

Standardization in support of safe and successful nanotechnologies

Dr Peter Hatto,
Director of Research, IonBond Ltd
Chairman ISO TC 229, CEN TC 352 and BSI NTI/1 Nanotechnologies
standardization committees

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Overview

- ***Standards and standardization***
 - *Role of standards*
 - *Standardization organisations*
 - *Development of formal standards*
- ***Standardization for nanotechnologies***
 - *What needs standardizing and why?*
 - *Current standardization committees*
 - *Existing standards, standardization projects and proposals*
 - *Cooperation, coordination and harmonization*

Standards

Standards can be of two types:

- Metrological standards
- Written standards

Written Standards provide agreed ways of:

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

To:

- *support commercialisation, market development and established markets*
- *provide a basis for procurement based on technical requirements and quality/environmental management*
- *support appropriate legislation/regulation*

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

Standards are **VOLUNTARY** unless called in a contract or regulation.

Standards are based on **CONSENSUS** not necessarily unanimity

Standards

Standards are:

- Ubiquitous – covering such things as 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 16,500 International Standards, many with multiple parts;
- Are absolutely critical to our modern way of life – covering things such as:
 - internet protocols,
 - CDs/DVDs,
 - credit cards,
 - pin numbers,
 - quality and environmental management,
 - carbon trading,
 - space vehicles
 -

and standardization

Standards can be:

- **FORMAL** – developed by independent experts working under the auspices of a National, Regional or International standards body
 - *AFNOR, BSI, DIN, JIS, (NSBs)*
 - *CEN, CENELEC, ETSI.....*
 - *ISO, IEC & ITU*
- **INFORMAL** – developed by a SDO (Standards Development Organisation)
 - *ASTM, IEEE, SAE, SEMI, VDI...(>600 SDOs IN US)*
- **PRIVATE** – developed by a company or trade association

FORMAL standards are:

- *PROPOSED, DEVELOPED AND APPROVED by the members of the standards body (or an accredited organisation)*
- *Based on CONSENSUS (i.e. no sustained opposition), not necessarily unanimity.*

International Organization for Standardization (ISO)

Paraphrasing the French philosopher Chamfort: *“It is easier to legislate than to legitimise”*

INTERNATIONAL STANDARDS PROVIDE LEGITIMACY:

Standards are:

- *Proposed, commented on and approved by members of the international community*
- *Developed by experts nominated by members*
- *Process is based on well established principle of CONSENSUS*
- *Voluntary*
- Standards provide critical elements of Governance through ISO 9001, 14001 (and ISO 26,000 – expected to be published in 2010).
- ISO structure includes committees on
 - **CERTIFICATION AND ASSESSMENT (CASCO),**
 - **CONSUMER POLICY (COPOLCO),**
 - **DEVELOPING COUNTRIES (DEVCO)**
 - **REFERENCE MATERIALS (REMCO)**

Extent of ISO System

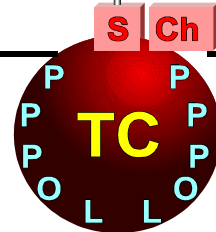
~150 full-time posts

ISO CENTRAL SECRETARIAT

More than 16,500 ISO Standards

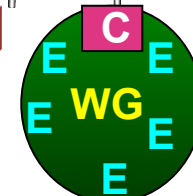
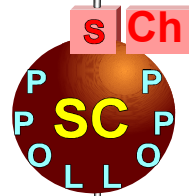
Secretary

Chairman



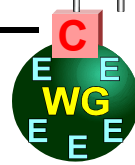
~750 Secretariats held by ~40 countries

>200 TCs



Convenor

>540 SCs



Standardization projects

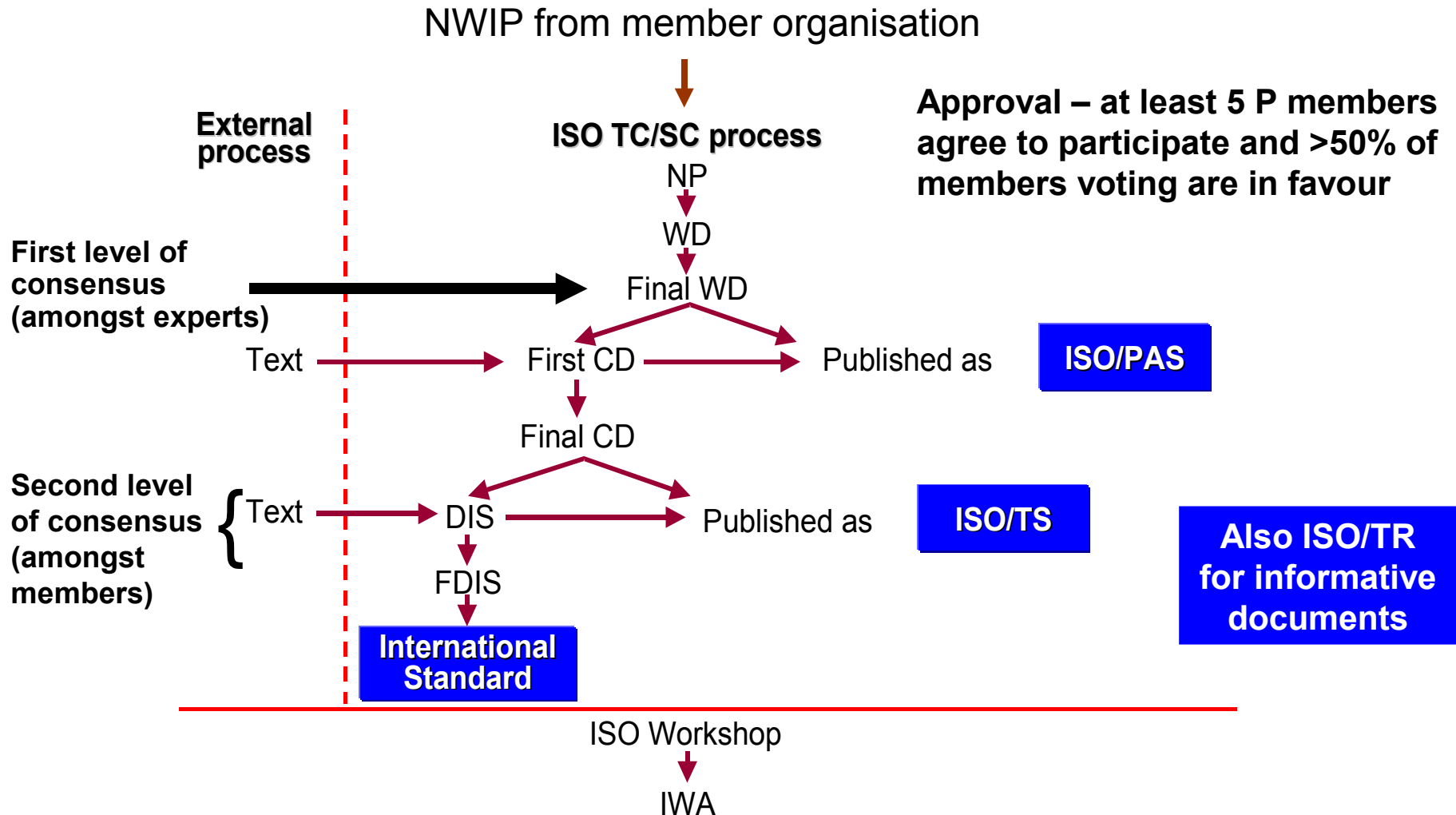
Standardization projects

>2 250 WGs

~ 3,500 active projects

Development of International Standards

Process accommodates special needs



Major issues for nano

- *Diversity of disciplines impacted by and contributing to nanotechnologies*
- *Global impact*
- *Rapid speed of development and apparent speed of commercialisation*
- *Critical areas:*
 - *Coordination and harmonization across standards developers and stakeholders*
 - *Terminology*
 - *Measurement and characterization*
 - *Health, safety and environment*
 - *Material specifications*

International Organisation for Standardization committee ISO/TC 229 - Nanotechnologies

- Established in June 2005
- 40 members – 32 “P” and 8 “O” (see http://www.iso.org/iso/standards_development/technical_cor)
- Liaisons with 16 other ISO TCs and 7 external bodies – IEC/TC 113, CEN/TCs 137 and 352, Asia Nano Forum, EC JRC, OECD and VAMAS
- Exploring additional external liaisons for other groups (e.g. International Alliance for NanoEHS Harmonization) and for emerging economies

International Electrotechnical Commission committee IEC/TC 113 – “Nanotechnology standardization for electrical and electronic products and systems”

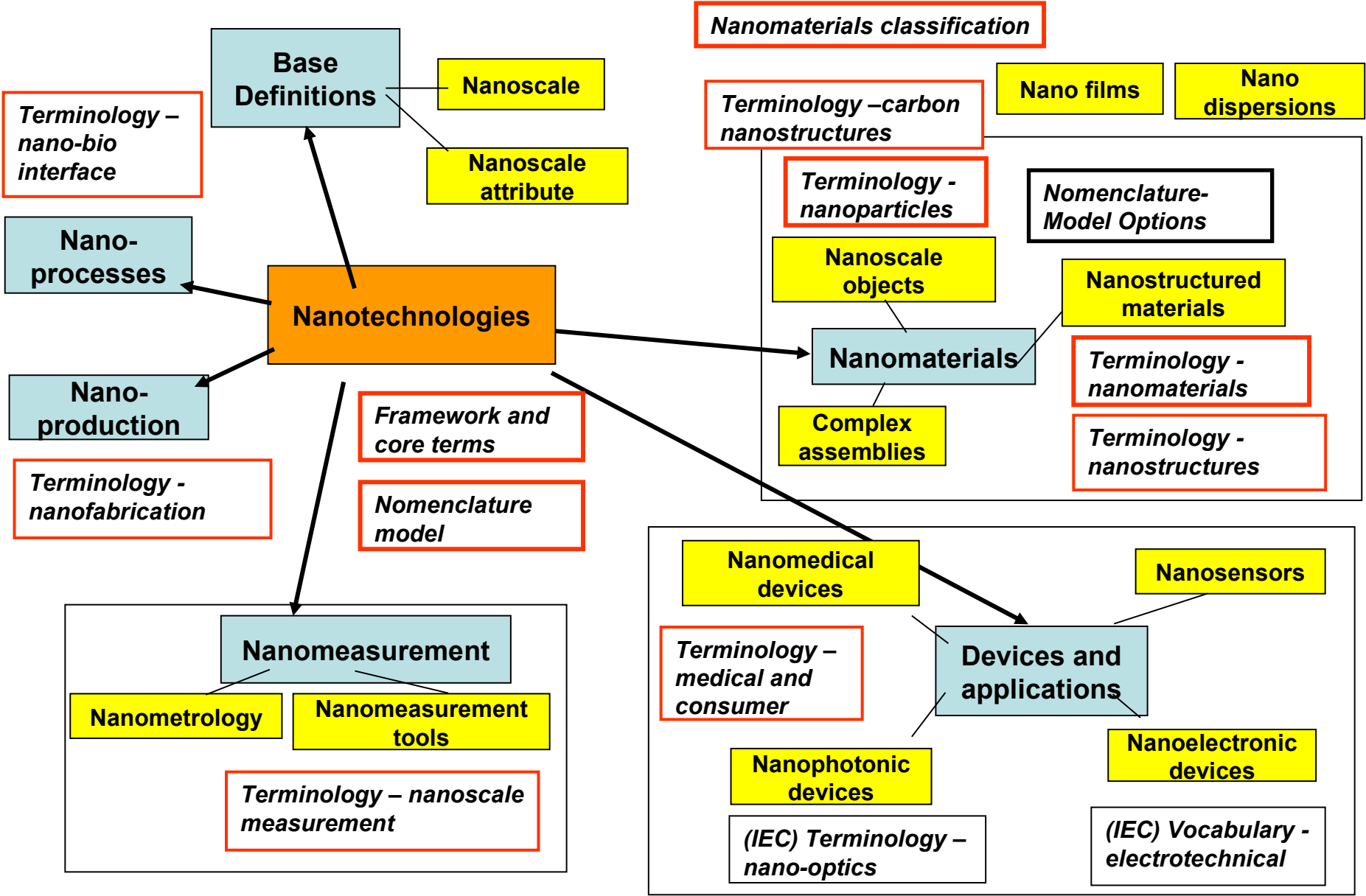
- Established June 2006 with US Chair and German secretariat
- <http://www.iec.ch/cgi-bin/procgi.pl/www/iecwww.p?wwwlang=e&wwwpri>
- 26 members - 15 “P” and 11 “O”
- Agreed to establish two Joint Working Groups with ISO TC/229:
 - JWG 1 – Terminology and nomenclature
 - JWG2 – Measurement and characterization
- Together with a third Working Group:
 - WG3 – Performance assessment
 - ***Work Item: GUIDE FOR CARBON NANOTUBE SPECIFICATION FOR ELECTROTECHNICAL APPLICATION***

TC 229 – Horizontal activities 1

Terminology and Nomenclature (JWG 1)

“what you call it” - Convened by Canada

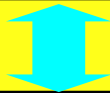
ISO/TC 229 JWG1: Strategic Roadmap



TC 229 – Horizontal activities 2

Terminology and Nomenclature (JWG 1)

“what you call it” - Convened by Canada



Measurement and Characterization (JWG 2)

“How you measure/test it” – Convened by Japan

ISO/TC 229 JWG2: Draft Roadmap

2005

2010

2015

Carbon Nano-Materials

Basic Character set
Purity Geometrical property
Morphology Dispersability Tube type

Advanced Character set
Electrical, Magnetic, Mechanical , Optical properties

Engineered nanoparticles

Basic Character set
Purity Composition, Geometrical property, Sampling method.

Advanced Character set
Elemental structure, Chemical functionality,
Electrical, Magnetic, Mechanical , Optical properties

Coatings/ Nanostructured materials

Basic Character set
Geometrical property, Composition, Density

Advanced Character set
Electrical, Magnetic, Mechanical , Optical properties

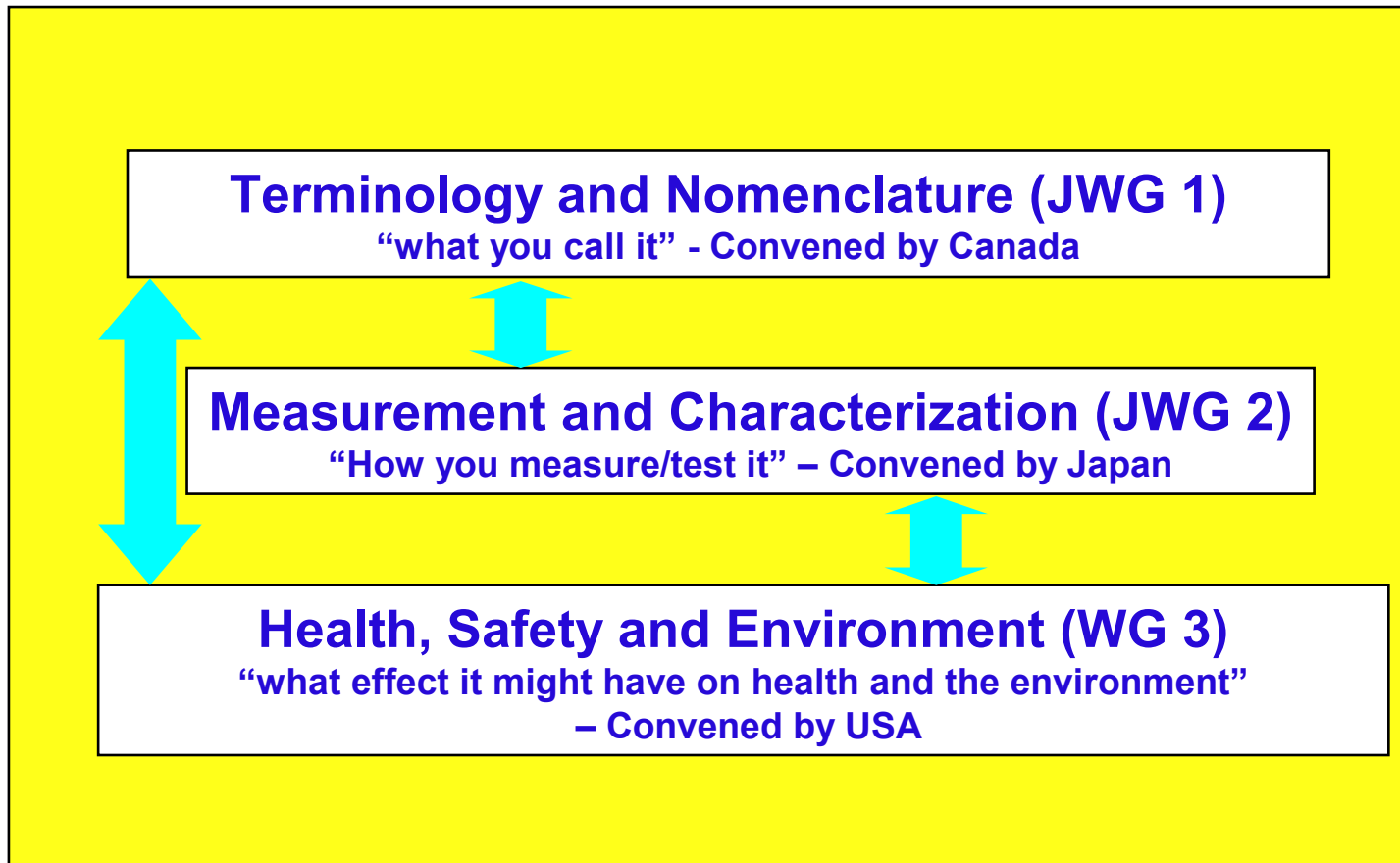
Basic Metrology

Length, Depth, Force, Traceability, Definition of Measurand, Uncertainty

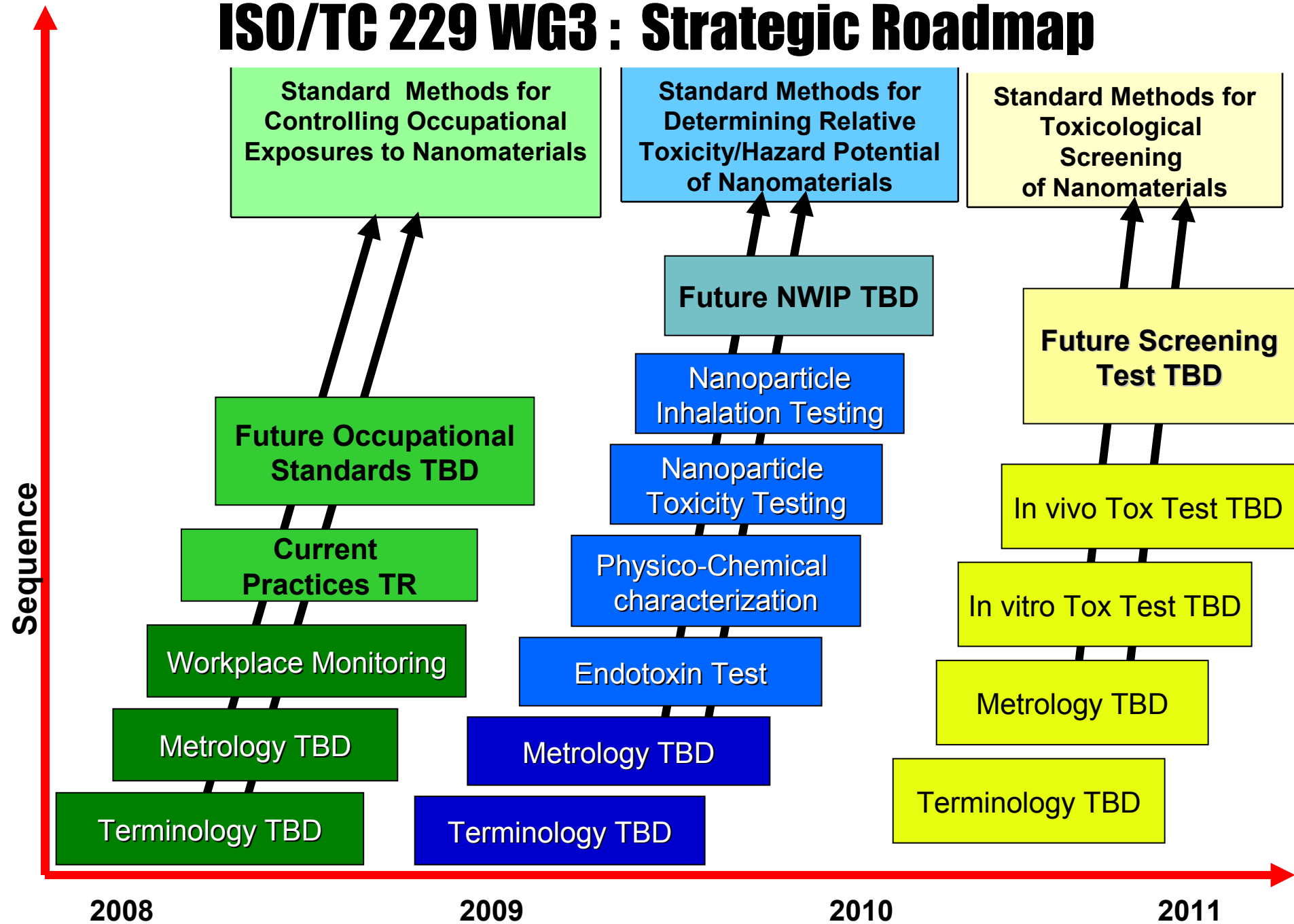
Interoperability

Support for WG3 activities

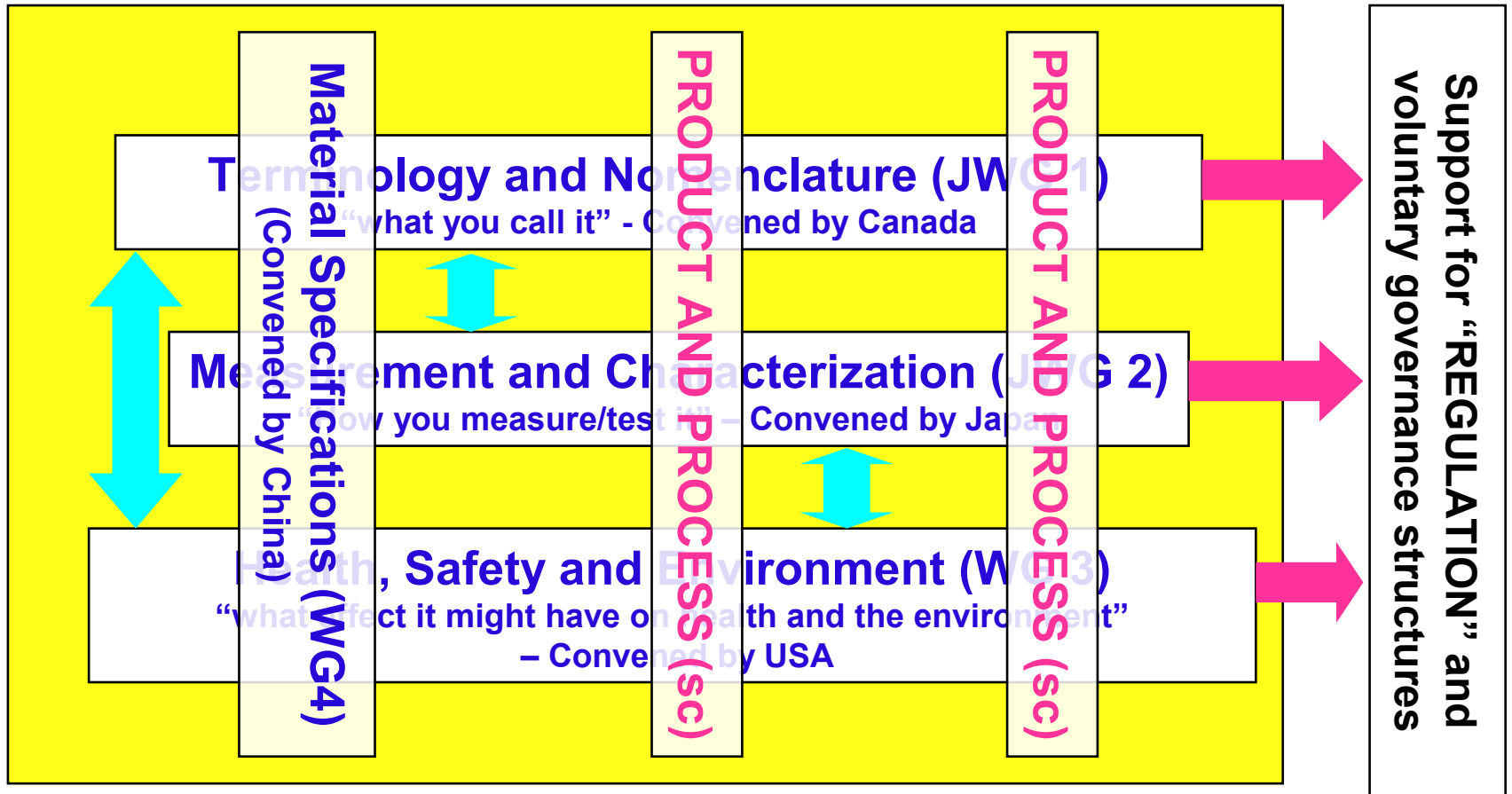
TC 229 – Horizontal activities 3



ISO/TC 229 WG3 : Strategic Roadmap



TC 229 – Structure/working areas



TC 229 Current work programme – JWG1 at 01.10.08

- *ISO/TS 27687: Terminology and definitions for nano-object – nanoparticle, nanofibre and nanoplate, published August 2008*
- *Under development:*
 - *ISO/TR: Terminology and nomenclature for nanotechnologies — Framework and core terms*
 - *ISO/TS: Terminology and definitions for carbon nanomaterials*
 - *ISO/TS: Core Terms - Terminology and Definitions*
 - *ISO/TS: Terminology and definitions for nanostructured materials*
 - *ISO/TS: Terminology for nanoscale measurement and instrumentation*
 - *ISO/TS: Terminology for the bio-nano interface*
 - *ISO/TS: Terminology for medical, health and personal care applications of nanotechnologies*
- *Committee resource document:*
 - *Outline of Nanomaterials classification ("Nano tree")*
- *New work item proposals:*
 - *ISO/TS: Terminology for nanomanufacturing*
- *TG on “Nomenclature model for nanomaterials”*

TC 229 Work programme at 01.10.08 – JWG2 (SWCNT work)

- *ISO/TS: The Use of Transmission Electron Microscopy (TEM) in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: The Use of Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Analysis (EDXA) in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: Technical Specification for the Use of UV-Vis-NIR absorption spectroscopy in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: Technical Specification for the use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the Characterization of Single-Walled Carbon Nanotubes*
- *ISO/TR: Use of Thermo Gravimetric Analysis (TGA) in the purity evaluation of Single Walled Carbon Nanotubes*
- *ISO/TR: Use of Evolved Gas Analysis-Gas Chromatograph Mass Spectrometry (EGA-GCMS) in the Characterization of Single-Walled Carbon Nanotubes*
- *ISO/TS: Use of Raman Spectroscopy in the Characterization of Single Walled Carbon Nanotubes.*

JWG2 – MWCNT and other work at 01.10.08

- *ISO/TS: Measurement Methods for the Characterization of Multi-Walled Carbon Nanotubes*
- *ISO/TS: Determination of meso-scopic shape factors of multiwalled carbon nanotubes*
- *ISO/IS: General Framework for Determining Nanoparticle Content in Nanomaterials by Generation of Aerosols*
- *Joint developments with CEN (CEN lead):*
 - *ISO/TR: Guide to nanoparticle measurement methods*
 - *ISO/TR: Guide to methods for nano-tribology measurements*

TC 229 Work programme – WG3 at 1.10.08

- ***ISO/TR 12885 - Safe Practices in Occupational Settings Relevant to Nanotechnologies - to be published early November***
- ***DIS stage***
 - ***ISO/IS: Endotoxin test on nanomaterial samples for in vitro systems***
 - ***ISO/IS: Standard for Generation of Metal Nanoparticles with the Evaporation/Condensation Method for inhalation toxicity testing***
 - ***ISO/IS: Standard for characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing***
- ***Under development:***
 - ***ISO/TR Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment.***
 - ***Guide to safe handling and disposal of manufactured nanomaterials***
- ***New proposal for a “nanomaterial risk evaluation framework” expected shortly***

TC 229 Work programme – Materials specifications (WG4)

- *ISO/TS: Materials specification for nano-titanium dioxide*
- *ISO/TS: Materials specification for nano-calcium carbonate*
- *ISO/TS: Guide to specifying manufactured nano-materials*

Other TC 229 structures

Chairman's Advisory Group

Task Groups on:

- *Planning and Coordination;*
- *Business Planning;*
- *Material Specifications;*
- *Nanotechnologies and Sustainability*

Nanotechnologies Liaison Coordination Group

JWG2 study groups on:

- *metrology*
- *strategy*

Current and potential liaisons for ISO/TC 229

229

MATERIALS

BIOMEDICAL

EXTERNAL LIAISONS

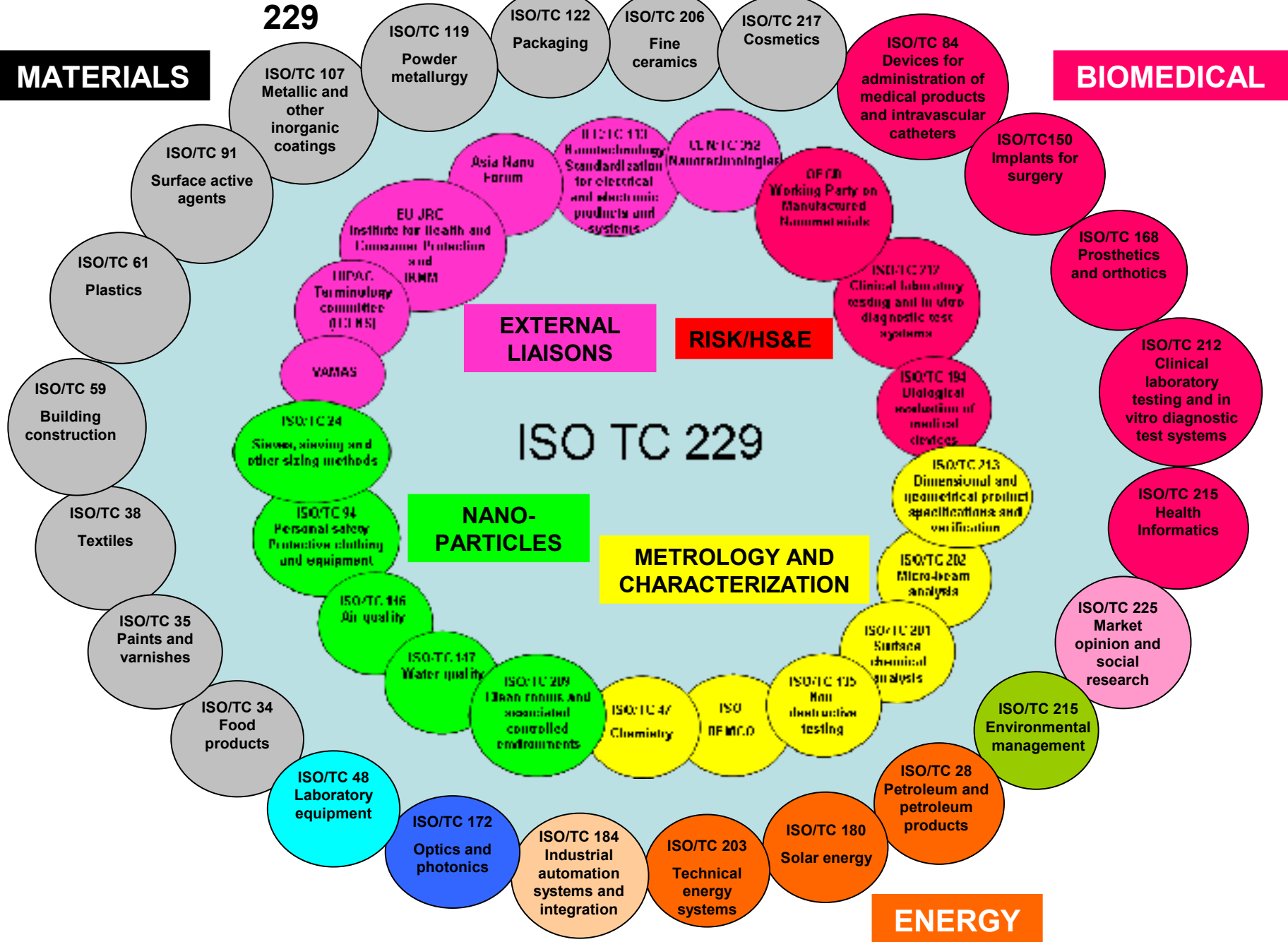
RISK/HS&E

ISO TC 229

NANO-PARTICLES

METROLOGY AND CHARACTERIZATION

ENERGY



European Committee for Standardization committee CEN/ TC 352 - Nanotechnologies

- Established November 2005
- All 30 members of CEN are notionally members – around 12 active ones
- Works closely with ISO/TC 229 using the ‘Vienna Agreement’ for cooperative working.
- Developing a work programme to include areas of specific interest to Europe and areas that will be relevant to European legislation.
- Awaiting a Commission response to M409 “elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials” submitted in May 2008.
- Currently 3 projects:
 - *Guide to nanoparticle measurement methods and their limitations (CEN/TR)*
 - *Guide to methods for nano-tribology measurements (CEN/TR)*
 - *Guide to labelling of manufactured nanoparticles and products containing manufactured nanoparticles*
- Undertaking an active review of relevant FP6 and FP7 RTD projects for possible standardization outputs:
 - *e.g. 17 potential standardization projects identified outputs of Nanosafe2*

Why standards for nanotechnologies are important

Standards will help to ensure that nanotechnology is developed and commercialised in an open, safe and responsible manner by supporting:

- *safety testing, legislation and regulation*
- *worker, public and environmental safety*
- *commercialisation and procurement*
- *patenting and IPR*
- *communication about the benefits, opportunities and potential problems associated with nanotechnologies*

This will be achieved by providing agreed ways of:

- *Naming, describing and specifying things*
- *Measuring and testing things*
- *Protocols for health and environmental safety testing, risk assessment and risk management*

Thank you!

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