memorandum of understanding—among various SDOs and other key stakeholders to identify and fill critical needs. The goal is to establish a common, shared workspace, enabled by and offering digital tools to facilitate collaborative activities and interorganizational communication. The platform could also include:

- Formation of joint (sub)committees
- Education and training opportunities
- Certification and qualification activities
- Development of technical reports and other non-standards publications

By aligning in purpose and commitment, the global collaboration platform will serve as the go-to resource and mechanism for all PPE standards-related activities.



Broader Participation and Information Sharing

This global platform, open to any interested stakeholder, enables broader participation in the standards developing process, as well as simplified exchange of ideas and current information among participants. It allows greater input from a diverse global constituency than the existing approach, which instead relies on singular and unique standards/standards development from a multitude of SDOs.

BENEFITS OF GLOBAL COLLABORATION

Efficient Standardization and Creation of Non-Standards Publications

Better alignment and cooperation in the standards developing community will save time and resources for SDOs and reduce confusion for the various organizations combatting the pandemic. The platform serves as a one-stop information exchange for all things technical and related to infection control PPE standards and test methods. The creation of other non-standards publications will also be explored to help address needs in an accelerated manner.

Coordinated R&D Leading to Standards

International standards development activities must be more proactive to keep pace with marketplace innovation. This platform could help organizations coordinate research supporting standards development and drive faster adoption of emerging technologies (e.g., 3D printing, exo technologies) across the PPE value chain.

Regulatory Impact

By engaging global regulators and agencies, the platform will have more impact than a traditional standards committee and give participants firsthand insight into what key decision makers are discussing and prioritizing. This collaborative relationship will

also provide awareness of changes to regulatory requirements when external factors such as a global health crisis puts pressure on existing processes. For example, during the COVID-19 pandemic, some government regulatory agencies modified requirements for product authorization to help increase availability of PPE but, as supply concerns recede, the requirements will likely change again.

Expanded Networks

The platform helps create greater transparency among the global PPE supply chain stakeholders and connect participants to the resources available to support their interaction for mutual benefit and the common good.



Potential Stakeholders

- American Academy of Emergency Medicine
- American Association of Textile Chemists and Colorists
- American College of Emergency Physicians
- American Industrial Hygiene Association
- American Medical Association
- American National Standards Institute
- American Nurses Association
- Association for Health Care Resource & Materials Management of the American Hospital Association
- Association for the Advancement of Medical Instrumentation
- ASTM International
- Bill and Melinda Gates Foundation
- Centers for Disease Control and Prevention
- CSA Group
- European Safety Federation
- Frontline Health Workers Coalition
- Health Canada
- Health Industry Distributors Association
- International Medical Device Regulators Forum
- International Organization for Standardization
- International Safety Equipment Association
- National Fire Protection Association
- National Institute for Occupational Safety and Health
- National Institute of Justice
- National Institute of Standards and Technology
- National Patient Advocate Foundation
- National Research Council of Canada
- National Safety Council
- Occupational Safety and Health Administration
- Pan American Health Organization
- Society of Academic Emergency Medicine
- United Nations Division of Health Management and Occupational Safety and Health
- U.S. Department of Homeland Security
- U.S. Environmental Protection Agency
- U.S. Food and Drug Administration
- Underwriters Laboratories
- World Health Organization

THE ROLE OF ASTM INTERNATIONAL

As a global leader in standards development, ASTM International maintains cooperation agreements with over 100 national, regional, and international standards bodies and is in a unique position to lead and champion the global collaboration platform. ASTM's role is to facilitate and maximize collaboration by acting as the coordinating organization for all global efforts. In particular, ASTM can support with several key tasks:

Communication and Outreach

Promote PPE product integrity and greater public awareness by developing a communications strategy. Lead outreach efforts by leveraging the existing ASTM network of manufacturers, suppliers, testing laboratories, academia, standards organizations, and approval bodies.

Partnership Formation

Bring together stakeholders and establish formal partnerships and memoranda of understanding that advance R&D and manufacturing of PPE.

Collaborative Engagement

Host workshops and other opportunities for live interaction on the topic that foster and capture knowledge that can be shared and applied globally.

Standards Assessment

Compile and maintain standards roadmaps and lead efforts to identify key needs both now and for the future.

Innovation

Accelerate the use and adoption of advanced technologies and new materials to enhance the manufacturing process.

Next Steps

ASTM intends to pursue the formation of this global collaboration platform as soon as possible. Immediate next steps will include:

1. Engaging potential stakeholders to gauge interest and gather input
2. Establishing an ad hoc leadership committee
3. Spreading awareness through various communications materials

As establishing global collaboration will take time, the focus of the platform will be to plan more effectively for the future by leveraging takeaways and ongoing learning from the COVID-19 global pandemic. Future global health crises may be inevitable, but with this effective collaboration platform, the global PPE community will be stronger, better prepared, and ready to act when the next challenge arrives.