ASTM International

• **About ASTM International**
  – Non-governmental, not-for-profit organization
  – Develops voluntary, consensus standards
  – Provides certain, specific certification and training programs (CCRL, SEI)
  – Does not provide accreditation services

• **ASTM’s objectives**
  – Promote public health and safety, and the overall quality of life
  – Contribute to the reliability of materials, products, systems and services
  – Facilitate national, regional, and international commerce
Role of Standards

• Standards in the Public and Private Sector
  – Impact global trade, innovation and competition
  – Guide product design, development, market access
  – Used by companies, research labs, government agencies

• ASTM International Standards
  – Voluntary consensus standards
  – Regularly reviewed
  – Meet World Trade Organization (WTO) principles for international standards
  – Remove barriers to the worldwide acceptance and use of our standards
U.S. Standards System

• Voluntary and led by the private sector

• Requires cooperation among stakeholders (Public-Private Partnership)
  – Standards Developing Organizations (SDOs)
  – Industry, consumers, and users
  – Government representatives
  – Academia

• Meets stakeholders’ needs
  – Protect safety, health, and environment
  – Improve industry competitiveness
  – Facilitate global trade and market access
Public Policy
ASTM in Washington, DC

• **Government Affairs**
  – United States Congress
  – Federal government agencies (EPA, FDA, CPSC, etc.)

• **Stakeholder Outreach**
  – Companies
  – Embassy officials based in Washington
  – Industry/Trade associations (NAM & U.S Chamber of Commerce)
  – International Non-Governmental Organizations (NGOs)
  – ANSI and other Standards Developing Organizations (SDOs)
U.S. Legal and Policy Framework

• National Technology Transfer and Advancement Act of 1995 (NTTAA)
  – Requires federal government agencies to use standards developed by voluntary consensus standards organization when possible
  – Encourages federal government agencies to participate in standards development organizations

• OMB Circular No. A-119
  – Reinforces goals of National Technology Transfer and Advancement Act
  – Discourages federal agencies from using government-unique standards
P.L. 104-113 National Technology Transfer and Advancement Act of 1995 (NTTAA)

“...all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, and shall, participate with such bodies in the development of technical standards.”
Federal Agencies & ASTM Standards

• **U.S. Code of Federal Regulations (CFR)**
  – 6,500 voluntary consensus standards incorporated by reference in federal law
  – About 3,000 ASTM standards listed in CFR for regulations and procurement

• **U.S. Federal Register**
  – Public notification of standards adoptions
  – Instructions for public comments
Incorporation By Reference (IBR)

- Regulation that incorporates standard by reference
  - An agency may adopt a voluntary standard (without changes) by incorporating the standard in a regulation by listing (or referencing) the standard by title.
  - This approach eliminates the cost to the agency of creating a new standard
- Regulation based on existing standard
  - An agency reviews an existing standard and makes changes to match its goal or need.
- Agency conducts rulemaking process to solicit public opinion and stakeholder input
  - Public Notification and Comments
  - An agency must publish a notice in the Federal Register when making a new rule or incorporating a standard by reference
- When creating a new rule based on an existing standard, an agency may change the proposed rule in response to public comments
## Top 10 Regulatory SDOs in US

<table>
<thead>
<tr>
<th>Standards Developing Organization</th>
<th>Acronym</th>
<th>Number</th>
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<tbody>
<tr>
<td>American Society for Testing and Materials</td>
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<tr>
<td>U.S. Environmental Protection Agency</td>
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<td>American Public Health Association</td>
<td>APHA</td>
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<td>American Society of Mechanical Engineers</td>
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<td>American National Standards Institute</td>
<td>ANSI</td>
<td>677</td>
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<td>National Fire Protection Association</td>
<td>NFPA</td>
<td>589</td>
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<td>International Maritime Organization</td>
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<tr>
<td>Society of Automotive Engineers</td>
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<td>Reprographic Technologies</td>
<td></td>
<td>351</td>
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<tr>
<td>National Highway Traffic Safety Administration, U.S. Department of Transportation</td>
<td>DOT/NHTSA</td>
<td>344</td>
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</table>
ASTM Assists in Transparency in Rulemaking

ASTM standards IBR are provided in a read only format to the general public in the reading room.
U.S. Federal Register - Do’s and Don’ts

• Formal comments are allowed on:
  • Rules, Propose Rules, and Notices

ASTM Commenting Guidelines

• **DO**
  ✓ Coordinate with the Staff Manager, Public Policy Team, and ASTM President’s Office
  ✓ Ask for approval before using ASTM branding

• **DO NOT**
  ✓ Misrepresent a relationship with ASTM
  ✓ Send unapproved comments
Federal Register – 2019 Comments

- FDA - Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality
  - Notice

- National Institute of Standards and Technology (NIST) - Federal development of technical standards for Artificial Intelligence technologies
  - Notice

- FDA - Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds
  - Notice

  - Notice

APRIL 8, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852


On behalf of ASTM International’s Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products, the Executive Committee has approved the attached letter in response to the draft guidance of industry entitled, “CDER’s Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality.”

For more than 100 years, ASTM has served society by providing a global forum for the development and publication of voluntary consensus standards that are utilized by over ninety industry sectors. Committee E55 is one of 148 ASTM technical committees composed of experts who represent producer, user, government and academic stakeholder interests in the development of voluntary consensus standards for materials, products, systems, and services. Committee E55 adheres to well-regarded, industry-recognized, and time-tested principles for the development of consensus standards that reflect current technology and industry practice.

Thank you for the opportunity to submit these comments. Please feel free to contact Jeff Grove in the ASTM Washington Office at 202-223-8505 or jgrove@astm.org to discuss these comments or any issues related to this letter.

Sincerely,

Katharine E. Morgan
President
# U.S. Government Membership in ASTM

<table>
<thead>
<tr>
<th>Agency Name</th>
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<tbody>
<tr>
<td>Department of Agriculture</td>
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<tr>
<td>Department of Commerce (incl. NIST)</td>
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<td>Consumer Product Safety Commission</td>
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<td>Department of Defense</td>
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<td>Department of Energy</td>
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<td>Federal Aviation Administration</td>
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<tr>
<td>Department of Health and Human Services (incl. FDA)</td>
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<td>Housing and Urban Development</td>
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<td>Department of Justice</td>
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<td>NASA</td>
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<td>Nuclear Regulatory Commission</td>
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<td>Occupational Safety &amp; Health Administration</td>
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<td>Department of Transportation</td>
<td>120</td>
</tr>
<tr>
<td>Department of Veterans Affairs</td>
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</table>
Proven Partnership

Chairman Kaye's Congressional Testimony

Elliot F. Kaye was sworn in as the 10th Chairman of the U.S. Consumer Product Safety Commission (CPSC) on July 30, 2014. President Barack Obama nominated Mr. Kaye on March 31, 2014, and he was confirmed by the U.S. Senate on July 28, 2014, to a term that expires in October 2020.
Stakeholder Outreach
ASTM Engages Decision-Makers

- **Raise awareness of standards and ASTM**
  - Standards facilitate trade and boost GDP
  - No WTO list of international bodies

- **Identify opportunities for collaboration on issues of mutual interest**
  - Reduce internal company specifications

- **Seek industry feedback on activities and challenges**
  - ASTM supports industry needs to choose the best standard, regardless of the source

- **Ensure ASTM is meeting stakeholder needs**
  - Satisfy regulations and laws
  - Facilitate global trade
Stakeholder Outreach – Examples

- National Association of County and City Health Officials (NACCHO)
  - Their members are active on D22 (Air Quality) and D19 (Water)

- U.S. Access Board
  - The agency is active on E17 (Vehicle Pavement Systems) and F08 (Sports Equipment, Playing Surfaces, and Facilities)
  - Contributed to a *Standardization News* article on F3021 and F3022

- U.S. House Manufacturing Caucus
  - Conduct briefings on topics ranging from Artificial Intelligence to Additive Manufacturing
  - Allows ASTM to engage with a variety of stakeholders
• **ASTM standards meet World Trade Organization (WTO) criteria for “international standards”**
  – No WTO list of international bodies
  – WTO recognizes multiple approaches to international standardization

• **ASTM makes it easy to participate in international standards development**
  – Technology drives efficiency
ASTM in Europe

European participation

Over 1,100 technical experts from European Member States work collaboratively with their peers from more than 100 other countries to develop global standards and solutions that improve performance and operability in manufacturing, materials, products, processes and more.

Opened an ASTM Office of European Affairs in 2013 in Brussels, to interface with European institutions, ESO’s and NSBs, trade federations, consumer groups, companies and research institutes.

+400 ASTM references in European Laws

ASTM Standards & Engineering Digital Library used by universities in UK, Denmark, France, Germany, Poland, Spain
ASTM’s Brussels Office

ASTM’s Brussels Office at your service:

– liaising with institutions and stakeholders in Europe and globally;
– liaising with European and National Standard Organizations (CEN, CENELEC, DIN, BSI, etc.);
– facilitating technical and political connections;
– building relationships with ASTM members worldwide;
– helping identify and address relevant EU policies;
– educating Europeans on ASTM and addressing misperceptions on the US standards system.

European Membership Benefits:

– develop new and revise existing standards;
– have equal say and voting rights in ASTM balloting process;
– network with peers from around the world and gain professional development opportunities;
– receive information on standards that can impact your business or organization on a daily basis.

50% of ASTM standards are distributed outside the United States.
Moving Forward

– ASTM seeks to enhance our level of cooperation and work with government and standards officials and stakeholders to:

– *Promote* a global marketplace that is open, efficient, free of costly duplication, free of technical barriers, and free of national or regional limitations.

– *Produce* high-quality and market relevant standards that advance R&D, product manufacturing, testing, quality assurance, marketing, and trade for both companies and SMEs.

– *Advance* the ability of industries to choose the standards which best meet their needs.

– Our global approach to standards development and use can *help the world to work better* through improved products, increased trade, and greater prosperity for the future.
Questions and Discussion
Contact Information

Jeff Grove
Vice President, Global Policy and Communications
jgrove@astm.org | (202) 223-8505

Anthony R. Quinn
Director, International Trade and Public Policy
aquinn@astm.org | (202) 223-8484

Sara Gobbi
Director, European Affairs
sgobbi@astm.org | +32 (0)2.8405127

Matthew Pezzella
Manager, Government and Industry Affairs
mpezzella@astm.org | (202) 223-8399
THANK YOU!