

U.S. Consumer Product Safety Commission
LOG OF MEETING

SUBJECT: Meeting of the ASTM E56 Committee (Nanotechnology)

DATE OF MEETING: November 3-4, 2021

PLACE OF MEETING: Teleconference

LOG ENTRY SOURCE: Joanna Matheson (HSTR)

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

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 Wednesday, November 3, 2021 and Thursday, November 4, 2021, the ASTM E56 (nanotechnology) subcommittees met by teleconference. Staff participated in the subcommittee meetings for Terminology and Informatics (E56.01), Physical and Chemical characterization (E56.02), Environmental, Health and Safety (E56.03), Nano-enabled Consumer Products (E56.06), Education and Workforce Development (E56.07), and Nano-enabled Medical Products (E56.08).

Brief updates were provided on a recent nanomedicine standard workshop as well as on ISO TC/229 (nanotechnologies) activities. With the shift from simple delivery

systems to complex multi-component systems, there is a need for measurement methods and standards for these more complex nanomedicine delivery systems.

The E56.01 subcommittee chair provided an overview of the EU project “GRACIOUS”, whose main goal is to generate a highly innovative science-based framework to enable practical application of grouping, leading to read-across and classification of nanomaterials/nanofoms.

The E56.02 subcommittee noted that the revisions are needed for test method E2859 *Guide for size measurement of nanoparticles using Atomic Force Microscopy*. Progress was delayed for several liposomal drug formulation activities, including WK68060 *Analysis of Liposomal Drug Formulations using Multidetector Asymmetrical-Flow Field-Flow Fractionation*; however, a peer-reviewed paper was published in 2021 on the joint project and a final draft of the standard is expected in June 2022. A new project proposal on determining lipid nanoparticle size and concentration using multi-detector asymmetrical flow field-flow fractionation (AF4) was presented. This proposed method is critical for the development and safety assessments of RNA-LNP therapeutics, the center stage of the SARS-CoV-2 vaccines.

An ASTM E56 task group provided background on their discussions regarding the determination of what is a “practice” versus a “test method”, relating to next steps for multiple test methods under revision in the E56.03 subcommittee. The issue was that “practices” produce a test result, which is not permitted under ASTM rules. There is an option in the ASTM rule book that allows a test method to be approved with a statement that declares that a precision and bias (P&B) statement based on a full inter-laboratory study (ILS) is not possible for reasons specified. The consensus of the task group was that this option be exercised for three of the methods referred to as practices, because many biological assays are too complicated or impractical to carry out a valid ILS. The converted standards would be withdrawn, P&B statements developed, and the standards balloted as test methods. Four additional methods would be reformatted as test methods, P&B statements drafted as appropriate, and the resultant methods balloted as test methods.

At the E56.06 meeting, E3171 *Standard Test Method for Determination of Total Silver in Textiles by ICP-OES or ICP-MS Analysis* was revised, approved and published. The technical lead has worked on a draft document *Identification of Silver Nanomaterials on Surfaces of Textile Fibers using SEM-EDX*. The technical lead is expected to register the project as a work item shortly. Multiple attendees volunteered to work on the project. E3025-2016 *Guide for Tiered Approach to Detection and Characterization of Silver Nanomaterials in Textiles* is due for revision. Subcommittee members, including CPSC staff, are reviewing the standard and planning to make minor revisions and submit for rebalot. Discussions continued on a possible work item *Terminology related to nano-enabled products*. Many terms are in use, but most are not defined. Attendees suggested focusing on terms used across E56, since there is a need for consistency.

New potential projects discussed were real-world mixture methods, projects on nanoplastics, and the CPSC-NIST-DoD abrasion method.

The E56.07 subcommittee noted that there are now six published standards on workforce education, three that are up for review. Three certificates have been developed that cover five of the six ASTM Nanotechnology Workforce Education Standards; one certificate is on health and safety, a second on characterization, and the third covers nanotechnology fabrication and related infrastructure. These certificates are attained by individuals completing the course-work and/or programs and passing corresponding exams developed by the subcommittee. This subcommittee will update the ASTM webpage for Education & Workforce Development to include an introduction section, information on standards, and information on the certificates.

During the E56.08 subcommittee meeting it was noted that the *Standard Guide for Visualization and Identification of Nanomaterials in Biological and Nonbiological Matrices Using Darkfield Microscopy and Hyperspectral Imaging Analysis*, as well as the *Standard Test Method for Lipid Quantitation in Liposomal Formulations Using High Performance Liquid Chromatography with Charged Aerosol Detector* were balloted, approved and published. Updates were provided on three liposomal formulation projects, a project on analytical considerations for the quantitation of RNA by UV and Fluorescence spectrophotometric techniques, and two projects assessing the *in vitro* immunotoxicity of nanomaterials. No new work items were proposed.