

Using and **referencing**
ISO and **IEC** standards
to **support public policy**



About the IEC and ISO

The IEC and ISO are both independent, non-governmental, not-for-profit organizations that develop and publish fully consensus-based International Standards. The members of the two organizations include government, private and public-private entities. For each organization, there can only be one member per UN-recognized country and every member country, no matter how large or small, has one vote and a say in what goes into the IEC or ISO International Standard. National positions on IEC and ISO International Standards are not necessarily government positions, but should be representative of all interested stakeholders, including government experts.

The IEC and ISO promote world trade and economic growth and encourage the development of products, systems and services that are safe, efficient and environmentally friendly.

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Foreword

The IEC and ISO wish to make their portfolio of International Standards more visible to public policy makers and ensure that their standards address the needs and concerns of public policy makers.

The International Standards developed by the IEC and ISO are voluntary. And while they do not seek to establish, drive or motivate public policy, regulations, or social or political agendas, they can certainly provide valuable support to the implementation of public policy.

This document was developed by the IEC and ISO to **help public policy makers understand and achieve the benefits of using IEC and ISO International Standards to support public policy initiatives**. This may include referencing IEC or ISO International Standards in legislation or regulation as well as using them to support public policy decisions or actions.

Another aim of this document is to stimulate dialogue between standards development organizations and public policy makers. Where there are high levels of engagement between public policy makers and standards developers there are excellent synergies (financial and others). Engagement allows policy makers to stay informed of (and provide input into) ongoing developments in International Standardization that they may find useful to support their policy goals. Engagement also allows policy makers to help ensure that IEC and ISO International Standards complement government efforts. At the same time, standardizers can collect essential feedback on difficulties experienced by policy makers in using standards, as well as gain important insight into public policy challenges which could potentially be solved by the development of International Standards.

This document will provide policy makers with the information needed to start a conversation with their national member bodies, to whom they can address questions about their particular

needs and circumstances. With this in mind, the IEC and ISO invite policy makers to engage in dialogue with their national member bodies in each organization, and vice versa. The lists of IEC or ISO national member bodies are available at www.iec.ch/members or www.iso.org/iso/iso_members respectively.

Note on terminology: In this document, standards developed by the IEC and ISO are referenced as “International Standards”. Other, more general, references to “standards” or “International Standards” conform to the definitions of these terms in *ISO/IEC Guide 2, Standardization and related activities – general vocabulary*.

Introduction

What is an IEC or ISO International Standard ?

IEC and ISO International Standards represent global consensus on a solution to a particular issue. They provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are safe to use and fit for their purpose. International Standards offer strategic answers for businesses in their attempt to decrease costs, increase productivity, access new markets, and facilitate freer and fairer global trade. They also embody universally agreed procedure or practice, drawing on the experience and expertise of all interested parties. Whenever possible, requirements in IEC and ISO International Standards are expressed in terms of performance rather than design or descriptive characteristics.

What makes IEC and ISO International Standards useful to public policymakers ?

International Standards and public policy often share similar objectives – for example, enhancing economic competitiveness and efficiency, and facilitating international trade. International Standards are useful tools for policy makers for a number of reasons:

Firstly, the use of IEC and ISO International Standards is **consistent with the obligations of countries that are members of the WTO** to reduce technical barriers to trade. Public authorities can therefore be confident that they are meeting these international obligations when using IEC and ISO International Standards and that the standards they are using are globally relevant¹. In today's globalised world where public policies can no longer be developed and implemented in isolation, International Standards also offer a means of communication and cooperation across borders, making them increasingly useful tools in the policy maker's kit.

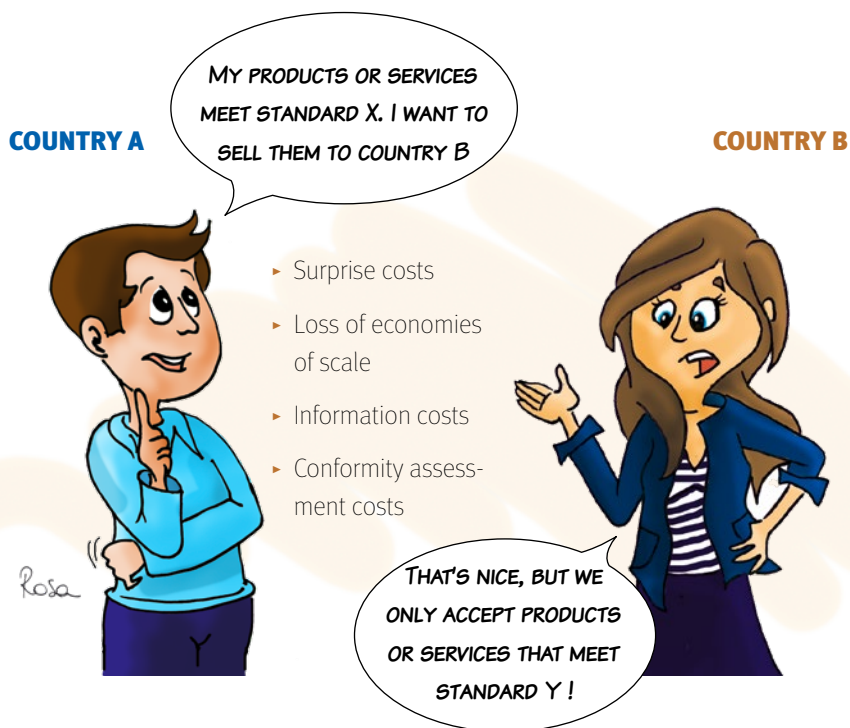


Figure 1 – International Standards contribute to eliminating these inefficiencies in trade

1) **Annex 4** and paragraph 20 of the 2nd triennial review of the WTO/TBT Agreement

Secondly, International Standards, by their very nature, are **powerful instruments of governance** because of the effects their use can have on goods, services and on quality of life. These effects are evident whether International Standards are employed by the private sector or by the public sector. In the private sector, they create market incentives for actors to follow internationally accepted practices by applying competitive pressure (while allowing fair competition) and also encourage innovation and growth by fostering technological development. In the public sector, they can enable greater transparency and competition in public procurement and provide essential requirements for industry via their referencing into regulations and laws. In either context, International Standards are efficient and cost-effective tools – they can provide detailed safety, process or performance requirements in the policy guidance or legislation without making it unnecessarily long and complicating it with technical information.

And finally, there are a number of important **parallels between good policy-making practice and good standardization practice**, which has led to the use and referencing of International Standards becoming widely and increasingly considered as forming *part of* good regulatory practice and good public governance. For example, common characteristics of good policy-making and good standardization practice include: openness, transparency, effectiveness, global relevance, consensus, and input from expert opinion, with a key criterion for both being that the policy/standard responds to a *verified need*. Ensuring stakeholder buy-in is also an essential part of good policy making practice. The IEC and ISO emphasize the importance of stakeholder engagement and believe that it is important that stakeholders be able to express their needs in standards development efforts related to public policy. IEC and ISO International Standards already have the buy-in of a wide range of stakeholders, including governments, industry, consumers, and more, which can help guarantee a high level of acceptance for the policy guidance or legislation.

**Good
policy making
practice**

**Good
standardization
practice**



Figure 2 – *Common characteristics of good policy-making practice and good standardization practice*

1 Advantages and benefits of using and referencing IEC and ISO International Standards in public policy

Public policy makers have multiple options when looking for a solution to a particular public issue. They have the option to develop their own guidance “in-house”, which can then be referenced in policy. However, this option can be very expensive in terms of the time, money and expertise required, and may also inadvertently create trade barriers, as the use of unique “in-house” solutions by a country could effectively restrict access to its markets. Policy makers also have the choice of using standards as a solution, which can save them considerable time and money. Of course, IEC and ISO International Standards are not the only standards they have to choose from. In this section, we explore the benefits of choosing IEC and ISO International Standards.

1.1 The IEC and ISO standards development process

IEC and ISO International Standards are developed using a process that values inclusiveness and is responsive to changing dynamics.

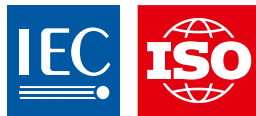
International Standards are developed in a **multi-stakeholder environment** which ensures that a wide range of technical views are represented, including those relating to social and economic interests. Different perspectives come from the national level, through a network of liaisons and cooperation with international governmental and non-governmental organizations. Because of this robust process, IEC and ISO International Standards reflect a double-layer of consensus – among experts from market players

at the drafting stages of the standards, and among countries at the formal commenting and voting stages of the standards.

As the needs of stakeholders evolve, so do IEC and ISO processes, which are constantly being fine-tuned to be simpler and more efficient for those who take part in the development; faster in order to get standards to market quickly for the users; globally relevant for the public and private sectors and compliant with the six core WTO/TBT principles for developing International Standards (see **section 2**).

1.2 The IEC and ISO brands ensure reliability and foster trust

The IEC was founded in 1906 and ISO in 1947. Both organizations therefore have a long history of producing International Standards, their brands are recognized in many countries around the world and for standards users, customers and consumers, **the IEC and ISO logos mean quality, confidence, reliability, trust and safety.**



A few reasons why this sense of reliability and trust is well-earned:

- IEC and ISO develop International Standards only if there is an established – and international – market need
- Established procedures are in place to ensure that the thousands of standards available avoid duplication and conflict with each other
- The IEC and ISO standards development process provides access to all relevant parties, allowing them to participate in the discussions and influence outcomes. Because their

funding comes from fees paid by national members and sales of standards, the IEC and ISO can keep participation costs low for stakeholders (neither organization charges fees to participate in standards development). This encourages broader participation and mitigates any risk of undue influence associated with sponsorship or direct funding from external parties

- Standards users can have confidence that IEC and ISO International Standards are correct and up-to-date. Regular review and, if necessary, revision of standards ensures that they evolve along with the state-of-the-art in the relevant discipline

For policy makers, in particular, there is an additional reason to trust in IEC and ISO International Standards. To guarantee that IEC and ISO International Standards can be effectively used by public policy makers, IEC and ISO members are responsible for ensuring that national governments, including their trade representatives, are aware of the IEC and ISO's portfolios, are informed about the IEC and ISO as venues for standards development, and are engaged in IEC and ISO standards development whenever appropriate. Furthermore, when IEC or ISO International Standards are anticipated to support a public policy initiative, the relationship between the standard(s) and the public policy initiative(s) should be clearly understood among all concerned parties, and the participation of the public authorities in the standards development process should occur as early as possible.²⁾

2) ISO has established a set of principles to guide its committees developing standards related to or supporting public policy initiatives. These principles are found in **Annex SO** of the Consolidated ISO Supplement to the ISO/IEC Directives Part 1: www.iso.org/sites/directives/directives.html#toc_marker-79

1.3 Global participation and applicability

International Standards from the IEC and ISO have the advantage of a **broad geographical reach** as the membership of these two organizations is made up of countries from all over the world, covering around 97% of the world's population. IEC and ISO members have the right to select the specific committees and standards for which they will participate in development, based on their national interests. The IEC, ISO and their respective members also actively encourage the involvement of developing countries, working with them to increase their capacity to participate in the standards development process, to help improve awareness of the benefits of International Standards and to help them adopt and use IEC and ISO International Standards in their country. Many countries and companies around the globe choose to recognize, accept and implement IEC and ISO International Standards, judging them to be beneficial for their commercial or national purposes. This makes IEC and ISO International Standards globally applicable for trade purposes.





1.4 Additional benefits and advantages of using IEC and ISO International Standards

IEC and ISO International Standards:

- ▶ Offer the same level of consumer protection whether applied in a mature or an evolving economy
- ▶ Allow products to be supplied and used across different markets, reducing market inefficiencies, facilitating regulatory compliance and enhancing the market access opportunities for small enterprises
- ▶ Reflect the globally agreed best practice and serve as a vehicle for the dissemination of new technologies and innovative practices
- ▶ Can become national standards (with or without modification) after a national public enquiry process has been carried out, which may reduce the need for the policy maker to hold further consultations when referencing the national standard in policy
- ▶ Are used for conformity assessment to enhance confidence in products, systems, processes, services or personnel

2 World trade and International Standards

One of the main benefits of standards is that they facilitate trade. The World Trade Organization (WTO) is the inter-governmental organization that deals with the global rules of trade between nations. Its Agreement on Technical Barriers to Trade (the WTO/TBT Agreement) exists to ensure that national regulations, standards, and procedures for assessment of conformity do not create unnecessary obstacles to international trade³⁾. One way to do this is to promote harmonization – which is the establishment, recognition and application of common measures by different WTO members. In this context, the WTO/TBT Agreement recognizes the contribution International Standards can make toward improving the efficiency of production and international trade.

3) For further information, see: www.wto.org/english/res_e/publications_e/tbttotrade_e.pdf

International standards are also being discussed in other areas of WTO work: trade in services (GATS), food safety (SPS) and trade and the environment (CTE). More information on each of these can be found on the WTO Website:

www.wto.org



The use of International Standards can play a key role in harmonization of regulations. This is expressed in particular in two requirements of the WTO/TBT Agreement⁴⁾ :

- WTO members should use International Standards, guides and recommendations, or relevant parts of them, when they exist, as a basis for their national technical regulations and conformity assessment procedures
- WTO members should play a full part, within the limits of their resources, in the preparation of International Standards, guides and recommendations by participating in International Standardizing bodies

4) WTO Agreement on Technical Barriers to Trade : Article 2, Preparation, Adoption and Application of Technical Regulations by Central Government Bodies ; Article 5, Procedures for Assessment of Conformity by Central Government Bodies.

WTO members in the TBT Committee – the WTO body tasked with implementing the TBT Agreement – have agreed on six core principles that should guide International Standards development: transparency; openness; impartiality and consensus; effectiveness and relevance; coherence; and addressing the concerns of developing countries⁵⁾. This set of principles is complemented by the procedures set out in **Annex 3** of the WTO/TBT Agreement – the *Code of good practice for the preparation, adoption and application of standards*.⁶⁾

The fact that the IEC and ISO follow these six core principles and that the majority of IEC and ISO members also follow the Code of good practice means that public policy makers can have confidence when using IEC and ISO International Standards to support their policy initiatives that they are not creating unnecessary technical barriers to trade.

5) 2nd Triennial review of the operation and implementation of the Agreement on Technical Barriers to Trade, **Annex 4**, Decision of the committee on principles for the development of International Standards, guides and recommendations with relation to Articles 2, 5 and **Annex 3** of the Agreement, G/TBT/9, 13 November 2000.

6) **Annex 3** of the WTO/TBT Agreement – the *Code of good practice for the preparation, adoption and application of standards*, www.wto.org/english/docs_e/legal_e/17-tbt_e.htm#annexIII

3 How can IEC and ISO International Standards be used to support public policy?

In this document, we define public policy as any actions taken by government to address public issues. These actions are based on a system of values and norms and can be **legislative** or **non-legislative** – IEC and ISO International Standards can be used to support either kind of action (see **table 1**).

Legislative actions	Non-legislative actions
<ul style="list-style-type: none">▶ Laws (or Acts of Parliament)▶ Technical regulations (which support the requirements of laws) e.g. relating to public responsibilities such as safety, security, health, social protection or the environment▶ Other actions include rules, notices, orders, determinations, and warrants.	<ul style="list-style-type: none">▶ Funding priorities▶ Incentive systems▶ Awareness campaigns▶ Public procurement▶ Codes of conduct

Table 1 – *Examples of types of policy initiatives where IEC and ISO International Standards can provide support*

When people think about standards and public policy, they often think first and foremost about standards being used and referenced in technical regulations (i.e. supporting a legislative action). This is indeed one of the main ways that standards are used by policy makers and we will cover the various methods of using and referencing standards in technical regulations in **section 4**. However, IEC and ISO International Standards can also support government policy actions beyond legislation.

Here are a few examples of International Standards being successfully used to support non-legislative actions :





Figure 3 – *International Standards can provide support to many kinds of policy actions*

- ▶ The Global Conference on Rural Energy Access organized by **UN DESA** (United Nations Department of Economic and Social Affairs), in collaboration with **UN-Energy**, **UNECA** (United Nations Economic Commission for Africa) and **UN SE4ALL** in Addis Ababa, Ethiopia, 4-6 December 2013, made the recommendation that “Technical standards for energy service delivery and energy systems appropriate for rural areas be developed to ensure quality and efficiency”. This highlights the need for IEC commitment to support the SE4ALL initiative by facilitating access to sustainable energy standards for various stakeholders in developing countries. The IEC is providing access to **IEC Technical Specification 62257 series**, including **IEC TS 62257-9-5**, a publication on a selection of stand-alone

lighting kits for rural electrification, and also the IEC International Standards that are referred to in the series.

- ▶ In its renewed EU strategy 2011-14 for Corporate Social Responsibility (CSR), the European Commission stated that it would take account of ISO 26000, *Guidance on social responsibility*, in its own operations and invited all large European enterprises to take account of this standard (or two alternative principle-based guidance documents)⁷⁾ when developing their approaches to CSR.
- ▶ The Canadian government offers grants for industrial organizations that adopt systems and processes to improve energy performance. The funding covers costs towards accreditation, including development of energy baseline, energy use assessment, energy performance monitoring and reporting, professional fees and training (50 % of eligible costs up to CAD 25 0000 in grant funding). To be eligible companies must implement the standard CAN/CSA ISO 50001 on energy management systems and submit energy performance improvement plan to NR CAN.

International Standards can also help public policy makers and their main contractors align their **procurement systems with international best practice and to make them fair, equitable, transparent, competitive and cost effective.**

Procurement is the process through which contracts are created, managed and fulfilled. It involves all the steps from the identification of the project or products to be procured, to soliciting and evaluating tender offers, to awarding and administering contracts and confirming compliance with requirements. Because governments are major buyers of goods and services, using International Standards in public procurement is another powerful way for policy makers to promote specific policy goals or the use of certain requirements in an economy.

7) The others are the UN Global Compact and the OECD's Guidelines for multinational enterprises. See **COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, A renewed EU strategy 2011-14 for Corporate Social Responsibility.**

Here are a few examples of standards being used to support public procurement :

- ▶ The Japanese government's 'Basic Policy for the Promotion of Procurement of Eco-Friendly Goods and Services' was established to promote comprehensive and planned procurement of materials, components, products and services with low environmental impact by governments, enterprises, and citizens. This policy defines 267 items as eco-friendly goods and, as of 2014, it references 72 JIS standards (including IEC and ISO International Standards that have been nationally adopted as JIS standards) as test and product standards



- ▶ The Australasian Procurement and Construction Council Inc. (APCC) is the main council whose members are responsible for procurement, construction and asset management policy for the Australian, State and Territory Governments and the New Zealand Government
- ▶ A technical group under the umbrella of the APCC coordinates an agenda of technical issues relevant to infrastructure procurement, including standard technical specifications. These specifications are prepared for use by government agencies across Australia and are considered priority specifications to ensure safety and longevity for public infrastructure. The specifications are used extensively across Australia and reference ISO, ISO/IEC and other standards (see www.apcc.gov.au). By specifying these standards it paves the way for other public and private construction contracts to also specify products that meet these specifications thereby promoting the use of the standards
- ▶ In 2013, the APCC released its **Sustainable Procurement Practice Note**, which provides practical step by step guidance and advice for government procurement practitioners on the integration of sustainability objectives in to the procurement process. This guidance includes, as examples, references to standards such as ISO 9001 on quality management, ISO 31000 on risk management, ISO 26000 on social responsibility, ISO 14000 on environmental management, and many more

4 Methods of using and referencing IEC and ISO International Standards to support regulations

4.1 General considerations

Once the decision to use an IEC or ISO International Standard in support of a regulation has been taken, the most appropriate method of making the reference in the legal text will need to be chosen. This section highlights some commonly used methods of using and referencing IEC and ISO International Standards in regulation. These methods are available to regulatory activity at the national, regional or international levels.

The main considerations for policy makers are:

- Should the use of the IEC or ISO International Standard be mandatory (providing the only solution) or voluntary (providing one possible solution)?
- What level of checks should be put in place to ensure the standard is suitable for use and addresses the needs?
- Will the reference be to the whole standard or selected parts of it (ie. only to certain clauses and subclauses)?
- How will the regulation be kept up-to-date if the IEC and ISO International Standards are revised?

4.2 Direct references to specific standards in the legal text

Direct referencing means that the reference of a specific standard is directly quoted within a legal text using its identification number and title. This method often supports the mandatory use of a standard, so careful wording of the regulation will be

necessary if the regulator wants the use of the IEC or ISO International Standard to remain optional (i.e. as one of a number of solutions to help comply with the regulation).

By directly referencing standards in this way, regulators avoid reproduction of the standard in the legal text and eliminate the need to obtain permission for the use of copyright (see also **section 6**). Another advantage is that certain parts, or even single clauses of a standard, can be referenced where only a small part of a standard supports a regulation. There are two forms of direct referencing : dated and undated



4.2.1 Direct dated references

Direct dated referencing is when the number and title of a standard is referenced and used with its date of publication. This means

that only a particular edition of a standard is used. This can help provide legal certainty by indicating the exact technical solution that may be used to comply with the regulation. Such legal certainty can help give assurance to the regulator and clarity for those who have to comply with the law. This is the most restrictive reference and is used when the objectives of future amendments and editions of a specific standard are uncertain.

As noted previously, IEC and ISO International Standards are reviewed on a regular basis to ensure they keep up to date with technological developments. It is therefore important when using dated references in regulations that any revisions of, or amendments to, IEC or ISO International Standards are taken into consideration by the relevant authority. The legal text will then need to be changed to note any amendments to, or revisions of, the standard.

References to specific clauses or subclauses, tables, figures or annexes of a standard should always be dated. This is because any amendment to, or revision of, a standard could lead to an alteration of its internal numbering.

In areas where there is continuous and rapid technical development, and therefore a similar rapid development of the standards, direct dated references in the regulation could become obsolete. Other methods of referencing standards may be appropriate in such cases.

While 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.

Example:

- ▶ The information security management system shall conform to ISO/IEC XXXX: 2013, *TITLE*

Example:

- ▶ The information security management system shall conform to ISO/IEC XXXX: 2013 (as amended), *TITLE*

4.2.2 Direct undated references

In the case of an undated reference, the regulation quotes only the number and title of a specific standard and not the date. This method is therefore more flexible. In the case of a revision of a referenced standard, the regulation itself does not need to be adapted and the reference automatically corresponds to the latest edition of the standard and therefore the globally agreed best practice within the sector. In other words, the regulation allows the use of subsequent revised editions of the same standard.

However, the use of an 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 (see 4.2.1).

As with dated references, any amendments to, or revisions of, the standard should be tracked. In such instances, regulatory authorities could add the phrase “latest edition of”, the aim being to permit them to respond easily and quickly to technical changes.

Example:

- ▶ The information security management system shall conform to the latest edition of ISO/IEC XXXX, *TITLE*

4.3 Indirect references to the use of IEC and ISO International Standards

Indirect referencing involves recognizing and registering standards on an official information source external to the regulatory text. In this way, a list of standards deemed suitable by the regulator is compiled and published by an official process which the regulator controls. If a standard is revised or amended, no change is necessary to the legal text, only to the list. The list of standards may also include the dates of publication of the standards so as to ensure the legal certainty of a dated reference and to indicate when a particular edition is valid.

Such a list of recognized references needs to be kept up to date and made easily available to users through a website or other means. This model has been applied in Europe where it is referred to as the “New Approach” (see www.newapproach.org).

Example:

- ▶ Where the product complies with the relevant IEC or ISO International 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

Example:

- ▶ A product shall be presumed safe, as far as the risks are concerned, when it conforms to voluntary IEC and ISO International Standards, the references of which have been registered on [refer to relevant official listing here]



5 Other considerations when choosing to use IEC and ISO International Standards to support public policy

5.1 Ensuring no delegation of legislative responsibility

Using IEC and ISO International Standards for technical regulation does not imply that regulators 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. Referencing IEC and ISO International Standards in technical regulation simply means that regulators make use of the existing consensus at international level.

The IEC and ISO processes benefit from a broad range of expertise and all standards are subjected to a period of public consultation at the national level before publication. This helps to ensure that they represent viable solutions which are the result of broad consultation. However, when a standard is to be used for regulatory purposes, the regulator should ensure that it is fit for that regulatory purpose. In particular, this will depend on the risks associated with the product, the national/regional situation and the purpose of the regulation.



5.2 Maintenance procedures

IEC and ISO technical committees keep their standards up to date to reflect best practice within the sector. The committees periodically review standards to ensure that they remain current and abreast of technology and practice.

Public policy makers can develop procedures to assist them in monitoring the status of standards referenced in policy. This monitoring could include the assessment of updates, amendments and withdrawals so that the regulatory authority can take appropriate action. There are various ways in which policy makers can be kept informed of such changes, for example participation in the relevant committee or making arrangements with the relevant IEC or ISO national member.

5.3 Conformity assessment

Conformity assessment is the means of determining whether products, services, processes, systems and persons, meet specified requirements. Depending on the type of product system, or person and the criteria being examined, public policy makers and specifically regulators may require that conformity assessment procedures be carried out by the supplier, the purchaser, the regulator or by an independent conformity assessment body. Public policies may specify which of these parties will carry out the conformity assessment activity appropriate to the level of risk involved. Conformity assessment can involve certification, inspection and/or the testing of a product system, or person.

Conformity assessment activities can be undertaken in various forms:

- **First-party conformity assessment:** when a person or an organization that provides a product makes a supplier's declaration (sometimes referred to as a self-declaration) of conformity, supported by test results from its own laboratory

or from an external laboratory that tests the supplier's products to required standards

- Second-party conformity assessment: when a person or an organization having a user interest, such as a procurement body, witnesses testing or performs other verification to standards directly, either on prototype or through market surveillance, or both
- Third-party conformity assessment: when an independent conformity assessment body certifies, inspects and/or tests products or systems to standards. The results are proprietary to the conformity assessment body and the supplier. However, they may be provided by the supplier to the authority having jurisdiction, when necessary

In some cases, policy makers may wish to have a further level of confidence in conformity assessment results. This may involve the particular technical regulation requiring that the competence of conformity assessment bodies be formally recognized. Such competence may be demonstrated, amongst other means, through accreditation by an independent accreditation body — often established by the government.

A regulatory authority may be considered a third-party when it undertakes conformity assessment activities itself, or it may delegate the conformity assessment activity to an independent third party. It is recommended that regulators acting as a third party use the relevant ISO/CASCO standard for the specific conformity assessment activity.

An alternative option is to refer to global conformity assessment systems (serving industries such as automotive, food, rail and electrotechnology), which provide:

- Consistency of testing and certification practises
- Consistency of information regarding conformity assessment status and related information
- Reduced time and costs for accessing markets

- Smaller economies access to latest developments, eliminating the cost burden of achieving local approvals for suppliers making commercial decisions to supply a market of limited demand

One example of this approach being used comes from the UNECE Common Regulatory Framework for equipment used in environments with an explosive atmosphere⁸⁾ which recommends that regulators use IEC and ISO International Standards supported by conformity assessment schemes such as the IECEX. Approaches such as this save the regulators the cost of establishing and maintaining their own conformity assessment operations. At the same time, many of these international conformity assessment systems do provide for stakeholder involvement, including policy makers, in their day to day operation. The IEC operates four international Conformity Assessment Systems, each covering a dedicated segment of electrotechnology (IECEE for electrical and electronic equipment, IECEX for explosive atmospheres, IECQ for electronic components, and IECRE for

8) www.iec.ch/about/brochures/conformity_assessment.htm#iecex-unece



renewable energy). More information on these systems can be found here: www.iec.ch/conformity/.

The IEC and ISO have developed a series of International Standards and guides (ISO/CASCO Toolbox) to ensure the international comparability and credibility of conformity assessment. The voluntary criteria these documents contain represent an international consensus on what constitutes best practice in conformity assessment. Using these documents means international compatibility is fostered and technical barriers to trade can be avoided.

Regulators who need to include conformity assessment requirements in their technical regulations can use these documents as elements for the specific requirements in those regulations. The ISO Committee on conformity assessment (ISO/CASCO) developed an online tool that introduces the basics of conformity assessment, the ISO/CASCO toolbox and explains why and how conformity assessment can be used by regulators. This tool contains a list of joint ISO/IEC conformity assessment documents as well as concrete examples, showing how they have been used in various domains. The online tool is available from: www.iso.org/cascoregulators. The following URL provides further information and a complete, regularly updated list of conformity assessment documents: www.iso.org/iso/casco

5.4 Market surveillance

Market surveillance is a key component of the safety and quality infrastructure of a country. This may be accomplished through pre-market assessment and approval systems, or post-market surveillance programmes. IEC and ISO International Standards can facilitate market surveillance by providing a common, well-known set of requirements which are known to all the market participants.

With pre-market assessment, policy makers have the opportunity to assess in advance the data provided by the party

responsible for the product and to determine whether or not the product complies with the standards or conformity assessment procedures referenced in a regulation.

Post-market surveillance can be carried out through a variety of mechanisms. These could include:

- Inspection and testing of products on the market
- Inspection of the requested marking on products and/or accompanying documents
- Validation of conformity assessment procedures followed by the supplier
- Verification of quality systems of the supplier's manufacturing processes
- Examination of the supplier's electronic and paper records
- Mandatory reporting of adverse incidents to the regulators
- Corrective actions for non-conforming products

Some international conformity assessment systems include a market surveillance component either by directly sampling from the market or by way of surveillance at the point of product release from the supplier.

A guide to good practice in market surveillance was developed by ISO and is available on **the ISO Website**.

6 Accessibility of IEC and ISO International Standards

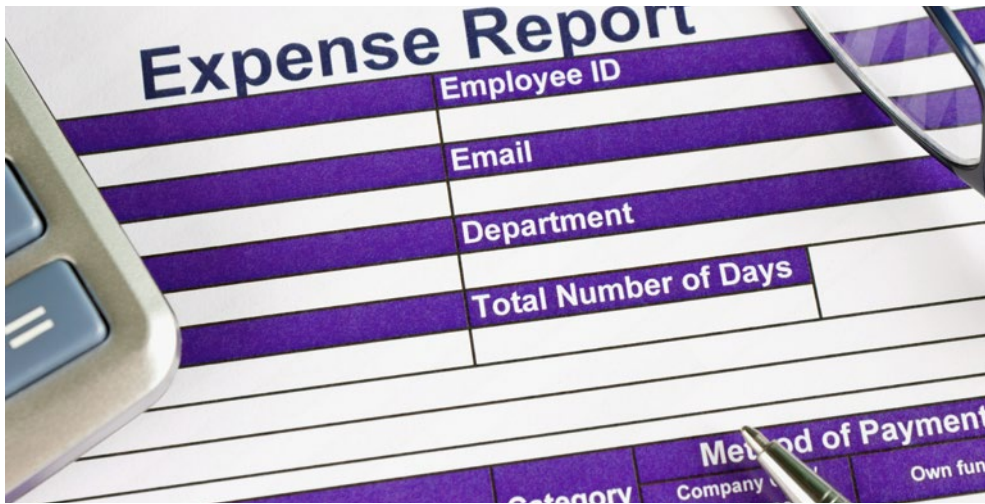
Transparency – a key principle of both good policy making and good standardization practice – dictates that the content of legislations and regulations, which may include references to standards, should be **easily accessible**. This is a principle widely accepted by IEC, ISO and their members, and is embodied in the WTO TBT Agreement and the 2002 Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations.

However, being easily accessible does not imply that standards should be made available for free. Moreover, IEC and ISO assert and maintain copyright in their International Standards at all times.

Under the IEC and ISO business model, the sale of standards guarantees that the system is financed in a fair manner, where the user who wants to benefit from a standard pays to use it. This model of financing keeps participation costs down, allows for the broadest possible stakeholder participation and, last but not least, ensures that IEC and ISO International Standards are developed in a neutral environment without undue influence from individual sponsors. The IEC and ISO are constantly looking at new ways to improve access to standards, while ensuring that the costs of developing them can be recovered. These costs are outlined below.

6.1 The costs of developing standards

IEC and ISO International Standards have an added value that is unique. This value comes from the long experience of the two organizations in international consensus building and the transparent and highly inclusive nature of their standards development processes. IEC and ISO members from all around the globe mobilize relevant stakeholders in their respective countries and



organize national enquiries to ensure appropriate public and market feedback as a precondition of publication. However, as with any product of value, there are costs involved in the development of standards. These costs are comprised of three elements:

- First, the cost in time, travel and other expenses of the thousands of experts working in technical committees. These costs are borne by the organizations that employ the experts, or by the individual experts themselves
- Second, the costs of running the secretariats of the technical committees, hosting meetings, providing and supporting the national infrastructure for physical and electronic work, gathering the views of national stakeholders, conducting national enquiries, agreeing and submitting national positions and distributing the published standards. These costs are borne by the IEC and ISO members, who may themselves be publically funded, privately funded, or a combination of both

- Third, the costs incurred by the IEC Central Office and the ISO Central Secretariat to maintain a sophisticated infrastructure of programme management, document distribution and tools for committee management, voting and collaborative working, as well as supplying information and providing procedural, editorial and publishing expertise to their committee experts and national members. These costs are borne by the IEC/CO and ISO/CS, from the fees paid by members (which give them the right to participate in the International Standardization process, to use, nationally adopt and sell the International Standards produced) and the revenue from sales of standards

It is through the sale of standards that the IEC, ISO and their members recover a large part of the costs they incur.



7 National policies on the use of standards to support public policy

As the benefits of using standards to support public policy have become more prevalent, major economies of the world have developed policies to actively encourage their use.

In some countries IEC or ISO International Standards may be used or referenced directly in regulations and other kinds of policy documents, based on an assessment of their suitability and without the need for them to be recognized as national standards in that country. However, in other countries or regions, adoption may be an important and *sometimes necessary* element for the use of IEC or ISO International Standards. What is common to both approaches is that the IEC or ISO International Standards have been assessed and judged by national stakeholders to suit needs and be fit for purpose in that country or region.

7.1 National and regional adoptions

IEC and ISO International Standards, as well as being stand-alone documents (with the designation IEC and ISO), can be formally adopted as national or regional standards and given designations combined with an IEC or ISO reference⁹⁾. National and regional adoptions of an IEC or ISO International Standard may involve a separate consultation process at national or regional level.

Example:

IEC 60601-1, *Medical electrical equipment*, is:

- ▶ adopted as EN 60601-1 in Europe

9) See ISO/IEC Guide 21-1, *Regional or national adoption of International Standards and other International Deliverables – Part 1: Adoption of International Standards*

- ▶ adopted as KS C IEC 60601-1 in the Republic of Korea
- ▶ adopted as ГОСТ МЭК 60601-1 in Russia
- ▶ adopted as ANSI/AAMI 60601-1 in the USA

ISO 14971, *Medical devices — Application of risk management to medical devices*, is:

- ▶ adopted as ANSI/AAMI/ISO 14971 in the USA
- ▶ adopted as EN ISO 14971 in Europe
- ▶ adopted as JIS T 14971 in Japan

7.2 Examples of national policies

Brazil

Regulation in Brazil was once an exclusively governmental domain, seen as a way for the government to impose changes of behaviour on the private sector via compulsory measures. The last several decades, however, have seen a dramatic change in perspective, with a wide variety of actors outside the public sector now playing a role in regulatory governance. The standardization practices and conformity assessment conducted by the private sector are now acknowledged by public authorities as useful tools and the adoption of normative documents as an alternative that offers a cost-effective way to achieve political goals. By using standards, public authorities obtain consensus and natural adhesion to achieve their political goals.

More details on the national policies summarized on next pages, including many more examples of references to IEC and ISO International Standards in public policies, can be found on www.iso.org/sites/policy/national_examples.html.



In Brazil, standards are seen as important tools to support legislation in many sectors and at all levels of government. In many cases, standards are fully incorporated into government regulations and have the same weight as law. The Brazilian National Oil, Natural Gas and Biofuel Agency (ANP) uses standards to help in the regulation of the sector when it comes to oil extraction, transport and safety of operations. Technical standards are also commonly used by the National Metrology, Quality and Technology Institute (INMETRO) as the basis for developing their technical regulations regarding health care products, adaptors of electrical cables, plugs and sockets, helmets for drivers and passengers of motorcycles and many other products and safety processes.

In addition, there are many other examples of standards serving as a basis for technical regulation in Brazil for example, related to health care agencies, pollutant emissions by vehicles, and performance of household appliances.

Regulation

Instrução Normativa DC/ANVISA No. 3 de 21/06/2011 – Establishes the list of technical standards whose requirements must be met for certification of compliance within the Brazilian System of Conformity Assessment (SBAC), equipment system under Health Surveillance, under Resolution DC/ANVISA No. 27 of 2011

Extract from the technical regulation

“[...] The equivalent of this standard within IEC, being IEC 60601-1 Ed. 3.0 b, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*, may be accepted in the certification processes, replacing the Brazilian version in place. [...]”
The Standards contained in the series ABNT NBR IEC 60601, listed, as well as its amendments, will be compulsory to all equipments under regimen of the Health Surveillance that are within its respective fields of application, considering the following situations



Canada

In accordance with the Government of Canada's **Cabinet Directive on Regulatory Management**, federal government departments and agencies are responsible for assessing the effectiveness and appropriateness of regulatory and non-regulatory instruments for achieving public policy objectives.

As part of the process of considering how to best address a public policy issue, Canadian federal departments and agencies must:

- Consider potential alternatives to regulation, including **voluntary standards**, information disclosure, and guidelines, and whether outcome or performance based approaches would be suitable
- Make use of all or parts of relevant national or **International Standards**, guidelines, and recommendations as a basis for technical regulations and for conformity assessment procedures when they fulfill intended policy objectives

IEC and ISO International Standards may be referenced in Canadian regulations without first being nationally adopted. For example :

Regulation

Organic Products Regulations, 2009 (SOR/2009-176) (Canadian Food Inspection Agency)

Extract from the technical regulation

s.9(1) : Subject to subsection (2), on the recommendation made in a report of the conformity verification body, the Agency shall suspend the accreditation of a certification body if the certification body has not complied with any provision of the Act, these Regulations or ISO/IEC 17065



China

One of the main forms of technical regulation in China is via the use of mandatory standards. The Standardization Law of the People's Republic of China states that certain standards categories such as pharmaceuticals, occupational health and safety, transportation, environmental protection and engineering construction (to name a few) can be **mandatory** standards depending on the risk that the product or activity poses. These standards can therefore have the characteristics of technical regulations. In addition, the use of standards becomes mandatory if they are quoted in regulatory documents such as legislative texts and departmental regulations.

When choosing which standard to reference, the WTO/TBT principles are applied. This means that if an International Standard is available and it is considered to be suitable for China's situation, efforts will be made to adopt the International Standard. At the time of writing this brochure, about 74 % of China's standards are developed based on related International Standards.

Regulation

Safety Production Law of the People's Republic of China

Extract from the technical regulation – indirect reference

Chapter II, Clause 29: The design, manufacturing, installation, use,



testing and inspection, maintenance, renovation and discard of safety equipment should comply with national or industrial standards

Regulation

The Order of the State administration of work safety of the People's Republic of China Implementation methods for safety production license for fireworks and firecracker production enterprises

Extract from the technical regulation – direct reference

Clause 11 : The variety, category, level, specification, quality, packaging and mark of products of the enterprises should conform to stipulations of national standards and industrial standards, such as Safety and quality for fireworks (GB10631)

Europe (the European Union)

European standardization is an integral part of European Union single market and is viewed as a tool to increase the competitiveness of enterprises and to remove barriers to trade at the international level. The European Union uses standards to support both its legislation and policies. The primary use of standards is as part of a co-regulatory model known since the 1980s as the 'New Approach' to technical harmonization. This has been updated and refined in the 'New Legislative Framework' from 2008.

The European Commission requests the European Standardization Organizations (ESOs) – the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI) – to develop and adopt European standards, referred to as 'harmonized standards', by issuing a standardization request ('mandate'). The policies of the ESOs are to use International Standards (such as IEC, ISO and ITU standards) wherever they exist and are suitable. As a result, more than 70% of CENELEC's portfolio of harmonized standards



are identical to or based on IEC standards and 32% of CEN's are identical to ISO standards.

Once the references are published, products manufactured in accordance with the harmonized standard receive a presumption of conformity with the relevant essential requirements of the legislation. The presumption of conformity is the crucial element in this co-regulatory approach that links the public interest (i.e. protecting public health and safety, consumer and environmental protection) and the interest of private business. Manufacturers are nevertheless free to choose any other technical solution that can demonstrate compliance with the essential requirements of the law, as long as they follow the appropriate conformity assessment model. Compliance with standards is therefore still voluntary, even though their use brings advantages in terms of simplicity and cost effectiveness.

Regulation

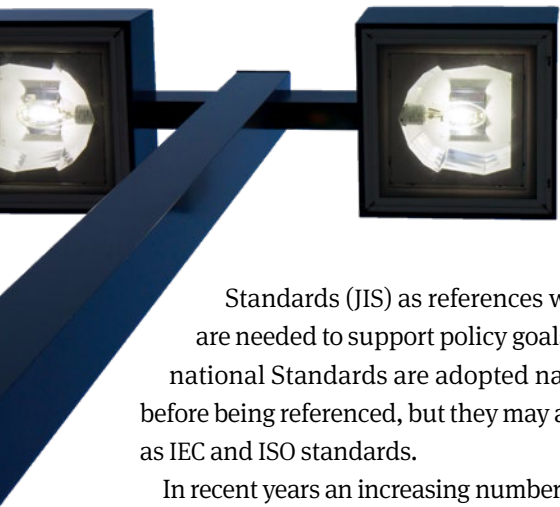
Directive 2009/48/EC, *Safety of Toys* (Note: this is an example of a European 'New Approach Directive' that meets the requirements of the New Legislative Framework.)

Extract from the technical regulation

Article 13 of the Directive states that "Toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the [essential requirements of the Directive]".

Lists of the harmonised standards that have been published in the Official Journal of the European Union are available via the Harmonised standards (HAS) database, see for example, http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/toys/index_en.htm





Japan

The Japanese government encourages the use of voluntary Japanese Industrial

Standards (JIS) as references when technical standards are needed to support policy goals. Many IEC and ISO International Standards are adopted nationally as JIS standards before being referenced, but they may also be referenced directly as IEC and ISO standards.

In recent years an increasing number of JIS standards are being used, as more and more regulations incorporate performance-based requirements. Industrial Standardization Law stipulates that JIS standards should be followed when national governments and local governments set technical standards related to mining and manufacturing, or when they create specifications for their procurement.

As a member of the WTO, the Japanese government is working to harmonize JIS standards with corresponding International Standards to the greatest degree possible. Of the over 10,000 JIS standards currently existing, 5,700 have corresponding International Standards, and 5,600 of these are harmonized with their corresponding International Standards.

Regulation

Electrical Appliance and Material Safety Law – Technical requirements pursuant to the provisions of the Ministerial Ordinance Specifying Technical Requirements for Electrical Appliances and Materials

Extract from the technical regulation

The harmonized standards are stipulated in Appendix Table 12 (see **Table 2**) of the Interpretation of the Ministerial Ordinance Specifying Technical Standards for Electrical Appliances and Materials, and the Technical Requirements pertinent to each of the relevant products shall be applied

Technical requirements for electrical appliances and materials			Notes
Number	Title	Text	
J60068-2-2 (H14)	Basic environmental testing procedures, Part 2: Tests, Test B: Dry heat	JIS C 0021:1995	Corresponding to IEC 60068-2-2 (1974), Amd. N°2 (1994)
J60068-2-3 (H14)	Basic environmental testing procedures, Part 2: Tests, Test C: Damp heat, steady state	JIS C 0022:1987	Corresponding to IEC 60068-2-3 (1969)

Table 2 – Appendix of **Table 12** of the Ministerial ordinance specifying technical requirements for electrical appliances and materials

Mexico

The Federal Law on Metrology and Standardization is the cornerstone of the Mexican Standardization and Conformity Assessment System, providing guidelines for the development of Mexican Mandatory Standards (NOM), Mexican Standards and (NMX) and Referenced Standards (NRF).

At the Federal level, Article 55 mentions that “without prejudice to the provisions of the relevant law, the goods or services purchased, leased or contracted agencies and entities of the federal government, must comply with the Mexican Mandatory Standards and, where appropriate, with the Mexican standards, and without them, International Standards”.

In several cases the NOMs are identical to or based on International Standards, for example :

NOM-001-SEDE-2012, *Electrical Installations (Utilization)*

This NOM is equivalent to part 1 of the International Standard IEC 60364, *Electrical Installations of Buildings*, Part 1: *Scope, Object and Fundamental principles*, regarding safety fundamentals. Approximately 30 Mexican Standards for electric products are adoptions of IEC standards

NOM-003-SCFI-2000, *Electrical Products Safety Specifications*

This Standard is equivalent to International Standards IEC 60335-1 and IEC 60745-1 via the Mexican Standards NMX-J-521/1-ANCE; NMXJ-524/1-ANCE; NMX-J-508-ANCE and NMX-J-515-ANCE, which were developed on the specifications and test methods contained within these International Standards

Other examples of national adoptions include:

NMX-J-618/3-ANCE-2011

NMX-J-618/3-ANCE-2011, *Photovoltaic (PV) module safety qualification – Part 3: Requirements for thin-film terrestrial photovoltaic (PV) modules – design qualification.*

This is identical (IDT) to the International Standard IEC 61646, edition 2.0 (2008-05)

NMX-J-618/4-ANCE-2011

NMX-J-618/4-ANCE-2011, *Photovoltaic (PV) modules safety qualification – Part 4: Requirements for crystalline silicon terrestrial photovoltaic (pv) modules – design qualification.*

This is identical (IDT) to the International Standard IEC 61215, edition 2.0 (2005-04)



South Africa

The development of voluntary national standards in South Africa is carried out by the South African Bureau of Standards (SABS) the official National Standards Body (NSB), which is authorized to do so in terms of the Standards Act (Act 8 of 2008). Any legislator in South Africa has the right to incorporate any national standard into legislation under whatever terms and conditions he/she chooses (IEC and ISO International Standards must therefore be nationally adopted before being referenced). Normally the legislator concerned will consult the SABS regarding the implications, and will regulate only to ensure compliance with the standard(s) at the point of use of a commodity.¹⁰⁾

National standards, being readily available, are often the most convenient choice for the legislator as the basis for regulation; they can readily be amended to keep up with technology (via the national standards process) and have the benefit of already representing a national consensus of experts as to the appropriate level of fitness for purpose (in the case of a physical product). Most commonly, a national standard will provide the technical requirements for a commodity and the administrative provisions will be given in the regulation. A legislator is free to choose under what conditions of use it wishes to regulate a commodity, to prescribe appropriate conformity assessment provisions and, if necessary, to require compliance with deviations from the referenced national standards. The regulation would then typically be published by the applicable government department in terms of an existing Act of Parliament.

10) Regulation using standards that is applicable to products at their point of sale is done using 'compulsory specifications' which are, as the name suggests, mandatory. It is a voluntary national standard that becomes law in its own right under the Standards Act.

Regulation

Water Services Act 108 of 1997 – Regulations under sections 9(1) and 73(1)(j) – Regulation 8 “Use of effluent”, subregulation 8 (3)

Extract from the technical regulation

8 (3) “A notice contemplated in subregulation (2) must be in more than one official language and must include the PV5 symbolic sign for non-potable water as described in SANS 1186, *Symbolic Safety Signs – Part 1: Standards, Signs and General Requirements.*”

United States

The United States considers standards to be a fundamental factor in the nation’s economy and vital to world commerce. Responsibility for coordination of the U.S. private sector standards system rests with the American National Standards Institute (ANSI). ANSI holds the Secretariat of the U.S. member body in the IEC and is the U.S. member body within ISO.

Federal policy regarding the use of standards and conformity assessments is contained in certain key provisions of the National Technology Transfer and Advancement Act (NTTAA) (Public Law 104-113), signed into law in early 1996. The NTTAA requires that:

- All Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments except where such usage would be inconsistent with applicable law or otherwise impractical, and that
- Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities and budget resources, participate with such bodies in the development of technical standards.





Office of Management and Budget (OMB) Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, provides federal agencies with guidance on how to implement these requirements in the NTTAA.

The full catalogues of IEC and ISO International Standards have the potential to be used or referenced in regulation by U.S. federal government agencies, if deemed appropriate. Decisions about which standards are most appropriate for U.S. government use are left to the discretion of individual agencies, though recent trends indicate that voluntary consensus standards from both national and international sources are being increasingly referenced by U.S. agencies and regulatory bodies. The U.S. Government has also increased its reliance on private sector consensus standards in its procurement activities.

Regulation

46 CFR 111.105-11, Title 46: *Shipping, Chapter 1: Coast Guard, Department Of Homeland Security, Part 111: Electric Systems – General Requirements, Subpart 111.105: Hazardous Locations, Sec. 111.105-11: Intrinsically safe systems*

Extract from the technical regulation

(a) Each system required by this subpart to be intrinsically safe must use approved components meeting UL 913 or IEC 60079-11 (both incorporated by reference; see 46 CFR 110.10-1).

Regulation

10 CFR 73.26, *Nuclear Regulatory Commission – Part 73: Physical Protection of Plants And Materials – Sec. 73.26, Transportation of physical protection systems, subsystems, components, and procedures.*

Extract from the technical regulation

(l) Shipment by sea. (1) Shipments shall be made only on container-ships. 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.



8 Examples of IEC and ISO International Standards supporting public policy in different sectors

In some sectors, there are sufficient motivating factors for governments, their regulators, and in certain cases manufacturers and other stakeholders, to work at the international level to promote regulatory cooperation. This may be, for example, because of the sheer volume of trade that is carried out internationally in a particular sector. Principles agreed to in the resulting international agreements are incorporated into national laws and regulations adopted by the agreement's Parties. Many of the examples presented on the websites referenced above are of IEC and ISO International Standards being used to support this international regulatory and other policy work.

Examples are available for the following sectors:

- Air transport (IEC)
- Electric motors (IEC)
- Energy management (ISO)
- Environmental management – climate change (ISO)
- Food products (ISO)
- Laboratory medicine (ISO)
- Medical devices (IEC/ISO)
- Medium power transformers (IEC)
- Product safety (IEC)
- Radio services (IEC/ISO)
- Railways (IEC/ISO)
- Road vehicles (IEC/ISO)
- Ships and marine technology (IEC/ISO)
- Standby power (IEC)
- Television (IEC)
- Transport of dangerous goods (ISO)

To supplement the examples presented in this brochure, further examples, organized by sector, are available for consultation online at:

- ▶ www.iec.ch/perspectives/government/sectors/
- ▶ www.iso.org/policy

9 Conclusion

Policy makers can make use of IEC and ISO International Standards in a variety of ways and with numerous benefits. For example, IEC and ISO International Standards support trade and can be used as a basis for technical regulations without causing unnecessary barriers to trade; they are widely recognized across the world; and they offer the same benefits whether applied in developed or developing countries. There is a full portfolio of different types of IEC and ISO International Standards on offer, and they cover all major subjects from product specifications to management procedures.

Policy makers can choose from a range of techniques for referencing IEC and ISO International Standards and decide for themselves the appropriate level of use and conformity assessment that should be applied. This ensures that they retain full control over their legal requirements.

The participation of policy makers in the standards process can take on many different forms, ranging from basic information exchange as a means of highlighting their priorities, to acting as a member of a delegation to an IEC or ISO meeting. Where such participation takes place, it fosters coordination and communication between the policy making and technical levels. In publishing this document, the IEC and ISO are making an offer to assist policy makers who wish to use International Standards to support their work or who are interested in finding out more.

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