

Welcome to ASTM Committee E56 on Nanotechnology

The purpose of this document is to provide new members with background information about ASTM Committee E56, including our meetings, officers, work items, and voting on standards. E56 meets face-to-face twice a year, usually in May and November, with about 15 to 25 members attending two days of technical meetings. The Committee currently has over 170 members who participate in six technical and three administrative subcommittees. All standards developed by E56 are published in the Annual Book of ASTM Standards, Volume 14.02. The most current information on the E56 subcommittee structure, our approved standards, and Work Items (standards under development) is available from the List of Subcommittees, Standards and Work Items on the ASTM web site (<http://www.astm.org/COMMIT/SUBCOMMIT/E56.htm>).

If you are a new ASTM member, you may find the new member orientation information on the ASTM web site helpful (<http://www.astm.org/MEMBERSHIP/newmembership.html>). ASTM members may join as many Committees and Subcommittees within each Committee as they wish. If you have not already done so, we encourage you to join E56 and subcommittees within E56 that interest you. You can do so on the left-hand side of your “MyCommittees” page, where it says “Join additional Committees.” E56 encourages its members to get involved with helping to develop standards. All committee members, whether new or existing, have useful knowledge and skills to impart in this process. Committee Officers and Subcommittee Chairs are listed below along with their contact information. Please feel free to contact them with questions or to discuss ideas for new and existing work items.

Much of the information exchange and deliberations of E56 are done at the main Committee and Subcommittee level during our biannual face-to-face meetings. Most of the standards development work is done between meetings via electronic communications. Members are encouraged to attend meetings in person when possible; remote participation such as WebEx may also be available for some meetings.

Committee Scope

- Development of standards and guidance for nanotechnology & nanomaterials.
- 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.
- Participation in the development of symposia, workshops, and other related activities to enhance the development of standards.

Officers

Chair: Stacey L. Harper, 541-737-2791, harpers@science.oregonstate.edu

Vice-chair: Debbie Kaiser, 301-975-6759, debra.kaiser@nist.gov

Recording Secretary: Tony Thornton, 770-662-3611, tony.thornton@micromeritics.com

Membership Secretary: Aleks Stefaniak, 304-285-6302, astefaniak@cdc.gov

Staff Manager: Kate Chalfin, 610-832-9717, kchalfin@astm.org

Admin Assistant: Lindsey Limone, 610-832-9722, llimone@astm.org

E56 TECHNICAL SUBCOMMITTEES

E56.01: Informatics and Terminology

Chair: Frederick Klaessig, 215-345-0321, fred.klaessig@verizon.net

Current Standards and Work Items (WK)

E2456-06(2012) Standard Terminology Relating to Nanotechnology

E2909-13 Standard Guide for Investigation/Study/Assay Tab-Delimited Format for Nanotechnologies (ISA-TAB-Nano): Standard File Format for the Submission and Exchange of Data on Nanomaterials and Characterizations

WK58111 Reporting Production Information and Data for Nano-objects

WK58112 Reporting the Physical and Chemical Characteristics of Nano-objects

E56.02: Physical and Chemical Characterization

Co-Chair: Alan Rawle, 508-768-6434, alan.rawle@malvern.com

Co-Chair: Vince Hackley, 301-975-5334, vince.hackley@nist.gov

Current Standards and Work Items (WK)

E2490-09(2015) Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS)

E2578-07(2012) Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions

E2834-12 Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Nanoparticle Tracking Analysis (NTA)

E2859-11 Standard Guide for Size Measurement of Nanoparticles Using Atomic Force Microscopy

E2864-13 Standard Test Method for Measurement of Airborne Metal and Metal Oxide Nanoparticle Surface Area Concentration in Inhalation Exposure Chambers using Krypton Gas Adsorption

E2865-12 Standard Guide for Measurement of Electrophoretic Mobility and Zeta Potential of Nanosized Biological Materials

WK54613 Standard Guide for the Analysis of Nanoparticles by Single Particle Inductively Coupled Plasma Mass Spectrometry (SP-ICP-MS)

WK54872 Measuring the Size of Nanoparticles in Aqueous Media Using Batch-Mode Dynamic Light Scattering

WK56764 Characterization of Graphene Flakes Produced by Exfoliation

E56.03: Environment, Health, and Safety

Chair: Dale Porter, 304-285-6320, dporter@cdc.gov

Current Standards and Work Items (WK)

E2524-08(2013) Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles

E2525-08(2013) Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies

E2526-08(2013) Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells

E2535-07(2013) Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings

WK48313 New Guide for Collection and Generation of Environment, Health, and Safety Information for Nanomaterials and Nano-enabled Products

E56.06: Nano-enabled Consumer Products

Chair: Aleks Stefaniak, 304-285-6302, astefaniak@cdc.gov

Current Standards and Work Items (WK)

E3025-16 Standard Guide for Tiered Approach to Detection and Characterization of Silver Nanomaterials in Textiles

WK52417 New Test Method for Detection of Total Silver in Textiles by ICP Analysis

E56.07: Education and Workforce Development

Chair: Debbie Kaiser, 301-975-6759, debra.kaiser@nist.gov

Current Standards and Work Items (WK)

E2996-15 Standard Guide for Workforce Education in Nanotechnology Health and Safety

E3001-15 Standard Practice for Workforce Education in Nanotechnology Characterization

E3034-15 Standard Guide for Workforce Education in Nanotechnology Pattern Generation

E3059-16 Standard Guide for Workforce Education in Nanotechnology Infrastructure

E3071-16 Standard Guide for Nanotechnology Workforce Education in Materials Synthesis and Processing

WK56677 Nanotechnology Workforce Education in Material Properties and Effects of Size

E56.08: Nano-enabled Medical Products

Chair (interim): Debbie Kaiser, 301-975-6759, debra.kaiser@nist.gov

Current Standards and Work Items (WK)

WK54615 Standard Practice for Performing Electron Cryo-Microscopy of Liposomes

E56 ADMINISTRATIVE SUBCOMMITTEES

E56.04: Intellectual Property Issues

Chair: Jorge Contreras, 314-566-6695, cntreras@gmail.com

E56.05: Liaison and International Cooperation

Chair: Vince Hackley, 301-975-5334, vince.hackley@nist.gov

Several E56 members serve as liaisons primarily through common memberships within ASTM (e.g., ASTM Committee F04 on Medical and Surgical Materials and Devices) and with other international standards development organization committees such as the US TAG to ISO TC229 and ISO TC24.

E56.90: Executive

Committee Officers, Subcommittee Chairs, and Members-at-Large

ASTM E56 STANDARDS DEVELOPMENT

Standards Writing

ASTM publishes several types of standards. For more information, see the ASTM Form & Style Manual.

classification— a systematic arrangement or division of materials, products, systems, or services into groups based on similar characteristics.

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. Examples include collection, preparation, sampling, screening, and training.

specification— an explicit set of requirements to be satisfied by a material, product, system, or service. Examples include requirements for; physical, mechanical, or chemical properties, and safety, quality. A specification identifies the test methods for determining whether each of the requirements is satisfied.

terminology— a document comprising definitions of terms; explanations of symbols, abbreviations, or acronyms.

test method— a definitive procedure that produces a test result. Examples of test methods include identification, measurement, and evaluation of one or more qualities, characteristics, or properties. A precision and bias statement shall be reported at the end of a test method.

When developing new standards, there are templates available on the ASTM web site, as well as other information resources including:

- ASTM Form & Style Manual (also referred to as the “Blue Book”) which provides instructions for how to populate standard templates (http://www.astm.org/FormStyle_for_ASTM_STDS.html),
- ASTM Terminology Dictionary (<https://myastm.astm.org/TERMINOLOGY/>)
- Collaboration area: an online workspace for ASTM members and non-member technical experts to develop a work item. You can choose to set up a new collaboration area for each work item and it is password protected within ASTM.
- Interlaboratory Studies Program: a free service that provides support to generate a precision statement for an existing or new ASTM test method
- Web conferencing, electronic balloting, and web access to committee information to facilitate the development process

Any individual or organization that identifies a need for standardization can request to develop a work item. Development of an ASTM standard begins when an individual member (referred to as the Technical Contact) or a group of individuals (referred to as the Task Group) develops a scope and obtains

approval from the relevant Subcommittee Chair or by vote of the Subcommittee members at a meeting to register a new work item. The Technical Contact (or Task Group) proceeds to write the draft standard (use of the Blue Book and setting up a collaboration area is highly recommended). Once a complete draft is written, the work item is submitted for ballot to the relevant Subcommittee as described below.

Standards Balloting and Voting

In the ASTM consensus process, every member of a Committee is encouraged to vote and provide comments on each new standard put to ballot. When a member joins an ASTM Committee, they are placed into a voting category of Producer, User, General Interest or Consumer based on their business interests. Although there can be multiple members from the same organization, only one member is assigned the “official” vote. This process assures that there is no dominance in a Committee by one organization. In addition, the number official votes from Producers must be less than the sum of official votes from the other three voting categories, ensuring that there is no dominance by Producer interests. Voting category assignments are typically done by the Committee Membership Secretary. Members without an official vote are strongly encouraged to vote on a ballot and provide comments. Negative votes submitted by unofficial voting members must be considered in the same way as for official voting members. In ASTM, everyone has a voice. For details on the balloting procedure please see the Regulations Governing ASTM Technical Committees at <http://www.astm.org/Regulations.html#s6>

There are five voting choices on a ballot:

- Affirmative
- Affirmative with Comment (does not stop the balloting process, could be used for suggested item of new business)
- Negative with Statement (must provide comments; negative stops the balloting process)
- Abstain
- Abstain with Comment (does not stop the balloting process, could be used for suggested item of new business)

After the initial Subcommittee ballot of a draft standard, the results are returned to the Technical Contact (or Task Group) to resolve any issues. Any technical changes result in the need for a new ballot. We encourage members to politely and respectfully discuss their negative votes with the Technical Contact (or Task Group) and make a good faith attempt to resolve the negative. A negative vote which cannot be resolved by this process is discussed at a Subcommittee meeting (or by ballot of the Subcommittee) along with a rationale for disagreement; the Subcommittee members may find the negative vote to be Non-Persuasive. If a negative cannot be resolved in this way, it is considered persuasive, and the draft standard is returned to the Technical Contact (or Task Group) for revision of the draft. Once all negatives have been resolved at the Subcommittee level, the standard is balloted at the Main Committee level (all E56 committee members vote on this ballot). Main Committee ballots are authorized by the Main Committee Chairman or by vote of the Main Committee members at a meeting. In addition, at the same time the standard is being balloted at the Main Committee level, it appears on ASTM’s Society Review. Negative votes at the Main Committee ballot level are handled the same way as Subcommittee negative votes. Once all negatives at this ballot level are resolved, the standard goes on to the ASTM Committee on Standards for procedural review, and is then published.

Committee E56 issues ballots four set times per calendar year; however, with permission of the Committee Chair, a ballot can be initiated at any time. Voting on each ballot is an important responsibility of members. For a ballot to be valid, at least 60% of voting members must cast votes. As

such, even if a ballot is outside your areas of expertise, an “abstain” vote will count toward the returned vote percentage. Voting is essential to produce high quality standards and, in accordance with ASTM Regulations, members holding official voting rights that have missed three (3) or more consecutive Main Committee ballots should be removed, in the absence of circumstances acceptable to the Executive Subcommittee. Any member who has missed three or more consecutive votes is automatically placed on the Main Committee Inactivity List; their vote may be reinstated by vote of the Executive Subcommittee.