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Preface

Good standardization practice (GSP) is, by definition, the best way of developing and publishing standards. Therefore, the objective of this publication is to provide guidance to a national standards body (NSB), primarily in a developing country, to operate in an effective and efficient manner the essential core-activities needed to develop and publish standards.

Standardization is one of the main elements of the national quality-infrastructure in a country, the others being metrology, accreditation, conformity-assessment services and market surveillance. Standardization occupies a special place as the other organizations involved in the national quality infrastructure, base much of their work on the standards published by the NSB. Furthermore, in a modern society, standards contribute to sustainable development and in particular to trade, health and safety, and environmental protection.

This publication describes the key elements of standardization, in the following logical sequence:

- the fundamentals of standardization;
- standardization in the light of the World Trade Organization Agreement on Technical Barriers to Trade (WTO TBT);
- internationally-agreed principles for the development of standards; and
- ▶ the value chain for the development of standards by an NSB.

Ever since Michael E. Porter¹⁾ defined the concept of a "value chain" in 1998, this concept has been widely used by organizations to identify all the elements of their operations and the linkages between them. The aim is to optimise these activities to make the process much more effective and efficient. Applying the value chain to an NSB identifies its "core activities", i.e. the operations the NSB has to perform to develop and publish standards based on the needs of the country, and the "support activities" which describe the infrastructure and resources that must be available in an NSB to enable it to operate the essential core-activities effectively and efficiently. A major part of this publication identifies these elements of the value chain of an NSB, which can then be optimised by applying GSP.

The "core activities" contain elements such as: (i) planning; (ii) development; (iii) publication; (iv) dissemination; and (v) customer services, as relating to national standards. The "support activities" deal with elements such as: (vi) administration and financial infrastructure; (vii) human resource management; (viii) product and technology development, and (ix) Technical Committees. This document describes all of these in great detail, allowing any NSB to evaluate its governance, infrastructure and processes in the light of established GSP. These value-chain elements also form the basis of a diagnostic tool, which. will allow an NSB to determine rapidly whether its value-chain elements are in place and whether they are effective.

This publication complements the WTO Agreement on Technical Barriers to Trade and the ISO/IEC Guide 59:2019, ISO and IEC recommended practices for standardization by national bodies, by providing guidance on how to comply with their necessary requirements. In this respect, ISO has taken the lead in capturing the collective good standardization practices of NSBs around the world, and making them available in a single publication for use for a wider audience, including not only NSBs in developing countries but all ISO members.

¹⁾ Porter, M.E. (1985). *Competitive Advantage: Creating and Sustaining Superior Performance.* The value chain is defined as all the activities that a company or organization needs to perform in order create a product or service.

This publication on GSP is a companion to previous publications ISO has made available, such as:

- Fast forward: National standards bodies in developing countries;
- Financing NSBs: Financial sustainability for national standards bodies; and
- *Building trust: The conformity assessment toolbox* (published in cooperation with UNIDO).

Based on these publications ISO is providing support to build capacity amongst its members, with respect to GSP as part of ISO's *Action Plan for Developing Countries*. ISO trusts that this publication will become a valuable addition to this knowledge base, for the benefit of the whole standardization environment. This publication on GSP is a "living" document and will periodically be updated.

Sergio Mujica

ISO Secretary-General

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Disclaimer

The publication does not imply the expression of any opinion whatsoever on the part of the ISO concerning the legal status of any country, territory, city or area or its authorities, or concerning the delimitation of its frontiers or boundaries. This document has been developed by the author mentioned above, with editing and publishing by ISO. Discussions and recommendations do not necessarily reflect the views of ISO and are not endorsed by ISO. While every effort has been made to verify the information contained in this document, ISO cannot accept any responsibility for any errors that it may contain. This document is strictly an information document and in no way represents the consensus views contained in ISO standards and other ISO deliverables.

Acronyms and abbreviations

ARSO African Organization for Standardization

BIPM International Bureau of Weights and Measures

CAC Codex Alimentarius Commission

CASCO ISO Committee on Conformity Assessment

CD committee draft

CEN European Committee for Standardization

CENELEC European Committee for Electrotechnical Standardization

COPANT The Pan American Standards Commission

CROSQ Caribbean Community Regional Organisation for Standards and Quality

CMC calibration and measurement capability

DCMAS Developing Country Network on Metrology, Accreditation and Standards

DEVCO ISO Committee for Developing Countries

DIS draft International Standard

ETSI European Telecommunication Standardization Institute

FDIS final draft International Standard

GAP good agricultural practice

GATT General Agreement on Tariffs and Trade

GSP good standardization practice

International Accreditation Forum

IEC International Electrotechnical Commission

ILAC International Laboratory Accreditation Cooperation

IPPC International Plant Protection Convention

ISO International Organization for Standardization

ISO/PAS ISO publicly available specification

ISO/TR ISO technical report

ISO/TS ISO technical specification

ITU International Telecommunication Union

KCDB key comparison database

KPIkey performance indicatorNABnational accreditation bodyNGOnon-governmental organization

NMI National Metrology Institute
NSB national standards body

NSS national standardization strategy

NTB non-tariff barrier

NWIP new work-item proposal

OECD Organization for Economic Cooperation and Development

OIE International Office of Epizootics

OIML International Organization of Legal Metrology

PEG process-evaluation group

POCOSA ISO Policies and Procedures for Copyright, Copyright Exploitation Rights

and Sales of ISO Publications

QI quality infrastructure

RIA regulatory impact assessment

RSB regional standards body **SWP** standards work programme

SC subcommittee

SPS Sanitary and Phytosanitary Measures

STC specific trade concernsTBT Technical Barriers to Trade

TC technical committee

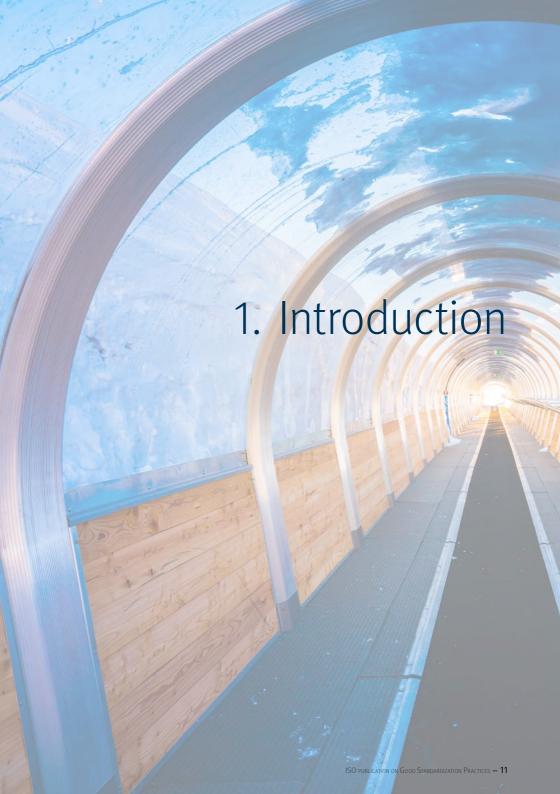
TMB technical management board

USD United States Dollar

UNIDO United National Industrial Development Organization

WG working group

WTO World Trade Organization



1.1 General

Good operating practice is a strategic management term. More specific uses of the term include good agricultural practices, good manufacturing practice, good laboratory practice, good clinical practice and now also good standardization practice (GSP). Generally speaking, a good operating practice is a method or technique that has been generally accepted as superior to any alternatives because it produces results that are superior to those achieved by other means, or because it has become a standard way of doing things due to the good results.

Driven by the growth of international trade and technological cooperation, standards bodies have developed procedures and modes of cooperation which are commonly considered to constitute good practices for standards development at all levels. Some of these have been codified in international agreements such as the WTO TBT Agreement, in procedures such as the ISO/IEC Directives, others in international guides such as ISO/IEC Guide 59, and many are found in the intrinsic knowledge base of standards bodies all over the world – all of which are collectively known as good standardization-practice (GSP).

This publication is a monograph on the history and the driving forces for standardization, the international context for standards development, the principles of standards development and the elements of the value chain of standards development, that are effective and efficient in fulfilling the GSP concepts. It may be utilized by any standards body to evaluate its standards development, publication and information systems in order to ascertain the level of its compliance with GSP. This knowledge should help the standards body to optimise its processes within the realities of its environment.

1.2 Terminology

It is important to use concepts and definitions consistently, because some terms mean different things to different practitioners. In general, this document uses

the terms and definitions contained within the following two, international documents:

- ► ISO/IEC Guide 2:2004 Standardization and related activities General vocabulary, and
- ► ISO/IEC 17000²⁾ Conformity assessment Vocabulary and general principles.

The definitions of concepts as provided for in the *WTO TBT Agreement* are also important, and where they differ from those in international documents, this difference is highlighted. Some of the more important terms and definitions are included below.

Standardization is the activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context.

NOTE 1: In particular, the activity consists of the processes of formulating, issuing and implementing standards.

NOTE 2: Important benefits of standardization are improvement of the suitability of products, processes and services for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation (ISO/IEC Guide 2).

A **Standard** is a document, established by consensus and approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

NOTE: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits. *(ISO/IEC Guide 2)*.

A **Product** is the output of an organization, and can be produced without any transaction taking place between the organization and the customer.

NOTE 1: Production of a product is achieved without any transaction necessarily taking place between provider and customer but can often involve this service element upon its delivery to the customer.

²⁾ Under revision. Stage at the time of publication: ISO/DIS 17000:2019.

NOTE 2: The dominant element of a product is that it is generally tangible.

NOTE 3: Hardware is tangible, and its amount is a quantifiable characteristic (e.g. tyres). Processed materials are tangible and their amount is a continuous characteristic (e.g. fuel and soft drinks). Hardware and processed materials are termed "goods". Software consists of information regardless of delivery medium (e.g. computer programme, mobile phone app, instruction manual, dictionary content, musical copyright, and a driving licence) (*ISO 9000:2015*).

An additional concept in this document, and not contained in any of the above international documents is the following description for *quality infrastructure*, as agreed by the International Network of Quality Infrastructure³⁾:

• The system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes.

The quality infrastructure is required for the effective operation of domestic markets, and its international recognition is important for enabling access to overseas markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. It relies on: metrology, standardization, accreditation, conformity assessment and market surveillance. Other terminology that is used consistently is illustrated below.

Interested party is any person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity. Therefore, in the context of standards, an interested party is any person or organization having an interest in the drawing up or use of a standardization document.

Stakeholder is any party that can affect or be affected by the actions of the NSB relating to strategic management, corporate governance, business purpose and corporate social-responsibilities. Stakeholders include parties with the most direct and obvious interests in the actions of the NSB, such as customers and employees,

³⁾ Refer to UNIDO Guide on Quality Policy at https://www.unido.org/sites/default/files/files/2018-06/QP_PRACTICAL_GUIDE_08062018_online.pdf.

as well as others who are less obvious, such as third parties that are affected economically, yet have no influence over that effect.

NOTE: In the latest revision of *ISO/IEC 59*, the terms *stakeholder* and *interested* party are considered as the same. In this publication, the difference is still maintained in order to differentiate between the broader stakeholder groups that would not of necessity be directly involved in the development of standards, but which are nevertheless affected by the implementation of a standard.



2.1 The history of standardization

Standardization has a very long history, dating back thousands of years. What started as a necessity to organize life in early civilizations was later used as a tool by rulers to enhance their power. The industrial revolution provided the real impetus for the growth of standardization, and even today, socio-political considerations give rise to standardization efforts.

2.1.1 Early beginnings

Primitive societies lived in communities according to rules passed on from generation to generation. This led to the development of language and writing. To establish a system of measurement, lengths from parts of the body were used. The *ell*, which is often mentioned in old writings, is the distance from the elbow to the tip of the long finger. The length of the foot and the breadth of the hand were other convenient measurements used.

An early reference to standardization is found on the statue of Gouda, King of Chaldea, in which the sculptor extols the virtues of the ruler and praises him for the introduction of standards in the building industry. Other early accounts of building standards are found on the Egyptian frieze of Thebes dating from BCE 1450; this shows brick-building and measurements. During the reign of the first Roman Emperor Augustus (BCE 27 to 14 CE), the Romans published the *Ten Books of Architecture*. In these, for example, the rules and specification for measurements and proportions for the spacing of pillars and how to pile them, were described comprehensively.

In the Middle East, various weight measurements were in common use for trade and paying tributes. In Babylonian times, typical weight measures were a Talent (30 kg), a Mina (500 g) and a Shekel (50 g). Around BCE 700, for example, King Hezekiah of Judah had to pay King Sennacherib of Assyria 300 Talents of silver and 30 Talents of gold as tribute for not invading Jerusalem.

2.1.2 Standardization as a political tool

Standards have been utilized extensively to further political goals.

Qin Shi Huang, first emperor of China (BCE 220-210) unified China economically by standardizing the Chinese units of measurements such as weights and measures, the currency, and the length of the axles of carts to facilitate transport on the road system.

In early European history, it is believed that King William the First of England (1028-1087) published a Royal Decree that led to the beginnings of a unified system of measurement in England. Before his time, the units of the *ell* and *foot* were frequently based on measurements of a king himself. Once he was replaced by a new king, the measurements also changed. Historians believe that later kings decreed that there should be a standardized measurement of the unit length, the *yard*, which consisted of three feet, and the foot itself would comprise twelve inches. The inch was the length of three barley corns; in so doing, kings had set standards for measurement and calibration.

The early English system evolved into the British Imperial system of weights and measures. Yet now, almost a millennium after King William the First's time, the standardised, metric system of measurement has largely replaced the Imperial system. Regarding the origins of the metric system, many historians believe that its originator was a French pastor, Gabriel Mouton, who in 1670, developed the idea of a logical, simple system based on multiples of ten. One hundred and twenty years later, the French National Assembly asked the French Academy of Science to develop a new, standardised system for units of length, volume and weight. The result was the beginnings of a unified system that found universal appeal. The new system not only replaced thousands of variants of measurement used throughout the French Republic, but also helped to enshrine the power of the government and enhance trade. The metric system eventually became an international system, established by an international treaty, the Metre Convention in 1875. The metric system under the Metre Convention developed continuously with the addition of further measurement units, and in 1960, the SI System of coherent units was established by the 11th General Conference on Weights and Measures.

2.1.3 Standardization in industrial development

The industrial revolution greatly advanced standardization as manufacturers tried to deal with unnecessary varieties of manufactured goods, leading to problems with interchangeability, and unnecessary costs. Health and safety issues also started to have an effect on the industry, as products such as pressure vessels failed and caused many fatalities. Standards coupled with legislation became the main instruments to solve such problems.

When the industrial revolution started in Britain, screw threads were already used extensively in manufacturing. The problem was that each manufacturer had its own system – there was no interchangeability. So in 1841, Joseph Whitworth, an English inventor, engineer and entrepreneur, proposed a standardized system for screw threads. Many railway companies then adopted this system, which eventually became a British Standard. The system of screw threads is named after Whitworth.

Across the Atlantic, early train travel in America was hampered by a lack of a standard gauge for railways, meaning that trains had to be frequently unloaded and reloaded because the track gauge was different between cities. During the Civil War, the US government recognized both the military and economic advantages of having a standardized track gauge. The government then worked with railway companies to promote the use of the most common railway gauge in the US at the time, which measured 4 feet $8\frac{1}{2}$ inches. This gauge was mandated for use in the Transcontinental Railroad in 1864 and by 1886, this gauge had become the US standard.

At the beginning of the 20th century, every electrical company worldwide utilized its own standards for electrification. This in turn meant that voltages and symbols were totally different. The British engineer, inventor and industrialist, Rookes Evelyn Bell Crompton, recognised the inherent dangers of such chaos, so he worked tirelessly to ensure that harmonized standards were established. His work eventually led to the formation of the International Electrotechnical Commission (IEC) in 1906.

2.2 Benefits of standardization

There are many benefits of standardization for the private sector, the public sector and consumers. The use of standards in international and local trade and everyday life is now commonplace and well embedded; so much so, that socio-economic systems without standards are not conceivable.

2.2.1 Standards and the private sector

The many benefits that standards bring to the private sector include:

- Reduction in production and transaction costs: This is achieved mainly through variety reduction and rationalization of processes leading to economies of scale. An additional benefit is that a broader choice of sub-suppliers of components and sub-assemblies is possible, all complying with the set standards:
- Increased market opportunities: Many goods in numerous markets have become standardized. Hence, compliance with such standardized goods provides the manufacturer with the opportunity to access more markets, instead of being limited to one where a different standard is expected;
- Competitive positioning: Being involved in standards development allows manufacturers and suppliers to anticipate market developments. Progressive companies leading technological developments in the marketplace, may see their company standards become the basis for national or even International Standards, further enhancing their position in the market; and
- Improved risk management: The risks associated with the introduction of technical regulations or the introduction of new technologies can be mitigated by the appropriate use of standards. Technical regulations based on known, proven standards lower the risk of non-compliance when a new technical regulation is published. The introduction of new technologies in the marketplace brings about inevitable costs; however, these costs can be shared with other manufacturers if the new technology is codified in standards that everybody can use.

2.2.2 Standards and the public sector

As well as specifying standards for government purchases, the public sector can benefit substantively from the use of standards, namely:

- A basis for regulation: Standards are recognized solutions to implement the health and safety requirements for regulated products. Legislators, for example, gain the acceptance of stakeholders for regulations because they were involved in the development of the standards used as the basis for regulation. Standards are kept up-to-date through five-year review programs; hence regulations using them as a basis can remain up-to-date as well depending on the mode of referencing⁴⁾;
- Efficient regulation through participatory processes: When regulations are based on standards, these can be used to provide guidance on essential requirements. This has the advantage that market forces can be utilized in keeping compliance costs to a minimum. Conformity-assessment service providers complying with standards such as ISO/IEC 17021 and ISO/IEC 17025 can be designated by the country to provide such services. If more than one service provider is designated, market forces will keep costs at reasonable levels, and the country need not provide such services; and
- Contribution to socio-economic development: Regulations based on standards give the country access to the latest state-of-the-art requirements for products agreed by a broad stakeholder group. In addition, local companies can gain easier access to foreign markets where the regulations are also based on the same standards; this means that such companies do not need to develop products that have to comply with a different set of standards.

2.2.3 Standards and the consumer

The consumer benefits from standardization in several ways, such as:

• **Consumer involvement**: The consumer is invited to be a participant in the standards-development process; hence the consumer has a voice in the process. Once products and processes are marketed, whether they

⁴⁾ Standards can be referenced dated or undated – see Section 3.4.1 for details.

need to comply with technical regulations or not, standards are useful in a legal sense when dangerous or non-compliant consumer goods have to be identified;

- Consumer safety: Products from many suppliers complying with the same underlying safety or compatibility standards provide the consumer with choices regarding other elements such as cost and design. This in turn means that consumers can be secure in the knowledge that the product will be safe and will integrate with common systems such as power supplies, telecommunications standards, the internet and common forms of machinery; and
- **Sustainability:** Standards are widely used in occupational health and safety systems, environmental protection and increasingly in determining the social aspects of sustainable development, ultimately benefitting the society.

2.2.4 Standards and small-to-medium sized enterprises (SMEs)

There is a perception that it is both difficult and expensive to comply with International Standards, especially for small-to-medium sized enterprises (SMEs), which constitute the bulk of the industry in many developing countries. However, the benefits that SMEs can achieve if they pursue the implementation of International Standards, either directly or as an adopted national standard, are widespread. For example, International Standards: (i) help improve the quality of goods and services; (ii) help to drive growth, cut costs and increase profits; (iii) give the business a competitive edge; (iv) open up markets for goods and services of SMEs; (v) open the door for new customers and strengthen the existing business; (vi) help SMEs to compete with bigger enterprises; (vii) enhance the credibility of SMEs; (viii) sharpen business practices and increase efficiency; (ix) strengthen marketing activities, and (x) help SMEs to comply with technical and other regulations. ISO has published a free brochure ⁵⁾ listing and discussing these benefits, and ISO recommends that NSBs promote this document.

⁵⁾ https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100283.pdf.

2.3 Definition of a standard

There are two definitions for a standard that are commonly utilized by practitioners. These are the definitions contained in *ISO/IEC Guide 2: Standardization and related activities — General vocabulary*, and the *WTO TBT Agreement*. Both are relevant, even though they differ; the *ISO/IEC Guide 2* definition is generally used in this publication. The difference between the *ISO/IEC Guide 2* and the *WTO TBT Agreement* definitions is explained in Section 3.3. The definition of a standard given in *ISO/IEC Guide 2* is the following:

• A standard is a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

NOTE: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

2.4 Diversity of standards

There are numerous ways to classify the many types of standards published by public and private organizations, and even non-governmental organizations (NGOs). A useful approach is to consider the classification as an environment with three facets, namely (i) technical content, (ii) development process, and (iii) legal status as shown in Figure 2.1.

2.4.1 Technical content

The technical content includes elements such as the purpose, the type of document and the requirements contained within the standard. As regards the purpose of a standard, this is wide-ranging and includes subject areas such as basic terminology, specifications for products, processes and services, testing, and; interface and data management. Standards can also be a combination of these types depending on their scope and envisaged use.

Standards, depending on their content, are not always called *standards*. In many cases, standards are also known as specifications, methods, guides, technical reports or code of practice, i.e. types of standards as defined in *ISO/IEC Guide 2*. Some are a vocabulary list or a classification of a product or service type. This is to some extent dependent on the custom and practice of the standards body and country.

Standards can also be classified in terms of the requirements contained within them. Two main types are commonly recognized, namely design standards and standards that contain performance requirements. These two types of requirements need not be dealt with in separate standards, as such requirements can also be combined in one standard.

2.4.2 Development process

The development process addresses two important elements, which are (i) the principles of standardization, and (ii) the organizations which are developing the standards. These principles include transparency and consensus, which apply to the development of national, regional and International Standards. They are discussed in detail in Section 4.

Secondly, there are numerous organizations developing standards, ranging from companies, consortia and industry in the private sector, to national, regional and international organizations. The latter three constitute the bulk of the international standardization system, required by the *WTO TBT Agreement* to follow its principles and requirements for standards development. There are also NGOs with specific socio-economic or environmental goals that develop and publish standards.

Technical content	Purpose			
	 Basic standard Terminology standard Testing standard Product standard 	Process standardService standardInterface standardData standard		
	Type of document			
	SpecificationMethodGuide	 Vocabulary Code of Practice Classification		
	Requirements			
	Design standardPerformance standard			
	-			
Development process	Development proces	Development process principles		
	➤ Openness ➤ Transparency ➤ Impartiality	► Consensus ► Effectiveness ► Relevance		
	Organization			
	 Company Consortium Industry sector association Non-Governmental Organization 	 Intergovernmental organization National standards body Regional standards body International standards body 		
Legal status	Voluntary			
	The WTO TBT Agreement definition considers standards voluntary in respect of their application Mandatory The WTO TBT Agreement considers mandatory application of a standard to be a technical regulation			
	application of a standard	to be a technical regulation		

Figure 2.1: The standards environment

INTERNATIONAL STANDARDS BODIES

Numerous bodies have been established to develop and publish International Standards; there are more than 50 such organizations. Six of these are generally considered to have a wider influence than many of the other more specialized International Standards bodies. The *WTO TBT Agreement* applies to products and the three major organizations dealing with such standards include the IEC, ISO and International Telecommunication Union (ITU). As regards the *WTO Sanitary and Phytosanitary Measures Agreement* (SPS), the food, plant and animal-related trio standardization bodies, the Codex Alimentarius Commission (CAC), the International Plant Protection Convention (IPPC) and World Organization for Animal Health (OIE) are the most important and are specifically mentioned in the *WTO SPS Agreement*.

The following facts about bodies that develop International Standards are noteworthy:

- ► The International Electrotechnical Commission (IEC) is an NGO, established in 1906, has its head office in Geneva and publishes International Standards for electrical and electronic goods and systems. Its members are the IEC National Committees in the relevant countries and there is only one member per country;
- The International Organization for Standardization (ISO) is an NGO, established in 1947 with its head office in Geneva and it publishes wide-ranging International Standards for scopes generally not handled by the others in this list. Its members are the foremost standards organizations in their countries and there is only one member per country;
- ► The International Telecommunication Union (ITU) is an inter-governmental organization belonging to the United Nations family, was established in 1897 with its head office in Geneva and it publishes International Standards for the telecommunications domain. Its membership comprises nearly 200 countries and almost 800 private-sector entities and academic institutions;
- The Codex Alimentarius Commission (CAC) is an inter-governmental organization belonging to the United Nations family, established in 1963 with its head office in Rome and it publishes International Standards for food products, sometimes in co-operation with others, e.g. ISO. Its membership consists of nearly 190 countries;

- The International Plant Protection Convention (IPPC) is a multilateral-treaty organization within the United Nations family, established in 1951 with its head office in Rome and it publishes International Standards for plant protection. Being founded by an international convention, it does not have members as the others, but contracting parties, i.e. countries that have acceded to the convention; and
- The World Organization for Animal Health (OIE) is an inter-governmental organization outside the United Nations family, established in 1924 with its head office in Paris and it publishes International Standards for animal health. It has a membership of just over 180 countries.

In the ITU, CAC, IPPC and OIE, all members have equal status. In the case of ISO and IEC, various levels of membership are possible with full membership being the highest level. Other membership grades such as associate or corresponding membership have fewer privileges. Full membership is required to participate in the governance of ISO and IEC, and the same applies largely to ISO/TCs.

There are differences between the organizations in the way in which the technical work on the formulation of standards is undertaken by their ISO/TCs. ISO, IEC and CAC operate a decentralised system whereby member bodies are given full responsibility for specific ISO/TCs, whereas IPPC, ITU and OIE work with expert level meetings managed by the Secretariats. All of them however, meet WTO requirements for International Standards. The International Standards bodies cooperate closely in many areas to limit overlaps to a minimum, an issue that is becoming more important due to technology convergence. There are also formal cooperation agreements between International Standards bodies and certain regional standards bodies, e.g. ISO and CEN, and IEC and CENELEC.

REGIONAL STANDARDS BODIES (RSBs)

Two main types of regional standards-bodies (RSBs) have developed over the years, namely:

 RSBs established through political processes aligned with the regional trade arrangements, e.g. common markets and free-trade zones; or RSBs established as a voluntary organization within given geographical regions, e.g. Africa and the Pacific rim.

In both cases, RSBs may publish regional standards developed through their own TCs, or it could just be a forum whereby harmonization of standards across the region is facilitated amongst the member states, i.e. no regional standards are developed and published. Well-known RSBs publishing regional standards include CEN, CENELEC and ETSI in the European Union.

For the first type of RSBs, NSBs of the region may have an obligation to participate actively in the development of regional standards through regional TCs. These regional standards may be published as official regional standards or just provided to NSBs for adoption as national standards. In either case, NSBs have to adopt regional standards as national standards within a given time period and withdraw any conflicting national standards. Typical examples are the EN Standards (European Union) and EAC Standards (East African Community).

In the second type of RSBs, the members are also NSBs, but membership is normally of a voluntary nature or by invitation. Typical examples are the African Organization for Standardization (ARSO), the Caribbean Community Regional Organization for Standards and Quality (CROSQ) and the Pan American Standards Commission (COPANT). Some of these would establish technical committees (TCs) to develop regional standards, but many operate as a forum where regional standardization issues can be discussed and harmonization of national standards of member states facilitated without reverting to the publication of regional standards.

NATIONAL STANDARDS BODIES

Many countries have established centralised NSBs in the past hundred years, even though a few countries have followed a more decentralised approach. Their organizational status can range from a government department, an organization of public law (i.e. a statutory body) or an organization of private law (i.e. either a "not-for-profit" or "for-profit" organization). The exact breakdown of the types is not known as no current common database exists in this respect, but details

regarding individual NSBs can be found on their websites⁶⁾. Government department type NSBs seem to be the majority, with NSBs as organizations of public law second, followed by private sector NSBs.

NSBs primary responsibilities include the development and publication of national standards, the provision of standards related information, and liaison with regional and international standardizing bodies. Many NSBs also provide standards related services such as inspection, testing, certification and training ⁷⁾. In fulfilling their primary responsibilities, NSBs should follow GSP. An important point for any NSB, irrespective of its organizational status, and whether it provides conformity assessment services or not, is that its standards development programme should function without undue political interference, i.e. its impartiality should be ensured.

INDUSTRY SECTOR AND NGO-TYPE STANDARDS ORGANIZATIONS

A vast array of *normative* documents is classed under the generic label of *private standards*. Generally, a normative document developed and published by an organization outside of the recognized standards development organizations at national, regional or international level is considered to be a private standard. There is not only a vast range of private standards (and growing in number), there are also significant differences between the bodies and organizations that develop these standards related to such aspects as governance, development approach, stakeholder engagement, transparency, and consensus⁸⁾.

There are several reasons for the growth of private standards, such as:

• The time-to-market for International Standards would be at least two to three years, and that is too long for the sponsors of a standard in fast moving technologies, who then develop a private standard amongst themselves in a much shorter time.

⁶⁾ The ISO membership list is a useful point of departure for accessing NSB websites. This can be accessed from the ISO website.

⁷⁾ More detail is provided in the ISO publication *Financing NSBs: Financial sustainability for National Standards Bodies* obtainable from the ISO Secretariat.

⁸⁾ These aspects are discussed in detail in Section 4 Principles for the Development of Standards.

- Consortia develop a private, product standard to gain a market advantage over rivals.
- Global-brand producers and retailers increasingly require their suppliers to comply with certain social, environmental and safety requirements as they respond to pressures from their customers. These requirements are then formalised within private standards, guidelines or principles that their suppliers have to comply with contractually.
- NGOs wishing to promote specific social and environmental changes then developing private standards and establishing certification schemes to support their goals.
- Multinational certification-bodies identifying a specific market niche, developing a private standard and implementing a certification scheme as a sound business-proposition.

Whatever the reasons for developing a private standard, these reasons have become an important factor in accessing the developed markets of Europe and the USA, and they are also spreading into the markets of Asia . A final – but still embryonic – trend relates to the harmonization and benchmarking of private standards as a response to the overwhelming growth in their number and variety, and pressures from suppliers on purchasers to harmonize requirements. Furthermore, despite the multiplicity of private standards, new ones continue to emerge frequently.

LEGAL STATUS

The WTO TBT Agreement is very clear in that standards are considered to be voluntary in their application, whereas technical regulations are mandatory. This has led to some confusion in the understanding of the use of standards in contracts. Clearly conformity with standards used in contracts has to be fulfilled by the supplier, but non-compliance would be an issue dealt with under civil law. It is not considered to be an offence in terms of public law as is the case for non-compliance with a technical regulation.

Another issue that has to be considered, is that national standards have to be given legal standing in many jurisdictions, otherwise they cannot be referenced in technical regulations or their copyright cannot be protected. Even though they

are promoted as national standards in terms of legislation and are considered as a legal document at the national level, their application remains voluntary in terms of the *WTO TBT Agreement* definitions.

2.5 Users of standards

The users of standards can be found in all constituents that make up a country and in all levels of society. They range from industry and commerce, government, consumers, labour, academic and research organizations, conformity assessment service providers and non-governmental organizations (NGOs).

2.5.1 Industry and commerce

Standards are used widely in industry and commerce in the complete product value-chain. This starts with the product design, continues with the purchasing of raw materials, through production and inspection, and includes packaging. Even marketing and after-sales service make a significant use of standards. To ensure consistency of production and supply, the management systems can be aligned with standards, for example such as *ISO 9001* for quality-management systems and *ISO 14001* for environmental-management systems.

2.5.2 Purchasers and consumers

Purchasers make extensive use of standards in their purchasing contracts and decisions. Bulk purchasers, e.g. large companies or the country's purchasing agency, utilize standards as a contractual requirement for the supply of bulk purchases. These are frequently coupled with compliance to quality management standards such as *ISO 9001*.

Consumers, on the other hand, use well-known product certification marks in their purchasing decisions or rely on test results published by independent test organizations. Anecdotal evidence suggests that more expensive products such as televisions are more likely to be chosen this way, than every-day, inexpensive consumables such as soap or toothpaste. Here advertising plays a much bigger role.

2.5.3 Conformity assessment service providers

Conformity-assessment service-providers utilize the same standards that purchasers typically demand In addition, these service providers have to comply themselves with International Standards such as *ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17025*, and *ISO/IEC 17065*, in order to be recognized as competent bodies. Many NSBs provide conformity-assessment services such as inspection, testing and certification, even though the bulk of such services in the more advanced economies is provided by private sector entities. As a matter of principle, NSBs should ensure that their standardization activities are independent of other activities such as conformity assessment, where this is the case.

2.5.4 Organizational and product innovators

Innovation is defined by the *Oslo Manual* of the Organization for Economic Cooperation and Development (OECD) as "the implementation of a new or significantly improved product (good or service) or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations". Others consider innovation as the development of completely different technology that revolutionizes the economic structure from within by disrupting or totally replacing old technology, e.g. cell-phones replacing landlines, and digital photography replacing film-based photography.

In an age of ever faster technological developments, innovation is widely recognised as one of the essential drivers of successful businesses and a key contributor to the productivity and socio-economic development of nations. Hence, in many countries, there is a strong focus on public funding of research and development and on intellectual property rights as instruments of innovation policy and business strategy. The International Standards of the *ISO 56000* series on innovation management can provide guidance in this respect.

The driver for innovation programmes in organizations should be to achieve growth, because organizations cannot grow through cost reduction and reengineering alone. Typical goals of innovation in manufacturing and services

organizations could include: (i) Improved quality; (ii) extension of the product range; (iii) reduction of labour costs; (iv) improved production processes; (v) reduction in material costs; (vi) reduction in the environmental footprint of the organization; (vii) replacement of products; (viii) reduced energy consumption; and (ix) compliance with regulatory requirements.

Looking at the above goals of innovation and mapping them against the quality-infrastructure services, it quickly becomes apparent that almost all of them would benefit from the appropriate and robust use of standards, metrology, accreditation and conformity assessment.

2.6 Quantifying socio-economic benefits of standardization

One of the key aspects of the mission of NSBs is to liaise with organizations from all stakeholder groups to engage them in standardization and to help them get the most from standards. Yet, whereas the people involved in standardization understand that their work generates considerable benefits for organizations, markets and society, it is important that they convey this point of view to industrialists, public administrations and other opinion leaders.

In order to substantiate and quantify the real-world value of voluntary standards, ISO has developed the *ISO Methodology*; this is a consistent approach to measuring this value, which has been tested in approximately 30 case studies for companies in over 20 countries across the globe. The results speak for themselves: standards do create value for the organizations that use them, and it is feasible to quantify the many benefits.

2.6.1 Assessment steps at the company level

To be able to apply the ISO Methodology, users can download a manual containing detailed steps to do so from the ISO Website⁹⁾. Figure 2.2 illustrates the ISO Methodology and it consists of the following stages:

⁹⁾ http://www.iso.org/iso/home/standards/benefitsofstandards/benefits_of_standards.htm.

- **Understand the company's value chain**: The ISO Methodology is based on the value chain, which subdivides the operations of a company into a number of key business-functions that, in turn, group together certain activities. The value chain of the company then needs to be understood in terms of its key business processes and its core value-adding activities.
- ► **Identify the impact of standards:** The second step consists in determining the business functions and activities in the company value chain where standards play a significant role. Existing company documentation (e.g. the quality manual, process and organizational charts, other corporate or departmental documentation) could be used to understand the processes, business functions and main activities included in each business function.
- ► Analyse the drivers and determine operational indicators: This step analyses the company value drivers (i.e. its competitive strengths) and determines the operational indicators that will be applied to measure the impacts of standards. The impacts of standards closely associated with value drivers will have a significant higher effect on value creation, and they should be considered in the first instance. Thereafter, one or more operational indicators associated with these value drivers should be identified to actually quantify the impacts. These could be company activities that show improvement or degradation of performance (e.g. time and cost, number of defects, waste, sales, and customer satisfaction).
- **Assess and calculate the results:** The purpose of the complete assessment process is to:
 - a) quantify the impacts of standards using the operational indicators and aggregate these impacts for each of the selected business functions;
 - b) convert the quantities resulting from the use of standards for each of the selected business functions into financial figures; and
 - c) add the figures for all the selected business functions at a given point in time to determine the total contribution of standards to the company gross profit or EBIT (Earnings Before Interest and Tax).

Understand the value chain

- Clarify industry boundaries
- ► Analyze the company value chain
- ► Identify the most relevant business functions

Identify the impacts of standards

- ► Identify and list standards used by the various business functions of the company
- Identify impacts deriving from standards for main business functions and activities associated with these functions

Analyze the value drivers and key operational indicators

- ► Identify value drivers to focus assessment on the most relevant standards impacts
- Select relevant performance indicators, possibly linked to value drivers, to identify major impacts of standards on the business functions in scope

Measure the impacts of standards

- Quantify most relevant standards impacts
- ► Calculate Earnings Before Interest and Tax
- ► Impact for each standard
- Consolidate the results

Figure 2.2: Quantifying benefits of standardization at company level

2.6.2 Case study results

Published case-studies span enterprises of varying sizes, from small companies of 25 employees with an annual sales revenue of approximately USD 4.5 million to large conglomerates of several thousand employees with an annual revenue exceeding USD 2.5 billion. Despite the huge differences in size, results consistently demonstrate that companies achieve tangible benefits from using standards. Some key benefits reported include:

- **Streamlining internal operations**: Standards can be used to streamline the internal processes of a company, for example by reducing the time needed to perform specific activities in the various business functions, decreasing waste, reducing procurement costs and increasing productivity. The case studies consistently report that the contribution of standards to the gross profit of companies ranges between 0.15% and 5% of the annual sales revenues.
- Innovating and scaling up operations: Some case studies provide examples where standards served as the basis for innovating business processes, allowing companies to expand their suppliers' network or to introduce and manage new product lines effectively. In other examples, standards helped companies to mitigate the risk of introducing new products into national markets.
- **Creating or entering new markets:** Standards have been used as the basis for developing new products, penetrating new markets (both domestic and export), supporting the market uptake of products, and even creating markets. In exceptional cases, the impact of standards far exceeded the figures mentioned above, with companies achieving a gross profit contribution of up to 33% of their annual revenue. This in turn helped the companies to position themselves as leaders in their field, at least over a certain period of time.

2.6.3 Other case study information

In addition to the ISO methodology and its results described in 2.6.1 and 2.6.2, ISO also developed a Web page that contains information on studies on the economic

and social benefits of standards for trade, national economies, industry sectors, individual companies and citizens ¹⁰⁾. It is intended as a reference work of studies that address economic and other benefits of standards, their impacts and their relevance for international trade, innovation and economic development. The studies have been undertaken by different authors, such as national and International Standards bodies, research institutes, universities and other international agencies. The Web page is updated continuously to ensure that the information remains up-to-date as far as possible.

¹⁰⁾ https://www.iso.org/sites/materials/benefits-of-standards/benefits_repository.html.



The WTO Agreement on Technical Barriers to Trade (WTO TBT Agreement) is likely to be the most influential international legal text on standardization. The Agreement prescribes the principles for standards, conformity assessment procedures and technical regulation development and their implementation, and all WTO members must comply with it. There are very few countries left in the world that are not members of the WTO; hence the majority of the world's nations need to comply with the Agreement. This has profound implications on virtually every national standards body. The same would apply to every regional and international standardizing body.

3.1 World Trade Organization (WTO)

The WTO is an intergovernmental organization which regulates international trade. The WTO endeavours to facilitate trade between participating countries by providing a framework for negotiating trade agreements and a dispute resolution process. These activities are aimed at enforcing participants' adherence to WTO agreements, which are signed by representatives of member governments and ratified by their parliaments.

Most of the issues that the WTO focuses on derive from previous trade negotiations, especially from the *Uruguay Round of the General Agreement on Tariffs and Trade* (1986–1994). The WTO oversees about 60 different agreements and decisions which have the status of international legal texts. Countries must accede to all WTO multilateral agreements when they join the organization.

From a standards and technical regulation perspective, the two important agreements negotiated during the Uruguay Round, and which entered into force with the establishment of the WTO, are:

► The Agreement on Technical Barriers to Trade (WTO TBT). This agreement seeks to ensure that technical regulations and standards, as well as testing and certification procedures for their implementation, do not create unnecessary obstacles to trade; and

• The Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS). This agreement encourages members to base their food safety and animal and plant health regulations on International Standards.

3.1.1 Trade barriers in the WTO TBT Agreement

Trade barriers consist of two types, namely tariff and non-tariff barriers (NTBs). NTBs refer to restrictions that result from prohibitions, conditions, or specific market requirements that make importation or exportation of products difficult and/or costly. NTBs arise from different measures taken by governments and authorities in the form of laws, regulations, policies, conditions, restrictions or specific requirements, and private sector business practices, or prohibitions that protect the domestic industries from foreign competition.

NTBs comprise technical (such as standards, technical regulations, sanitary and phyto-sanitary measures or environmental protection measures) and non-technical measures, such as quotas, price controls, exports restrictions, or contingent trade protective measures. Other types of NTB include behind-the-border measures, such as competition, trade-related investment measures, government procurement or distribution restrictions.

The WTO TBT Agreement deals specifically with a number of the technical NTBs, namely to ensure that technical regulations, standards, testing, and certification procedures do not become unnecessary barriers to trade. The agreement prohibits technical requirements created in order to limit trade, as opposed to technical requirements created for legitimate purposes such as health and safety of the population, and consumer or environmental protection. It is therefore a balancing act between free trade and the legitimate responsibility of governments to protect their society and environment against unsafe or fraudulent products. To this end it promotes the use of International Standards.

3.1.2 Scope of the WTO TBT Agreement

The *WTO TBT Agreement* applies to all products, even those of agricultural origin. This is important to understand as there is a perception by some, that food products fall only under the *WTO SPS Agreement*. The *WTO TBT Agreement* and *WTO SPS Agreement* are mutually exclusive by definition, i.e. a measure within the scope of the *WTO SPS Agreement* that is not subject to the *WTO TBT Agreement*. The scope of the *WTO SPS Agreement* covers only very specific issues and are clearly defined. Hence, a product can be subject to requirements of both the agreements, depending on the measures.

Typical WTO SPS measures include: food standards that are enforced by governments to ensure the safety of food, and; biosecurity controls that are enforced at international borders to keep out exotic animal pests, plant pests and diseases. Anything else falls under the scope of the WTO TBT. For example, residues of veterinary drugs or pesticides in food or drink would be an SPS measure, whereas the labelling on the composition of the same food or drink would be a TBT issue. The WTO TBT Agreement also does not apply to purchasing specifications prepared by governmental bodies for production or consumption requirements of governmental bodies. They are addressed in the Agreement on Government Procurement.

3.1.3 Legitimate objectives of the WTO TBT Agreement

The *WTO TBT Agreement* lists the objectives for which technical regulations can legitimately be implemented. These include: the protection of life and health of individuals, animals and plants; and the protection of the environment. They also include the prevention of deceptive practices which would seriously affect consumers. However, the scope of the WTO TBT does not apply to the general quality of products, or the protection of the local industry.

Some countries may consider protecting local industry from foreign competition as a legitimate policy. This is usually achieved through country specific mandatory standards or technical regulations – in reality, these are disguised tradebarriers, e.g. the restrictions are not based on International Standards. Apart from

contravening WTO TBT rules, it is also a short-sighted strategy that will only result in the local industry becoming totally non-competitive over time. Such strategies should be avoided.

3.2 WTO TBT Agreement principles

There are five principles that underpin the *WTO TBT Agreement*; all of these are derived from the General Agreement on Tariffs and Trade (GATT). These have a large impact on all standardization activities.

The **Most Favoured Nation** principle requires imported products from all WTO members to be accorded the same treatment. This means that governments must ensure that TBT measures do not discriminate between foreign producers (for example, by favouring one country over another).

The **National Treatment** principle requires imported and domestic products to be treated in a like manner, i.e. imported products should not be subject to more stringent inspection and certification than local products. In developing countries, local manufacturers are sometimes subject to much higher conformity-assessment requirements through mandatory certification than imported products. This is a violation of the National Treatment principle in reverse – it puts local manufacturers at a disadvantage with regard to imported products.

The **Least-Restrictive-Means** principle seeks to ensure that technical regulations should not be more restrictive to trade than necessary. However, technical regulations are, by their very nature, trade restrictive. The question is what is considered to be more restrictive to trade than necessary? The evaluation would embrace several factors, including how much the measure contributes to the achievement of the objective, the types of risks and the potential consequences from the non-fulfilment of the objective, and the restrictiveness of the measure. If the objective is applied by the imposition of a technical regulation based on International Standards, then this principle is considered fulfilled even though this can also be challenged.

The **Transparency** principle is a cornerstone of the *WTO TBT Agreement*. It is applied through the notification provisions, along with the relevant TBT Committee

decisions and recommendations. These decisions and recommendations reveal how members intend to regulate, gives trading partners an opportunity to provide comments, thereby assisting in improving regulation. This in turn helps producers and exporters adapt to changing requirements.

The **Sham** principle requires that standards, conformity-assessment procedures and technical regulations are not simply trade barriers in disguise. This easily happens when local manufacturers pursue the development of a national standard that differs significantly to the International Standard, in order to protect themselves from unwanted competition from imported products. It also happens when governments erroneously consider protecting local industry against foreign competition, by creating technical regulations which differ from International Standards. Neither is good for the country's industrial development in the long run, apart from contravening the requirements of the *WTO TBT Agreement*.

3.3 Standards and Technical Regulations

Standards and technical regulations can look very much alike, thereby leading to confusion. That said, there are some very important differences as determined in the *WTO TBT Agreement*. The following sub-sections describes these differences.

3.3.1 Definitions

The *WTO TBT Agreement* definitions for a technical regulation and a standard are very clear. The foremost difference is that compliance with a technical regulation is mandatory, whereas compliance with – or conformity to – a standard is not mandatory, unless the standard is embodied within a regulation. In contrast to the *WTO TBT Agreement*, *ISO/IEC Guide 2* definitions do not prescribe compliance.

Technical regulation

Document which lays down product or service characteristics or their related processes and production methods, including the administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

WTO TBT Agreement

Regulation (document providing binding legislative rules, that is adopted by an authority) that provides technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice.

ISO/IEC Guide 2:2004

The WTO TBT Agreement definition of a technical regulation and that provided for in ISO/IEC Guide 2 differ in wording, but not in substance. The ISO/IEC definition does mention the way in which standards can be used as the basis of a technical regulation, whereas the WTO TBT Agreement definition does not. On the other hand, the WTO TBT Agreement itself is clear in that governments should utilize International Standards as the basis for the technical requirements of their technical regulations. The WTO TBT Agreement definition of a technical regulation also includes administrative provisions, which are absent from its definition of a standard.

Standard

Document approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for products and services and related processes or production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

WTO TBT Agreement

Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

ISO/IEC Guide 2:2004

The definition of a standard as contained in the *WTO TBT Agreement*, differs from that commonly quoted definition from *ISO/IEC Guide 2*. The ISO/IEC definition lists consensus as a principle of development and does not say anything about a standard being voluntary or not. It deals with products and services, whereas the WTO definition only considers products and their production methods, because that is the scope of the Agreement.

The *WTO TBT Agreement* definition is very clear in that the application of a standard is considered to be voluntary, whereas the ISO/IEC definition does not mention anything about its legal status. Due to the impact of the *WTO TBT Agreement*, it is now generally accepted practice throughout the world that standards are considered to be voluntary in their application, in contrast to technical regulations, which are mandatory. The narrow scope of the *WTO TBT Agreement* definition, however, is not generally used – whereas the scope of standards as accepted by practitioners is wide, and includes products, services, processes, and systems. A standard is developed by a recognized body in both definitions. The *WTO TBT Agreement*, however, is abundantly clear that the development of a technical regulation is a government responsibility. In terms of the *WTO TBT Agreement*, compliance with a standard is not mandatory. This wording has led to some discussion,

because if a standard is specified in a purchasing contract, then compliance is mandatory in terms of the contract. That said, non-compliance is then an issue of civil law, not an offence in terms of national legislation.

To ascertain whether a technical regulation exists, WTO jurisprudence to date has established three criteria: (i) that the requirements (set out in the document containing the technical regulation) must apply to an identifiable product or group of products (even if this is not expressly identified in the document); (ii) that the requirements must specify one or more characteristics of the product (these may be intrinsic to the product itself, or simply related to it, and they may be prescribed or imposed in either a positive or a negative form); and (iii) that compliance with the product characteristics must be mandatory. Clearly, the *WTO TBT Agreement* definitions apply in considering the implementation of the *Agreement*, not the ISO/IEC definitions.

3.3.2 Committee on Technical Barriers to Trade

The *WTO TBT Agreement* establishes a Committee on Technical Barriers to Trade, composed of WTO Members. This Committee affords WTO Members the opportunity of consulting on any matters relating to the operation of the Agreement or the furtherance of its objectives, and most of these deal with standards, technical regulations and their implementation. Three specific objectives for the Committee are listed in the *Agreement*.

REVIEW OF SPECIFIC MEASURES

WTO Members/Observers use the TBT Committee to discuss specific trade-concerns (STCs) – specific laws, regulations or procedures that affect their trade, usually in response to notifications. Essentially, members raise STCs to find out more about the scope and implementation of each other's regulations in light of the core TBT obligations. The discussion is mostly about measures under development but can also be about the implementation of existing measures. To date, more than 400 STCs have been raised, which can be accessed through the TBT Information

Management System – the database of WTO information on TBT notifications, specific trade concerns, and enquiry points.

STRENGTHENING IMPLEMENTATION OF THE TBT AGREEMENT

Members exchange experiences on the implementation of the *Agreement*, with a view to making implementation more effective and efficient. This discussion revolves around generic, cross-cutting themes, including transparency, standards, conformity assessment and good regulatory practice. These are frequently organized in the form of a workshop held back-to-back with a TBT Committee meeting and have become an integral part of the calendar. Useful exchanges of information regarding standardization and the implementation of technical regulations have been generated over the years; information about this is accessible through the *WTO TBT Agreement* Website.

TRIENNIAL REVIEWS

Once every three years, the Committee reviews the operation and implementation of the *Agreement* including the provisions relating to transparency, with a view to recommending an adjustment of the rights and obligations of this *Agreement* where necessary to ensure mutual economic advantage and balance of rights and obligations. Following such reviews, the Committee has developed a series of decisions and recommendations over the years intended to facilitate implementation of the *Agreement*, some of which have a major impact on standardization. Documented Decisions of the TBT Committee include the following activities:

- Good Regulatory Practice;
- Conformity Assessment Procedures;
- Indicative List of Approaches to Facilitate Acceptance of the Results of Conformity Assessment;
- Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations;
- Transparency;
- ▶ Technical Assistance; and
- Special and Differential Treatment.

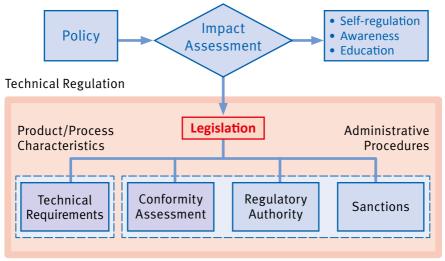
Knowledge regarding these TBT Committee decisions should be an integral part of the implementation of GSP, and NSBs are recommended to familiarize themselves with these decisions. Too often they are considered part of the political world and not so important for the NSB – this is incorrect. The Decisions have a major impact on the standardization and other activities of the NSB. All of the above documented Decisions are accessible from the *WTO TBT Agreement* Website.

3.4 Technical regulations and SPS measures

Technical regulations and SPS measures are complex largely due to many differences in approach in their development and implementation amongst WTO Members, in spite of the requirement that WTO members must comply with the requirements of the two *Agreements*. There is also confusion amongst some practitioners regarding the differences between technical regulations and SPS measures; this requires explanation.

3.4.1 Technical regulation building-blocks

In order to better understand the many different approaches to technical regulations, it is useful to consider their building blocks that can be derived from the definitions of a technical regulation and the text of the *WTO TBT Agreement* – see Figure 3.1. Anecdotal evidence would suggest, that if any of the building blocks are not properly provided for in the technical regulation, then it may prove to be ineffective. The building-block approach also highlights the importance of standards in the development and implementation of technical regulations.



Source: Author's elaboration

Figure 3.1: Technical regulation building blocks

A government may contemplate implementing a technical regulation, once a product that has been marketed, is thought to be deleterious to the health or safety of people, the fauna and flora and the environment, or if it is considered a deceptive practice.

REGULATORY IMPACT ASSESSMENT (RIA)

Before a technical regulation is considered, a regulatory impact assessment (RIA) should be conducted to determine the triggers for the regulation, the risks involved, the socio-economic costs and benefits of implementing the technical regulation, and whether the infrastructure to implement it exists in the country. This is also important in the case of standards being declared mandatory, thereby rendering them as technical regulations.

Without a RIA to evaluate all aspects, a new technical regulation may lead to negative impacts on the economy or society, or impacts that may not have been evaluated or even considered. The outcome of a RIA may be that a technical regulation

is not implemented, but that other less onerous measures are preferable. These would include self-regulation by the suppliers, or an awareness and/or education campaign to sensitize consumers. If the outcome of the RIA points towards the implementation of a technical regulation, then the rest of the building blocks have to be given appropriate attention.

LEGISLATION

A technical regulation is, by definition, a legislative measure. Hence, its format should comply with national legislative practices and norms. Good practice would suggest that enabling legislation is the better way. Enabling legislation does not contain the details of a technical regulation, but provides the framework for sublegislation, e.g. regulations promulgated by the government, that can be updated fairly rapidly. First-level legislation usually has to go through one or more levels of government, which can be a long and arduous process, making the updating of technical regulation that contains all the details a major challenge. Being able to put the details in sub-legislation helps authorities to be more flexible and timely in implementing technical regulations.

TECHNICAL REQUIREMENTS

The technical requirements of the technical regulation should be based on International Standards (or their national adoption) as indicated by the *WTO TBT Agreement*. A number of methods are listed below.

- The standards can be referenced in the regulation as:
 - **Undated references** have the advantage that should the standard be revised, then the technical regulation is kept up to date. However, the responsibility for the technical regulation is assigned to a body other than the regulatory authority.
 - Dated references have the disadvantage that should the standard be revised the technical regulation has to be updated. The responsibility, however, remains with the relevant regulatory authority. The choice whether the reference is dated or undated will depend on the regulatory authority preferences and custom and practice of the country. Compliance with the

standard then becomes a prerequisite for meeting the requirements of the regulation. Referencing standards is a concept that is followed widely in both the developed and developing economies.

- Standards can be published as deemed to satisfy regulation requirements in a separate official list. In this case, compliance with the standard listed confers compliance of the product with the requirements of the regulation. This system has the advantage that other standards may also be used, but a sophisticated legal system is necessary to apply this approach. The EU Regulations and European (EN) standards are a well-known example of this practice where those EN standards, elaborated under a standardization request of the European Commission, provide the presumption of conformity with applicable EU Regulations (i.e. EU Directives).
- The technical requirements of the standard can be included in the text of the technical regulation. Even though legally acceptable, this is no longer considered good practice. Keeping the regulation up-to-date with rapidly moving technologies and changing standards is extremely challenging, and often not effectively managed by regulatory authorities. The result is that such regulations become out-of-date, are not updated, and the supplier has to provide products complying with out-of-date requirements. This can render the technical regulation unsafe, or increase the transaction costs for the supplier, costs that the consumer ultimately has to bear. Furthermore, it should be noted that the copyright of standards organizations may be compromised with this practice.

CONFORMITY ASSESSMENT

Conformity assessment to prove compliance with the technical requirements of the regulation could be any combination of inspection, testing and certification. The conformity assessment can either be performed by the supplier (i.e. self-declaration of conformity) or by independent third parties whose competency is demonstrated by accreditation, and who are acceptable to the regulatory authority (e.g. designated, notified bodies).

Self-declaration of conformity (SDOC) presupposes ethical behaviour of the suppliers and effective product-liability legislation. Anecdotal evidence would suggest this is a major challenge in developing countries, which are often the target of dumping of non-compliant products. SDOCs are therefore seldom encountered in developing economies. In developed countries, SDOC is most often accompanied by some level of market surveillance.

Developing-country regulators may prefer conducting their own conformity assessments, but this is costly to the country and is considered a barrier to trade by many. Hence, liberating the conformity assessment to include private-sector service-providers, providing their competency can be demonstrated (usually through accreditation), is the current best practice and can limit the transaction costs of compliance by the suppliers.

REGULATORY AUTHORITY

The regulatory authority is primarily responsible for in-market surveillance to ensure continued compliance of products with the technical regulation by all suppliers. In high-risk cases, pre-market approvals may be required as well. The regulatory authority has to initiate sanctions if suppliers do not meet requirements. The regulatory authority does not necessarily have to perform the conformity assessment of products but should accept the services of technically competent and designated service-providers.

SANCTIONS

The regulatory authority applies administrative sanctions such as directives for recall, rework or destruction of non-compliant products. If suppliers do not heed administrative sanctions, then courts of law may be required.

3.4.2 The WTO TBT and SPS Agreements

The terminology of standards, technical regulations and SPS measures is frequently a source of confusion. Common usage of these terms does not always correspond with their legal meaning provided for in the WTO TBT and SPS *Agreements*. For

example, many countries have food standards that are mandatory, whereas the *WTO TBT Agreement* considers a standard to be voluntary in nature. Furthermore, the legal status of a standard has a slightly different meaning in the WTO TBT and SPS *Agreements*. In the *WTO TBT Agreement*, a standard is purely voluntary, whereas in the *WTO SPS Agreement*, a food standard could be mandatory.

COMPLEMENTARY BUT MUTUALLY EXCLUSIVE

It is important to understand that the WTO TBT and SPS *Agreements* are complementary but mutually exclusive. A measure falling within the scope of the *WTO SPS Agreement* is, by definition, excluded from the *WTO TBT Agreement*. A very important point to note is that it is the measure that is mutually exclusive, not the product. There are numerous examples of products that are subject to both the WTO TBT and SPS *Agreements* depending on the product characteristic that is being examined – see Table 3.1. Another common misunderstanding is that food products are only subject to the *WTO SPS Agreement*. This is not correct: the *WTO TBT Agreement* not only applies to manufactured products, but also to agricultural products insofar as they are not subject to an SPS measure.

THE SCOPE OF THE WTO SPS AGREEMENT

The WTO SPS Agreement defines sanitary and phytosanitary measures as any measure to:

- Protect human life or health from risks arising from: additives, contaminants, toxins or disease-causing organisms in food and beverages, or; disease carried by animals or plants or their products, or from pests.
- **Protect animal life or health** from risks arising from: additives, contaminants, toxins or disease-causing organisms in feedstuffs; diseases carried by animals or plants, or; pests, diseases or disease-carrying organisms.
- Protect plant life or health from pests, diseases or disease-causing organisms.
- Protect or limit other damage to a country from the entry, establishment or spread of pests.

Some of the elements of food standards enforced by governments to ensure the safety of foods, and the biosecurity controls enforced at international borders to keep out exotic animal and plant pests, are typical SPS measures. The difference between SPS and TBT measures is further elaborated in Table 3.1, through a couple of examples dealing with food, safety and health.

Table 3.1: Differences between the WTO SPS and TBT Agreement applications

SPS measures typically deal with	Technical regulations typically deal with
 additives, contaminants and toxic substances in food or drink; residues of veterinary drugs or pesticides in food or drink; processing methods with implications for food safety; labelling requirements directly related to food safety. plant and animal quarantine; declaring areas free from pests or disease; preventing pests or disease from 	 with labelling on the composition or quality of food or drink; quality requirements for fresh food; weight, volume, shape and appearance of packaging for food or drink. packaging and labelling of dangerous chemicals and toxic substances, pesticides and fertilizers; electrical safety of appliances; vehicle safety; safety of toys; labelling of textiles and garments.
spreading to or within a country.	labelling of textiles and garments.

Source: The WTO Agreement Series: Sanitary and Phytosanitary Measures 11).

USE OF STANDARDS IN THE WTO SPS AND TBT AGREEMENTS

The WTO SPS Agreement requires of WTO Members to base their SPS measures on the International Standards, guidelines and recommendations developed by three specific organizations. These are: the Codex Alimentarius Commission (CAC); the

¹¹⁾ https://www.wto.org/english/res_e/booksp_e/agrmntseries4_sps_e.pdf.

International Office of Epizootics (OIE), and; the Secretariat of the International Plant Protection Convention (IPPC).

The WTO TBT Agreement requires WTO Members to base their technical regulations on International Standards but does not specifically mention any International Standards bodies. Furthermore, WTO Members have to ensure that any sanitary or phytosanitary measure is based on scientific principles and is not maintained without sufficient scientific evidence. Such a focus on scientific principles is not mentioned specifically in the WTO TBT Agreement when deciding on whether to implement a technical regulation or not; instead, this requirement is implied and the Agreement broadly lists only valid reasons. The WTO TBT Agreement requires products from all countries to be treated in similar fashion, while the SPS Agreement allows for differences.

3.5 Annex 3 of the WTO TBT Agreement

Annex 3: Code of good practice for the preparation, adoption and application of standards of the WTO TBT Agreement has a major influence on the standardization activities of an NSB if the country is a WTO Member. This would be the bulk of the world's NSBs as most countries are now members of the WTO.

3.5.1 Notification provisions

Any NSB within the territory of a WTO Member, whether a central government body, a local government body or a non-governmental body, should notify its compliance with the requirements of Annex 3. The same applies to any RSB which are WTO Members. The standards body should notify its acceptance (or withdrawal) of Annex 3 and its compliance with its requirements. This is a self-declaration of conformity by the standards body, i.e. no independent assessment precedes it. However, an independent assessment is beneficial as it typically highlights areas where the standards body can improve.

The standards body then has to send the notification to the *WTO ISO Standards Information Gateway*¹²⁾. A notification template, ensuring that all the necessary information is provided, is shown in Figure 3.2. The details of the standards bodies that have accepted Annex 3, for example, can be found on the ISO Webpages.

Country/Customs Territory/Regional Arrangement:		
Name of the standardizing body:		
Address of the standardizing body:		
Telephone:	Fax	
E-mail:	Internet:	
Type of standardizing body:		
[] central governmental [] local go	overnmental [] non-governmental	
Scope of current and expected standardization activities:		
Date:		

Figure 3.2: Annex 3 acceptance template

3.5.2 Substantive provisions of Annex 3

A standards body has to comply with a number of substantive provisions listed in Annex 3. These are discussed below, while a standards body should ensure it complies fully with all the provisions exactly as recorded in Annex 3.

¹²⁾ https://tbtcode.iso.org/sites/wto-tbt/home.html.

STANDARDS SHOULD NOT BE THE CAUSE OF UNNECESSARY TRADE BARRIERS (PROVISIONS D AND E)

It is not only in regulation that imported and local products should be treated in the same manner. It is also a clear requirement for the development of national standards. If national standards are very different from international or related national standards, then the national standards can then become an unnecessary barrier to trade. This is because standards are often used in purchasing contracts and as a basis for technical regulation. There should therefore be safeguards in place to prevent the following:

- local industries steering the process of standards development in such a
 way that the national standard is based on local products, meaning that the
 national standards differ from International Standards, in order to protect
 themselves from imports; and
- the government, seeking to protect local industry as a political imperative, does exactly the same.

Both strategies are detrimental for industrial development in the long run, because the local industry will not be able to market their products in international markets that are far larger than the local market, and frequently much more economically sustainable.

ADOPT INTERNATIONAL STANDARDS WHEREVER POSSIBLE (PROVISIONS F AND G)

Annex 3 requires NSBs to adopt International Standards are far as possible. This is not an absolute, i.e. if the International Standard cannot be strictly applied, then adoption with some technical changes is possible. This could be due to infrastructural incompatibilities, such as differences in electricity-supply voltages, localised temperatures or dusty environments outside the scope an International Standard. These differences should be kept to an absolute minimum, however; otherwise the national standard again becomes an unnecessary barrier to trade. These are subtle issues that the NSB has to manage carefully.

The first priority is to participate actively in the development of the International Standard, i.e. participate actively in the relevant TC. By doing so, the country will be

able to present its needs in discussion and it will be part of the consensus-building process. In such cases it should not be a problem at all to adopt the International Standard as a national standard without any deviations. All countries should therefore develop a strategy as to which international TCs are important, and make sure that the funds for participants are made available, so that a country's representatives can actively contribute to developing International Standards (see also 7.1.1).

COORDINATE STANDARDIZATION WORK WITH OTHERS (PROVISION H)

If RSBs or trading partners are developing standards, it would be counterproductive to develop a national standard in parallel that might turn out to be completely different. It would be much more productive to participate actively in the regional standard being developed, or to try and harmonize the national standards development with trading partners in the region.

The same holds true for International Standards. If an International Standard is under development, and a country is not actively involved in its development, then the country can always wait to see how it develops. This way, an NSB can avoid having to withdraw a recently published national standard, that is completely different from an International Standard, once it has been published.

FOCUS ON PERFORMANCE CRITERIA (PROVISION I)

It is good practice in standardization to focus on performance criteria, rather than detail specifics in a standard. For example: It is better to provide for a dezincification test, rather than specify that brass taps should contain at least 64% copper to prevent dezincification of the metal in soft waters. The reason is that suppliers should be given the choice to implement different technical solutions rather than be forced to follow a proven but redundant one. It should be understood however, that not all criteria can be performance-based. There are criteria such as dimensions that have to be specified in order to ensure compatibility of products that have to be combined to fit into larger systems, e.g. screw threads, container dimensions, bricks, etc.

PUBLISH THE STANDARDS WORK PROGRAMME (PROVISIONS | AND K)

One of the key principles underpinning the *WTO TBT Agreement* is transparency. Hence, the *Agreement* requires all standards bodies to publish a work programme at least every six months that WTO Members can consult to keep up-to-date with the standards under development.

The work programme should contain at least the NSB's name, address and contact details, the standards it is currently preparing and the standards which it has adopted in the preceding period. A standard is under preparation from the moment a decision has been taken to develop a standard, until that standard has been adopted. If requested, the titles of specific draft standards have to be provided in English, French or Spanish. A notice of the existence of the work programme must be published in a national or, as the case may be, regional publication of standardization activities. These may be public Internet sites.

Furthermore, the work programme shall, for each standard indicate the classification relevant to the subject matter, the stage attained in the standard's development, and the references of any International Standards used as a basis for developing a standard. No later than at the time of publication of its work programme, the standards body has to notify the WTO using the WTO ISO Information Gateway (see 3.5.1).

This notification has to contain the name and address of the standards body, the name and issue of the publication in which the work programme is published, the period to which the work programme applies, its price (if any), and how and where it can be obtained. The notification may be sent directly to the WTO ISO Information Gateway, or, preferably, through the relevant national member or international affiliate of ISO. Further information can be obtained from the ISO Website.

CIRCULATE DRAFT STANDARDS FOR PUBLIC COMMENT (PROVISION L)

Another provision to foster transparency is the publication of a notice of any draft standard for a period of at least 60 days to invite public scrutiny and comments. The notice need not contain the complete text of the draft standard published

for comment as this creates too many issues with copyright, especially if it is an adoption of an ISO or IEC international standard.

The notice should contain the title and scope of the draft standard published for comment and the reason for its development. It should be made clear if the draft standard is based on or a complete adoption of an International Standard, and any differences between the draft standard and the international standard should be highlighted. Most NSBs typically now use their Websites for such notifications instead of printed media.

The *WTO TBT Agreement* Secretariat need not be notified of draft standards that are issued for comment. This is only necessary in the case of technical regulations. However, if the draft standard is due to be promoted and disseminated (i.e. put into effect by official proclamation) as a compulsory standard once it is approved and published, it then becomes a technical regulation in terms of the *WTO TBT Agreement*. In such a case, it needs to be notified to the *WTO TBT Agreement* Secretariat also at least 60 days before it is published.

DO NOT IGNORE THE COMMENTS (PROVISIONS M AND N)

In order to permit commenting on draft standards, the drafts must be made available. Therefore, copies should be provided on request. In many countries, the NSB now charges a small fee for providing the draft standard. This is acceptable, as long as the NSB charges all interested parties the same.

Once the comment period is over, all comments should be collated and properly considered by the technical committee. The comments can be valid, invalid or challenging; it is the task of the TC to consider all of them. It is good practice to respond to each commenting organization and provide reasons for not accepting their comments, especially in the case of non-acceptance of elements of related International Standards.

PUBLISH THE STANDARD PROMPTLY (PROVISION 0)

Once the standard has been approved, it is important that the standard is published promptly. It is no use if the standard is approved, and then cannot be published

because the budget for printing has been exhausted for example. Nowadays, the standard will be made available in electronic format and sold over the Internet either electronically or printed to order.

REACT POSITIVELY TO REQUESTS FROM OTHERS (PROVISIONS P AND Q)

Transparency is a fundamental tenet of the *WTO TBT Agreement*. Hence, Annex 3 is very clear that a standards-development organization, NSB or otherwise, must react positively to any reasonable requests from interested parties, locally or abroad, especially as regards the work programme, and the development and publication of standards.

The standards body should consider and provide adequate opportunity for consultation, regarding representations with respect to the operation of Annex 3 presented by standards bodies that have accepted it. The standards body also has to make an objective effort to solve any complaints.



The WTO TBT Agreement does not identify international standardizing bodies by name whose standards it considers to be International Standards. Instead, in the year 2000, the TBT Technical Committee defined the characteristics of International Standards, by establishing six mandatory principles for their development. These principles have been applied successfully when determining whether a standard, when used as the basis for technical regulation in a trade dispute between two countries, was in fact an International Standard. These principles are now also applied at the national level to determine whether the processes utilized in developing national standards meet international expectations, i.e. conform to GSP.

4.1 The Six Principles of Standardization

The six principles are contained within a formal decision-document that the WTO TBT Committee adopted and entitled *Decision of the Committee on Principles for the development of International Standards, Guides and Recommendations with relation to Articles 2, 3 and Annex 3 of the Agreement.* Whenever the question arises whether a specific standard is an International Standard, standards experts can use this document to decide on the issue.

The six principles listed by the TBT Committee regarding International Standards are 13):

- transparency,
- openness,
- impartiality and consensus,
- effectiveness and relevance,
- coherence, and
- development dimension.

ISO had regard for these six principles and added another three that it considered to be important. These are:

- stakeholder engagement,
- due process, and
- national implementation.

¹³⁾ The relevant WTO document number: G/TBT/9, 13 November 2000, para. 20 and Annex 4.

4.2 ISO's strengths in meeting the standardization principles

ISO is underpinned by a decentralized, professional, member-based system for developing International Standards. ISO can therefore make full use of the strengths of its many members to manage over 240 ISO/TCs and call on the expertise of many thousands of international experts from member countries. The organizational structure of ISO is well-defined with clear responsibilities. The standards development process which is based on openness, transparency and consensus, is clearly defined in the ISO/IEC Directives. Standards developers must apply these principles, with compliance assured by the ISO Technical Management Board (ISO/TMB) overseeing the whole system.

This in turn is accountable to the ISO Council. Nevertheless, in recent years, to be responsive to both current and new stakeholder needs and to maintain itself as a highly relevant International Standards developer, ISO has seen its work programme expand and evolve into new subject areas. Compelling challenges for ISO regarding its standards-development processes have accompanied this evolution, as stakeholder expectations of the ISO system are changing. As a result, the ISO/TMB formed its Process Evaluation Group (PEG) to investigate the responsiveness of the ISO standards development processes to these changing dynamics – see 4.9.1 for more details. The ultimate intent of the PEG's efforts was to safeguard the outcomes of the ISO system and to promote the existing value, strength and authority of International Standards and the processes by which they are produced.

As a further enhancement to the principles of standards development within the ISO and IEC systems, *ISO/IEC Guide 59* has recently been revised. Whereas the first edition of *ISO/IEC Guide 59* provided general guidance, the second edition focusses specifically on ISO and IEC recommended-practices of standardization for NSBs. Therefore this publication, with its broader approach to GSP and the revised *ISO/IEC Guide 59*, are complementary in that they address similar issues. Therefore, it is recommended that they should be considered together by NSBs within the ISO/IEC system.

4.2.1 ISO Code of Ethics

The *ISO Code of Ethics* consolidates principles and commitments that already exist in a number of statutory documents, Directives and General Assembly or Council resolutions. The *ISO Code of Ethics* deals with the conduct of all ISO members in matters related to standardization at international, regional and national levels. As a provider of standards to governments, industry and civil society, and committed and organized to meet the challenges of the 21st century, all ISO members are expected to act in accordance with the *ISO Code of Ethics* to ensure the high standing of the organization. The *Code* contains four principles, dealing with the following:

- developing globally relevant International Standards in a fair, responsive and efficient manner;
- promoting the implementation of International Standards and associated good conformity-assessment practices;
- monitoring ISO's integrity and promoting ISO's image; and
- considering the development dimension.

The ISO Code of Ethics can be downloaded from the ISO Website.

4.2.2 ISO Code of Conduct

The ISO Code of Conduct provides the ethical framework for ISO's technical work which is carried out in an international, multi-stakeholder, multi-sector environment. It applies to standards developers who choose to participate in an ISO/TC, Subcommittee (SC), Working Group (WG) or another consensus group. The Code is an obligation for participation in the above groups that work within the framework of the ISO/IEC Directives. Participants specifically commit to the following:

- working the net benefit of the international community;
- upholding consensus and governance;
- agreeing to a clear purpose and scope;
- participating actively and manage effective participation;
- escalating and resolve disputes;
- behaving ethically; and

respecting others in meetings.

The *ISO Code of Conduct* can be downloaded from the ISO Website. The document is a useful guide for NSBs to develop their own, national version for their technical committee members to follow.

4.3 Principle #1: Transparency

In general, transparency is being clear and open about rules, plans, processes and actions, i.e. getting to know why, how, what, and how much. This means that in the standardization world, officials, managers and technical committee members act in a manner that is visible and comprehensible, and report on their activities so that people outside the system are able to hold those inside to account. This increases the trust in the standards body and the people on which standardization depends.

According to the WTO TBT Committee, when providing essential information, the transparency procedures should include at least the following:

- publication of a notice at an early appropriate stage, in such a manner as to enable interested parties to become acquainted with it, that the international standardizing body proposes to develop a particular standard;
- notification or other communication through established mechanisms to members of the international standardizing body, providing a brief description of the scope of the draft standard, including its objective and rationale.
 Such communications shall take place at an early appropriate stage, when amendments can still be introduced, and comments taken into account;
- upon request, the prompt provision to members of the international standardizing body of the text of the draft standard;
- provision of an adequate period of time, for interested parties in the territory
 of at least all members of the international standardizing body, to make comments in writing and take these written comments into account in the further
 consideration of the standard;
- prompt publication of a standard upon adoption; and
- publishing periodically a work programme containing information on the standards currently being prepared and adopted.

It is recognized that the publication and communication of notices, notifications, draft standards, comments, adopted standards or work programmes electronically, i.e. via the Internet, can provide a useful means of ensuring the timely provision of information. At the same time, it is also recognized that the requisite technical means may not be available in some cases, particularly in some areas of developing countries. Accordingly, it is important that procedures are in place to enable hard copies of such documents to be made available upon request.

4.3.1 What ISO does

The ISO system is considered to be fully transparent:

- All the processes of ISO are covered by formal rules and procedures. They are contained in the ISO/IEC Directives which are common to both ISO and IEC, supplemented by some ISO-specific rules, all of which can be found online on the ISO Website without any restrictions.
- The membership (national ISO members and liaison organizations), Chairs, convenors and secretariats of all the ISO TCs, SCs and WGs can be found online on the ISO Website, without any restriction.
- Extensive voting-procedures are in place to approve proposed projects and draft International Standards. The results of any voting are communicated to all members.
- The TMB looks after the technical-committee structure of ISO, approves new ISO/TCs together with their Chairs and Secretariats, holds ISO/TCs to account on progress (or lack of it), and considers appeals against decisions of the ISO/TCs.

4.3.2 What NSBs should do

The NSB should implement processes that are very similar to those required of an international standardizing body, the main difference being that it operates at a national level, rather than at the international level. Some elements that need to be given attention include the following:

- The NSB should implement formal procedures to guide the process of standards development, publication and information. These procedures should be kept up-to-date, demonstrably implemented and should be available to any interested party. Some NSBs have developed and published a "Standard for a standard" containing the principles, overview and framework of their standards development and publication process. The implementation of a formal quality-management system, such as a system conforming to ISO 9001, is also a useful mechanism in this respect.
- Annex 3 of the *WTO TBT Agreement* requires NSBs to publish a work programme at least every six months. In addition to all the specified requirements (see 7.1.4), this work programme should communicate proposals for new standards to be developed, communicating to any interested party at an early stage, in a clear and comprehensible way. It is useful if a brief description of the scope of the draft standard, including its objective and rationale, are provided so that interested parties can decide whether or not they wish to participate in its development.
- Nonce the technical committee determines that a draft standard is ready for open consultation, it should be made available to interested parties. NSBs now typically do this through the electronic media. How, if countries do not have widespread Internet access, then additional ways of communicating, such as a notice in the daily press or government gazette, or a newsletter sent directly to relevant stakeholders, may still be required. An adequate period of time should be provided to allow interested parties the opportunity to submit written comments − 60 days is considered a minimum. A clear and well-understood procedure should be in place for the management of these comments.
- Interested parties should be able to gain access to the text of draft documents circulated for public comment in order to provide meaningful responses. This can be a sensitive issue for the NSB that has to look after the copyright of International Standards, such as ISO and IEC standards. If the draft standard is an adoption of these, then the NSB cannot just publish the draft in such a way that anybody can obtain a copy free of charge. Hence, NSBs should only provide a copy on request, and in some cases may even require some form of

- payment. Another possibility would be read-only Internet-access without the possibility of downloading the draft documents.
- The NSB should make available a catalogue of the published standards. Whereas this was a bulky, hard-copy document in the past, an electronic version on the Website is much more appropriate and useful. The catalogue should contain not only the unique identification of the standard, i.e. title, number, date of publication, but also the scope of the standard. The catalogue should also state whether the standard has superseded a previous version and whether it is an adopted standard or based on one. It is extremely useful if a list of withdrawn standards is also available.

4.4 Principle #2: Openness

In general, openness is about collaboration that enriches the process to develop better content. An open system is one in which participation is expanded to include a wide and relevant audience, as well as developing an inclusive document or strategy that is more likely to be accepted by a wider audience.

Regarding international standardization, the WTO TBT Committee *Decision* on the issue requires that membership of an international standardizing body should be open on a non-discriminatory basis to relevant bodies of at least all WTO Members. This would include openness without discrimination, with respect to the participation at the policy development level and at every stage of standards development, such as the:

- proposal and acceptance of new work-items;
- technical discussion on proposals;
- submission of comments on drafts in order that they can be considered;
- reviewing existing standards;
- voting and adoption of standards; and
- dissemination of the adopted standards.

Any interested member of an international standardizing body, including developing country members who have an interest in a specific standardization activity, should be provided with meaningful opportunities to participate in all stages of standards development. It is noted that with respect to standardizing bodies

within the territory of a WTO Member that have accepted the *Code of Good Practice for the Preparation, Adoption and Application of Standards by Standardizing Bodies* (Annex 3 of the *TBT Agreement*) participation in a particular international standardization activity takes place, wherever possible, through one delegation representing all standardizing bodies in the territory that have adopted, or are expected to adopt, standards for the subject-matter to which the international standardization activity relates.

4.4.1 What ISO does

Within the ISO system, the meaning and interpretation of openness with regard to standards development relates largely to:

- proposal and acceptance of new work items;
- submission of comments on drafts in order that they can be considered; and
- voting and adoption of standards.

Any ISO member body with an interest in a specific standardization-activity is provided with meaningful opportunities to participate at all stages of standards development in accordance with its membership level criteria. Many countries make full use of these opportunities, others less so as a result of resource constraints. In addition, ISO encourages members to share the message about the benefits of full membership with decision makers in their countries and the fact that an NSB can join ISO at any level, with the opportunity to upgrade at any time. In this way, ISO members may decide their own level of participation and involvement, according to their needs and economic, social and environmental priorities.

4.4.2 What the NSB should do

Similar to an international standardizing body, participation in the NSB's standards-development process should be open at all stages to any interested party. This would include the stages of:

- proposal and acceptance of new work items;
- a technical discussion of proposals;

- submission of comments on drafts;
- review of existing standards;
- voting and approval of standards; and
- dissemination of approved standards.

The NSB should safeguard the participation of a range of interested parties appropriate to each standard under development. The participation should not be contingent on membership in any specific organization (see also 6.4.1 on the composition of TCs). This is especially important in the case of potentially underrepresented participants, such as small and medium enterprises (SMEs), consumers and representatives of societal interests (typically trade unions, consumer and environmental NGOs). This implies putting in place procedures for monitoring the participation of different categories of interested parties, and when considered necessary, waiving any membership requirements or participation fees to encourage the participation of all interested parties.

As regards participation of all interested parties at the policy level, not everybody can be represented at the NSB Board or Council, as this would render the governance structure very cumbersome and even ineffective (see 6.1.5 on the composition of the NSB Board or Council). To augment the governance activities of the NSB Board or Council, the NSB may wish to consider the establishment of a standardization forum in which all stakeholders can participate freely. Such a forum would meet maybe once or twice a year, deliberate on standardization issues, identify market demands and provide recommendations that the NSB Board or Council, and senior management can then consider in going forward.

4.5 Principle #3: Impartiality and consensus

Impartiality (also called even-handedness or fair-mindedness) is a principle holding that decisions should be based on objective criteria, rather than bias, prejudice or preferring the benefit to one person over another for improper reasons. Bias in this context is an inclination or outlook that holds a particular perspective, often accompanied by the refusal to consider the merits of alternatives. In contrast,

impartiality leads to the consideration all alternatives in an objective way, i.e. without partiality or undue external influence.

Consensus is defined in *ISO/IEC Guide 2* as general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves taking into account the views of all parties concerned, and to reconcile any conflicting arguments. An important outcome of this definition is that consensus need not imply unanimity.

The WTO TBT Committee *Decision* determines that all relevant bodies of WTO Members should be provided with meaningful opportunities to contribute to the elaboration of an International Standard, such that the standards development process will not give privilege to, or favour the interests of a particular supplier(s), country/countries or region(s). Impartiality should be accorded throughout the entire process of developing standards with respect to, amongst other things:

- access to participation in work;
- submission of comments on drafts;
- consideration of views expressed, and comments made;
- decision-making through consensus;
- obtaining of information and documents;
- dissemination of the International Standard;
- fees charged for documents;
- the right to transpose the International Standard into a regional or national standard; and
- review and vision of the International Standard.

4.5.1 What ISO does

This culture of building consensus has a long tradition in ISO, and the ISO standards development-procedures exemplify the consensus process. The appointment of the Chair and Secretariat of the various ISO/TCs by the ISO/TMB is to ensure that competent and experienced persons are appointed to these important positions. They will be the ones that are accountable for reaching consensus within the

ISO/TCs. The process is monitored continuously by the committee managers and ISO Central Secretariat staff, to ensure compliance at all times.

4.5.2 What the NSB should do

When addressing consensus and impartiality, the NSB should strive to ensure that it provides an impartial and neutral platform for its standards development work, with the ambition of providing all parties with a level-playing field. The NSB should ensure that the standardization process remains collaborative and consensus-based, taking into account all views expressed and bringing together diverging opinions. Whenever referring to consensus, it is useful if the NSB cites its definition in full, along with a precise reference to its source.

The NSB should assist its participants and those leading the standards-development process in building consensus. For this, the following practices have been found to be useful:

- **Establish representative TCs**: See 6.4.1 regarding the balancing of interested parties in TCs, SCs and WGs.
- Promote the right attitude: It would be good practice for the NSB to formally request those leading the standards-development process to act impartially in the discussions and normative work in which they take part, and to commit to this in writing. Likewise, the NSB should invite the participants involved to cooperate fully and in good faith in the standardization work. Developing and implementing an NSB Code of Conduct for committee members is a useful approach see 4.2.2.
- **Deal decisively but impartially with objections**: In the process of reaching consensus, many different points of views will be expressed as a draft standard evolves. Some of these may differ quite appreciably and could become "sustained opposition to substantive issues". The Chair needs to determine whether it is a substantive issue and whether the sustained opposition is from an important part of the concerned interests (see the definition of consensus in *ISO/IEC Guide 2*). If it is not a substantive issue, or if not from an important part of the concerned interests, then the opposition should be registered, and the work continued.

If both are true, the situation is potentially much more awkward, and the Chair should strive to bridge the differences. Sometimes it is more productive to temporarily shelve a contentious subject and continue working on the remainder of a draft standard, returning at the end when a WG or TC has reached consensus on most of the draft. Otherwise spending a great deal of time on contentious issues can disrupt the progress of a draft standard. Furthermore, sometimes it is useful to call a break and discuss the issues individually with the protagonists of contentious issues outside of the main discussions within the TC The training of Chairs should therefore include training in mechanisms to achieve consensus – see 6.2.2.

If the differences are important and the sustained opposition continues, the issue may have to be deferred to the next meeting to give participants time to rethink their position and the NSB the chance to discuss it with their principals. At some time, however, a decision will have to be made to complete the work after registering the sustained opposition – a decision best taken collectively by the NSB and the Chair.

- Achieving consensus rather than voting: The NSB should refrain from voting as far as is possible because the result is frequently very far from a consensus position, over and above the fruitless discussions on who has the right to vote. The NSB should make use of voting procedures only as a very last resort and only when the setting is appropriate and the rules for voting clear and acceptable to all.
- Record the proceedings: It is a good practice to record the points-of-view expressed with rationales, including any sustained opposition, the decisions taken, the actions launched and, if need be, the initiatives taken to reach consensus.
- **Utilize the appeals process:** Those parties with sustained opposition that remain unsatisfied with the process or the outcome may use the NSB's appeals mechanisms, which should be a formal procedure ultimately involving the NSB Board or Council.

4.6 Principle #4: Effectiveness and relevance

Effectiveness and relevance can be summarized as having the following four attributes:

- The needs of the audience that have to be addressed. In the context of standards, this means that the needs of the users, i.e. industry, authorities, suppliers and consumers, have to be determined.
- The message to the audience has to be clear, unambiguous and effective in addressing their needs, i.e. the standards should be focussed on the quantified needs.
- ► The message, i.e. the standard, needs to be provided in a timely manner. It is not beneficial if the standard is published long after technology or the market has moved on, and the standard is then no longer relevant. This is a particular challenge in fast moving technologies hence *time-to-market* is an important parameter.
- The message, especially an International Standard, has to be relevant to both developed and developing nations. It is more useful if the International Standard is relevant for a wider range of countries, therefore serving the bulk of its potential users.

The WTO TBT Committee's *Decision* requires International Standards to be relevant and to effectively respond to regulatory and market needs, consider scientific and technological developments in various countries, facilitate international trade and prevent unnecessary trade barriers. They should not distort the global market, have adverse effects on fair competition, or stifle innovation and technological development. In addition, standards should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions.

A similar principle is applicable to products subject to patents and copyright. The objective of standards is to ensure compatibility of technologies and systems on a worldwide basis. To meet this objective, which is in the common interests of all those participating, it must be ensured that standards, their applications and use are accessible to everybody.

Therefore, standards should not give additional protection to patented products, thereby excluding similar products which would serve the same purpose. ISO, IEC and ITU for example, have published a common patent-policy in this regard ¹⁴⁾. This requires that a patent embodied fully or partly in an International Standard or recommendation must be accessible to everybody without undue constraints. If not, then the standard may not include provisions subject to the patent.

Whenever possible, International Standards should be performance based rather than based on design or descriptive characteristics (see 3.5.2 on performance-based standards). Finally, procedures should be in place aimed at identifying and reviewing standards that have become obsolete, inappropriate or ineffective for whatever reasons.

4.6.1 What ISO does

ISO endeavours to ensure that the standards that are developed and published under the ISO branding are relevant, otherwise the market will soon abandon them and go elsewhere. ISO therefore reviews all published standards in a five-year cycle, it has developed and implemented policies to ensure that no single country or region can influence the contents of International Standards to the disadvantage of others and ISO standards are by and large performance based. All technical committees develop and operate in accordance with business plans that take market requirements and emerging needs into consideration. In ISO, the TMB approves the first strategic business plan only and committees are responsible for ensuring regular updates and revisions.

As an example of relevance, the ISO/IEC CASCO standards for conformity assessment – e.g. the $ISO/IEC\ 17000$ series are widely used as the norm for conformity assessments and mutual recognition, and even by conformity-assessment schemes owners within the private sector.

¹⁴⁾ The ISO/IEC/ITU policy on patents can be downloaded free of charge from: https://www.iso.org/iso-standards-and-patents.html.

4.6.2 What the NSB should do

The NSB should follow the stated requirements of the WTO TBT Committee interpreted for the national level and should develop standards to meet the needs of the marketplace and contribute to advancing trade in the broadest geographical and economic contexts. In particular, the NSB should:

- Take account of relevant regulatory or market needs, as feasible and appropriate, as well as scientific and technological advances in the development of standards, for example by developing an appropriate strategy for national standards.
- Give submitted proposals for the development of new or revised standards prompt consideration, irrespective of where these proposals originate.
- Ensure that new standards do not distort the market or have adverse effects on fair competition, or stifle innovation and technological development.
- Guide committees to express requirements in terms of performance characteristics, rather than design or descriptive characteristics, whenever possible to ensure standards developed do not stifle technical development. This in turn would reduce the risk of undesirable market impacts, e.g. restriction of innovative solutions.
- Focus on user-friendliness, simple language and limit the usage of normative references to those that are essential for meeting the requirements of the standard.
- Put in place procedures aimed at identifying and reviewing standards that have become obsolete, inappropriate or ineffective. All standards should be reviewed periodically, and revised in a timely manner to ensure their relevance in the context of changing market or regulatory needs, and new scientific and technological developments. A review period of five years is a common approach.
- Make available historical versions of standards when applicable. If historical versions are available, the status of the standard should be clearly stated, for example, if the standard has been withdrawn or superseded.

4.7 Principle #5: Coherence

Coherence is the quality of being logical and consistent, and the quality of forming a unified approach.

The WTO TBT Committee *Decision* resolves that it is important that International standardizing bodies avoid duplication of, or overlap with, the work of other international standards-bodies, in order to avoid the development of conflicting International Standards. In this respect, cooperation and coordination amongst relevant international bodies is essential.

This requirement has become even more topical in the last decades as technologies converge. For example, motor vehicles used to be the sole domain of ISO, but now electrically-driven cars are becoming available which would require a closer cooperation between ISO and IEC. The same applies in photography, which used to be based on a film and chemical process, nowadays digital photography dominates the market.

Careful cooperation and coordination of International Standards amongst international standards-bodies has therefore become a very important challenge that such bodies have to manage; otherwise chaos will develop very quickly.

4.7.1 What ISO does

In order to ensure coherence amongst ISO Standards and with standards published by other international standards-bodies, ISO has implemented a number of measures:

- The ISO/TMB approves the technical committee structures of ISO and ensures that there are no overlaps or gaps that could result in different ISO standards covering the same product or service, albeit with differing requirements.
- ISO coordinates its activities with IEC and ITU (the three main bodies for developing International Standards) within the World Standards Cooperation, to address any potential overlap between standards developed by the three main bodies. This is a particular challenge, for example, with fast moving technologies, and technologies where electronics are replacing mechanical components.

- ISO, together with IEC, are publishing common standards in the sector for information and communication technologies (ICT).
- ► ISO is implementing a number of memoranda-of-understanding (MOUs) and other agreements with standards development-bodies such as CEN and IEEE, for example.
- ► ISO pursues cooperation and coordination with more than 700 inter-governmental organizations, international-trade organizations, and civil society.

4.7.2 What the NSB should do

For standards to be mutually consistent and free from contradiction for the benefit of the user communities, standardization activities should be actively coordinated within the country and also within the region, if applicable. Initially, standardization activities should be coordinated within each standards body, and thereafter amongst different national bodies, should there be more than one. Not only will such coordination keep overlaps and duplications to a minimum, it will also benefit the efficient application of limited resources of experts participating in standardization. Typical measures that would enhance coherence include the following:

- All national bodies should publicly provide information via suitable media, regarding their work programmes, especially for new projects, as early as possible to assist in understanding where overlaps and duplications may occur and to support early engagement and participation of experts.
- All national bodies should conduct a thorough study before starting new projects to understand if and where complementary, overlapping or duplicative projects may already exist. Ideally, this check should be carried out and the results should be reflected in any proposal to start new work.
- When it is known that an international or regional standard is being developed, national bodies should consider whether the international or regional standard may be adopted, to avoid duplicating efforts that may diverge in their results.
- All national bodies should make a good-faith effort supported by policies, procedures and agreements, to coordinate standardization activities and to resolve potential conflicts. A good-faith effort should demonstrate

- substantial, thorough and comprehensive efforts while respecting each other's values, objectives and membership and NSBs should retain documentation of such efforts.
- The NSB should have in place a system that allows identification of the possible role of standardization in support of legislation. In this context, the involvement of public authorities and officials is also necessary, especially in case of those standards that are aimed at supporting legislation.

4.8 Principle #6: Development dimension

The development dimension is aimed at the process of economic and social transformation based on cultural and environmental factors and their interactions, e.g. the process of adding improvements to a developing country through the transfer of knowledge and skills and facilitating access to global markets.

The WTO TBT Committee *Decision* advocates that constraints on developing countries, in particular, to effectively participate in standards development, should be taken into consideration in the standards development process. Tangible ways of facilitating developing countries' participation in the development of International Standards should be sought. The impartiality and openness of any international standardization-process requires that developing countries are not excluded *de facto* from the process. With respect to improving participation by developing countries, it may be appropriate to use technical assistance, in line with Article 11 of the *WTO TBT Agreement*. Provisions for capacity building and technical assistance within international standards-bodies are important in this context.

4.8.1 What ISO does

ISO recognizes that increased and effective participation of developing countries in international standardization is fundamentally important and that its developing country members need specific assistance to fully exploit the value of standards in support of their country's development. Hence, measures that ISO has implemented in this respect include the following:

- ISO/DEVCO is a policy committee of the ISO Council that provides guidance and management on matters related to developing countries.
- Developing countries are supported in participating actively in International Standards development through the twinning programme. This enables a country in need of capacity building (often a developing country) to partner with another country, that in turn can provide training or share knowledge and experience (see detailed discussion below).
- The ISO Capacity Building Unit implements technical-development projects that are funded by donor countries or their agencies. These projects, guided by the ISO Action Plan for Developing Countries 2016-2020, aim to build capacity for NSBs in developing countries to become effective standards-bodies, especially with regard to the development and publication of national standards and their active participation in international standardization.
- Support is also provided to developing countries through the ISO sponsorship programme.

ISO ACTION PLAN FOR DEVELOPING COUNTRIES

The *ISO Action Plan for Developing Countries 2016-2020* builds on the solid foundation of the two previous editions of the *Plan* (2005-2010 and 2011-2015), the results achieved in the past ten years and the lessons learned. While ISO, with support from donors, can assist developing-country members in making the best use of their membership, the objectives of the *Plan* can only be achieved if members take full ownership of the activities carried out under the *Plan*. Developing country members therefore have to play a major role in directing the process of ISO's capacity building support by:

- actively contributing to the development of the *Plan* (i.e. current and future plans);
- providing specific input linked to its implementation (in particular through the needs assessment process);
- making a commitment to the success of the *Plan* at the level of the NSB and contributing resources for the implementation of the *Plan*; and
- monitoring progress and evaluating results.

In addition, ISO members from developing countries should make every effort to promote standardization, in order to secure engagement and support from stakeholders and relevant organizations for the implementation of the *Plan*.

PARTICIPATION IN ISO'S "TWINNING RELATIONSHIP" PROGRAMME

Developing countries find it a challenge to participate actively in ISO and IEC for a variety of reasons, whether financial, technical, or procedural. The international standardizing bodies are therefore looking for ways and means to enhance the participation of developing country members. ISO, for example, has introduced a "Twinning programme" ¹⁵. In a twinning relationship, two members work together, with one more experienced member (the 'lead partner') acting as mentor to build capacity of the less experienced member (the 'twinned partner', often a developing country). There are four possibilities, namely:

- ► Twinning between participating-members: This allows a member, that may not yet have the level of competency required to cooperate on a leadership position, to participate actively in the technical work of standards development. Participating-member twinning allows the twinned partner to gain specific experience related to the work of a committee at the international and national levels (including the role of national mirror committees) and insight into the obligations of a participating-member.
- Twinning between Convenors and Twinned Convenors: The twinned partner has the opportunity to gain the skills and experience needed to assume the convenorship of a WG in the future (e.g. leading meetings, building consensus, managing projects at WG level).
- Twinning between Chairs and Vice-Chairs: The twinned partner has the opportunity to learn the skills and responsibilities needed to assume the Chairmanship of a ISO/TCs or SCs in the future (e.g. leading meetings, building consensus, and managing projects at the ISO/TC level).
- ► **Twinning between Secretariats and Twinned Secretariats:** The twinned partner has the opportunity to learn the skills and responsibilities needed to

¹⁵⁾ More detail can be obtained in the ISO Brochure: *Twinning is winning - How to engage developing countries in standardization work.* Copies can be obtained from the ISO Central Secretariat or can be downloaded from ISO website.

assume the role of a committee manager in the future (e.g. preparing meetings, managing projects, and promoting the committee).

4.8.2 What the NSB should do

At the national level, the NSB should engage all parties who are interested in development of national standards and offer them special support to enhance their participation in the standards development process. Special attention should be given to interested, yet underrepresented parties. In this respect, it is important to consider the scope of the standard and the impact it may have on various groups in the community (including underrepresented groups such as the elderly and young persons, women, consumers, small business, and those who are physically impaired) in order to provide relevant differential treatment to facilitate participation. Furthermore, to improve the accessibility of information regarding standardization activities for those who are underrepresented, it is also important to consider how drafts and finalised documents are disseminated, so that the information can reach as wide a range of stakeholders as possible.

4.9 Principle #7: Stakeholder engagement

Nearly all of the principles of GSP are underpinned by stakeholder engagement. It is essential to engage others in order to get them to become part of the process. This often requires a large amount of promotional or outreach activities, making others aware of the benefit and application of standards. From these stakeholders, the interested parties emerge, and then engage in the actual standards development process.

4.9.1 What ISO does

ISO relies heavily on its members to engage stakeholders, to foster interested parties to become involved in standards development. That said, recognizing

the importance of stakeholder engagement, the ISO/TMB established a PEG and tasked this group to:

- review the current situation and consider the possibility of alternative models
 of standards development operations and participation in ISO; and
- examine processes for consensus decision-making and stakeholder engagement within NSBs and liaison organizations, which may impact the credibility of resulting ISO standards.

The results of the PEG's work are presented in the guidance document *Engaging stakeholders for ISO national standards bodies*. This document can be downloaded from the ISO website.

At the international level, ISO engages with stakeholders that are not only active in the standardization domain, but also those that can have an influence on the work. This in turn enhances and maintains the status of ISO as a trusted international-standards organization. These actions include participation in liaison activities, meetings and workshops of diverse organizations such as the: WTO; organizations in the UN family; international quality-infrastructure organizations such as the International Bureau of Weights and Measures (BIPM), the International Organization of Legal Metrology (OIML), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC), and; various international development organizations. The liaison that ISO maintains with the many other international and regional standards organizations completes the picture. A list of these can be found on the ISO Website.

4.9.2 What the NSB should do

The first priority for the NSB would be to create a diagram that maps its stake-holders. It should be noted that the stakeholder group would be bigger than the interested parties that are eventually involved in the development of a standard. Stakeholders do not only consist of parties that are going to use the standard, or those who will be directly affected by its implementation, but also parties which can influence the actions of the NSB. These include the media, authorities,

academia and others who did not choose to bear the cost or experience the benefits, i.e. bearers of externalities.

The NSB should develop and implement a long-term engagement strategy (including a communication strategy) with its stakeholders to enhance its standing in society, amongst the authorities, business and industry. In this way, the NSB can attain an overarching position, from which it can mobilise support and resources to promote the importance of standardization. The interested parties involved in the development of a standard will originate from the stakeholders, and if the NSB has engaged well with its stakeholders, the interested parties will be more willing to contribute to standards development in a meaningful way (see 4.4 on the establishment of TCs).

4.10 Principle #8: Due process

Due process is a course of formal proceedings carried out regularly and in accordance with established principles and rules. Due process should be at the heart of all standards development activities, ensuring that the process is open, transparent and known to all participants, i.e. there are no surprises.

4.10.1 What ISO does

The whole process of developing International Standards has been codified within two documents jointly published by ISO and IEC – these are the ISO/IEC Directives. These are augmented by a *Consolidated ISO Supplement*. All of them can be found on the ISO Website ¹⁶. They are:

- ISO/IEC Directives, Part 1 and consolidated ISO Supplement

 Procedures specific to ISO;
- ► ISO/IEC Directives, Part 2 Rules for drafting International Standards; and
- ► Consolidated JTC 1 supplement Procedure specific to JTC 1.

¹⁶⁾ www.iso.org/directives.

4.10.2 What the NSB should do

Similar to ISO and IEC, any NSB should develop standards in a manner guided by due process. This means that the principles and rules should be made known to any interested party, e.g. on the Website or as a national standard (see also 7.2). These principles and rules should be aligned with the ISO/IEC Directives and should comply fully with the requirements of the *WTO TBT Agreement*. Frequently, such principles are also contained in the legislation establishing the NSB, if the NSB is a governmental type organization.

An appeals process, for the case of deadlock of objections, is an important element that has to be properly codified. This will provide a means for interested parties to make appeals and have them heard independently, with the decision recorded and communicated to all concerned. The appeal and the resulting decision should be based on the principle of escalation, i.e where appeals are taken to the next highest level as appropriate. For example:

- a working group appeals to the SC Chair;
- a working group appeals to the TC Chair, if it is a WG under the TC;
- a subcommittee appeals to the TC Chair;
- ▶ a TC appeals to the NSB management; or
- ▶ the NSB management appeals to the NSB Board or Council.

4.11 Principle #9: National adoption

One of the major objectives of international standardization is to facilitate trade. Therefore, once an International Standard has been developed and published with the participation of many, the task is not yet complete. Otherwise it is not logical to develop an International Standard, unless and NSB adopts and then applies the International Standard at the national level.

Therefore, in order to complete the tasks at the national level, NSBs that are ISO members are committed to promote, contribute to, and implement locally International Standards such as ISO and IEC standards, together with the resulting

conformity assessment procedures. Some of the mechanisms available to ISO members include the following:

- ISO member bodies can adopt ISO standards as national standards, withdrawing conflicting national standards;
- national members can sell adopted standards based on their own pricing scheme; and
- users can put an International Standard into practice without it having been adopted as a national standard.

However, adopting International Standards is the best way to ensure a cohesive and coherent standards system at national, regional and international levels. The adoption of International Standards is GSP, especially for developing countries. It is also a strong theme of the *WTO TBT Agreement*. *ISO/IEC Guide 21-1*¹⁷⁾ describes the process for adopting International Standards and promoting them at a national level (see 7.2.10 for more details).

4.12 Gender equality

The United Nations Sustainable Development Goal Number 5 aims to provide for gender equality, empowering all women and girls. This goal is gaining momentum amongst trade-related organizations ¹⁸⁾. ISO has signed the declaration on the initiative for gender-responsive standards, that was developed by the UNECE. This initiative aims at providing a practical way forward for standards bodies wishing to ensure that the process of developing standards is gender responsive.

Within the ISO environment, an initial analysis in 2009 of existing data of those taking part in ISO work indicated that ISO is broadly made up of 25% women and 75% men across technical experts, among CEOs, and in governance groups, albeit with some exceptions. Therefore, the ISO Council has resolved to address the issue of gender equality in a pro-active manner and develop a gender-action plan, considering good practices by members and other international organizations.

¹⁷⁾ ISO/IEC Guide 21-1, Regional or national adoption of International Standards and other International Deliv-erables – Part 1: Adoption of International Standards.

¹⁸⁾ https://www.un.org/sustainabledevelopment/.



This chapter focusses on the NSB value chain within a given international and regional context. To better understand the NSB value-chain, it is useful to consider the complete standardization environment, i.e. from the development of the standard to its ultimate implementation, and how NSB services relate to those of the other institutions that play important roles in the implementation of standards. The NSB is one of the three fundamental organizations of the quality infrastructure (QI) of a country, the other two being the National Metrology Institute (NMI) and the National Accreditation Body (NAB). All other services of the QI, such as calibration, inspection, testing and certification, derive their recognition from these three bodies, which are also the link between the national and the international systems that in turn lead to international recognition of the outputs of the QI.

5.1 The Quality Infrastructure (QI)

The QI provides a framework for standardization, accreditation, metrology and conformity-assessment services (see 1.2 Terminology). Many of these would be voluntary in nature, i.e. compliance is a choice of the supplier and/or the purchaser – non-compliance with a voluntary standard is not a criminal offence. However, governments do require mandatory compliance in specific instances, known as technical regulations – non-compliance then becomes a breach under legal requirements (see also 2.4.3 Legal status of standards). The development and implementation of technical regulations utilize all the services of the QI, and its implementation is further enhanced by market surveillance.

The QI may also be considered at the regional or international level, at which a vast number of inter-governmental and non-governmental institutions have been established over the years. Furthermore, in addition to the regional and international institutions applying the core elements of the QI, there are numerous multinational companies providing a wide range of conformity-assessment services in many countries.

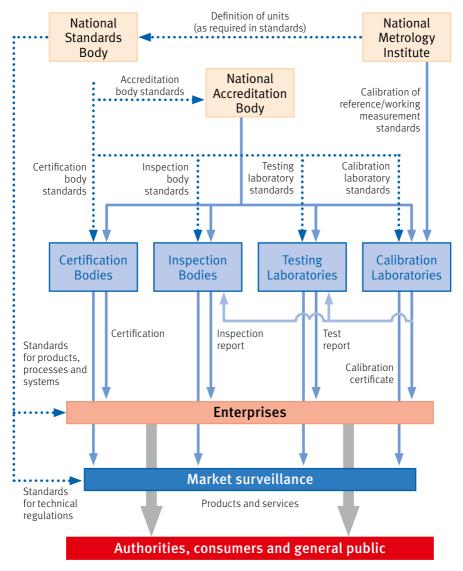
5.1.1 The place of the NSB in the QI

The interrelationship between the various parts of the QI is shown in Figure 5.1¹⁹. All the organizations within the QI are necessary to provide for the demonstration of compliance of products and services. This compliance can be required by regulatory authorities in the case of technical regulations, it can be required in terms of purchasing contracts, or it can simply be preferences prevailing in the marketplace. Therefore manufacturers, producers and suppliers offering products and services are major users of the services of the QI.

Figure 5.1 also clearly indicates the importance of an effective and efficient NSB, with national standards published by the NSB utilized by all the elements of the QI. These include the metrology and accreditation institutions, as well as a wide variety of stakeholders served by the QI.

Calibration assures that measuring equipment is traceable to the national measurement-standards maintained by the NMI, which in turn are calibrated to international measurement-standards. Calibration is not considered a conformity-assessment service *per se*, but it is a very necessary link in the value chain of conformity-assessment services. These services themselves – i.e. inspection, testing and certification – are directly responsible for assuring whether a product or a service complies with a national standard, International Standard, or a technical regulation. The competence of inspection, testing and certification services is in turn assured through accreditation, and the measurement capabilities of such services assured through calibrated measuring-equipment.

¹⁹⁾ Racine JL (Editor) (2011), Harnessing quality for global competitiveness in Eastern Europe and Central Asia, World Bank: Washington, ISBN 978-0-8213-9509-8.



Source: World Bank (see the definition of QI in page 14)

Figure 5.1: The National Quality Infrastructure

5.1.2 International recognition of the QI

All the services of the QI need to be recognized internationally; otherwise users of these services such as exporters will find it difficult to access foreign markets without having to re-inspect, re-test and re-certify their products. This would be a time consuming and expensive undertaking that may render them uncompetitive. Such recognition is based on the technical competency of the QI organization, as determined by the relevant combination of peer reviews, accreditation and inter-laboratory comparisons. In particular:

- The NAB must comply with ISO/IEC 17011, and needs to be recognized internationally through peer reviews and the signing of the IAF and ILAC multilateral recognition agreements or arrangements.
- ► The NMI is recognized by the listing of its calibration and measurement capabilities (CMCs) on the key-comparison database (KCDB) of the BIPM, following inter-laboratory comparisons and peer review²⁰⁾.
- The NSB needs to signify compliance with Annex 3 of the WTO TBT Agreement to the WTO Secretariat and its standards development process should comply with principles codified in decisions of the WTO TBT TC and in the ISO/IEC Directives.

International standards have been published for many of the QI organizations that they need to comply with to gain international recognition. The conformity assessment service providers and calibration laboratories are accredited by the accreditation body in accordance with International Standards for accreditation such as:

▶ inspection bodies: ISO/IEC 17020;

management-system certification bodies: ISO/IEC 17021-1;

bodies certifying persons: ISO/IEC 17024;

test laboratories: ISO/IEC 17025;

calibration laboratories: ISO/IEC 17025;

proficiency-testing providers: ISO/IEC 17043;

product-certification bodies: ISO/IEC 17065.

²⁰⁾ For developing countries, accreditation of the NMI will provide a measure of international recognition, before it has developed to the stage where its CMCs can be listed in the KCDB.

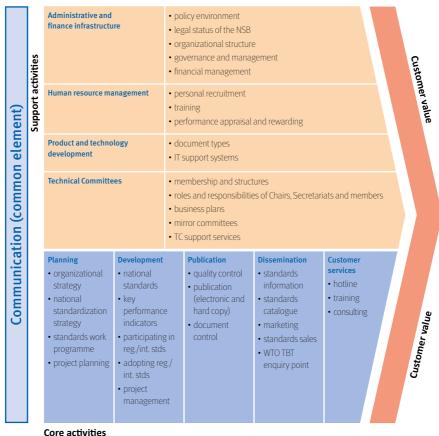
International recognition of the QI organizations and their services is therefore a complex undertaking that can only succeed if: the appropriate government policies are in place; there is coordination amongst the three core QI organizations (NAB, NMI and the NSB); it is cohesive and effective, and; if the individual QI organizations prioritize international recognition.

5.2 NSB value chain

A value chain is a set of activities that a firm operating in a specific industry performs in order to deliver a meaningful product or service to the market. The concept has its roots in business management and was first described by Michael Porter in his 1985 best-seller, *Competitive Advantage: Creating and Sustaining Superior Performance*. The value chain consists of two main areas of activity, which are: the core activities depicting the actual operations the company has to perform to create value for the customer, and: the support activities which underpin the core activities. The core activities and the support activities are therefore of equal importance. The value chain concept is used widely as a paradigm to view and optimize the strategies of a company or an organization, leading to optimum performance.

The elements of a value chain for standards development, publication and information in an NSB is shown in Figure 5.2. The NSB can only function optimally if considered as a whole. Taking the NSB value chain shown in Figure 5.2 as the point of reference, each of the elements of the core activities and the support activities have to be considered. In addition, the NSB does not exist in a vacuum; it has to operate within the context of national, regional (where relevant) and international systems. Therefore, considering the context is equally important.

Each of the four support activities and the five core activities are discussed in detail in this publication – the support activities in Chapter 6 and the core activities in Chapter 7. The international and regional context has been discussed in the preceding Chapters 4 and 5.



Source: Author's elaboration

Figure 5.2: The NSB value chain

Communication is a common element between the core and support activities. Although it is not discussed as a separate section, it is mentioned extensively in many sections and subsections, including in the principles of GSP. Due to its importance, the NSB needs a well-defined, documented strategy for communication to work effectively and efficiently with the different elements of the value chain.

5.3 Diagnostic tool

If any one of the elements of the value chain is sub-optimal, then the NSB services will also be sub-optimal; this in turn will compromise the value to the customer. Therefore, all of the elements have to be optimized in order to be fully functional. The diagnostic tool, which is part of this publication on GSP, enables an NSB to determine whether its performance is optimized within the value chain. The tool is based on the five elements of the core activities, the four support activities, and the interaction the NSB has with national, regional or international systems. The diagnostic tool will enable an NSB to review and evaluate its current situation and performance, and can be utilized to identify the solutions that are appropriate for an NSB to comply with GSP. A short introduction to the use of the diagnostic tool is provided in Annex A.

These value chain elements also form the basis of a diagnostic tool in the form of a spread sheet, which is available from ISO/CS for any NSB in a developing country. This spreadsheet will assist an NSB to rapidly determine whether its value-chain elements are in place, and whether they are effective.



The NSB can only function optimally as a developer and publisher of national standards and the provider of information regarding these, if the support activities are appropriately organized and functioning effectively and efficiently. These include: (i) administrative and financial systems; (ii) human-resource management; (iii) product and technology development, and; (iv) the TC structures operating within the NSB. Clearly, the NSB must be established with the appropriate mandate, governance and management before all of this can become a reality.

6.1 Administration and financial infrastructure

Most countries have established an NSB, whether decades ago or relatively recently. However, in view of the rapidly changing environment brought about by the growth of international trade and the increasing role that standardization plays in this regard, it would be prudent for the NSB to revisit its legal environment, governance, organizational structure and infrastructure, before focusing in detail on the NSB value chain for its standards development, publication and information services.

6.1.1 The policy environment of the NSB

The QI can provide effective and efficient services to the country as a complete system only if its elements are established and maintained with clear mandates, seamless interfaces without costly overlaps, and international recognition. In addition, the regime of technical regulations of the country must be aligned with international and regional obligations, as well as being acceptable to its main trading partners. In many countries, these have developed organically over the years and their effectiveness and efficiency may be less than optimal. Therefore, many countries are now revisiting the policy environment in which the QI and technical regulations operate, as the start of a re-appraisal of the QI as a whole. Within the QI framework, the National Quality Policy is a best-practice document that deals with the QI and technical regulations within a framework of other policies, e.g. industrial policy, export policy, and environmental policy. The Quality

Policy provides for the overall structure of the QI, the responsibilities of the various participants, and ensures that technical regulation is effective and efficient. Additionally, the Policy also provides for following international best practice, ensures that the QI is complete, does not duplicate any functions, and does not constitute an unnecessary barrier to trade.

As regards the NSB, its statutory instrument should ensure that it is not subject to undue political interference, even though it should support the government's industrial, trade and other relevant policies. It is useful if the NSB is officially recognized by the government as being responsible for standards development, standards distribution and membership in international and regional standards organizations. In some jurisdictions, it may even be necessary to provide exclusive rights to the NSB for publishing national standards, even though all of these may not be developed under its auspices. This provides the country with a single point of entry for all standards and is the most effective way of meeting its *WTO TBT Agreement* obligations if it is a WTO member.

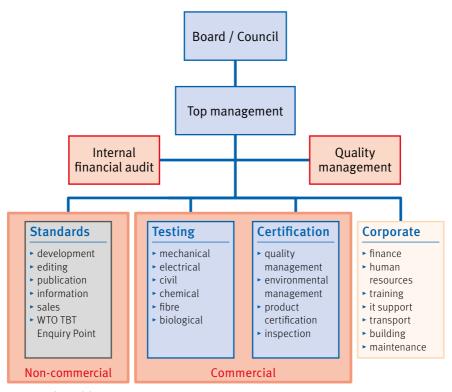
6.1.2 Legal status of the NSB

The legal status of NSBs differs from country to country. ISO membership data from a survey in 2009 showed that 47.5% of the NSBs are government departments, 30.9% are organizations of public law, 20.4% are "not-for-profit" private organizations and 1.2% operate as profit orientated private businesses. Compared with previous data, the percentage of NSBs as government departments or organizations of public law is slowly diminishing, whereas the not-for-profit private NSBs are on the increase. Anecdotal evidence would suggest that NSBs in developing economies are still mostly government departments or organizations of public law. The advantage of the NSB being an organization of public law over a government department is that it gains a measure of management freedom as regards business practices, i.e. the Council or Board can respond in a more agile fashion within the commercial environment, and services can be priced according to market requirements. As a government department, the NSB will of necessity have to follow departmental rules that may not be flexible enough to meet market requirements.

Private NSBs always have to confront the challenge of financial sustainability, even though most are not-for-profit organizations. This can be mitigated by a contract between the country and the NSB for the financing of activities for the common good, such as standards development, standards information and international liaison by the country. Conformity-assessment services on the other hand must be financially self-sufficient, related to market needs and operate as a business without national support other than the country paying for the services it sources from the NSB.

6.1.3 NSB organizational structure facilitating impartiality of standards development and publication

The organizational structure of an NSB is dependent on the services it provides, irrespective of whether it is a public or private-sector enterprise, and on country practices. Many NSBs in developing countries provide conformity-assessment services, and in this case the organizational structure should be set up in such a way that the impartiality of standards development and publication is assured. The two main activities that cannot be combined in any one organization are certification and accreditation. It is required that these two activities are performed by different organizations. An NSB can develop standards and carry accreditation but not conformity-assessment activities such as certification, inspection and testing. Alternatively, an NSB can develop standards and carry conformity-assessment activities such as certification and testing, but not accreditation. The NSB however, should not be involved in the administration of technical regulations. The structure that is shown in Figure 6.1 is one of the most common, although other types of structure are also possible.



Source: Author's elaboration.

Figure 6.1: Example on NSB organizational structure in developing economies

"Form follows function" is an old wisdom. This holds true also for the organizational structure of the NSB – see Figure 6.1. Hence, the three operational entities of an NSB also providing conformity-assessment services, should be focussed on standards, testing and certification respectively. The corporate functions are utilized by all and are essentially overheads. Top management would be the Director and the senior departmental-heads. Internal-audit reports to the Director to ensure financial systems are followed and robust.

The structure allows for the implementation of a financial system that clearly separates activities for the common good, or non-commercial activities from commercial activities. This would provide clear financial data, should the State decide

to only finance activities for public services. Corporate services can be allocated to the three operational entities on an equitable basis. This structure also facilitates compliance with the responsibilities and requirements for accreditation, and thus provides an appropriate measure of independence of standardization activities from other activities, i.e. impartiality.

Within the structure defined in Figure 6.1, the management-function responsible for standards can focus on the development of standards, their publication, and the provision of information on standards, as a complete package, thereby enhancing effectiveness and efficiency. The key performance-data such as financial efficiency, time-to-market of the standards development process, and other related activities can easily be captured to provide for a proper management of the activities.

The two commercial entities can be managed in accordance with good business-practices, and the key performance-indicators would be business and financially orientated. This is the area that has to compete in the marketplace and requires a different mindset to those managing the standards entity²¹⁾. They should generate an excess of income over expenditure.

The quality-management entity ensures that the NSB entities comply with relevant accreditation requirements, and the NSB's overall formal management-system.

6.1.4 Governance and management of the NSB

It is a good governance principle to separate governance and management roles in the NSB if, for example, the NSB is not a government department. The governance, vested in a Board or Council, provides the strategy for the NSB, ensures proper financial systems are followed and oversees the activities of the management, i.e. it looks after the interests of the main shareholders of the NSB (the government or private sector as relevant). Hence, the Board or Council should not be involved in the day-to-day running of the organization, as this would constitute a conflict of

²¹⁾ Detailed information on the conformity assessment business can be found in the ISO publication *Building trust: The conformity assessment toolbox*. Copies can be obtained from the ISO Central Secretariat or can be downloaded from ISO website.

interest with its "oversight" role. Management performs the day-to-day operation of the NSB and is accountable to the Board or Council – see Figure 6.2. Governance relates to all processes of oversight. Either a Board or a Council is the permanent governing body of most NSBs and is usually appointed by the relevant Minister if the NSB is a government department or an organization of public law. If the NSB is a private organization, then the members of the Board or Council are usually stakeholder representatives appointed by the NSB's general assembly. To be relevant in a modern economy, the composition of the Board or Council should meet criteria such as:

- Having a good blend between public sector, private sector, academia and consumer representatives.
- Ensuring Members should bring with them strategic and business skills, financial knowledge, market knowledge and good management practices. The NSB should operate as a business entity, with the Board or Council playing a role similar to the Board of Directors of a private company. Such an approach facilitates the long-term financial sustainability of the NSB.
- Appointing leaders of industry in their personal capacity rather than calling for representatives from business associations is more useful. In this way, advanced business skills, strategic thinking and market knowledge are more readily available in the Board or Council. In addition, such industrialists will act as goodwill ambassadors for the NSB in the private sector, thereby enhancing its stature and promoting the use of standardization.
- Defining whether the Director of the NSB is an *ex officio* full member of the Board or Council will depend on the legal system of the country and custom and practice. In some countries it is considered ideal if the Director is not a full member, whilst in others, good governance principles allow the Director to be a full member. However, if the Director or CEO is a full member of the Board or Council, he or she should not hold any office such as Chair or Vice Chair. This is good governance practice, that in turn ensures that the Board or Council's oversight function is separated from the management function of the NSB.

Governance

- set strategic vision and direction and formulate overarching goals and policies
- oversee management and organizational performance to ensure that the nsb is working in the best interests of the stakeholders
- direct and oversee the management to ensure that the nsb is achieving the desired outcomes
- ensure that the NSB is acting prudently, ethically and legally

Management

- manage the NSB in line with the broad goals and direction set by the governing body
- implement the decisions within the context of the mission and strategic vision
- make operational decisions and policies, keep the governance body informed
- be responsive to requests for additional information
- act as communication channel between the governing body and the NSB

Source: Author's elaboration.

Figure 6.2: Responsibilities of governance and management of the NSB

In terms of good governance practice, the responsibilities of the Board or Council should include the following:

- Establishing a policy-based governance system within the scope of legislation or Articles of Association. These guide the NSB and how it will function. Typical polices will cover, for example, core activities including: standards development and providing information; involvement in international or regional standardization activities; the extent of conformity-assessment services (if the NSB provides them); remuneration of staff, investment of surplus funds, and; marketing.
- Providing the strategic direction for the NSB. It establishes the vision, mission and goals of the NSB in cooperation with management. Future strategies and business plans also need to be approved and even developed in cooperation with the Council or Board.

- Providing full fiduciary responsibility, i.e. the final approval of the annual budget, the NSB organizational structure, any future business expansions, remuneration framework, and major financial investments (the level at which this is elevated to the Council or Board will vary from country to country). The external financial auditors should be accountable to the Board or Council, to help ensure proper financial management of the NSB by the management.
- Acting as the final arbiter in the case of an appeal against a standard even though the approval of a standard may rest with a Standards Approvals Committee.

6.1.5 Financial management²²⁾

Financial sustainability relates to the ability of the NSB to continue to serve its stakeholders in the long term, rather than having to curtail its operations due to lack of funding. Meeting the standardization needs of its stakeholders in a sustainable manner in the long term should therefore be a strategic objective for the NSB. Strategies that contribute to the financial sustainability include fostering strong stakeholder-relationships, accessing a range of types of funding, building financial reserves and assessing and managing risks and overhead costs.

These NSB should provide for these strategies in a financial policy. In many countries, NSBs may be dependent on the government for funding of the development and publication of national standards. Nevertheless, the NSB's financial policy and implementation should be guided by sound business principles to facilitate its long-term sustainability. It is desirable that the government should commit to long-term support where this is necessary, even though the NSB may be able to offset some of the costs with sales of standards. In the developing country context however, these are seldom adequate to offset standards development and publication costs.

²²⁾ A more complete discussion on the financial system of the NSB can be found in the ISO publication *Financing NSBs: Financial sustainability for National Standards Bodies*, which can be obtained from the ISO Central Secretariat.

The country should ideally provide for activities that benefit its population, but conformity-assessment services should be paid for by clients. The NSB needs to be able to manage its budget and use its net income for future development – it should not be obliged to revert all of this back to the country in those cases where it is linked to the government or where it receives government funding.

6.1.6 NSB premises

The premises of the NSB are an important issue to consider in order for it to be successful and render an effective and efficient service. Only the standards-related premises listed below are discussed in this publication.

- Location: The location should be selected carefully and easily accessible, especially for the clients that need to visit the NSB in person is important, also from the perspective of delivery of products to be tested or instruments to be calibrated.
- Standards information centre: The standards information centre is frequently the window into other NSB activities. It is advisable that it is easy to access with adequate space for computer screens and tables where visitors can browse through standards and purchase them. This will make finding and purchasing the right standard a pleasant experience.
- Meeting rooms for TCs and for training: Meeting rooms with appropriate IT equipment to conduct TC meetings are very important. The number of meeting rooms should be carefully planned and based on the projected number of meetings, and whether they will be held in parallel or not. They should be easily accessible by outside committee members, fairly sound-proof and located such that the integrity of laboratories and offices of personnel is not compromised. The same applies to training venues. In such cases, appropriate IT equipment is even more important.
- Corporate offices: Offices for the corporate entities should be appropriate
 for the specific service to be rendered. Human resources need some rooms for
 interviews and private discussions with staff. Workshops and garages have
 their own requirements, as do IT support.

6.2 Human resource management

Standards development, publication and information has become a very complex endeavour and requires a great deal of labour. Most of the activities related to standards development and publication are not taught in secondary or tertiary training institutions; hence the NSB should provide for such training. Additionally, it is not only the NSB staff that has to be trained and managed, but also the large number of outside people that are involved, such as Chairs and members of the TCs.

6.2.1 Recruitment of NSB staff

Staff with the appropriate qualifications and competencies to work in the field of standards development and publication is a precondition for the effectiveness and efficiency of any NSB operation. The requirements for the various positions should therefore be clearly defined and documented and these should be used when recruiting and appointing staff. Such requirements should be based on clearly identified skill sets for the various positions in the NSB organizational structure that are necessary to fulfil its mandate effectively and efficiently. Once recruited and appointed, every effort should be made to retain staff because a high turnover is usually detrimental to service delivery.

6.2.2 Training of NSB staff

Secretariats of ISO/TCs are usually vested in the NSB, as is the editing and publication of national standards. It follows that the staff in the Secretariats, the editing departments and the standards information-centre need to be properly trained in order to ensure effective and efficient operations in developing, publishing and disseminating standards. It is also good practice to offer annual refresher courses. New advances in technologies and methods of managing the standards development, publication and information activities can then also be provided. In addition to training in the administrative procedures of the NSB, typical subject matter of such training could include the following:

GSP as the measure of all activities for all staff;

- project management;
- procedures for the development and publication of standards for Secretariat staff;
- editing of standards for editing staff; and
- ways of providing standards information for the information centre staff.

Project management is a major component of the planning and organization of TC work; portfolio, programme and project managers in the Secretariats need to be trained in this vital skill, whether by the NSB or an outside training institution specializing in project management. ISO has published for NSBs two, supporting, guidance documents on project management for standards development, which are *Project Management Methodology in the ISO environment*, and *Project Management Methodology: Roles, responsibilities and capability requirements*.

6.2.3 Training of TC Chairs

It is good practice to appoint TC Chairs who are independent of the NSB. They may be, for example, eminent scientists, other types of specialist, from industry, or government representatives. This means that they would not necessarily be knowledgeable regarding the key steps and procedures that guide the development of standards. They have a very important leadership role to fulfil ensuring that the TC meets its objective of producing standards, following the rules of standards development, whilst avoiding distractions and obstructions. Hence any person appointed as the Chair of a TC or SC should be properly trained for this role before commencing their duties.

Secondly, it is extremely beneficial for all the TC Chairs, as well as NSB/TC secretarial staff and management, to attend an annual refresher workshop. During such a workshop, new developments in the standardization environment can be shared by NSB staff. The TC Chairs can be apprised of new policies and procedures regarding standards development, whilst the they can also share positive and negative experiences of the previous year that would help everybody enhance the effectiveness and efficiency of the standards-development process. The use of appropriate IT systems to assist in the training should be considered.

6.2.4 Performance appraisal and incentives

Performance appraisals are essential for the effective management and evaluation of staff. If properly conducted, appraisals help develop individuals, improve organizational performance, and feed into business planning. There are many performance-appraisal methodologies available, and the choice will be determined by the NSB's policies and organizational structure, as well as having to comply with the labour or employment laws of the country. Performance appraisals should be conducted at least annually, and they consist of reviewing each individual's performance against objectives and quality of work for the year, agreed to at the previous appraisal meeting.

The results of performance appraisals enable management to manage the employee's work more effectively, agree on expectations and objectives, and delegate responsibilities and tasks. Staff performance appraisals also establish individual training needs and enable an analysis of organizational training-needs and planning. Performance appraisals also typically feed into the NSB's annual pay and grading reviews. If incentives are available within the remuneration structure of the NSB, then performance appraisals are a very important element in allocating these.

6.3 Product and technology development

Although the product, i.e. the standard, is very clearly defined, there are other types of normative document. Technology, IT services and digital-media production now typically dominate the standardization environment in many countries.

6.3.1 Document types

A national standard is the end product of a carefully defined and complete development process. Standards development and publication have to comply with internationally agreed principles such as transparency, openness and consensus (see section 4), but this process can be very time consuming. Frequently, the interested parties wish to have a normative document available before the full process of developing, for example, an ISO International Standard, has been completed.

Therefore, ISO has developed simpler, streamlined procedures for two types of normative document, which are the technical specification (ISO/TS), and; the publicly available specification (ISO/PAS) – see Figure 7.3 in Section 7 on the ISO deliverables. These specifications do not have the same status as an ISO International Standard, although the streamlined procedures for developing them enables an ISO/TC and SC to produce a normative document quickly. Furthermore, an ISO/TS or ISO/PAS can form the basis of an International Standard and develop into one at a later stage. An NSB can use the same process to produce similar types of normative documents such as a TS or PAS when it would take too long to develop a full standard.

6.3.2 IT services

Standards development, publication and information in many countries has become totally reliant on modern IT-based communication-services. International, regional and national standards from developed countries, as well as the many types of private standards, are available in electronic format via the Internet, Hard copies have become less common and, in some cases, no longer available. Furthermore, the whole process of standards development also relies heavily on efficient IT services. In addition, efficient communications between the NSB and its vast stakeholder environment is of paramount importance for the ultimate success of standardization in the country.

NSBs therefore ideally should have a good Intranet service for standards development, and stable and fast Internet services to connect to the international world of standardization. Failure to provide either of the two will seriously hamper the efficacy of the NSB in delivering the standardization services to its stakeholders. Some of the specific areas within the NSB value chain that would benefit from an effective and efficient IT service include the following:

▶ In TC, SC and WG meetings, IT services can streamline the discussions if draft texts can be displayed on screen for all committee members to see. Furthermore, decisions and changes to the document can be entered instantly to provide members with an updated document when they leave the meeting;

- Standards development is to a large extent project management see subsection 7.2.6. Due to the complexity of the process, especially if a Secretariat is handling a number of different standards and ISO/TCs, an effective IT-based project-management system will be a very useful tool to ensure efficient and timely completion of the various projects;
- enhanced through an effective IT system. Committee documents, meeting details and responses on drafts published for public comment can be more efficiently handled through electronic media than through paper-based ones. The same applies even more to regional and international committee communication where distances between committee members can be challenging. In some cases, it may even be possible to hold virtual TC meetings through IT systems rather than for all committee members to gather in a physical place. Such a virtual meeting will be much more cost effective than a physical meeting, especially at the regional and international level;
- Standards information at the international level has moved from hard copy systems to IT based systems. The search for specific standards is immensely more profitable through effective IT systems, rather than trying to find them in hard copy libraries, if they are available as hard copies;
- Communication between the NSB and its many stakeholders is best served with a well-designed Website and social media communication systems.
 These also rely completely on the availability of fully functional IT systems; and
- An effective and innovative IT system can support knowledge management in the NSB and also e-learning systems.

When standards are provided in an electronic format, copyright requirements must be considered, especially when International Standards such as ISO and IEC standards adopted as national standards. This means they should not be available free of charge. A number of NSBs are developing Internet-based search and reading applications whereby users can look at the text of national standards without being able to download them or copy parts of the text free of charge.

6.4 TCs

Standards should be developed in TCs that represent all interested parties. This approach ensures that some of the key principles of standards development, such as transparency, openness, impartiality and stakeholder engagement, all of which underpin the process of standards development.

6.4.1 TC membership and structures

TCs are formally established by the NSB. Once the need for a TC has been recognized, the NSB should invite all interested parties to participate. An open invitation to interested parties should include the appropriate combination of the following as relevant for the specific standard to be developed²³⁾:

- Industry and commerce manufacturers, producers, service industries, warehouse and transport operators, retailers, banks and financial institutions, business and trade associations.
- Government national government and local government departments and agencies, regulatory authorities.
- Consumer national and local consumer organizations, individual experts engaged from a consumer perspective.
- ▶ **Labour** national and local trade unions, federations of trade unions
- Academia and research bodies universities and other higher educational bodies, professional associations, research institutions.
- Users of standards not otherwise covered accreditation, inspection, testing and certification bodies, organizations devoted to promoting the use of standards.
- Non-governmental organizations (NGOs) organizations operating on a not-for-profit basis that have a public interest objective related to social, or environmental concerns.

The establishment of a new TC should be approved by the NSB Board or Council or by the NSB Executive as considered appropriate in each country. This is because

²³⁾ Derived from Annex A of ISO/IEC Guide 59.

the establishment of TCs will have long-term strategic and financial implications for the NSB. Membership changes thereafter should be managed by the NSB or the TC itself, otherwise the system becomes very cumbersome. TCs that are no longer active should be dissolved or paused, depending on the review process for published standards developed under the auspices of this TC.

Achieving a representative balance of members of a TC can be a challenge and therefore the NSB should consider the following:

- The relevance of the various participant categories should be assessed, depending on the standard under development. Not all categories are relevant to all standards projects.
- Membership should not be unduly limited. If interested parties wish to participate, they should be able to do so. It is often better to start with a larger TC which will eventually get smaller as parties decide to leave, rather than denying participation in the first place to some parties, which might cause opposition to the standard being developed.
- The NSB should guard against domination of the TC by a combination of stakeholders with very specific interests. Knowledge of the stakeholder linkages is helpful in managing this challenge.
- A specific challenge concerns participation of interest groups that lack the finances or lack experienced experts, e.g. consumer organizations and NGOs.
 The NSB should consider ways and means to facilitate the participation of these.
- The NSB should remove organizations from the TC once they have missed a number of meetings, typically three, without justifiable reasons. This needs to be made clear to all committee members at the outset.
- It is usually counterproductive to assign specific percentages to the groups of interested parties in the above list, and the application of common sense in getting the right composition of the TC, is a more realistic approach. It is a prerequisite that the NSB has a good understanding of the stakeholders and their preferences, so that the NSB can achieve the right composition of members of the TC.

If the subject matter is large, then SCs or WGs should be established to deal more efficiently in developing the multiplicity of standards required to cover the subject matter. A typical example would be the ISO 9000 series of standards for quality-systems. The SCs would be accountable to the main TC. A WG deals with a specific technical subject, is accountable to the TC or SC that establishes it, and is disbanded when its work is completed (see Figure 6.3). WGs generally consist of experts, rather than representatives, with specific knowledge regarding the subject matter of the draft standard to be developed.

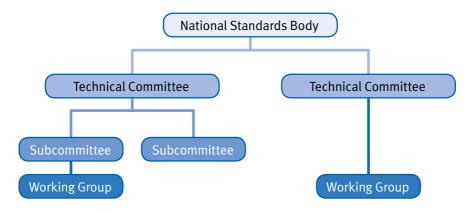


Figure 6.3: Technical Committees, Sub-committees and Working Groups

6.4.2 Role and responsibilities of the Chair

The Chair of the TC may be nominated but by an NSB but should always be approved by the NSB. Usually the NSB Executive would be authorized to do so by the Council or Board. It is good practice to nominate a Chair outside of the NSB – it supports the notion that the NSB does not force the standard onto anybody. TCs generally appoint the Chairs of their SCs and the Convenors of the WGs. It is good practice to nominate the Chair for an initial period of a few years that can be extended once.

The role of the Chair is to ensure that the TC functions effectively and efficiently. A Chair must remain neutral and therefore cannot continue to representative his or her organization. If that organization wishes to continue to participate actively in the discussions of the TC or SC, then an additional representative needs to be found.

The main responsibilities of the Chair are:

- ► To ensure that all representatives get the opportunity to participate fully in the proceedings. This includes ensuring that a specific representative does not dominate the committee proceedings and the discussions;
- To ensures that the TC reaches agreements that can be accepted by all stakeholders at the national level. The Chair should therefore have a good understanding of the products, services or issues under discussion, and the market and/or regulatory realities of the country; and
- ► To steer the TC towards reaching consensus and realizes when this point has been reached. It is good practice for the Chair to summarize the decision reached so that all are aware of it, and the Secretariat can record it properly in the minutes or decisions of the meeting.

ISO has published a document *Project Management Methodology: Roles, responsibilities and capability requirements*²⁴⁾ for the individuals involved in the development of International Standards, including the Chair and committee manager (known as the secretary in the past). The document describes all the responsibilities and capability requirements for these various positions. Although the document is aimed at ISO/TCs, its approach, suitably adjusted, would also be a useful reference document for NSBs establishing and managing TCs at the national level.

6.4.3 Role and responsibilities of the Secretariat

The role of the Secretariat is to provide professional management support in the form of administrative, operational and technical services to the TC or SC and its Chairs to ensure that the TC or SC operates effectively and efficiently. The Secretariat should normally be provided by the NSB rather than an organization outside the NSB where it may not be given the appropriate attention and resources and where it may be difficult to ensure strict impartiality. The latter is an important point to consider if the NSB decides to let others run the Secretariat.

²⁴⁾ Project Management Methodology: Roles, responsibilities and capability requirements, available from ISO.

The responsibilities of the Secretariat include:

- arranging the meeting schedules in consultation with the Chair;
- ensuring that all documentation is distributed to committee members in due time;
- ensuring that resources for the meeting are available (e.g. venue, IT support, refreshments, lunch, and extra copies of documents);
- recording the decisions of the committee, including the update of the working documents being discussed; and
- preparing and distributing the minutes, updated working documents and other relevant information in a timely manner after the meeting.

The Secretariat is also responsible for handling the internal processes in the NSB once the TC or SC has completed its task to produce the draft standard ready for public comment, collating comments, and managing the final editing of the standard for approval. See also 6.4.2 on a related guidance document from ISO.

6.4.4 Role and responsibilities of committee members

The members of the TC, SC and WG have the responsibility to participate actively and provide their knowledge without prejudice to the product, service or issue subject to the standards development process as well as market or regulatory needs of the same.

TC, SC and WG members should prepare for the meeting, which starts with careful consideration of the documentation sent out, i.e. working drafts of the standard. It is not helpful if the documents are only read for the first time during the meeting itself. Clearly, members have to represent interests of their stakeholder groups, but not to the detriment of ultimately reaching consensus. Members should always recognize that they should work towards the net benefit of all stakeholders.

It is important that members highlight areas of disagreement and then actively help to resolve such disputes. Members should act ethically at all times and show respect for their fellow committee members and the Chair and the Secretariat. Differences of opinion should remain at a technical level. And once consensus

has been reached, members should uphold the consensus position even outside the meeting.

Standards enjoy copyright, and TC, SC and WG members should respect this copyright. This is especially important for the adoption of ISO and IEC standards that may be circulated as working documents to TC members. This means that members should not distribute them freely, they should be considered as working documents with restricted distribution.

6.4.5 Business plans of TCs

It is good practice for TCs and SCs to develop their own business plans. This provides clear guidance on strategy and operational issues and will be very useful for the NSB, as well as the TC and SC to monitor performance. Making the business plans available on the Website of the NSB is a further enhancement of the openness and transparency principles of GSP.

Following on from the information provided in the NSB and standards work plan (see 7.1.2 and 7.1.3), the business plan should articulate the rationale for the development of the standard, and list information that should have been gathered prior to approval of the project. This rationale can be further enriched by gathering additional information from the whole TC or SC membership, instead of just a few that originally requested the development of the standard.

The scopes of the standards to be developed must be clearly articulated. The TC structures must be clarified, especially if a number of SCs and WGs are also involved. The responsibilities of each of these relating to the standards to be developed need to be clearly defined to ensure that no overlaps or gaps develop.

6.4.6 National mirror committees

The involvement of the NSB in International Standards development is best conducted through a national mirror-committee as the national counterpart to the international TC. The mirror committee provides the input that is submitted by national delegations to the international TC. The establishment of a national

mirror-committee and its relationship with the international TC is discussed below. For the functioning of the national mirror committee, see 7.2.4.

INTERNATIONAL TCS

TCs of ISO and IEC function in much the same way as national committees. The difference is that the participants represent countries rather than, for example, individual industries, authorities, and NGOs, whilst the Chair and Secretariat are from a specific member country that has been allocated the responsibility for the TC. Once an international TC has been established, ISO or IEC members can participate or not as they deem appropriate for the country.

Full members of ISO and IEC may participate in all technical work, and can choose between two different levels, namely:

- Participating members (P-members) participate actively in the work and have an obligation to vote; or
- Observing members (O-members) follow the work as observers; they
 receive committee documents and have the right to submit comments and to
 attend meetings but do not have the right to vote within the committee.

From 2015 to 2019, ISO operated a pilot-programme which allowed correspondent and subscriber members of ISO to become P-members of up to five TCs. ISO developed this programme, approved by the ISO Council, to encourage greater participation by developing countries in ISO's technical work. In June 2019, ISO made the programme permanent, subject to certain limitations. These are that: a member can only participate in the programme once; there is a five-year time limit, and there is a transition period of two years for those members who have been participating in the programme as P-members for four or more years.

Affiliate country members of IEC do not participate in the technical work.

NATIONAL MIRROR COMMITTEE

Best practice for a developing country is for the national TC to act as the mirror committee to avoid unnecessary and costly duplication of effort, i.e. there should not be a mirror committee and a separate national TC working in the same field

and with the same or overlapping scopes. The responsibilities of the mirror committee amongst others would be to:

- nominate the delegates to the international TC;
- comment on Committee Drafts of the international TC;
- forward proposals to interested parties at national level, collate their comments and from these develop a national position;
- vote on Draft International Standards (DIS) and Final Draft International Standards (FDIS);
- participate in reviewing existing standards;
- participate in the balloting of New Work Item Proposals (NWIP); and
- propose the national adoption of said international standard.

It is also very important that the NSB staff must not vote on a CD, DIS or FDIS on their own without being in a position to rely on a national mirror committee. The NSB must consider the needs of the country and its interested parties, and the mirror committee is the most effective vehicle to determine how the NSB should be voting whilst at the same time also provide meaningful comments. The mirror committee would also represent the stakeholder interests of the country if it has been established appropriately (see 4.9 for detailed information).

6.4.7 TC support services

TCs cannot function in a vacuum; they need support services to help them achieve their goals in the most effective and efficient manner. In smaller NSBs, these support services could be the responsibility of the TC secretaries, but in larger NSBs such support will typically need to be provided by dedicated units due to the complexity of the support required. Frequently the "legal office" of the NSB may have to be involved as well. Typical elements of such support services would be:

Monitoring of TC performance: TCs conduct their work according to planned schedules (see 7.2.2). It is important that their progress is monitored and reported, to ensure that the standards-development projects are completed on time and within budget. Any shortcomings need to be identified as early as possible so that corrective action can be taken. Modern IT systems

- ease the monitoring of TC performance, but well-thought-out manual systems can be usefully employed in smaller NSBs.
- Handling copyright issues: Standards should enjoy copyright, and this needs to be enforced. It could mean ultimately that the NSB may need to institute legal proceedings against persons or organizations violating copyright. If standards or portions of standards are referenced in publications, the NSB should be requested to grant copyright permission, and such permissions should be noted and followed up to ensure that the conditions of granting such permissions are adhered to.
- ▶ **Handling patent declarations**: In some standards, technical details of patents may be included provided the patent holder allows everybody access without undue constraints to the patent (see 4.6). This situation should be formalised before the standard is published, and the NSB should retain copies of such formal agreements.
- Handling of complaints: Complaints and especially appeals against the decisions of a TC in relation to the contents of a standard under development must be handled formally and in a professional manner. They need to be logged, dealt with and responded to formally. They are also an important source of information for enhancing the processes being followed by the NSB.
- Maintenance of TC membership records: This is a fairly easy task when the NSB manages only a few TCs, but it can become complicated very quickly once the number of TCs grows. TC membership, especially the representatives of organizations active in the TCs, changes continuously and these changes have to be kept track of to ensure communications between the NSB and the TC remains intact.
- **Granting access to TC documentation:** TC documentation will become increasingly available in electronic format and through IT systems. Members of TCs need to be given access to these documents. Therefore, a system needs to be put in place to manage such access. Hard-copy systems need to be in place where IT systems are not yet fully functional.
- **Issuing appreciation certificates for TC members**: It is good practice to recognize TC members that have provided more than their fair share in the standards-development process by presenting them with an appreciation certificate. The criteria for doing so need to be applied consistently.

Providing statistical information on TCs and their deliverables: The NSB needs to keep track of the TCs and the standards under development in order to plan and manage the TC activities. Likewise, this information should be made available to the TCs for them to manage their affairs better. As the number of TCs increases, the volume of statistics will increase correspondingly, and effective systems need to be in place to provide information that is accurate and up-to-date.



In order to complete the discussion regarding the NSB value chain (see 5.2) and having been appraised of the international context of developing and publishing standards (Section 3), the principles of GSP (Section 5) and the support activities required (Section 6), the core activities of the standards development, publication and information process can now be described in detail. These consist of (i) planning, (ii) development, (iii) publication, (iv) dissemination, and (v) customer services – see Figure 5.2.

7.1 Planning

"If you do not know where you are going, any road will do" is an old wisdom. The same applies to the standards development, publication and information activities of the NSB. These need to be properly planned.

Planning is one of the most important project management and time management techniques. Planning consists of preparing a sequence of action steps to achieve a specific goal; in this case the development and publication of standards. Hence, planning not only includes the activities themselves, but takes its rationale from the specific goal the NSB wishes to achieve. If an NSB plans effectively, it can substantially reduce time and effort in achieving the goal.

An effective planning process starts with the development of a national standardization strategy, from which follows a standards work programme. The latter in an up-to-date format can then serve as the work programme the NSB has to publish every six months in accordance with the *WTO TBT Agreement* requirements²⁵⁾.

7.1.1 National standardization strategy²⁶⁾

The national standardization strategy (NSS) should be developed as a cooperative exercise between the NSB Board or Council and the senior management.

²⁵⁾ Many NSBs would develop an organizational strategy that deals not only with the development and publication of national standards, but also with other services the NSB may offer such as conformity assessment, metrology services, etc. The standards related strategies discussed here should then be appropriately integrated with the organizational strategy to provide a holistic strategic approach the NSB should be following.

²⁶⁾ The ISO Capacity Building Unit provides training in the development of a National Standardization Strategy and the Standards Work Programme. Details can be obtained from ISO.

The process should include a broad consultation of stakeholders. It should be formally approved by the NSB Board or Council, and it is good practice to make it publicly known on the NSB Website. The NSS should be utilized to make decisions regarding the development and publication of standards, standards information services and overall marketing and communication regarding the importance of standardization in the socio-economic development of the country.

Useful steps in developing the NSS include the following:

- an analysis of available data and documentation from qualified sources such as the National Development Plan, socio-economic data from national statistics and industry association feedback;
- consultation of key stakeholder groups to capture their overall perspectives and specific recommendations; and
- setting the standardization priorities to be addressed in the given timeframe, along with the methods to be pursued, e.g. national development or international involvement, indigenous standard or international/regional standard adoption.

7.1.2 Standards work programme

Once the NSS has been developed and agreed at the Board or Council level, the NSB can develop a multi-year standards work programme (SWP) and identify how to fulfil needs, by whom it should be implemented, when, and with what resources. A typical time period would be three years. This would help the NSB to develop its annual business plans and budgets.

In developing the SWP which should include standards that require revision, the NSB would analyse the following in quantifiable detail:

- socio-economic priorities of the country;
- stakeholder proposals with priorities; and
- human and other resources required.

The WTO TBT Agreement requires the NSB to publish a work programme every six months (see 3.5.2). This three-year SWP would be an appropriate vehicle to fulfil this requirement provided that it is updated regularly to also include needs that

have emerged after the previous publication. Whereas it was published in hard copy in times past, nowadays publishing it on the NSB Website is much more efficient. This also facilitates the inclusion of new development proposals in a timely and continuous manner.

According to *WTO TBT Agreement* requirements, the published work programme should contain as a minimum the following information:

- the NSB's name, address and contact details;
- the standards it is currently preparing (i.e. title and scope); and
- the standards which it has adopted in the preceding six-month period.

As regards each individual standard, the following information has to be provided as a minimum:

- the classification relevant to the subject matter;
- the stage attained in its development; and
- the references of any International Standards taken as the basis of its development.

Whereas the above is the minimum information required by the *WTO TBT Agreement*, Annex 3 (see 3.5.2), it is also useful to provide additional information such as the TC responsible for the development thereof, the Chair of the TC and a link to the business plan of the TC (see 6.4.5). The existence of the SWP has to be notified to the WTO ISO Standards Information Gateway – see 3.5.2 for details.

7.1.3 Project planning

The six-monthly work programme would be the start of project management of the standards to be developed (see 7.1.2). It is derived from the SWP and augmented by the development proposals (see 7.2.1) that have emerged since the development of the SWP. The six-monthly work programme is extremely important, because otherwise important and immediate needs would not be considered until the SWP is reviewed which could be as long as three years in the future.

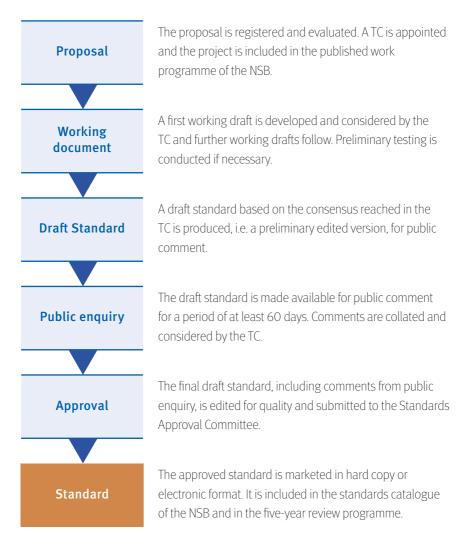
7.2 Development

The standards-development process should be an open and transparent process in which no specific interest group dominates the outcome. Over the years, good practices have evolved that are captured in rules and procedures, such as the ISO/IEC Directives. Similarly, the NSB should develop a formal procedure that is made publicly available. A good way is to develop and publish a "standard for a standard" and make this national standard available free of charge to any interested party. There are quite a few examples of such a specifications for a standard amongst NSBs, in both developed and developing countries.

Each of the steps shown in Figure 7.1 would include a number of processes and these should be formalized in procedures. These should be demonstrably followed by the NSB in managing the development of standards. In this manner, all interested parties know exactly how the process works, thereby focussing their efforts and enhancing the effectiveness of the process. This will also help the NSB in defending the process should an interested party question the resulting standard, or appeal to the Board or Council to have the standard set aside or revised in a major way. Key performance indicators (KPIs) (see 7.2.2) should be established for each of the steps to manage the efficiency of the process.

An important issue in the process is the approval criteria and mechanism that would allow the document to move from one stage to the next – see also 7.2.8 on project management of the standards development process. At the NSB this could be the following:

- Proposal: Approved by the senior management of the NSB, taking into account the results of stakeholder consultations, thereby also allocating the resources to develop the standard. The quantitative country and stakeholder needs should be the determining factor in the allocation of scarce resources.
- Working Document: Decision rests with the TC or SC or WG depending on
 where the working document is developed to move the document to the next
 stage. This decision would normally be considered during the meeting by
 consensus.
- **Draft Standard**: The decision to move from committee working documents to a draft standard to be circulated for public comment would normally be



Source: Adapted from the ISO/IEC Directives.

Figure 7.1: Standards development process steps

taken by the TC. This should be a consensus decision. Some NSBs utilize voting due to stalling tactics by some committee members, but this should be a last resort measure – working toward consensus is much more profitable in the end. Voting will just heighten the chances of a formal appeal against the approval of the standard later on.

- **Public Enquiry:** Once all the comments emanating from the public enquiry have been dealt with appropriately, the TC should make the decision that the final draft standard should be presented for approval. The same comment regarding voting as in the previous point applies.
- ▶ **Approval**: In many NSBs, standards are approved by the highest governance level, e.g. the Board or Council, or by a Standards Approval Committee accountable to the Board or Council. The latter can then meet more frequently than the Board or Council to expedite approvals and meet time-to-market criteria. To speed-up the process it may also be useful to gain approval by correspondence, as in many cases the TC decisions are confirmed without further discussion at a meeting.

7.2.1 National standards

In developing and publishing national standards, NSBs should comply fully with the principles of standards development as provided for in the *WTO TBT Agreement* and the decisions of its committee as described in section 4. The specific steps as indicated in 7.1 are discussed in more detail in the following.

STEP #1: PROPOSAL

The proposal is registered and evaluated. A TC is appointed and the project is included in the published work programme of the NSB. Interested parties are approached to participate in the standard's development.

Evaluation of the proposal

The proposal for a new standard can come from any interested party, such as industry, regulatory authorities, consumer organizations or NGOs – even from within the NSB. It can also stem from the NSS. It is good practice if a template is

available that can be used to present the proposal. Such a template would ensure that the necessary questions are asked and answered to facilitate a purposeful evaluation of the proposal by the NSB management, such as:

- What is the justification for the proposal? Is it a technological need of industry, safety and health of society or the environment, consumer protection against fraud in the marketplace, or required for an envisaged new technical regulation? It is useful to provide both qualitative and quantitative information.
- Which regional or International Standards could form the basis of the national standard? Have standards of similar scope been published by major trading partners? Will the scope overlap with scopes of published national standards? Which types of specifications are used in industry?
- Are the resources available to commence the work, i.e. are funds available in the budget? Does the NSB have the staff to manage the TC work?
- Can the work be allocated to an existing TC? Will a new TC or SC have to be established?
- Who are the interested parties, and are they willing to participate in the standards development?

Rather than using the above information in an *ad hoc* way to arrive at a decision whether or not a proposal should go forward, it can assist in determining the net benefit of a proposed standard. The net benefit can be seen as the value or benefit of a standard to the country that exceeds the costs likely to be imposed on suppliers, users and other parties in the country, as a result of its development and implementation.

The reasons for this requirement are varied. One is to avoid the preparation of standards for "standardisation's sake" without a consideration of what the potential impact the preparation of all these "nice to have" standards may have on the NSB's resources or on society, if they are ever implemented. Another is to avoid an overly restrictive or "gold plated" solution to a problem. While it may be a superb engineering-solution, implementation of the standard could be hugely expensive and well beyond the benefit delivered.

NSBs should follow a formal work programme for developing standards (see 7.1.4). This is good practice, but it should not imply that new proposals are shelved until the next year. The work programme should be flexible enough that important new proposals can be slotted in at any time. Once the proposal has been accepted by the NSB, it should be listed in the work programme that is publicly available with an invitation to contact the NSB should an interested party wish to participate in the work.

Allocation to a TC

Once the decision has been made that the proposed standard will be developed, the project has to be allocated to a TC. If a TC already exists in the field of the proposed standard, the project is allocated, and the TC has to include it in its work programme. If the standardization field is broad, the project may even be allocated to a SC by the TC. If a TC or SC does not exist in the field of the proposed standard, then a new TC or SC has to be established. This requires the NSB to map the stakeholders of this specific field and invite interested parties to form the new TC or SC. A generic checklist of stakeholder groups is a useful *aide memoire* to ensure that none are inadvertently overlooked. See Section 4 on the establishment and management of TCs.

STEP #2: WORKING DOCUMENT

A first working draft is developed and considered by the TC or SC and further working drafts follow. Preliminary testing is conducted if necessary. There are no fixed rules for developing the first working document to be considered by the TC or SC. A number of possibilities present themselves:

- If an international or regional standard exists, then this could be presented to the TC to evaluate it and discuss options for adoption. If language is a challenge, then the standard might have to be translated beforehand;
- If the standard has to be developed from basic principles because no international or regional standard exists, and no national standards from other countries or trading partners come to mind, it may be desirable to hold a TC or SC meeting to decide on the content and the requirements in principle before embarking on developing the first working draft. Consultations with

- manufacturers and suppliers to discuss the standard, may also be helpful, even visits to the manufacturers should be considered; and
- ► If the first working draft has to be developed i.e. no standard exists that can be adopted, it could be supplied by the proposer then it can be developed by a small WG, or an expert in the NSB could do so.

Once a working document is available, this is to be considered by the TC. It will be enhanced and revised as appropriate, but finally agreed to by consensus. This could take a few TC meetings depending on the complexity of the work. The text should be clear and unambiguous, and there should not be any contradictions within the text or with national legislation. The text should take the state-of-the-art of science and technology into account, as well as the economics of the product or service.

STEP #3: DRAFT STANDARD

Once the TC has concluded its deliberations, the NSB should ensure that the final decisions concerning the contents are carefully documented to limit later arguments to a minimum. Nowadays, it is useful to utilize all the electronic tools that are available. In some NSBs the changes to the working documents are captured electronically already during the meeting, with the result that the participants go home with a final copy of the document. Documentation control of the various stages of TC work as provided for in a quality system conforming to at least ISO 9001 is very important (see also 7.3.4).

The NSB needs to prepare the draft standard for public comment. It should include all the TC decisions, and it is useful practice to conduct a preliminary editing of the text to ensure that the draft meets the NSBs defined editing rules for a national standard. This ensures that the draft standard presented for public comment is as close to a finished standard as possible. A draft standard badly presented will invite all sorts of editorial comments and lead to a negative image of the NSB and the TC, whereas a high-quality draft standard will focus public comments on technical issues.

STEP #4: PUBLIC COMMENT

The draft standard should then be circulated for public comment to interested parties. A notification of the draft standard should be published; it should at least include the title and full scope of the draft standard and a brief description of the reason for its development. It is not necessary to publish the complete draft. In fact, it may be problematic as regards copyright protection, especially if the draft standard is an adoption of an ISO or IEC international standard.

Information on the draft standard could be made public on the Website of the NSB, technical journals and daily press as circumstances require. Furthermore, it is important to sensitize major stakeholders individually, such as business and industry associations, relevant ministries, regulatory authorities and consumer organizations. In all cases, comments should be invited, the final date for receipt of comments should be stated, and the contact details of where to send the comments has to be clearly indicated. The period for public commenting of the draft standard should be at least 60 days as provided for in the WTO TBT Agreement. Instead of publishing the complete text online, as this may lead to unauthorized downloads violating copyright, it is better to supply the text to interested parties on request, alternatively to provide it on line with an appropriate IT solution that allow a "read only" function to exclude downloads. In developing economies, it may be necessary to provide a few hard copies in cases where interested parties lack sufficient Internet access. A small covering fee could be charged to keep spurious requests to a minimum, depending on the custom and practice of the country. Once comments are received, the Secretariat collates them for consideration by the TC. A standard template is an effective tool to do so. The responses to all comments should be recorded, specifically reasons for rejection. Commenting parties should be invited to present and defend their comments should they be of a substantive nature. Usually organizations or persons do follow the invitation when they consider their comments seriously. Discussing the arguments together with them supports consensus building and might prevent appeals.

STEP #5: APPROVAL

Once the comments have been considered by the TC, the Secretariat finalises the text accordingly. The draft standard is subjected to scrutiny by the editing division of the NSB which should be independent of the Secretariat or any expert involved in developing the text. Editing is discussed in detail in 7.3.1.

The final draft standard is presented for approval. In many NSBs approval is the responsibility of the Board or Council. This may create a problem with the "time to market" because the Council or Board may meet only three or four times a year and if a TC misses the date for submission to their next meeting, approval can take many months. Hence, many Boards or Councils have established a Standards Approvals Committee (SAC) that meets once a month or even more frequently. The approval can even be considered by correspondence to further speed up the process. The SAC is accountable to the Board or Council and will present a report on their work at every Council or Board meeting. In larger NSBs the approval of draft standards have been delegated to the Executive of the NSB.

Approval of the draft standard is not meant to be a re-visit of the technical details. This is the responsibility of the TC. For approval, the draft standard must have been demonstrably developed in accordance with all the steps of the formally stated process. If there are any appeals from interested parties that are unhappy about the outcome of the standards-development process or decisions of the TC, then the TC needs to deal with these according to a formal appeals process. Appeals against the approval of the draft standard as a national standard should remain with the Board or Council.

STEP #6: PUBLICATION

Once the standard has been approved, it is important to publish it without delay. It is not helpful having the NSB and the TC members investing considerable resources, if it then takes months to publish the standard. Annex 3 of the *WTO TBT Agreement* is also quite clear on this issue. Publication is discussed in detail in section 7.3.

7.2.2 Key performance indicators (KPIs)

In order to determine the effectiveness and the efficiency of the standards-development process, it is important to identify specific indicators that would measure whether the process is better or worse than envisaged, i.e. the key performance indicators (KPIs). Such indicators usually measure the input, the output and they have a time element to them. Typical KPIs used by NSBs are:

- **fulfilling the SWP** indicates achievement of the overall objective;
- **time to market** indicates the periodic achievement of set strategic goals;
- cost per page defines progress towards becoming more efficient; and
- average time between systematic reviews helps determine compliance with maintenance criteria of the complete body of standards.

These criteria for KPIs should be used as a management tool to render the whole standards development and maintenance process more efficient, identify weaknesses in the process to be addressed, and provide feedback to the Board or Council and the relevant Ministries as to the meaningful allocation of country or other funds.

The number of standards is frequently used as a KPI as it is very easy to measure. However, it is not a very useful one: standards are not of similar length, it fosters the development of vast numbers of standards that are not really needed, and it does not reflect the efficiency with which the NSB operates. The number of standards should therefore be avoided as a KPI.

FULFILLING THE SWP

The SWP should be published at least every six months (see 7.1.3 for details). Its development is based on the NSS, and the emerging needs of stakeholders. It lists the body of standards that will be developed by the NSB within the six months, guides the allocation of resources and forms the basis of the planning and project management of the standards development, editing and publication divisions of the NSB. Hence, monitoring whether or not these divisions collectively and individually meet the target is a very useful KPI. The progress should not be

checked only at the end of the period but continuously, to determine problems early enough that something can still be done about them.

TIME TO MARKET

A standard will only be relevant in the marketplace if it is developed and published as speedily as possible. It is no use if the standard is completed only to find out that technology has moved on and the standard is no longer necessary. In the absence of an appropriate national standard, the market will find its own solutions which are not always for the benefit of all interested parties. But, reaching consensus takes time, and no step should be short-circuited in the defined standards development process.

"Time to market" is therefore a very meaningful KPI. The total time from the receipt of the proposal to the approval and publication of the standard is a strategic imperative set by the Board or Council. From this, the time allowed for individual steps in the standards development process can be derived. Some of them, like the public enquiry, are set through international requirements. Such a specified "Time-to-market" indicator should be seen as the maximum time the standards development process steps should take. It remains important for the NSB to bring the standard to the market in the shortest time possible.

It is quite obvious that there will be a difference in the "Time to market" between an adoption of an international or regional standard, and the development of an indigenous standard from beginning to end. Typical times for the individual steps in standards development are shown in Figure 7.2.

Once a monitoring system is established, the first set of results will provide an indication of the state of the NSB's standards development activities. Then remedial actions can be considered until the set time limits are met. Thereafter process activities should be managed in such a way that the time limits are maintained, and no slippages occur. The monitoring system should highlight individual problem cases as early as possible for remedial actions to be most effective. IT based systems are much more efficient than manual paper-based systems.

It is not only important to track the times for the individual standards that are under development in order to manage the individual projects more effectively, but it is also a very useful metric to determine the averages over all the standards developed within a given time period. This could even be a rolling metric measured every six to twelve months to indicate to management whether there are bottlenecks in the process that need attention, e.g. editing may take too long on average indicating a lack of resources in that area, or the approvals process takes too long indicating the need for rethinking the process, etc.



Source: Author's elaboration.

Figure 7.2: Typical maximum development times for standards development steps

Figure 7.2 provides some typical maximum targets for the individual steps in the standards development process. Each NSB should, however, consider these and

determine their own targets. These are only general guidelines, and not any binding international or regional rule. If these times can be shortened even more without compromising the steps necessary to ensure robust standards-development practices, then the time-to-market can even be less than those in Figure 7.2. This may even become imperative when national standards have to be developed as a matter of national priority, especially in the case of standards referenced in a new technical regulation that needs to be promulgated rapidly due to pressing safety and health concerns, for example.

COST PER PAGE

Production efficiency is normally measured as the output that has been achieved in relation to the input of resources. Any production unit endeavours to maximise production efficiency, i.e. get the most out of the resources applied. And the resources are frequently measured in terms of their monetary value as a common denominator. The same applies to the NSB, i.e. how efficient is the NSB utilising its budget for standards development?

This should be a critical question for any NSB, even when the budget is provided in full by the country. The NSB should always be able to give account of the usage of national funds. Taking a cue from the KPI used by industry for efficiency, namely cost of production per item produced, for standards development "cost per page" of the standards developed and published could be a useful metric. Using the number of standards is not appropriate since the length of standards varies tremendously. The data should be developed in cooperation with the financial section of the NSB in order to give it legitimacy.

All the costs incurred by the standards development, editing and publication sections should be captured. This includes personnel costs, accommodation, telephone, electricity and others needed to keep the sections fully operational. Also included should be the costs of the management of the standards divisions. Photocopying is frequently a large cost item that should not be neglected. The costs of hosting TCs are very much part and parcel of the total cost.

The total number of actual pages of standards completed during the period are fairly easy to determine. Cover pages, empty pages, back pages, etc. should not really be part of this count. The cost per page can then be calculated and managed year on year. A common experience is that the cost per page is fairly high when first measured, and as more efficient processes are introduced it will come down until such time that there are few inefficiencies left, and then it will climb slowly as input costs increase over time due to inflation.

This could also be a very useful KPI to utilize in discussions with parties on allocating funding for standardization work, especially if it can be shown that the NSB is becoming more efficient or when the needs for national standards are on the increase. It should be noted that the cost per page metric is not the basis for the determination of the selling price of national standards. The price of standards should be a decision that is based on strategic issues such as the need to provide standards to SMEs at a fair price, facilitating their use in industry and regulation, etc. – see 7.4.1.

AVERAGE TIME BETWEEN SYSTEMATIC REVIEWS

It is good practice to review standards at least every five years $^{27)}$ to ensure they are kept up-to-date. After such a review, the standard should be confirmed if no amendments or revisions are contemplated. Otherwise the standard should be amended or revised in accordance with later developments, or it should be withdrawn if no longer relevant. A useful KPI would be the percentage of standards older than five years which have been reviewed. The target should be $100\,\%$, and anything less than $80\,\%$ should be a matter of concern requiring management attention.

A calculation of the average time between systematic reviews of the whole body of the standards published is an additional metric that will give a quick indication as to whether the five-year review cycle has been implemented. If the average time is below five years, then it is a good sign, but it should not exceed five years. An average of five to eight years indicates that something is amiss, and the review

²⁷⁾ A standard can be reviewed much sooner if the need arises for a specific reason.

programme should be strengthened. An average time of more than eight years indicates that a major problem exists, and it its quite conceivable that the review programme is dysfunctional. Clearly, once a standard has been reviewed and confirmed without any amendments or revision, the "clock" should be started afresh, otherwise this metric will not make sense, i.e. some standards remain stable over many years.

It is not only the percentage reviewed or average time between reviews that should be determined. It is also extremely important to list those standards whose age has exceeded five years, so that the NSB can attend to their reviews.

7.2.3 Participation in development of regional standards

If the RSB has established regional TCs, member NSBs should endeavour to participate actively in order to gain the maximum advantage of being involved in the development and implementation of such standards across the region, because they will eventually have a marked influence on trade, technical regulations and SPS measures. The mirror committee concept is also useful to determine country positions in these situations (see 7.2.4).

Regional TCs should adopt International Standards as regional standards with the minimum of changes, even though the perception of the region being different to the rest of world may surface from time to time. If the members of the region are also WTO members, then the RSB has no choice but to comply with the *WTO TBT Agreement* as regards standards development, and any of its TCs likewise. RSBs can play a very important part in facilitating the meaningful participation of their member NSBs in International Standards development, through:

- supporting active participation of NSBs in international TCs; and
- developing a regional position on International Standards being developed that NSBs could advance at international TCs.

7.2.4 Participation in development of International Standards

Participation in International Standards development holds many advantages for the NSB and its stakeholders. Developing countries, like developed countries, each have a vote when approving International Standards. More importantly however, developing countries should participate actively in international TCs. Sometimes it is crucial that the voice of the developing country is heard clearly in order to ensure that the international standard is useful not only in a developed country context. Obviously the same holds true also at the regional level.

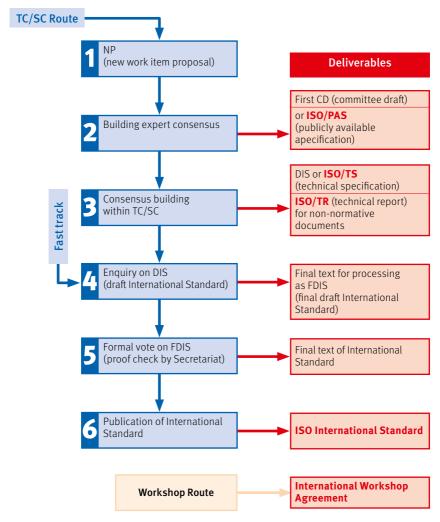
THE ISO PROCESS

The stages utilized by ISO in developing International Standards follow the same steps as discussed for national standards (see 7.2.1), albeit with slightly different nomenclature – see Figure 7.2. The ISO system is a decentralized system with ISO members being responsible for the development of the draft International Standard. The ISO Central Secretariat then circulates the draft for comment, and once the final draft has been agreed to by the TC, it is circulated for voting by ISO members. The latter takes the place of the approval process at national level, e.g. by a Standards Approvals Committee. Full details of the individual stages can also be obtained in ISO documentation, specifically in the ISO/IEC Directives.

Table 7.1: ISO deliverables and approval criteria

Type of document	Intended use	Consensus level	Approval criteria
International Standard (IS)	Normative	Highest level Experts (WG) TC/SC ISO Member Bodies	2/3 ^{rds} majority of votes cast by ISO Members No more than 25 % of total votes against
technical specification (TS)	Normative	Lower than IS Experts (WG) TC/SC	2/3 ^{rds} majority of voting TC/SC P-members
publicly available specification (PAS)	Normative	Lower than TS	Simple majority of voting TC/SC P-members
technical report (TR)	Informative	Lower than PAS No systematic review	Simple majority by P-members voting in the TC/SC
International Workshop Agreement (IWA)	Informative	Outside of the ISO committee system Proposed by outsider (usually an ISO Member Body)	Approved by TMB

The ISO process provides for different types of normative or informative documents to be published depending on the level of consensus that has been reached, pressure to reach the market more rapidly and the intended users. Table 7.1 and Figure 7.3 provide an overview of the ISO deliverables, their consensus level and approval criteria. The time to market is linked to the consensus level, the higher the consensus level the longer it takes.



Source: ISO.

Figure 7.3: The ISO standards-development process

Some NSBs also publish normative documents other than national standards, with consensus levels lower than national standards, due to time-to-market pressures. The ISO system could be used as a point of departure to determine the criteria for such lower-level normative documents at the national level.

DELEGATION TO THE INTERNATIONAL TC

The dynamics of international TCs is usually such that participants need to be present in order to represent their country's position on a standard. Comments may be submitted in writing but commenting has more impact when presented in person. Yet most NSBs have limited resources for participating in international TCs – it is therefore important that a proper strategy is developed and followed that will optimize participation in those international TCs that are very important to the country. It is not beneficial to be a P- or O-member of a large number of TCs, SCs or WGs and never attend meetings. The NSB may look good on paper, but it is meaningless as regards promoting the interests of the country. As regards financing attendance, it may be useful to establish a fund managed by the NSB, that the government and the private sector contribute to, and which can then be utilized to fund the country's participation in relevant TCs.

The delegation should have an appointed head, as identified by the relevant mirror committee. The head of delegation could be an NSB or a stakeholder representative and manages the delegation's participation in the proceedings. The important point is that the delegation members should be able to present a cohesive view. It should be quite obvious that the delegation does not necessarily represent the government of its country. It is good practice to establish a mirror committee (see 6.4.6 for details) that can provide the delegation with a consolidated country view which can be promoted at the international TC meetings. The delegation should report back to the mirror committee after the meetings, and should receive future input from the mirror committee. Once the International Standard is published, it is then easier to adopt it as a national standard because of the country's active participation.

ESTABLISHING A NATIONAL POSITION

The national position regarding an International Standard under development should be ascertained in the mirror committee based on the country's priorities and industry realities. This should not start when a draft or final draft is available, but at the very beginning when a new work item is proposed, and all ISO members are invited to comment. In the process of defining a national position:

- Important issues need to be identified. These may relate to the industrial-base capabilities and the requirements of the regulatory authorities. The issues may be technical in nature or policy related – there are many aspects that need to be considered.
- Priorities need to be identified and a consensus should be developed. If it is not possible to establish a consensus, then there is essentially no countryposition possible, and the country will have to accept what others decide on in the international TC. During voting on the approval of an International Standard, formal abstention is possible.
- Delegation to the international TC must be made fully conversant with the national position, because this is what the delegation will have to present and promote.
- If it is not possible to attend the international TC in person, then comments can be provided which will be presented during the meeting, but this does not provide the country with a platform to persuade others in discussion on the merits of the country's position.

Once the draft International Standard has been circulated for voting, the national position should include any comments that the NSB wishes to make, as well as the country's position on voting for or against the International Standard or abstaining from voting. Comments accompanying the voting papers need to be provided in writing in voting on a CD, DIS or FDIS.

7.2.5 Adopting international or regional standards as national standards

International Standards have reached a dominant position in international trade. It may therefore be self-evident that any country wishing to integrate with the global trade system has little choice but to adopt International Standards as national standards in order to support its industry in the export markets or to ensure the smooth implementation of technical regulations based on such standards. It is however useful to also consider the other benefits that accrue by doing so, namely:

- enabling knowledge and technology transfer (that can be used to improve products, services and processes);
- obtaining results of work of experts worldwide (including those from industry and governments) covering needs of stakeholders in a broad variety of countries;
- increaseing opportunities to access the global market and to participate in transnational supply chains; and
- meeting the obligations under the WTO TBT Agreement and avoid unnecessary barriers to trade.

WHEN TO ADOPT

Adopting International Standards is a useful mechanism especially for developing countries to connect with international markets. If the country or the NSB (depending on the international standardizing body's practices – see 2.4.2) has participated in the development of the International Standard, and the country's position has been taken into consideration, then adoption should even be a given. Clearly, adoption of International Standards can also take place long after the International Standard has been published, and even if the country or the NSB has not participated in its development, but when it discovers a need for a specific existing standard. Once an International Standard is adopted, any existing national standards of the same scope need to be withdrawn.

As regards regional standards, the country may be obliged under Regional Trade Protocols or the like to adopt the Regional Standard as is. The country or its NSB would have participated in its development; hence adoption should not be a major issue. Once the regional standard has been adopted, any national standard of the same scope has to be withdrawn.

ISO/IEC GUIDE 21

The mechanism for adoption of International Standards is provided for in *ISO/IEC Guide 21*. This Guide could also be the basis for the adoption of regional standards. The Guide details the way in which adoptions should be numbered at the national level, the way in which technical deviations are indicated and the degree of correspondence between the international and the national standard. It is very good practice to follow this Guide, as a national standard identified in this manner immediately indicates to users its equivalence to the International Standard. There are quite a few permutations available for the adoption of International Standards as national standards – see Table 7.2. The adoption can be:

- identical which includes a direct translation but no editorial, structural or technical changes, if endorsement is the chosen option and not republication;
- modified which may include editorial changes provided that the editorial changes are clearly indicated in the text of the standard; and no substantive structural or technical deviations with minor ones clearly identified; or
- not equivalent which includes editorial changes and technical deviations even though the international standard may have served as the basis for the national standard.

Table 7.2: ISO/IEC Guide 21

Degree of correspondence	Adoption / publication method	Editorial changes as specified	Structure	Deviations as specified
Identical	Endorsement	No	No	No
	Re-publication (reprint, identical translation)	Yes ^a	No	No
Modified	Re-publication	Yes	Yes⁵	Yes ^c
Not equivalent	Re-publication	Yes	Yes	Yes

- a. Editorial changes are limited to safeguard the identical status of the adoption see *ISO/IEC Guide 21* for details.
- b. Provided there can be easy comparison of the content of the two standards, or, if more than one ISO standard is adopted, there is a list identifying the changes.
- c. Provided that the technical deviations are identified and explained.

The NSB staff should know and clearly understand the details of *ISO/IEC Guide 21* in order to advise national TC members in this regard. If the NSB does not adhere to the limitations recommended by the *ISO/IEC Guide 21*, the national standard cannot be considered to be an adoption of the international or regional standard.

THE PROCESS FOR ADOPTING AN INTERNATIONAL OR REGIONAL STANDARD

The process to adopt an international or regional standard as a national standard follows the same logic as the development of an indigenous standard, i.e. one that is developed from scratch – see Figure 7.4. The main difference is that the development of working drafts that are continuously worked on and revised to render them more relevant to the situation and to achieve consensus, falls away. These steps are replaced by the committee considering the international or regional standard as is for adoption, only making small changes that are absolutely necessary in the process. Even the public comment period should be maintained.

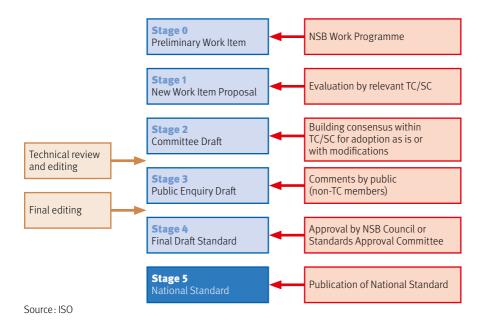


Figure 7.4: Process for adopting international or regional standards

7.2.6 Project management of national standards development

The purpose of project management is to ensure the success of the individual project, i.e. developing and publishing the standard, and meeting the project objectives, i.e. within a given time frame and within budget. Therefore, the development of a national standard, and the standards development programme and portfolio, fit clearly within the realm of project management as defined in the ISO 21500 series of International Standards on project management. Hence, project-management principles can be very effectively applied to all the steps of standards development. The purpose of managing the standards development process includes the successful completion of the project, i.e. the publication of the standard, as well as doing so within the applicable time limit and within budget.

In the context of project management, the following terms should be considered:

- ▶ **Portfolio** represents all of the standards in the six-monthly work plan.
- **Programme** represents the activities related to a specific sector, e.g. agriculture, services, etc. and contains more than one project.
- **Project** represents a single standard.

The Director of Standards would be the portfolio manager, the various heads of divisions the programme managers and the technical officers handling the various standards development projects would be the project managers.

In ISO 21500, project-management processes are grouped into five process groups, namely *initiating*, *planning*, *implementing*, *controlling* and *closing*. These five process groups can be applied to each of the standards-development process steps, thereby facilitating effective project management of the whole process in the most efficient manner. In between, the steps will always be a decision-making point, before moving to the next standards-development step and implementation of further project management logic. A formal project plan that details the what, how, who and when of each of the five process steps supports all involved in the standards development process to fulfil their responsibilities.

The initiating process determines the nature and scope of the standards-development project. If this stage is not performed well, it is unlikely that the project will be successful. A clear understanding of the NSBs resources and capabilities are needed here and any gaps should be identified early and addressed before the project goes any further.

After the initiation stage, the project is planned to an appropriate level of detail. The main purpose is to plan time, cost and resources adequately to estimate the work needed and to effectively manage risk during project execution. A failure to adequately plan greatly reduces the project's chances of successfully accomplishing its goal, i.e. the development of the standard.

The implementation phase ensures that the deliverables of the project-management plan are executed accordingly. This phase involves proper allocation, coordination and management of human resources and any other resources such as material and budgets. The output of this phase are the project deliverables.

Controlling consists of those processes performed to observe project execution so that potential problems can be identified in a timely manner and corrective action can be taken, when necessary, to control the execution of the project. The key benefit is that project performance is observed and measured regularly to identify variances from the project management plan.

Closing includes the formal approval of the standard and the ending of the project. Administrative activities include the archiving of the files and documenting lessons learned for use in future project planning.

ISO has developed a *Project Management Methodology*²⁸⁾ based on ISO 21500:2012, *Guidance on project management* for TCs operating within the ISO system. It contains the concepts and processes of project management that are important for, and have an impact on, the effective and efficient management of International Standards development projects. Its sections, together with examples, detail: (i) preparation of the proposal; (ii) planning of the project including developing a draft project plan and the detailed project plan; (iii) development of the project; (iv) controlling the project; (v) lessons learnt, and; (vi) portfolio management. Its contents, appropriately customized for the development of national standards, would be a useful guideline for an NSB to implement project management to streamline its standards development process.

7.3 Publication

Publication is the final stage in the development process of a standard. It comprises a number of individual steps, such as (i) final quality control of the standard, (ii) publication of the standard, and (iii) documentation control.

7.3.1 Final quality control

Editing is a final check on the quality and integrity of the draft standard. Hence, editing should not be conducted by the Secretariat, but by an independent editing section. Editing considers the format, checks all references, deals with ambiguities

²⁸⁾ Project Management Methodology in the ISO environment can be obtained from the ISO/CS.

in the language, and ensures that the draft standard complies with the NSB's stated editing rules for national standards. Editing is not allowed to change the technical content of the draft standard and editorial changes have to be discussed at least with the Secretariat and sometimes even with the Chair of the TC. Good practice indicates that a comprehensive editing manual which is part of the NSB's formal procedures should guide this activity.

It is good practice to also conduct a preliminary editing of the draft standard before it is circulated for public comment (see 7.2.3) otherwise there is the risk that many of the comments will deal with editing issues rather than technical content. Editing should take place before the draft standard is presented for approval. A final check before the approved standard is made publicly available is another useful safeguard to ensure the integrity of the published standard and to integrate any comments the approvals committee might have made.

7.3.2 Publication of the standard

Once the draft standard has been approved as a national standard, it must be published without delay. Firstly, public notice should be given that the standard has been approved. This depends to some extent on the legislation the NSB operates under in the case of a government department or a statutory body. In some countries this notice has to be placed in the Government Gazette to give the national standard legal standing; otherwise it cannot be referenced in regulations. The new standard should immediately be listed in the standards catalogue of the NSB. Nowadays this catalogue is usually electronically based and available on the Internet – see also 7.4.3. The standard should be made available for purchase as hard copy or electronically on the Internet. Failure to provide for the purchase of an electronic version (usually as a PDF file) will seriously compromise standards sales of the NSB. Purchasers will just go elsewhere on the Internet to other NSBs if they cannot get it from their country's NSB, or worse get obsolete or illegal copies from others.

It is counterproductive to print vast numbers of the standard and more efficient to establish a print-on-demand system. Once a customer orders a standard, this

system should produce a hard copy printed and bound within a few minutes. A dedicated desk computer, a printer that can print both sides, and a machine to bind copies are required. Once volumes increase, more sophisticated commercial type solutions can be considered.

7.3.3 Documentation control

Documents are very important in the standards business in terms of supporting transparency and traceability. It is important that everybody knows exactly which version we are working from, and the integrity of the approved standard has to be secured for legal and other reasons. Quality-management systems such as those that conform to at least ISO 9001 therefore place an emphasis on proper document control and document management.

ISO 9001 REQUIREMENTS

ISO 9001 requires that a documented procedure shall be established to define the controls needed to:

- approve documents for adequacy prior to issue;
- review and update as necessary and re-approve documents;
- ensure that changes and the current revision status of documents are identified;
- ensure that relevant versions of applicable documents are available at points of use;
- ensure that documents remain legible and readily identifiable;
- ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled; and
- prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

In addition, the organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.

APPLYING DOCUMENTATION CONTROL TO THE STANDARDS DEVELOPMENT AND PUBLICATION PROCESS

An important element of such documentation control is to establish a proper document register, with a clear control over who has only access to view, and who has access to change or update a document. The revision status of the document needs to be clearly identified including its date of approval. Documents that have been withdrawn need to be archived. The same holds true for all stages of the standards development and publication process.

Committee documentation, draft standards for public comment and the final draft standard could be the responsibility of the TC Secretariat. It is important, though, that the system should be a common system for all. The integrity of the system will be compromised if each Secretariat establishes its own independent, small system. The system integrity needs to be such that if staff move, the system remains intact – see Figure 7.5.

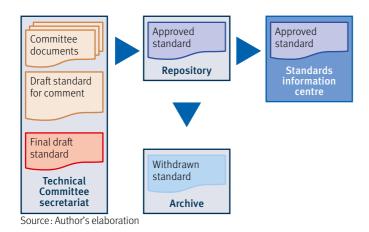


Figure 7.5: Documentation control system

Approved standards and the archive of withdrawn or superseded standards would be the responsibility of a specific repository. The standards information centre should always provide the most recent version of the approved standard to any interested party, either electronically or in hard copy. The system architecture should facilitate searching for specific drafts or standards, and it should support determining key performance criteria such as "time for each standards development stage".

APPLYING DOCUMENTATION CONTROL TO COMMITTEE DOCUMENTS

Committee documents should always be identified in such a way that the revision status can easily be seen. This is to ensure that the TC members all use the same document during discussions. The final draft standard will be edited, so the preediting and post-editing versions should also be clearly identified.

Committee members should be given access to committee documents. This needs to be controlled through password or other relevant means. Committee members should not be able to change these documents, this is the sole responsibility of identified NSB staff.

APPLYING DOCUMENTATION CONTROL TO APPROVED STANDARDS

Once a standard has been approved, the approved text should be identified and secured in such a way that it can only be changed by a person authorised to do so, e.g. the person responsible for managing the IT system. This system should be able to stand up in a court of law if the standard is subjected to legal proceedings. In some countries, a signed hard copy will be necessary. The requirements of the country should therefore be followed carefully in the case of current, approved standards. This definitive copy of the approved standard should be kept in a safe depository away from every-day usage of the standard.

Once a standard has been withdrawn or replaced by a revised standard, it should be placed in an archive for reference purposes. This is a very important element of the document control system for standards, as it happens quite frequently that earlier versions of the standards need to be consulted for technical requirements of a product that was manufactured years ago, e.g. for maintenance or repair purposes, or in a court of law in legal proceedings.

Generally speaking, the standards information-centre should not double for the repository of the definitive text, even though great care has to be taken that their data is kept up to date with the most recently approved standards. Due to copyright requirements of standards, access to standards by interested parties needs to be controlled. Normally read-only access is available in the NSB, outside the standard has to be paid for before the text is downloaded. Modern IT systems that provide read only access externally are being implemented in some NSBs and may be a way for the future.

7.4 Dissemination

Once a standard has been developed and published, the NSB should do its utmost to disseminate the standard for use by government, business and industry, and even by society in general. This means that the NSB has to establish appropriate marketing schemes, ensure that an effective standards information-centre is in operation, and that standards can easily be obtained, i.e. purchased, by customers. If the NSB is the designated National TBT Enquiry Point, additional systems need to be in place to fulfil the requirements of the *WTO TBT Agreement* should the country be a WTO member.

7.4.1 Standards information

Standards are information, and the NSB should establish a well-equipped standards information-service to disseminate this knowledge into industry, authorities and society in the most effective way. National standards should occupy the centre stage, but information on regional and International Standards are equally important, as are standards of the major trading partners. The standards information-service entity of the NSB should become the automatic first port of call for anybody wishing to obtain standards information in the country and even beyond.

FIRST CONTACT OF THE CUSTOMER WITH THE NSB

The standards information-service is frequently the first contact a customer has with the NSB. Therefore, it should be easily accessible, i.e. in close proximity to the entrance to the NSB, and with a functional design. The standards information-service should be open to the public as long as possible, e.g. it should not be closed during lunch time.

The staff should be trained to deal with customers in a very friendly and professional manner. The staff should know the national standards well, and they should be able to find their way around international or regional standards fairly easily. A professional service will go a long way to convince customers that the NSB is an organization they can rely on and with which they can do business.

It is not only the walk-in customers that are important. Requests arriving by telephone, e-mail, SMS and other electronic media need to be attended to promptly and professionally as well. Although various KPIs are available to manage and measure prompt attention, easy ones that could be implemented include a telephone that should be answered within three or four rings, or e-mails that are responded to within the hour.

FROM HARD COPY TO IT BASED STANDARDS

The past few decades have seen a revolution as regards standards information-centres. In the past, the centre was like a library, with thousands of standards in hard copy arranged by country in racks. These days, the standards only available in hard copy are very few. Most of them will be available electronically. Hence, the more modern approach to a standards information-centre is to provide computer screens for the customers on which they can search and read national, international and other standards in the centre. This demands investment in the appropriate hardware, software, network connections and process – see also 6.3.2.

7.4.2 Catalogue

The NSB should maintain a catalogue of all its current national standards. This catalogue should be accessible in the public domain and an IT-base catalogue (also known as a standards database in some NSBs) is most efficient, since it facilitates electronic searches by the standards information service and customers. The catalogue should be readily accessible on the NSB Website.

For every approved standard the catalogue should list the number, date of publication, the *International Classification for Standards* (ICS) number ²⁹⁾, full title and a short synopsis of the contents of the standard. The catalogue entry should also identify any International Standards which the NSB has adopted as a national standard. All of this information should enable customers to unequivocally identify the standards they are looking for before purchasing them. The NSB should ensure that the catalogue is meticulously kept up-to-date. Newly approved standards need to be listed in the catalogue immediately, together with a note on whether they are new developments or revisions of older standards. Withdrawn standards should be removed from the catalogue.

7.4.3 Marketing

Marketing is defined in many ways, but a useful one to consider is to see it as "the management process responsible for identifying, anticipating and satisfying customer requirements profitably". This is an area where many NSBs still operate in a "wait and see", reactive mode, thinking that customers who require information on standardization will eventually come to see the NSB. In the fast-moving

²⁹⁾ The ICS (International Classification for Standards) is intended to serve as a structure for catalogues of international, regional and national standards and other normative documents, and to be used for classifying standards and normative documents in, for example, databases and libraries. The ICS is a hierarchical classification which consists of three levels. Level 1 covers 40 fields of activity in standardization, e.g. road vehicle engineering, agriculture, and metallurgy. The fields are subdivided into groups (level 2) and some of these groups are further divided into sub-groups (level 3). The ICS notation consist of three groups of number separated by a point, e.g. 40.040.20 Lighting, signalling and warning devices. Further information can be found in the ISO publication International Classification for Standards, available as a free download from: http://www.iso.org/iso/international classification for standards.pdf.

modern trade environment this no longer holds true, and NSBs, like any other business will have to market their services proactively, in competition with many others, especially the private sector operators providing conformity-assessment services based on their own standards. It is also not a given that the public sector will automatically think about the NSB and national standards when they are developing technical regulations or SPS measures, or have to define national purchases. The NSB has to market the advantages of using national standards also to the public sector.

The process of marketing is that of bringing a product, in this case the national standard, to market, which includes these steps:

- 1. broad market research:
- 2. market targeting and market segmentation;
- 3. determining distribution, pricing and promotion strategies;
- 4. developing a communications strategy;
- 5. budgeting; and
- 6. visioning long-term market development goals.

The traditional marketing mix refers to four broad levels of marketing decision, namely:

- The **product** aspects of marketing deal with the specifications of the actual goods or services, and how it relates to the end-user's needs and wishes. In standards, the product element not only consists of the design and quality of the standards (i.e. without errors), but could also mean the format, packaging (selling in sets), licensing models and branding. Branding, a key aspect of marketing, refers to the various methods of communicating and maintaining a brand identity for the NSB, the national standards and the related derivative products.
- The **price** refers to the process of setting a price for standards or related services (e.g. training or consultancy) and it is the amount that a customer pays for it. The NSB should set a price for national standards that is appropriate for the market realities in the country. National standards that are adoptions of ISO or IEC standards may not be given away without charge, as this would

negate their copyright³⁰⁾ and undermine the value they bring. The price has little to do with the cost of developing standards, as this would render them very costly and basically unaffordable (see also 7.2.2). Most NSBs price their standards in accordance with the number of pages of the standard. The price of the standard should be devised and proposed by the marketing and/or sales department to the Board or Council for consideration and/or approval. The prices have to be reviewed and if needed revised periodically (annually) to accommodate market conditions.

- The place refers to how the standard and related services get to the customer. In the case of standards this would be more related to the mode of distribution: a hard copy purchased from the NSB directly, a copy sent through email, or downloaded from a webstore or through online viewing (see 7.4.4). Other services, such as training and consultancy should be provided in appropriate places accessible to the customers.
- Promotion includes all aspects of marketing communications such as advertising, sales promotion, including promotional education, public relations, personal selling, product placement, branded entertainment, event marketing, trade shows and exhibitions.

Marketing is expensive but absolutely essential. Hence, it should be carefully planned and managed. It should have a proper budget with KPIs and should be approved by the Board or Council. Top management should be accountable for its proper functioning. Some NSBs have established marketing divisions, and these need to report to an appropriate management level in the organization.

7.4.4 Sales of standards

As regards standards sales, the mode of operation has shifted from printing a thousand or so hard copies to providing standards online. Hard copy standards are still required though, especially for SMEs and others that do not yet have access to the internet. Such hard copies should be provided by a print-on-demand system

³⁰⁾ In the case of ISO, members have to fulfil the requirements of the ISO POCOSA agreement.

which need not to be very elaborate – a server, printer and binding machine is all that is required.

The most common way to obtain standards is to purchase them online from a Webstore. It is therefore important for the NSB to establish its own Webstore. Customers should be able to purchase standards by credit or debit card payment, or other relevant electronic fund-transfer systems, not only from within the country, but also outside the country. The standards that are provided as an electronic file should be watermarked so that they cannot be tampered with to ensure the integrity of the purchased standard as far as is possible. Such a purchase must clearly imprint details of the customer, the member and the type of licence, on each page of the standard. This serves the purpose of constantly reminding the customer on the proper use of the publication and help the member track unauthorized use. The NSB that fails to provide standards in such a Webstore might lose standards sales to other NSBs, especially if the national standard is an adoption of an International Standard as other NSBs may have adopted the same. Typical examples would be standards such as ISO 9001, ISO 14001 and similar that would be purchased more often than other, more product typical standards. Such a Webstore presupposes an effective and efficient IT system and connectivity to the Internet - see also 6.3.2.

The NSB should keep track of the standards purchased by number, title and quantities and provide this information on a quarterly and annual basis to its senior management and Board or Council. This information is extremely useful in shaping future marketing endeavours (see 7.4.3) and it can be used as feedback to enhance the SWP (see 7.1.3).

7.4.5 WTO TBT National Enquiry Point

The *WTO TBT Agreement* requires all member states to establish a National TBT Enquiry Point. This enquiry point must answer all reasonable requests for information from WTO member states regarding the country's:

- current and draft technical regulations;
- current and draft standards:

- conformity assessment procedures or systems;
- membership of regional or international standardization bodies; and
- source of the text for any draft technical regulations or draft standards.

For more than 60% of the WTO members the NSB is the National TBT Enquiry Point³¹⁾. Most of the others are the ministry responsible for trade or industry. In this respect the standards information-service has a very important part to play as the information window of the country towards the global trading system in respect of standards and technical regulation information.

The Committee on Technical Barriers to Trade (the "TBT Committee") requested that the WTO Secretariat prepare a guide on best practices for enquiry points. In 2019, the TBT team in the WTO's Trade and Environment Division has developed the WTO TBT Enquiry Point Guide³²⁾ that addresses the establishment of enquiry points, tasks that relate to notifications, responses to requests for information or comments, and the coordination of, and reactions to members' notifications. Also, this guide discusses other activities undertaken by enquiry points and outlines some of the challenges that have emerged with experience.

Each year the WTO receives more than 3500 TBT and SPS notifications proposing new measures that may affect international trade. Evaluating these notifications on the WTO Website is a laborious but essential process. The WTO, UN and ITC have developed an electronic support system designed to help government agencies and SMEs to keep track of the latest information on regulatory requirements for international trade. This system, known as ePing³³⁾, allows access to WTO members' notifications of TBT and SPS measures. It also facilitates dialogue among the public and private sector in addressing potential trade problems at an early stage. Users of ePing will be able to easily keep up-to-date with notifications affecting foreign markets and products of particular interest to them.

³¹⁾ All the TBT Enquiry Points of WTO members and their contact details are listed on the WTO website at: http://tbtims.wto.org/en/NationalEnquiryPoints/Search.

³²⁾ WTO TBT Enquiry Point Guide is available on the WTO website at: https://www.wto.org/english/tratop_e/tbt_e/tbt_enquiry_point_guide_e.pdf.

³³⁾ http://www.epingalert.org/en.

7.5 Customer services

The NSB should be a centre of excellence not only for the development, publication and dissemination of standards, but also for the implementation of standards. One of the objectives of standardization is the transfer of technology and good business and organizational practices, and the NSB should be able to facilitate such transfers related to specific standards and even standardization in a broader sense. Two mechanisms for such transfers would be training and consultancy. A customer hotline is a different type of service that could also be established.

7.5.1 Training

The NSB should provide training for its Secretariats and the Chairs of ISO/TCs – see 6.2 – but it could provide training on a much wider basis. It has been shown that once an NSB offers good training schemes, e.g. with regard to quality management systems, then trainees are very likely to come back to the NSB once the decision is made to have the company certified to *ISO 9001* or *ISO 14001* if the NSB is also an accredited certification body.

Some training possibilities include the following:

- implementation of management-system standards such as ISO 9001, ISO 14001, ISO 45001;
- the effective utilization of standards as the basis for technical regulation and SPS measures; and
- implementation of selected standards with a wider impact, e.g. wiring requirements for houses and factories, building material standards, vehicle safety standards, and welding standards.

In some countries, training institutions may have to apply for and receive formal recognition from the authorities, e.g. ministry responsible for education or similar, before they may provide training schemes. In addition, in many countries, industry can claim tax benefits if their employees are trained at such recognized training institutions. Where such systems are in place, it is recommended that the NSB participates fully in order to gain the maximum advantage for its training services.

7.5.2 Consultancy

Consultancy, i.e. providing information or training to a company on an individual basis, can be a very useful and more focussed mechanism to transfer knowledge regarding the implementation of specific standards, be they system management type standards or product standards. Such services do however, come with an important *caveat*: If the NSB is a provider of any type of conformity-assessment services, this would constitute a major conflict of interest, and the NSB would never be able to gain accreditation for its conformity-assessment services. If the NSB does not provide testing and certification services, consultancy for the implementation of standards may be a useful addition to the services the NSB provides to its customer base.

7.5.3 Customer hotline

The NSB is frequently a complex organization with many divisions and sections. Hence, for somebody from the outside it may be difficult to connect with the appropriate person in the NSB regarding a specific issue. This could be a complaint, request for general information regarding the NSB or standardization or even providing the NSB with information the person believes the NSB should take note of. It may be useful for the NSB to establish a customer hotline (e.g. telephone number, e-mail address, etc.) staffed by professional employees who are well-versed in standardization issues and with strong communication skills.

Conclusion

This publication, following on from earlier ISO publications such as Fast Forward: National Standards Bodies in Developing Countries and Financing NSBs: Financial sustainability for National Standards Bodies, deals with the subject of GSP at a greater level of detail and much more comprehensively. It includes information relevant to the standards-development process as contained in the WTO TBT Agreement, as well as the collective experience from many NSBs that have endeavoured to enhance their effectiveness and efficiency in the face of rapidly changing market conditions and dwindling government financial support.

The major innovation of this publication is that it looks at the NSB through the "lens" of value chain concepts that are routinely used in business circles to optimise strategic and operational activities of a company. It is focussed on smaller NSBs operating in developing countries, but the concepts can be equally applied to well-established NSBs in the developed countries. On the other hand, this is not a recipe that should be applied without thinking and adjustment to take national realities into account. Good business-acumen and effective project-management

will always be necessary to optimise the standards development process in any country and in any NSB.

The publication therefore fills a need that has been articulated more frequently in recent times, especially since the *WTO TBT Agreement* contains broad principles, the ISO/IEC Directives are focussed more on the international scene and *ISO/IEC Guide 59* deals with the very specifics of the process rather than with the NSB as an organization. ISO/CS trusts that ISO members and others will find the publication useful to evaluate their activities and to establish GSP in their organizations for the benefit of stakeholders and the country as a whole. Standardization practices are not static, and ISO/CS invites all users to communicate new and different insights in GSP so that future revisions of the publications can take these into account.

Standards referenced

ISO/IEC Guide 2:2000, Standardization and related activities – General vocabulary ISO/IEC Guide 17:2016, Guide for writing standards taking into account the needs of micro, small and medium-sized enterprises

ISO/IEC Guide 21-1:2005, Regional or national adoption of International Standards and other International Deliverables – Part 1: Adoption of International Standards ISO/IEC Guide 59:2019, ISO and IEC recommended practices for standardization by national bodies

ISO/IEC 17000: –, Conformity assessment – Vocabulary and general principles ISO/IEC 17020:2012, Conformity assessment – Requirements for the operation of various types of bodies performing inspection

ISO/IEC 17021-1:2015, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements

ISO/IEC 17024:2012, Conformity assessment – General requirements for bodies operating certification of persons

ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories

ISO/IEC 17043:2010, Conformity assessment – General requirements for proficiency testing

ISO/IEC 17065:2012, Conformity assessment – Requirements for bodies certifying products, processes and services

ISO 9001:2015, Quality management systems – Requirements

ISO 14001:2015, Environmental management systems – Requirements with guidance for use

ISO 45001:2018 Occupational health and safety management systems – Requirements with guidance for use

ISO 21500:2012, Guidance on project management

Annex A: Using the diagnostic tool

The diagnostic tool, available from ISO/CS in the form of an Microsoft Excel spread-sheet, provides member bodies with a mechanism to consider their organization and its governance, assess their own standards development practices and the resultant national standards to see whether they achieve the key principles of GSP³⁴⁾. It is based on the NSB value chain as described in chapters 5, 6 and 7 of this GSP publication.

The diagnostic tool consists of a series of questions based on the NSB value chain depicted in Figure 5.2 arranged as a series of milestones. These are arranged in the following nine value-chain areas:

- 1. administration and finance infrastructure;
- 2. human-resource management;
- 3. product and technology development;
- 4. technical committees;
- **5.** planning;
- **6.** development;
- 7. publication;
- 8. dissemination; and
- 9. customer service.

For each of the milestones, a series of questions needs to be answered. Some of these will be for information only, but most of them will be scored depending on how well the organization complies with them. These scores are aggregated for each of the milestones after which a radar diagram can be constructed that would indicate to the NSB how well it complies with international good practices as in the example of Figure A-1. These radar diagrams are a useful visual indicator for management and other governance entities to determine progress in becoming an effective and efficient NSB over time.

The scoring is based on a 0 to 4 points system, and the evaluation of the aggregated scores can be broadly considered as follows:

• **Score 0 to 1.0**: Little or nothing is in place and the NSB has to develop the relevant milestone from scratch.

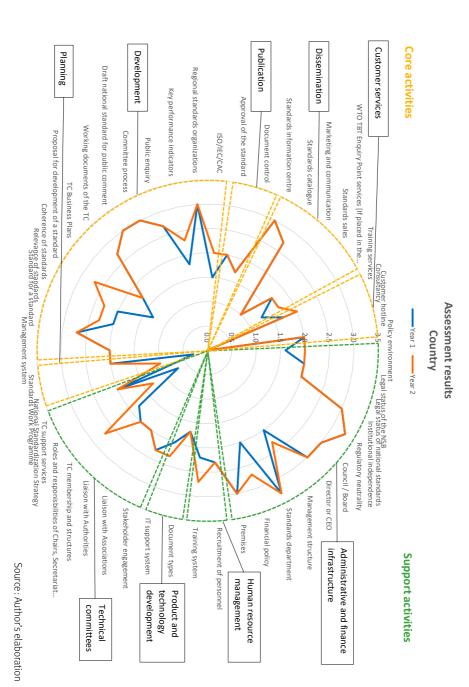
³⁴⁾ The GSP diagnostic tool can be downloaded via this link: go.iso.org/gsptool.

- **Score 1.1 to 2.0**: Rudimentary systems and in need of much fundamental development.
- Score 2.1 to 3.0: Reasonable system in place but in need of further development.
- ► **Score 3.1 to 4.0 :** Good system no need for fundamental development, but maintenance is important.

Aggregate scores should be calculated to at least one decimal place to allow for a meaningful depiction in the radar diagram. However, the quantitative analysis is a very coarse one, and the aggregate scores should not be taken as absolutes. They provide a quick reference as to the current state and future development of the NSB. This tool does not replace a proper assessment of processes such as would be undertaken, for example, to determine compliance with ISO 9001, or other in-depth management-system assessment techniques.

In the example radar diagram in Figure A-1 the series 1 could constitute the assessment of the first year, and series 2 that of the second year, showing the progress that has been achieved. The segments denoting the nine value-chain areas are indicated by green (support activities) and yellow (core activities) segments. This is a further visual help for the NSB to determine which of the value chain areas require attention.

Figure A-1: Example of a GSP assessment radar



About ISO

ISO (International Organization for Standardization) is an independent, non-governmental international organization with a membership of 164* national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensusbased, market-relevant International Standards that support innovation and provide solutions to global challenges.

ISO has published more than 22500* International Standards and related documents covering almost every industry, from technology to food safety, to agriculture and healthcare.

For more information, please visit ${\bf www.iso.org}$

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