



Consensus Standards for Nanotechnology: ASTM International Committee E56

Workshop on Characterization of Nanomaterials for Medical and Health Applications • Reno, NV • May 19, 2005

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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
 - 4,400+ International Members from 126 Countries
 - 'Audited Designator' accreditation by American National Standards Institute (ANSI)
 - All stakeholders involved (Public & Private Sector Cooperation)
 - Neutral forum
 - Consensus-based procedures
- Development and delivery of information made uncomplicated
- A common sense approach driven by industry
- Market relevant globally
- No project costs





138 Technical Committees

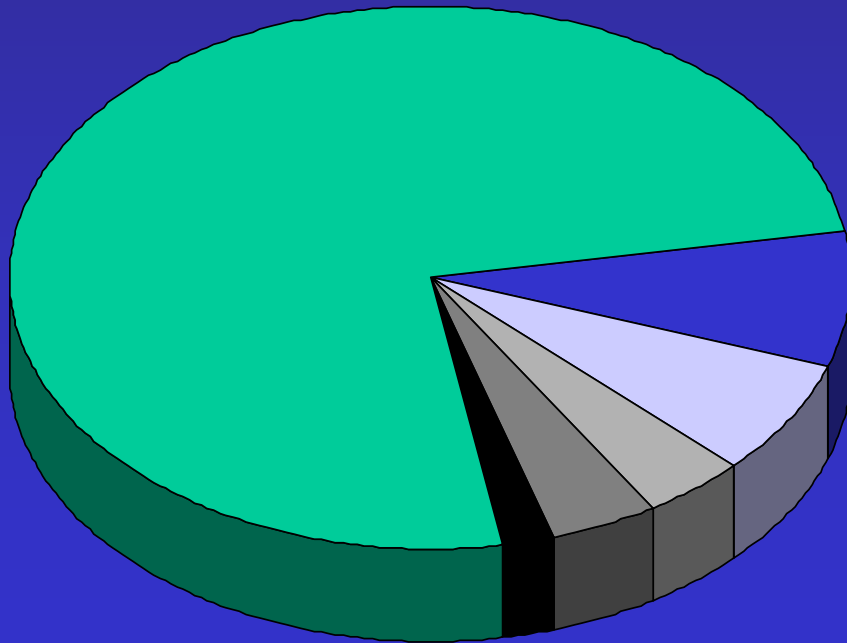
Examples

- A1 on Steel, Stainless Steel, and Related Alloys
- D1 on Paint
- D2 on Petroleum Products and Lubricants
- E30 on Forensic Science
- E50 on Environmental Assessment
- E54 on Homeland Security Applications
- E55 on Pharmaceutical Application of PAT
- E56 on Nanotechnology
- 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 Business Model

Annual Budget of \$35 Million
Revenue Sources 2004



- Publications = 75%
- Interest = 8%
- Administrative Fees = 7%
- Proficiency Test Program = 4%
- Training = 4%
- Miscellaneous = 2%

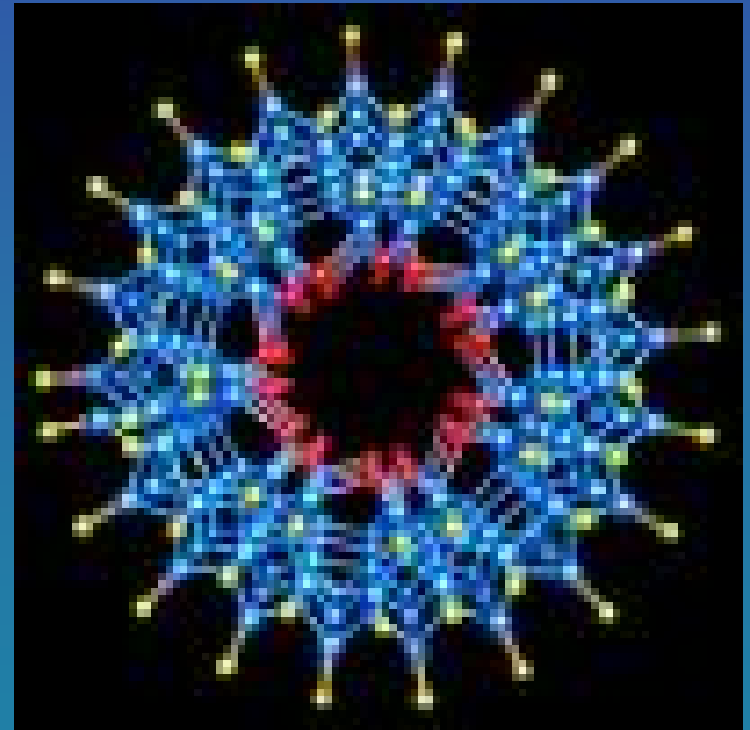
Standards for Nanotechnology

- ASTM International Committee E56 on Nanotechnology



ASTM Committee E56

- Organized January 2005 by Industry
- Current Roster: 113 Individuals & Organizations
- 6 Technical Subcommittees
 - Subcommittee on Terminology & Nomenclature
 - Subcommittee on Characterization
 - Subcommittee on Environmental & Occupational Health & Safety
 - Subcommittee on International Law & Intellectual Property
 - Subcommittee on Liaison & International Cooperation
 - Subcommittee on Standards of Care/Product Stewardship



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.

Committee Structure

Executive Subcommittee
Membership is composed of Main Committee Officers, Subcommittee Chairpersons, and Members-at-Large

Chairman - Vicki Colvin, CBEN/Rice University
Vice Chairman - Akira Ono, AIST
Secretary - Chinh Pham, Greenberg Traurig, LLP
Membership Secretary - Brij Moudgil, Particle Engineering Research Center, UF

E56.01
Terminology &
Nomenclature

Chairman
Vicki Colvin
CBEN/Rice Univ.

E56.02
Characterization

Chairman
Martin Fritts
SAIC

Chairman
Alan Rawle
Malven Instruments

E56.03
Environmental & Occupational
Health and Safety

Chairman
James Le Quynh
Organic Metals

E56.04
International Law &
Intellectual Property

Chairman
Sonia Miller
CTBA

E56.05
Liaison &
International Cooperation

Chairman
Ramani Narayan
Michigan State Univ.

E56.06
Standards of Care &
Product Stewardship

Chairman
Kristen Kulinowski
CBEN/Rice Univ.



E56.01 – Work Items

- Terminology Standard
 - Nano Properties
 - Structural Terminology/Nomenclature – Liaise with IUPAC & ACS
 - 30K foot as well as fine structure (what are the variables & what will they be called)
 - Parallel process (in relationship with characterization) to determine what variables should be included

E56.02 – Work Items

- ID of Measurement Techniques
- Thermal Management
- Measurement Methodology & Metrology (Test Methods)
- Reference/Calibration Standards
- Properties (physical, chemical, biological, structural, thermal, etc.)
- Manufacturing – GMP (Good Manufacturing Practices), Quality Control, Batch Consistency, Traceability

E56.03 – Work Items

- Worker Safety
- Medical surveillance of workers
- Particle Penetration for Protective Clothing (through filters)
- Best Practices for Handling
- Hazards Assessment/Classification for Nano-particles
- (Test) Methodology for Toxicological Measurement
- (Test) Methodology for Environmental Fate
- Exposure Limits (what is safe for public/workplace?)
- Measurement of Airborne Nano-particles/Exposure Assessment (critical need for tools)

E56.04 – Work Items

- Relevance of Terminology to Existing Patents (National & Global)
- Monitoring of Global IPR

E56.05 – Work Items

- Fabrics
- Textiles
- Rubber
- Protective Clothing
- Composites
- Powder Metallurgy
- Plastics
- Electronics
- Explosives

E56.06 – Work Items

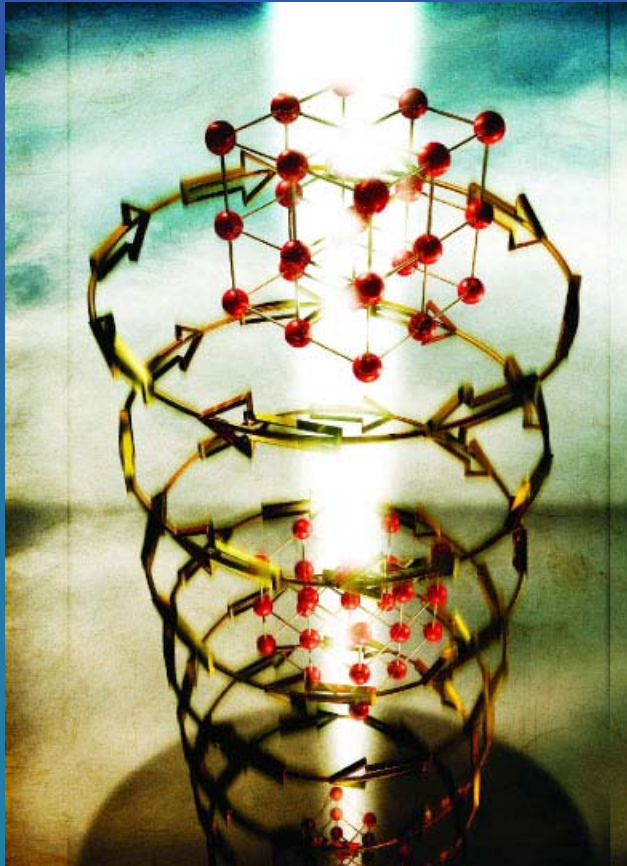
- Management Practices
- Communications

ASTM Partnership

- Who: ASTM, IEEE, ASME, NSF International, AIST (at present)
- What: Nanotechnology Terminology Standard
 - Joint Logos
 - Virtual-only Document (easier to update)
 - Available at no Cost (Royalty-Free License)
- When: 1st Draft to Ballot May 2005
- Why: Eliminate Redundant Resource Allocation, Pool Technical Experts, Create Truly Global Document (Input & Application)



Evolution of Activity



- Organizational Outreach
 - Information sharing
 - Document Reference
- Membership Promotion
 - Improve International Membership – at present, 12 countries on E56 Roster (Peoples Republic of China, Switzerland, Mongolia, United Kingdom, Japan, Zimbabwe, Taiwan, Canada, United States, Germany, Korea, Egypt)
- Access to Information
 - www.astm.org/COMMIT/COMMITTEE/E56.htm
- Future Meetings
 - November 7-9, 2005, Dallas, TX

Questions?



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ASTM Website
www.astm.org

