

Developing standards for nanotechnologies – an international perspective

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"Nanotechnology Governance: Environmental Management from a Global Perspective."
Environmental Law Institute and the Vanderbilt Center for Environmental Management Studies,
Nashville, May 19, 2006

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Standards and standardization

Standards provide agreed ways of:

- **Doing things**
- **Naming, describing and specifying things**
- **Measuring and testing things**

Standards are:

- **Ubiquitous – shoe sizes, nuts and bolts, petrol grades, warning signs, pipes and fittings, fire extinguishers, gas cylinders, electrical sockets and plugs, steel specifications,.....**
- **Virtually invisible to “the man in the street” – there are over 15,000 International (ISO) Standards , many with multiple parts;**
- **But are absolutely critical to our modern way of life – CDs/DVDs, internet protocols, credit cards, pin numbers, quality and environmental management,.....**

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Functions of standards

Standards can perform any of the following four functions:

- **Interoperability/Compatibility**
 - as with e.g. nuts and bolts, railway gauges, electrical plugs and outlets, and interoperability standards for computers and telecommunications systems
- **Quality**
 - Fitness for purpose or safety
- **Variety reduction/optimization (based on best practice)**
 - E.g. shoe sizes, suit sizes – leading to mass production and price reduction
- **Information/Measurement**
 - Test and measurement methods for describing, quantifying and evaluating product attributes such as material, processes and functions

DIN has reported that in Europe standardization adds approximately 1% to the value of gross domestic product and that the added value generated by standardisation is at least as important as the value generated by patents!

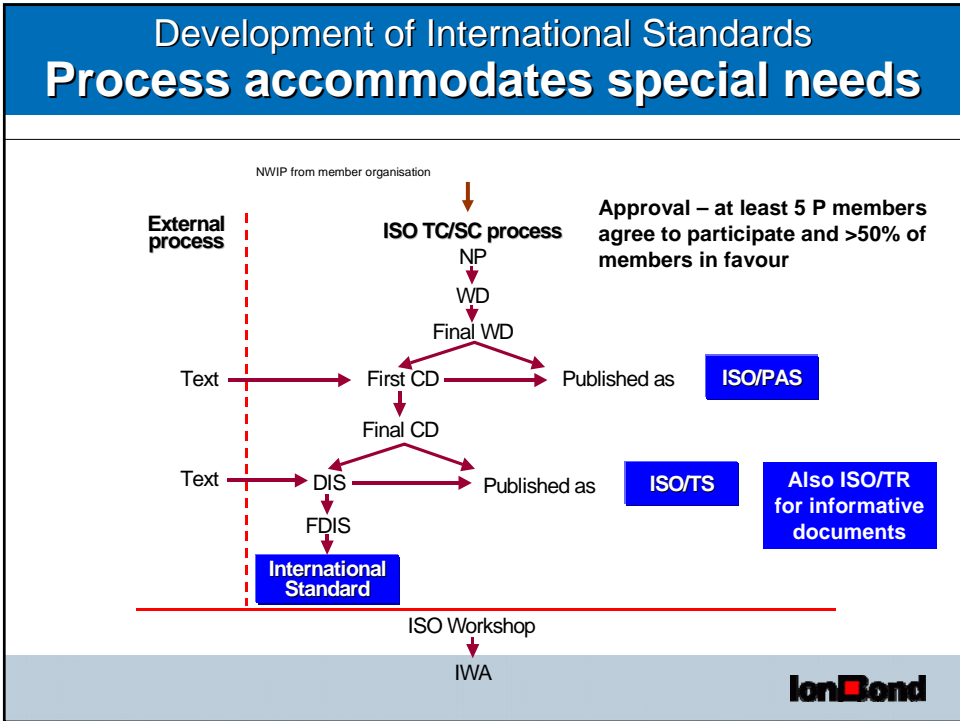
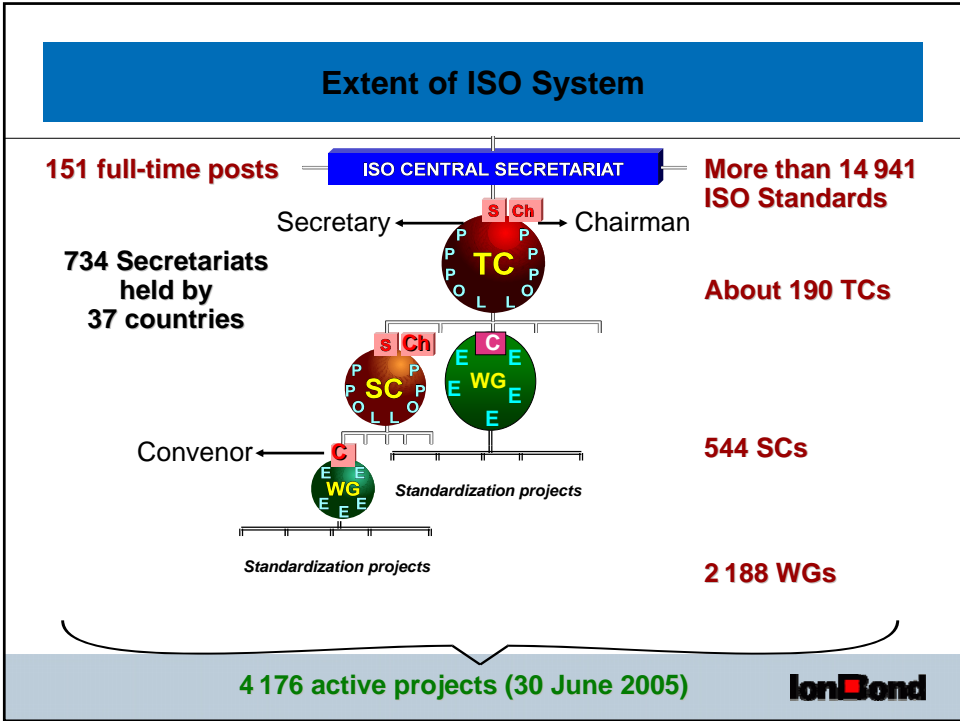
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Standards are developed by:

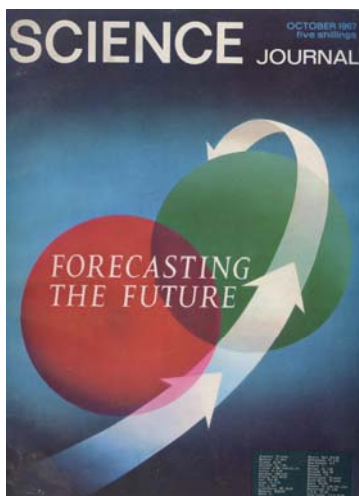
- **Formal Standards:**
 - National standards bodies: BSI, DIN, AFNOR, JIS, SAC, etc
 - Regional standards bodies: CEN, CENELEC,.....
 - International standards bodies: ISO, IEC, ITU
- **Professional Standards:**
 - Standards Development Organisations (SDO's): ASTM, IEEE, SAE, SEMI, VDI,..... (>600 in the US alone)
- **Private standards**
 - Private companies for internal use;
 - Trade associations
- **And are generally based on consensus amongst experts (there are over 50,000 technical experts involved in the development of standards with ISO) working in Technical Committees in specific subject areas – e.g. ISO/TC 229 (Nanotechnologies); CEN/TC 184 – Advanced Technical Ceramics; ISO/TC 61 – Plastics.**

Standards are voluntary (unless called up in a contract or legislation)

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A word of Caution about nano projections!



Transport forecasts:

By 2000:

- *Fly from London to Sydney in 50 minutes*
- *800km/hr trains in evacuated tubes*
- *Fully automatic "driving"*
- *Continuous integrated transport systems*

But the difference is:

- *there is a world-wide focus on nanotechnology, with >>\$5BN annual investment in R&D*
- *Timescale is significantly shorter!*

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Needs for standardization for Nanotechnologies

1. To support commercialisation and market development
2. Provide a basis for procurement – technical/quality/environmental management
3. To support appropriate legislation/regulation

Currently there are:

- *No internationally agreed terminology/definitions for nanotechnology(ies).*
- *No internationally agreed protocols for toxicity testing of nanoparticles.*
- *No standardized protocols for evaluating environmental impact of nanoparticles.*
- *Existing "methods of test" may not be suitable for nanoscale devices and nanoscale dimensions.*
- *Measurement techniques and instruments need to be developed and/or standardized.*
- *New calibration procedures and certified references materials are needed for validation of test instruments at the nanoscale.*
- *Multifunction nanotechnology systems and devices will need new standards.*
- *But some existing standards may be applicable e.g. for chemical analysis and imaging (ISO TCs 201 and 202) and particle detection/sizing (ISO TC 24)*

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ISO TC 229 adopted Scope:

“Standardization in the field of nanotechnologies that includes either or both of the following:

- *Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications;*
- *Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties*

Specific tasks include developing standards for: *terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; and science-based health, safety, and environmental practices.”*

Note: Scope is further defined by the TC’s “Strategy Statement”

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TC 229 Strategic statement

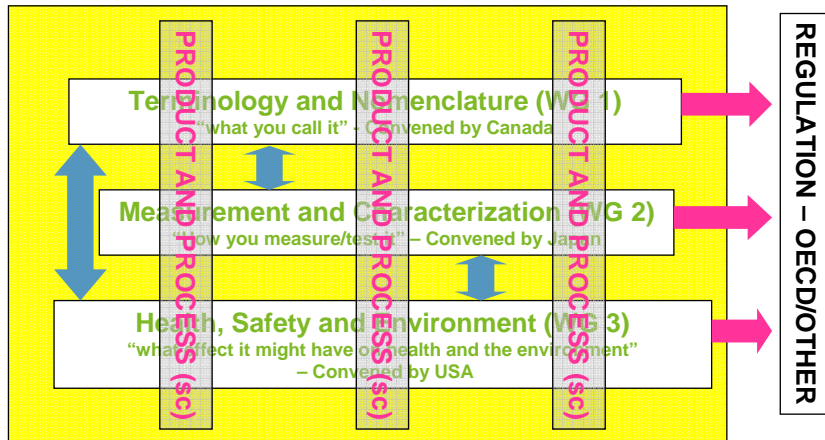
ISO TC 229 will, in accordance with ISO’s strategic plan for 2005 to 2010, develop robust standards and other deliverables relevant to nanotechnologies that will:

- *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 nanomaterials, nanotechnology products and nanotechnology enabled systems and products.*

The work of the Technical Committee will focus initially on the areas of terminology and nomenclature, metrology and test methods, and health, safety and the environment. Where relevant TCs exist in either ISO or IEC, TC 229 will cooperate with such committees to develop robust product/application standards, but where no relevant committee exists then such product standards will fall within the remit of ISO TC 229. The development of such product standards will accord with the strategic plan.

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TC 229 – Structure/working areas



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Current nanotechnology standards

- Only National standards to date:
 - China – National standards published Dec 2004, implemented Apr 2005:
 - GB/T19619-2004 Terminology for nanomaterials
 - Sizing:
 - GB/T13221-2004 Nanometer powder - Determination of particle size distribution - Small angle X-ray scattering method (ISO/TS13762)
 - GB/T19587-2004 Determination of the specific surface area of solids by gas absorption using the BET method (ISO 9277:1999)
 - GB/T19627-2005 Particle size analysis - Photon correlation spectroscopy (ISO 13321:1996)
 - Nano-material specifications:
 - GB/T19588-2004 Nano-nickel powder
 - GB/T19589-2004 Nano-zinc oxide
 - GB/T19590-2004 Nano-calcium carbonate
 - GB/T19591-2004 Nano-titanium dioxide
- UK – PAS 71: 2005 – Vocabulary – Nanoparticles
- Several standards (International, regional and national) that also apply to the nanoscale

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How standardization can help address the issue of risk in nanotechnologies

- Identifying gaps in knowledge.
- Identifying needs for, and encouraging the development of instruments and test methods for use at the nanoscale.
- Development and delivery of:
 - test methods to detect and identify nanoparticles, and to characterize nanoscale materials and devices.
 - protocols for bio- and eco-toxicity testing, including protocols to evaluate effects of short term and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanoparticles and nanoscale devices.
 - protocols for whole life cycle assessment of nanoscale materials, devices and products.
 - risk assessment tools relevant to the field of nanotechnologies.
 - protocols for containment, trapping and destruction of nanoparticles and nanoscale entities.
 - occupational health protocols relevant to nanotechnologies, in particular for industries dealing with nanoparticles and nanoscale devices.
- Support regulation in the area nanotechnologies.
- Support communication of accurate and quantifiable information on nanotechnologies.

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Things that go bump in the night.

washingtonpost.com

Nanotech Product Recalled in Germany

Thursday, April 6, 2006

Government officials in Germany have reported what appears to be the first health-related recall of a nanotechnology product, raising a potential public perception problem for the rapidly growing but still poorly understood field of science.

At least **77 people reported severe respiratory problems over a one-week period at the end of March -- including six who were hospitalized with pulmonary oedema, or fluid in the lungs -- after using a "Magic Nano" bathroom cleansing product**, according to the Federal Institute for Risk Assessment in Berlin.

Federal Institute for Risk Assessment
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Implications for labelling
– need guidelines until
regulation is introduced

08/2006, 31.03.2006

Exercise caution when using "nano-sealing sprays" containing a propellant can cause respiratory problems when used in confined spaces

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And:

[CTA files Legal Action to force FDA to regulate nanomaterials in sunscreens](#)

[Legal Petition on FDA's Failure to Regulate Health Threats from Nanomaterials](#)

[Executive Summary of CTA Legal Action to Challenge FDA failure to regulate nanotechnology](#)

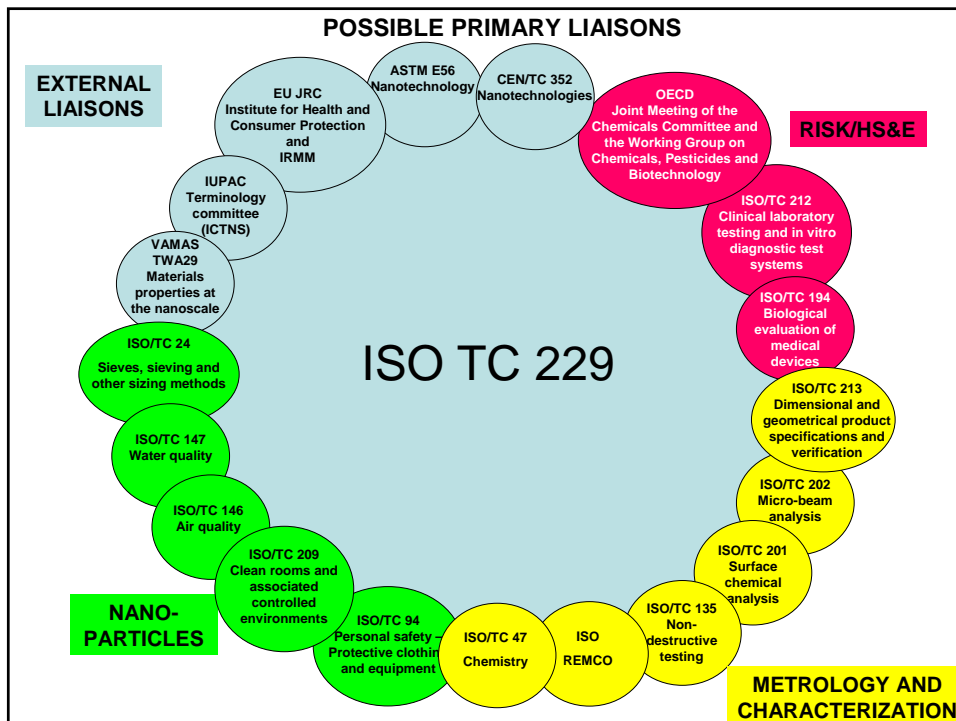
[Center for Technology Assessment and Friends of Earth power point on challenge to nanotechnology](#)

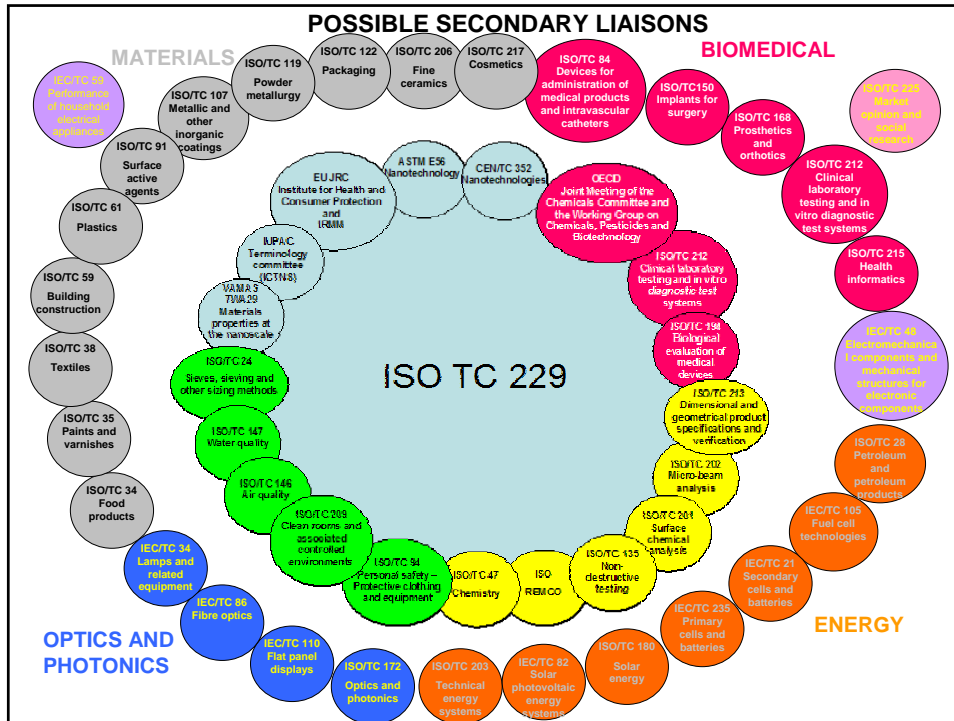
[CTA and other groups call on EPA to regulate nanotechnology](#)

[ICTA Comments on FDA Gene Therapy Guidance Document](#)

[Friends of the Earth publishes report on use of nanotechnology in cosmetics](#)
<http://www.icta.org/template/index.cfm>

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Role of ISO TC 229 will be to identify requirements in cooperation with stakeholders, including industry, governments, regulators, e.g. OECD, European Commission, and the public, to coordinate standards development with relevant TCs, and to develop standards where no TC exists or existing TC does not have the necessary resources.

Thank you for your attention