

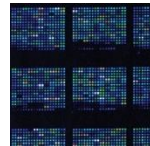
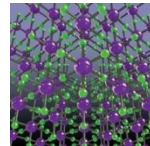
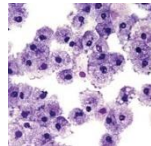
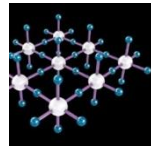
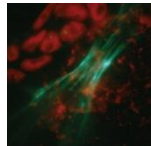
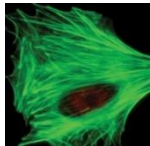
OECD - 15th Meeting of the Working Party on Manufactured Nanomaterials

ISO TC 229 Nanotechnology Standards Development Update

Steven Brown
Head of US Delegation to ISO TC229
On behalf of Dr. Simon Holland
ISO TC229 Chair

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



ISO Technical Committee 229 *Nanotechnologies*

- Established in June 2005
- 35 Participating Countries, 15 Observers
- 44 Published ISO Standards, Technical Specifications, Technical Reports
- 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 nanometres 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 and material specification**.
- Website http://www.iso.org/iso/iso_technical_committee?commid=381983



ISO TC229 Nanotechnologies

Participating countries: 35

Observing countries: 15

Participating Countries

- Australia
- Austria
- Belgium
- Brazil
- Bulgaria
- Canada
- China
- Columbia
- Czech Republic
- Denmark
- Finland
- France
- Germany
- India
- Indonesia
- Iran
- Ireland
- Israel

Italy
Japan
Korea, Republic of
Malaysia
Mexico
Netherlands
Norway
Peru
Poland
Russian Federation
Singapore
South Africa
Spain
Sweden
Switzerland
United Kingdom
USA

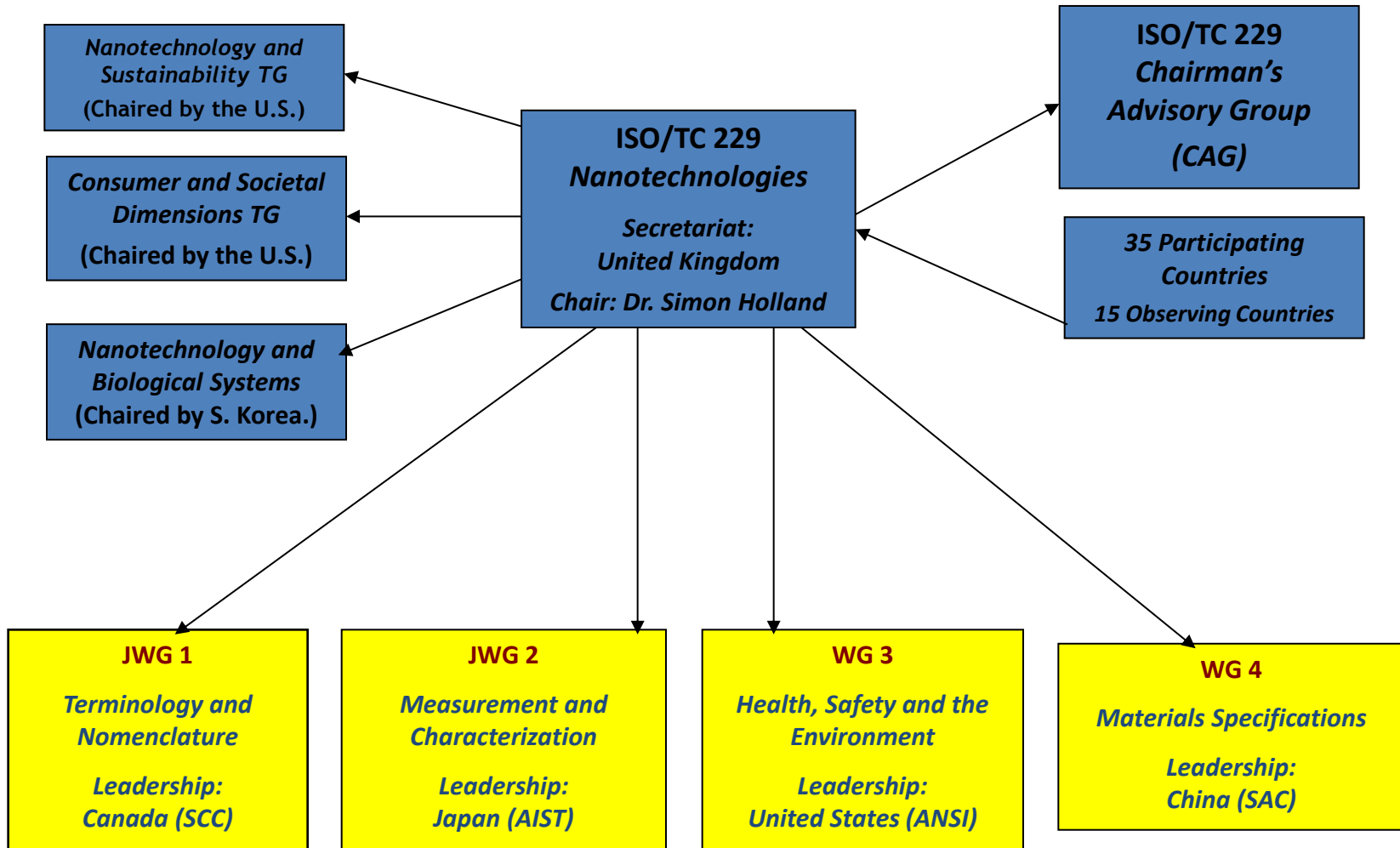
Observing Countries

Argentina
Egypt
Estonia
Greece
Hong Kong, China
Jamaica
Kazakhstan
Kenya
Mongolia
Morocco
Portugal
Romania
Serbia
Sri Lanka
Thailand



Next Meeting: Singapore, November 2016

ISO/TC 229 Organizational Chart



ISO/TC 229 *Working Groups*

Working Group 1

Terminology and Nomenclature

Define and develop unambiguous and uniform terminology and nomenclature in the field of nanotechnologies to facilitate communication and to promote common understanding.

Working Group 2

Metrology and Characterization

The development of standards for measurement, characterization and test methods for nanotechnologies, taking into consideration needs for metrology and reference materials.

Working Group 3

Health, Safety and Environment

The development of science-based standards in the areas of health, safety, and environmental aspects of nanotechnologies.

Working Group 4

Materials Specifications

To specify relevant compositions and properties and characteristics of manufactured nanomaterials. Excluded are areas of duplication in other technical committees from ISO and IEC. NOTE These documents will aim to facilitate communications between buyers, sellers and regulators of raw and intermediate materials.



ISO/TC 229 WG 1 Terminology and Nomenclature

11 Documents Published

| | |
|----------------|---|
| ISO/TS 80004-1 | Vocabulary – Part 1: Core terms |
| ISO/TS 80004-2 | Vocabulary – Part 2: Nano-objects |
| ISO/TS 80004-3 | Vocabulary – Part 3: Carbon nano-objects |
| ISO/TS 80004-4 | Vocabulary – Part 4: Nanostructure materials |
| ISO/TS 80004-5 | Vocabulary – Part 5: Nano/bio interface |
| ISO/TS 80004-6 | Vocabulary – Part 6: Measurement and instrumentation |
| ISO/TS 80004-7 | Vocabulary – Part 7: Diagnostics and therapeutics for healthcare |
| ISO/TS 80004-8 | Vocabulary – Part 8: Nanomanufacturing |
| ISO/TR 11360 | Methodology for the classification and categorization of nanomaterials |
| ISO/TR 12802 | Model taxonomic framework for use in developing vocabularies -- Core concepts |
| ISO/TR 14786 | Considerations for the development of chemical nomenclature for selected nano-objects |

ISO/TC 229 WG 2 Measurement and characterisation

12 Documents Published

| | |
|--------------|---|
| ISO/TS 10797 | Characterization of single-wall carbon nanotubes using transmission electron microscopy |
| ISO/TS 10798 | Characterization of single-wall carbon nanotubes using scanning electron microscopy and energy dispersive X-ray spectrometry analysis |
| ISO/TS 10867 | Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy |
| ISO/TS 10868 | Characterization of single-wall carbon nanotubes using ultraviolet-visible-near infrared absorption spectroscopy |
| ISO/TR 10929 | Characterization of multiwall carbon nanotube samples |
| ISO/TS 11251 | Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry |
| ISO/TS 11308 | Characterization of single-wall carbon nanotubes using thermogravimetric analysis |
| ISO/TS 11888 | Characterization of multiwall carbon nanotubes -- Mesoscopic shape factors |
| ISO/TS 12025 | Quantification of nano-object release from powders by generation of aerosols |
| ISO/TS 13278 | Determination of elemental impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry |
| ISO/TS 16195 | Guidance for developing representative test materials consisting of nano-objects in dry powder form |
| ISO/TS 17466 | Use of UV-Vis absorption spectroscopy in the characterization of cadmium chalcogenide colloidal quantum dots |



ISO/TC 229 WG 3 Environmental Health & Safety

13 Documents Published:

| | |
|----------------|---|
| ISO 10801 | Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method |
| ISO 10808 | Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing |
| ISO/TR 12885 | Health and safety practices in occupational settings relevant to nanotechnologies |
| ISO/TS 12901-1 | Occupational risk management applied to engineered nanomaterials -- Part 1: Principles and approaches |
| ISO/TS 12901-2 | Occupational risk management applied to engineered nanomaterials -- Part 2: Use of the control banding approach |
| ISO/TR 13014 | Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment |
| ISO/TR 13121 | Nanomaterial risk evaluation |
| ISO/TR 13329 | Preparation of material safety data sheet (MSDS) |
| ISO/TS 13830 | Guidance on voluntary labelling for consumer products containing manufactured nano-objects |
| ISO/TS 14101 | Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method |
| ISO/TR 16197 | Compilation and description of toxicological screening methods for manufactured nanomaterials |
| ISO/TS 16550 | Determination of silver nanoparticles potency by release of muramic acid from Staphylococcus aureus |
| ISO 29701 | Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amoebocyte lysate (LAL) test |

ISO/TC 229 WG 4 Materials specifications

4 Documents Published

| | |
|--------------|---|
| ISO/TS 11931 | Nanoscale calcium carbonate in powder form -- Characteristics and measurement |
| ISO/TS 11937 | Nanoscale titanium dioxide in powder form -- Characteristics and measurement |
| ISO/TS 12805 | Materials specifications -- Guidance on specifying nano-objects |
| ISO/TS 17200 | Nanoparticles in powder form -- Characteristics and measurements |

ISO/TC 229 WG 1 Terminology and Nomenclature

Work Items/Standards Under Development

| | |
|------------------|--|
| ISO/DTR 17302 | Framework for identifying vocabulary development for nanotechnology applications in human healthcare |
| ISO/DTS 18110 | Vocabularies for Science, Technology and Innovation Indicators |
| ISO/DTR 18401 | Plain Language Guide for Terminology |
| ISO/DTS 80004-11 | Vocabulary - Part 11: Nanolayer, nanocoating, nanofilm and related terms |
| ISO/DTS 80004-12 | Vocabulary – Part 12: Quantum phenomena |
| ISO/DTS 80004-13 | Vocabulary – Part 13: Graphene and other 2d materials |
| ISO/DTS 20477 | Standard terms and their definition for cellulose nanomaterials |



ISO/TC 229 WG 2 Measurement and characterisation

Work Items/Standards Under Development

| | |
|---------------|--|
| ISO/DTR 18196 | Measurement technique matrix for nano-objects |
| ISO/DTS 19590 | Detection and characterization using single-particle ICP-MS |
| ISO/DTR 19716 | Characterization of cellulose nanocrystals -- Particle morphology, purity and surface properties |
| ISO/DTR 19733 | Matrix of characterization and measurement methods for Graphene |
| ISO/DTR 20489 | Separation and size fractionation for the characterization of metal-based nanoparticles in water samples |
| ISO/DTS 19809 | Guidelines for collection and sample preparation of airborne nanoparticles for microscopy techniques |
| ISO/PWI | Determination of size and size distribution of nano-objects by scanning electron microscopy |
| ISO/PWI | Structural characterization of graphene |
| ISO/PWI | Measurement of average nanoparticle size and assessment of agglomeration state by static multiple light scattering in concentrated media |
| ISO/PWI | Application of field flow fractionation for characterization of nanomaterial contents |
| ISO/PWI | Protocol for particle size distribution by transmission electron microscopy |



ISO/TC 229 WG 3 Environmental Health & Safety

Work Items/Standards Under Development

- ISO/DTR 16196 Compilation and description for sample preparation and dosing methods for engineered and manufactured nanomaterials
- ISO/DTR 18637 General framework for the development of occupational exposure limits for nano-objects and their aggregates and agglomerates
- ISO/DTS 18827 ESR as a method for measuring ROS generated by metal oxide nanomaterial
- ISO/AWI 19007 *In vitro* MTS Assay for measuring the cytotoxic effect of nanoparticles
- ISO/DTS 19006 Dichloro-dihydro-fluorescein diacetate (DCFH-DA) Assay for evaluating nanoparticle-induced intracellular ROS production in Raw 264.7 macrophage cell line
- ISO/DTR 19057 Use and application of acellular *In Vitro* Tests and Methodologies to assess Nanomaterial Biodurability
- ISO/DTS 19337 Characteristics of working suspensions of nano-objects for *in vitro* assays to evaluate inherent nano-object toxicity
- ISO/DTR 19601 Aerosol generation for NOAA air exposure studies
- ISO/DTS 20787 Aquatic toxicity assessment of nanomaterials using *Artemia* sp
- ISO/AWI 20814 Photocatalytic activity assay for nanoparticles in aqueous suspension

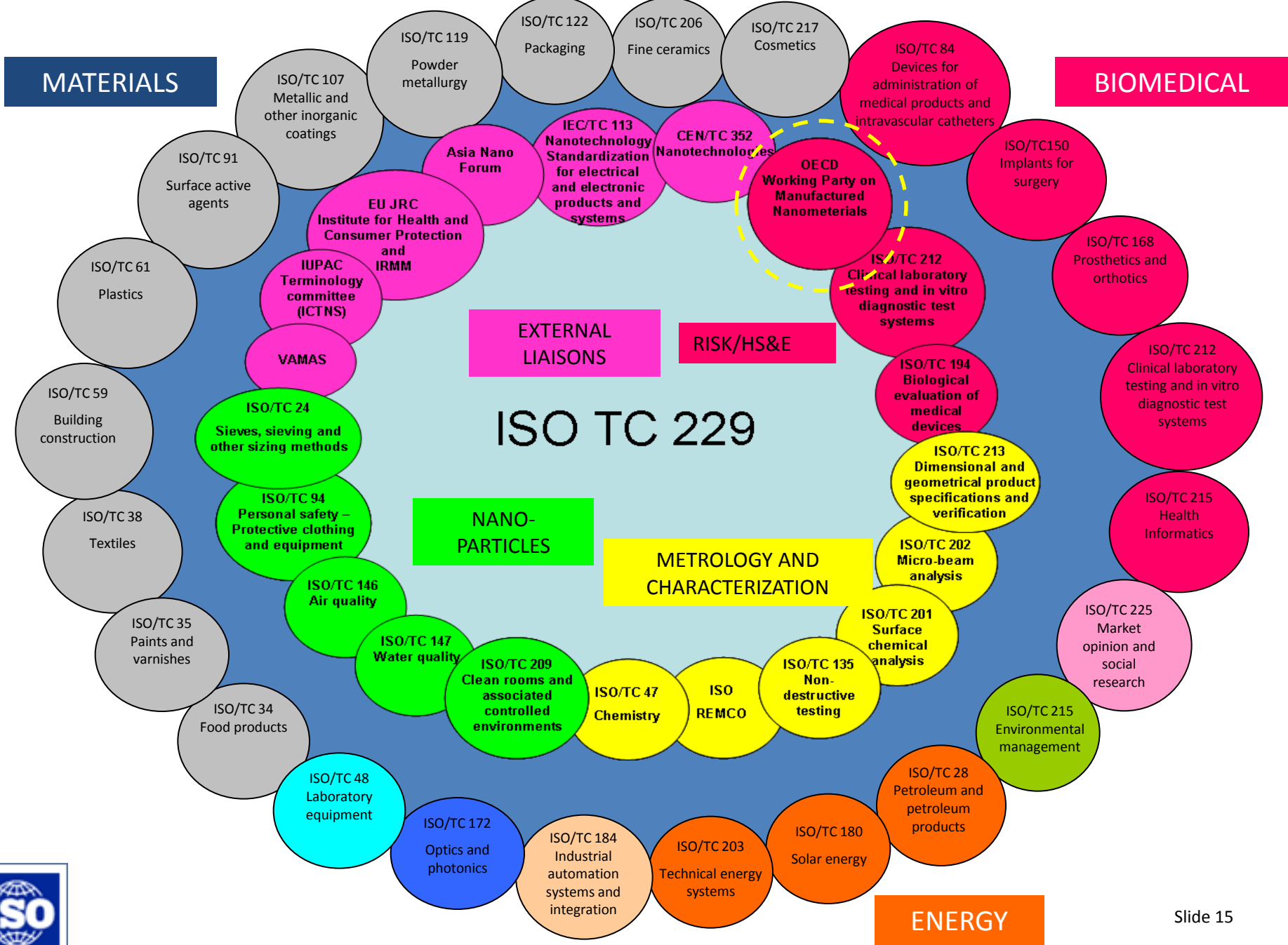


ISO/TC 229 WG 4 Materials specifications

Work Items/Standards Under Development

- ISO/DTS 19807 Specification for magnetic nanoparticle suspensions
- ISO/DTS 20660 Materials specification -- Antibacterial silver nanoparticles
- ISO/DTS XXXXX Nanoclays: ; Characteristics, Performances and Measurement Methods
- ISO/DTS XXXXX Nano-enhanced air filter media using nanofibres; Characteristics, Performances and Measurement Methods
- ISO/DTS XXXXX Nanotechnology - Specifications for Carbon Nanotube Suspension: characteristics and test methods

Current and potential liaisons for ISO/TC 229



Back Up Information



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 Technical Committee (TS) or Sub Committee (SC))**
 - **TC/SC Secretariat**
 - **Another TC/SC**
 - **Liaison Organizations**
 - **TMB or Advisory Group**



What factors drive ISO TC229 nanotechnology standards development activities?

As a national body based membership organization, standards development activities 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;

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 lack 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;



About ISO

- ISO = International Organization for Standardization
- ISO develops and publishes voluntary international standards
- A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.
- ISO is a network of national standards bodies. These national standards bodies make up the ISO membership and they represent ISO in their country.
- ISO has members from 164 countries and 3,335 technical bodies to take care of standards development.



ISO TC229 Liaisons

- **ISO committees in liaison:** [TC 24/SC 4](#), [TC 35](#), [TC 44](#), [TC 45/SC 3](#), [TC 48](#), [TC 61](#), [TC 142](#), [TC 146/SC 2](#), [TC 150](#), [TC 184/SC 4](#), [TC 194](#), [TC 201](#), [TC 202](#), [TC 206](#), [TC 207](#), [TC 207/SC 1](#), [TC 209](#), [TC 213](#), [TC 215](#), [TC 217](#), [TC 246](#), [TC 256](#), [REMCO](#)
- **IEC committees in liaison:** IEC/TC 113
- **Organizations in liaison:** [ANEC](#), [ANF HQ](#), [BIPM](#), [ECOS](#), [ETUI](#), [EU](#), [IRMM](#), [IUPAC](#), [OECD](#), [VAMAS](#)