ASTM Committee E56 Nanotechnology

Overview of Recent Activities and Work Items

September 10, 2024

Vince Hackley (Membership Secretary, Chair E56.02, E56.05)

https://www.astm.org/get-involved/technical-committees/committee-E56

Committee E56 Committee

- Formed in 2005 to develop standards and guidance for nanotechnology & nanomaterials
- Currently about 130 members
- Meets twice annually in May and November
- E56 standards published in the *Annual Book of ASTM Standards*, Volume 14.02

- Six technical subcommittees
  - E56.01 Informatics and Terminology
  - E56.02 Physical and Chemical Characterization
  - E56.03 Environment, Health, and Safety
  - E56.06 Nano-Enabled Consumer Products
  - E56.07 Education and Workforce Development
  - E56.08 Nano-Enabled Medical Products

E56 Committee Organization

Officers (new as of January 2024)

- Chair: Aleksandr Stefaniak (US CDC/NIOSH)
- Vice-chair: Shan Zou (NRC-Canada)
- Recording secretary: Katrina E. Varner (US EPA)
- Membership secretary: Vince Hackley (US NIST)
- Staff manager: Frank McConnell (ASTM) fmcconnell@astm.org
- Admin assistant: Lindsey Limone (ASTM) llimone@astm.org

- Members-At-Large

Adam Crowe (Cytiva), Anil Patri (FDA), Debbie Kaiser (NIST), Lawrence Murphy (Cabot), Luigi Calzolai (EC-JRC), Sigrid Kuebler (Yokogawa)

E56 Standards by Subcommittee (33 total)

- E56.01 Informatics and Terminology (4)
- E56.02 Physical and Chemical Characterization (11)
- E56.03 Environment, Health, and Safety (4)
- E56.06 Nano-Enabled Consumer Products (2)
- E56.07 Education and Workforce Development (6)
- E56.08 Nano-Enabled Medical Products (6)

E56.02 Physical and Chemical Characterization

- Chair: Vince Hackley, NIST (vince.hackley@nist.gov)

- Most recently published standard
  - E3409-24 Standard Test Method for Analysis of Liposomal Drug Formulations Using Multidetector Asymmetrical-Flow Field-Flow Fractionation
    - Collaboration between NIST, SINTEF (Norway), EC-JRC (Italy), LNE (Paris), FDA/CDER, Wyatt Technology (US) and Postnova Analytics (Germany)
- External recognition
  - E3247-20 Standard Test Method for Measuring the Size of Nanoparticles in Aqueous Media Using Dynamic Light Scattering
    - First standard recognized by FDA/CDER voluntary consensus standards program (3/19/24)
    - Allows CDER to communicate to stakeholders that "FDA experts have evaluated a consensus standard" and determined the it is "potentially useful to industry and FDA staff".
    - Developed in close collaboration with FDA subject matter experts across multiple centers
- Current work items
  - WK83164 Standard Test Method for Analysis of Lipid Nanoparticle Formulations Using Multi-Detector Asymmetrical-Flow Field-Flow Fractionation
    - Contact: Dr. Jeremie Parot (SINTEF Industry, Norway)

E56.03 Environment, Health, and Safety

- Chair: Dale Porter, CDC/NIOSH (dhp7@cdc.gov)

- Most recently published standards
  - E2524-22 Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles
  - E2525-22 Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies
  - E2526-22 Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells
- Current work items
  - WK76878 The Analysis of Nanoparticle Effects on Human Platelets in vitro
  - WK76861 In vivo Analysis of Nanoparticle-Mediated Physiological Changes Accompanying Hypersensitivity Reactions
  - WK76860 Preparation and Analysis of Culture Supernatants for the Presence of Cytokine Biomarkers by Nanoparticles in Human Whole Blood Cultures
  - WK76862 Identification of Nanoparticles Ability to Induce Infusion Reactions

E56.06 Nano-Enabled Consumer Products

- Chair: Aleks Stefaniak, CDC\NIOSH (boq9@cdc.gov)

- Most recently published standards
  - ASTM E3171-21a Standard Test Method for Determination of Total Silver in Textiles by ICP-OES or ICP-MS Analysis
    - Led by Aleks Stefaniak
- Current proposal under consideration for development
  - Identification of Silver Nanomaterials on Surfaces of Textile Fibers using Scanning Electron Microscopy-Energy Dispersive X-ray Analysis
    - Standard Guide focused on the measurement challenges associated with this type of analysis

E56.08 Nano-Enabled Medical Products

- Chair: Bryant Nelson, NIST (bryant.nelson@nist.gov)

- Recently published standards
  - E3297-21 Standard Test Method for Lipid Quantitation in Liposomal Formulations Using High Performance Liquid Chromatography (HPLC) with a Charged Aerosol Detector (CAD) (P&B under revision)
  - E3323-22 Standard Test Method for Lipid Quantitation in Liposomal Formulations Using High Performance Liquid Chromatography (HPLC) with an Evaporative Light-Scattering Detector (ELSD) (P&B under revision)
  - E3324-22 Standard Test Method for Lipid Quantitation in Liposomal Formulations Using Ultra-High-Performance Liquid Chromatography (UHPLC) with Triple Quadrupole Mass Spectrometry (TQMS) (P&B under revision)
  - E3351-22 Standard Test Method for Detection of Nitric Oxide Production In Vitro

E56.08 Nano-Enabled Medical Products

- Current work items
  - WK60553 Test Method for Evaluating the Impact of Nanomaterials on Phagocytic Function in Vitro (subcommittee ballot)
  - WK67980 Test Method for Quantifying Poly(ethylene glycol) Coating on the Surface of Gold Nanostructured Materials Using High Performance Liquid Chromatography with Evaporative Light Scattering Detection (HPLC/ELSD)
  - WK69051 Test Method for Assessing the Activation of the Complement System in Human Plasma Through Quantification of iC3b Concentration by ELISA
  - WK75607 Standard Guide for Characterization of Encapsulation, Extraction, and Analysis of RNA in Lipid Nanoparticle Formulations for Drug Delivery (subcommittee ballot)
  - WK86057 Test Method for Measuring Sulfate and Ammonium Ion Concentrations in Liposome Drug Formulations
  - WK86056 Test Method for Measuring In Vitro Drug Release from Liposomal Drug Formulations

Takeaways

- Most E56 technical standards are **Test Methods** requiring P&B statements based on interlaboratory studies conducted according to ASTM E691 and supported by the ASTM ILS Program.
- Standards development supported through collaboration teams with dedicated web space for each work item to facilitate information sharing
- Key SMEs who are not ASTM members can contribute through the online collaboration interface
- Over the past 5+ years the committee has engaged increasingly in the regulatory space and specifically nano-enabled medical products including lipid-based vectors
- Collaboration with multiple FDA centers and experts has been critical in this transition
- FDA standards recognition programs are important metrics for validity and value of standards developed by E56 (since 2016, 11 standards have been formally recognized by FDA under the specialty task group *Nanotechnology*)

Future Meetings

November 2024 Committee Week

- Wednesday November 13, 2024 - Thursday November 14, 2024
- Renaissance Orlando at SeaWorld, 6677 Sea Harbor Dr, Orlando, Florida, United States of America

May 2025 Committee Week

- Monday May 05, 2025 - Tuesday May 06, 2025
- Sheraton Centre Toronto Hotel, 123 Queen St W, Toronto, Ontario, Canada

Thank You!