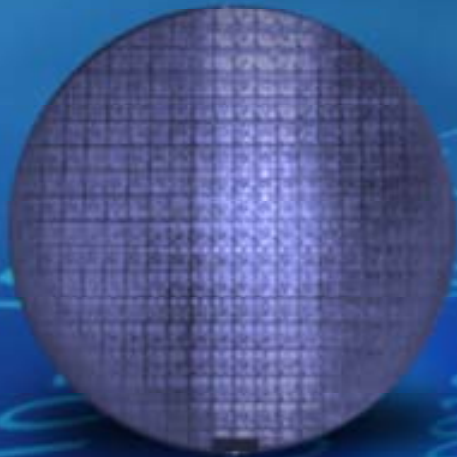


Processes required to effectively manage nano-materials

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Processes required to effectively manage nano-materials

- **International Standards are needed to facilitate nanotechnology commercialization and social acceptance of nanotechnologies**
- **International Standards provide industries, societies and academia with common**
 - ✓ languages
 - ✓ methods
 - ✓ practices
 - ✓ products

Current International Standards Organizations involved in Development of Nanotechnology Standards

➤ **American Society for Testing and Materials International (ASTM International)**

❖ *Technical Committee on Nanotechnology E56*

➤ **International Organization for Standardization (ISO)**

❖ *Technical Committee on Nanotechnologies TC229*

ASTM International Technical Committee E56 Nanotechnology

Scope:

- The development of standards and guidance for nanotechnology & nanomaterials

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

[E56.06](#) Risk Management and Product Stewardship

[E56.90](#) Executive

[E56.91](#) Strategic Planning and Review

ISO

Technical Committee TC229

Nanotechnology

First Meeting November 2005

- ❖ 24 participating countries

ISO TC 229 Scope;

- ❖ Support the sustainable and responsible development and global dissemination of these emerging technologies;
- ❖ Facilitate global trade in nanotechnologies, nanotechnology products and nanotechnology enabled systems and products;
- ❖ Improve quality, safety, security, consumer and environmental protection, together with the rational use of natural resources in the context of nanotechnologies;
- ❖ Promote good practice in the production, use and disposal of nano-materials, nanotechnology products and nanotechnology enabled systems and products.

ISO

Technical Committee TC229

Committee Structure

➤ **WG1 Terminology and Nomenclature led by Canada**

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 led by Japan**

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 led by USA**

Scope: To develop standards in the areas of health, safety, and environmental protection

Key EHS Research Areas Needed for Successful Use of Nanotechnology and Standards Development

- 1. Testing methodologies and metrics for assessing human and ecological toxicity of nanomaterials**
- 2. Occupational, environmental, and public exposure monitoring methodologies**
- 3. Risk assessment methodologies**
- 4. Disposal, dispersion, and waste treatment of nano-engineered materials**
- 5. Engineering controls, personal protective equipment, and other measures to assure safety of workers, researchers, and the public**

ICON is uniquely positioned to help identify research needs and promote funding

Back Up Information

ASTM International Technical Committee E56 Nanotechnology

Work Items (standards in development)

- [WK8051](#) Standard 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 (PCS)
- [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

Testing Strategy

Need:

- Standardized approach for evaluating nano-sized materials for mammalian and environmental toxicology.

Current Situation:

- Globally harmonized studies can serve as a basis:
 - ❖ OECD and EPA Testing Guidelines for Testing Chemicals
- BUT many limitations:
 - ❖ What is the best dose metric (weight/body weight)
 - ❖ How to administer nano-sized materials using a relevant exposures
 - ❖ What enhancements to the OECD protocols would be helpful
 - ❖ Proper characterization of test material
- Limited number of comprehensive toxicological safety assessments on newly development nano-sized materials.

Testing Strategy Recommendation

- **Development of a screening/prioritizing strategy for the testing of nano-sized materials with the highest ESH 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

Best Metric for Assessing Nano-sized Material Toxicity

Need:

- Metric or set of metrics that accurately reflects the risk associated with exposure to nano-sized materials.

Current Situation:

- Dose (weight/body weight) may not be the best metric.
- Research has shown that other metrics may be more applicable.
 - ❖ Number of particles
 - ❖ Surface area
 - ❖ Surface charge
 - ❖ Surface chemistry

Best Metric Recommendation

- It is unlikely that a “one-size fits all” metric will be able to adequately address the broad range of nano-sized materials.
- Appropriate metrics may vary by media: air, water, solids, etc.

Recommendation:

- Further explore relevant metrics (size, surface characteristics, etc)
- Delivered-dose (concentration in bloodstream or at target site) metric should also be explored.

Exposure Monitoring

Need:

- Exposure monitoring methodologies to assess both occupational and non-occupational exposures to nano-sized materials.

Current Situation:

- Nano-sized materials may behave differently than larger sized materials.
- No standardized occupational exposure methodologies exist.
- Uncertainty over what parameter should be measured to quantify exposure (e.g. surface area, particle count, mass, degree of agglomeration)
- Industry studies underway to develop monitoring protocols and measurement devices for nano-sized aerosol particles.

Exposure Monitoring Recommendation

- **Development of standardized exposure monitoring techniques and analytical methodologies.**
- **Key Factors to Consider:**
 - ❖ Should incorporate work to define “best metric”
 - ❖ Should consider hazard and risk variables.

Risk Assessment Tool

Need:

- Development of an risk assessment tool to assess occupational and non-occupational exposures to nano-sized materials.

Current Situation:

- No published methodologies or standardized risk assessment tools.
- Current risk assessment tools may not be suitable for nano-sized materials due to toxicity and exposure unknowns.
- Limited information on nano-sized particle behaviors in air streams.
- Unknown exposure routes.

Risk Assessment Tool Recommendation

- **Development of an risk assessment tool for nano-sized materials.**
- **Key Factors to Consider:**
 - ❖ Potential risk based on toxicity of nano-sized material
 - ❖ In absence of toxicity data, what conservative, but reasonable measures can be taken to minimize risk?
 - ❖ Potential risk based on exposure to the material given the nature of its use (e.g. aerosol vs. aqueous solution)

Communication/Education

Need:

- Open communication of benefits and risks associated with nanotechnology.

Current Situation:

- Opportunity and need to educate is NOW:
 - ❖ 70% of consumers “somewhat” or “very hopeful” about nanotechnology (NCSU, 2004).
 - ❖ 80% know “little” or “nothing” about nanotechnology (NCSU, 2004).
 - ❖ Studies suggest consumers will be influenced by mass media, likely toward the negative (UW, 2004)
 - ❖ Low trust in industry and government to get it right (WWIC, 2005)
 - ❖ Public wants to be included (WWIC, 2005)

Communication/Education Recommendations

- **Coordinate communication for ESH impacts, societal impacts and overall benefits of nanotechnology**
 - ❖ Single voice – non-technical
 - ❖ Government should take lead
- **Coordinate communication across international geographies.**
 - ❖ ESH and Societal topics should not be competitive.
 - ❖ Ongoing communication and coordination needed.
- **Conduct ongoing surveying/monitoring of public opinion.**