



ASTM INTERNATIONAL  
Helping our world work better

# IMDRF Stakeholder Forum

September 2022





# Topics

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About ASTM International

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Key MedTech Committees, CoEs

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ASTM Collaboration Platform on PPE  
and Related Activities

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Conclusion/Q&A

# Helping Our World Work Better



13,000+ ASTM standards operate globally

Applied to just about everything from steel to sustainability

They improve the lives of millions every day

# ASTM by the Numbers



30,000+

global ASTM members  
in over 148 countries  
participating in ASTM

90

industry sectors  
represented and  
80% of world  
commodity trade  
affected by standards

147

main committees

2,030

subcommittees

6,700+

ASTM standards have  
been adopted, used as  
a reference, or used  
as the basis of national  
standards outside  
the USA

52

proficiency testing  
programs involve 4,700  
Laboratories and 6,500  
units of participation  
58% of participation  
from outside USA

120+

memorandums  
of understanding with  
national standards  
bodies and regional  
groups around the world

1,500

people trained  
annually across  
145 ASTM courses

13,000+

volume of international  
standards

# 2021 OECD Case Study of ASTM International



- Developed in the context of the OECD Partnership of International Organisations for Effective International Rule-Making
- Studies ASTM International’s standard-setting practices and related governance mechanisms
- It contributes to the OECD’s analytical work on international rulemaking with the perspective of an atypical form of international organization
- The report cites ASTM’s “unique membership structure”, “open participation” and “inclusive and representative decision-making process” as features that enable ASTM International to quickly develop standards in fast-moving markets.



International Regulatory Co-operation and  
International Organisations

**The Case of ASTM International**



## **ASTM International standard-setting activities**

*“Quick to react to emerging areas in need of standardisation action, notably around key new production technologies.” --*

*OECD*



# 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 (34 Total)

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

# Committee F04 on Medical Devices



## Noteworthy Members Include (among 1,000+)

- 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
  - SpineServ

## Full List of Members' Home Countries

- Africa and Middle East: Israel
- Asia/Oceania: Australia, China, India, Japan, Korea, New Zealand, Malaysia, Philippines, Thailand, Vietnam
- Europe: Austria, Czechia, Finland, France, Germany, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland, UK
- Latin America: Brazil, Colombia, Peru
- North America: Canada, Mexico, USA

# Committee F04 on Medical Devices



## New/Recent Standards of Note

- F3570-22, *Standard Terminology Relating to Microphysiological Systems*
- F3504-21, *Standard Practice for Quantifying Cell Proliferation in 3D Scaffolds by a Nondestructive Method*
- F3574-22, *Standard Test Methods for Sacroiliac Joint Fusion Devices*
- F3505-21, *Standard Test Method for Stent and Endovascular Prosthesis Kink Resistance*
- F3438-21, *Standard Guide for Detection and Quantification of Cleaning Markers (Analytes) for the Validation of Cleaning Methods for Reusable Medical Devices*

## Draft Standards (Work Items, Wks) of Note

- WK74668, *Standard Guide for Bioinks and Biomaterial Inks Used in Bioprinting Tissue-Engineered Medical Products*
- WK70410, *Standard Test Method for Formula for a Cleaning Agent Intended to Clean Clinically-Used Stainless Steel Medical Device Soiled with Dried Blood*
- WK78091, *Standard Guide for Identification of Risks Associated with the Manufacturing and Use of Absorbable Polymer Based Implants*
- WK70031, *Standard Practice for Clinically Relevant Preconditioning of Polymer-based Bearing Materials for Non-Clinical Testing of Joint Arthroplasty Devices*



# Successful ISO/TC 150 and ASTM F04 Workshop on Duplication

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## Coordination among SDOs and across Committees

- In June 2022, ASTM and ISO hosted a virtual workshop on reducing standard duplication for medical devices, testing and materials
- Duplication can occur across SDOs and even within the same SDO, causing waste of member resources, in addition to identical, different or conflicting requirements between standards, leading to confusion in the marketplace
- Workshop identified ways to avoid future duplication and address existing duplication, for example using an Action Plan Report developed by the members
- “Mirror” committees will work together to monitor and manage duplication moving forward, with the goal of enhancing medical devices standards for all stakeholders

# ASTM Keys for Health Technologies



## Technical Committees

- D11 on Rubber and Rubber-like Materials
- D13 on Textiles
- D20 on Plastics
- E55 on Pharmaceutical Manufacturing
- E56 on Nanotechnology
- F04 on Medical and Surgical Devices
- F23 on Personal Protective Equipment
- F42 on Additive Manufacturing
- F48 on Exoskeletons and Exosuits

## Centers of Excellence (Research-to-Standards)

- Additive Manufacturing
- Exo and Exoskeleton Technology

147

main committees  
plus 2,030+  
subcommittees

# PPE-Related Activities

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

- Identifying, discussing market, data, and standards needs
- Open to participation
- See <https://astmppecollaboration.org>. Next meeting: October 5, 2022

## ASTM-IFC MOU on Development and Dissemination of Knowledge on PPE Standards and Compliance Globally

- Working to provide awareness, capacity building, standards cooperation, and good international practices related to PPE

## APEC SCSC03 2021S Project on Addressing “Last Mile” of AM Use for PPE – Assisting Regulators

- Project concluded June 2022. Report shares recommendations for standards that support AM for PPE and swabs

# ASTM Supports Convergence

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- Technical cooperation agreements with other international standards bodies like ISO and IEC
- MoUs support technical cooperation with over 120 regional and national standards bodies
- UNECE Declaration on Gender Responsive Standards (2019)
- UNECE initiative on Standards for the SDGs
- OECD Partnership of International Organizations (with ISO, WIPO, WTO)
- Advocating globally for policies that allow regulators flexibility to choose standards based on important attributes such as technical quality, relevance, and suitability to task
- Recognized by OECD as a unique contributor to international regulatory cooperation ([2021 Case Study](#))

# ASTM at Its Core

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- 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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