Standards Supporting Informed Decision Making – Risk and Nanotechnology

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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

    [Ref: ISO/IEC Guide 2:2004, definition 3.2]

Standards Do Matter

Courtesy: www.treehugger.com

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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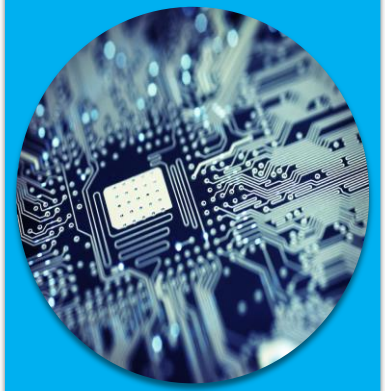
Courtesy: http://www.gizmag.com/smartphone-comparison-2012/24901/

Courtesy: www.boeingcapital.com

Impact of Nanotechnology Standardization

Trade



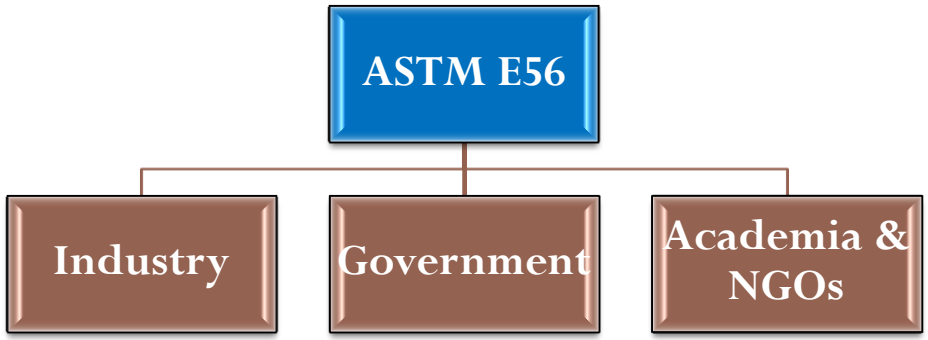
Technology

Innovation

Competition

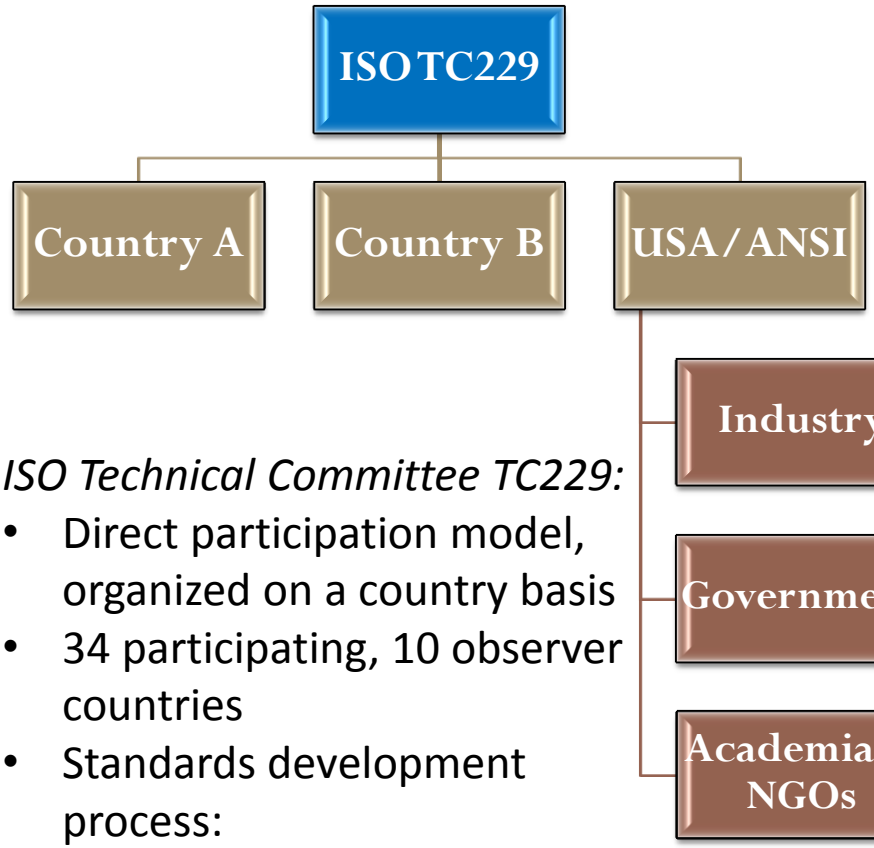
http://www.technologyed.com/courses/c160/index.ph
http://econintersect.com/wordpress/?p=17696
http://www.guzer.com/pictures/sumo_mismatch.php

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"

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

Some Examples of Relevant Standards

- Terminology:
  - ASTM E2909-13: Standards Guide for Investigation/Study/Assay Tab-Delimited Format for Nanotechnologies (ISA-TAB-Nano): Standard File Format for the Submission and Exchange of Data on Nanomaterials and Characterizations
  - 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

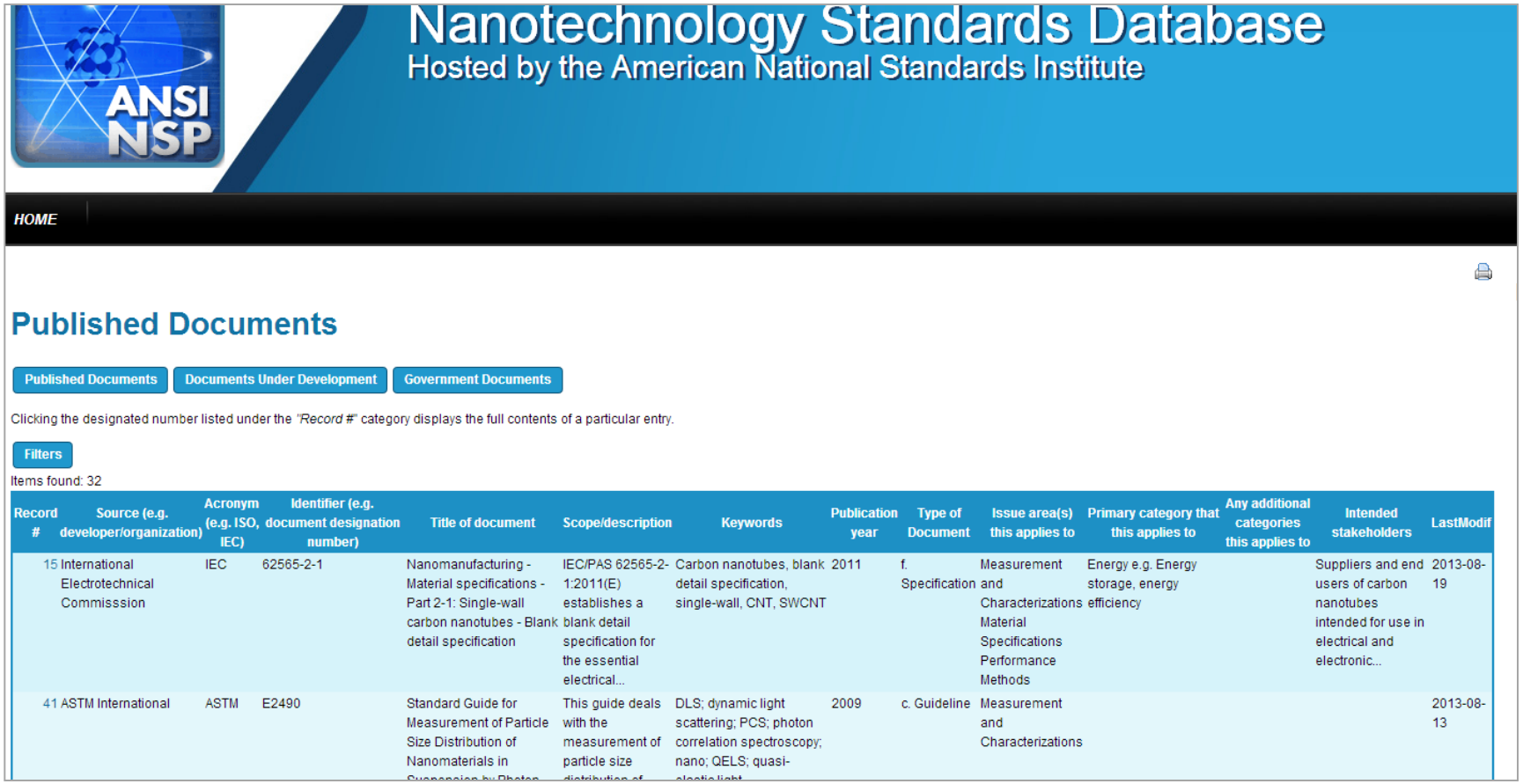
Some Examples of Relevant Standards

- Measurement and characterization:
  - ASTM 2578-07 (2012) Standard Practice for Calculation of Mean Diameters and Standard Deviations of Particle Size Distributions
  - 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)*
  - ISO/TR 13014: 2012 and /Cor 1:2012: Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment
  - ISO/TS 14101:2012: Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method

Some Examples of Relevant Standards

- EHS aspects:
  - ASTM E2535-07: Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings
  - ASTM WK 34427: New Guide for Nanotechnology Environment, Health and Safety (EHS) Education and Training (*under development*)
  - ISO/TR 13121:2011 Nanomaterial risk evaluation
  - ISO 10808:2010 Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing
  - ISO/TS 12901-1:2012 Occupational risk management applied to engineered nanomaterials – Part 1. Principles and approaches

Examples of Available Resources



Nanotechnology Standards Database
Hosted by the American National Standards Institute

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Published Documents

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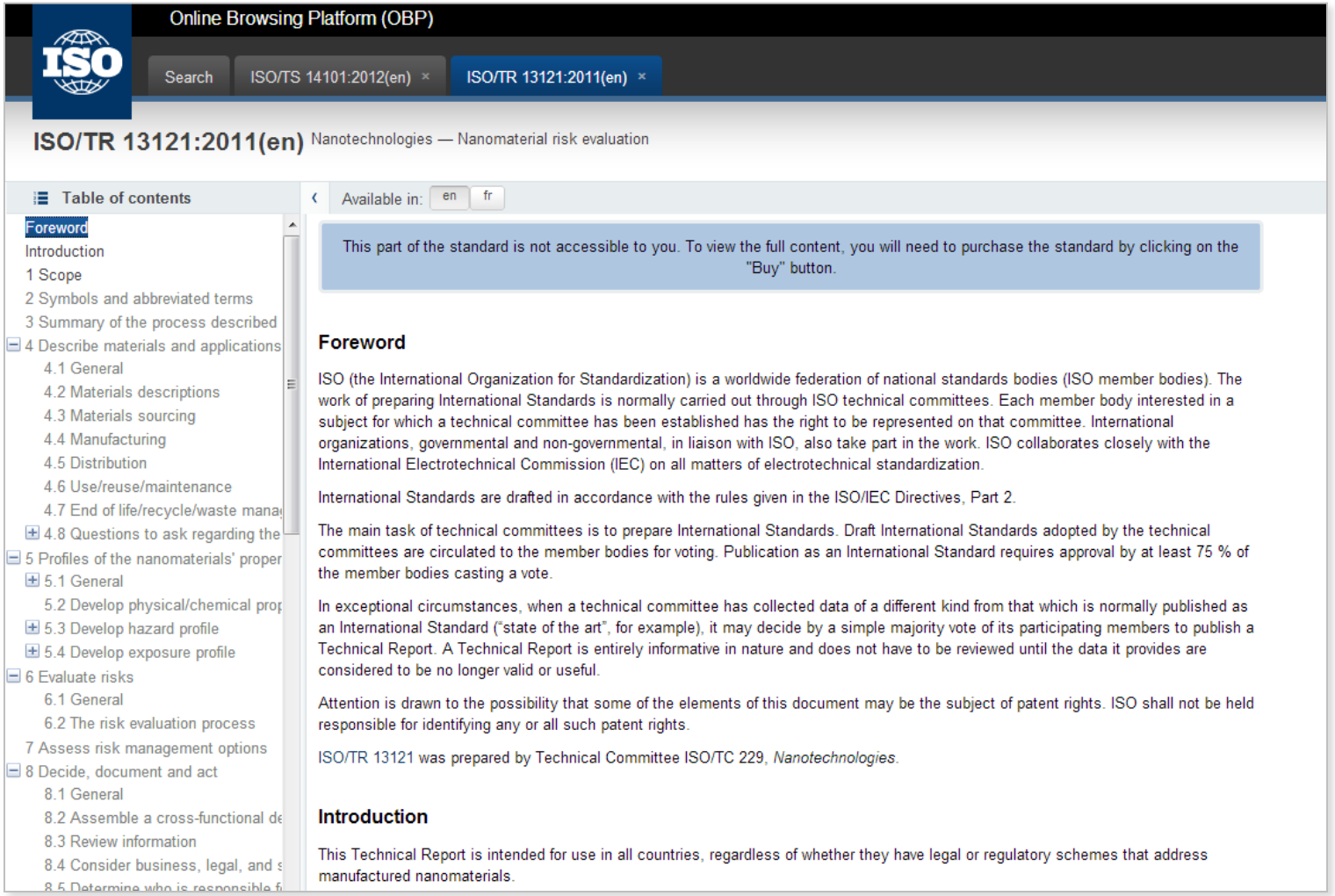
Items found: 32

Record #	Source (e.g. developer/organization)	Acronym (e.g. ISO, IEC)	Identifier (e.g. document designation number)	Title of document	Scope/description	Keywords	Publication year	Type of Document	Issue area(s) this applies to	Primary category that this applies to	Any additional categories this applies to	Intended stakeholders	LastModif
15	International Electrotechnical Commisssion	IEC	62565-2-1	Nanomanufacturing - Material specifications - Part 2-1: Single-wall carbon nanotubes - Blank detail specification	IEC/PAS 62565-2-1:2011(E) establishes a blank detail specification for the essential electrical...	Carbon nanotubes, blank detail specification, single-wall, CNT, SWCNT	2011	f. Specification	Measurement and Characterizations Material Specifications Performance Methods	Energy e.g. Energy storage, energy efficiency		Suppliers and end users of carbon nanotubes intended for use in electrical and electronic...	2013-08-19
41	ASTM International	ASTM	E2490	Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in	This guide deals with the measurement of particle size	DLS; dynamic light scattering; PCS; photon correlation spectroscopy; nano; QELS; quasi-	2009	c. Guideline	Measurement and Characterizations				2013-08-13

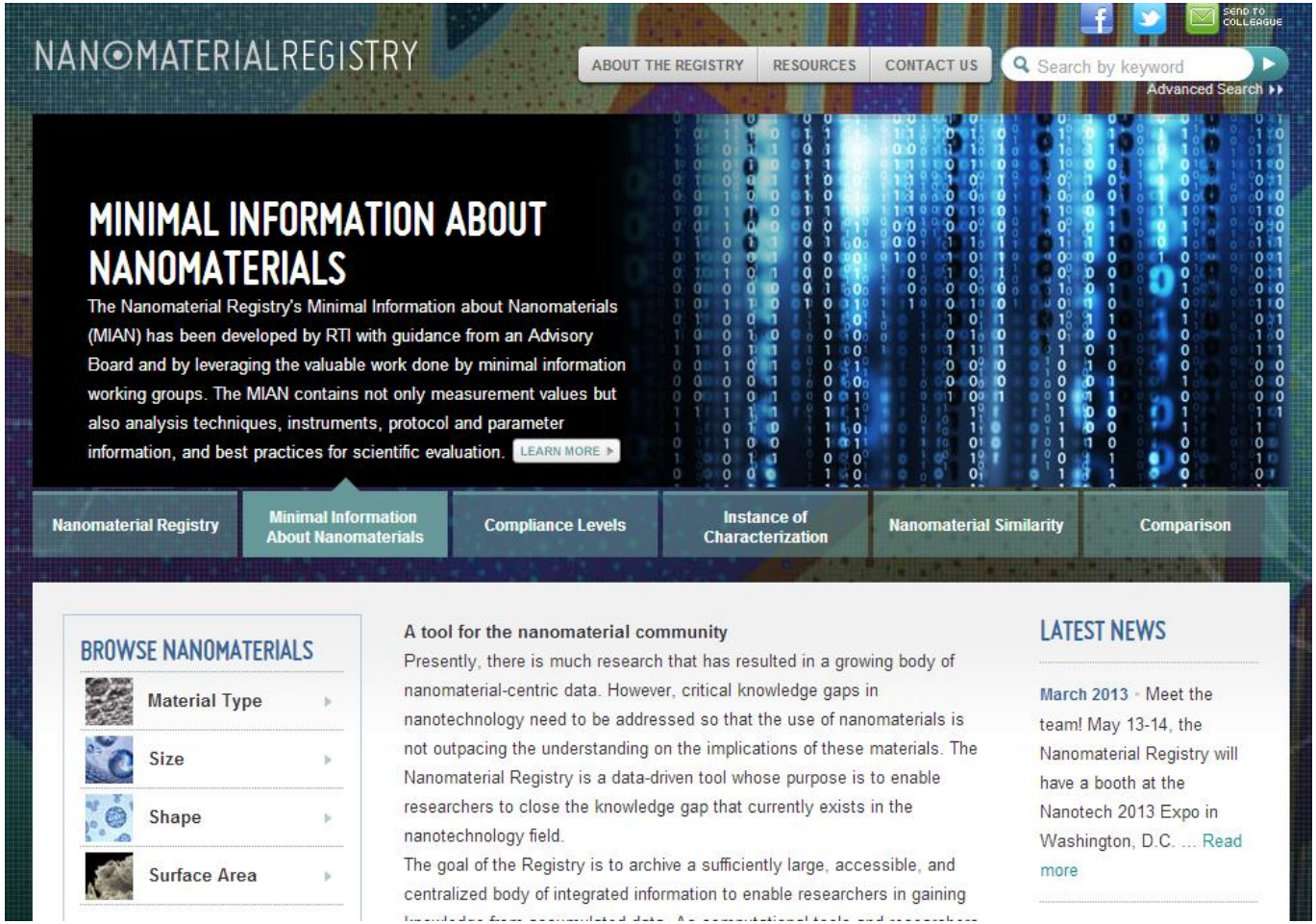
http://nanostandards.ansi.org/tiki-index.php

Examples of Available Resources



https://www.iso.org/obp/ui/

Examples of Available Resources



https://www.nanomaterialregistry.org/

Examples of Available Resources

BAM
Federal Institute for Materials Research and Testing

Nanoscaled Reference Materials

Contact | Disclaimer

Home

Home
- ISO/TC 229
- IEC/TC 113
- CEN/TC 352
- DIN NA 062-08-17
- COMAR

Cooperation with ISO/TC 229 Nanotechnologies

Nanoscaled Reference Materials

Reference materials are the key to guaranteeing realiability 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/nanoparticles/nanomaterial
- Nanocrystallite materials
- Porosity
- Depth profiling resolution
- Others

If no information is available the data fields are blank

Information on this website

Category: Nanoobjects / nanoparticles / nanomaterials

Description	Certified value (nm)	RM name	RM type	RM no.
Absolute contamination standards polystyrene latex spheres on Si Wafer, sphere diameter, concentration; 40 nm - ...; used to calibrate instruments which size and detect particles on the surface of bare silicon wafers	40	Absolute Contamination Standard	RM	42
Size standard particles Available for particle diameter and particle number indication of liquid particle counters which is used for a washing process control of semiconductor and precision electronic device, clean control of chemical reagent and Japanese Pharmacopoeia (JP test)	168	CLINTEX 017-10K	RM	61
Polystyrene particle size standard sphere diameter	948	GBW 12009	RM	65
Polystyrene particle size standard sphere diameter	352	GBW 12010	RM	66
Polystyrene particle size standard sphere diameter	61	GBW 12011	RM	67

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

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

Contact Information

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