

Using and referencing ISO and IEC standards for technical regulations

This presentation

- Advantages and benefits
- International trade
- Global applicability
- Different types standards

This presentation

- Methods of referencing
- Other considerations
- Best practice
- Overview of national and regional policies

Advantages and benefits

Standards from ISO have a:

- ✓ broad **geographical** reach
- ✓ multi-stakeholder environment

Different perspectives from:

- ✓ the **national** level
- ✓ a **network** of liaisons (inter-gov orgs).

Advantages and benefits - of using and referencing ISO and IEC standards

Advantages and benefits

In the context of regulation IS:

- Support **societal** and **environmental** policies
- Offer **consumer** protection
- Are used across different **markets**
- Reflect the **state of the art**
- Disseminate **new technologies**

Advantages and benefits

ISO standards:

- Can become **national** standards
- Are a suitable basis for **national** technical regulations
- Are used for conformity assessment - **enhance confidence**
- Are **coherent** (with each other)

Advantages and benefits

- Value of International Standards from ISO and IEC is that they are
 - recognized, accepted and implemented world wide
 - provide solutions to policy and technical issues agreed upon by a consensus, involving all parties including regulators

International Standards and Trade

International standards and trade

- WTO TBT Agreement ensures that national measures do not constitute TBTs
- **Harmonization** of national measures is the goal
- WTO members are encouraged to:
 - **Participate** in international standards work
 - **Use** international standards as a basis

International standards and trade

Specifically for standards bodies:

The Agreement contains a.

Code of Good Practice for the Preparation, Adoption and Application of standards

- Ensures their standards support trade facilitation
- ISO and its members follow this Code

International standards and trade

- Main goal of WTO is to ensure that trade flows freely
- WTO sees value in international standards

*In helping to achieve the elimination of
Technical Barriers to Trade (TBT)*

- Demonstrated in the WTO Agreement on TBT

Global applicability - of ISO and IEC standards

Global applicability

- At first sight, it would appear that countries in all stages of development have identical needs for technical regulations.
- Any goods and services that have the potential to cause serious harm to the health or safety of the population, or to the environment, would seem to be obvious candidates for technical regulation.
- However, the differences between countries mean that this concept can be applied differently

Global applicability

Most developed countries have:

- **Market** economies
- Domestic **manufacturing and services**
- A culture of **competition**
- Consumer protection - with organized **groups**
- **Systems** for standards, quality, accreditation, metrology
- A demand for **harmonization**
- **Litigation**

(developed systems of civil litigation that support, when necessary, the application of sanctions)

Global applicability

Some countries, these elements exist to varying degrees :

- Have **subsistence economies**, little domestic manufacturing capacity for finished products
- Rely on their subsistence on extraction of **raw materials**
- Depend on the quality of **imported products**
- Lack a consumer infrastructure
- **No** highly developed quality, accreditation and metrology infrastructure
- May not have **implementation systems** for regulation

Global applicability

So when dealing with a problem:

- Such countries may make certain standards mandatory in response to a specific need for technical regulation
 - can benefit from the savings they make when applying a wide range of ISO and IEC standards.
 - encourage use of and, where necessary, adoption of IS that address their needs
- Vital to have a portfolio of national standards based on ISO standards

These countries can really benefit!

Different types - of ISO and IEC standards

Different types

- **Product** specifications:
- Organizational **management**
- **Labelling** and **Packaging**
- **Health and safety** principles
- **Measurement**, test and analytical methods

Different types

- Graphical **symbols**
- **Terminology** and definitions
- Services
- Personnel
- **Conformity** Assessment

A single standard could cover one or all of these!

Methods of referencing and using ISO standards

Methods of referencing

Principles:

- Regulatory authorities decide **themselves**
- Once decided - appropriate method will need to be **chosen**
- There are commonly used methods
- The methods are applicable at national and international levels

Methods of referencing

Some considerations:

- Will the use be **mandatory** or **voluntary**?

Regulators will need to decide whether to use the standard as mandatory (providing the only solution) or voluntary (providing a solution).

- What level of **checks** are needed? to ensure the standard is suitable for use and addresses their needs
- **Whole** standard or selected **parts** of it?

Methods of referencing - Direct references

- Specific standard quoted by: **number** and **title**
- Often supports the **mandatory** use
- **Avoids reproduction** of the standard in the legal text
- **NOTE:** There are two forms: **dated** and **undated**

Methods of referencing - Direct references

- Direct referencing means that the reference of a specific standard is directly quoted within a legal text using its identification number and title.
- method often supports the mandatory use of a standard,
- standard to remain optional (i.e. as one of a number of solutions to help comply with the regulation)

Methods of referencing - Direct references

By directly referencing standards in this way,

- avoid reproduction of the standard in the legal text.
- parts, or even single clauses of a standard, can be referenced where only a small part of a standard supports a regulation.
- two forms of direct referencing:
 - dated and undated

Methods of referencing - Direct references

Dated direct references:

- Number and title of standard referenced with **date of publication**.
- Only a particular version of a standard is used.
- Gives **legal certainty**
- Can help give **assurance** and **clarity**

Methods of referencing - Direct references

Dated direct references:

- **Restrictive** reference
- Standards are **amended** and **revised**
- Changes to the standard should be **followed**
- New editions (with new dates) will always require a change to the legal text
- Amendments could be dealt with by "**as amended**"

Methods of referencing - Direct references

Examples of dated direct references:

- *The waste hazardous material container shall conform to ISO XXXX:2003 TITLE.*
- The waste hazardous material container shall conform to ISO XXXX:2003 (as amended) TITLE.

Methods of referencing - Direct references

completely new editions of a standard (with new dates) will always require a change to the legal text,

amendments to the standard could be dealt with by the addition of a phrase such as “as amended” after the reference in the legal text.

Methods of referencing - Direct references

Undated direct references:

- Quotes the number and title but **not** the date
- method is **more flexible**
- No update to legal text if the standard is revised
- Changes to the standard should still be **tracked**.
- Could add the phrase "**latest edition of**"

the aim being to permit them to respond easily and quickly to technical changes

Direct references to ISO standards

Example of an undated direct reference:

The waste hazardous material container shall conform to the latest edition of ISO XXXX TITLE

NOTE: undated reference is not possible when specific clauses or subclauses, tables, figures or annexes of a standard are cited. In these cases, the reference should always be dated

Methods of referencing - Indirect references

- Registering standards on an official information source
- A list of standards is decided and published by an official process
- The list is external to the regulatory text. If standard is revised or amended, no change is necessary to the legal text, only to the list
- The list needs to be kept up to date and be available to everyone
- This model has been applied in Europe where it is referred to as the “New Approach”

Methods of referencing - Indirect references

Specific advantages of indirect references:

- If there is a revision/amendment to the standard...

no change is necessary to the legal text – only to the list

- The lists may include publication dates of standards...

legal certainty of a dated reference is offered

Indirect references to ISO standards

Examples of indirect referencing:

- *Where the product meets the relevant ISO (IEC) standard whose reference number has been published in (REFER TO OFFICIAL LISTING) the relevant authorities shall presume compliance with the requirements of this law.*
- *A product shall be presumed safe as far as the risks are concerned when it conforms to ISO (IEC) standards, the references of which have been registered on (REFER TO OFFICIAL LISTING).*

General actions to encourage the use

For some objectives:

- It is enough to encourage the **use** of ISO and IEC standards
- **Voluntary Take up** by the market means regulators objectives are met.
 - enhancing quality of a product or service
 - achieved through targeted procurement.

(where this occurs, the standard may become the de facto tool for market access)

Examples

Example of a direct reference - Canada

A copy of the quality management system certificate certifying that the quality management system under which the device is manufactured satisfies....

..... National Standard of Canada **CAN/CSA-ISO 13485:03**, Medical devices — Quality management systems — Requirements for regulatory purposes.

Examples

Example of a direct reference - US

The ANSI Standard MH5.1 (1971) and the **(ISO) 1496 (1978)** have been approved for incorporation by reference by the Director of the Federal Register.....

.....A copy of each of these standards is available for inspection at the NRC Library, 11545 Rockville Pike, Rockville, Maryland 20852-2738.

Examples

Example of an indirect reference - Europe

Article 5,2: Conformity of toys with the national standards which transpose the harmonized standards....

....the reference numbers of which have been published in the *Official Journal of the European Communities*...

....shall result in a **presumption of conformity to the essential safety requirements** referred to in Article 3.....

Examples

Example of indirect references - China

Chapter 1, Clause 3: Food additives must comply with national **safety and sanitary standards**.

Chapter 3, Clause 13: Production and Management: For those who produce compound food additives, the range and amount of every single food additive must comply with the “**Safety and sanitary standards for the use of food additives**” for the categories and their range and amount of use specified in the list announced by the Ministry of Health.

Other considerations

Other considerations

Ensuring no delegation of responsibility:

- Note the ISO and IEC **processes**
- Regulatory procedures are required **for approving** references
- Regulatory procedures which can ensure **regulators' confidence**
- Procedure chosen will depend on the **risk posed**

Other considerations

- Using ISO and IEC standards for technical regulation does not imply that regulators have reduced power or that they delegate responsibility to other parties.
- Regulators still have the power to change or update their legislation at any time, or to delete a reference if the standard loses its validity for the relevant legislation.

Other considerations

- Referencing ISO and IEC standards in technical regulation simply means that regulators make use of the existing consensus at international level.

Other considerations

National adoptions:

- ISO and IEC standards, can be **formally adopted** as national standards
- May involve a **separate national consultation**
- In some countries, national adoption may be a **necessary element of** using the standard in regulation
- Ensures the standard is **fit** for national needs

Other considerations

Maintenance procedures:

- ISO and IEC maintain their standards to reflect the **state of the art**.
- The committees periodically **review** their standards.
- There are various ways that regulators can be kept informed
 - participation in the committee
 - Information exchange arrangements with the relevant ISO or IEC member.

- ISO or IEC standards may be used or referenced directly in national technical regulation, based on an assessment of their suitability, without the need for them to be recognized as national standards for the country

Other considerations

Role of conformity assessment:

Conformity assessment is the determination that products, including services, processes, systems and persons meet specified requirements.

- Depending on the type of product or system and the criteria being examined, regulators may require that conformity assessment procedures be carried out by the supplier, the purchaser, the regulator or by an independent body
- Conformity assessment can involve certification, inspection and/or the testing of a product or system.

Other considerations

Conformity Assessment (CA):

- Depending on the type of product or system
- Depending what characteristic is being assessed
- Regulators may want CA - and that it be carried out by:
 - **manufacturer/supplier,**
 - **the purchaser/user,**
 - **the regulator, or by an independent conformity assessment body.**

Other considerations

CA continued:

- ISO and IEC have developed a series of documents for CA
- Ensure **comparability** and **credibility** of CA
- Represent an **international consensus** on best practice in CA
- When regulations have CA requirements – **use these documents!**

Other considerations

Examples:

- ISO/IEC 17000 Conformity assessment – Vocabulary and general principles
- ISO/IEC 17021 Requirements for bodies providing audit and certification of management systems
- ISO/IEC 17024 General requirements for bodies operating certification of persons
- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

Best practice - examples of different sectors

Best practice

In some sectors:

- Regulatory initiatives have occurred at the national and international level.
- These often use international standards to support the technical aspects

Best practice - sectors

- Ships and marine
- Transport of dangerous goods
- Medical devices
- Road vehicles
- Food products
- Radio services
- Railways
- Ships

Best practice

Regulators **and** ISO Committees

- Aim for **mutual representation** at each others meetings
- Keep constant **communication**
- Avoid duplication of work
- Regulatory interest should be **recorded** in official documents and communications

Best practice

Regulators **and** ISO Committees together:

- Develop a **long-term** relationship and strategy
- Use tools such as **MOUs**
- Ensure focused and targeted **liaison** with specific projects
- Consider aligning technical structures
- Explore **joint** work and synchronized publication

Best practice

Regulators can:

- Formally **request** work in specific areas.
- **Flag** their interest at the earliest stage
- **Check** that the standard reflects the regulatory need throughout its development
- Refer only to **published** ISO standards
- **Involve** relevant ISO committees in drafting regulation intended to be standards receptive.

Best practice

Regulators can:

- Assess the **appropriateness** of each standard
- **Reject** ISO standards that do not meet their needs
- Give a formal **endorsement** when satisfied

Accept standards as part of the regulatory infrastructure

Best practice

ISO Committees should:

- Concentrate on **performance** requirements
- Avoid **prescriptive** standards
- **Give a timely** response
- Ensure regulators **receive drafts** during development
- Encourage regulators to submit comments
- Be aware that they are **contributing** to regulatory harmonization

National and regional policies

Standards receptive regulatory policy exists in:

- China
- Europe
- Japan
- South Africa
- US

Summary

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- Different types standards
- Methods of referencing
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- Best practice
- Overview of national and regional policies

Summary

Chose ISO and IEC standards to support your regulatory initiatives