Nanotechnologies - supporting industrial and societal needs through international standardization

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Outline

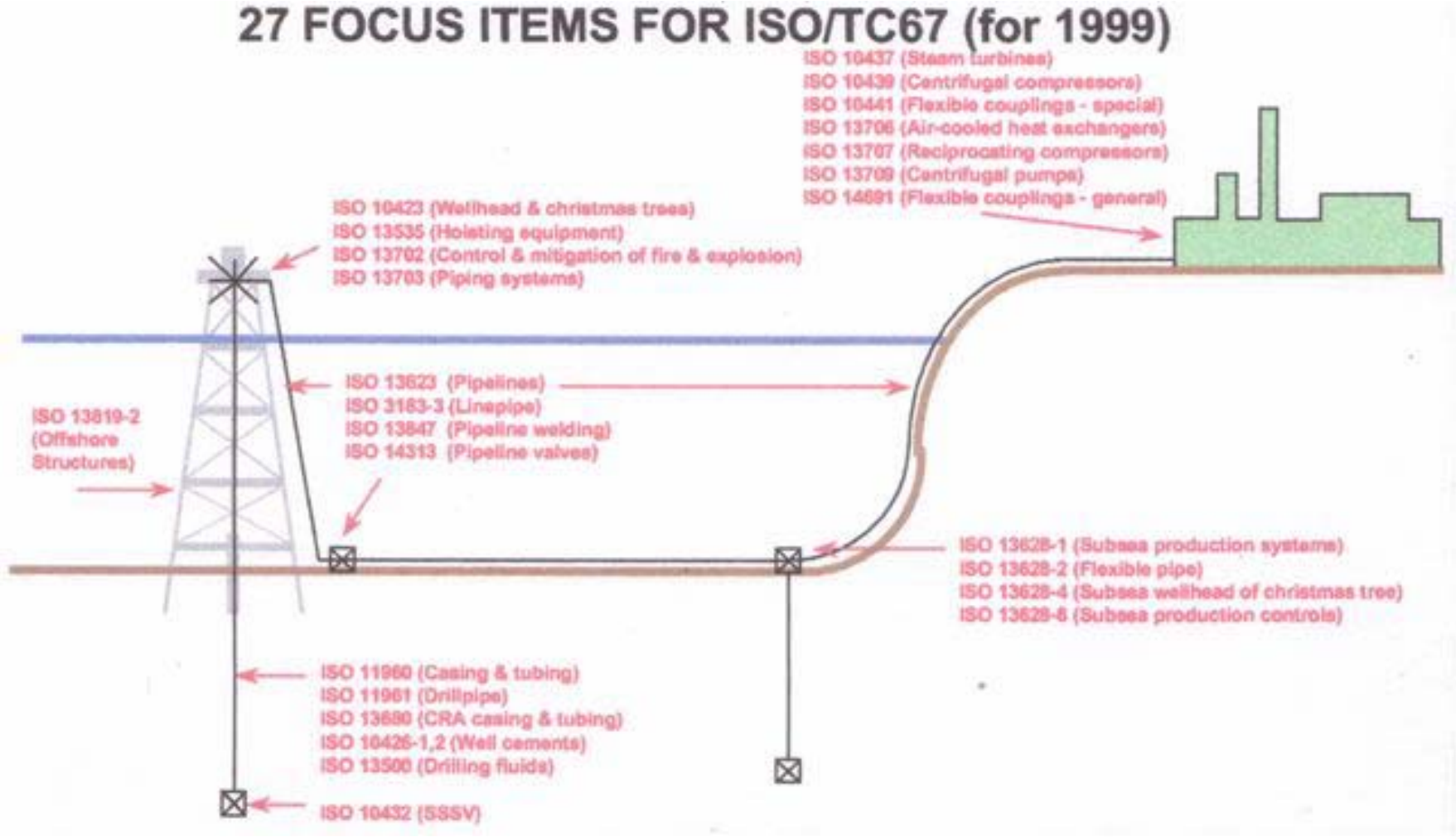
- Introduction to standardization
- Overview of ISO structure and activities
- Introduction to ISO TC 229 and its interaction with other TCs
- Nanoparticles
  - Terminology/definitions/nomenclature
  - Test methods
  - Health safety and environment
- Closing remarks on coordination and cooperation

STANDARDS ARE UBIQUITOUS!

almost as ubiquitous as nanoparticles!!

There are 567 ISO standards and other documents applying to road vehicles plus ISO 3779 covering the vehicle identification number (VIN)

ISO/TC 67: Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries

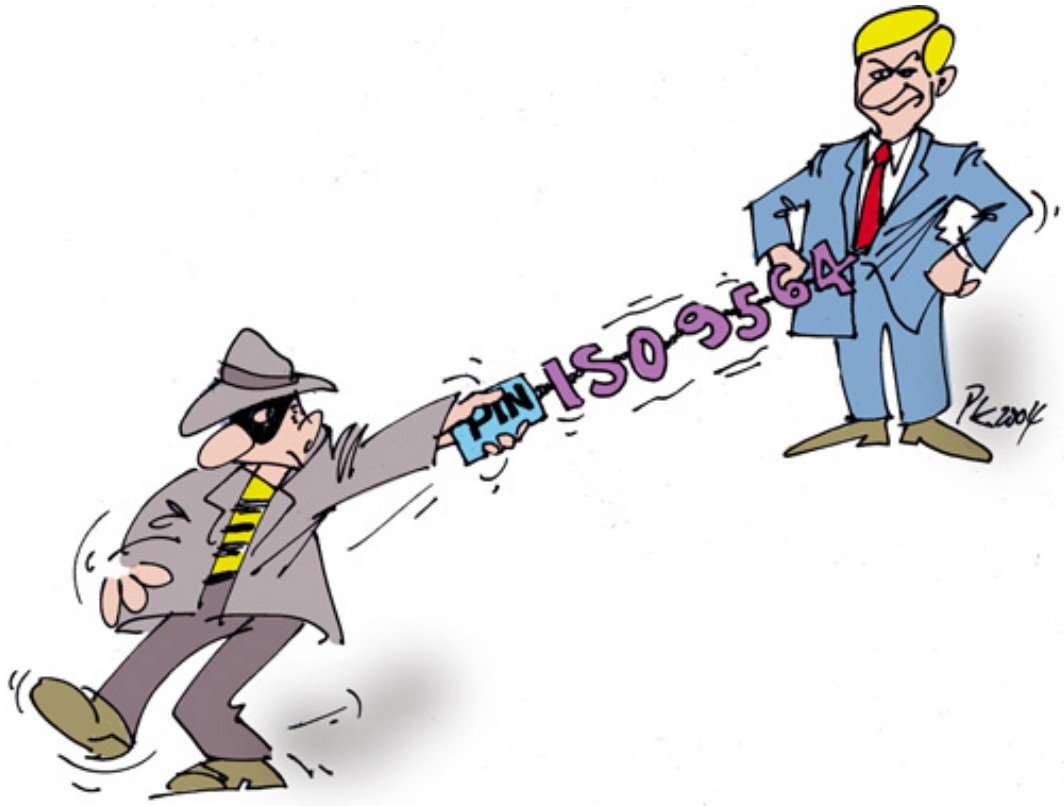


There are 193 ISO standards and other documents applying to fasteners

Even wine tasting glasses have a standard – ISO 3591, Sensory analysis – Wine tasting glass

ISO TC/145 has developed ISO 9186, Graphical symbols – Test methods for comprehensibility and for comprehension, and ISO, 7010:2003, Graphical symbols – safety colours and safety signs – Safety signs used in workplaces and public areas

ISO 9654-1, Banking – “Personal Identification Number management and security” provides instructions to financial institutions in the development, implementation and/or the operation of systems and procedures for the protection of PIN throughout their lifecycle.



ISO 10002:2004, Quality management -- Customer satisfaction -- Guidelines for complaints handling in organizations

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ISO/TC 222 – “Personal financial planning” is developing the first round of standards in this area

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ISO/IEC Guide 71:2001, Guidelines for standards developers to address the needs of older persons and persons with disabilities

Quality management

- 15 quality management standards (ISO 9000 and others) including sector specific standards, e.g.
  - ISO 13485:2003: Medical devices -- Quality management systems -- Requirements for regulatory purposes
  - ISO 16038:2005: Rubber condoms -- Guidance on the use of ISO 4074 in the quality management of natural rubber latex condoms
  - ISO/IEC 19796-1:2005: Information technology -- Learning, education and training -- Quality management, assurance and metrics -- Part 1: General approach (available in English only)
  - ISO/TS 29001:2003: Petroleum, petrochemical and natural gas industries -- Sector-specific quality management systems -- Requirements for product and service supply organizations

Environmental management

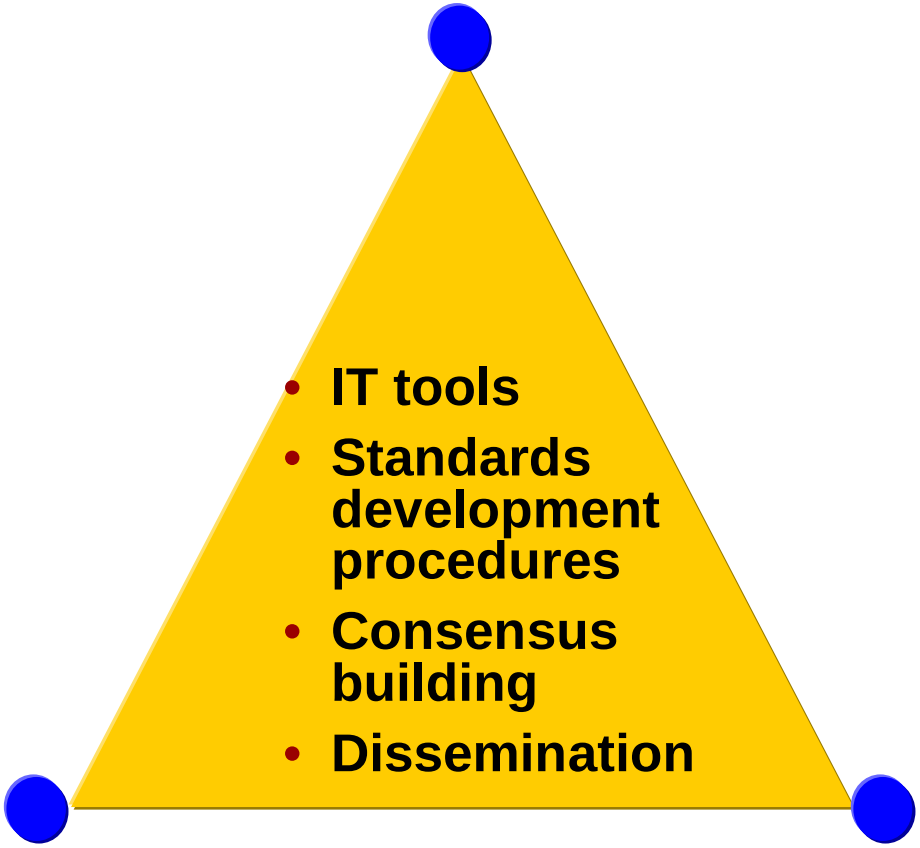
- 9 environmental management standards (ISO 14000 series), e.g.
  - ISO 14004:2004: Environmental management systems -- General guidelines on principles, systems and support techniques
  - ISO 14015:2001: Environmental management -- Environmental assessment of sites and organizations (EASO)
  - ISO 14042:2000: Environmental management -- Life cycle assessment -- Life cycle impact assessment
- and various Technical Reports (TR) – informative documents - including:
  - ISO/TR 14062:2002: Environmental management -- Integrating environmental aspects into product design and development

International Organization for Standardization

www.iso.org

The 3 pillars of the ISO system

156 national members



190 TCs

3 000 technical bodies

50 000 experts

Central Secretariat in Geneva

150 staff

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Members - general

ISO is made up of its 156 members

- **one member per country**
- **ISO member = ISO entrance door in the country**
- **three categories of members**
  - **member body (full member) (101)**
  - **correspondent member (45)**
  - **subscriber member (10)**

ISO and the international scene

WTO: observer status and collaboration

UN and UN agencies: CODEX, ILO, IMO, ITC, UN/ECE, UNIDO, WHO, WTO-T …

578 liaisons with international organizations in technical work

Links with 6 regional bodies (ACCSQ, AIDMO, ARSO, CEN, COPANT, EASC) and PASC

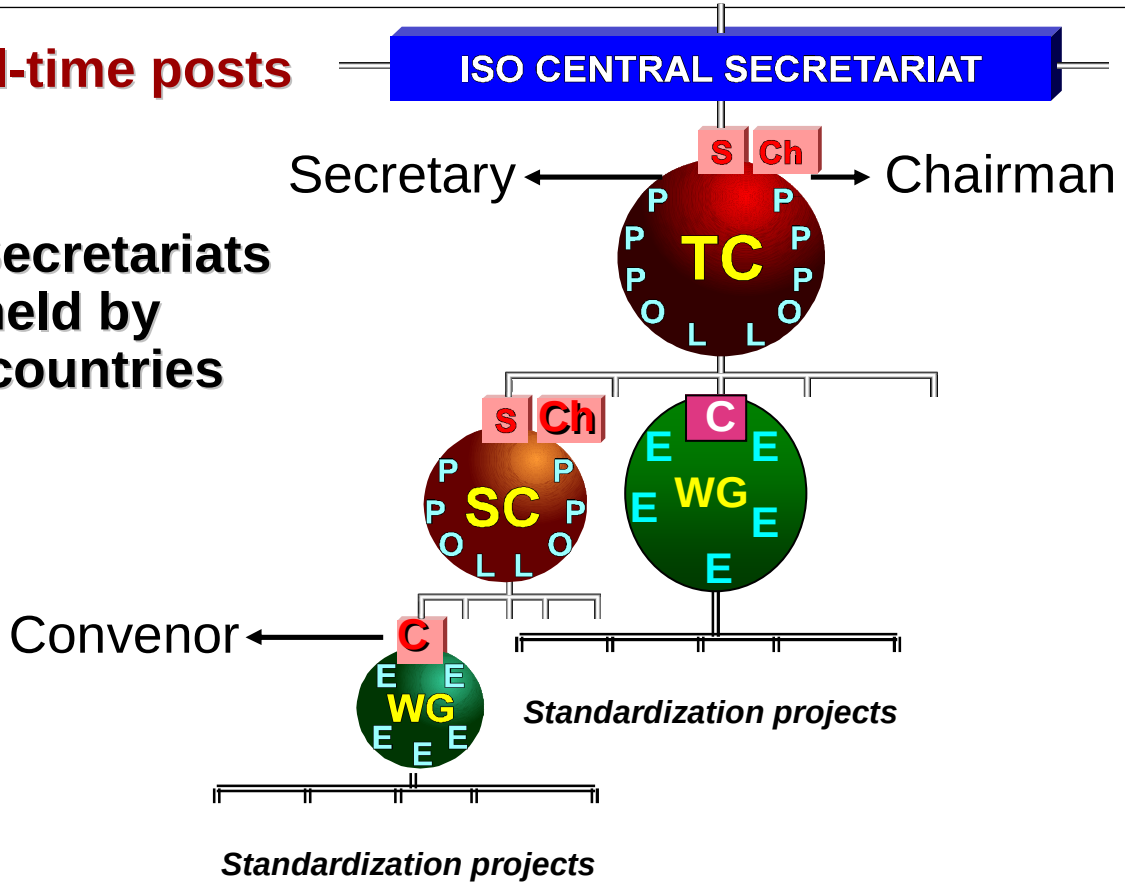
Economic actors: WEF, ICC, IFAN, Companies, Consumers International, IAF, ILAC

Extent of ISO System

Last update : 2004-01

151 full-time posts

734 Secretariats held by 37 countries



More than 14 941 ISO Standards

About 190 TCs

544 SCs

2 188 WGs

4 176 active projects (30 June 2005)

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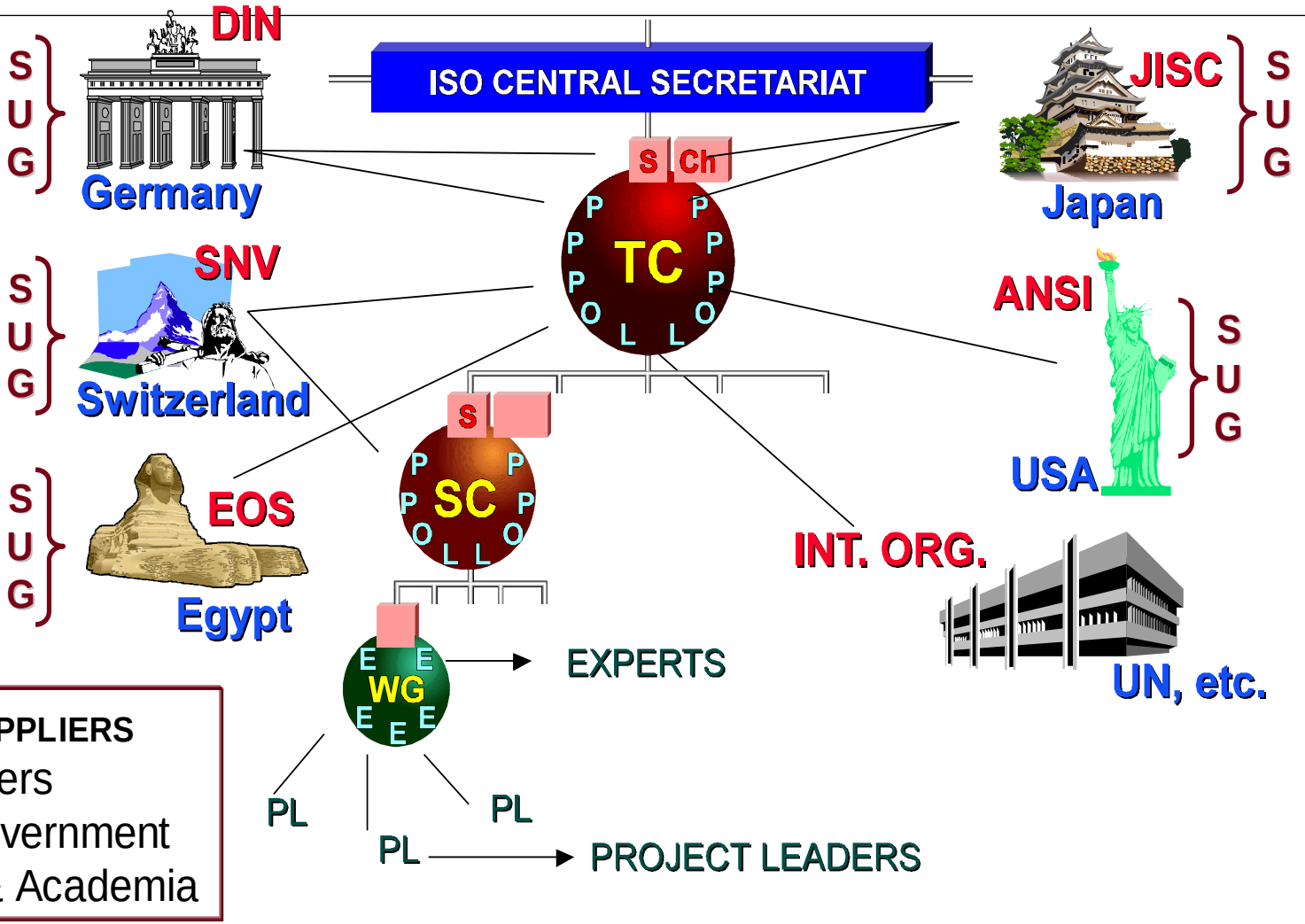
Extent of ISO System (cont.)



One Country: One Vote

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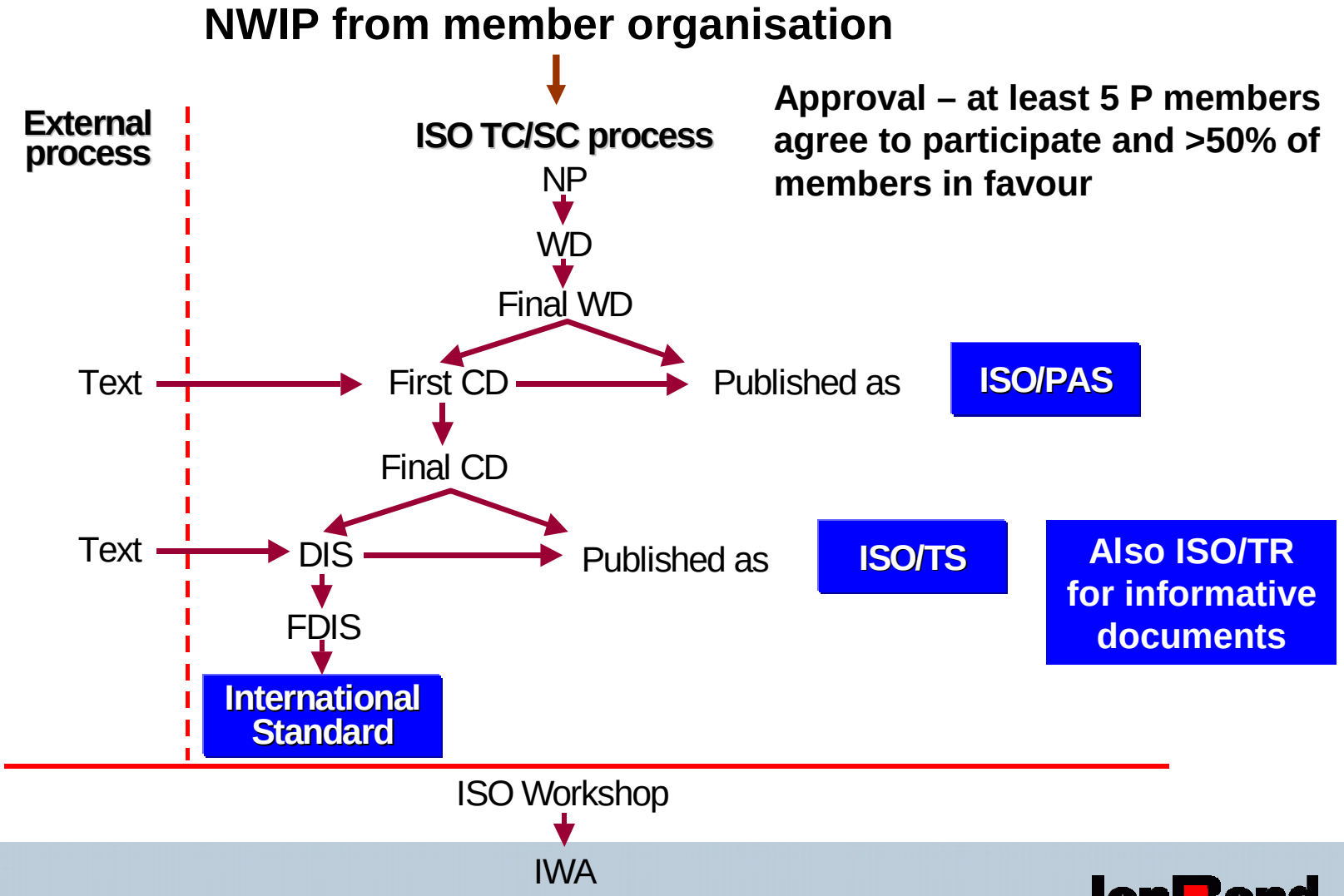
Development of International Standards
Process accommodates special needs



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Standards for safety and security

- Current ISO, IEC and ITU safety and security standards relate to:
  - Products, systems and the global supply chain;
  - Medical technologies and telemedicine;
  - Measurement of the effects of nuclear or electromagnetic emissions on the human body;
  - Means to monitor illicit trafficking of radioactive material;
  - Biometric technology for identifying people and protecting access to sensitive areas;
  - Effective communications following a natural disaster or during an emergency;
  - Cybersecurity and protection of the integrity of fixed and mobile communications networks

- “they assist in disseminating best practices and new technologies, while avoiding new barriers to trade that national security and safety regulations may create”

ISO TC 229 - nanotechnologies

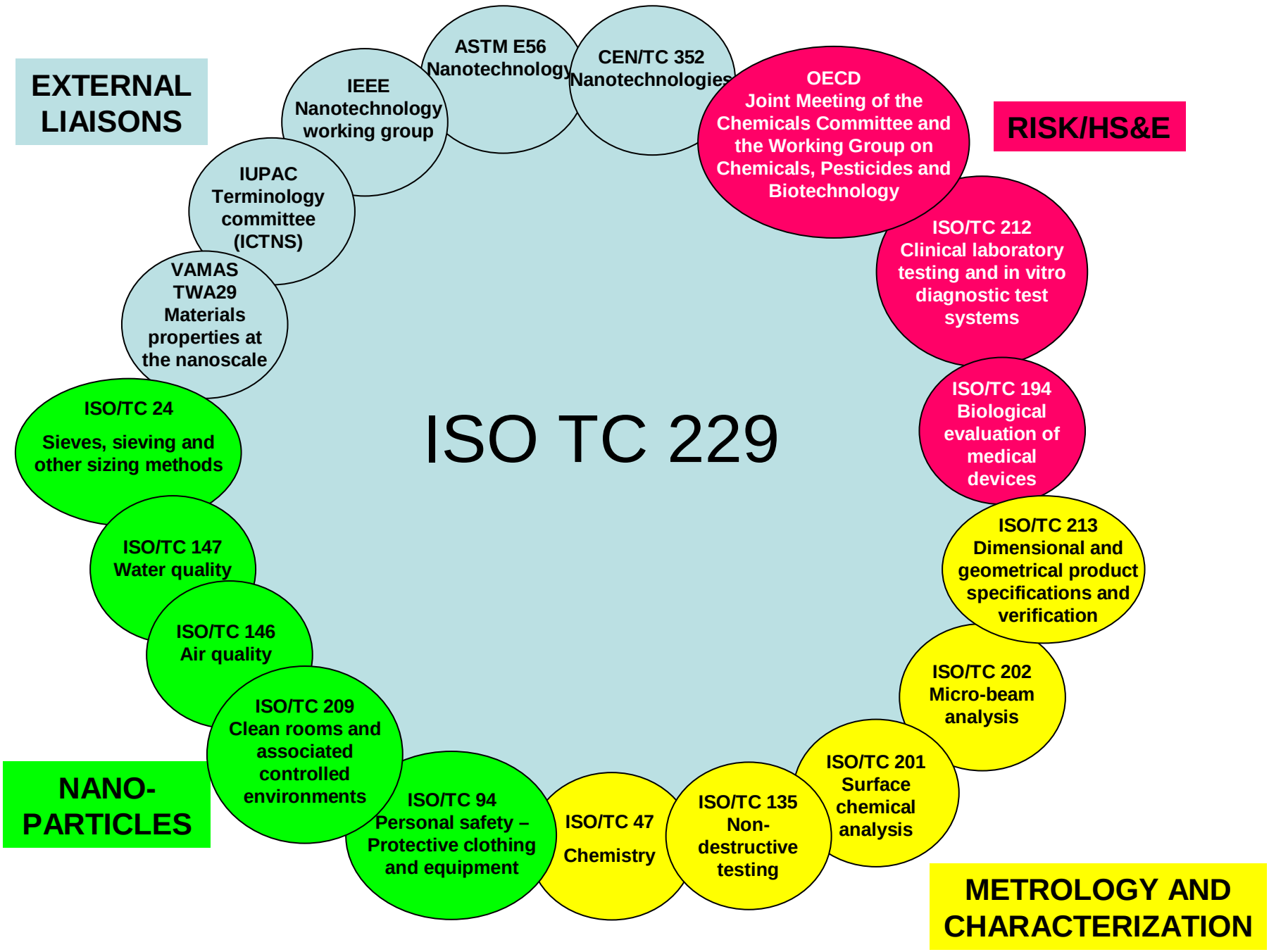
- Established June 2005 – UK Secretariat and Chair
- Currently 24 “P” members and 8 “O” members
- First plenary 9 – 11 November 2005 in London
- SCOPE:
  - “Standardization in the field of nanotechnologies that includes either or both of the following:
    - Understanding and control of matter and processes 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,
    - 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; modelling and simulation; and science-based health, safety, and environmental practices.

TC 229 Structure

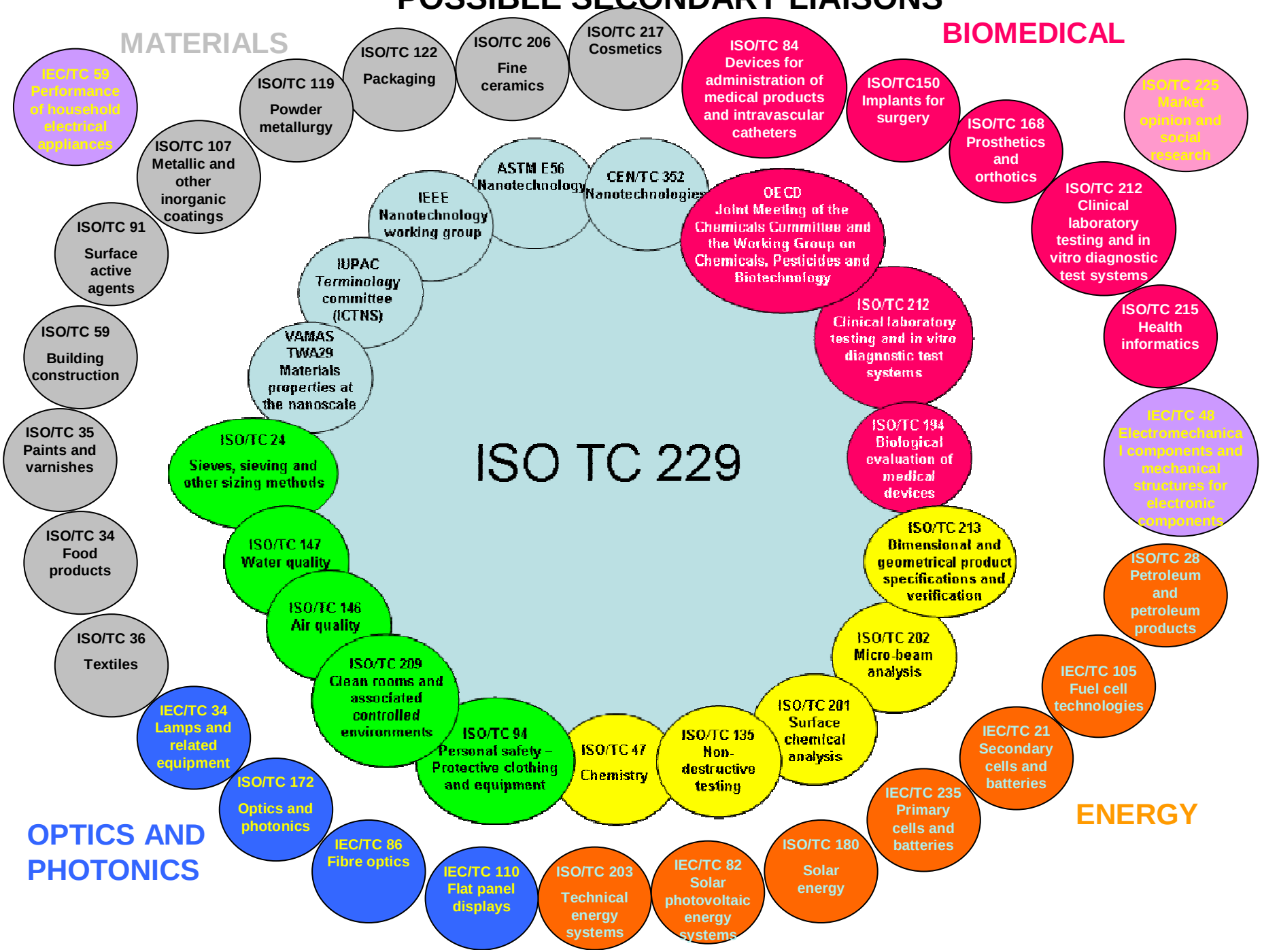
- Initial structure:
  - WG 1 Terminology and nomenclature
    - Led by Canada
  - WG 2 Measurement and characterization
    - Led by Japan
  - WG 3 Health, safety and environment
    - Led by USA

- Not the only committee with an interest in nanotechnologies!

POSSIBLE PRIMARY LIAISONS



POSSIBLE SECONDARY LIAISONS



Current nanotechnology standards

- Only National standards to date:
  - China – National standards published Dec 2004, implemented Apr 2005:
    - GB/T19619-2004 Terminology for nanomaterials
    - GB/T13221-2004 Nanometer powder - Determination of particle size distribution - Small angle X-ray scattering method (ISO/TS13762, Particle size analysis - Small angle x-ray scattering method, MOD)
    - GB/T19587-2004 Determination of the specific surface area of solids by gas absorption using the BET method (ISO 9277:1999, NEQ)
    - GB/T19588-2004 Nano-nickel power
    - GB/T19589-2004 Nano-zinc oxide
    - GB/T19590-2004 Nano-calcium carbonate
    - GB/T19591-2004 Nano-titanium dioxide
    - GB/T19627-2005 Particle size analysis - Photon correlation spectroscopy (ISO 13321:1996,IDT)
  - UK – PAS 71: 2005 – Vocabulary – Nanoparticles
- Several standards (International, regional and national) that also apply to the nanoscale

How standardization can help address the issue of risk in nanotechnologies

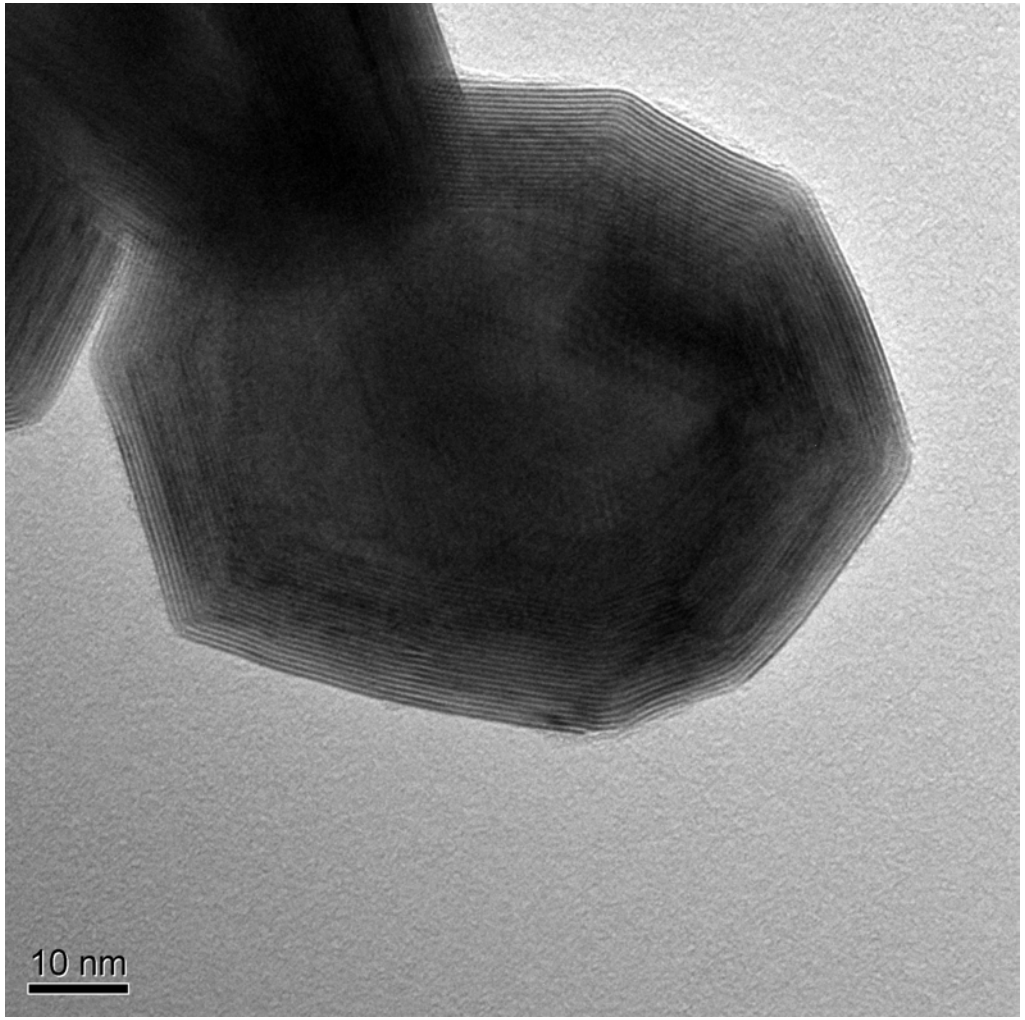
- Identifying gaps in knowledge.
- Identifying needs for, and encouraging the development of instruments and test methods for use at the nanoscale.
- Development and delivery of test methods to detect and identify nanoparticles, and to characterize nanoscale materials and devices.
- Development and delivery of protocols for bio- and eco-toxicity testing, including protocols to evaluate effects of short term and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanoparticles and nanoscale devices.
- Development and delivery of protocols for whole life cycle assessment of nanoscale materials, devices and products.
- Development and delivery of risk assessment tools relevant to the field of nanotechnologies.
- Development and delivery of protocols for containment, trapping and destruction of nanoparticles and nanoscale entities.
- Development and delivery of occupational health protocols relevant to nanotechnologies, in particular for industries dealing with nanoparticles and nanoscale devices.
- Support regulation in the area nanotechnologies.
- Support communication of accurate and quantifiable information on nanotechnologies.

“Manufactured” nanomaterials – also applies to waste steam nanomaterials!

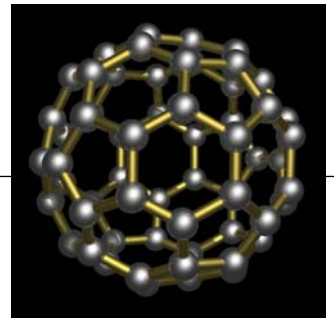
- Characterized by a wide range of materials, surface chemistries, geometries, size distributions, and specific surface areas:
- Examples include:
  - Quantum dots
  - Nanoshells
  - Metallic and ceramic powders
  - Inorganic fullerene-like/nanotube materials
  - Carbon nanotubes and nanofibres
  - Ceramic and organic fibres
  - Dendrimers
  - ……

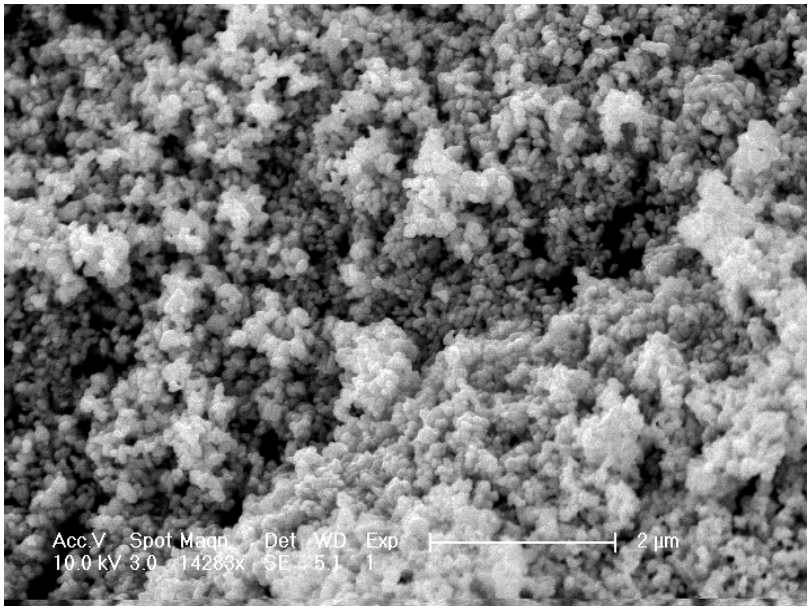
- For 10 nm diameter Al_2O_3 nanoparticles, each gram contains about 5x10^17 particles with a surface area (specific surface area) of about 150 square m/g (cf suggested threshold for pulmonary inflammation of 200 – 300 square cm – for rat – i.e. 0.1 to 0.2 mg).

IFLM WS_2 nanoparticles - nanostructure

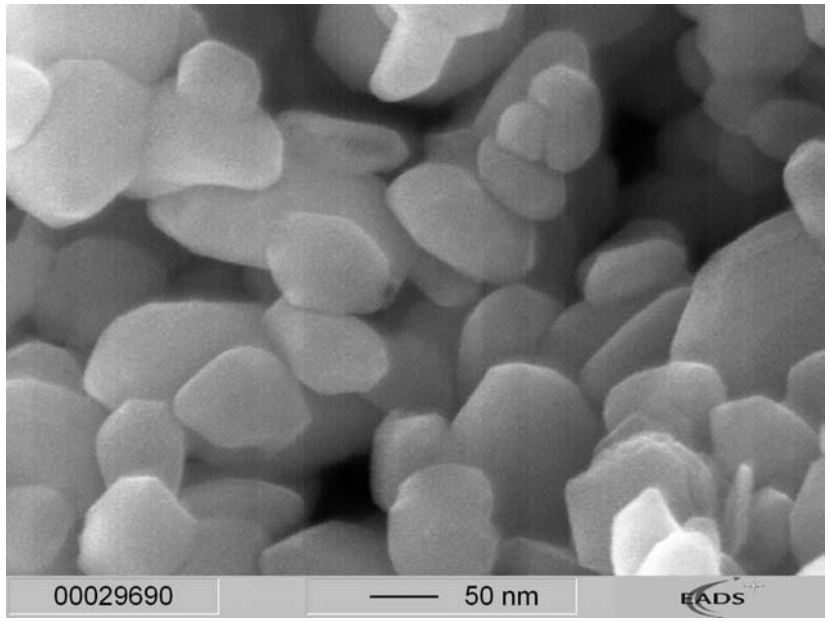


Nanoparticles



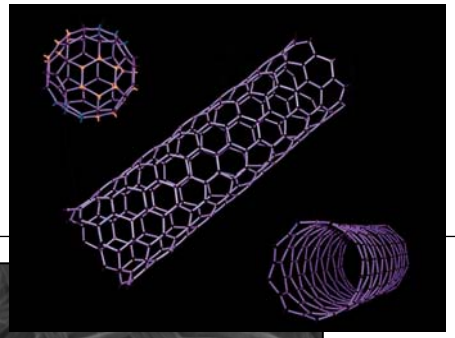


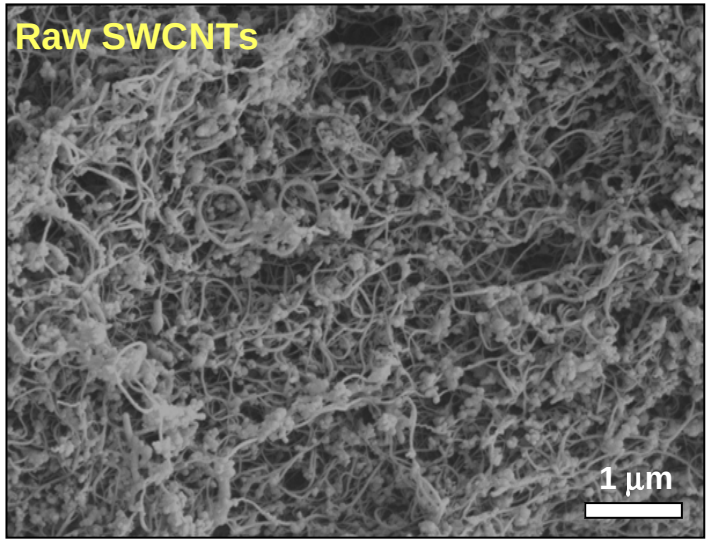
IFLM WS_2 nanoparticles - agglomerated

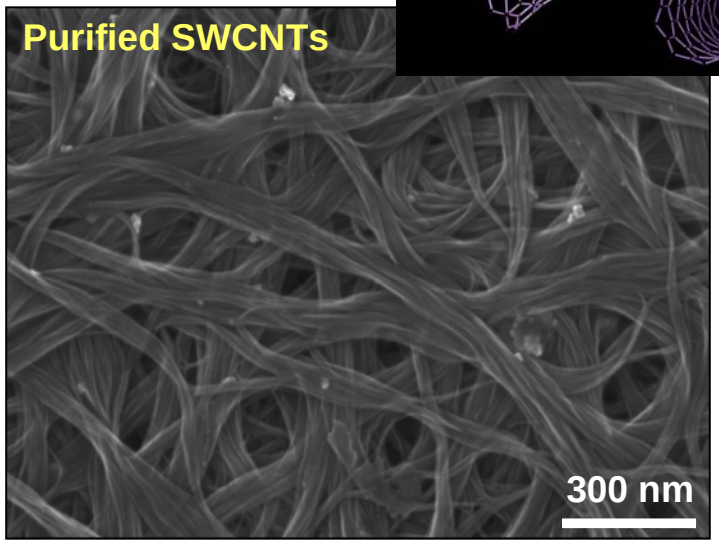


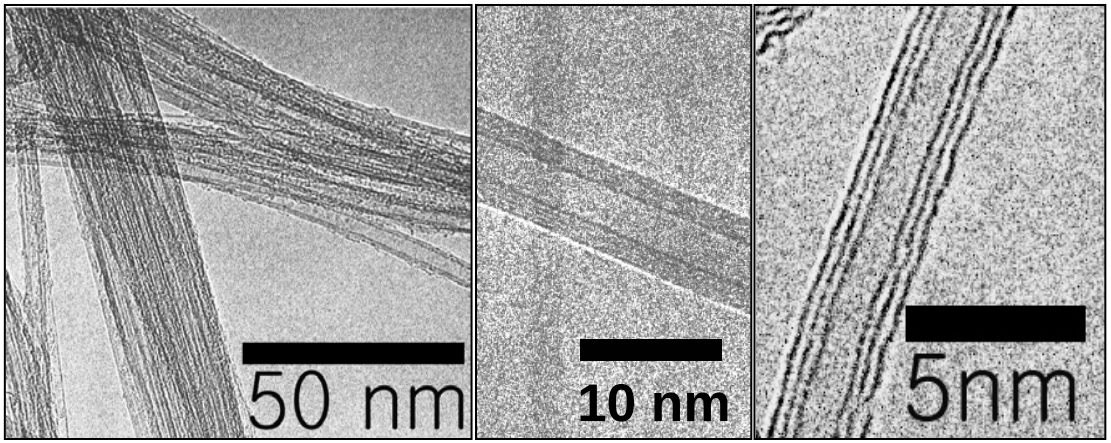
IFLM WS2 nanoparticles – high magnification

Carbon nanotubes - CNTs









nanostructure

Terminology and nomenclature for nanoparticles and nanotechnologies

- Only one current document specific to nanoparticles:
  - UK PAS 71 - available for free download at http://www.bsi-global.com/Manufacturing/Nano/Download.xalter
- For fullerenes (nanoparticles or molecular structures???), there is a provisional nomenclature developed by IUPAC - http://www.chem.qmul.ac.uk/iupac/fullerene/#r3
- Chinese National standard for nanomaterials: GB/T19619-2004 Terminology for nanomaterials
- ASTM E56 is developing a terminology for nanotechnology: WK8051 Standard Terminology for Nanotechnology – see http://www.astm.org/COMMIT/COMMITTEE/E56.htm
- ISO TC 229 approach:
  - Develop series of terminologies/vocabularies in various topic areas, which together will form a terminology for nanotechnologies. This will :
    - allow documents to be developed in tandem with technology developments rather than trying to shoe horn a new technology into an existing terminology;
    - allow consensus to be achieved more easily, allowing earlier publication;
    - enable changes in one topic area to be implemented without altering a substantial document.

TC 229 - terminologies for nanotechnologies

- **Proposed topic areas:**
  1. nanoparticles;
  2. Other nanomaterials (this could include nanostructured materials, including manufacturing methods, nanocoatings, etc);
  3. nanomedicine;
  4. nanofabrication - covering the fabrication of nanosystems;
  5. nanoscale measurement, including instrumentation;
  6. the bio-nano interface (as opposed to nanomedicine).
  7. HS&E
  8. carbon nanostructures;

Do we need a nomenclature for nanomaterials?

- "a structured naming system that can allocate unique names to unique entities, which allows as yet undiscovered entities to be similarly named, and which ideally allows the nature of all such entities to be determined from their name"

  - needs to provide recognisable added value in comparison to existing descriptions, without being so complex as to make it unusable;
  - must take account of range and complexity of particles under consideration;
  - Perhaps easier to agree an ordered structure for describing nanoparticles containing e.g.
    - core composition and crystal structure;
    - composition of any deliberately applied surface layers;
    - any surface functionalization;
    - specific surface area;
    - particle shape descriptor;
    - and particle size distribution.

Characterization – test methods

- **Critical areas for risk/regulation:**
  Development and delivery of:
  - **test methods to detect and identify nanoparticles, and to characterize nanoscale materials and devices.**
  - **protocols for bio- and eco-toxicity testing, including protocols to evaluate effects of short term and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanomaterials and nanoscale devices.**
  - **protocols for whole life cycle assessment of nanoscale materials, devices and products.**
  - **risk assessment tools relevant to the field of nanotechnologies.**
  - **protocols for containment, trapping and destruction of nanoparticles and nanoscale entities.**
  - **occupational health protocols relevant to nanotechnologies, in particular for industries dealing with nanoparticles and nanoscale devices.**

Nanomaterial test methods for risk/regulation

- **Need:**
  Particle detection and measurement
  - **Fast, accurate methods for particle "size" measurement in air, water, food and the environment:**
    - **Specific Surface Area (SSA)**
    - **Particle size distribution**
    - **Shape factor**
    - **Particulate density/Exposure**
  - **Work relevant to ISO TC 24 SC4 - Sieves, sieving and other sizing methods, active in Particle Characterisation, Size, Surface area and Zeta potential**

  Identification of composition and surface functionalities, including any catalytic and enzymatic characteristics
    - **"bulk" or "individual particle" measurements?**
  - **Work relevant to ISO TC 201 – Surface Chemical Analysis and ISO TC 202 – microbeam analysis**

- **May be that only particulate density and SSA + "chemistry" will be needed as HS&E particle measures? For some "particles" shape may also be important.**

Particle size measurement – current standards (TC 24/SC4 Sizing by methods other than sieving Sizing by methods other than sieving)

ISO 9277:1995	Determination of the specific surface area of solids by gas adsorption using the BET method
ISO 13320-1:1999	Particle size analysis -- Laser diffraction methods -- Part 1: General principles
ISO 13321:1996	Particle size analysis -- Photon correlation spectroscopy
ISO 13323-1:2000	Determination of particle size distribution -- Single-particle light interaction methods -- Part 1: Light interaction considerations
ISO/TS 13762:2001	Particle size analysis -- Small angle X-ray scattering method

Particle size measurement – standards under development in TC 24/SC4

ISO/CD 13319	Determination of particle size distributions -- Electrical sensing zone method
ISO/AWI 15900	Determination of particle size distribution -- Differential electrical mobility analysis for aerosol particles
ISO/DIS 21501-2	Determination of particle size distribution -- Single particle light-interaction methods -- Part 2: Light-scattering liquid-borne particle counter
ISO/DIS 21501-3	Determination of particle size distribution -- Single particle light-interaction methods -- Part 3: Light-extinction liquid-borne particle counter
ISO/DIS 21501-4	Determination of particle size distribution -- Single particle light-interaction methods -- Part 4: Light-scattering airborne particle counter for clean spaces
ISO/CD 22412	Particle size analysis -- Dynamic light scattering (DLS)

Other ISO TC's with an interest in the area

- 94 – Personal safety – protective equipment
- 146 – Air quality
- 147 – Water quality
- 207/SC 5 – environmental management – life cycle assessment
- TMB Working Group on Risk Management (Risk Terminology defined in ISO/IEC Guide 73)

- Role of ISO TC 229 will be to identify requirements in cooperation with e.g. OECD, coordinate standards development with relevant TCs, and develop standards where no TC exists or existing TC does not have the necessary resources.

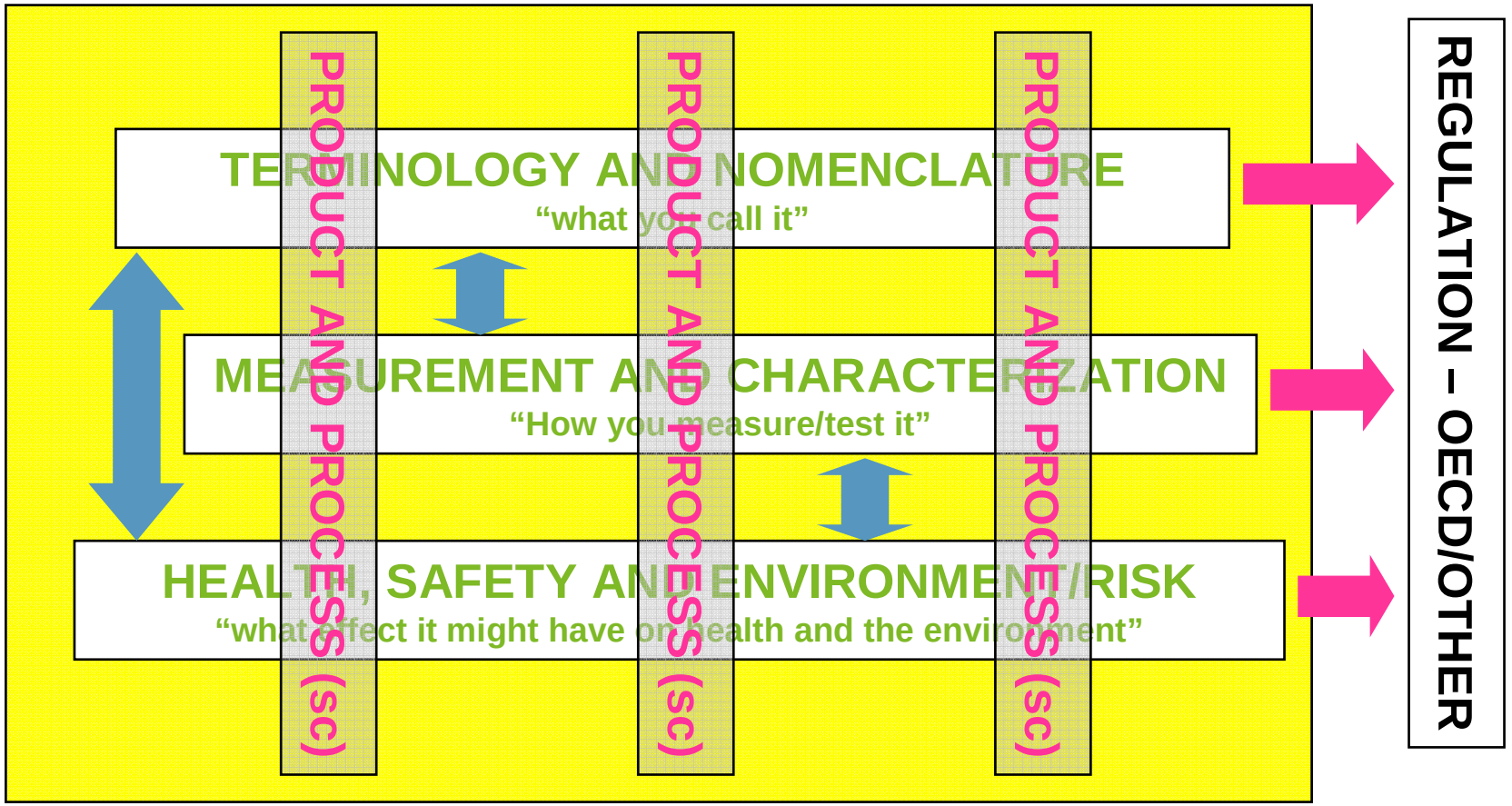
TCs relevant to specific “human” applications of nanoparticles

- Cosmetics
  - ISO/TC 217: Cosmetics
- Food
  - TC 34: Food and food products
  - TC 122: Packaging
- Medical devices
  - ISO/TC 84: Devices for administration of medical products and intravascular catheters
  - ISO/TC150: Implants for surgery
  - ISO/TC 188: prosthetics and orthotics
  - ISO/TC 194: Biological evaluation of medical devices

Cooperation and coordination

- Contend that ISO TC 229 is the most appropriate forum for developing and coordinating standards for terminology, characterization and test methods for nanotechnologies to support future regulation that might be agreed within OECD, the EU or other regional or National bodies.
- OECD and ISO are in liaison – a memorandum of understanding in this particular area would be useful.
- Other international activities in risk/safety of nanoparticles/manufactured materials:
  - International Risk Governance Council project "Addressing the need for adequate risk governance approaches at the national and international levels in the development of nanotechnology and nanoscale products" – Nanotechnology risk governance workshop – 30/31 January 2006, Switzerland
  - "International Symposia on Nanotechnology and Occupational Health"
  - Various EU projects – Nanosafe 2, Nanoderm, etc
  - International Dialogue on Responsible Development of Nanotechnology
  - International Council on Nanotechnology – ICON?
- Different actions need to cooperate to avoid duplication of effort.
- ISO is the only international standards development body recognised by the WTO.
- Note: CEN TC 352 and ISO TC 229 will cooperate closely, using the "Vienna Agreement" with ISO lead for areas of mutual interest

Summary of TC 229 standardization activities



Acknowledgements

- ISO Central Secretariat for permission to use the cartoons in the first few slides of this presentation
- Mr Pascal Krieger the artist who produced the cartoons, which are covered by ISO copyright
- Anyone wishing to know more about ISO should visit their web site WWW.ISO.ORG

Thank you!