

# Adding value to nanotechnology Framework Projects through standardization

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Chairman ISO TC 229, CEN TC 352 and BSI NTI/1 Nanotechnologies  
standardization committees***

***Horizontal session on standardization  
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# Overview

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- ***Standards and standardization***
  - *Role of standards*
  - *Standardization organisations*
  - *Development of formal standards*
- ***Infrastructural standards to support research and innovation***
  - *Major challenges for standardization*
  - *Current standardization committees*
  - *Existing standards, standardization projects and proposals*
- ***Adding value to RTD projects through standardization***
  - *Supporting dissemination and implementation*

# Standards

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Two types of standards:

- 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 emissions: ISO 9001 and ISO 14000*
- *Reporting things as in e.g. proposed ISO 26000 (Social Responsibility)*

To:

- *Support innovation, commercialisation, market development and established markets*
- *Provide a basis for procurement*
- *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 incorporated into a contract or regulation.

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



# Standards

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## Standards are:

- Ubiquitous – covering such things as shoe sizes, nuts and bolts, petrol grades, warning signs, pipes and fittings, fire extinguishers, gas cylinders, shipping containers, electrical sockets and plugs, steel specifications,.....
- Too successful - 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 such things as:
  - *internet protocols,*
  - *aircraft fuels*
  - *credit cards,*
  - *business continuity management*
  - *quality and environmental management,*
  - *carbon trading,*
  - *sustainable development*
  - *life cycle assessment*
  - .....
  - *“Unmanned spacecraft residual propellant mass estimation for disposal manoeuvres”, under development by ISO/TC 20/SC14*

## and standardization

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Standards can be:

- **FORMAL** – developed by independent experts working under the auspices of a National, Regional or International standards body
  - *AFNOR, BSI, DIN, JIS, SABS,..... (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.*
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# Standardization

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

## **FORMAL STANDARDS PROVIDE LEGITIMACY:**

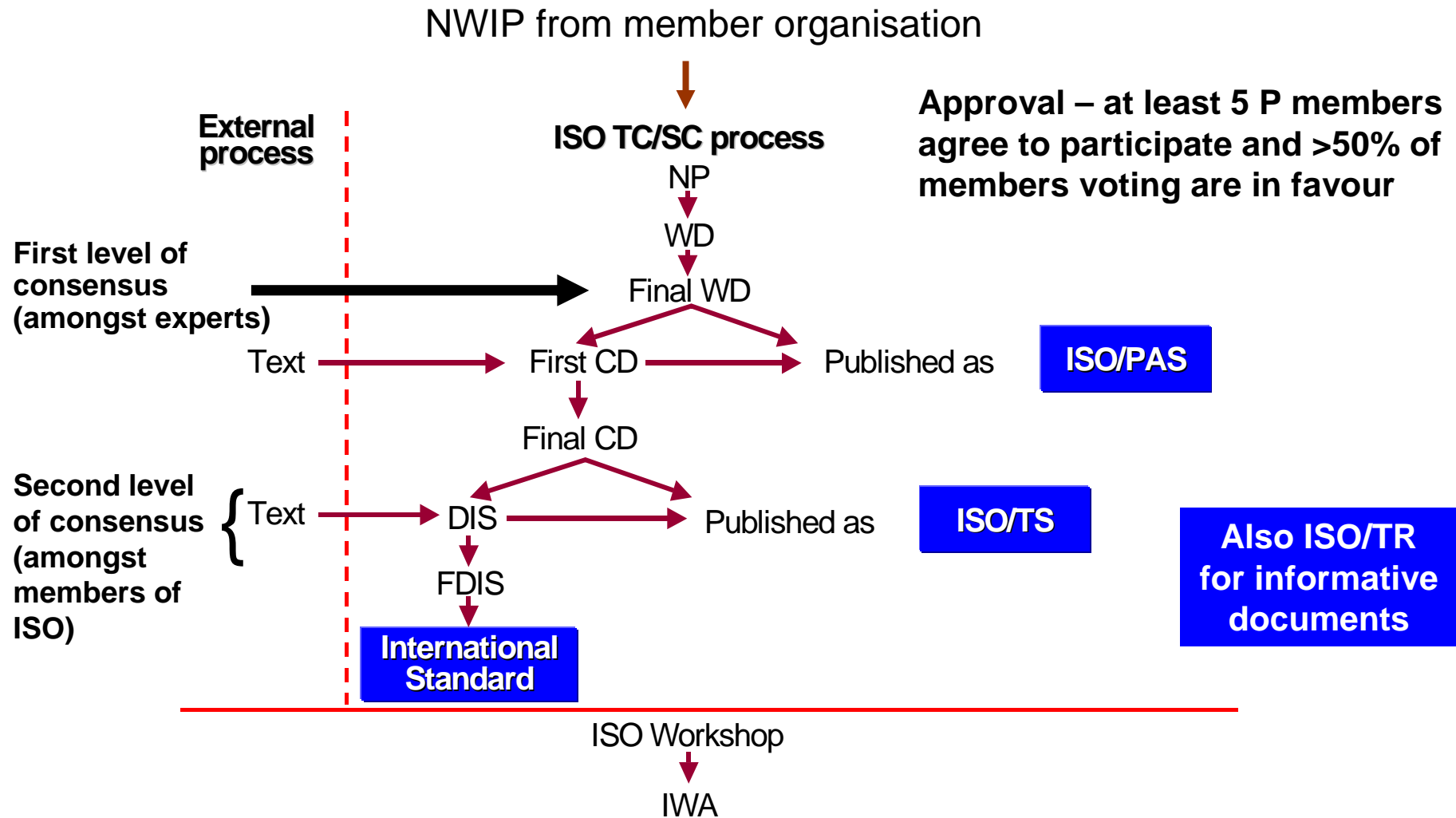
Standards are:

- *Proposed, commented on and approved by members of the international community (160 members of ISO – 1 member 1 vote)*
  - *Developed by experts nominated by members*
  - *Based on well established principle of CONSENSUS*
  - *VOLUNTARY*
  - Standards provide critical elements of “soft” governance through eg. ISO 9001, 14001 (and ISO 26,000 – expected to be published in 2010).
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# Development of International Standards

## Process accommodates special needs



## Infrastructural standards to support research and innovation - major challenges for and needs of standardization for nanotechnologies


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- **Major challenges:**
  - *Diversity of disciplines impacted by and contributing to nanotechnologies*
  - *Global impact*
  - *Rapid speed of development and apparent speed of commercialisation (over 800 consumer products on the market – see Woodrow Wilson International Center for Scholars inventory: <http://www.nanotechproject.org/inventories/consumer/> )*
- **Critical needs:**
  - *Coordination and harmonization across standards developers and stakeholders*
  - *Common language and understanding - Terminology*
  - *Validated measurement and characterization techniques and protocols*
  - *Robust protocols to ensure health and environmental safety*
  - *Agreed and achievable specifications for nanomaterials.*

# International Organisation for Standardization

## ISO/TC 229 - Nanotechnologies

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- *Established in June 2005*
  - *40 members – 32 “P” and 8 “O” (see [http://www.iso.org/iso/standards\\_development/technical\\_committees/list\\_of\\_iso\\_technical\\_committees/iso\\_technical\\_committee.htm?commid=381983](http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983) )*
  - *Liaisons with 25 other ISO/IEC/CEN TCs and SCs and 5 external bodies – Asia Nano Forum, BIPM, EC JRC, OECD and VAMAS*
  - *Exploring additional external liaisons with other groups, e.g. International Alliance for NanoEHS Harmonization, NanoAf-Net, and with emerging economies*
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# International Electrotechnical Commission

## IEC/TC 113 – “Nanotechnology standardization for electrical and electronic products and systems”

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- *Established June 2006 with US Chair and German secretariat*
- [http://www.iec.ch/cgi-bin/procgi.pl/www/iecwww.p?wwwlang=e&wwwprog=dirdet.p&progdb=db1&css\\_color=purple&committee=TC&number=113](http://www.iec.ch/cgi-bin/procgi.pl/www/iecwww.p?wwwlang=e&wwwprog=dirdet.p&progdb=db1&css_color=purple&committee=TC&number=113)
- *29 members - 15 “P” and 14 “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*

# European Committee for Standardization CEN/TC 352 - Nanotechnologies

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- *Established November 2005 following a recommendation from CEN/BTWG 166*
- *UK chair and secretariat*
- *All 30 members of CEN are notionally members – around 14 active*
- *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.*
- *Two working groups established in September 2008:*
  - ***WG 1 'Measurement, characterization and performance evaluation'***
  - ***WG 2 'Commercial and other stakeholder aspects'***

## UK Publications to date:

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### ***Publicly Available Specifications (PAS):***

- PAS 71 Vocabulary – Nanoparticles
- PAS 130 Guidance on the labelling of manufactured nanoparticles and products containing manufactured nanoparticles
- PAS 131 Terminology for medical, health and personal care applications of nanotechnologies
- PAS 132 Terminology for the bio-nano interface
- PAS 133 Terminology for nanoscale measurement and instrumentation
- PAS 134 Terminology for carbon nanostructures
- PAS 135 Terminology for nanofabrication
- PAS 136 Terminology for nanostructured materials

### ***Published Documents (PD)***

- PD 6699-1 Guide to specifying nanomaterials
- PD 6699-2 Guide to safe handling and disposal of manufactured nanomaterials

All of these are available for free download at [www.bsigroup.com/nano](http://www.bsigroup.com/nano)

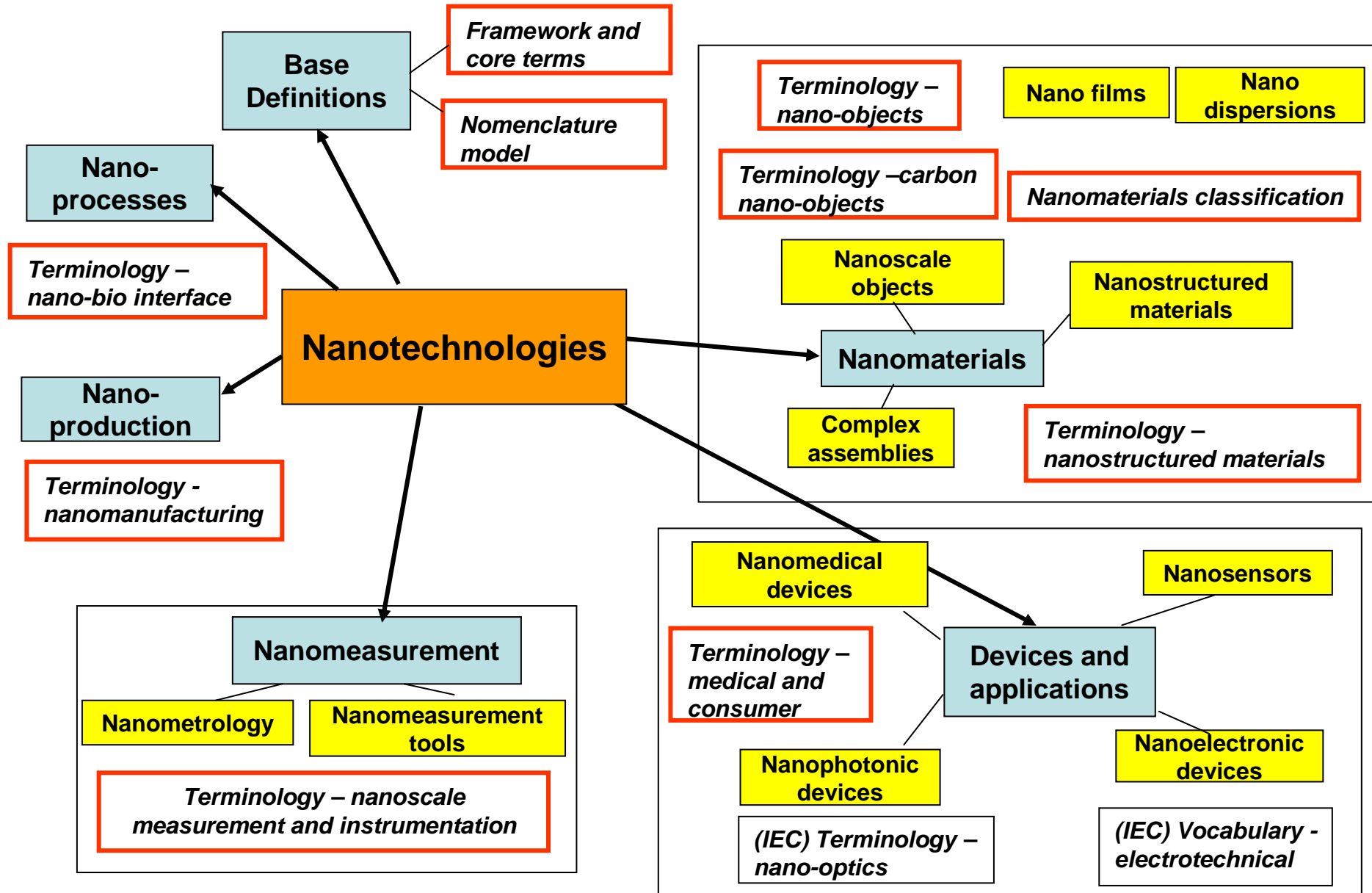
# TC 229 – Horizontal activities 1

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## Terminology and Nomenclature (JWG 1)

“what you call it” - Convened by Canada

# ISO/TC 229 JWG1: Strategic Roadmap

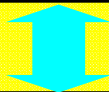


# TC 229 – Horizontal activities 2

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**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

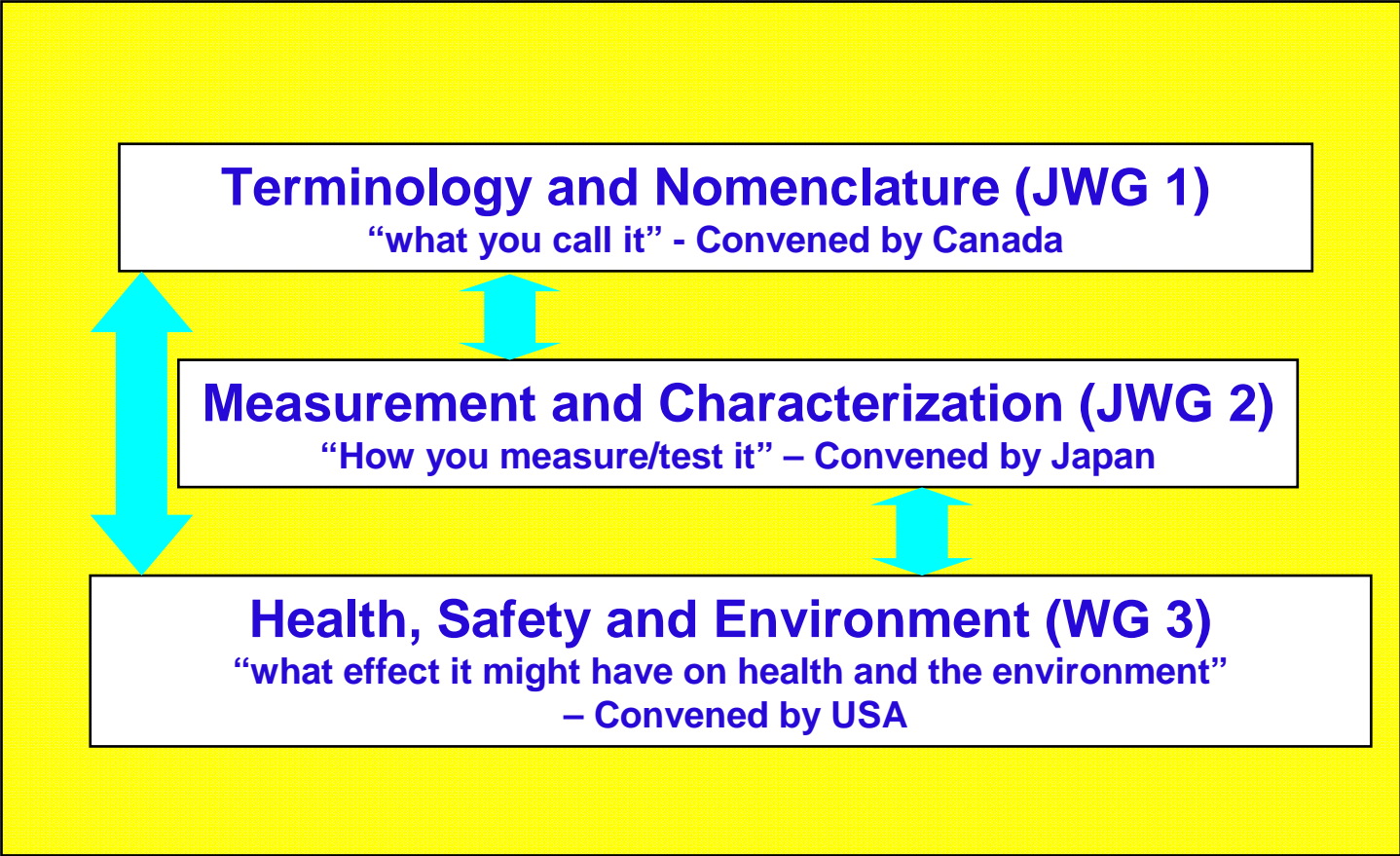
Length, Depth, Force, Traceability, Definition of Measurand, Uncertainty

Interoperability

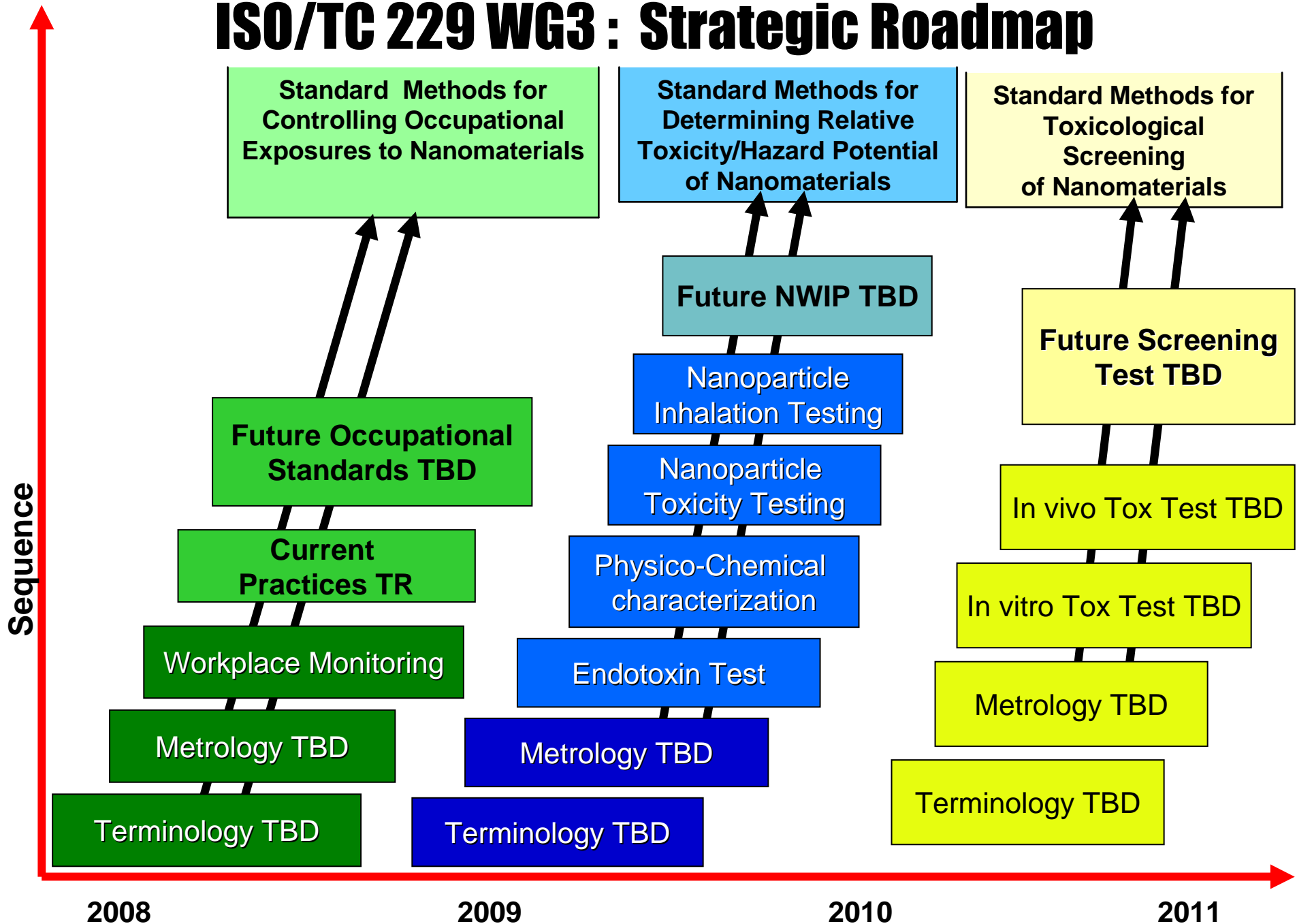
Support for WG3 activities

# TC 229 – Horizontal activities 3

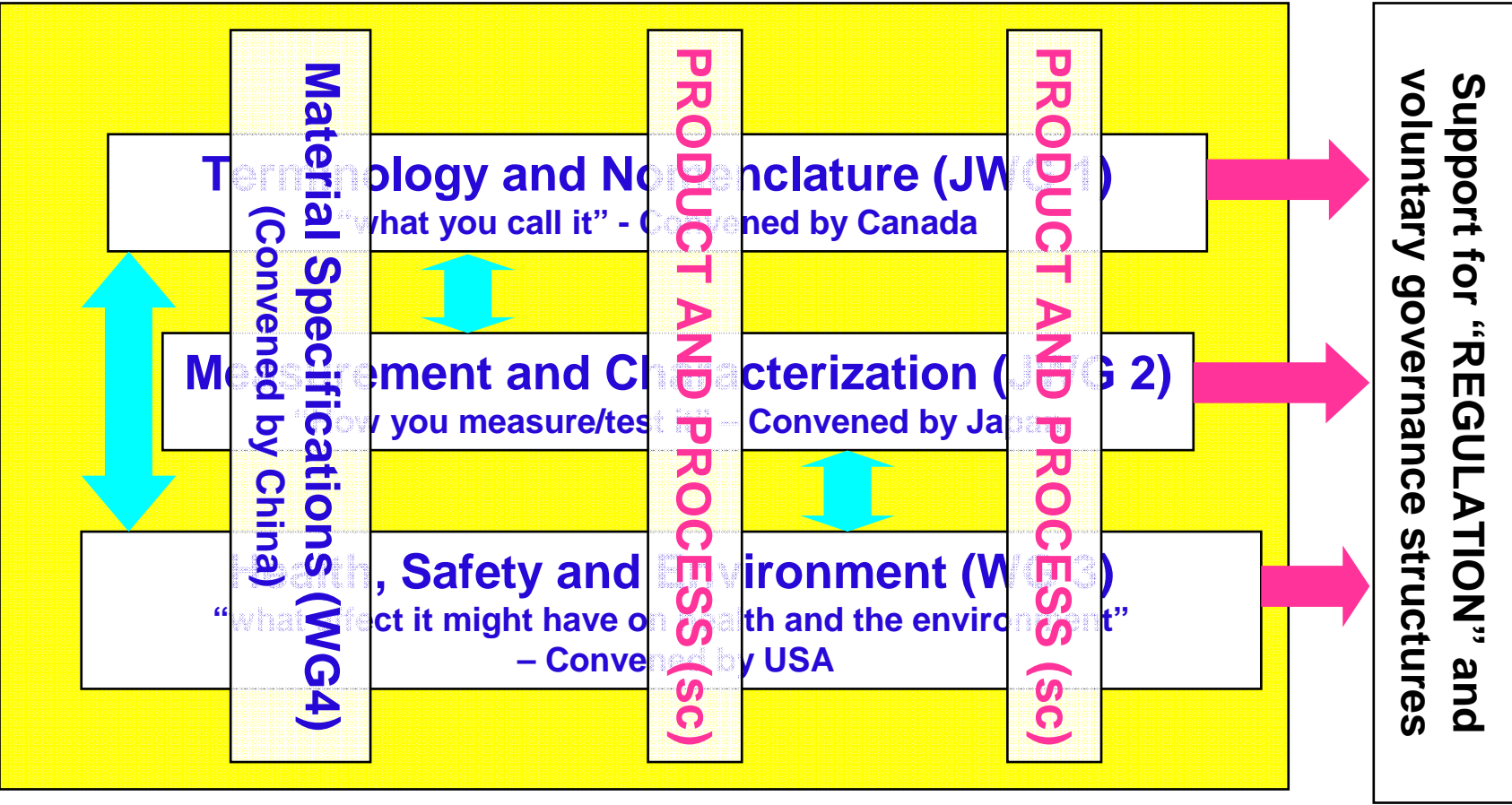
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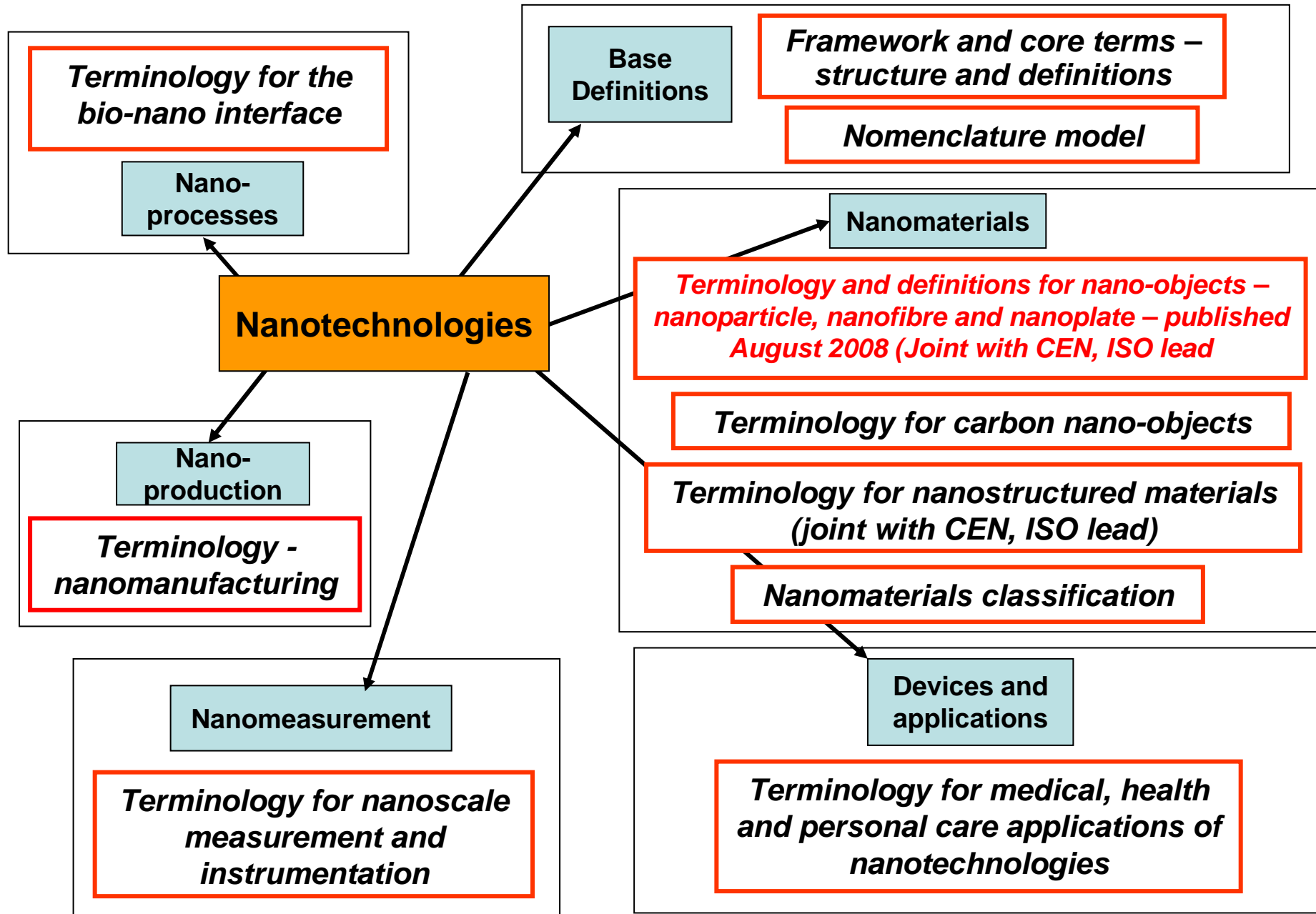
# ISO/TC 229 WG3 : Strategic Roadmap



# TC 229 – Structure/working areas

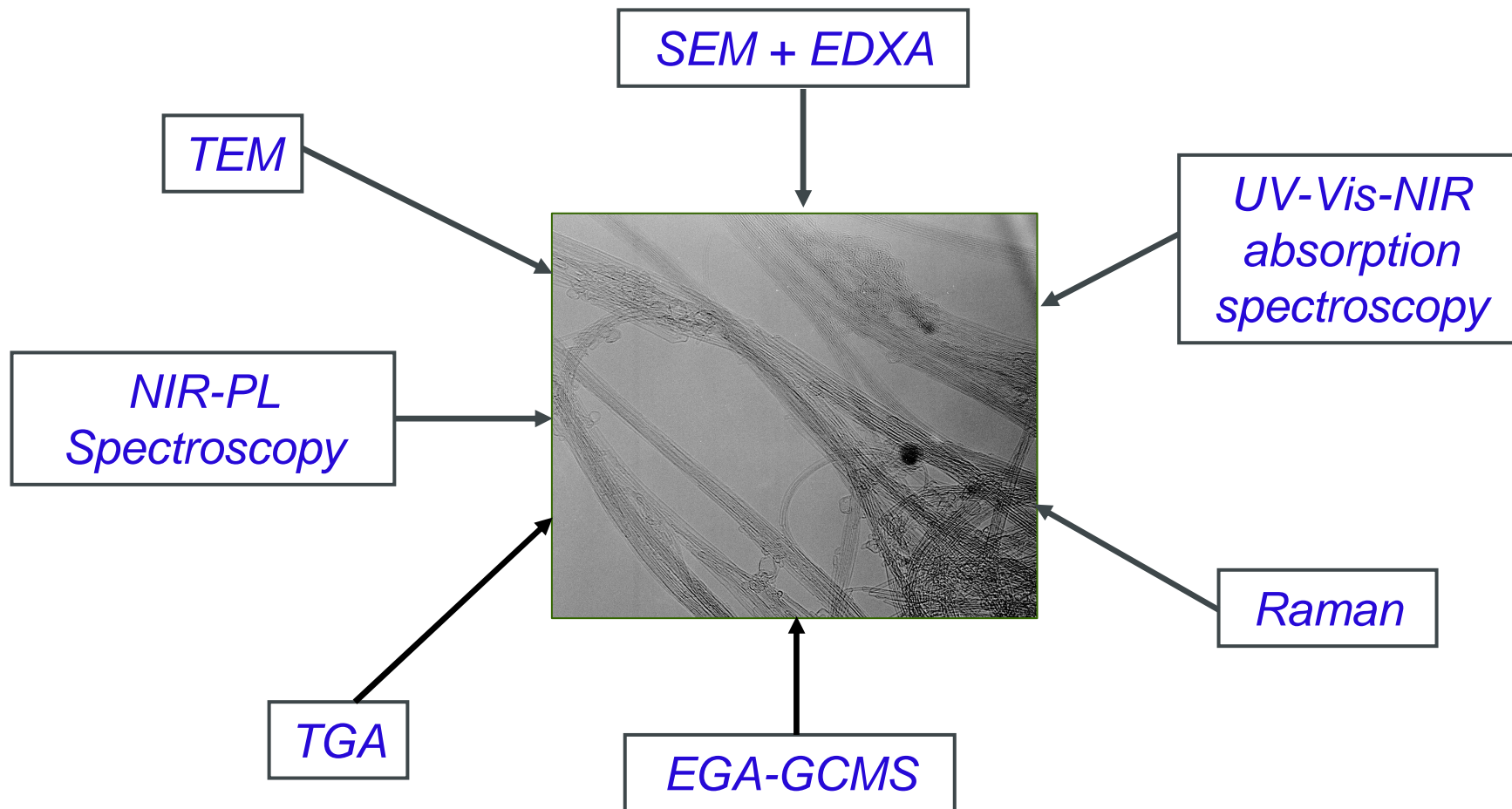


# ISO/TC 229 JWG1: Current Work Programme

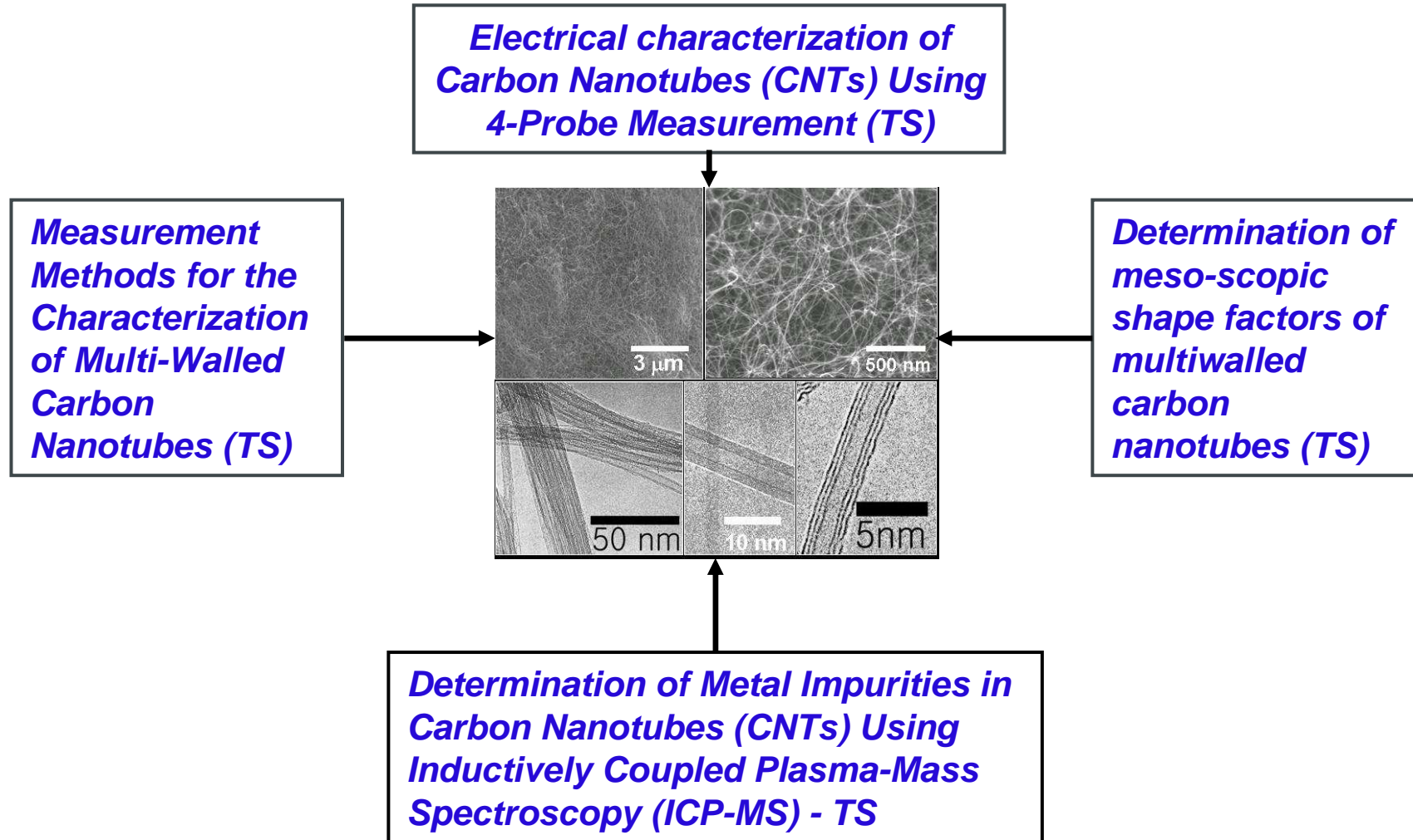


# TC 229 Work programme JWG2 (SWCNT work)

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# JWG2 – MWCNT and other work



## **JWG2 other projects under development**

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- *ISO/IS: General Framework for Determining Nanoparticle Content in Nanomaterials by Generation of Aerosol*
- *ISO/TS Artificial gratings used in nanotechnology: description and measurement of dimensional quality parameters*

### ***Joint developments with CEN (CEN lead):***

- *ISO/TR: Guide to nanoparticle measurement methods*
  - *ISO/TR: Guide to methods for nano-tribology measurements*
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## TC 229 Work programme – WG3

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- **ISO/TR 12885 - Safe Practices in Occupational Settings Relevant to Nanotechnologies - now published**
- **DIS stage**
  - **ISO/IS: Endotoxin test on nanomaterial samples for in vitro systems (joint with CEN, ISO lead)**
  - **ISO/IS: Generation of Metal Nanoparticles with the Evaporation/Condensation Method for inhalation toxicity testing (joint with CEN, ISO lead)**
  - **ISO/IS: Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing (joint with CEN, ISO lead)**
- **Under development:**
  - **ISO/TR Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment.**
  - **ISO/TS Guidance on safe handling and disposal of manufactured nanomaterials**
  - **ISO/TR Nanomaterial risk evaluation framework (based on ED-DuPont Nano Risk Framework)**
  - **TS Guidelines for occupational risk management applied to engineered nanomaterials based on a "control banding approach"**
  - **TR Preparation of Material Safety Data Sheet (MSDS) for nanomaterials**

## TC 229 Work programme – Materials specifications (WG4)

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- *ISO/TS: Materials specification for nano-titanium dioxide – Part 1 General requirements*
  - *ISO/TS: Materials specification for nano-titanium dioxide – Part 2 Requirements for specific applications*
  - *ISO/TS: Materials specification for nano-calcium carbonate – Part 1 General requirements*
  - *ISO/TS: Materials specification for nano-calcium carbonate – Part 2 Requirements for specific applications*
  - *ISO/TS: Guidance on specifying manufactured nano-materials*
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## Other projects under development

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### *Joint developments with CEN (CEN lead):*

- *Guidance on labelling of manufactured nanoparticles and products containing manufactured nanoparticles*

## Other TC 229 structures

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*Task Groups on:*

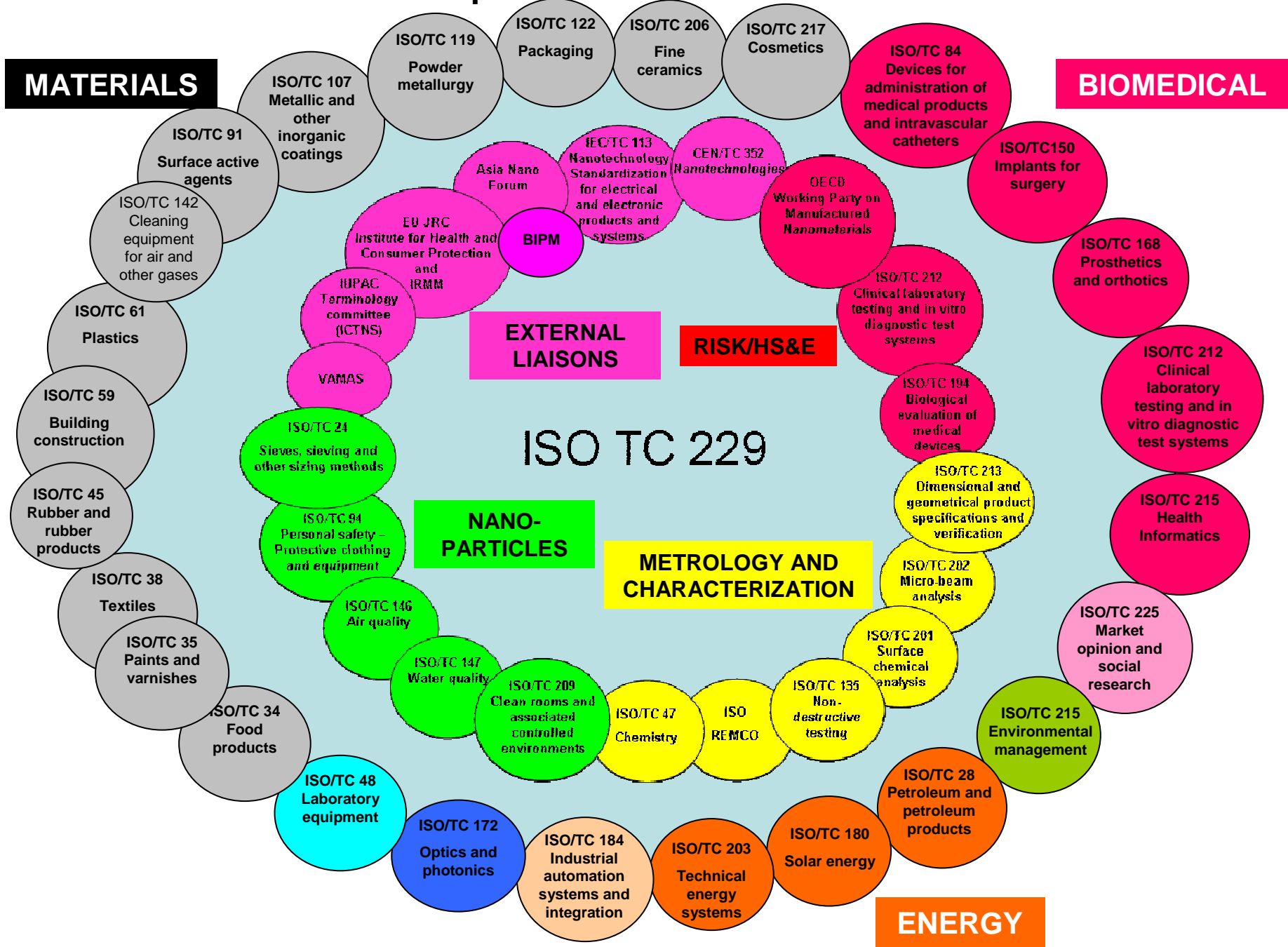
- ***Planning and Coordination;***
- ***Business Planning;***
- ***Nanotechnologies and Sustainability;***
- ***Societal and Consumer Dimensions of Nanotechnologies.***

*JWG2/WG3 Task Group on measurement and characterization for EHS issues relevant to nanomaterials*

*Nanotechnologies Liaison Coordination Group (NLCG)*



# Current and potential liaisons for ISO/TC 229



# Adding value to RTD projects through standardization


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Standardization can add value to projects by:

- *Provision of good practice guides or validated protocols for measurement and characterization (including instrument calibration), EHS practices, sample preparation or manipulation, etc - allows researchers to focus on unique aspects of project;*
- *Validation of project developments in measurement and characterization methods, EHS protocols, etc;*
- *Dissemination of project outputs – published standards make information accessible to industry and other stakeholders;*
- *Implementation of project outputs – the availability of a standard developed from project outputs ensures those outputs can be applied by industry and other stakeholders.*

## Examples of possible standards from NanoSafe2

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- *Labelling of CNTs and other nanoparticles for subsequent source identification*
  - *Guidance on measurement of CNTs by particle counters*
  - *Standard method for generation of a nanoparticle flux for the calibration of particle counters*
  - *Risk analysis methodology for explosion potential of nanomaterials*
  - *Qualification of filters and Personal Protective Equipment relevant to nanoparticle manufacture and handling*
  - *Nanoparticle penetration of biological membranes – method and equipment*
  - *In silico models of site specific toxicity of nanomaterials and algorithms to predict body distribution*
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*Thank you for your attention!*

