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Helping our world work better

Presentation to IMDRF Stakeholders Forum

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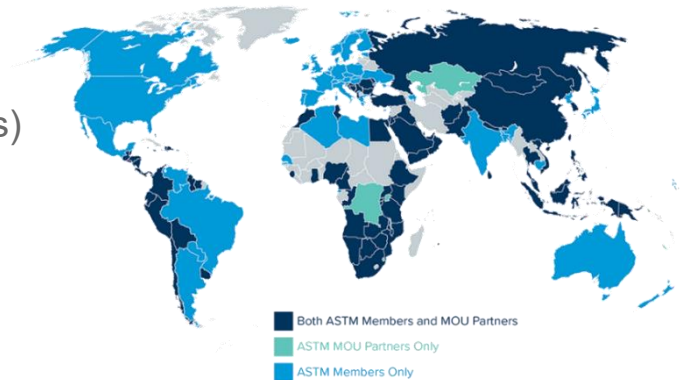
About ASTM

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



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ASTM Committees F04 and F23

Committee F04 on Medical Devices



Scope

- Development of standardized nomenclature and definitions of terms, test methods, recommended practices, guides, specifications and performance standards for medical and surgical materials and devices
- Encourage research in this field and sponsor symposia, workshops and publications to facilitate the development of such standards
- Promote liaison with other ASTM Committees and other organizations with mutual interests

Subcommittees Include

- Orthopaedic Devices
- Medical/Surgical Devices
- Tissue Engineered Medical Products
- Cardiovascular
- Cell Signaling
- Neurosurgical
- Urological
- Etc.

Committee F04 on Medical Devices



Examples of Noteworthy Members (among 1,100+)

- Government Agencies
 - Brazil INMETRO
 - Canada NRC
 - China NMPA
 - Japan AIST
 - U.K. MHRA
 - U.S. FDA and NIST
- Private Sector
 - 3M, Abbott, Boston Scientific
 - Johnson & Johnson
 - Medtronic, Pfizer
 - Stryker, WL Gore

Sample of Current Activities/Work Items of Interest

- WK8279, New Standard Terminology Relating to Vascular Stents
- WK70330, Standard Guide for Chronic Particulate Characterization and Coating Integrity Testing of Coated Vascular Stents
- WK65452, Guide for Determining the Bioactivity for Bioactive Glass and Bioactive Glass-Ceramic Implantable Materials
- WK68696, Intra-operative Impaction Durability of Intervertebral Body Fusion Devices
- WK61103, New Guide for Corrosion Fatigue Evaluation of Absorbable Metals

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*

Scope of the Standard

- Purposes
 - Source control (protect the public)
 - Offer protective capability (protect the wearer)
- Performance Requirements
 - Protection
 - Comfort
 - Re-Use
- Test Methods
 - Leverage existing text methods to evaluate performance to accommodate expected range of products
- Conformity Assessment

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."



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

Challenges Identified



PPE Quality and Availability

- Lack of Standardization, Qualification and Certification
- Re-Use of Single-Use Units
- Non-Traditional Manufacturing
- New Environments and Uses

Standards Development

- Lack of Data
- *Coordination of Stakeholders*
- *Dissemination of Standards*
- *Timeframe and Anticipating Future Needs*

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

- Particle filtration efficiency testing
- Optical particle counter detector limits and alternative detector methods

Reprocessing and Re-Use of PPE

Conformity Assessment

- Testing to identify counterfeit materials, kits and devices

Standards Needs



Conformity Assessment

- Testing to identify counterfeit materials, kits and devices

Modeling and Additive Manufacturing

- Guidance document for computational modeling of aerosol leakage through AM face masks
- Modeling and simulation standards to test PPE designs prior to printing
- Computational and physical test methods

Other

- Modifications to standard for infrared thermometers
- Field test methods to verify PPE function during PPE shortages
- Testing methods/guidance for decontamination of 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



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

Benefits of Global Collaboration



Efficient Standardization and Creation of Non-Standards Publications

Coordinated R&D Leading to Standards

Broader Participation and Information Sharing

Regulator Involvement

Expanded Networks

ASTM Leadership to Facilitate and Maximize Collaboration





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Promoting Global Convergence

APEC Project Proposal



- During the pandemic, PPE and nasopharyngeal (NP) swabs are in short supply.
 - Additively manufactured PPE and NP swabs can assist in addressing the bottlenecks.
- PPE and NP swabs may require regulatory review and approval.
 - Consensus standards can assist in providing data for additively manufactured PPE and NP
- APEC economy stakeholders (regulators, manufacturers, researchers, academia) invited to identify gaps
 - Identified needs shared with international SDOs to expedite development of required standards
 - Draft framework, citing developed standards, formulated to assist regulators
- Project CN submitted and approved in second cycle 2020
 - Awaiting final approval
- Project targeted to run from Q1 2021 through Q2 2022
- Outcomes
 - Prioritized list of international voluntary consensus standards to deliver data required for additively manufactured product approval
 - Framework of standards for use in regulatory citations
 - Regulatory acceptance of additively manufactured PPE and NP swabs to eliminate supply bottlenecks
 - Support for regulatory convergence

ASTM Supports Global Convergence



- ASTM has entered into technical cooperation agreements with other international standards bodies like ISO and IEC.
- ASTM maintains Memorandums of Understanding to support technical cooperation with over 100 regional and national standards bodies – including CEN, Singapore Enterprise, Standards Institute of Israel, and others in the Middle East, Latin America, APEC/ASEAN, and Eurasia.
- Signatory of UNECE Declaration on Gender Responsive Standards (2019)
- Supporting UNECE initiative on Standards for the SDGs
- Member of the OECD Partnership of International Organizations (with ISO, WIPO, WTO, etc.)
- We advocate globally for policies where regulators have the flexibility to chose standards based on important attributes such as technical quality, relevance, and suitability to task.

ASTM at Its Core



- Open and Transparent in deliberations, global in scope and reach
- Direct and balanced participation for all
- Keep science in and politics out
- Promote choosing standards based on merit
 - Ultimate measures of worth are technical quality and market relevance
 - Respect the choices of the market and needs of stakeholders

*The most innovative companies in the world demand flexibility and choice in standards so that they can offer exciting new products and services that meet emerging demands of the marketplace.
By enabling prosperity, innovation, and safety, ASTM helps our world work better!*



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Thank you! Questions?

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