



ASTM INTERNATIONAL
Helping our world work better

ASTM International's Contributions in Personal Protective Equipment to Face Public Health Challenges

25 March 2021
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www.astm.org

ASTM International

Operating Globally

- ASTM is one of the world's largest Standards Developing Organizations, with global reach and influence
- With over a century of experience, ASTM offers trusted, relevant, and high quality standards that are accepted globally
 - Established in 1898
 - 30,000 volunteer members from 160 countries
 - 148 main committees and 2,111 subcommittees, covering over 90 industry sectors
- The choice for many global industries



Growing Collaboration in the MENA Region

Discussion, Information Exchange, Training

www.astmuae.org

- 2003: ASTM signs an MoU with IMANOR (Morocco)
- 2006: ASTM signs an MoU with GSO
- 2014-2019: ASTM and the International Code Council partner for Standards and Codes for Sustainable Construction Project to support standardization and economic growth in the Gulf
- 2019: ASTM establishes the first International Chapter in the U.A.E.
- 2020: ASTM signs an MoU with LNCSM (Libya)



Six Ways to Adopt and Reference ASTM Standards

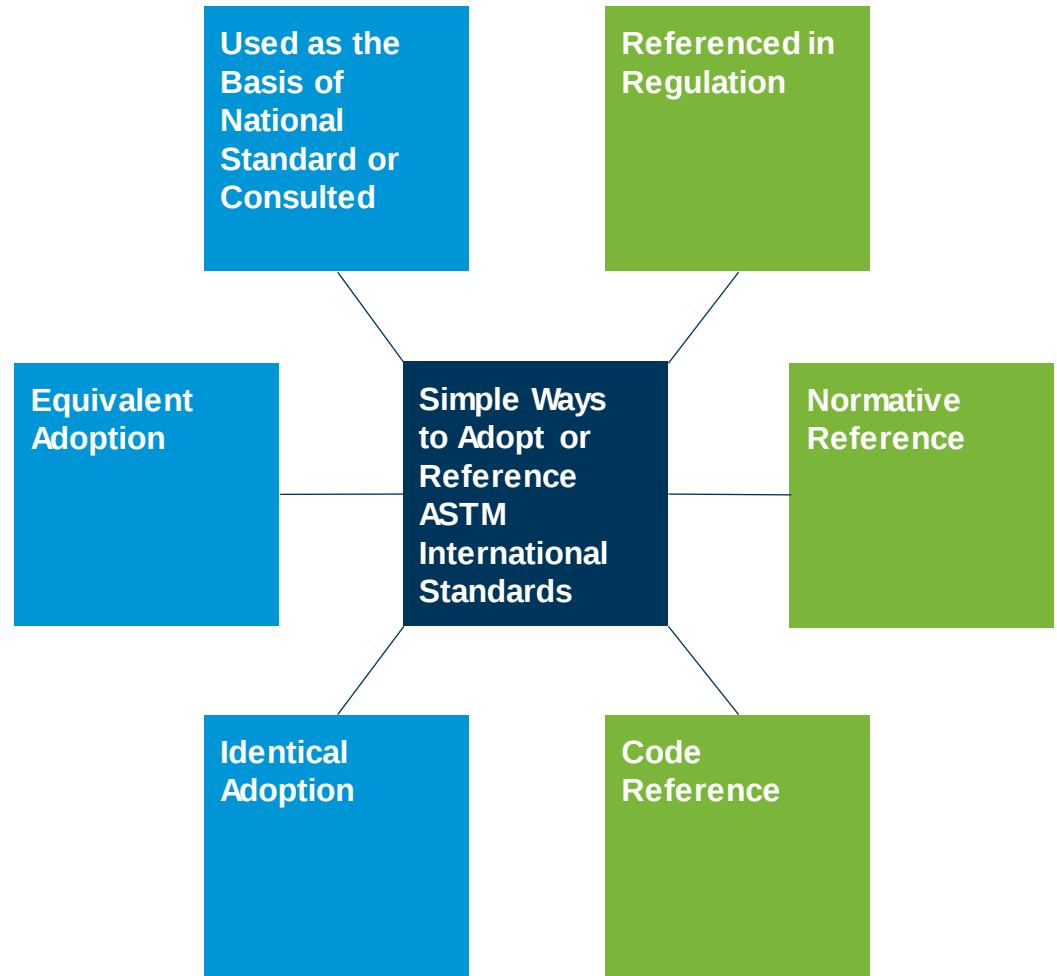


Available to all Public and Private Standards' Users

- Referenced in Regulations
- Normative Reference
- Code Reference

Available Only to MoU Partners

- Identical Adoption
- Equivalent Adoption
- Used as the Basis of a National Standard or Consulted



Responding to the Global Pandemic

Standards Access

- In response to the COVID-19 pandemic, ASTM has made 25+ standards related to Personal Protective Equipment (PPE) available for no-cost public access

(<https://www.astm.org/COVID-19/>)

- Face masks
- Medical gowns
- Gloves
- Hand sanitizers



المنظمة العربية للتنمية الصناعية والتعدين

خطوات تحميل نصوص المواصفات القياسية
الجمعية الأمريكية للفحص والمواد (ASTM)
والمعلقة بالمعدات والمستلزمات الطبية
لمواجهة جائحة كورونا المستجد (COVID-19)

 COVID-19

<https://aidmo.org/covid19/>

ASTM Committee F23 on Personal Protective Clothing and Equipment



Call to Action Meeting – April 2020

- Ad-hoc meeting to address PPE needs based on the pandemic situation
- Committee reviewed, prioritized and assigned leaders to the actions that required immediate attention
- **F23.40 Biological**
 - F2100 Specification for Performance of Materials Used in Medical Face Masks – Several work items initiated
 - WK75932 New Specification for Reusable Non-Surgical Gown Products
- **F23.50 PPE Conformity Assessment, Interoperability and Compatibility**
 - WK73613 Revision to F3050 –Guide for Conformity Assessment of Personal Protective Clothing and Equipment
- **F23.65 Respiratory**
 - WK73468 New Specification for First Responder All-Hazards Reusable, Elastomeric Half-Mask Air Purifying Respirator
 - **WK73471 Specification for Barrier Face Coverings**

Types of PPE



Masks



Respirators



Gloves



Gowns



Face shields



Barriers to biological agents



Infrared thermometers



Thermometer caps



Test swabs and testing materials



Lab supplies



Cleaning, sanitizing, disinfecting, and sterilizing supplies



Related products and materials

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."

Fast-Tracking PPE Standards Development



ASTM 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

Link to White Paper

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

The image shows the front cover of a white paper from ASTM International. The top right corner features the ASTM International logo and the tagline 'Helping our world work better'. The main title 'White Paper' is in a large, bold, blue font, followed by the subtitle 'Global Collaboration to Advance Personal Protective Equipment (PPE) Safety, Quality, and Innovation' in a smaller black font. Below the subtitle is the date 'February 2021'. The cover is divided into two main columns. The left column is titled 'About This White Paper' and contains several paragraphs of text. The right column is titled 'Current Landscape' and contains a 'WORKSHOP SUMMARY' section. At the bottom right, there is a photograph of a person wearing a full-body protective suit, including a hood and face shield, and holding a green liquid in a beaker. Below the photo is a 'Scope' section. The bottom left corner of the cover has a small disclaimer.

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Helping our world work better

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 disease. 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 taking valuable insights from ongoing research 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 clarify 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 effectively 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
- Contaminant 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, barrier membranes, thermoplastic films, heat seals, bonding materials, laboratory supplies, cleaning, disinfecting, and sterilizing supplies, and related products and materials.

¹ World Health Organization, "COVID-19 Control: The effectiveness of personal protective equipment (PPE) in the control of infectious diseases," <https://www.who.int/publications-detail/119693ba761446e8ba8927ae4f6422301>, accessed 11/11/2020.

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)



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



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



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.”

Global Collaboration Forum



NEED

The global PPE community needs to collaborate to accelerate standards development and address the numerous challenges facing PPE



SOLUTION

A global collaboration forum that unifies PPE standardization efforts by leveraging the collective capabilities of the PPE industry



For more information:
www.astmppecollaboration.org



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Thank you

www.astm.org

**ASTM International
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