

The role of standardization in risk governance of nanotechnologies

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‘THE RISK GOVERNANCE OF NANOTECHNOLOGY:
RECOMMENDATIONS FOR MANAGING A GLOBAL ISSUE’
Swiss Re Centre for Global Dialogue
Rüschlikon
Switzerland
6 – 7 July 2006

Standards

Two types:

- **Metrological standards: length, mass, time, quantity of matter – primary and secondary 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)**

Can be NORMATIVE OR INFORMATIVE

Standards are voluntary unless called in a contract or regulation.

Standards provide the means of validated quantification

and standardization

Standards can be:

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

FORMAL standards are:

- **PROPOSED, DEVELOPED AND APPROVED** by the members of the standards body
- **Based on CONSENSUS**

International Organization for Standardization

–GLOBAL

International Organization for Standardization

– GLOBAL

– **INCLUSIVE**

International Organization for Standardization

- GLOBAL
- INCLUSIVE

– DEMOCRATIC

International Organization for Standardization

- GLOBAL
- INCLUSIVE
- DEMOCRATIC

—MEMBER DRIVEN

International Organization for Standardization

- GLOBAL
- INCLUSIVE
- DEMOCRATIC
- MEMBER DRIVEN
- Process is based on well established principle of CONSENSUS
- Standards are:
 - Proposed, commented on and voted by members
 - Developed by experts nominated by members
 - Voluntary
- Already recognised as providing critical elements of Governance through ISO 9001, 14001 (and ISO 26,000 – expected to be published in 2008).
- ISO structure includes committees on CERTIFICATION AND ASSESSMENT (CASCO), CONSUMER POLICY (COPOLCO), DEVELOPING COUNTRIES (DEVCO), and REFERENCE MATERIALS (REMCO)
- RISK MANAGEMENT and SAFETY covered by:
 - TMB WG on RISK MANAGEMENT:
 - ISO Guide 73 Risk management — Vocabulary — Guidelines for use in standards
 - “Risk Management – Guidelines for principles and implementation of risk management” – under development
 - JOINT ISO/IEC TECHNICAL ADVISORY GROUP, SAFETY:
 - Safety aspects — Guidelines for their inclusion in standards
 - BY TC’s FOR SPECIFIC AREAS, e.g. for medical devices by ISO TC 194 Biological Evaluation of Medical Devices (e.g. ISO/DIS 22442-1.2 Medical Devices Utilising Animal Tissues and Their Derivatives – Part 1: Application of Risk Management.

Extent of ISO System

151 full-time posts

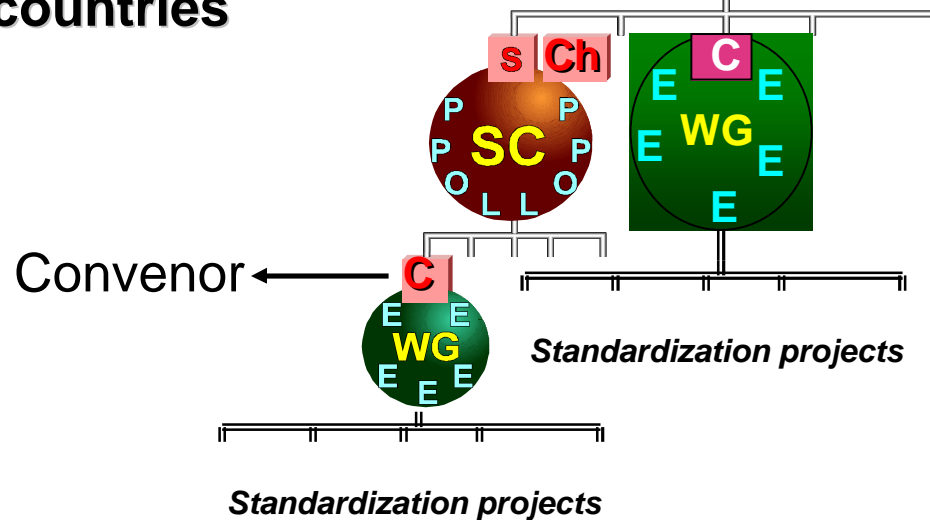
ISO CENTRAL SECRETARIAT

More than 14 941 ISO Standards

Secretary ←  Chairman

734 Secretariats held by 37 countries

About 190 TCs



544 SCs

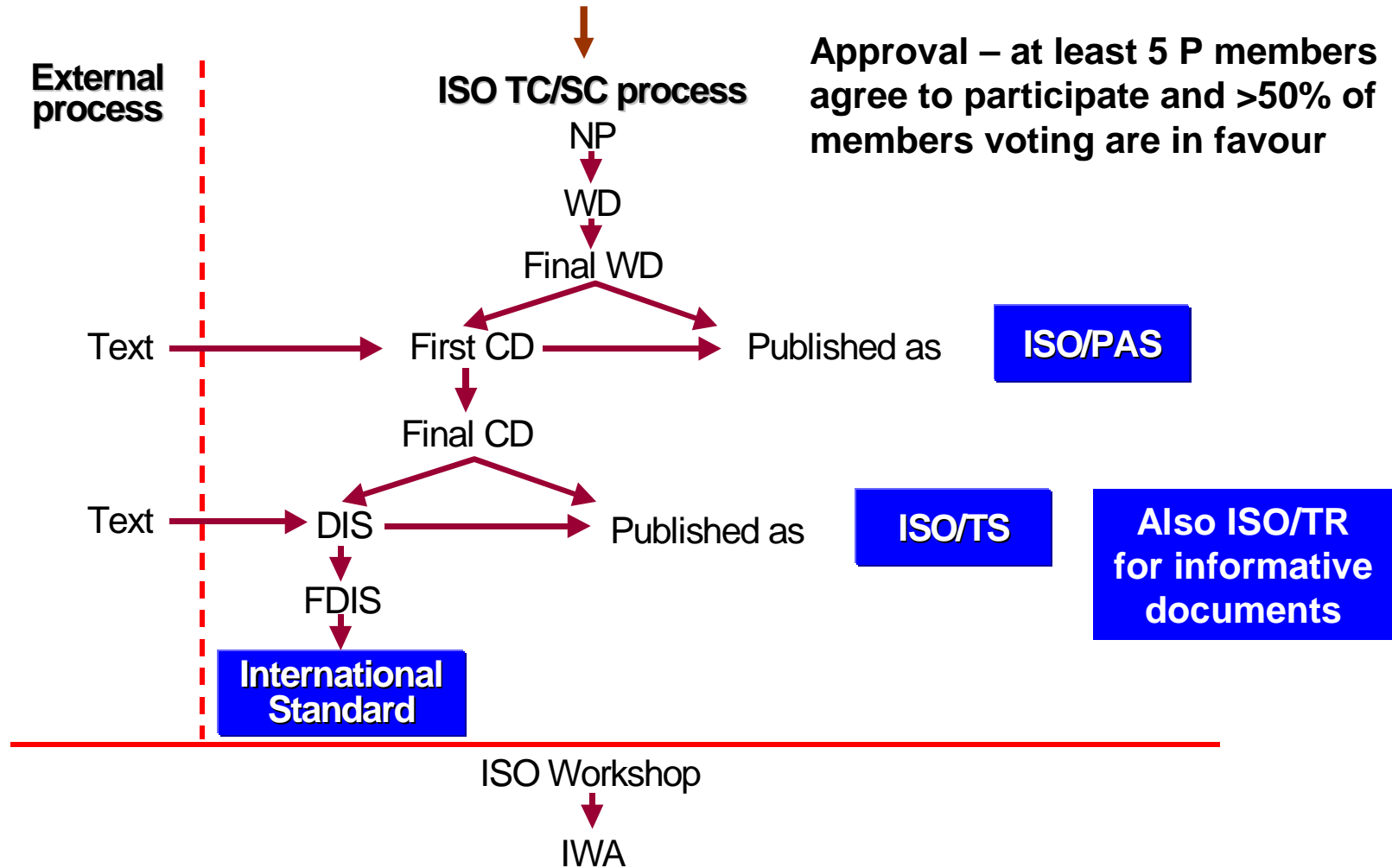
2 188 WGs

4 176 active projects (30 June 2005)

Development of International Standards

Process accommodates special needs

NWIP from member organisation



Risk = f(hazard and exposure)

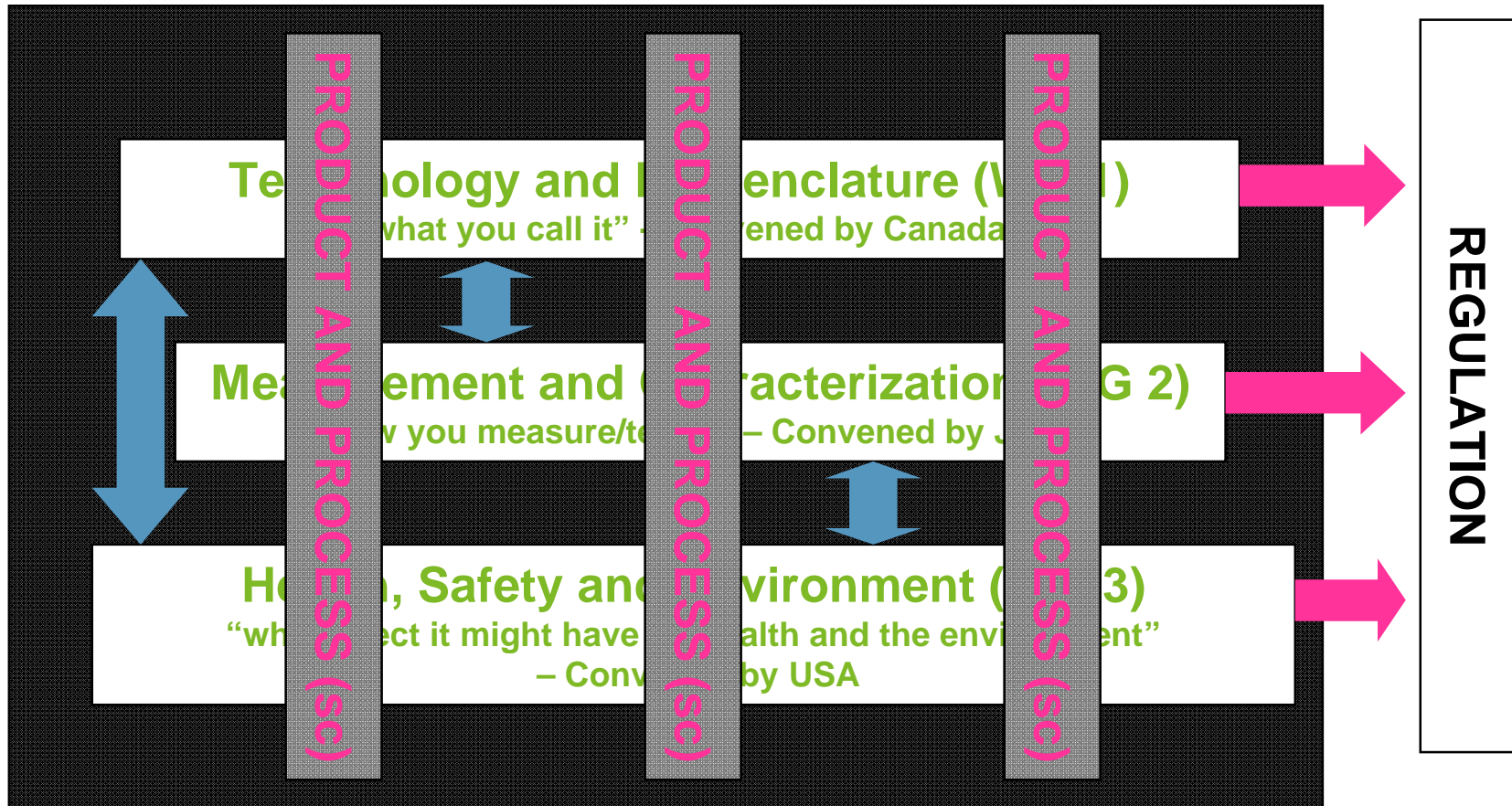
Consensus based standards can provide internationally validated means to quantify both hazard and exposure through standardized methods for:

- Detection**
 - Identification**
 - Characterization**
 - Testing**
 - Assessing**
 - Controlling**
 - Protecting**
 - Eliminating**
 - Communicating**
-
- Applies to Frame 1 and Frame 2 but for Frame 2 additional considerations will apply**

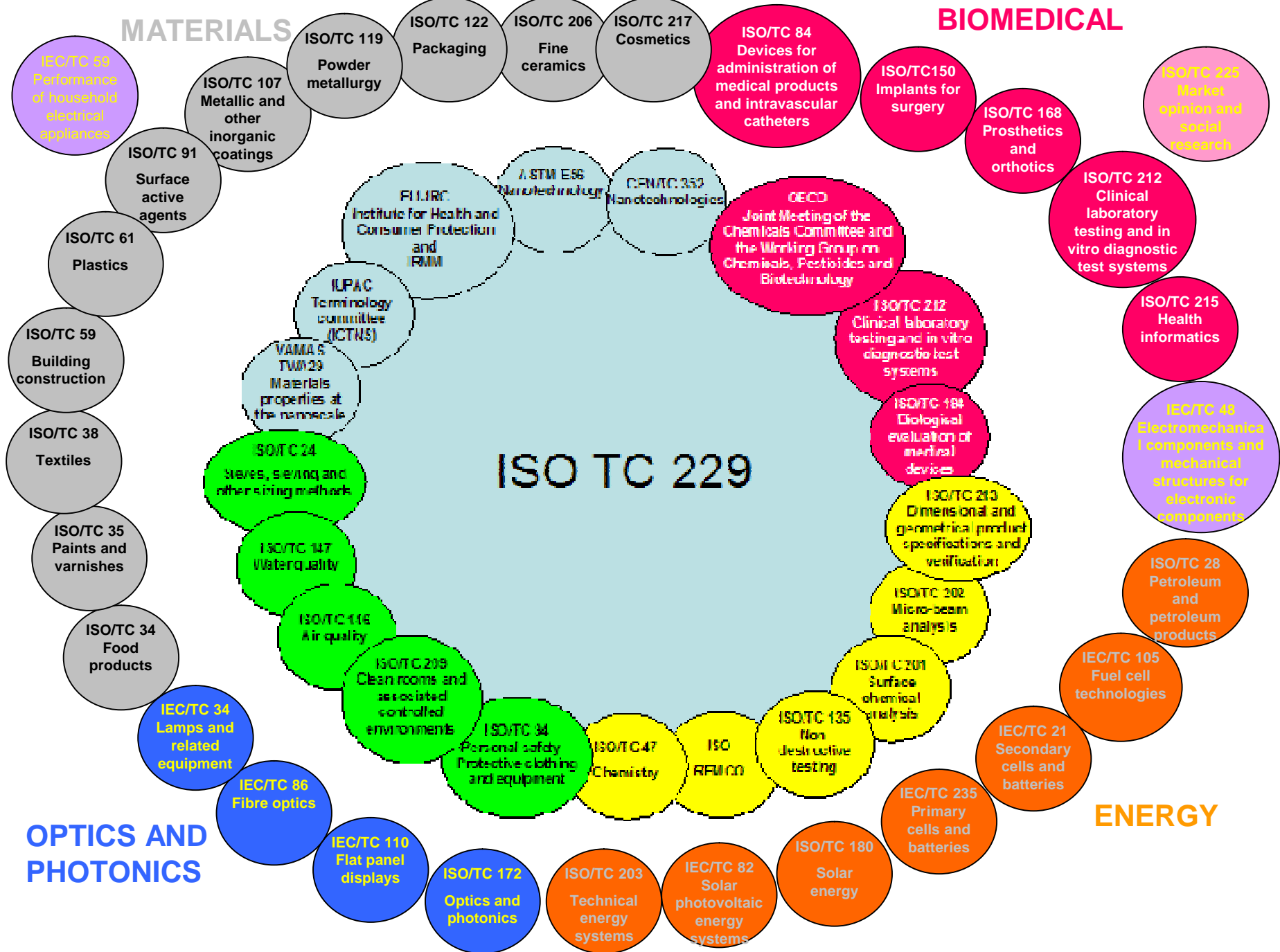
ISO/TC 229

- **Established in June 2005**
- **34 members – 27 “P” and 7 “O”**
- **Liaisons with 8 other ISO TCs and 2 external bodies – OECD and EC JRC**
- **Exploring additional external liaisons for emerging economies through eg ANF**

TC 229 – Structure/working areas



POSSIBLE LIAISONS



TC 229 Work programme – some possible examples

Terminologies and nomenclatures - WG1

Nanoparticles –WG2 and WG3

- **Size and shape measurement and distributions** – scientific and commercial
- **Product “consistency”** – e.g. chemical functionalization
- **Protocols for toxicology, fate and degradation testing** (requires detailed characterization to know what exactly is being tested!)
- **Life cycle analysis**
- **“Guides” on handling and disposal of nanomaterials, preparation of material specifications, labelling, etc.**

Carbon and other nanotubes/nanofibres – WG2

- **Length and diameter distributions in a batch.**
- **Fraction of a batch that is nanotubes and batch “quality”.**
- **Physical properties** – mechanical, electrical, magnetic, thermal, etc

Nanometre thick films – WG2

- **Thickness**
- **Physical properties**
- **Interfacial strength**

NB work will be relevant to all nanoscale entities and systems whether or not they fit any restrictive definition of “Nanotechnology(ies)”