



How ASTM Works with Government Agencies

Anthony R. Quinn

Director, Public Policy and International Trade
ASTM International

Thursday, May 9, 2013

Today's Discussion



- Overview of ASTM International
- Electronic Tools for Participation
- Government Involvement in ASTM & Standards Incorporated by Reference (IBR)
- Examples of Standards used by Federal Agencies
- Questions

ASTM International

- Develops voluntary consensus standards for materials, products, systems, and services
- Established in 1898
- Headquartered in West Conshohocken, PA, USA
- Offices in:
 - Washington, D.C.
 - Mexico City
 - Beijing
 - Brussels
 - Ottawa
- International Board of Directors:
 - Canada, Netherlands, South Korea, USA
 - Deloitte & Touche, Dow Corning, Mattel/Fisher-Price, Walt Disney
 - EPA, NIST, FDA

ASTM International Committees, Standards and Members

- **143** Technical committees
- **12,396** Standards
- **35,000+** Members
- **8,300+** International members from 145 countries
- **7,000+** references to ASTM standards used in 75 countries



ASTM International Principles are WTO/TBT Principles

WTO / TBT Principles

- ✓ Transparency
- ✓ Openness
- ✓ Impartiality and consensus
- ✓ Effectiveness and relevance
- ✓ Coherence
- ✓ Consideration of developing nations



ASTM Principles

- ✓ Transparency
- ✓ Openness
- ✓ Impartiality and consensus
- ✓ Effectiveness and relevance
- ✓ Coherence
- ✓ Consideration of developing nations



Why ASTM International?

- A proven and practical system
 - *Consensus-based procedures*
 - *Private and public sector cooperation*
- Information development and delivery made uncomplicated
 - *Extensive support / infrastructure*
- A common sense approach driven by stakeholders
 - *All stakeholders involved in a neutral and balanced forum:*
 - *Product manufacturers* • *Regulatory agencies* • *Associations* • *Professional societies* • *Professionals and consultants* • *Financial organizations* • *Academia* • *Research institutions and laboratories*
- Global market relevance
 - *ASTM International develops international standards in accordance with the WTO TBT Agreement, Annex IV*
 - *Global Participation = Global Consensus*
- No project costs

ASTM's Balloting Process

Main Committee

Subcommittee
.01

Subcommittee
.02

Subcommittee
.03

Task
Group 1

Task
Group 2

- Committees form to address industry subjects, with subcommittees addressing specialized subsets
- Approved Standards Achieve Separate Subcommittee and Main Committee Approvals, as well as a Society Review and “Internal Audit”

ASTM Electronic Tools

Virtual Meetings

- 1,137 virtual meetings were held in 2011

Electronic Balloting

- My meeting tools
- Document Library

The ASTM International Website

- English
- Chinese
- Spanish



Access to information on work items

- Searching new work items
- Collaboration tools

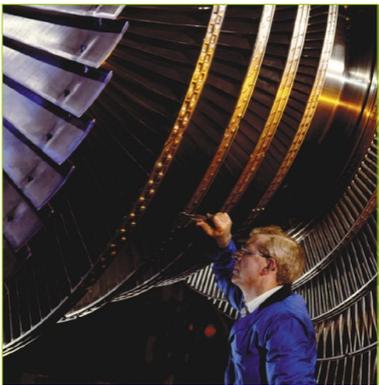
The ASTM Standards Tracker Provides information on

- Newly approved standards
- Actions on existing standards

Time Frame for Standards Development



- ASTM's average standard development time is 19 months
- New committees average lesser times (7 – 14 months)



- Complexity of the job
- Urgency of needs
- Time devoted by members
- Utilization of new informational technologies

U.S. Government is a partner and key stakeholder

- Active U.S. Government participation in 93% of ASTM committees
- Broad range of federal agencies represented on ASTM committees
- Over 1400 units of U.S. Government participation in ASTM

| U.S. Federal Agency | ASTM Members | U.S. Federal Agency | ASTM Members |
|----------------------------|---------------------|----------------------------|---------------------|
| Agriculture | 23 | Interior | 38 |
| Commerce (incl. NIST) | 211 | Justice | 20 |
| CPSC | 40 | NASA | 55 |
| Defense | 341 | NRC | 21 |
| Energy | 150 | OSHA | 13 |
| EPA | 119 | Transportation | 121 |
| FAA | 12 | Treasury | 13 |
| HHS (incl. FDA) | 151 | VA | 12 |
| HUD | 4 | Homeland Security | 37 |

Top 10 Regulatory SDOs Referenced in Federal Regulations

| Standards Developing Organization | Number |
|--|--------|
| American Society for Testing and Materials | 2260 |
| American National Standards Institute | 569 |
| American Society of Mechanical Engineers | 554 |
| U.S. Environmental Protection Agency | 465 |
| Society of Automotive Engineers | 436 |
| National Fire Protection Association | 379 |
| American Petroleum Institute | 281 |
| Insulated Cable Engineers Association | 274 |
| AOAC International | 237 |
| International Maritime Organization | 237 |

Standards Incorporated by Reference

- The **ASTM International Reading Room is a free service where you can view and read ASTM’s safety standards incorporated in United States regulations.** ASTM International developed the Reading Room because it supported our mission to serve the public’s interest and foster public-private cooperation.
- **ASTM International retains the copyright to all standards posted in the Reading Room.** ASTM does not allow any public or private entity to publish ASTM standards on its own website; however, ASTM does allow for other entities to post a link on their website to our Reading Room.
- Link: <http://www.astm.org/READINGLIBRARY/index.html>

U.S. Laws of Interest

Consumer Product Safety Improvement Act

- 15,000 different types of consumer products

Food and Drug Administration (FDA) Modernization Act of 1997

- Food safety, drugs, and cosmetic products

Occupational Safety and Health Act of 1970

- Workplace safety and health



Consumer Product Safety Commission

CRAYOLA 8 PC REGULAR CRAYONS 1DZ BOXES - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail Stop

Address <http://www.orientaltrading.com/application?origin=page.jsp&namespace=browse&event=link.item> Go Links

» [Shop Our Catalogs Online](#)

Shop By Category

Party Supplies

- » [Theme Packs](#)
- » [Go Gifts](#)
- » [Luau](#)
- » [See All](#)

Crafts & Hobbies

- » [Scrapbooking](#)
- » [Beads](#)
- » [Crafts](#)
- » [See All](#)

Teacher Supplies



CRAYOLA 8 PC REGULAR CRAYONS 1DZ BOXES

[Click Here to See Larger Image](#)

3 5/8" x 5/16" Crayola® 8-Piece Regular Crayons. Set of 8 classic colors. (1 dozen boxes per unit) Safe and non-toxic. Conforms to ASTM D-4236.

32 Items Online

start | Internet | 9:15 AM



Designation: D 4236 – 94 (Reapproved 2005)

Standard Practice for Labeling Art Materials for Chronic Health Hazards¹

This standard is issued under the fixed designation D 4236; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

INTRODUCTION

Uninformed or careless use of some art material products can give rise to health hazards, either acute or chronic, or both. Specific and readily available warnings are needed to help protect users of any age. One way to disseminate such information is to provide appropriate precautionary labeling on art material products.

Labeling for acute health hazards, including those associated with art materials, is being addressed



ASTM International and FAA

A proven partnership

- LSA
- Aircraft Wiring
- UAS
- Part 23 Aircraft

F38 on Unmanned Aircraft Systems -

A cooperative partnership with regulators to outline a unique system-safety approach for airframe airworthiness and human interface with high-tech communication and control needs – from large UAS to an ARC for small UAS.

Use of F37 Standards – Regulatory Frameworks Analysis

10470

Federal Register / Vol. 70, No. 41 / Thursday, March 3, 2005 / Notices

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Consensus Standards, Light-Sport Aircraft

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of availability; request for comments.

consideration. The standards may be changed in light of the comments received. The FAA will address all comments received during the recurring review of the consensus standards and

The Consensus Standards

The FAA finds the following consensus standards acceptable for certification of the specified aircraft under the provisions of the Sport Pilot and Light-Sport Aircraft rule:

- a. ASTM Designation 2240-03, titled: Standard Specification for Manufacturer Quality Assurance Program for Powered Parachute Aircraft.
- b. ASTM Designation 2241-03, titled: Standard Specification for Continued Airworthiness System for Powered Parachute Aircraft.

is aware that the con
the development of
consensus standards
that are needed to ce
under 14 CFR, part 2
21.191. This ongoing
a. Sailplane design
and continued opera
b. Powered parach
documentation.
c. Weight shift air

F38 Outlined Workflow

- Existing Subcommittee Structure

What do you need to fly?
...A System Safety Case

System Certification and
Flight Authority

Operations protocols &
component performance

Crew training & human factors
consideration

- **F38.01 Airworthiness Standards**
 - Safe design, construction, test, modification, & inspection of the individual component, aircraft, or system; hardware oriented
- **F38.02 Operations Standards**
 - Safe employment of the system within the aviation environment among other aircraft & systems; procedure/performance oriented
- **F38.03 Pilot & Maintenance Qualifications**
 - Safe practices by the individuals responsible for employing the system; crew oriented

Example of FDA's Use of ASTM Standards

GUIDANCE FOR THE PREPARATION OF PREMARKET NOTIFICATIONS (510(k)s) FOR CEMENTED, SEMI-CONSTRAINED TOTAL KNEE PROSTHESES

H. Materials

Provide the voluntary standards to which the materials used in each component of the device conform. Most of the materials used in legally marketed or predicate knee prostheses conform to an American Society for Testing and Materials (ASTM) ... standard for implant usage. If not, then data must be provided demonstrating the material's biocompatibility. In addition, information about the processes and effects of any additional manufacturing techniques... must be provided... Range of Motion and Constraint Data on the expected range of motion for the device should include all modes of rotation ...

ASTM Standard F-1223 provides a standard test method for evaluating constraint... it may be used for comparison purposes to commercially available total knee prostheses. Alternatively, constraint may be measured using a worst case analysis of the anterior, posterior, medial, lateral and rotational tibiofemoral shearing forces...

Examples of EPA's Use of ASTM Standards: E44 on Solar, Geothermal and Other Alternative Energy Sources

In December 2011, EPA officially delegated and presented the newly forged partnership of ASTM and IAPMO with the heat metering standard framework.

ASTM Committee E44 are currently developing **WK37952, New Specification for equipment and instrumentation of heat metering technologies**, which will lead to enhanced energy, financial and environmental benefits generated from thermal energy sources and technologies.

“The U.S. Environmental Protection Agency supports the development of a U.S. heat meter standard as a means to both credibly and accurately measure the environmental, energy and financial benefits generated by distributed clean heating and cooling technologies nationwide.”

- James Critchfield, director of EPA's Renewable Energy Technology Market Development

Examples of EPA's Use of ASTM Standards: D19 on Water

According to the EPA, **the new and revised standards** added to 40 CFR 136 (May 2013), Guidelines Establishing Test Procedures for the Analysis of Pollutants, through the final rule ***“will provide increased flexibility to the regulated community and laboratories in their selection of analytical methods for use in Clean Water Act programs.”***

By their inclusion in the final rule, the following approved methods can be used for determining compliance with National Pollutant Discharge Elimination System permits or other monitoring requirements:

- **D6888-09**, Test Method for Available Cyanide with Ligand Displacement and Flow Injection Analysis (FIA) Utilizing Gas Diffusion Separation and Amperometric Detection;
- **D7284-08**, Test Method for Total Cyanide in Water by Micro Distillation Followed by Flow Injection Analysis with Gas Diffusion Separation and Amperometric Detection;
- **D7511-09**, Test Method for Total Cyanide by Segmented Flow Injection Analysis, In-Line Ultraviolet Digestion and Amperometric Detection;
- **D4282-02**, Test Method for Determination of Free Cyanide in Water and Wastewater by Microdiffusion;
- **D7237-10**, Test Method for Free Cyanide with Flow Injection Analysis (FIA) Utilizing Gas Diffusion Separation and Amperometric Detection;
- **D888-09 (A)**, Test Methods for Dissolved Oxygen in Water;
- **D7365-09a**, Practice for Sampling, Preservation and Mitigating Interferences in Water Samples for Analysis of Cyanide;
- **D7573-09**, Test Method for Total Carbon and Organic Carbon in Water by High Temperature Catalytic Combustion and Infrared Detection; and,
- **D7065-06**, Test Method for Determination of Nonylphenol, Bisphenol A, p-tert-Octylphenol, Nonylphenol Monoethoxylate and Nonylphenol Diethoxylate in Environmental Waters by Gas Chromatography Mass Spectrometry.
- **D2036-09 (B)**, Test Methods for Cyanides in Water;

Facts and Challenges

- Standards are not always a top priority
 - Constant educational process
- Agencies must use lengthy rulemaking process to update or revise references
- Roles and attitudes vary across federal agencies
- Eliminate/reduce costs of developing standards
- Decrease costs of good purchased
 - Commercial off the shelf procurement
- Relies on the private sector to meet needs
 - Access to industry experts and technology
 - Process is faster and more dynamic



HOW DID THE
INDUSTRY STANDARDS
MEETING GO?



Dilbert.com DilbertCartoonist@gmail.com

DID YOU CONVINC
83 COMPANIES TO
ADOPT STANDARDS
THAT BENEFIT ONLY US
WHILE DOOMING THE
ENTIRE INDUSTRY IN
THE LONG RUN?



9-2-07 © 2007 Scott Adams, Inc./Dist. by UFS, Inc.

OR ARE YOU
A COMPLETE
FAILURE?



CAN I
HEAR
THOSE
CHOICES
AGAIN?

Thank You



Questions?

ASTM Washington DC Office – Staff Contact Information

Anthony R. Quinn
aquinn@astm.org
202-223-8484

Jeff Grove
jgrove@astm.org
202-223-8505

Sarah Petre
spetre@astm.org
202-223-8399
www.astm.org