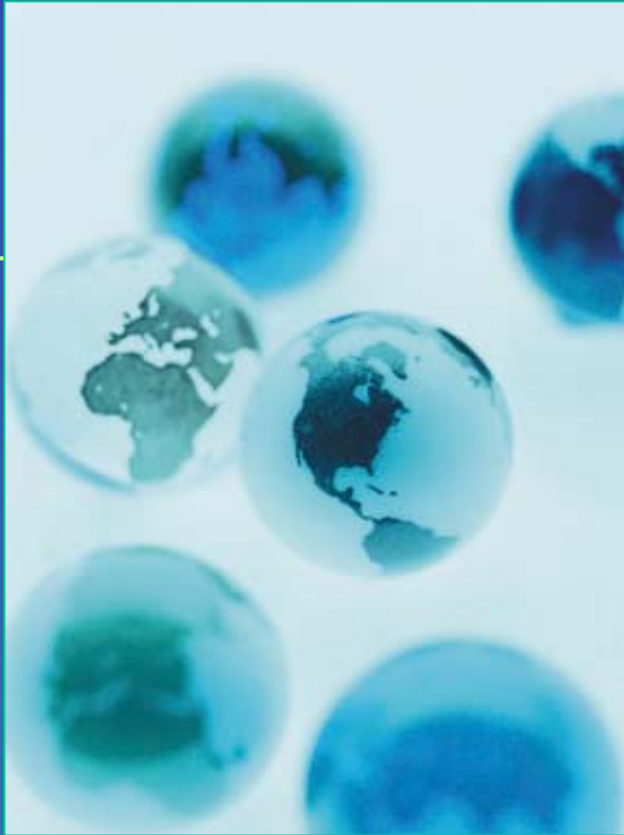


Standards for Nanotechnology

Thanks to Pat Picariello for slides

- ASTM International Committee E56 on Nanotechnology





ASTM's primary objective

...is to be the foremost developer and provider of consensus standards, related technical information, and services having globally recognized quality and market relevance.

Why ASTM?

- A proven and practical system
 - Established in 1898
 - 138 Committees & 12,000+ Standards
 - 30,000 members
 - 5,500+ International Members from 125 countries
 - 3,000 ASTM standards used in 60+ countries
 - ‘Audited Designator’ accreditation: American National Standards Institute (ANSI)



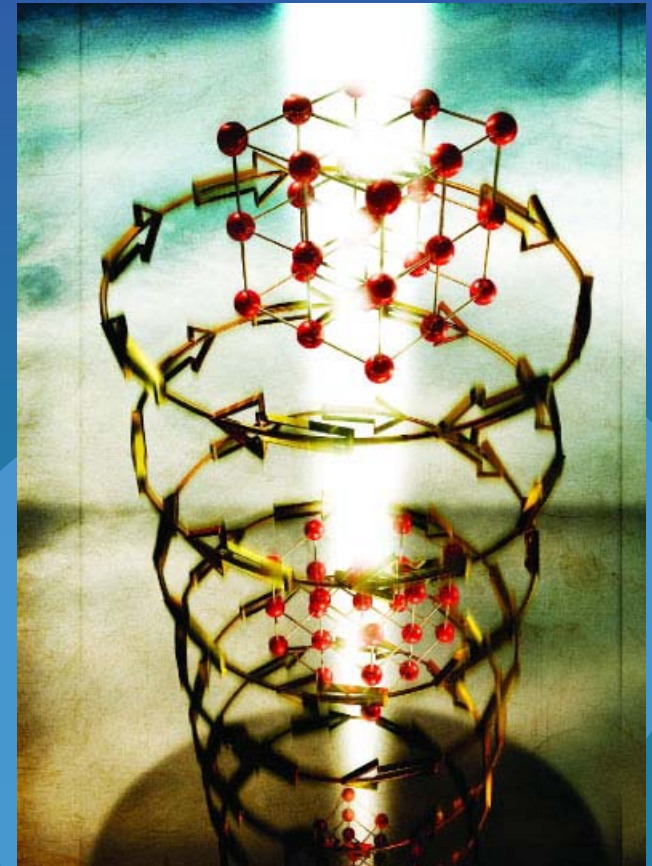
Why ASTM?

- A practical system
 - Process complies with WTO principles: Annex 4 of WTO/TBT Agreement
 - All stakeholders involved (Public & Private Sector Cooperation)
 - Neutral forum
 - Consensus-based procedures
- Development and delivery of information made uncomplicated
- A common sense approach: industry driven
- Market relevant globally
- No project costs

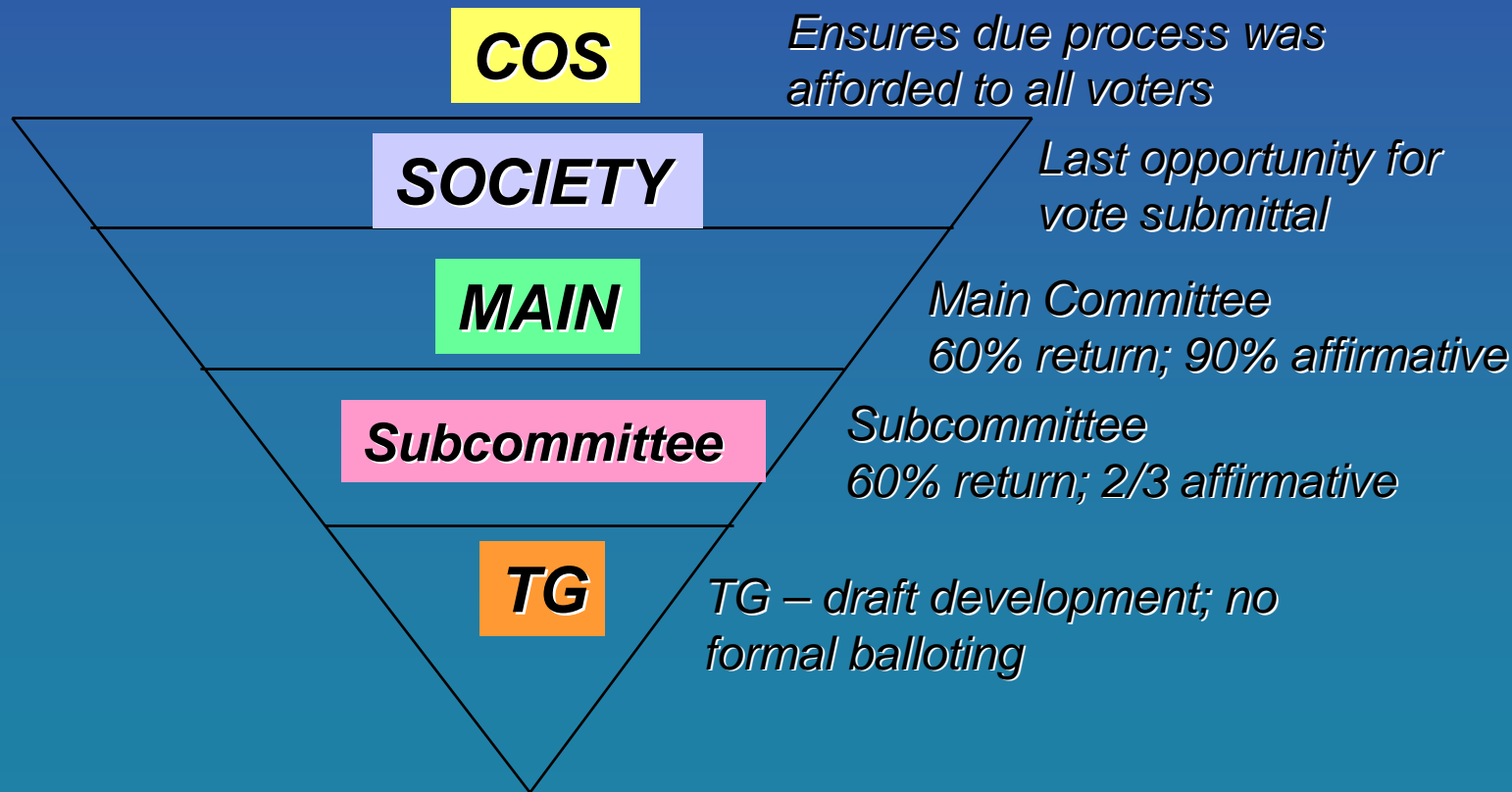
138 Technical Committees

Examples

- A1 on Steel, Stainless Steel, and Related Alloys
- B1 on Electrical Conductors
- D1 on Paint
- D2 on Petroleum Products and Lubricants
- D4 on Road and Paving Systems
- D18 on Soil and Rock
- E28 on Mechanical Testing
- E17 on Vehicle Pavement Systems
- E29 on Particle Size Characterization
- E30 on Forensic Science
- E50 on Environmental Assessment
- E54 on Homeland Security Applications
- E55 on Pharmaceutical Application of PAT
- E56 on Nanotechnology
- F1 on Electronics
- F4 on Medical & Surgical Materials & Devices
- F8 on Sports Equipment and Facilities
- F15 on Consumer Products
- F24 on Amusement Rides and Devices
- F25 on Ships and Marine Technology
- F29 on Anesthetic & Respiratory Equipment
- F37 on Light Sport Aircraft
- F38 on Unmanned Air Vehicle Systems
- F40 on Declarable Substances in Materials



ASTM's Balloting Process



The ASTM process

- 1 member = 1 vote (not 1 country = 1 vote)
- Must be 100% - no consensus: any negative needs resolution
- Fast to market...

1 →

Work Item Registration

- New ideas discussed & agreed upon
- New standard or revision
- Registration provides an e-copy

2 →

Document Construction

- Revisions: Word copy provided
- New: Templates
- Assistance: Up-front & back-end editorial services

3 →

Collaboration Tools / Authoring

- Conference calls
- Virtual Meetings
- Interactive Forums
- Email

↓ **4** →

Ballot Submittal

- Deadline dates from Staff
- On-line submittal form
- Provide cover letter

5 →

Electronic Balloting

- Automatic generation by staff upon receipt of a ballot item
- Email notification of ballot
- Platform independent, web-based system / write-in & uploaded input
- Electronic reporting & feedback

6 →

Negative Resolution

- Electronic receipt of feedback
- Done at a meeting or Virtual Meeting
- Use of persuasive & withdrawal options
- Future improvements

↓ **7a** →

Important Information-

Going into the Meeting

- Minutes & agendas
- Items, reports, & materials
- Schedules & logistics

7b →

Important Information-

Tools and Forms

- Tools page
- "My ASTM"
- Standards Tracker
- Committee Page

8 →

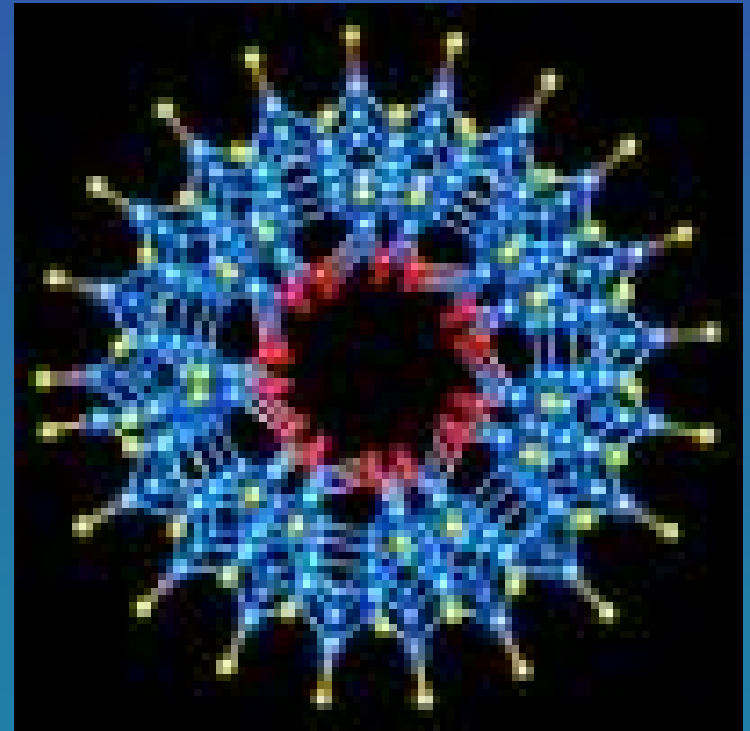
Production & Distribution

- Back-end editorial support
- Proofing / Editorial services
- Set in SGML & global distribution
- Product types (CD, HC, VV)



ASTM Committee E56

- Organized January 2005 by Industry
- Current Roster: 280 Individuals & Organizations
- 22 Countries Represented
- 3 Technical Subcommittees
 - Subcommittee on Terminology & Nomenclature
 - Subcommittee on Characterization: Physical, Chemical, and Toxicological Properties
 - Subcommittee on Environment, Health & Safety
- 2 Resource Subcommittees
 - Subcommittee on International Law & Intellectual Property
 - Subcommittee on Liaison & International Cooperation



Committee Scope



- The Scope of the Committee shall be twofold: 1) the development of standards and guidance for nanotechnology & nanomaterials, and 2) the coordination of existing ASTM standardization related to nanotechnology needs. This coordination shall include the apportioning of specific requests for nanotechnology standards through ASTM's existing committee base, as well as the maintenance of appropriate global liaison relationships with activities (internal and external) related to this subject area. The Committee shall participate in the development of symposia, workshops, and other related activities to enhance the development of standards.

E56.01 – Terminology

- Chairman: Vicki Colvin, Rice University
- Membership: 95 Individuals & Organizations
- Standards Developed:
 - [E2456-06 Standard Terminology Relating to Nanotechnology](#)
 - Developed in Partnership with: American Institute of Chemical Engineers (AIChE), American Society of Mechanical Engineers (ASME), Institute of Electrical and Electronics Engineers (IEEE), Japanese National Institute of Advanced Industrial Science and Technology (AIST), NSF International, and Semiconductor Equipment and Materials International (SEMI)
 - Terms defined include Nanotechnology, Nano, Nanoparticle, Nanoscale, Nanoscience, Nanostructured, Particle, Fine Particle, Ultrafine Particle, Transitive Nanoparticle, Non-Transitive Nanoparticle, Aggregate, & Agglomerate

E56.02 – Characterization: Physical, Chemical, and Toxicological Properties

- Co-Chairmen: Martin Fritts, Nanotechnology Characterization Laboratory & Alan Rawle, Malvern Instruments
- Membership: 100 Individuals & Organizations
- Standards Developed:
 - E2578-07 Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions
 - E2524-08 Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles
 - E2525-08 Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies
 - E2526-08 Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells

ASTM Interlaboratory Studies (ILS)

#166, #201, & #202

Generate data necessary to develop precision and bias statements for;

- E56 WK8705**: *Standard guide for measurement of particle size distribution of nanomaterials in suspension by photon correlation spectroscopy (PCS)*
- E2524-08**: *Standard Practice for Analysis of Hemolytic Properties of Nanoparticles*
- E2526-08**: *Standard Practice for Evaluation of Cytotoxicity of Nanoparticulate Materials on Porcine Kidney Cells and Human Hepatocarcinoma cells*

Generate ancillary data to support E56 WK8705 bias statement using

- Atomic Force Microscopy (AFM)
- Transmission Electron Microscopy (TEM)

Test sample preparation methods for E56 WK10417: Standard Practice for the Preparation of Nanomaterial Samples for Characterization

Test Materials:

RM 8011, Nominal 10 nm Diameter Gold Nanoparticles

RM 8012, Nominal 30 nm Diameter Gold Nanoparticles

RM 8013, Nominal 60 nm Diameter Gold Nanoparticles

Amine terminated G6 PAMAM dendrimers

Hydroxy terminated G6 PAMAM dendrimers



E56.03 – Environment, Health, and Safety

- Chairman: Kristen Kulinowski, Rice University
- Membership: 103 Individuals & Organizations
- Standards Developed:
 - [E2535-07 Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings](#)
 - Significance & Use: This Guide is intended for use by entities involved in the handling of UNP in occupational settings. The Guide covers handling principles and techniques that may be applied, as appropriate, to the variety of UNP materials and handling settings. These settings include research and development activities, material manufacturing, and material use and processing. The Guide may also be used by entities that receive materials or articles containing or comprising nanoscale particles fixed upon or within a matrix (i.e., bound nanoscale particles), but whose own processes or use may reasonably be expected to cause such particles to become unbound.

Drivers (1)

Factors that shape prioritization of activities

- Based around the needs and the contribution of members and member organizations
- Time devoted by members
 - Driven by one or 2 (key?) volunteer individuals (as are most standards activities)
 - These individuals have to fit this (standards writing) in with other activities (unless they're retired)
- Complexity of the job
- Urgency of needs
- Utilization of new informational technologies

Drivers (2)

Factors that shape prioritization of activities

- Easy to criticize rather than participate
- One negative holds up the ASTM process – these need work to resolve. Some negatives appear not logical!
- How can we change this?

Strategy teams within E56

- E56.90 Executive
- E56.91 sets strategy – these are 'standard' groups within ASTM committees

E56.91 Strategic Planning and Review

- Subcommittee Scope: This subcommittee acts in an advisory and coordination role, supporting the E56 main committee and all E56 subcommittees. Two main activities will be pursued:
 1. Collaborative definition and coordination of strategic visions, long range plans, and high-level goals across E56 and its subcommittees
 2. Quarterly review of progress against agreed-upon visions, plans, and goals, as defined by #1, above.

Short term activities

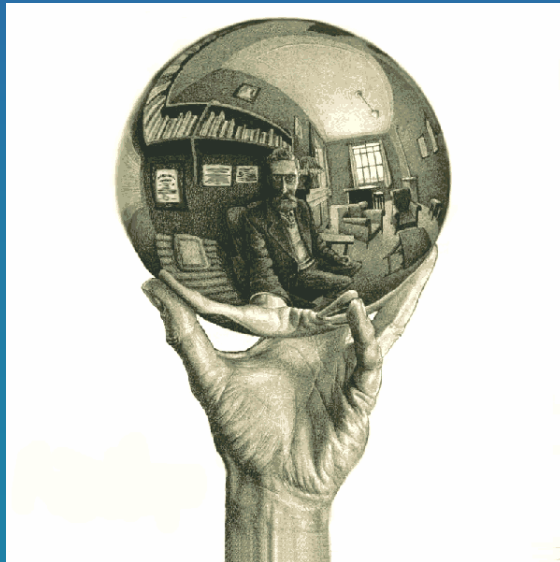
- In ASTM a standard can be revised at any time – just has to go to ballot (and be approved by voting members). Automatic revision (or dropping after 6 years)
- WK8051 Standard Terminology for Nanotechnology – continuous update and revision

Short (1-2years) term plans for E56.02 proposed activities

- (WK8705) GUIDE FOR MEASUREMENT OF PARTICLE SIZE DISTRIBUTION OF NANOMATERIALS IN SUSPENSION BY PHOTON CORRELATION SPECTROSCOPY (PCS)
- Mobility/Zeta Potential (Rawle)
- Prioritize needs for new standards from existing protocols and initiate work on 6-10 new draft standards (Fritts)
- Accelerate standard development time through the use of electronic tools (a goal of 4 months to become a standard after electronic draft approval)
- Provide “hands-on” testing of draft standards through informal ILS testing
- Expand ILS testing to achieve faster dissemination of standards and to qualify laboratories in instrumentation and protocols that are becoming increasingly complex
- New work item for nanotechnology ontology

Medium (2-5 years) term plans for proposed activities

- We need a crystal ball! With apologies to Escher.....
- 2 years is a long time in politics - and nanotechnology!



Next E56 Committee Week

- Title: Nanotechnology
- Dates: Monday May 5th 2008 - Wednesday May 7th 2008
- Location: Hyatt Regency Denver; Denver, CO US
- Event Name: May 2008 Committee Week
- All are welcome! Only \$75 to join ASTM

Questions?



ASTM Website
www.astm.org

