

**U.S. Consumer Product Safety Commission**  
**LOG OF MEETING**

**SUBJECT:** Meeting of the ASTM E56 Committee (Nanotechnology)

**DATE OF MEETING:** November 6-7, 2023

**PLACE OF MEETING:** Hybrid (Washington, DC)

**LOG ENTRY SOURCE:** Joanna Matheson (HSTR)

**COMMISSION ATTENDEES:** Joanna Matheson (HSTR), Treye Thomas (EXHR)

**NON-COMMISSION ATTENDEES:** Contact ASTM for a complete list.

**SUMMARY OF MEETING:**

ASTM E56 focuses on standardization in the field of nanotechnologies, understanding and control of matter and processes at the nanoscale where the onset of size-dependent phenomena usually enables novel applications, as well as use of nanoscale materials to create improved materials, devices, and systems that exploit these new properties. Specific subcommittees address the development of standards and guides for terminology and nomenclature; education and outreach; physico-chemical characterization; nano-enabled consumer products; environmental health and safety; and nano-enabled medical products.

On Monday, November 6, 2023, through Tuesday, November 7, 2023, the ASTM E56 (nanotechnology) committee and subcommittees met in person and by teleconference. Staff participated virtually in the executive committee meeting and subcommittee meetings for Physical and Chemical characterization (E56.02), Environmental, Health and Safety (E56.03), Nano-enabled Consumer Products (E56.06), and Nano-enabled Medical Products (E56.08).

During the executive committee meeting, status updates were provided by the leads of the Education and Workforce Development subcommittee (E56.07) and the nanoplastic task group. E56.07 has developed a suite of 6 standards that cover basic skill sets for

the nanotechnology workforce. The coursework is geared for training U.S. Armed Forces veterans for careers in nanotechnology. While students have improved in passing the Characterization exam, about 50% fail. ASTM committee members will work with the subcommittee lead to revise the questions. The Nanoplastic task group is new in 2023. This task group will continue defining the scope at the upcoming meeting on December 5, 2023. The goal of this group is to assess and document standard readiness for nanoplastic characterization; they have defined nanoplastics as 1-1000nm in size. Staff informed the committee about ISO TC/229 nanoplastic activities and will participate in the ASTM nanoplastic task group.

During the E56.02 subcommittee, the work item, led by NIST, on determining lipid nanoparticle size and concentration using multi-detector asymmetrical flow field-flow fractionation (AF4) was discussed. This item was removed from a September 2023 ballot due to a negative vote and a number of proposed technical changes; balloting is expected by year end. An update was given on a similar work item 83164 *Analysis of lipid nanoparticle size and concentration using multi-detector AF4*. They have optimized the method for different formulations and a draft is expected by the end of 2023. Presentations were given on two new project proposals, *Challenges for the analysis of complex drug products using AF-4 based methods* (FDA led), and *An integrated workflow using continuous manufacturing for nanoparticle drug products and vaccines*.

Three projects (E2524, E2525, and E2526) under subcommittee E56.03 have been placed on hold due to leadership issues. CPSC staff reached out to OSHA regarding their interest in participating in the revision of E2535-2007 (2018), a guide for handling unbound engineered nanoscale particles in work settings. OSHA agreed to participate and has completed their review. Once updates are completed the E2535 standard is expected to undergo balloting by year end.

At the E56.06 meeting, discussion continued on the proposed project *Identification of Silver Nanomaterials on Surfaces of Textile Fibers using Scanning Electron Microscopy-Energy Dispersive X-ray Analysis (SEM-EDX)*. This method can provide information on both nanomaterial size and form, whereas other methods using ICP-MS cannot. In response to a query on whether the standard would be used, CPSC staff replied that it could be used as part of a batch of tests in a weight of evidence approach when performing a risk evaluation on a nano-enabled textile product. Other participants supported this position. SEM-EDX was used along with other analytical methods in a CPSC supported interagency study on silver nanomaterials in consumer products. Participants suggested that the subcommittee could start off with a guidance document, which was well received as a path forward.

During the E56.08 subcommittee meeting updates were provided on multiple liposomal formulation projects, three of which are in interlaboratory studies involving 13 countries. More than 20 organizations are involved in the development of work item 75607, a standard guide for the characterization of encapsulation, extraction and analysis of RNA in lipid nanoparticles for drug delivery. The scope of the project was changed from

mRNA to RNA lipid nanoparticles to reflect the current use siRNA, miRNA, mRNA, and saRNA lipid nanoparticles. The draft standard should be ready for ballot by the end of the year. A new project proposal, *Standard test method for measuring sulfate and ammonium ion concentrations in liposome drug formulations using ion chromatography with conductivity detection* (FDA lead) was presented on. Discussions revolved around how to report data analysis (as mass or volume) and terminology. The subcommittee stated a need for biologists to review new work items, for example ones assessing the activation of the complement system in human plasma and the chemoattractant capacity of nanoparticles. CPSC staff contacted Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) expert groups on nanotoxicity and immunotoxicity to encourage participation in this subcommittee. ICCVAM is a permanent committee of NIEHS.

Upcoming meetings will be held in Philadelphia (May 6, 2024 – May 7, 2024) and Orlando (November 11, 2024 – November 12, 2024).