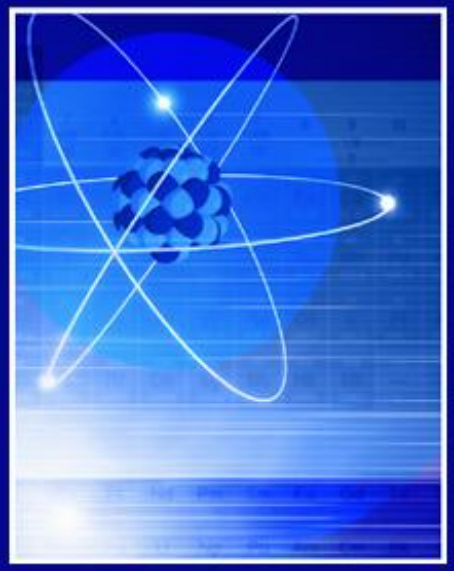


International Workshop on Challenges to Increased Use of Documentary Nanotechnology Standards

December 13-14, 2011

Washington, DC

Development of ISO Standards on Nanotechnology in ISO Technical Committee 229

Steven Brown

Head of Delegation

ANSI-Accredited U.S. TAG to ISO/TC 229

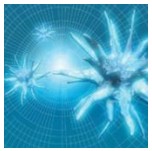
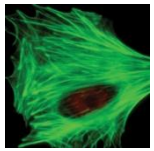
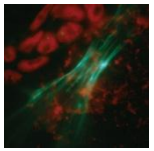
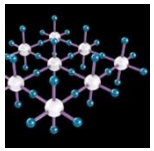
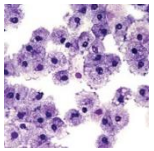
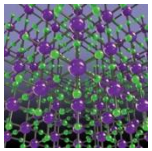
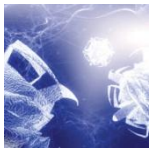
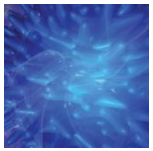
Technical Committee on Nanotechnologies

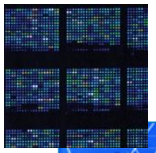
ANSI

American National Standards Institute

Why Nanotechnology Standards Are Important

- Encourage the development and commercialization of new technologies
  - Improve communication among stakeholders
  - Foster innovation – encourage diffusion of new technologies
  - Lower barriers to market entry
  - Promote market efficiency
- Protect public health and environment
  - Can be utilized to support national technical regulations



Scope of ISO/TC 229 *Nanotechnologies*

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

  1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometers in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications,

  2. 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; modeling and simulations; and **science-based health, safety, and environmental practices.**

ISO TC229 Nanotechnologies

Participating countries: 32 Observing countries: 8

Participating Countries

- Argentina
- Australia
- Austria
- Belgium
- Brazil
- Canada
- China
- Czech Republic
- Denmark
- Finland
- France
- Germany
- India
- Iran,
- Israel
- Italy

Japan
Kenya
Korea, Republic of
Malaysia
Netherlands
Norway
Poland
Russian Federation
Singapore
South Africa
Spain
Sweden
Switzerland
Thailand
USA

Observing Countries

Egypt
Estonia
Hong Kong, China
Ireland
Mexico
Morocco
Slovakia
Venezuela

ISO/TC 229 Organizational Chart

ISO/TC 229
Nanotechnologies
Secretariat:
United Kingdom (BSI)
Chair: Dr. Peter Hatto

Nanotechnology and Sustainability TG
(Chaired by the U.S.)

Consumer and Societal Dimensions TG
(Chaired by the U.S.)

ISO/TC 229
Chairman's Advisory Group
(CAG)

32Participating Countries
9 Observing Countries

ANSI-ACCREDITED U.S. TAG
ISO TC 229 - NANOTECHNOLOGIES

JWG 1
Terminology and Nomenclature
Leadership:
Canada (SCC)

JWG 2
Measurement and Characterization
Leadership:
Japan (AIST)

WG 3
Health, Safety and the Environment
Leadership:
United States (ANSI)

WG 4
Materials Specifications
Leadership:
China (SAC)

Initiation of International Standards Development

- International Standardization activities begin with the submission of a New Work Item Proposal (NWIP) to the respective ISO TC or SC, for one of the following
  - new standard
  - new part of an existing standard
  - revision of an existing standard
  - amendment to an existing standard or part
  - ISO Publicly Available Specification
  - ISO Technical Specification
- Proposals can come from many sources, both within and outside ISO
  - National body member (participating on the respective TC or SC)
  - TC/SC Secretariat
  - Another TC/SC
  - Liaison Organizations
  - TMB or Advisory Group
  - CEO

What factors drive ISO TC229 nanotechnology standards development activities?

As a national body based membership organization, standards development activities with ISO/TC 229 are informed by:

- **New work item proposals submitted by national members**. These are reviewed for their relevance to technical committee's scope and the working group roadmaps prior to being balloted by members. The criteria for approval of new work item proposals is that more than 50% of P members voting approve the proposal and at least five P members agreed to actively participate in the work;
- **Regular surveys of member's, including liaison members, standardization needs**, the latest of which has recently been completed and reported to the TC meeting in November. The results of this survey will be incorporated into the working group and TC roadmaps;
- **Specific requests by members, including liaison members, for work in particular areas.** For example CEN/TC 352 has invited TC 229 to contribute to the development of standards in support of a European Commission mandate for standards to address issues associated with health, safety and the environment;

SO TC229 WG3 Nanotechnologies Work Group Roadmap and Project Timelines

KEY
- Completed Work Items are highlighted in Grey
- Approved Work Items In Progress are highlighted in Green
- Potential New Work Items (NWIP) are highlighted in Yellow

1H 2008	2H 2008	Q1 2009	Q2 2009	Q3 2009	Q4 2009	Q1 2010	Q2 2010	Q3 2010	Q4 2010	Q1 2011	Q2 2011	Q3 2011	Q4 2011	1H 2012	2H 2012	1H 2013	2H 2013

Standard Methods for Determining Relative Toxicity/Hazard Potential of Nanomaterials

PG#2 ISO 29701 Endotoxin test on nanomaterial samples for *in vitro* systems, Limulus amebocyte lysate (LAL) test, Japan COMPLETED

PG#3 ISO 10801Nanotechnologies -- Standard for Generation of Metal Nanoparticles with the Evaporation/Condensation Method for Inhalation Toxicity Testing, Korea Completed

PG#4 ISO 10808 Nanotechnologies — Standard for Characterization of Nanoparticles in Inhalation Exposure Chambers for Inhalation Toxicity Testing, Korea Completed

PG#5 ISO/TR 13014 Guidance on physico-chemical characteristics of engineered nano-objects for toxicologic assessment, USA

PG 10 ISO/TS 14101 Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening FT-IR method - Korea

PG12 ISO/TR 16197Compilation and description of sample preparation and dosing methods for engineered and manufactured nanomaterials. USA

PG 13 ISO/AWI 161550 Determination of muramic acid as a biomarker for silver nanoparticles activity - Iran

Standard Methods for Toxicological Screening of Nanomaterials

PG11 ISO/TR 16196 Compliation and description of toxicological and ecotoxicological screening methods for engineered and manufactured nanomaterials. USA

Standard Methods for Environmentally Sound Use of Nanomaterials

PG#7 ISO TR 13121 Nanomaterial Risk Evaluation, USA

Standard methods for evaluating Environmental Fate & Transport of nanomaterials

Standard methods for evaluating Ecotoxicity of nanomaterials

Guidance on releasing nanomaterials into the environment during manufacture or use of nanomaterials

Standard Methods for ensuring Product Safety of nanomaterial products

PG#9 ISO/TR 13329 Preparation of Safety Data Sheet (SDS) for nanomaterials, Korea

Life cycle assessment methods for nanomaterial containing products

Standard method to determine nanoparticle generation rate from products containing nanomaterials

How are TC229 nanotechnology standards development activities prioritized?

- The role of the National Body membership of ISO is critical in both the prioritization and development of standards in ISO/TC 229.
- Standards development may only take place on the basis of new work item proposals submitted by members and support by at least 50% of the P members voting. However, members are encouraged to submit only proposals that align with the committee and working group roadmaps, which all members contribute to.
- In addition, all proposals are reviewed by a Task Group on Planning and Coordination to ensure work item meets scope/objectives of TC299.
- It should be noted that the national body members themselves comprise a broad cross section of their respective national stakeholder interests.

What are the greatest challenges in nanotechnology standards development and use?

- The absence of established and validated measurement and characterization equipment and protocols for use in the nanoscale;
- A serious shortage of knowledge regarding health and environmental impacts of exposure to nanomaterials and an absence of agreed protocols for how these knowledge gaps should be addressed;
- The ongoing emerging and general pre-commercialisation nature of nanotechnology and hence the need for parallel activities in the three principal areas of working – terminology and nomenclature, measurement and characterization, and health, safety and the environment;
- The committee's remit to develop horizontal standards means that it has a duty to actively engage with those sector specific standards committees that will be impacted by nanotechnologies in order to ensure they are aware of, make use of and ideally contribute to the standards developed by ISO/TC 229, which they will ultimately use to support their own product and application standards.

What are the greatest challenges faced by ISO TC229 in nanotechnology standards development and use?

- Lack of active participation by nanotechnology manufacturing organizations in the standards development process. The current niche market nature of nanotechnology is dominated by small to medium sized enterprises, many of them spin-outs from universities, which are inevitably highly focused on business development and have little time or inclination to get involved in standards development. Issue is compounded by the current need to develop horizontal standards that are not seen as directly contributing to their business activities;
- The early stage development of nanotechnologies means that many players that do get involved are from academic communities and have little or no experience of standards development. This has resulted in significant efforts having to be expended to coach/educate national body members in order to assure the relevance and quality of the documents being developed;

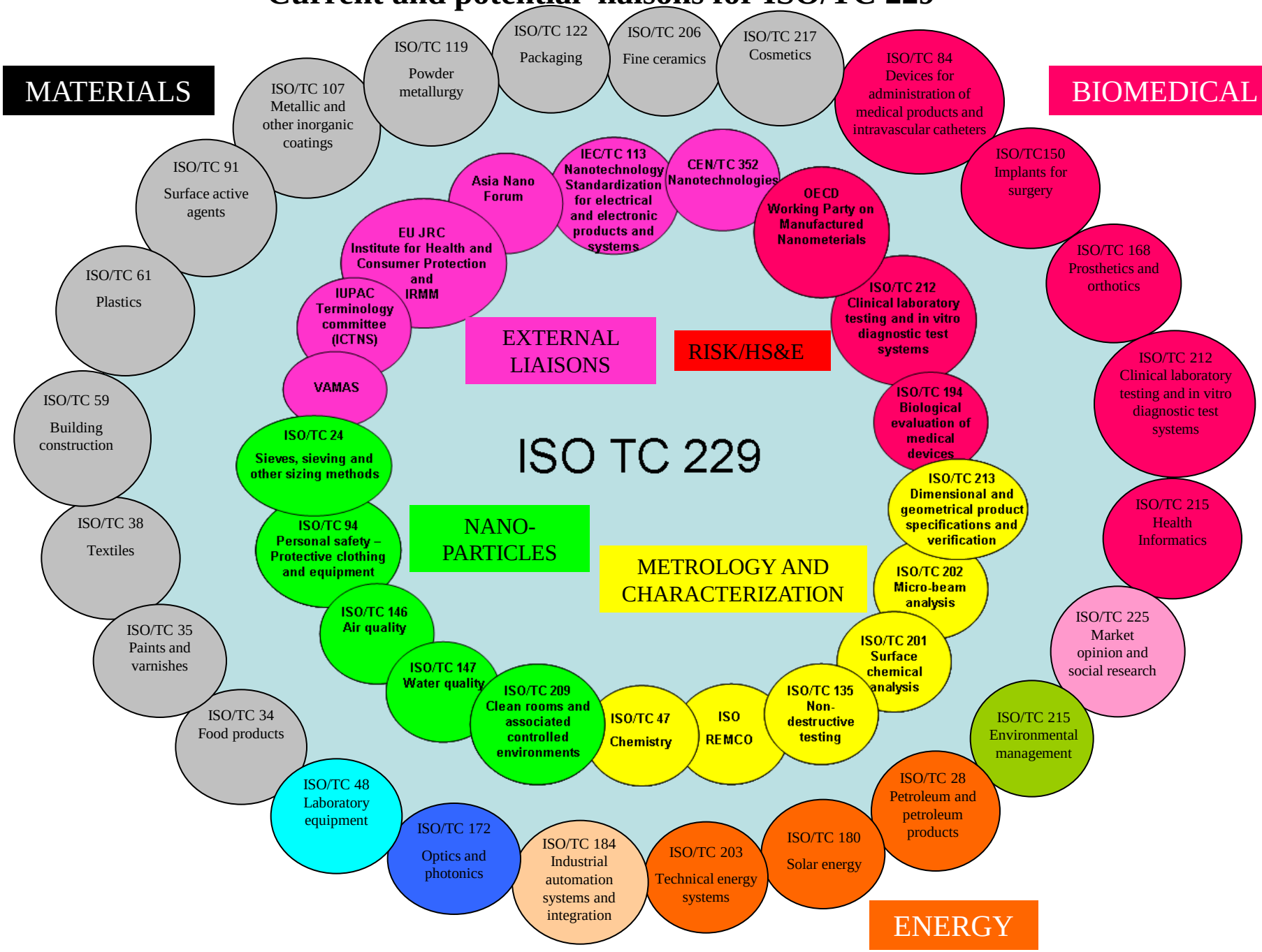
Major challenges for nanotechnologies standardization

- *Diversity of disciplines contributing to and impacted by nanotechnologies*
- *Global impact*
- *Rapid speed of development and apparent speed of commercialisation (over 1200 consumer products on the market – see Woodrow Wilson International Center for Scholars inventory: http://www.nanotechproject.org/inventories/consumer/)*
- *Concern about potential negative health and environmental impacts of exposure to some nanomaterials (nanoparticles and nanofibres)*

– *Critical areas*

  – *Protocols to ensure health and environmental safety (EHS)*
  – *Terminology and nomenclature*
  – *Measurement and characterization*
  – *Materials specifications*
  – *Coordination and harmonization across standards developers and stakeholders*

Current and potential liaisons for ISO/TC 229



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www.ansi.org/nsp | www.ansi.org/isotc229tag

WG 1 Terminology and Nomenclature (Convenor - Canada)

- Terminology and Definition of Nano-objects *Published*
- Outline of nanomaterials classification (Nano tree) *Published*
- Terminology – Framework and core concepts *Published*
- Terminology and definitions – 80004 SERIES Part 1: Core terms *Published*
- Terminology and definitions – Part 3: Carbon nano-objects *Published*
- Terminology and definitions – Part.4: Nanostructured materials
- Terminology and definitions – Part 5: Bio/nano interface
- Terminology and definitions – Part. 6: Nanoscale measurement and instrumentation
- Terminology and definitions – Part 7: Medical, health and personal care applications
- Terminology and definitions – Part 10: Nanomanufacturing processes
- Framework for nomenclature models for nano-objects
- Framework for identifying vocabulary development for nanotechnology applications in human healthcare

WG 2 Measurement & Characterization (Convenor - Japan)

- Characterization of SWCNTs using TEM
- Characterization of SWCNTs using SEM/EDXA *Published*
- Characterization of SWCNTs using NIR-PLS *Published*
- Characterization of SWCNTs using UV-Vis-NIR absorption spectroscopy
- Measurement methods for the char. MWCNTs
- Characterization of SWCNTs using EGA-GCMS *Published*
- Characterization of SWCNTs using TGA
- Determination of mesoscopic shape factors of MWCNTS
- General framework for determining nanoparticle content in nanomaterials by generation of aerosols
- Artificial gratings used in nanotechnology -- Description & measurement of dimensional quality parameters
- Determination of metal impurities in CNTs using ICP-MS
- Generic requirements for reference materials for development of methods for characteristic testing, performance testing and safety testing of nanoparticle and nano-fiber powders'

WG 3 EHS Aspects (Convenor - US)

- Health and safety practices in occupational settings relevant to nanotechnologies - *Published*
- Endotoxin test on nanomaterial samples for *in vitro* systems: LAL Assay - *Published*
- Generation of metal nanoparticles with the evap./condensation method for inhalation toxicity testing *Published*
- Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing *Published*
- *Guidance on phy.-chem. char. MNOs submitted for toxicological testing*
- Guide to safe handling & disposal MNMS
- Nanomaterial risk evaluation *Published*
- Guidelines for occupational risk management applied to ENMs based on a "control banding approach"
- Preparation of safety data sheets (SDS) for nanomaterials
- Detection of surface bound molecules to gold nanoparticles using FT-IR spectroscopy
- *Guidance on Toxicological Screening Methods for MNMs*
- *Guidance on Sample Prep. Methods & Dosimetry Considerations for MNMS*
- *Muramic Acid as a Biomarker for Silver Nanoparticles Activity*

WG 4 Materials specifications (Convenor – China)

- Nano-calcium carbonate -- Part 1: Characteristics and measurement methods
- Nano-titanium dioxide –
  Part 1: Characteristics and measurement methods
- Nanomaterials - Guidance on specifying nanomaterials
- Nanotechnology - nano particles in powder form - characteristics and measurements
- Nanotechnologies – Nanotechnology in powder form: characteristics and measurements