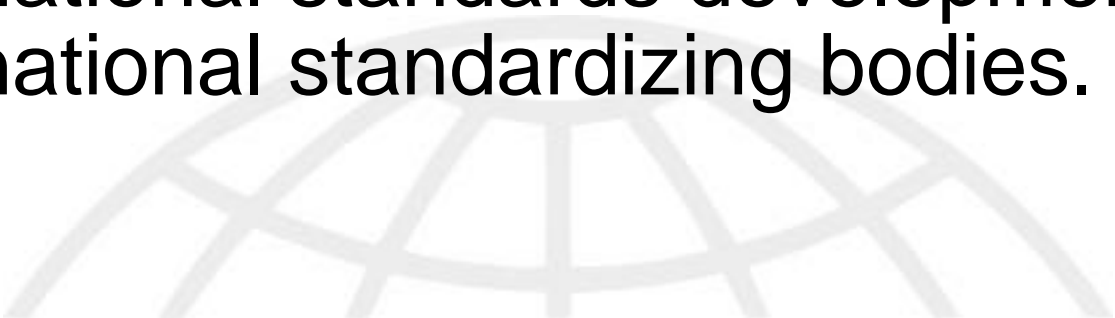


CONFOMITY ASSESSMENT AND REGULATORS -- PRINCIPLES

WTO and standards

WTO requires members to :

- Use international standards, guides and recommendations, or relevant parts as basis for national technical regulation and conformity assessment procedures.
 - Play a full part (within resources) in international standards development by international standardizing bodies.
- 
- A faint, light gray globe graphic is visible in the background at the bottom of the slide, showing latitude and longitude lines.



Standards supporting technical regulations

Reflect best experience of industry, researchers, consumers and regulators worldwide.

ISO standards are adopted at regional and national level.

One important basis for removal of Technical Barriers to Trade (TBT).

Organization for Economic Cooperation (OECD) also recognizes role of international standards in support of regulation.



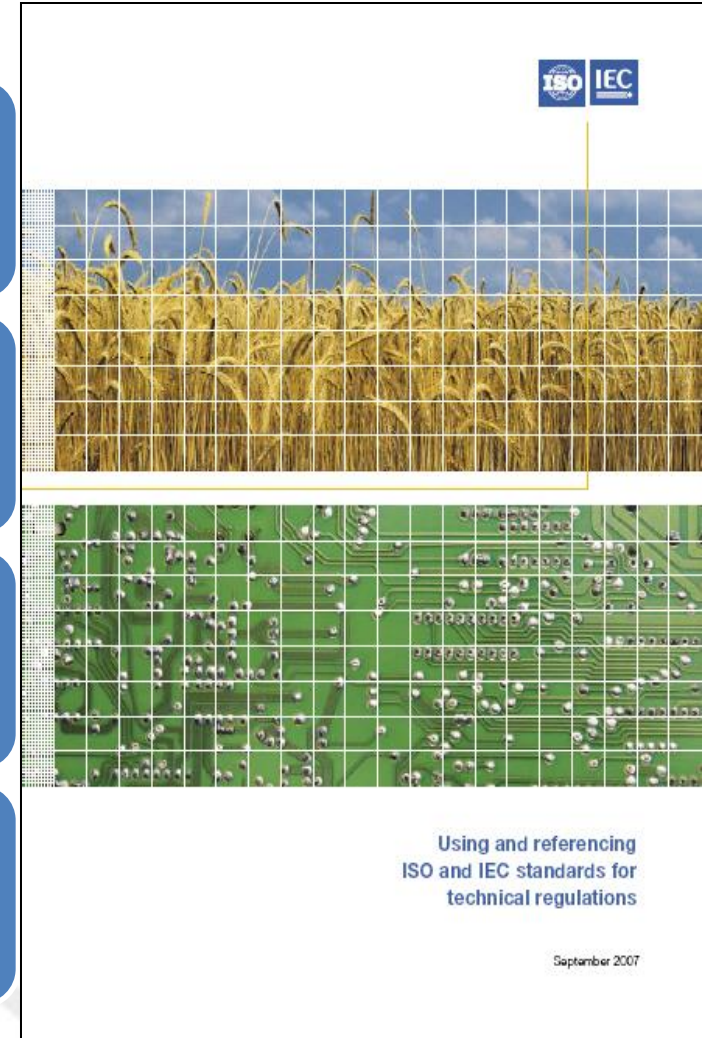
Conformity assessment standards and good regulatory practice

Use of standards in regulation supports **national, regional** and **global** policies.

National adoption may be an important element encouraging the use of ISO or IEC standards in national technical regulation.

National adoption process can give confidence that the international solution is **fully acceptable to the national situation.**

Standards published by **other organizations** may also be referenced in regulations





ISO/IEC standards & good regulatory practice

How do
standards
get
incorporated
in
regulations?

- Direct reference to specific standard (dated or undated)
- Indirect reference to ISO standards
- Some regulators reproduce text of standard directly in regulation



ISO/IEC standards & good regulatory practice

How do standards get incorporated in regulations?

- **Direct reference - reproduced directly in regulations**
 - Statute directly references standard (title & identification number), avoiding reproduction of standard in legal text and copyright issues.
 - Allows for specific parts of standard to be referenced where regulation only requires part of standard.
 - Regulation's legal certainty given by dated reference.
 - Undated references allow more flexibility when required. Example: waste emissions shall be less than clause 4 of ISO XXXXX:2011, TITLE



ISO/IEC standards & good regulatory practice

How do standards get incorporated in regulations?

- **Indirect references to ISO & IEC standards use**
- Involves official recognition of standards external to regulatory text
- Regulator compiles and publishes list of suitable standards by official process and controls
- If standard amended or revised no need to change legal text – only the list



Standards – regulation comparison

Standards	Regulations
Standards development process.	Regulatory development process.
Standards development organizations (SDOs) facilitate development of standards in response to requests.	Governments lead in developing regulations.
SDOs seek consensus on content of standards.	Governments consult interested parties, not necessarily seeking consensus . Regulations may reference standards or require use of accredited conformity assessment bodies .
Conformity assessment.	Compliance assurance.
Certification bodies and testing labs (conformity assessment bodies) assess conformity	Governments enforce regulations themselves or remain accountable for enforcement when others do



European Union (EU) approach to conformity assessment

European legislation designed to remove technical barriers to trade and to facilitate trade within Europe.

It specifies a series of conformity assessment modules to be used by legislators when drafting legislation to align the laws of the various member bodies relating to safety.

Legislation is in the form of an EU Directives and the modules are chosen according to the risk of non conforming product.

For low risk the suppliers declaration of conformity (SDoC) is sufficient whereas for higher risk products it requires third party assessment etc.

The modules can be combined in various ways to give choice of complying whilst maintaining the level of conformity assessment needed.

The modules cover:

- self assessment by the manufacturer
- type assessment by an independent body (notified body)
- quality assurance assessment by a notified body
- inspection of production items by a notified body



Conformity assessment standards and good regulatory practice

Objectives of the WTO/TBT Agreement

- ensure that national technical regulations, standards and conformity assessment procedures do not constitute unnecessary barriers to international trade
- achieve a balance between allowing WTO Members to take regulatory measures to protect legitimate interests and ensuring that national technical regulations, standards and CA procedures do not become unnecessary obstacles to international trade

Harmonization is central to the TBT Agreement and is articulated in particular in two requirements:

- WTO members shall use international standards, guides and recommendations, or relevant parts of them, as a basis for their national technical regulations and conformity assessment procedures
- WTO members shall play a full part in the preparation of international standards, guides and recommendations by participating in international standardizing bodies

The WTO also has specific policy areas where international standards are being discussed: trade in services (GATS), food safety (SPS) and trade and the environment (CTE)

