Research Needs For Future Development of EHS Nanomaterial Standards and Practices

January 9, 2007
Steve Brown
Standards Development Organizations Involved in Nanotechnology EHS Standards

- American Society for Testing and Materials International (ASTM International)
- International Organization for Standardization (ISO)
- Organization for Economic and Commercial Development (OECD)
- Government Agencies
- Industry/Trade Organizations
Technical Committees

Technical Committees / Committee E56 / List of Subcommittees and Standards

Committee E56 on Nanotechnology
Staff Manager: Pat Picariello 610-832-9720

Subcommittees and Standards

Standards under the jurisdiction of E56

Each main committee in ASTM International is composed of subcommittees that address specific segments within the general subject area covered by the technical committee. Click on the subcommittee links below to see the title of existing standards for each subcommittee. Then, click on the resulting titles to see the standard's scope, referenced documents, and more.

E56.01 Terminology & Nomenclature
E56.02 Characterization: Physical, Chemical, and Toxicological Properties
E56.03 Environment, Health, and Safety
E56.04 International Law & Intellectual Property
E56.05 Liaison & International Cooperation
E56.90 Executive
ASTM International

Technical Committee E56 Nanotechnology

Scope:

- The development of standards and guidance for nanotechnology & nanomaterials

- The coordination of existing ASTM standardization related to nanotechnology needs. The Committee shall participate in the development of symposia, workshops, and other related activities to enhance the development of standards
E56 Subcommittees

- E56.01 Terminology & Nomenclature
- E56.02 Characterization
- E56.03 Environmental & Occupational Health & Safety
- E56.04 International Law & Intellectual Property
- E56.05 Liaison & International Cooperation
- E56.90 Executive
Showing results 1-0 of 0 matching ACTIVE standards under the jurisdiction of E56.02   E56 Home

Showing results 1-8 of 8 matching Proposed New Standards under the jurisdiction of E56.02   E56 Home

WK8705 Measurement of particle size distribution of nanomaterials in suspension by Photon Correlation Spectroscopy (PCS)

WK8997 Standard Practice for Analysis of Hemolytic Properties of Nanoparticles


WK9952 Standard Practice for Measuring Length and Thickness of Carbon Nanotubes Using Atomic Force Microscopy Methods


WK10417 Standard Practice for the Preparation of Nanomaterial Samples for Characterization

WK13577 Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions
ASTM E56 Work Items

- **E2456-06** Terminology for Nanotechnology
- **WK8985** Standard Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings
- **WK8705** Measurement of particle size distribution of nanomaterials in suspension by Photon Correlation Spectroscopy
- **WK8997** Standard Practice for Analysis of Hemolytic Properties of Nanoparticles
- **WK9326** Standard Practice for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies
- **WK9327** Standard Practice for Evaluation of Cytotoxicity of Nanoparticulate Materials on Porcine Kidney Cells
- **WK9952** Standard Practice for Measuring Length and Thickness of Carbon Nanotubes Using Atomic Force Microscopy Methods
- **WK9953** Standard Practice for Measuring Diameter and Wall Thickness of Multi-wall Carbon Nanotubes (MWNT) Using Transmission Electron Microscopy Methods
- **WK10417** Standard Practice for the Preparation of Nanomaterial Samples for Characterization
- **WK13577** Standard Practice for Calculation of Mean Sizes Diameters and Standard Deviations of Particle Size Distributions

January 9, 2007
1. Scope

The guide will describe actions that could be taken in occupational settings to minimize human exposures to unbound, intentionally produced nanometer-scale particles, fibers and other such materials in manufacturing, processing, laboratory and other occupational settings where such materials are expected to present. It is intended to provide guidance for controlling such exposures as a precautionary measure where relevant exposure standards and/or definitive risk and exposure information do not exist. The manufacturing of nano-scale materials may pose an occupational health risk to personnel involved in their handling or use. There is a need for guidance in how to control employee exposures to nano scale materials with in occupational settings during both research/development activities and manufacturing processes. The development of a ASTM International Standard for "Handling Unbound Engineered Nanoparticles in Occupational Settings" is intended to provide guidance for controlling such exposures as a precautionary measure where relevant exposure standards and/or definitive risk and exposure information do not exist.
ASTM WK8985 “STANDARD GUIDE FOR HANDLING UNBOUND ENGINEERED NANOPARTICLES IN OCCUPATIONAL SETTINGS”

• The guide will describe actions that could be taken in occupational settings to minimize human exposures to unbound, intentionally produced nanometer-scale particles, fibers and other such materials in manufacturing, processing, laboratory and other occupational settings where such materials are expected to present.

• It is intended to provide guidance for controlling such exposures as a precautionary measure where relevant exposure standards and/or definitive risk and exposure information do not exist.
Nanotechnologies

Secretariat:
BSI

Secretary:
Mr. Jose Alcorta

Chair:
Dr. Peter Hatto (United Kingdom)

Scope:
Standardization in the field of nanotechnologies, with specific tasks being classification, terminology and nomenclature, basic metrology, characterization, including calibration and certification, risk and environmental issues. The methods of test are to include methods for determining physical, chemical, structural and biological properties of materials or devices for which the performance, in the chosen application, is critically dependent on one or more dimension of <100nm. Test methods for applications, and product standards shall come within the scope of the TC.

Total number of published ISO standards
ISO Technical Committee 229 Nanotechnology

First Meeting November 2005

• 28 participating countries

ISO TC 229 Scope;

• Support the sustainable and responsible development and global dissemination of these emerging technologies;

Specific tasks include developing standards for:

• terminology and nomenclature;
• metrology and instrumentation, including specifications for reference materials;
• test methodologies;
• modeling and simulation; and
• science-based health, safety, and environmental practices.
ISO TC229 Committee Structure

• **WG1  Terminology and Nomenclature**

  Scope: To define and develop uniform terminology and nomenclature in the field of nanotechnologies. It is intended to facilitate communications to ensure common understanding among interested parties.

• **WG2  Measurement and Characterization**

  Scope: Standardization of metrology and test methods (including reference materials) which is used to characterize nano-materials and nano-structures from the aspect of physical and chemical properties.

• **WG3  Health, Safety and Environment**

  Scope: To develop standards in the areas of health, safety, and environmental aspects of nanotechnologies
ISO Survey of Standardization Needs by National Body Members in the Next 1-3 years

<table>
<thead>
<tr>
<th>Standard Methods for Toxicological Screening of Nanomaterials</th>
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<tbody>
<tr>
<td>Standard Methods for Determining Relative Toxicity/Hazard Potential of Nanomaterials</td>
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<tr>
<td>Standard Guide for Controlling Occupational Exposures to Nanomaterials</td>
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<tr>
<td>Standard Template for Material Safety Data Sheet (MSDS) for Products Containing Nanomaterials</td>
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<tr>
<td>Nanomaterial Product Information For Use In Determining Health &amp; Safety Precautions</td>
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<tr>
<td>Standard Method for Selection of Personal Protective Equipment (PPE) for Use With Nanomaterials</td>
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<tr>
<td>Standard method for determining physical hazards of nanomaterials (i.e. explosive, flammability, water reactivity, etc.)</td>
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<tr>
<td>Standard Method to Establish Occupational Exposure Limits for Nanomaterials</td>
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<tr>
<td>Standard Methods to Assess Exposure to Nanomaterials During Consumer Product Use</td>
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<td>Standard methods for determining nanoparticle concentrations in air and water</td>
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ISO Survey of Standardization Needs within the next 3-8 years

<table>
<thead>
<tr>
<th>Standard Methods for Measuring Personal Exposure to Nanomaterials in Occupational Settings</th>
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<tr>
<td>Standard Method for Performing Risk Assessments on Use of Nanomaterials</td>
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<tr>
<td>Product Safety Standards for Consumer Products Containing Nanomaterials</td>
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<td>Standard Method to Develop Nanomaterial Product Labelling</td>
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<td>Standard Method to Assess Emissions from Handling, or Machining of Nanomaterial Containing Products</td>
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<td>Standard Method for Reporting Toxicity of Nanomaterials in Consumer Products</td>
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<td>Standard Methods to Determine Exposure to Nanomaterials in Food</td>
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<tr>
<td>Methodology to Determine effectiveness of Filtration Media against Nanomaterials</td>
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<tr>
<td>Standard Method of Life Cycle Analysis for Consumer Products Containing Nanomaterials</td>
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<td>Standard test methods for measurement of nanomaterials in manufacturing discharges</td>
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OECD's Work on the Safety of Manufactured Nanomaterials

Action Items from the 1st meeting (updated 29 November)

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** Please note that the documents accessed from this page are not for general distribution **

Background Information
- Public Website
- Briefing to OECD Permanent Delegations, 2 June 2006, Documents

Information on International Organisations
- ISO/TC 229 Nanotechnologies

Meetings
- 3rd Meeting of the Working Party on the Safety of Manufactured Nanomaterials
  28-30 November 2007, Paris, France
- 2nd Meeting of the Working Party on the Safety of Manufactured Nanomaterials
  25-27 April 2007, Berlin, Germany
- 1st Meeting of the Working Party on the Safety of Manufactured Nanomaterials
  26-27 October 2006, London, UK
  Documents, Summary Record

Steering Group Information
Teleconference Schedule
Meeting of SG 2, 3 and 4
The main topic areas to be included in the programme of work will include:

- Definitions, nomenclature and characterisation (physicochemical properties, uses) where not otherwise available.

- Environmental fate and effects (hazard identification, hazard, exposure and risk assessment methods).

- Human exposure and health effects (hazard identification, hazard, exposure and risk assessment methods).

- Exchange of information on regulatory and risk management frameworks as well as environmental benefits.
The OECD Working Party on Nanomaterials programs of work:

- Development of an OECD (nanosafety) Database on Human Health and Environmental Safety (EHS) Research
- Human Health and Environmental Safety (EHS) Research Strategies on Manufactured Nanomaterials
- **Safety Testing of a Representative Set of Manufactured Nanomaterials**
- Manufactured Nanomaterials and Test Guidelines
- Co-operation on Voluntary Schemes and Regulatory Programmes
- Co-operation on Risk Assessment and Exposure Measurements
Standards Necessary for the Safe Use of Nanomaterials

Nanomaterial Characterization

Nanomaterial Metrology

Toxicological Testing Methods

Measurement Techniques

Toxicity Rating / Hazard Rating

Exposure Assessment Methods

Risk Assessment
Toxicity x Exposure = Risk

Exposure or Environmental Controls Based on Risk

EHS Program Best Practices
Nanomaterial Characterization

Nanomaterial Metrology

Toxicological Testing Methods

Measurement Techniques

Toxicity Rating / Hazard Rating

Exposure Assessment Methods

Risk Assessment
Toxicity $\times$ Exposure = Risk

Exposure or Environmental Controls Based on Risk

EHS Program Best Practices
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Toxicity Rating / Hazard Rating

Exposure Assessment Methods

Risk Assessment
Toxicity??? x Exposure = Risk???

Exposure or Environmental Controls Based on Risk

EHS Program Best Practices
Research Needed for Standards Development

- Development of a screening/prioritizing strategy for the testing of nano-sized materials with the highest EHS concerns.

- Key factors to consider:
  - Production volume of nano-sized material
  - Exposure potential – occupational, consumer and environmental
  - Physiochemical properties indicative of potential toxicity
  - Validation of available in-vitro and short-term toxicity assays

January 9, 2007
• Development of a nanomaterial toxicity screening processes will include;
  • Identification or develop of appropriate *in vitro* and *in vivo* assays/models to predict *in vivo* human responses to nanomaterials exposure
  • Development of methods to quantify and characterize exposure to nanomaterials
  • Development of methods to quantify and characterize nanomaterials in biological matrices.
  • Standardized approach for evaluating nanomaterials for mammalian and environmental toxicology
  • Metric or set of metrics that accurately reflects the risk associated with exposure to nano-sized materials.
Summary:

The development of nanomaterial toxicity screening protocols and toxicological testing of representative classes of nanomaterials will enable;

- The development of sound nanomaterial EHS standards
- The implementation of science based EHS control programs for the safe use of nanomaterials.

Thank you for opportunity to present.