ASTM International Committee E56 on Nanotechnology

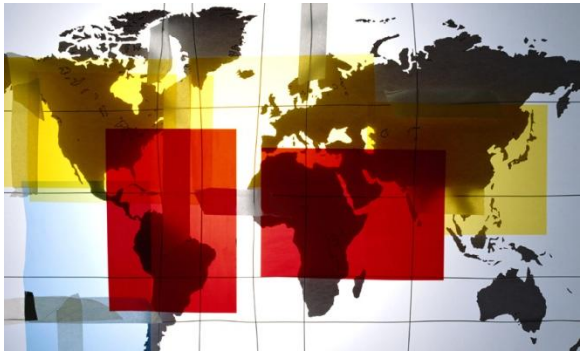
http://www.astm.org/COMMIT/COMMITTEE/E56.htm

Debra L. Kaiser
Chief, Ceramics Division, Material Measurement Laboratory, NIST
Chair, Committee E56

NIST-ANSI International Workshop on Challenges to Increased Use of Documentary Nanotechnology Standards
December 13-14, 2011

ASTM E56

Overview



- Established in 2005
- Membership: 178 individuals and organizations
- 22 countries represented in membership
- Activity by a few individuals from 2007-2009
- Committee "revitalized" in 2009
- Committee meets twice yearly (May and November)

Scope

- Develop standards and guidance for nanotechnology and nanomaterials
- Coordinate with existing ASTM standardization efforts of other ASTM committees as they relate to nanotechnology
- Maintain appropriate global liaison relationships with activities (internal and external) related to this subject area
- Participate in the development of symposia, workshops, and other related activities to enhance the development of standards

Types of ASTM Standards

- **Classification:** a systematic arrangement or division of materials, products, systems, or services into groups based on similar characteristics such as origin, composition, properties, or use
- **Guide:** a compendium of information or series of options that does not recommend a specific course of action
- **Practice**: a definitive set of instructions for performing one or more specific operations that does not produce a test result
- **Specification**: an explicit set of requirements to be satisfied by a material, product, system, or service
- **Terminology standard:** a document comprising definitions of terms; explanations of symbols, abbreviations, or acronyms
- **Test method:** a definitive procedure that produces a test result; requires an interlaboratory study

Interlaboratory study: conducted to develop precision and bias statements

- **Precision:** closeness of agreement between test results obtained under prescribed conditions; includes repeatability and reproducibility standard deviations
- **Bias:** systematic error that contributes to the difference between the mean of a large number of test results and an accepted reference value

The ASTM Standards Development Process

1. Interested party (producer, user, general interest member) proposes a needed standard to the Executive Committee
2. Executive Committee discusses and approves the proposal
3. The proposal is registered as a Work Item and assigned a number and technical lead
4. A task group (typically 2-5 people) is formed to draft and vet the standard
5. The technical lead for the Work Item submits the draft standard for balloting at the subcommittee level with the chair's approval
6. An announcement is sent to all members of the Subcommittee to vote and comment on the draft standard by a specified date (not less than 30 days after posting)
7. The technical contact receives the results of the initial ballot (affirmative with or without comments, abstain, or negative with comments)
8. Negatives must be addressed: negatives can be withdrawn, the draft can be re-balloted after addressing the negative, the negative can be voted "not persuasive" during the next committee meeting, or the Work Item may be withdrawn.
9. A revised draft can be balloted concurrently (sub + main). Steps 7-9 are repeated, as necessary. A societal review is opened for a specified period following a successful main or concurrent ballot.
10. A standard is approved for publication only after all negatives have been resolved and the minimum required votes and % affirmatives are received during balloting at each level.

E56 Organization

Chair: *Debbie Kaiser* (NIST)
Vice-Chair: *Stacey Harper* (Oregon State)
ASTM Staff Manager: *Kate McClung*
Membership Secretary: *Tony Thornton* (Micromeritics)
Secretary: *Aleksandr Stefaniak* (NIOSH)

Technical Subcommittees

E56.01
Informatics and Terminology

E56.02
Characterization: Physical and Chemical

E56.03
Environment, Health, and Safety

E56.06
Nano-enabled Products

E56.90
Executive

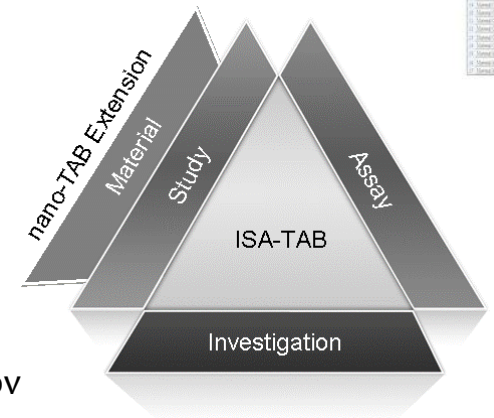
E56.04
Intellectual Property Issues

E56.05
Liaison and Int'l Cooperation

Advisory Subcommittees

E56.01 – Informatics and Terminology

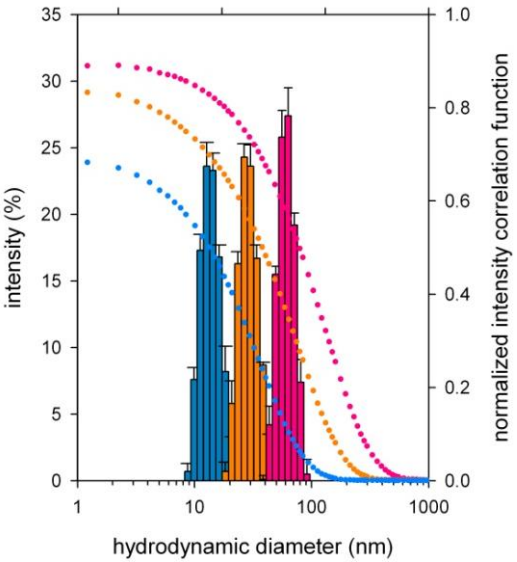
- Co-Chairs: *Nathan Baker* (PNNL), *David Paik* (Stanford University), *Dennis Thomas* (Washington University in St. Louis)
- Membership: 51 individuals and organizations
- Published Standards:
  - **E2456-06**: Standard Terminology Relating to Nanotechnology
- Work Items (in ballot stage):
  - **WK28974:** Standard Specification for Nanotechnologies (nano) Tab-Delimited (TAB): Standard File Format for the Submission and Exchange of Data on Nanomaterials and Characterizations



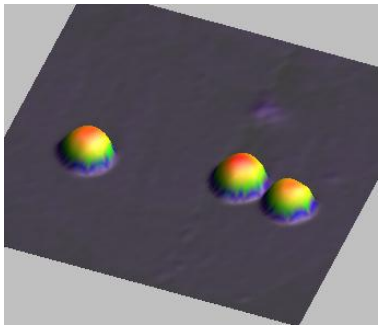
https:// wiki.nci.nih.gov

E56.02 – Characterization: Physical and Chemical

- Co-Chairs: *Martin Fritts* (NIST), *Alan Rawle* (Malvern Instruments)
- Membership: 78 individuals and organizations
- Published Standards:
  - **E2578-07:** Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions
  - **E2490-09:** Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS)
- Approved for Publication:
  - **WK29480:** Standard Guide for Size Measurement of Nanoparticles Using Atomic Force Microscopy



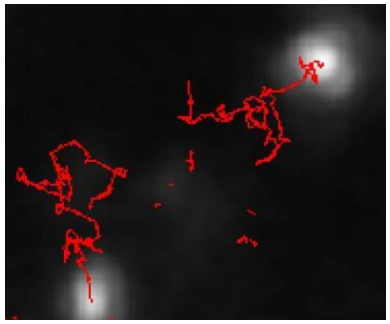
V. Hackley, NIST



AFM image of 30 nm gold NP reference material (R. Cook, NIST)

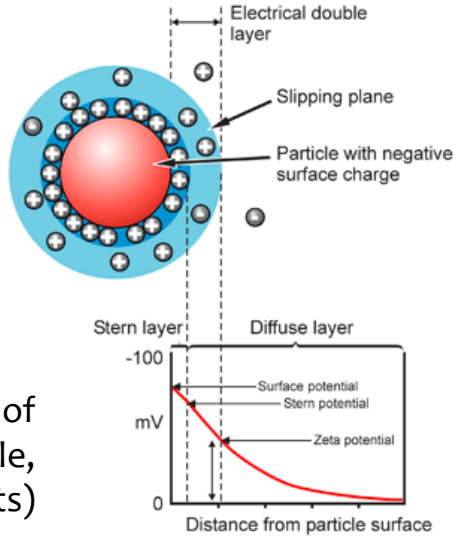
E56.02 – Characterization: Physical and Chemical

- Work Items (in ballot stage):
  - **WK26321:** Standard Guide for a Measurement of Particle Size Distribution of Nanomaterials in Suspension by Nanoparticle Tracking Analysis (NTA)
  - **WK32796:** Standard Test Method for Measurement of Airborne Metal and Metal Oxide Nanoparticle Surface Area in Inhalation Exposure Chambers using Gas Adsorption
  - **WK21915:** Standard Guide for Measurement of Electrophoretic Mobility and Zeta Potential of Nano-sized Biological Materials



D. Griffiths, Nanosight

Particle tracks by NTA



Schematic representation of zeta potential (A. Rawle, Malvern Instruments)

E56.03 – Environment, Health, and Safety

- Chair (interim): *Debbie Kaiser* (NIST)
- Membership: 69 individuals and organizations
- Published Standards:
  - **E2535-07**: Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings
  - **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
  - Standard Test Methods involved interlaboratory studies using NIST gold nanoparticle reference materials

- Work Items: none

E56.06 – Nano-enabled Products

- Chair: *Aleksandr Stefaniak* (NIOSH)
- Subcommittee formed in 2010
- Membership: 38 individuals and organizations
- Scope: develop scientifically-credible standards for detection, identification, and release of manufactured nanomaterials in products in commerce, including consumer-ready products and medical devices
- Strategic plan: under development

Cosmetics: 23%

Clothing: 21%

Sporting goods: 15%

Challenges to Standards Development and Use

Nanotechnology-specific:

- Rapidly evolving field
- Unknown risk drives regulatory uncertainty and may stifle innovation
- Many different types of nanomaterials—broad applicability?
- Various media of *importance—e.g., serum*, tissue, air, water, soil, sludge
- Sample preparation is a key factor
- Surface dominates properties leading to stability issues, even during measurement

General:

- Too few volunteers to develop standards
- Duplication of standards by different organizations
- All stakeholders "at the table" throughout the development process?
- Standards that generate a quantitative result require:
  - Interlaboratory studies
  - Reference materials or well-characterized materials
- Advertise availability and applicability of a published standard: *better web delivery?*