



**International Organization
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Using and referencing ISO and IEC standards for technical regulations

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*3rd ANSI Conference on
Leadership in ISO and IEC*

Chicago, 24 May 2007

Meeting global needs

International standards can complement policy makers and regulators to address:

- Globalization of trade in products and services
- Deregulation/privatization of public services
- Challenges of global climate change and improved energy efficiency
- Public demand for consumer safety, environmental protection, corporate social responsibility
- Need for international solidarity to face global terrorism, pandemics and natural disasters
- Pace of innovation and convergence of new technologies

Context for examining the subject of standards supporting regulations

- ISO Strategic Plan 2005 – 2010, “Key Objective 5”
“Promoting the use of voluntary standards as an alternative or as a support to technical regulations”
- IEC Masterplan 2006, “IEC Standards as a strategic tool”
“The IEC will enhance its promotion, marketing and communications efforts with decision makers ... among regulators and developing countries, particular emphasis will be given to the importance of adopting and referring to IEC Standards ...”
- ISO TMB and IEC SMB - supporting development of a joint document providing information to regulators

ISO/IEC Special Publication (draft May 2007)

Using and referencing ISO and IEC standards for technical regulations

- to convey to regulators the benefits of choosing to use and reference ISO and IEC standards
- in support of evolving good regulatory practices

Content of draft ISO/IEC Special Publication on *Using/referencing ISO & IEC standards for tech regs*

1. *Advantages and benefits*
2. *Introduction/background*
3. *International trade and standards*
4. *Global applicability of ISO and IEC standards*
5. *Different types and aspects of ISO and IEC standards*
6. *Methods of referencing/using ISO and IEC standards for technical regulations*
7. *Other considerations*
8. *Conclusion*

Annex A — Examples supporting regulations in different sectors

Annex B — Examples of national and regional regulatory texts

Annex C — Examples of national and regional policies

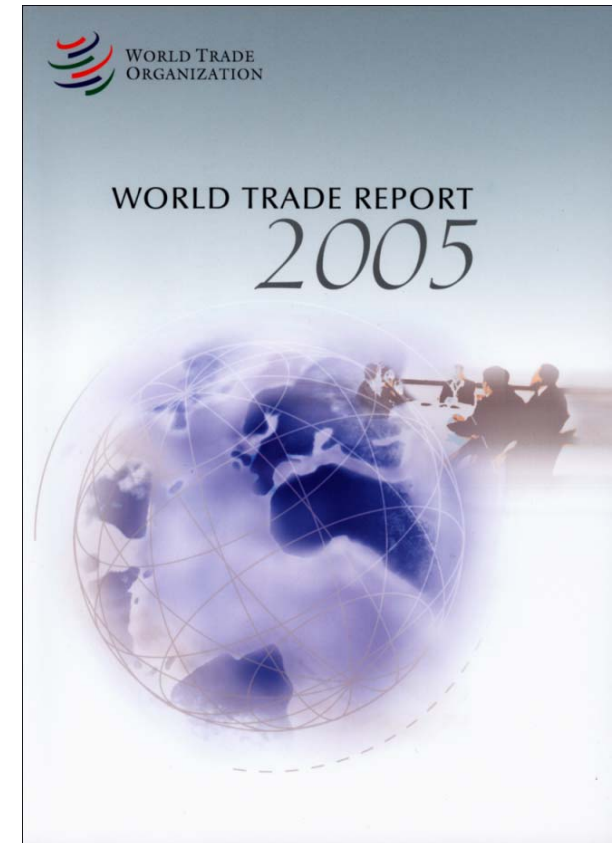
Why use or reference ISO and IEC Standards? (CI 1)

- *Support societal/environmental policies and sustainable development*
- *Consistent level of consumer protection*
- *Facilitate compliance across different regions enhancing market access (SMEs)*
- *State-of-the art and vehicle for dissemination of new technologies*
- *Basis for national standards and consultations (avoiding regulatory consultations)*
- *Basis for national technical regulations avoiding barriers to trade*
- *Complete range of tools for various modes of conformity assessment*
- *Process providing coherence and avoidance of duplication*

Providing the WTO and trade context (CI 3)

Ensuring that national technical regulations, standards and conformity assessment procedures do not constitute unnecessary barriers to international trade

- use international standards, guides and recommendations as basis for national technical regulations and conformity assessment procedures
- play a full part, within the limits of resources, in preparation by participating in international standardizing bodies



Methods of referencing and using ISO and IEC standards for technical regulation (CI 6)

- *Direct references to specific standards in the legal text*
 - *Dated references*
 - *Undated references*
- *Indirect reference to the use of ISO or IEC Standards*

“Example: Where the product meets the relevant ISO or IEC standard whose reference number has been published in [refer to relevant official listing here], the relevant authorities shall presume compliance with the requirements of this law.”
- *Actions by regulators/authorities to encourage the use of ISO and IEC standards*
 - *government procurement policies*
 - *acknowledgment that ISO or IEC Standard meeting regulatory objectives*

Other considerations (CI 7)

- *Ensuring no delegation of legislative responsibility*
 - *regulator always maintains choice of techniques to assess and ensure the suitability of an ISO or IEC standard*
- *National and regional adoptions of ISO and IEC standards*
- *Maintenance of ISO and IEC standards and regulator monitoring*
- *Regulator participation in standards development*
- *Role of conformity assessment in technical regulations*
 - *CASCO conformity assessment toolbox*
 - *First, second and third party conformity assessment*

Some concrete examples (Annex A)

- *UN Recommendations for the Transport of Dangerous Goods and the work of ISO/TCs 58 and 220*
- *GHTF and work of ISO/TC 194 (Bio eval of med devices), ISO/TC 210 (QM for med devices) and IEC/TC 62, Electrical equipment in medical practice*
- *UN/ECE Working Party 29 (World Forum for Harmonization of Vehicle Regulations) and ISO/TC 22*
- *FAO/WHO Codex Alimentarius Commission and the test methods and food safety work of ISO/TC 34*
- *Radio spectrum regulatory authorities and work of the IEC/CISPR (International special committee on radio interference)*
- *IMO framework regulations in maritime field and work of ISO/TC 8 (Ships and marine technology) and related IEC TCs 18 (ship electrical) and 80 (navigation)*

ISO General Assembly 2007

Open Session on:

International Standards and Public Policies

20 September 2007, Geneva

- *International Standards supporting public policies for sustainable development - am*
- *International Standards in relation to public safety and security policies - pm*
- *Key speakers from United Nations and agencies, international regulatory fora and policy makers*
- *Communication on ISO-IEC Special Publication*

Thank you for your attention



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