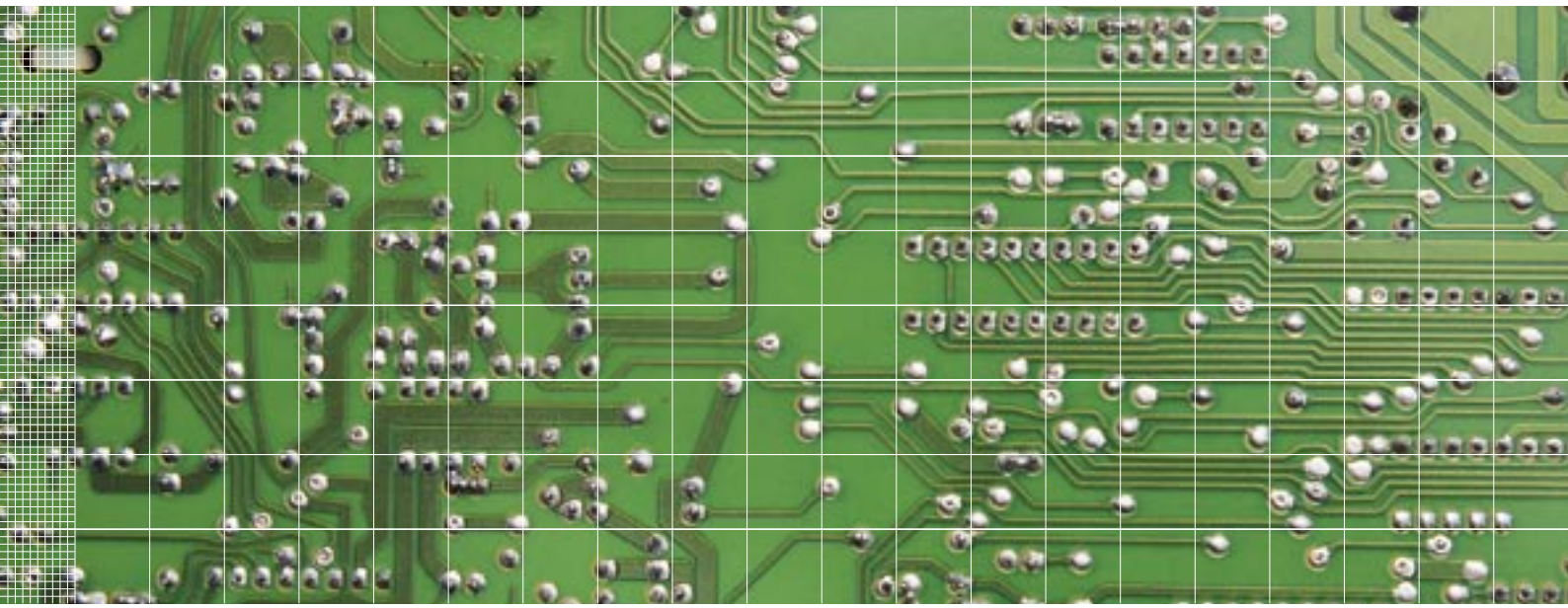

Using and referencing ISO and IEC standards for technical regulations

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Using and referencing ISO and IEC standards for technical regulations

This document was developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) to convey to regulators the benefits of choosing to use and reference ISO and IEC standards for regulations and to demonstrate that doing so can support good regulatory practice.

Contents

1 Advantages and benefits of using and referencing ISO and IEC standards in technical regulations

Standards from ISO and IEC have the advantage of a **broad geographical reach**. Both of these organizations have a membership made up of national members the world over. This geographical reach is combined with a **multi-stakeholder environment** which ensures the representation of a wealth of technical views including those relating to social and economic interests. Different perspectives come from the national level and through a network of liaisons and cooperation with international governmental and non-governmental organizations. Therefore, the value of International Standards from ISO and IEC is that they are recognized, accepted and implemented around the globe.

Regulators can save time and money by choosing ISO and IEC standards as solutions to policy and technical issues — solutions which have been agreed upon by a consensus reached with the involvement of all parties, including the regulators themselves.

ISO and IEC standards:

- support the technical aspects of societal and environmental policies and contribute to sustainable development across the world;
- 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, facilitating regulatory compliance and enhancing the market access opportunities for small enterprises;
- reflect the state of the art and serve as a vehicle for the dissemination of new technologies and innovative practices;
- can become national standards after a national public enquiry process carried out by a country's standards body, which can reduce the need for the regulator to hold national consultations;
- can be used as a basis for national technical regulations without causing unnecessary technical barriers to trade;
- offer a complete range of tools for the various modes of conformity assessment;
- are used for conformity assessment to enhance confidence in products, systems, processes, services or personnel;
- are developed using procedures which ensure that the thousands of standards available avoid duplication and conflict with each other.

For further information,
visit the ISO and IEC websites:

International Organization for Standardization (ISO):
www.iso.org

International Electrotechnical Commission (IEC):
www.iec.ch

2 Introduction

This document demonstrates the potential value of using ISO and IEC standards in support of technical regulations. It explains how ISO and IEC standards can be used by governments to support good regulatory practice. This document may also be useful for those involved in ISO and IEC standardization who wish to engage better with the regulatory bodies relevant to their fields.

ISO and IEC standards are widely adopted at the regional or national level and are used by all interested stakeholders, such as manufacturers, trade organizations, purchasers, consumers, certification bodies, testing laboratories and authorities. Since these standards reflect the best experience of industry, researchers, consumers and regulators worldwide and cover common needs in a variety of countries, they constitute one of the important bases for the removal of unnecessary technical barriers to trade. The use of international standards that are developed under a process meeting Decision G/TCT/1Rev.8, 23 May 2002, has been acknowledged by the Technical Barriers to Trade Committee of the World Trade Organization (WTO/TBT) (see Chapter 3).

The incorporation of standards in legislative instruments by means of a reference constitutes a method of drafting a code or regulation in such a way that a detailed statement of technical requirements is replaced in the text of the code or regulation by a reference to one or more standards, or to the relevant parts thereof. The use in regulation of standards, and preferably of ISO and IEC standards, is an effective means of supporting national, regional and global policies. It is already widely used in several regions of the world in concepts, agreements and frameworks such as the New Approach in the European Union, Good Regulatory Practice developed by the Asia-Pacific Economic Cooperation, Subcommittee on Standards and Conformance, and the North American Free Trade Agreement.

Depending on policy, in some countries, national adoption may be an important element encouraging the use of the ISO or IEC standard in national technical regulation. Where it is needed, the 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, but this document deals only with International Standards published by ISO and IEC.

3 International trade and standards

One of the main benefits of standards is that they facilitate trade. The World Trade Organization (WTO) is the international organization that deals with the global rules of trade between nations. Its main goal is to ensure that trade flows as smoothly, predictably and freely as possible. The use of international standards facilitates the elimination of unnecessary barriers to trade. In this context, the WTO/TBT Agreement recognizes the contribution international standards can make toward improving the efficiency of production and international trade. In 2005, the WTO's World Trade Report concentrated on the theme of standards and trade and was supportive of the role of international standards.

The basic objective of the WTO/TBT Agreement is to ensure that national technical regulations, standards and conformity assessment procedures do not constitute unnecessary barriers to international trade. The WTO/TBT Agreement seeks to achieve a balance between allowing WTO Members to take regulatory measures to protect legitimate interests and ensuring that national technical regulations, standards and conformity assessment procedures do not become unnecessary obstacles to international trade. Harmonization is therefore a central discipline of the TBT Agreement and is articulated in particular in two requirements[1]:

- WTO members should 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 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.

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). More information on each of these can be found on the WTO website: **www.wto.org**.

The Organization for Economic Cooperation and Development (OECD) also recognizes the role of international standards in support of regulation. In June 2005, the OECD member countries adopted the Guiding Principles for Regulatory Quality and Performance, one of which specifically encourages harmonization towards international standards. It also recommends support for the development and use of internationally harmonized standards as a basis for domestic regulations.

ISO and IEC and their members adhere to the requirements of the WTO

The WTO/TBT Agreement also contains a list of rules that standards bodies should follow to ensure that their standards support the trade facilitation objectives of the WTO. This list appears in Annex 3 of the WTO/TBT Agreement and is called the *Code of good practice for the preparation, adoption and application of standards*. The majority of ISO and IEC members follow this Code and governments are encouraged to work with their national standards bodies to make sure they adhere to it.

ISO and IEC are also observers in the WTO/TBT Committee and contribute regularly to its work. Many ISO and IEC national members work closely with their WTO representatives and can be included in national delegations to the WTO/TBT Committee meetings. For further information, see **www.iso.org/wtocode**.

[1] WTO Agreement on Technical Barriers to Trade, Article 2, Preparation, Adoption and Application of Technical Regulations by Central Government Bodies.

4 Global applicability of ISO and IEC standards

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.

Most developed countries are, in general, characterized by:

- fully fledged market economies;
- large, diversified domestic manufacturing and service bases;
- a culture of competition in industry and commerce;
- consumer protection entrenched in law with organized and influential consumer organizations and special interest groups;
- efficient and functioning standards systems, quality assurance infrastructure, accreditation and legal metrology systems;
- a growing demand for harmonization through regulation which is kept light and market forces that take care of quality-related issues;
- developed systems of civil litigation that support, when necessary, the application of sanctions.

In some countries, these elements exist to varying degrees. For example, some may:

- have subsistence economies and little domestic manufacturing capacity for finished products;
- rely heavily for their subsistence on agriculture or the extraction and exportation of raw materials;
- be highly dependent on the quality of imported products, which is often outside their control;
- lack a consumer infrastructure;
- have an under-developed quality assurance, accreditation and legal metrology infrastructure — even basic legal metrology "weights and measures" may not exist;
- not have implementation systems developed to a degree that would facilitate an efficient regime of technical regulation;
- depend on a command and control regulatory regime.

In some countries, for example, the response by authorities to a specific need for technical regulation may be a general declaration that certain standards in a subject area must be mandatory. It is therefore vital that a portfolio of ISO and IEC standards exists to help such countries. These countries can benefit from the savings they make when applying a wide range of ISO and IEC standards. They are encouraged to make use of and, where necessary, adopt those International Standards that address their needs.

ISO and IEC standards have an important role to play across the range of diversity and development in the world. Therefore, both organizations have programmes to raise awareness, increase capacity and promote the participation of all countries in international standardization. More information is available at the following URLs:

www.iso.org/devco

www.iec.ch/affiliates

5 Different types and aspects of ISO and IEC standards

The following are examples of the different types of standards and aspects of products and services that ISO and IEC standards cover. A single standard could cover one or several of these aspects.

Product specifications

These can often be all-encompassing, dealing with several of the requirements for a specific product as well as fitness for use and performance levels. They can cover sizes, health and safety, protection of the environment, interchangeability and data processing.

Organizational management

A suite of ISO standards is available to provide guidance to organizations on management issues in order to help them implement good practice and an effective management system. These deal with key aspects such as quality, security and environmental management.

Labelling and packaging

There are many standards that focus on providing information on products through labelling. These ensure that consumers and users around the world obtain reliable and clear information on properties of products, such as their size and their impact on the environment. Standards for safe packaging help convey best practice on key user issues, such as child-protective packaging. They can also show good practice procedures in such areas as reuse or storage.

Health and safety principles

There are standards providing generic principles for safety, security and ergonomic design and assessment.

Measurement, test and analytical methods

There are many standards specifying measurement, test and analytical methods. These standards are important because they ensure that measurement and test data produced around the world will be comparable.

Graphical symbols

A comprehensive range of internationally agreed graphical symbols is listed in ISO and IEC standards (e.g. ISO 7001, *Graphical symbols — Public information symbols)*. The use of symbols helps to surmount linguistic barriers in fields dealing with road safety and situations of emergency.

Terminology and definitions

Some standards are exclusively dedicated to definitions for use when addressing technical barriers to trade and their elimination. They standardize terms and definitions to facilitate mutual understanding in different fields.

Services

When providing services, suppliers have to meet the needs of their clients. ISO and IEC provide standards that define a level of service and/or the procedure for performing the service (e.g. ISO 24510, *Activities relating to drinking water and wastewater services — Guidelines for the assessment and for the improvement of the service to users)*.

Personnel

These standards concern specified professions and trades where there exists normative and informative requirements for personnel. These include expected qualifications, work experience and levels of technical competence (e.g. ISO 22222, *Personal financial planning — Requirements for personal financial planners)*.

Conformity assessment

These standards and guides contain requirements for activities and bodies involved in the assessment of conformity, including suppliers' declarations of conformity, inspection, certification, accreditation, peer assessment and mutual recognition.

6 Methods of using and referencing ISO and IEC standards for technical regulations

6.1 General considerations

Regulatory authorities decide themselves whether to use ISO and IEC standards to support their technical regulation. Once the decision to use an ISO or IEC 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 chapter highlights some commonly used methods of using and referencing ISO and IEC standards in regulation. The methods are available to regulatory activity at the national, regional or international levels.

The main considerations are listed below:

- Regulators will need to decide if they want the use of the ISO or IEC standard to be mandatory (providing the only solution) or voluntary (providing a solution).
- Regulators will need to decide what level of checks they wish to put in place to ensure the standard is suitable for use and addresses their needs.
- As ISO and IEC standards are subdivided into defined clauses and subclauses, the regulator can choose to reference the whole standard or selected parts of it.
- ISO and IEC standards are regularly revised to keep up with technological and market changes.

6.2 Direct references to specific standards in the legal text

6.2.1 General

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 ISO or IEC 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. 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.

6.2.2 Direct dated references

Direct dated referencing is when the number and title of the ISO or IEC 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, ISO and IEC 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, ISO or IEC 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.

It should be borne in mind that 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 waste hazardous material container shall conform to ISO XXXX: 2003, *TITLE*.

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

6.2.3 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 state of the art. In other words, the regulation allows the use of subsequent revised editions of the same standard.

It should be noted, however, that 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 6.2.2).

As with dated references, any amendments to, or revisions of, the standard should be tracked. In such instances, regulatory authorities could — although they are not obliged to — add the phrase "latest edition of", the aim being to permit them to respond easily and quickly to technical changes.

> Example:
> The waste hazardous material container shall conform to the latest edition of ISO XXXX, *TITLE*.

6.3 Indirect references to the use of ISO and IEC 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"[2] (see **www.newapproach.org**).

> Example:
> Where the product complies with 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.

> Example:
> A product shall be presumed safe, as far as the risks are concerned, when it conforms to voluntary ISO and IEC standards, the references of which have been registered on [refer to relevant official listing here].

6.4 Actions by regulators/authorities to encourage the use of ISO and IEC standards

In some cases, it may be adequate merely to encourage the use of ISO and IEC standards on the assumption that their voluntary take-up by the market means that regulators' objectives are met — for example, enhancing the quality of products or services in a particular sector. Such measures would not imply the creation of legal instruments, but could rather be achieved through, for example, government policy in targeted areas such as procurement. In cases where this occurs, the standard may become the *de facto* tool for market access.

[2] Where ISO or IEC standards are to be used to support the New Approach Directives, they are first formally adopted as European Standards.

7 Other considerations when choosing to use and reference ISO and IEC standards for technical regulations

7.1 Ensuring no delegation of legislative responsibility

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

The ISO and IEC processes benefit from a broad range of expertise and all standards are subjected to a period of public consultation before publication. This helps to ensure that they represent viable solutions which are the fruit of broad consultation.

It is acknowledged that, when a standard is to be used for regulatory purposes, the regulator will wish to 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.

Regulatory procedures are therefore required when approving references to standards regardless of which method of referencing is used. There is a range of regulatory procedures which can be followed to ensure regulators' confidence. The extent and type of the procedure chosen will depend on the risk posed by the product or service.

To summarize, regulators have a choice of techniques to assess and ensure the suitability of an ISO or IEC standard. They have at their disposal a broad range of methods for making reference to, and use of, the standard.

7.2 National and regional adoptions of ISO and IEC standards

ISO and IEC standards, as well as being stand-alone documents (with the designation ISO and IEC), can be formally adopted as national or regional standards and given designations combined with the ISO or IEC reference[3]. National and regional adoptions of an ISO or IEC standard may involve a separate consultation process at national or regional level.

> Example:
> ISO 14971, *Medical devices — Application of risk management to medical devices,* is:
>
> - adopted as ANSI/AAMI/ISO 14971 in the U.S.A.;
> - adopted as EN ISO 14971 in Europe;
> - adopted as JIS T 14971 in Japan.

In some countries or regions, adoption may be an important and sometimes necessary element for the use of the ISO or IEC standard in technical regulation or public procurement. In other countries, 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. What is common to both approaches is that the ISO or IEC standards have been assessed and judged by national stakeholders to suit needs and be fit for purpose in that country or region.

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

7.3 Maintenance procedures of ISO and IEC standards and recommendations to regulators for their monitoring

ISO and IEC technical committees keep their standards up to date to reflect the state of the art. The committees periodically review standards to ensure that they remain current and abreast of technology. Regulatory authorities can develop procedures to assist them in monitoring the status of standards referenced in their regulations. 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 regulators can be kept informed of such changes, for example participation in the relevant committee or making arrangements with the relevant ISO or IEC national member.

7.4 The importance of regulator participation in standards development

The effective development and maintenance of a standard suitable for incorporation by reference in a legislative instrument requires that a cooperative effort between the regulatory authority and the standards development committee be established from the outset. Regulator participation greatly assists rendering the standards suitable for application in regulation.

From the outset, the standards committee and regulator should have some understanding of the conformity assessment system that is likely to be in place to assess conformity to the standard in the future.

Participation in the national standardization process is facilitated by the ISO or IEC member. To find your ISO or IEC member, click on the following URLs:

www.iso.org/isomembers

www.iec.ch/about/members

7.5 Role of conformity assessment in technical regulations

Conformity assessment is the means of determining whether products, 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 conformity assessment body. Regulations 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 or system.

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 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. A regulatory authority may be considered a third-party when it undertakes conformity assessment activities itself.

In some cases, regulators 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.

ISO and IEC have developed a series of standards and guides 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. 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. Using these documents means international compatibility is fostered and technical barriers to trade can be avoided.

Examples of relevant conformity assessment documents from ISO and IEC are provided in the following table:

The following URL provides further information and a complete, regularly updated list of conformity assessment documents: **www.iso.org/casco**

ISO/IEC 17000	*Conformity assessment — Vocabulary and general principles*
ISO/IEC 17011	*Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*
ISO/IEC 17020	*General criteria for the operation of various types of bodies performing inspection*
ISO/IEC 17021	*Conformity assessment — Requirements for bodies providing audit and certification of management systems*
ISO/IEC 17024	*Conformity assessment — General requirements for bodies operating certification of persons*
ISO/IEC 17025	*General requirements for the competence of testing and calibration laboratories*
ISO/IEC 17040	*Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies*
ISO/IEC 17050-1	*Conformity assessment — Supplier's declaration of conformity* — Part 1: *General requirements*
ISO/IEC 17050-2	*Conformity assessment — Supplier's declaration of conformity* — Part 2: *Supporting documentation*
ISO/IEC Guide 65	*General requirements for bodies operating product certification systems*

7.6 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. ISO and IEC 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, regulators 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, and
- corrective actions for non-conforming products.

8 Conclusion

Regulators can make use of ISO and IEC standards in a variety of ways. Choosing to use them to support their regulations and policies affords numerous benefits: ISO and IEC 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 offer the same benefits whether applied in developed or developing countries. There is a full portfolio of different types of ISO and IEC standards on offer, and they cover all major subjects from product specifications to management procedures. Regulators can chose from a range of techniques for referencing ISO and IEC 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 regulators in the standards process can take on many different forms, ranging from basic information exchange as a means of highlighting their priorities through to acting as a member of a delegation to an ISO or IEC meeting. Where regulatory participation takes place, it fosters coordination and communication between the regulatory and technical levels. In publishing this document, ISO and IEC are making an offer to assist regulators who wish to use International Standards to support their work or who are interested in finding out more.

Annexes A, B and C provide practical examples of the key themes contained within this document.

Annex A

Examples of ISO and IEC standards supporting regulatory work in different sectors

In some sectors, there are sufficient motivating factors for people to take regulatory initiatives at international level. This may be, for example, because of the sheer volume of trade that is carried out internationally in a particular sector. Regulations at international level are developed with a view to being adopted by many countries as national regulations. The following are examples of the way ISO and IEC standards have been used to support this type of international regulatory framework[4]. While this annex concentrates on international regulatory initiatives, it is important to stress that ISO and IEC standards are equally beneficial for supporting national regulations. Their use at national level is not dependent on the existence of international regulatory activity.

A.1 Transport of dangerous goods

This sector provides an example of the successful use of ISO standards at the regulatory level. One key feature of this success is the representation of the ISO Technical Committee during the drafting of the regulatory recommendations. Another key feature is that the recommendations deal with issues of health and safety, so extra confidence is required in these standards. A mechanism is therefore put in place by the regulator to check the appropriateness of each standard before making reference to it. This example shows how clearly expressed, regulatory needs can lead to revisions and improvements in ISO standards.

Who is involved?

United Nations Economic and Social Council's Committee of Experts on the Transport of Dangerous Goods

This is the main international regulatory forum of experts responsible for harmonizing requirements in different countries for the safe transportation of dangerous materials. It is made up of experts from national government departments.

ISO/TC 58, *Gas cylinders*

ISO/TC 58 is responsible for preparing standards on gas cylinders, their fittings and characteristics for manufacture and use.

ISO/TC 220, *Cryogenic vessels*

ISO/TC 220 is responsible for standardizing the containers needed for the safe storage and transport of refrigerated liquefied gases.

How is regulatory cooperation in this field achieved?

The UN Recommendations for the Transport of Dangerous Goods define the international requirements for the transport of dangerous goods in order to prevent, as far as possible, accidents to persons or property and damage to the environment. They are addressed to governments and international organizations concerned with drafting regulations for the transport of dangerous goods.

The UN Recommendations include a key section on requirements for the construction and testing of pressure receptacles, aerosol dispensers and gas cartridges. Throughout this section there are many references to the ISO standards produced by ISO/TC 58 and ISO/TC 220. This was achieved by ensuring effective representation of the ISO Technical Committee when the UN Recommendations were being drafted.

[4] The individual submissions are from experts in the different sectors who have been involved in the discussions that led to the ISO and IEC standards being used.

As key aspects of health and safety are involved, the appropriateness of each standard is assessed at special meetings of the UN Experts with the participation of delegates from the ISO Technical Committee. If the ISO work is deemed to be unsatisfactory, the ISO standard is rejected. The ISO Technical Committee can then revise and improve the standard accordingly.

It should be added that this UN Committee has adopted a policy of only referring to published ISO standards. They are also willing to receive drafts of the standards during their development. This enables them to submit comments. This process helps avoid rejection of published ISO standards, which can then lead to a longer process.

A.2 Medical devices

The medical devices industry, with products ranging from implantable cardiac pacemakers to syringes and needles, and from joint replacement implants to wheelchairs, is both rapidly evolving and highly regulated. Standards play an important role in allowing the rapid development of medical device technology while meeting the expectations of the public and regulators that medical devices are safe and perform as intended.

Key features are:

- the acceptance of standards as a key element in the regulatory infrastructure for medical devices: standards are not mandatory but provide a presumption of conformance with certain regulatory requirements;
- the participation of regulators alongside medical device manufacturers and users in the development of International Standards;
- close cooperation between ISO/IEC and other bodies in the development of medical device standards.

Who is involved?

Global Harmonization Task Force (GHTF)

The Global Harmonization Task Force is not in itself a regulatory authority. It is a forum for national regulatory authorities and industry representatives to promote international convergence in regulatory requirements and practices. In particular, the GHTF aims to promote the safety, effectiveness/performance and quality of medical devices to encourage technological innovation, foster international trade and serve as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with established systems. This is done through the development of guidance documents and recommended procedures in order to work towards a convergence of the medical device regulatory systems of its members within the boundaries of their legal and institutional constraints.

Participation in the GHTF includes medical device regulatory agencies and the regulated industry representatives from countries and regions having experience with medical device regulations. Members of the GHTF include representatives from Europe, the U.S.A., Canada, Japan and Australia.

ISO and IEC

A number of ISO and IEC Technical Committees actively develop standards that play an important role in the regulation of medical devices. These include:

- ISO/TC 121, *Anaesthetic and respiratory equipment*
- ISO/TC 150, *Implants for surgery*
- ISO/TC 194, *Biological evaluation of medical devices*
- ISO/TC 198, *Sterilization of health care products*
- ISO/TC 210, *Quality management and correspon ding general aspects for medical devices*
- CEI/CE 62, *Electrical equipment in medical practice*

How is regulatory cooperation in this field achieved?

ISO cooperates with the GHTF as a liaison body to ensure overall coordination of activities. As such, ISO has participated in Open Sessions of the GHTF Steering Committee.

In addition, Memoranda of Understanding are in place between specific Study Groups (SGs) and ISO Technical Committees.

ISO/TC 210 and the GHTF have prepared and agreed upon a Memorandum of Understanding, defining the roles of each organization in their collaboration towards standardization and harmonization in the medical devices sector.

ISO/TC 210 has a very successful and active liaison with the GHTF SG 3 in relation to quality management systems. The Convener of ISO/TC 210/WG 1, *Application of quality systems to medical devices*, has been named a technical expert to the GHTF SG 3 for several projects. Members of the GHTF SG 3 have

been invited to attend meetings of ISO/TC 210 and its Working Groups. Upon publication, ISO 13485 was formally recognized by GHTF as an appropriate model for a quality management system for regulatory purposes with respect to medical devices.

ISO 13485 has been fully accepted by Australian, European and Canadian regulators as a means of demonstrating conformance to aspects of the medical devices directives relating to conformity assessment requirements in Australia and the European Union, and to the quality management system regulatory requirements in Canada. Similarly, medical device regulators in Japan and the U.S.A. have also aligned or harmonized their requirements with ISO 13485.

Additionally, expert members of ISO/TC 210-IEC/SC 62A JWG 1, *Application of risk management to medical devices*, have acted as technical experts to GHTF SG 3 for the GHTF guidance document, *Implementation of risk management principles and activities within a quality management system*.

In addition to the work of ISO/TC 210 on general aspects related to medical devices, other technical committees, including those listed above, have produced a wide range of product and process standards that are widely recognized and well respected by regulators responsible for ensuring the safety and performance of medical devices.

ISO/TC 194 and the GHTF have prepared and agreed upon a Memorandum of Understanding, defining the roles of each organization in their collaboration towards standardization and harmonization in the medical devices sector, in particular in relation to the work of Study Group 5, which promotes convergence of regulatory requirements for evidence of the clinical safety and performance of medical devices.

These joint efforts have proven to be very successful in combining the expertise from both memberships and avoiding any duplication of work.

A.3 Road vehicles

Work to harmonize worldwide regulations for road vehicles has been on-going for over 50 years since regulators first realized that accidents could be caused by the features of the cars involved. Cooperation with ISO has taken place from the start, and the relevance of ISO's working methods and the technical quality of the ISO standards produced is appreciated by regulators taking part in this work. Of the 123 ECE regulations that exist on vehicle regulation, 56 of them now make reference to ISO standards (135 ISO standards are referenced in total).

Who is involved?

UN/ECE Working Party 29, World Forum for Harmonization of Vehicle Regulations

This group establishes worldwide regulations governing vehicle characteristics in the fields of the active safety of vehicles and their parts (crash avoidance), the passive safety of vehicles and their parts (crash worthiness), environmental considerations (relating to pollution of the environment, noise disturbances and conservation of energy), general safety considerations (windshield wipers and washers, controls and display, glazing) and special technical considerations.

New regulations and amendments are prepared by one of the six working parties subsidiary to WP29, dealing with lighting and light signalling, brakes and running gear, passive safety, pollution and energy, noise, and general safety questions.

ISO/TC 22, *Road vehicles*

ISO/TC 22 deals with standardization concerning compatibility, interchangeability and safety, with particular reference to terminology and test procedures for evaluating the performance of road vehicles and their equipment, systems and subassemblies. All the technical domains of the vehicle construction are taken into account in one of the 23 active subcommittees of ISO/TC 22. The structure of ISO/TC 22 is similar to the structures of WP29 with active and passive safety, environment protection and other areas such as electronics and human machine interfaces.

How is regulatory cooperation in this field achieved?

With 600 published standards, ISO/TC 22 has a large number of standards giving test methods, measuring methods, terminology and interchangeability requirements. From the outset, ISO/TC 22 has been represented in the meetings of WP29. Both organizations try to avoid any duplication of the work. Some demands have been made by WP29 to ISO in the field of road vehicles, and ISO/TC 22 has answered positively by producing some of the 135 ISO standards to which the ECE Regulations refer. In addition, experts from industry attend the ISO meetings as well as the WP29 meetings.

A.4 Food products

ISO standards play an important role in the food industry, both for trade purposes and in order to ensure that food is safe for consumption. Food safety is obviously a well-regulated area, so there is a long history of collaboration between the Codex (the international forum for food regulators) and ISO/TC 34, *Food products*.

Who is involved?

Codex and ISO activities are complementary. Codex, as a governmental organization, prepares documents to assist governments in their statutory and regulatory task of protecting their citizens from health hazards caused by food consumption. ISO, as a non-governmental organization, prepares standards on test methods to assist stakeholders along the whole food chain to fulfil both the statutory and regulatory requirements, as well as the requirements of consumers of these products.

How is regulatory cooperation in this field achieved?

The Codex Committee on Methods of Analysis and Sampling endorses analytical and test methods from various standards writing bodies, following recommendations from the relevant Codex Commodity Committee. In the field of milk and milk products, ISO/TC 34/SC 5, *Food products — Milk and milk products*, and the International Dairy Federation (IDF) work together to prepare analysis methods that are published jointly. Most of these analysis methods are endorsed by the Codex Committee on Methods of Analysis and Sampling. Several analysis methods from ISO/TC 34/SC 9, *Food products — Microbiology*, have also been endorsed by this committee as have standards from ISO/TC 34/SC 4, *Food products — Cereals and pulses*, and ISO/TC 34/SC 11, *Food products — Animal and vegetable fats and oils*. More than 100 standards by ISO/TC 34 have now been endorsed by Codex as the official test method.

In 2005, ISO/TC 34 published ISO 22000, *Food safety management systems — Requirements for any organization in the food chain*, which is based on a management systems approach similar to that detailed in ISO 9001:2000 as well as on the Codex hazard analysis and critical control point (HACCP) system. The HACCP system is widely accepted worldwide, but it has been implemented in different ways in different countries. In addition, retailer organizations have prepared documents (British Retail Consortium and International Food Standard) for the establishment and auditing of food safety systems, possibly including HACCP requirements. ISO 22000 should help to clarify and harmonize the present situation. Codex played an active role in the development of ISO 22000.

ISO/TC 34 is also working on ISO 22005, *Traceability in the feed and food chain — General principles and basic requirements for system design and implementation*. The traceability of food products "from the farm to the fork" is an important requirement. This standard is intended to complement the Codex work on traceability, as it explains the design of a suitable system.

A.5 Radio services

IEC/CISPR (International special committee on radio interference) is responsible for the protection of radio services and promotes international agreements on aspects of radio interference. Trade facilitation at an international level has become an integral part of CISPR activity, as it covers a range of products and systems in the protection of radio reception from interference sources, such as electrical appliances of all types, ignition systems, electricity supply systems, industrial, scientific and electromedical radiofrequency, sound and television broadcasting receivers and information technology equipment.

Who is involved?

CISPR comprises experts from many areas, including radio regulatory authorities, test houses, manufacturers, numerous IEC and ISO committee liaisons, and international organizations such as the European Post and Telecommunications Conference (CEPT) and the International Telecommunication Union (ITU).

How is regulatory cooperation in this field achieved?

Virtually all countries belong to the ITU and hence have a responsibility to protect the reception of radio services from interference. With the wide proliferation of electrical and electronic products, there is a need to ensure that emissions from such products do not unduly affect radio reception. Consequently, the limits used in CISPR product standards are almost universally used in some form to ensure that products have emissions at acceptable levels. As a result, although IEC standards are generally drafted with a view to being voluntary standards, almost all CISPR standards are embodied in some form in national legislation in many of the world's major markets. The success of CISPR standards lies in the fact that the membership of CISPR is very broad, taking account of all interests. However, given the rapid developments in technology and changes in radio services, keeping CISPR standards effective and relevant presents a continuing challenge.

A.6 Railways

IEC/TC 9, *Electrical equipment and systems for railways*, is responsible for the international standardization of the electrical equipment and systems used in railways. These include rolling stock, fixed installations, management systems for railway operation, and their interfaces and ecological environment. IEC/TC 9 standards not only cover railway networks but also metropolitan transport networks, including metros, tramways, trolley buses and fully automated transport systems. These standards relate to systems, components and software and they will deal with electrical, electronic and mechanical aspects, the latter being limited to items depending on electrical factors. These standards deal with electromechanical and electronic aspects of power components as well as with electronic hardware and software components.

Who is involved?

With the safety of passengers and the environment being of paramount importance, stringent regulations are required worldwide. A close relationship is maintained with the International Union of Railways (UIC) and the International Association of Public Transport (UITP). Through this cooperation, various worldwide solutions have been prepared to satisfy design needs and regulatory requirements. Examples include the safety of signalling or control-command systems, EMC, protective provisions for traction circuits, RAMS principles and methods, the design of automatic guided transportation systems and, more generally, generic concepts ensuring safety for every urban system.

How is regulatory cooperation in this field achieved?

These developments are closely and actively followed by the industry and its designers in the main regions involved in the development of railways, i.e. Europe, Canada and the Far East. Specifications and standards needs identified worldwide allow for technical cooperation, railway system coherence and interoperability. The future priorities of IEC/TC 9 emphasize the growing importance of urban transport and identify a need for standardization in order to avoid reinventing a costly new solution for each new metro system around the world.

A.7 Ships and marine technology

Regulatory bodies can have an important role in defining standards and requirements which affect safety, security and the environment, both at the organization/company level or at the individual level. The ships and marine sector provides a good example of what can be achieved over a period of time when appropriate links are maintained between the regulatory body and ISO and IEC Technical Committees.

The main lesson from this example is that the regulatory authority can be provided with continuous representation by the ISO and IEC Technical Committees and their work when discussing how standards can help ensure uniform international implementation by industry. This is a good example of active utilization of the ISO and IEC liaison approach with other organizations, which requires long-term commitment, close cooperation and political sensitivity.

Who is involved?

International Maritime Organization (IMO)

IMO provides a forum and framework for cooperation among governments in the field of governmental regulation and practices relating to technical matters of all kinds affecting shipping engaged in international trade. It encourages and facilitates the general adoption of standards in support of its international agreements concerning maritime safety, security, efficiency of navigation and prevention and control of marine pollution from ships.

ISO/TC 8, *Ships and marine technology*

ISO/TC 8 is responsible within ISO for the standardization of design, construction, structural elements, outfitting parts, equipment, methods and technology and marine environmental matters which are used in shipbuilding and the operation of ships, comprising sea-going ships, vessels for inland navigation, offshore structures, ship-to-shore interface and all other marine structures subject to IMO requirements. ISO/TC 8 is also the leading technical committee for matters relating to security of the supply chain.

IEC/TC 18, *Electrical installations of ships and of mobile and fixed offshore units*

IEC/TC 18 is responsible for the electrical installations and equipment on ships and on mobile and fixed offshore units. Its standards form a code of practical interpretation of the requirements of the International Convention on Safety of Life at Sea. IEC/TC 18 standards foster interchangeability of parts and ease the selection and procurement of equipment, including cables for transport of energy, signals and data by indicating IEC standards of ratings, types, dimensions, materials, quality and test methods.

IEC/TC 80, *Maritime navigation and radiocommunication equipment and systems*

IEC/TC 80 is responsible for preparing standards for maritime navigation and radiocommunication equipment and systems making use of electrotechnical, electronic, electroacoustic, electro-optical and data processing techniques. Its standards requested by IMO or other regulating body are typically the technical standard that IMO will use as an interpretation of IMO decisions. The suite of shipborne equipment set by IEC/TC 80 must be compatible with shore navigation systems in all IMO signatory countries, thus ensuring that vessels can navigate in their waters. IEC/TC 80 also addresses requirements for other international bodies, such as the International Association of Lighthouse Authorities (IALA), especially regarding Automatic Identification Systems (AIS) and other systems requiring compatibility with shore navigation systems.

How is regulatory cooperation in this field achieved?

By ensuring mutual representation at each other's meetings and almost constant communication, both verbally and electronically, these bodies have ensured that the standards reflect the needs of the regulatory body and avoid any unwanted duplication of work. As well as ensuring representation at each other's meetings, this sector has also developed other practical steps to facilitate the use of standards in regulations.

When work items are considered to be of mutual interest to ISO/TC 8, IEC/TC 18, IEC/TC 80, and IMO, these items are either requested by IMO or are initiated by the technical committees themselves. The mutual interest is recorded in the Annex of the Business Plan of ISO/TC 8 (**www.iso.org/tc8**) and the Strategic Policy Statements of IEC/TC 18 and IEC/TC 80 (**www.iec.ch**). IMO has confirmed its interest by submitting a number of requests to ISO and IEC. Many ISO and IEC standards and specifications have become pertinent documents in connection with the regulatory work of IMO.

As an international regulatory body with members comprising national governments, IMO has the capability, through these delegations, to prescribe and define its requirements at all levels. ISO and IEC play a critical role in saving scarce resources in IMO by providing the industry input and by facilitating the implementation of IMO requirements. This allows maximum focus on the performance requirements by IMO and permits reference to the technical work of non-governmental organizations such as ISO and IEC. This relationship is thus founded on long-term trust and confidence. It demands awareness of an IMO interest at the earliest stages and a timely response to meet its needs as well as those of industry stakeholders.

This fruitful working relationship, mutual trust and respect is based on years of close understanding. ISO/TC 8, IEC/TC 18 and IEC/TC 80 have proved that standards can be developed in months rather than years. This has made ISO and IEC attractive partners for IMO.

Annex B

Examples of national and regional regulatory texts which refer to standards

The following are extracts of regulatory texts from around the world. When reading, it should be noted that the terms "standard", "national standard" or "harmonized standard" are used. This is how some countries/regions refer to standards in their regulatory texts and these terms can mean ISO or IEC standards or national/regional adoptions of ISO or IEC standards. For instance, in the European examples below, the term "harmonized standard" is used. The European standards organizations have policies and rules in place to ensure that, when possible, ISO and IEC standards are adopted as European standards. Therefore, the term "harmonized standard" can mean an adoption of an ISO or IEC standard. Also, for clarification, references to CISPR standards are made in some of the examples from the U.S.A. CISPR is a special committee of IEC which provides International Standards dealing with radio interference.

Country/ region	Regulation	Extract from the technical regulation
Canada	Medical Devices Regulations (SOR/98-282) (Ministry of Health – Health Canada)	s.32(2)(f): 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.*
Canada	Canada Oil and Gas Installations Regulations (SOR/96-118) (Ministry of Natural Resources – Natural Resources Canada)	s.11(2)(a): Electrical wiring on an offshore installation shall be (a) designed in accordance with International Electrotechnical Commission Publication 92-3, *Electrical Installations in Ships,* Part 3: *Cables (construction, testing and installations)* and tested for Category A in accordance with International Electrotechnical Commission Publication 332-3, *Tests on electrical cables under fire conditions* — Part 3: *Tests on bunched wires or cables.*
Canada	Ship Station (Radio) Technical Regulations, 1999 (SOR/2000-265) (Ministry of Transport – Transport Canada)	s.16(1)(a)(ii): 16. (1) A VHF radio installation on board a Safety Convention ship shall meet the standards set out in International Maritime Organization Resolution A.803(19) entitled Performance Standards for Shipborne VHF Radio Installations Capable of Voice Communication and Digital Selective Calling and be certified by a country to which the Safety Convention applies as having passed the tests set out in the following standards of either (a) the International Electrotechnical Commission: (i) IEC 1097-3, entitled Global maritime distress and safety system (GMDSS) — Part 3: Digital selective calling (DSC) equipment — Operational and performance requirements, methods of testing and required testing results.
China	Safety Production Law of the People's Republic of China	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.

China	Energy Conservation Law of the People's Republic of China	Clause 12: The design and construction of fixed assets investment engineering projects should comply with standards on the rational use of energy and the design criteria on energy conservation. Authorities responsible for the legal examination and approval of these cannot ratify the construction of these projects if they fail to meet the requirements specified in the standards on the rational use of energy and the design criteria on energy conservation; after completion of the projects, any of these projects can not be accepted if they fail to meet the requirements specified in the standards on the rational use of energy and the design criteria on energy conservation.
China	Product Quality Law of the People's Republic of China	Clause 13: Industrial products that could possibly endanger people's health and the safety of persons and their properties must comply with national and industrial standards special for safeguarding people's health, safety and properties. Industrial products that fail to meet the standards and requirements special for safeguarding people's health, safety and properties are prohibited to be produced and sold. Clause 14: Government promotes enterprise quality system certification according to the internationally practiced quality management standards.
China	The Order of the Ministry of Health of the People's Republic of China Safety and Sanitary Management Method for Food Additives	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" or the categories and their range and amount of use specified in the list announced by the Ministry of Health. Chapter 4, Clause 19: In the instruction for use of labels it is stipulated: For compound food additives, in addition to the requirements of labels specified in Clause 18, the name of any single food additive should also be labelled at the same time, and listed from big to small according to the amount contained in the compound food additives; the name used for any single food additive must be the same as specified in "Safety and sanitary standards for the use of food additives".
Europe	Directive 1999/5/EC on radio equipment and telecommunication equipment (Note: This is an Example of a New Approach Directive.)	Article 2(h) of this Directive defines a "harmonized standard as a technical specification adopted by a recognized standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34 for the purpose of establishing a European requirement, compliance with which is not compulsory". Article 5 of the same Directive stipulates that "where apparatus meets the relevant harmonized standards or parts of it whose reference numbers have been published in the *Official Journal of the European Communities*, Member States shall presume compliance with the essential requirements referred to …" Article 9 of the Directive establishes a procedure of formal objections against shortcomings of harmonized standards not complying with the essential requirements of the Directive.
Europe	88/378/EEC, *Safety of Toys* (Note: This is an Example of a New Approach Directive.)	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. Member States shall publish the reference numbers of such national standards.

		Article 6,1: Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 (1) do not entirely satisfy the essential requirements referred to in Article 3, the Commission or the Member State shall refer the matter to the Standing Committee set up under Directive 83/189/EEC, hereinafter referred to as "the committee", setting out its reasons. The committee shall issue an opinion as a matter of urgency. After receiving the committee's opinion, the Commission shall notify the Member States whether or not the standards concerned or a part thereof have to be withdrawn from the publications referred to in Article 5 (1). The Commission shall inform the European standardization body concerned and, if necessary, issue a new standardization brief.
Europe	Directive 2001/95/EC on general product safety (Note: This is not a full New Approach Directive, but uses similar principles by referring to standards.)	A product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards, the references of which have been published by the Commission in the *Official Journal of the European Communities* in accordance with Article 4. The Member States shall publish the references of such national standards. If a standard does not ensure compliance with the general safety requirement, the Commission shall withdraw reference to the standard from publication in whole or in part.
Europe	Directive 2006/95/EC on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (Note: This is an example of a New Approach Directive.)	Article 5: The Member States shall take all appropriate measures to ensure that, in particular, electrical equipment which complies with the safety provisions of harmonized standards shall be regarded by their competent administrative authorities as complying with the provisions of Article 2, for the purposes of placing on the market and free movement as referred to in Articles 2 and 3 respectively. Article 9: 1: If, for safety reasons, a Member State prohibits the placing on the market of any electrical equipment or impedes its free movement, it shall immediately inform the other Member States concerned and the Commission, indicating the grounds for its decision and stating in particular whether its non-conformity with Article 2 is attributable to a shortcoming in the harmonized standards referred to in Article 5, the provisions referred to in Article 6 or the standards referred to in Article 7.
Europe	Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (Note: This is an example of a New Approach Directive.)	Article 6: Harmonised standards 1. Harmonised standard means a technical specification adopted by a recognised European standardisation body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement. Compliance with a "harmonised standard" is not compulsory. 2. The compliance of equipment with the relevant harmonised standards whose references have been published in the Official Journal of the European Union shall raise a presumption, on the part of the Member States, of conformity with the essential requirements referred to in Annex I to which such standards relate. This presumption of conformity is limited to the scope of the harmonised standard(s) applied and the relevant essential requirements covered by such harmonised standard(s). Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential requirements referred to in Annex I, it shall bring the matter before the Standing Committee set up by Directive 98/34/EC (hereinafter "the Committee"), stating its reasons. The Committee shall deliver an opinion without delay.

<table>
<tr>
<td>Japan</td>
<td>Building Law
Quality of Building Materials</td>
<td>Article 37:
Such building materials as wood, steel, concrete and other materials specified by the Minister of Land, Infrastructure and Transport used for the foundations, principal building parts, and other parts of building specified by Cabinet Order which are important from the viewpoint of safety, fire prevention and sanitation (hereafter in this Article referred to as “designated building materials” shall come under either one of the following items:

Those qualities conform to the Japanese Industrial Standards or Japanese Agricultural Standards designated for each designated building materials by the Minister of Land, Infrastructure and Transport.</td>
</tr>
<tr>
<td>Japan</td>
<td>Enforcement Regulation
of Pharmaceutical Affairs Law

Designated medical equipment that the Ministry of Health Labour and Welfare specifies standards pursuant to the provisions of Item 1 of Article 23-2 of the Pharmaceutical Law.</td>
<td>Designated Medical Equipment that the Ministry of Health, Labour and Welfare specifies standards pursuant to the provisions of Item 1 of Article 23-2 of the Pharmaceutical Affairs Law shall conform to the standards given in the table below.

<table>
<tr><th rowspan="2">Medical Equipment</th><th></th><th>Standards</th></tr>
<tr><th>JIS</th><th>Purpose of use, effect or impact</th></tr>
<tr><td>Thermometer</td><td>T1140</td><td>Making temperature measurement section contact, measures the body temperature of rectum, armpit, buccal cavity (hypoglossal), keeps the highest temperature and indicates it digitally.</td></tr>
</table>
</td>
</tr>
<tr>
<td>Japan</td>
<td>Electrical Appliance
and Material Safety Law

Technical requirements pursuant to the provisions of Article 2 of the Ordinance of the Ministry that specifies technical standards for electrical appliances and materials.</td>
<td>The technical Requirements set by the Minister of Economy, Trade and Industry pursuant to the provisions of Article 2 of the Ordinance of the Ministry shall be as prescribed in the following Tables 1, 2 and 3, and the Technical Requirements pertinent to each of the relevant products shall be applied.

<table>
<tr><th colspan="3">Technical Requirements
for Electrical Appliances and Materials</th><th rowspan="2">Notes</th></tr>
<tr><th>Number</th><th>Title</th><th>Text</th></tr>
<tr><td>J60068-2-2(H14)</td><td>Basic environmental testing procedures, Part 2: Tests, Test B: Dry heat</td><td>JIS C 0021: 1995</td><td>Corresponding to IEC 60068-2-2 (1974) Amd.N° 2 (1994)</td></tr>
<tr><td>J60068-2-3(H14)</td><td>Basic environmental testing procedures, Part 2: Tests, Test C: Damp heat, steady state</td><td>JIS C 0022: 1987</td><td>Corresponding to IEC 60068-2-3 (1969)</td></tr>
</table>
</td>
</tr>
<tr>
<td>South Africa</td>
<td>Occupational Health
and Safety Act 85 of 1993

(The example on the right is of direct incorporation of a national standard into legislation by reference in a Schedule to Regulations promulgated in terms of an Act of Parliament, followed by an extract from the actual regulation.)</td>
<td>Incorporation (abridged): “Under section 44 of the Occupational Health and Safety Act,1993 (Act 85 of 1993) I, MMS Mdladlana, Minister of Labour, hereby incorporate SANS 10019 Code of practice for portable metal containers for compressed gasses’ into the Diving Regulations 2001”

Extract from Diving Regulations 2001: “The employer must take all reasonable steps to ensure that the air supplied to the divers is pure and that it meets the requirements of SANS 10019.”</td>
</tr>
</table>

South Africa	National Building Regulations and Building Standards Act 103 of 1977 (as amended) Regulations under Section 17 (1), Regulation F5	F5. Soil poisoning "Where so required by the local authority, the soil in all areas within the site as defined in code of practice SANS 10124 shall be treated in accordance with the recommendations of SANS 10124."
South Africa	Water Services Act 108 of 1997 – Regulations under sections 9(1) and 73(1)(j) – Regulation 8 "Use of effluent", subregulation 8 (3)	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 : Partie 1: Standards, Signs and General Requirements."*
U.S.A.	47 CFR 15.109 Federal Communications Commission Part 15_Radio frequency devices Subpart b Unintentional radiators Sec. 15.109 Radiated emission limits.	(g) As an alternative to the radiated emission limits shown in paragraphs (a) and (b) of this section, digital devices may be shown to comply with the standards contained in the Third Edition of the International Special Committee on Radio Interference (CISPR), Pub. 22,"Information Technology Equipment — Radio Disturbance Characteristics — Limits and Methods of Measurement".
U.S.A.	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.	(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.
U.S.A.	46 CFR 111.105-11 Title 46 — Shipping Chapter I — Coast Guard, Department Of Homeland Security Part 111_Electric Systems — General Requirements Subpart 111.105_Hazardous Locations Sec. 111.105-11 Intrinsically safe systems.	Sec. 111.105-11 Intrinsically safe systems. (a) Each system required under this subpart to be intrinsically safe must use approved components meeting UL 913 or IEC 79-11.
U.S.A.	47 CFR 15.109(g)	As an alternative to the radiated emission limits shown in paragraphs (a) and (b) of this section, digital devices may be shown to comply with the standards contained in Third Edition of the International Special Committee on Radio Interference (CISPR), Pub. 22, "Information Technology Equipment — Radio Disturbance Characteristics — Limits and Methods of Measurement" (incorporated by reference, see §15.38). In addition: (1) The test procedure and other requirements specified in this part shall continue to apply to digital devices. (2) If, in accordance with §15.33 of this part, measurements must be performed above 1000 MHz, compliance above 1000 MHz shall be demonstrated with the emission limit in paragraph (a) or (b) of this section, as appropriate. Measurements above 1000 MHz may be performed at the distance specified in the CISPR 22 publications for measurements below 1000 MHz provided the limits in paragraphs (a)

		and (b) of this section are extrapolated to the new measurement distance using an inverse linear distance extrapolation factor (20 dB/decade), e.g. the radiated limit above 1000 MHz for a Class B digital device is 150 uV/m, as measured at a distance of 10 meters. (3) The measurement distances shown in CISPR Pub. 22, including measurements made in accordance with this paragraph above 1000 MHz, are considered, for the purpose of §15.31(f)(4) of this part, to be the measurement distances specified in this part. (4) If the radiated emissions are measured to demonstrate compliance with the alternative standards in this paragraph, compliance must also be demonstrated with the conducted limits shown in §15.107(e). Note: CISPR is a Committee within the IEC.
U.S.A.	47 CFR 15.31(a)(3)	Other intentional and unintentional radiators are to be measured for compliance using the following procedure excluding sections 4.1.5.2, 5.7, 9 and 14: ANSI C63.4-2003: “Methods of Measurement of Radio-Noise Emissions from Low — Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz” (incorporated by reference, see §15.38). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Note to paragraph(a)(3): Digital devices tested to show compliance with the provisions of §§15.107(e) and 15.109(g) must be tested following the ANSI C63.4 procedure described in paragraph (a)(3) of this section.

Annex C

Examples of national and regional policies on using standards in technical regulations

As the benefits of using standards in technical regulation have become more prevalent, major economies of the world have developed policies to actively encourage their use. This annex contains summary positions from different countries highlighting their current policies on using standards (national and international) in their technical regulations. The national contributions in this annex were provided by ISO members in the different countries and are reproduced as received.

As with Annex B, it is important to note that the terms "standards" or "national standards" can mean adoptions of ISO and IEC standards.

C.1 China

C.1.1 Background

One of the main forms of China's technical regulation is mandatory standards at national, professional and local levels. It is stipulated in the Standardization Law of the People's Republic of China that "standards for assuring health, and the safety of persons and their properties, and standards prescribed in laws and administrative regulations are compulsory, mandatory standards. Products that do not comply with mandatory standards are prohibited to be produced, sold or imported." Thus, it can be seen that mandatory standards have the characteristics of technical regulations.

Since China joined the WTO in accordance with the relevant requirements of the WTO, all China's mandatory standards concerning trade have been notified and have been largely recognized by the international society. By the end of the year 2005, the total number of China's mandatory standards was 3024.

It is stipulated in the Standardization Law of the People's Republic of China that certain standards from the following categories can be mandatory standards depending on the risk that the product or activity poses:

- Pharmaceutical standards; food sanitary standards; animal medicine standards,
- Safety and sanitary standards for products and standards for the production, storage and transportation, and use of products; occupational health and safety standards; transportation safety standards,
- Quality, safety and sanitary standards for engineering construction, and other engineering construction standards that the government needs to control,
- Pollutant emission standards and environment quality standards for environmental protection,
- Important general technical terminology, symbols, codes and drawing method standards,
- General testing, checking and inspecting method standards,
- Some interchanging and fitting standards,
- Important quality standards that the government needs to control.

C.1.2 Main forms of using standards in Chinese technical regulations

China's national standards are mainly used in technical regulations in the following three forms:

A A mandatory standard itself becomes the technical regulation

As described above this is the most important form of technical regulation in China.

B Standards are either directly or indirectly quoted

The use of standards will become mandatory if quoted in regulatory documents such as legislative texts and departmental regulations. In most cases, the indirect option is chosen. For example, the relevant text of the regulatory document will state *"…should comply with national or industrial standards…"*

C Part of a recommended standard is quoted in mandatory standards

This is where an extract of a standard is reproduced as part of the text of the regulatory document. The requirements in the extract will then be compulsory.

C.1.3 Summary

The above three methods of referencing standards reflect the situation of how China's national standards are used in technical regulations. When choosing which option to use and indeed 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. This ensures that international standards indeed become China's technical regulations. At the time of writing this Guide, about 40 % of China's standards are developed based on international standards.

The Chinese view on using standards in support of technical regulation is that, on the one hand, technical standards can help laws to regulate the market and, on the other hand, they can help legal and administrative measures to conduct necessary intervention in order to establish fair and reasonable competition for the market economic order. In China, laws only stipulate the general rules, while standards specify the technical criteria that facilitate the implementation of laws; and, in return, the implementation of laws can promote the carrying out of standards. Therefore, laws and standards actually supplement each other, working together for the realization of the overall objectives specified in the law and the implementation of technical standards. At the same time, standards are implemented compulsorily during the implementation process of laws.

C.2 Europe

C.2.1 Background

The European standardization system is based on the following principles: integration with International Standards, voluntary use of standards, openness and transparency, participation of all stakeholders, and ensuring consensus in decision making.

Standardization is an integral part of the European policies to carry out "better regulation", to increase the competitiveness of enterprises and to remove barriers to trade at the international level. In Europe, standardization is seen as an effective tool to help implement regulation. Indeed, in 2004 the European Commission published a paper stating:

> *"The Commission, in cooperation with the European Standards Organizations, will continue* ***to encourage the development of international standards*** *by the appropriate international standards bodies and promote their use. Where international standards exist, they shall, wherever possible, be uniformly transposed by the European Standards Organizations and used as a basis for Community legislation."*

In the portfolio of European legislation there are examples of standards being referenced in legislation. The different methods discussed in Chapter 6 are used but one of the most successful methods is the European New Approach model.

C.2.2 The European "New Approach" to legislation

An example of a regulatory model which aims to be standards-receptive is the European "New Approach". This new approach to legislating in Europe was devised over 20 years ago to help simplify legislative requirements and compliance by using tools such as standards.

There are now over 25 European Directives using these New Approach principles. They cover products from household appliances to lifts in buildings and this model of regulation has been a major success factor in helping to create Europe's single market.

C.2.3 Key features of the New Approach and how it works are detailed below

The regulation only defines the "essential requirements" for products and services, for example those concerning protection of health and safety. The procedures and infrastructure that support these directives are now well established and ensure an

effective operation in different sectors. The New Approach style of legislation is therefore being promoted into other areas of European Policy.

A simplified overview of how the New Approach principles work is given below:

- New Approach type directives contain a format and text which allow for the voluntary use of standards as one method by which legal obligations can be met. Depending on the product and the risks associated with it, the directives may also contain conformity assessment requirements.

- Once the directive has been drafted and approved through the European legislative process, a dialogue begins with the European Standards Bodies.

- A formal request is then drafted by the European Commission reflecting the discussions with the European Standards Bodies. This will list the standards and types of standards which are considered necessary to support the directive.

- This formal request (known as a Standardization Mandate) will first need approval through the European political process. This will be made up of expert committees for the specific field being regulated and of committees dealing with broader standardization policy. These committees will be made up of Government representatives from the different European Member States.

- Once all parties approve this formal request, it is then passed on to the European Standards Bodies who will organize the work required using a wealth of expertise and technical structures from different European countries.

- The policies of the European Standards Bodies demand that International Standards are used wherever they exist and are suitable.

- Depending on the sector, individual standards which are to be used in support of a directive will be assessed by independent consultants to make sure that they are suitable for regulatory requirements.

- Once they are published, the standards are then passed on to the regulator via the European Commission. If all procedures are considered to have been satisfied, the standard's reference will then be listed as being suitable for legislation. These official lists are recorded in official documentation and are regularly updated on a designated website for public access.

- Manufacturers can then choose to use standards from these lists (they remain voluntary). Those who do can be confident that they will be meeting their legal obligations.

- The correct use of the harmonized standard gives the "presumption of conformity" of the product complying with that standard and the associated regulatory requirements.

The New Approach has proven to be a specific model of legislation by which both the public interest (i.e. protecting public health and safety, consumer and environmental protection) and the interest of private business to produce standards (for products and services) in accordance with the relevant state of the art could be merged in an adequate way. It allows for more flexible and less stringent forms of legislation in areas where, otherwise, any detail would have to be determined by the legislation.

More information and a full list of product areas governed by the New Approach legislation (or legislation which is based on New Approach principles) can be seen at the following URL:

www.ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist.html

C.2.4 Taking standards into new European policy areas

By means of the New Approach model and principles, the use of standards to support European legislation will be extended to new areas. In the last few years, European legislation in new fields such as that of ICT, the environment and consumer protection have started to use its benefits. The European Commission intends to continue to promote, in accordance with its commitment to better regulation, the broader use of standards to support its legislation. The services sector will be the next area of focus as it is thought that standardization will help create the European internal market for services and increase the competitiveness of European businesses.

More information on the European Commission's overall policy on standardization can be seen at the following URL:

www.europa.eu.int/comm/enterprise/standards_policy

C.3 Japan

C.3.1 Background

In recent years, with the progress of regulatory reform, an increasing number of voluntary Japanese Industrial Standards (JIS) are being adopted as technical standards in regulations, 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. At the same time, the WTO/TBT Agreement specifies that both regulations and technical standards should be harmonized with international standards with a view toward not creating unnecessary obstacles to international trade. The WTO/TBT Agreement reads: "Where technical regulations are required and relevant international standards exist or their completion is imminent, members shall use them, or the relevant parts of them, as a basis for their technical regulations." As a member of the WTO, the Japanese government is working to harmonize JIS standards with corresponding international standards to the greatest degree possible. At the same time, it is encouraging the use of JIS standards as references when technical standards are required in regulations. Of the over 9,700 JIS standards currently existing, 4,800 have corresponding international standards, and 4,500 of these are harmonized with their corresponding international standards.

C.3.2 Referencing of JIS standards to regulations

Ensuring the safety of industrial products is the most important consideration in the context of protection of consumers and labour. JIS standards are referenced as technical standards for self-declaration and third-party conformity assessment in regulations governing safety. There are about 2,000 JIS standards that are referenced in regulations. The Building Law, Pharmaceutical Affairs Law, and Electrical Appliance and Material Safety Law are examples of regulations referencing JIS standards.

Building Law

The Building Law and its related laws stipulate standards for sites, structures, equipment, and the usage of buildings. According to these laws, the quality of building foundations, principal building parts and materials used for building parts that are important in terms of safety, fire prevention, and sanitation must be approved by the Minister of Land, Infrastructure and Transport. JIS standards are used in this approval testing. Building materials conforming to the JIS standards referenced in these laws, however, are not required to obtain such ministerial approval. Nearly 240 JIS standards are referenced in these laws, and, of these, about 100 are harmonized with their corresponding international standards.

Pharmaceutical Affairs Law

The Pharmaceutical Affairs Law and its related laws provide regulations required to ensure the quality, efficacy and safety of drugs, quasi-drugs, cosmetics and medical devices. For in vitro diagnostic medical devices designated in these laws, manufacturing distributors are required to obtain certification by a third-party certification organization designated by the government. About 140 JIS standards are referenced in these laws as performance standards for medical devices. Of this number, about 40 are harmonized with their corresponding international standards.

Electrical Appliance and Material Safety Law

The Electrical Appliance and Material Safety Law and its related laws establish restrictions on the manufacturing, import and sale of designated electrical products in order to prevent accidents caused by electrical products. Manufacturers or importers of electrical products are obligated to (1) produce or import electrical products that conform to the technical standards stipulated in the laws; (2) ship those products with a mark ("PSE" mark) that shows that the electrical products conform to technical standards; and (3) only sell electrical products with the PSE mark. About 60 JIS standards are referenced in these laws, and almost all of them are harmonized with their corresponding international standards.

C.4 South Africa

The development of national standards in South Africa is carried out by the South African Bureau of Standards (SABS), which is authorised to do so in terms of the Standards Act (Act 29 of 1993). At the time of preparing this text, the Standards Act was under revision to separate the standards development and conformity assessment functions carried out by the SABS from its regulatory functions, which latter in the future would more appropriately be carried out by a separate national regulatory authority.

In terms of South African legal practice, reference to standards in national legislation has to be such that the standards are deemed to be readily available to all who might have a need to consult them. In the Internet age this ready availability is less of a practical problem than it might have been in the past, but legal precedents have been established that effectively require reference to standards in legislation to be limited to National Standards developed by the SABS. This term would include International Standards that have been adopted and republished as national standards, but has in the past excluded direct reference to the International Standards in their own right, especially where they have not, for whatever reason, been transposed as National Standards. This is advantageous in that it avoids confusion in the marketplace over applicable standards relevant to regulated products, and lessens the chances of the national standards body publishing national standards that are repugnant to existing or future legislation.

Any legislator in South Africa has the right to incorporate any national standard into legislation under whatever terms and conditions it chooses. Normally the legislator concerned will consult the SABS regarding the implications, and will regulate using standards only in terms of the need to ensure compliance with standards at the point of use of a commodity (for example, in the mining industry it is important to ensure that miners' head lamps always conform to relevant requirements when in use — not merely when they are purchased new). In some cases, however, where safety, market failures, unfair trade practices, etc. need to be prevented, it is necessary to regulate using standards, at the point of sale (for example, all automotive brake fluid sold in the country is required to conform to relevant standards at all points of sale, including at points of importation, wholesale and retail distribution. This type of regulation is normally the prerogative of the national Department of Trade and Industry, and is achieved through the means of "Compulsory specifications" (see (3) below).

Technical Regulation in South Africa, whether at national, provincial or lower levels, typically takes one of three forms:

1. Full publication of all technical requirements, including administrative provisions, conformity assessment or deemed-to-satisfy requirements, in legislation per se. Often this type of regulation excludes any reference to standards, although for practical reasons the "full publication" route is not used very widely. Modern regulatory good practice, as endorsed by government policies, would favour making use of reference to standards, where they exist, over the full publication method, but examples of the latter still exist.

2. Reference to national standards under relevant legislation (national or lower level). In this method, 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, where such are deemed necessary. In this method, which is the most common, the national standard typically provides the technical requirements for the commodity and the administrative provisions would be given in the regulation. At national level the regulation would typically be published by the applicable government department in terms of an existing Act of Parliament. In this method the national standard, being readily available, is often the most convenient choice for the legislator as the basis for regulation; it can readily be amended to keep up with technology (via the national standards process) and has the benefit that it already represents a national consensus of experts as to the appropriate level of fitness for purpose (in the case of a physical product).

3. Publication of a "Compulsory specification". This is a mandatory standard, applicable to certain products and commodities at their point of sale, and is typically used to regulate safety-critical items where market failures would otherwise occur in the absence of regulation. Examples of the fields covered by compulsory specifications include electrical fittings, food safety, automotive components, etc.

   The SABS has developed around 80 compulsory specifications (compared to its national standards base of around 5,000 standards).

   A compulsory specification has historically been developed by a SABS Technical Committee, sometimes initially as a national standard and

sometimes as a separate document, and then recommended via the SABS Council to the Minister of Trade and Industry for implementation as a Compulsory Specification. After a public enquiry process, a Compulsory Specification is published in full in the Government Gazette (including provisions for the application of the technical requirements, administrative provisions, etc.). The Compulsory Specification then becomes law in its own right under the Standards Act. It is not a national standard and, typically, is applicable at the point of sale.

Proposed changes to the Standards Act will do away with the need for full publication of Compulsory Specifications and will bring about a development process for such legislation that will involve the development of a "normal" national standard and reference to that national standard by a means similar to that given in (2) above. One important difference is that Compulsory Specifications regulate the sale and availability (as opposed to the use) of commodities and are always published by the national Department of Trade and Industry.

C.5 The United States

C.5.1 Background

As a signatory of the World Trade Organization, the U.S. is responsible for pursuing standardization activities that are in full compliance with the WTO/TBT, as this is the key international agreement which mandates how countries use standards and conformity assessment in regulation. Specifically, section 2.4 should be noted as this is one of the key linkages the agreement makes regarding how standards should be used in technical regulations.

> 2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

The U.S. federal government is the largest single creator and user of specifications and standards — current estimates point to more than 44,000 distinct statutes, technical regulations or purchasing specifications. 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. Add the more than 50,000 standards estimated to come from the private sector in America and the nation's total inventory of standards quickly approaches 100,000. These documents are produced and maintained by nearly 600 standards organizations in the United States, 200 of which are accredited by ANSI as developers of American National Standards (ANSs). In addition, the full catalogues of ISO and IEC have the potential to be used or referenced in regulation by U.S. federal government agencies if deemed appropriate.

C.5.2 Standards usage

Government agencies can use externally developed standards in a wide variety of ways, including the following:

- Adoption: An agency may adopt a voluntary standard without change by incorporating the standard in an agency's regulation or by listing (or referencing) the standard by title. For example,

the Occupational Safety and Health Administration (OSHA) adopted the National Electrical Code (NEC) by incorporating it into its regulations by reference.

- Strong deference: An agency may grant strong deference to standards developed by a particular organization for a specific purpose. The agency will then use the standards in its regulatory programme unless someone demonstrates to the agency why it should not.

- Basis for rulemaking: This is the most common use of externally developed standards. The agency reviews a standard, makes appropriate changes, and then publishes the revision in the Federal Register as a proposed regulation. Comments received from the public during the rulemaking proceeding may result in changes to the proposed rule before it is instituted.

- Regulatory guides: An agency may permit adherence to a specific standard as an acceptable, though not compulsory, way of complying with a regulation.

- Guidelines: An agency may use standards as guidelines for complying with general requirements. The guidelines are advisory only; even if a firm complies with the applicable standards, the agency may conceivably still find that the general regulation has been violated.

- Deference in lieu of developing a mandatory standard: An agency may decide that it does not need to issue a mandatory regulation because voluntary compliance with either an existing standard or one developed for the purpose will suffice for meeting the needs of the agency.

Where standards are referenced in regulations, regulatory policies emphasize that regulations (including any referenced standards) be cost-effective, consistent, sensible and understandable, and that the regulatory process should be open, transparent and fair to all interested parties. Government regulations may address health, product safety, operator/user safety, environmental effects, quarantine requirements, consumer protection, packaging and labelling, product characteristics, or other matters in the public interest.

C.5.3 Legislation

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.

Other laws and policies that reinforce the strong public-private partnership approach to standards and conformity assessment in specific sectors or areas of interest include the following:

Standards Development Organization Advancement Act of 2004 (H.R. 1086)

HR 1086 provides qualified standards developers with an opportunity to file for, and obtain, a limited exclusion from antitrust liability for treble damages. This protection is identical to the protection which has been available to joint ventures under the National Cooperative Research and Production Act since 1993, which also remains available to those utilizing a consortium or other informal processes to develop standards.

The Consumer Product Safety Act

Under the Consumer Product Safety Act, the Consumer Product Safety Commission specifically relies upon voluntary consensus consumer product safety standards rather than promulgate its own standards. The relevant portion of the law is set forth below:

> "…The Commission shall rely upon voluntary consumer product safety standards rather than promulgate a consumer product safety standard prescribing requirements described in Subsection (a) whenever compliance with such voluntary standards would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with such voluntary

standards." (Source: Section 7(b)(1) of the Consumer Product Safety Act (15 USC 2056; PL 92-573; 86 Stat. 1207, Oct. 27, 1972, as amended in 1981.)

The Health Insurance Portability and Accountability Act of 1995

This Act requires the Secretary of Health and Human Services to adopt standards developed by ANSI-accredited standards developers whenever possible.

The Telecommunications Act of 1996

The first major overhaul of U.S. telecommunications law in almost 62 years, the act contains several provisions that propel the Federal Communications Commission (FCC) toward reliance upon private sector standards. In particular, the FCC is seeking to ensure that the standards development process in the telecommunications area is open and consensus-based — the very things provided for by ANSI accreditation requirements.

The Food and Drug Administration (FDA) Moderization Act of 1997

This act contains provisions which allow the FDA in some instances to accept manufacturers' declarations of compliance to certain standards during the evaluation of pre-market submissions for electrical medical devices. This is expected to result in a substantial reduction of time-to-market for some medical devices while still ensuring that fundamental regulatory health and safety responsibilities are met.

C.5.4 Procurement reform

In addition, the U.S. Government has increased its reliance on private sector standards in its procurement activities. In 1994, Secretary of Defense, William Perry, announced that one of the Department of Defense's (DoD's) top priorities would be to move away from military-unique specifications and standards (milspecs) and toward reliance upon private sector standards to ensure that DoD continued to meet its military, economic and policy objectives in the future in a cost-effective manner.

C.5.5 Summary

The United States considers standards to be a fundamental factor in the nation's economy and vital to world commerce. Within the United States, standards are developed through a complex but effective system administered by the private sector, with the participation of industry, academia, consumers and government. The U.S. system has evolved over the last 100 years to meet the needs of U.S. industry and society in general. Rooted in the private sector, it has successfully met domestic marketplace needs on a sector-by-sector basis. Responsibility for coordination of the U.S. private sector standards system rests with the American National Standards Institute (ANSI). ANSI is also the U.S. member body within ISO and IEC. Organizations that are accredited by ANSI to develop American National Standards (ANSs) or to serve as U.S. Technical Advisory Groups (U.S. TAGs) to the International Organization for Standardization (ISO), or organizations that are approved by ANSI's U.S. National Committee (USNC) of the International Electrotechnical Commission (IEC) to serve as U.S. TAGs to IEC committees, are required to adhere to a set of essential requirements that are aligned with the WTO principles. These principles include transparency, openness, impartiality, effectiveness and relevance, consensus, performance-based coherence, due process, and the provision of technical assistance where appropriate. The U.S. system, both domestically and internationally, benefits from strong industry support and participation of both government and private sector technical experts as equals at all levels in the process.

International Organization for Standardization
International Electrotechnical Commission