



Addressing sustainability challenges through global collaboration on PPE standardization

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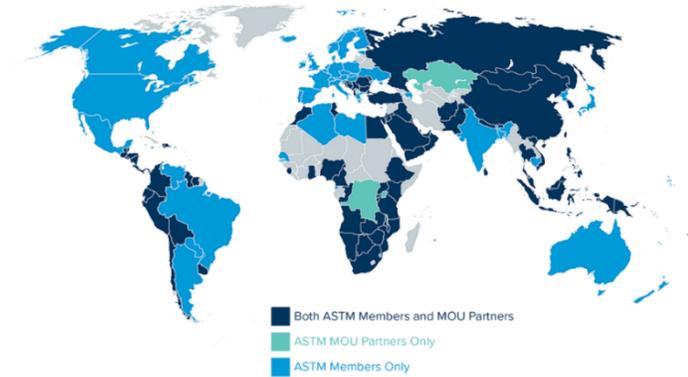


ASTM INTERNATIONAL
Helping our world work better

About ASTM International

A Proven and Practical System

- Established in 1898
- 150 Committees & 12,700+ Standards (Covering 90 industry sectors)
 - Recent: Additive Manufacturing, Exo and Exoskeleton Technology, etc.
 - Older: Medical Devices, Pharmaceuticals, Plastics, etc.
- 34,000+ members
 - 8,000+ International Members from 135 countries
 - 8,400+ ASTM standards used in 83 countries
- Headquartered in PA/USA, Offices in Washington DC, Europe (Brussels/London/Stockholm), Middle East (Dubai), China (Beijing), Canada (Ottawa), South America (Lima, Peru)
- Accreditation:
 - American National Standards Institute (ANSI)
 - Standard Council of Canada (SCC)
- ASTM standards are globally recognized for quality and relevance
 - Development and delivery of information made uncomplicated
 - A common-sense approach: industry driven
 - Consensus based
 - Market relevant globally



150

main committees
plus 2,030+
subcommittees

COVID-19 Response

- Key ASTM PPE standards available for the public to both view and download at no-cost.
 - 100,000+ visits to our site, 50,000+ views of our PPE standards by individuals in 100+ countries
- Additive Manufacturing Center of Excellence published a COVID-19 Response Guide, providing guidance on additive manufacturing for product designers and manufacturers
- WHO Technical Specifications for PPE and infection prevention control supplies (Aug. 2020) reference ASTM standards for medical gloves, masks, and gowns; hand sanitizers; and bio-hazard bags
- Developed New Standard for barrier face coverings (F3502)
- Launched Global Collaboration to Advance Personal Protective Equipment (PPE) Safety, Quality, and Innovation

Committee F23 on Personal Protective Clothing and Equipment

Scope

- Development of standard specifications, test methods, practices, guides, terminology, and classifications for protective clothing and related personal protective equipment (PPE) designed and constructed to protect the user from potential occupational hazards
- Where applicable, development of the requirements for conformity assessment of protective clothing and related personal protective equipment
- Coordination of its efforts with other ASTM Committees and outside organizations having mutual interests

Noteworthy Members (among 500+)

- Canada NRC, China NIMTT, Trinidad & Tobago, U.S. CDC, U.S. EPA, U.S. FDA
- 3M, BV, Covestro, CSA Group, Honeywell, Instituto Biomecanica Valencia (Spain), Korea Apparel Testing & Research Inst., SGS, Solvay, UL, Walt Disney World

New Standard

- F3502-21, *Standard Specification for Barrier Face Coverings*

ASTM F3502-21: Barrier Face Coverings

SCOPE OF THE STANDARD

Purpose

- Provide a consistent way to benchmark products to inform user selection decisions
- Define performance requirements for source control and protective capability

Performance Requirements

- *Protection*: (1) how well the particles are blocked going through the face covering, and (2) leakage assessment, how well it seals to the face and prevents particles going around its perimeter
- *Comfort*: face coverings must be comfortable enough for people to wear for long periods of time
- *Re-Use*: the potential that products could be used over again

Test Methods

- Leverage existing text methods to evaluate performance to accommodate expected range of products

Conformity Assessment

- Approach based on risk; oversight on most important parts

AREAS NOT ADDRESSED

- Specification does not set regulatory requirements or cover all safety issues



Barrier Face Coverings

"3.1.3 barrier face covering, n – a product worn on the face specifically covering at least the wearer's nose and mouth with the primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter."

ASTM F3502-21 & Sustainability

Reduce and Re-Use

- Providing better information to consumers leads to **better-informed purchasing**
- Defining **minimum performance requirements** allows manufacturers to devise and design innovative approaches, to meeting sustainability and well as protection objectives
- **Greater comfort and breathability** supports sustainability because a user is less likely to remove – and discard into the waste stream – a mask that is comfortable, thereby **reducing potential waste**.
- Plus, **mandatory minimum product-package labeling** increases likelihood consumer will get the product they want.
- Mandatory user instructions include how to select correct size or make adjustments (if applicable), **how to launder or clean (if reusable), and maximum number of laundering cycles, and procedures for disposal**.
- Included among the minimum performance requirements is the potential for **re-use**.
 - Re-usable products are evaluated for filtration efficiency and airflow resistance before and after the maximum number of laundering or cleaning cycles specified by the manufacturer using manufacturer-specified laundering/cleaning procedures

Work of F23 Related to Sustainability

- F3502-21 includes a clear statement forecasting future efforts to revise and update to the standard will **include environmental impact**.
- Work Item WK73468 is for a “New Specification for First Responder All-Hazards Reusable, Elastomeric Half-Mask Air Purifying Respirator”
<https://www.astm.org/DATABASE.CART/WORKITEMS/WK73468.htm>
- New standard and standard-revision activities include **decontamination** of PPE (to permit re-use).
 - A new Work Item is in development to leverage the results of ongoing research on PPE disinfection methods, furthering the potential for reuse and conservation of PPE. PPE categories being evaluated as part of the research are eye protection, face protection (shields), respiratory protection and body protection.
- Subcommittee F23.40 on Biological has a Work Item for a new standard on re-use of non-surgical gown products
 - The purpose of WK 75932 is to create a standard that contains methods and requirements to determine how many times reusable non-surgical gown products can be worn and re-processed before they are no longer protective.

Fast-Tracking PPE Standards Development

WORKSHOP – SEPTEMBER 2020

- Held workshop on fast-tracking standards development to address PPE shortages
- Jointly sponsored by ASTM Committees F04 (Medical and Surgical Materials and Devices) and F23 (Personal Protective Clothing and Equipment)
- Included 26 presentations from leading international experts
- Outlined the current state of the industry and identified gaps in standardization

Types of PPE

- | | | | |
|---|-------------------------------|--|--|
|  | Masks |  | Thermometer caps |
|  | Respirators |  | Test swabs and testing materials |
|  | Gloves |  | Lab supplies |
|  | Gowns |  | Cleaning, sanitizing, disinfecting, and sterilizing supplies |
|  | Face shields |  | Related products and materials |
|  | Barriers to biological agents | | |
|  | Infrared thermometers | | |

Fast-Tracking PPE Standards Development

WHITE PAPER

Developed white paper to discuss the current state of standards development for infection control PPE and the formation of an ASTM-led global collaboration platform

Methodology

- Reviewed materials from Sept. workshop
- Conducted follow-up interviews with workshop organizers

Contents

- Challenges facing PPE quality, availability, and standards development
- Standards needs
- Benefits of global collaboration

Link to White Paper

- <https://www.astm.org/ABOUT/PPE-White-Paper-R2.pdf>



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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>.

Challenges Facing PPE Quality and Availability



LACK OF STANDARDIZATION, QUALIFICATION, AND CERTIFICATION

- There are major gaps related to some high-demand equipment (e.g., cloth face coverings, transparent face shields)



NON-TRADITIONAL MANUFACTURING

- Healthcare systems have turned to non-traditional manufacturing options (e.g., additive manufacturing, cut-and-sew shops) to meet demand
- Need specific guidance to create high-quality products



REUSE OF SINGLE-USE PPE

- PPE units designed for single use are being reprocessed and reused to address PPE shortages
- Challenges include lack of tests and methods for washing and sanitizing



NEW ENVIRONMENTS AND USES

- PPE is being used in new and unexpected ways



The magnitude of the pandemic led to shortages, which have negatively impacted PPE quality.



Challenges Facing Standards Development



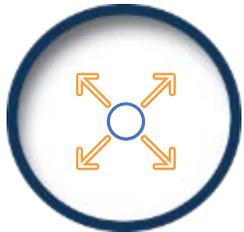
LACK OF DATA

- Many needed standards cover new areas that are not yet well understood
- Industry needs more info from a wider set of stakeholders before developing a standard



COORDINATION OF STAKEHOLDERS

- Coordinating and ensuring that all PPE supply chain stakeholders (materials suppliers, manufacturers, users, government agencies) understand and are engaged in the standards development process can be challenging



DISSEMINATION OF STANDARDS

- 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

- Standards development needs to be forward-looking and anticipate future needs and challenges



For PPE such as face masks, we are starting from scratch with standards development.



Standards Needs



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)

RESPIRATORS AND FACE MASKS

- Respirator filtration testing per NIOSH 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 CFU concentration in ASTM Standard F2101, including culture conditions

Standards Needs (continued)



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

Standards Needs (continued)



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

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

Global Collaboration Forum



To address the numerous challenges facing PPE and accelerate standards development, the community needs a **global collaboration forum** that unifies PPE standardization efforts by leveraging the collective capabilities of the PPE industry



Goal

To establish a common, shared workspace, enabled by and offering digital tools to facilitate collaborative activities and interorganizational communication

Benefits of Global Collaboration



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



EFFICIENT STANDARDIZATION AND CREATION OF NON-STANDARDS PUBLICATIONS

- Save time and resources for SDOs
- Reduce confusion
- Serve as one-stop technical information exchange



COORDINATED R&D LEADING TO STANDARDS

- Coordinate research supporting standards development and drive faster adoption of emerging technologies

“ The global collaboration forum needs to be a call to the world to **work on critical standards and get broad input.** ”

Benefits of Global Collaboration (continued)



BROADER PARTICIPATION AND INFORMATION SHARING

- Enable broader participation in the standards developing process and greater input from a diverse global constituency
- Simplify exchange of ideas and current information among participants



REGULATORY INVOLVEMENT

- Increase impact by engaging with global regulators and agencies



EXPANDED NETWORKS

- Enable greater transparency among the global PPE supply chain stakeholders
- Connect participants to available resources

Next Steps



Immediate next steps for ASTM

1

Engage potential stakeholders to gauge interest and gather input

2

Establish an ad hoc leadership committee

3

Spread awareness through communications materials

Future global health crises are inevitable. But, with this effective collaboration forum, the global PPE community will be **stronger, better prepared, and ready to act** when the next challenge arrives.

THANK YOU!



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