Standards Supporting Informed Decision Making – Risk and Nanotechnology

A Standards Stakeholder Perspective

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Discussion

- Standards and why standards matter
- Current activities
- Standards addressing questions relating to aspects of risk and nanotechnology
- What do we need for effective standardization
What Are Standards

• Standards – multiple meanings (physical standards, documentary standards, measurement protocols, specifications, guidelines, best practices, etc.)

• Focus on documentary standards for this discussion
  • ISO/IEC definition (emphasis added): document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

Standards Do Matter

Courtesy: www.treehugger.com

2013 NNI Stakeholder Perspectives on the Perception, Assessment, and Management of the Potential Risks of Nanotechnology
Why Standards Matter

- Clarity in communication
- Enable protection of health, safety and environment
- Reflect state of technology
- Foundation for technological innovation
- Enable economies of scale


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Courtesy: www.boeingcapital.com 9/10/2013
Impact of Nanotechnology

Standardization

Trade  Technology  Innovation  Competition

http://econintersect.com/wordpress/?p=17686
Some Examples of Relevant International Nanotechnology Standardization Activities

**ASTM Intl. Committee E 56**
- Direct participation model
- 170 participants from 20 countries
- Standards development process:
  - Open, transparent, consensus driven, balance of participation, due processes

**ISO Technical Committee TC229**
- Direct participation model, organized on a country basis
- 34 participating, 10 observer countries
- Standards development process:
  - Open, transparent, consensus driven, balance of participation, due processes
Focus Areas for Nanotech Standardization

Terminology
- “What is it called”

Measurement
- “How is it measured”

EHS
- “What effect it may have on health, safety and environment”
Some Examples of Relevant Standards

• Terminology:


  • ISO/TS 80004-1:2010 Vocabulary – Part 1: Core terms

  • ISO/DTR 14786 Nanotechnologies -- Framework for nomenclature models for nano-objects (pending publication)

  • ISO/TS 80004-3:2010 Vocabulary – Part 3: Carbon nano-objects
Some Examples of Relevant Standards

- Measurement and characterization:
  - ASTM WK32796 Test Method for Measurement of Airborne Metal and Metal Oxide Nanoparticle Surface Area in an Inhalation Exposure Chamber Using Gas Adsorption (*under development*)
Some Examples of Relevant Standards

- EHS aspects:
  - ASTM E2535-07: Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings
  - ISO/TR 13121:2011 Nanomaterial risk evaluation
  - ISO 10808:2010 Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing
Examples of Available Resources

![Nanotechnology Standards Database](http://nanostandards.ansi.org/tiki-index.php)

### Published Documents

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<tr>
<th>Record #</th>
<th>Source (e.g., developer/organization)</th>
<th>Acronym (e.g., ISO, IEC)</th>
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<td>ASTM E2490</td>
<td>Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Composites</td>
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<td>DLS; dynamic light scattering; PCS; photon correlation spectroscopy, nanoscale; GELS; quasi-elastic light...</td>
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<td>2013-08-13</td>
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Examples of Available Resources

ISO/TR 13121:2011(en) Nanotechnologies — Nanomaterial risk evaluation

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard (“state of the art”, for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 13121 was prepared by Technical Committee ISO/TC 229, Nanotechnologies.

Introduction

This Technical Report is intended for use in all countries, regardless of whether they have legal or regulatory schemes that address manufactured nanomaterials.

https://www.iso.org/obp/ui/
Examples of Available Resources

https://www.nanomaterialregistry.org/
Examples of Available Resources

Cooperation with ISO/TC 229 Nanotechnologies

Nanoscaled Reference Materials

Reference materials are the key to guaranteeing reliability and correctness for results of chemical analyses and technical measurements.

List of currently available nanoscaled reference materials

- Certified Reference Material (CRM)
- Quality Control Materials (QCM)
- Reference Material (RM)
  ** List does not claim to be exhaustive
  ** RM = Reference material NOT specified as CRM or QCM

Categories

- Flatness
- Film thickness
- Single step, periodic step, step grating
- Lateral X-Y-axis, 1-dim
- Lateral X-Y-axis, ±2-dim
- Critical dimensions
- 3-dimensional
- Nanoobjects/nanoparticle/nanomaterial
- Nanocrystallite materials
- Porosity
- Depth profiling resolution
- Others

If no information is available the data fields are blank.

http://www.nano-refmat.bam.de/en/

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Nanotechnology, Risk and Standards

- Standards are already used to address many aspects of risk, in various industries, e.g.:
  - Information security
  - Financial industry
  - Business operations and continuity

- Different drivers and so differences in approaches, application, impact, etc.
Nanotechnology, Risk and Standards

- Some common elements in various approaches (ISO 31000:2009 Risk management – Principles and guidelines):

  - *Context* – what is the overall risk framework
  - *Identify* – what are the threats
  - *Measure or assess* – how do you quantify vulnerabilities, elements of the risk framework
  - *Determine the risk* – what are the consequences
  - *Mitigate* – measures to manage the impact
  - *Prioritize* - risk reduction measures
  - *Implement and review* – lessons learned from use and continuous process improvement
Effective Standardization

For effective and meaningful standards to support addressing questions about risk and nanotechnology, consider:

- What standards are needed?
- When are these standards needed?
- Are standards needs prioritized?
- Is there reliable or validated data that can be used?
- Are there agreed upon techniques that can be leveraged?
- How will the standards be used?
- Are experts willing to assist in the development of these standards?

- Importance of outreach – industry and government
The Imperative for Cooperation

- Engage
  - Inform standards developers about standards needs
  - Ask standards developers about what they are developing
  - Participate in standards development
- Inform
  - What data sources are there
  - Round robin testing
- Validate
  - Use standards developed and validate the relevance of the standard – iterative process
- Adopt
  - Use through voluntary processes or adopt through other processes
Closing Thoughts

• Standards can be effective and low cost tools to assist in addressing many of the questions relating to potential risks of nanotechnology

• Consider lessons learned from other areas – avoid re-inventing the wheel, and cognizance of limitation of approaches

• Effectiveness of standards as tools can be improve by greater engagement between the nanotechnology/risk/standards development stakeholders

• Having a broadly accepted framework is an important element towards the development and use of effective standards

• Need for a robust and consistent exchange between the standards development community and standards users
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