



Standardization for nanotechnologies in support of the market, regulators and the public

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BioCentre symposium on
 Products, Privacy and People: Regulating on the Nanoscale
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Definitions

(Documentary) Standard

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

NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.
 [ISO/IEC Guide 2:2004, definition 3.2]

Consensus

general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a Process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments

NOTE Consensus need not imply unanimity.
 [ISO/IEC Guide 2:2004, definition 1.7]

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Standards

Written Standards provide agreed ways of:

- Naming, describing and specifying things
- Measuring and testing things
- Managing and reporting things e.g. quality and environmental management:
 - ISO 9001 and ISO 14000
- Good practice, as in e.g. ISO 26000 (Social Responsibility)

Standards can be:

- **NORMATIVE**, defining what **MUST** be done in, e.g., a specific test method
- **INFORMATIVE**, providing information only.

Standards are **VOLUNTARY** unless agreed to in a contract or referred to in regulation.

Standards – “not essential to life but absolutely essential to modern living”:

- internet protocols,
- aircraft fuels
- credit cards,
- business continuity management
- carbon trading,
- sustainable development
- life cycle costing
- feed and food chain traceability

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Example - A little local difficulty:



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Tyres and rims

ISO 4000-1:2007
 Passenger car
 tyres and rims --
 Part 1: Tyres
 (metric series)



ISO 4000-2:2007
 Passenger car
 tyres and rims --
 Part 2: Rims

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Petrol and diesel



EN 13817-1:2008+A1:2009
 Petrol filling stations -
 Part 1: Safety
 Requirements for
 construction and
 performance of
 metering pumps,
 dispensers and remote
 pumping units

ISO 9158:1988
 Road vehicles -- Nozzle spouts
 for unleaded gasoline
 ISO 9159:1988
 Road vehicles -- Nozzle spouts
 for leaded gasoline and diesel
 fuel

EN 228:2008
 Automotive fuels --
 Unleaded petrol --
 Requirements and test
 methods
EN 590:2005
 Automotive fuels - Diesel -
 Requirements and test
 methods

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Credit cards and PINs



ISO/IEC 7810:2003
 Identification cards – Physical characteristics
 ISO/IEC 7810:2003/Amd 1:2009
 Criteria for cards containing integrated circuits
 ISO/IEC 7811:2002
 Identification cards – Recording technique – Part 1: Embossing
 ISO/IEC 7816:1:1998
 Identification cards – Integrated circuit(s) cards with contacts – Part 1: Physical characteristics

ISO 9564-1:2002
 Banking – Personal Identification Number (PIN) management and security – Part 1: Basic principles and requirements for online PIN handling in ATM and POS systems
 ISO 9564-2:2002
 Banking – Personal Identification Number management and security – Part 2: Approved algorithms for PIN encipherment

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Thank God for CEN and ISO



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WHY are standards important ?

Standards:

- make the development, manufacturing and supply of products and services more efficient, more reliable and safer
- facilitate trade between countries by removing technical barriers and making it fairer
- potentially lead to cost reduction through open competition
- provide governments with a technical base for health, safety and environmental legislation, and regulation
- share technological advances and good management practice
- facilitate the dissemination of innovation
- safeguard consumers, and users in general, of products and services
- make life simpler by providing solutions to common problems

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Why is nanotechnology important?

US Interagency Working Group on Nano Science, Engineering and Technology (IWGN) workshop on Nanotechnology Research Directions (Sept. '99):
"nanotechnology will be a strategic branch of science and engineering for the 21st century, one that will fundamentally restructure the technologies currently used for manufacturing, medicine, defence, energy production, environmental management, transportation, communication, computation and education."

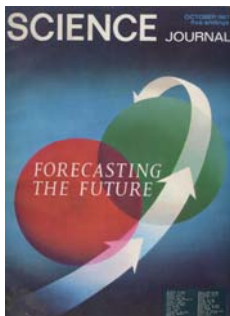
US NSF report on "SOCIETAL IMPLICATIONS OF NANOSCIENCE AND NANOTECHNOLOGY" March 2001:
"the impact of nanotechnology in the 21st century is likely to be at least as significant for health, wealth and security as the combined influences of antibiotics, integrated circuits and polymers."

Projected world-wide market for n-t enabled products will be between \$500 billion and \$3 trillion by 2015

"It is estimated that Nanotechnology is presently at a level of development similar to that of computer/information technology in the 1950s" (Nanostructure Science and Technology: A Worldwide Study, WTEC Panel report, 1999)

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A word of Caution!



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 >\$10BN annual investment in R&D
- Timescale is significantly shorter!

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'International' standardization committees for nano

ISO TC 229 Nanotechnologies

- Established June 2005
- Currently 36 'P' members and 8 'O' members (see http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee_participation.htm?Committee=3819&3)

- Liaisons with 26 other ISO/IEC/CEN TCs and SCs and 9 external bodies – ANF, BIPM, EC JRC, ECOS, IRMM, IUPAC, OECD, VAMAS and ETUI

IEC TC 113 Nanotechnology standardization for electrical and electronic products and systems

- Established June 2006
- Currently 18 'P' members and 14 'O' members (see http://www.iec.ch/99/99new87pa162-17-0...?SP_SEARCH_TC=113)

- Liaisons with 4 IEC/ISO TCs and 3 external bodies – ANF, IEEE and SEMI

CEN TC 352 Nanotechnologies

- Established November 2005
- All 30 members of CEN are notionally members – around 12 active (see http://www.cen.eu/cen/Sectors/TechnicalCommittees/Workshops/CENTechnicalCommittees/Pages/default.aspx?param=506478&file=CEN_TC35200521)

- Liaisons with 10 CEN/ISO TCs and 9 external bodies – ECOS, ENTA, NORMAPNE, NIA, EC DGs Enterprise and Industry, Environment, Health and Consumer Protection, JRC & Research

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UK Publications and work programme

Publicly Available Specifications (PAS):

- PAS 71 Vocabulary – Nanoparticles (under revision) (1453)
- PAS 131 Terminology for medical, health and personal care applications of nanotechnologies (825)
- PAS 132 Terminology for the bio-nano interface (588)
- PAS 133 Terminology for nanoscale measurement and instrumentation (744)
- PAS 134 Terminology for carbon nanostructures (602)
- PAS 135 Terminology for nanofabrication (588)
- PAS 136 Terminology for nanostructured materials (905)

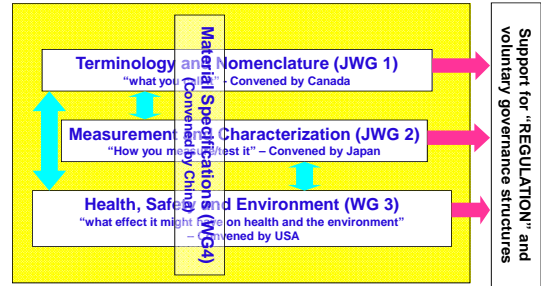
Published Documents (PD)

- PD 6699-1 Guide to specifying nanomaterials (975)
 - PD 6699-2 Guide to safe handling and disposal of manufactured nanomaterials (2106)
 - PD 6699-3 Guide to assessing airborne exposure in occupational settings relevant to nanomaterials
- All documents are available for free download at www.bsigroup.com/nano except PD 6699-3

Under development: PAS 137 - Nanomaterials and nanotechnology-based products – Guidance on legislation and standards for SMEs

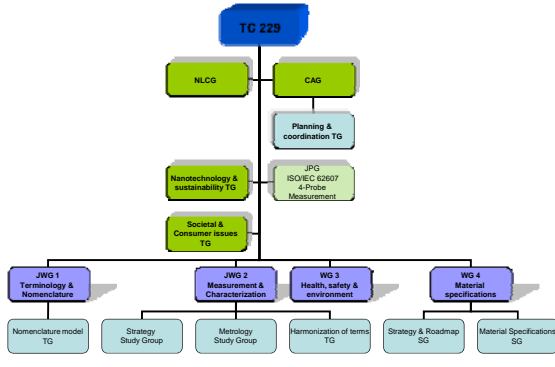
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TC 229 - Nanotechnologies – Structure/working areas



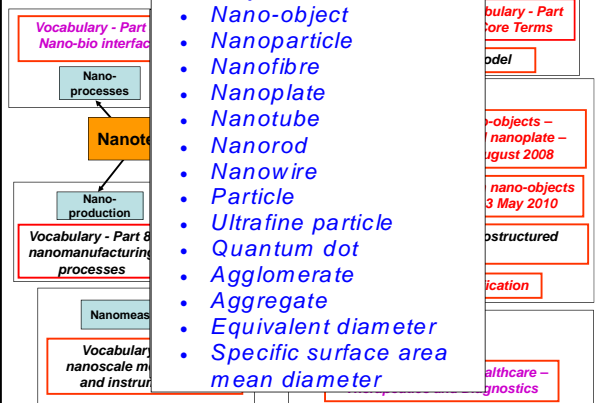
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ISO/TC 229 STRUCTURE



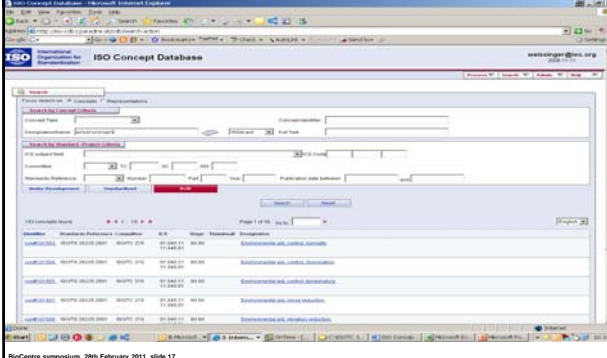
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ISO/TC 229 JWG 1 Nano-object terms



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definitions – the ISO Concept Database – <http://cdb.iso.org>



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EC consultation on its recommendation for a draft regulatory definition of 'nanomaterial'

Article 2

1. Nanomaterial: means a material⁸ that meets at least one of the following criteria:
 - consists of particles, with one or more external dimensions in the size range 1 nm – 100 nm for more than 1 % of their number size distribution;
 - has internal or surface structures in one or more dimensions in the size range 1 nm – 100 nm;
 - has a specific surface area by volume greater than 60 m²/cm³, excluding materials consisting of particles with a size lower than 1 nm.
2. Particle: means a minute piece of matter with defined physical boundaries (ISO 14646:2007)

TC 352 and NTI/1 responses submitted before deadline of 19/11/10

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ISO/TC 229 JWG2: Published/Approved documents and current work

SWCNT characterization

- TEM
- AFM
- Raman
- EDX-EDS
- UV-Vis-NIR spectroscopy

MWCNT characterization

- Electrical characterization of Carbon Nanotubes Using 4-Probe Measurement (TS)
- Measurement Methods for Characterizing Multi-Walled Carbon Nanotubes (TR)
- Determination of shape factors of multiwalled carbon nanotubes (TS)
- Determination of Metal Impurities in Carbon Nanotubes Using Inductively Coupled Plasma-Mass Spectroscopy (ICP-MS) - TS

IS: General Framework for Determining Nanoparticle Content in Nanomaterials by Generation of Aerosol
TS: Artificial gratings used in nanotechnology: description and measurement of dimensional quality parameters
TS: Generic requirements for reference materials for development of methods for characteristic testing, performance testing and safety testing of nano-particle and nano-fiber powders

Joint developments with CEN (CEN lead):
TR: Guide to methods for nano-tribology measurements

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ISO/TC 229 WG3: Published/Approved documents and current work

Controlling Occupational Exposures to Nanomaterials

- ISO/TR 12885 - Safe Practices in Occupational Settings Relevant to Nanotechnologies - published autumn 2008
- TR: Nanomaterial risk evaluation framework
- TS: Guidance on safe handling and disposal of manufactured nanomaterials
- TS: Guidelines for occupational risk management of nanomaterials based on "control banding"
- TR: Preparation of Material Safety Data Sheet (MSDS) for nanomaterials

Determining Relative Hazard Potential of Nanomaterials

- TR: Guidance on physico-chemical characterization of nanomaterials for toxicology testing
- IS: Endpoints test on nanomaterial samples for in vitro systems
- IS: Generation of Metal Nanoparticles for Inhalation Toxicity Testing
- IS: Characterization of nanoparticles for inhalation toxicity testing

Toxicological Screening of Nanomaterials - cooperation with OECD WPMN

- TS: Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening - FT-IR method
- TR: Guidance on toxicological screening methods for manufactured nanomaterials
- TR: Guidance on sample preparation methods and dosimetry considerations for manufactured nanomaterials (for toxicology screening)
- TS: Determination of Muramic Acid as a biomarker for silver nanoparticles activity

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TC 229 Work programme – Materials specifications (WG4)

- TS: Materials specification for nano-titanium dioxide – Part 1 General requirements
- TS: Materials specification for nano-titanium dioxide – Part 2 Requirements for specific applications
- TS: Materials specification for nano-calcium carbonate – Part 1 General requirements
- TS: Materials specification for nano-calcium carbonate – Part 2 Requirements for specific applications
- TS: Guidance on specifying manufactured nano-materials

Other Projects
Joint development with CEN (CEN lead):

- Guidance on labelling of products containing manufactured nanoparticles – under preparation for ballot in both committees

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What standards are still needed – for commerce

"if you can't measure it you can't make it"

- Validated characterization techniques for manufactured nano-objects:
 - Basic character set - composition, geometrical properties, sampling methods
 - Advanced character set – e.g. elemental structure, chemical functionality, electrical, magnetic, mechanical, optical properties
- Validated characterization techniques for coatings and nanostructured materials
 - Basic character set: geometrical properties, composition, density
 - Advanced character set – e.g. electrical, magnetic, mechanical, optical, thermal properties
- Materials specifications – generic and specific
- H, S and E, including end of life treatment
- Application standards will be done by sector committees

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What standards are still needed – for regulation

"if you can't define it and you can't measure it then you can't regulate it"

EC Mandate M461 calling for standards development in the following areas

- Validated methods for determination of physicochemical properties relevant to hazard characterisation of nanomaterials
- Sampling and measurement of workplace, consumer and environment exposure
- Methods to simulate exposures to nanomaterials
- H, S & E

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Thank you!

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