GUIDE 59

Second edition 2019-08

ISO and IEC recommended practices for standardization by national bodies

Pratiques de normalisation recommandées par l'ISO et l'IEC à leurs organismes nationaux



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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see http://www.iso.org/patents) or the IEC list of patent declarations received (see http://www.iso.org/patents) or the IEC list of patent declarations received (see http://www.iso.org/patents) or the IEC list of patent declarations received (see http://www.iso.org/patents) or the IEC list of patent declarations received (see http://www.iso.org/patents) or the IEC list of patent declarations received (see http://www.iso.org/patents) or the list of patent declarations received (see http://www.iso.org/patents) or the list of patents iso.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see <u>www.iso</u> .org/iso/foreword.html.

This document was prepared by a Joint Working Group of the ISO Technical Management Board and the IEC Standards Management Board.

This second edition cancels and replaces the first edition (ISO/IEC Guide 59:1994), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the structure, content and language used have been updated to allow easier application;
- a scope has been added to define the subject of the document and the aspects covered, thereby
 indicating the limits of applicability of the document;
- <u>Clauses 4</u> and <u>5</u> have been added to support the implementation of the WTO TBT agreement.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <u>www.iso.org/members.html</u>.

Introduction

Standardization brings technological, economic and societal benefits. Standards help to harmonize technical and other specifications of products and services making industry more efficient and removing barriers to trade.

Standards are considered an essential component of the "quality infrastructure", the system comprising organizations (public and private), policies, relevant legal and regulatory framework and practices which is needed to support and enhance the quality, safety, and sustainable soundness of goods, services and processes.

Standards are developed by many bodies, at the national, regional and international levels. Alongside the growth of international trade, technological and societal cooperation, standards bodies have developed procedures and modes of cooperation which are commonly considered to constitute good practices for standards development at all levels. The use of standards is voluntary unless they are cited as requirements in legislation or in legal contracts.

The foundations of ISO's and IEC's membership and participation models are at the national level. ISO and IEC, together with their national bodies, are responsible for fostering and ensuring coherence and coordination.

The ISO and IEC system for standardization is based on collaboration agreements between ISO and IEC and an extensive array of collaboration agreements among regional, national and other standards bodies.

The WTO TBT agreement has provided a framework to facilitate international trade through international standards. ISO and IEC are committed to the implementation of the WTO TBT framework when developing International Standards (see <u>Annex A</u>). The national bodies should set guidelines to define their organizational culture, which consists of the values, beliefs, attitudes and behaviour that their national experts should share and use regularly in their work. ISO and IEC have developed and apply Codes of Conduct to be followed by participants in standardization work. These Codes of Conduct include responsibilities to consider:

- inclusiveness;
- consensus-building attitude and skills;
- compliance with the procedures;
- efficiency;
- impartiality;
- commitment to quality;
- dedication of personnel and experts.

International deliverables other than International Standards can perform similar functions in reducing technical barriers to trade and thereby facilitating trade. Information about other deliverables published by ISO and/or IEC can be found in the ISO/IEC Directives, Part 1.

The first edition of this document predated the existence of both the WTO TBT Committee decision on principles for the development of international standards, guides and recommendations (G/TBT/9, 13 November 2000) and the WTO TBT Agreement's Code of Good Practice for the Preparation, Adoption and Application of Standards (Annex 3 of the 1995 WTO TBT agreement). The purpose of this edition of this document is to provide recommendations for implementing good standardization practices that are intended to support, but do not replace or supersede, the two WTO TBT Committee documents.

This document does not constitute an official interpretation of the two WTO TBT documents cited above.

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ISO and IEC recommended practices for standardization by national bodies

1 Scope

This document provides recommended standardization practices that are intended to support the application of the following:

- the WTO TBT Committee decision on principles for the development of international standards, guides and recommendations (G/TBT/9, 13 November 2000);
- the WTO TBT Agreement's Code of Good Practice for the Preparation, Adoption and Application of Standards (Annex 3 of the 1995 WTO TBT Agreement).

This document is intended to be used by the national members of ISO and IEC, hereafter referred to as national bodies.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 2, Standardization and related activities — General vocabulary

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 2 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <u>https://www.iso.org/obp</u>
- IEC Electropedia: available at <u>http://www.electropedia.org/</u>

3.1

basic standard

standard (3.8) that has a wide-ranging coverage or contains general provisions for one particular field

Note 1 to entry: A basic standard may function as a standard for direct application or as a basis for other standards.

[SOURCE: ISO/IEC Guide 2:2004, 5.1]

3.2

consensus

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 seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments

Note 1 to entry: Consensus need not imply unanimity.

[SOURCE: ISO/IEC Guide 2:2004, 1.7]

3.3

current version

status assigned by a *national body* (3.6) to a normative document at the time of publication, or to a draft at the time of issue, and which remains in effect until withdrawal or being superseded

Note 1 to entry: The status "current" does not indicate the validity or non-validity of a normative document.

Note 2 to entry: A *standard* (3.8) can be either a current version or a *historical version* (3.4).

3.4

historical version

status assigned by a *national body* (<u>3.6</u>) to a normative document or draft at the time of withdrawal or being superseded

Note 1 to entry: The status "historical" does not indicate the validity or non-validity of a normative document.

Note 2 to entry: A *standard* (3.8) can be either a *current version* (3.3) or a historical version.

3.5

stakeholder

organization, company, public entity or individual that can affect, be affected by or perceive itself to be affected by a decision or activity coming from a standardization process or its deliverables

Note 1 to entry: In English, the term "stakeholder" is equivalent to "interested party".

3.6

national body

ISO member body or IEC National Committee

Note 1 to entry: This term refers to any current or future ISO member body or IEC National Committee that develops national *standards* (3.8).

3.7

participant

stakeholder (3.5) that becomes involved in the *standards* (3.8) development process

3.8

standard

document, established by *consensus* (3.2) 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 1 to entry: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

[SOURCE: ISO/IEC Guide 2:2004, 3.2]

3.9

standardization

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 to entry: In particular, the activity consists of the processes of formulating, issuing and implementing *standards* (3.8).

Note 2 to entry: 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.

[SOURCE: ISO/IEC Guide 2:2004, 1.1]

3.10

withdrawn standard

standard (3.8) that has been discontinued by the publishing standards developer following consultation with its responsible committee, because it no longer represents the most current, reliable and/or available technical information

3.11

superseded standard

standard (3.8) that has been replaced with a newer version of the same standard, or by a suitable other standard that contains the most current, reliable and/or available technical information

4 Guidance with respect to the implementation of the principles of standards development

4.1 General

This clause provides guidance to support the application of the WTO TBT Committee decision on principles for the development of international standards, guides and recommendations (G/TBT/9, 13 November 2000).

The development of consensus-based standards is a process that, at the national level, consists of several distinct, but closely related activities.

- The first phase is the identification of the need for a standard, followed by prioritization of the work required to develop the standard based on the available resources.
- The second phase is the development of the standard, usually in a committee, taking into account all stakeholders concerned at the national level.
- The third phase is the open consultation to allow for public input and consideration of comments received by the committee during public consultation.
- The fourth phase corresponds to the approval of the standard.
- The last phase is the publication, promotion and maintenance of the standard.

The recommendations given in 4.2 to 4.7 should be followed when national bodies are developing standards or contributing to international standardization work. These recommendations are aligned with the WTO TBT Committee decision on principles for the development of international standards, guides and recommendations (see <u>Annex A</u>).

4.2 Transparency

4.2.1 Transparency implies that sufficient and regularly updated information is easily accessible in due time to allow all stakeholders to participate in the standardization process if they want to. Procedures should be established so that adequate time and opportunities are provided for the submission of written comments. Information on these procedures should be effectively disseminated.

4.2.2 The national body should have appropriately documented procedures to support its standards management and development processes. These procedures should be up to date and freely available to any stakeholder.

4.2.3 When a new standard is proposed, the national body should make this information publicly available at an early stage in the standards development process, so that stakeholders can follow or take an active part in the process as participants. A brief description of the scope of the draft standard, including its objective and rationale should be provided. The notice used to communicate this proposal should be clear and easily understood by all stakeholders.

© ISO/IEC 2019 – All rights reserved Copyright by ISO. Reproduced by ANSI with permission of and under license from ISO. Licensed to Ansi Isot. Downloaded 07/16/2024. Not for additional sale or distribution. **4.2.4** Participants should receive all draft documents and should be informed of the action taken on any comments they have made relating to drafts.

4.2.5 Once consensus is reached and the draft standard is ready for open consultation, it should be made available to stakeholders. At least 60 days should be provided to allow stakeholders the opportunity to submit written comments. This period may, however, be shortened in cases where urgent problems of safety, health or environment should be addressed. A clear and well-understood procedure should be in place for the management of these comments (see <u>5.10</u>).

4.2.6 Information on current versions of standards as well as on historical and withdrawn standards should be made available by adequate means such as via websites, subscriptions, etc.

4.2.7 The national body should make an up-to-date work programme available publicly. The standards work programme should contain relevant information, as described in <u>5.9</u>.

4.3 **Openness**

4.3.1 Participation in standards development should be open via the national body at all stages of the standards development process on a non-discriminatory basis to all stakeholders. This includes participation at every stage of standards development, such as the following:

- proposal and acceptance of new work items;
- technical discussion on proposals;
- submission of comments on drafts;
- review of existing standards;
- resolution of comments and approval of standards;
- availability of approved standards.

4.3.2 National bodies should facilitate the participation of a range of stakeholders appropriate to each standard under development. Participation should be inclusive and not impose undue membership barriers.

4.3.3 The national body should promote and enable the involvement of all stakeholders, including those potentially under-represented, such as small and medium-sized enterprises and representatives of societal interests. National bodies can consider putting in place awareness-raising activities, as well as procedures for monitoring the participation of different categories of stakeholders.

4.3.4 The national body should promote its commitment to openness by maintaining and making publicly available its standards development procedures, which address issues such as conditions for participation (e.g. membership, participation fees, waiver provisions, copyright, intellectual property rights and privacy obligations).

4.3.5 The national body should provide advance notice of standards development meetings, and it should ensure availability of meeting agendas and documents prior to the meeting, according to specified timeframes.

4.4 Impartiality and consensus

4.4.1 Impartiality should be accorded throughout the standards development process with respect to the following (among other things):

- access to participation in work;
- submission of comments on drafts;
- consideration of views expressed and comments made;
- decision-making through consensus;
- obtaining information and documents;
- availability of draft and approved standards;
- adopting an ISO or IEC standard as a regional or national standard;
- revision of the standard.

4.4.2 When addressing consensus and impartiality, the national body should provide an impartial and neutral platform for its standards development work, with equal access for all participants. The work is expected to be conducted in a consensual and impartial manner, where no party is favoured over another (see 4.4.5). No one organization or participant category should dominate the standards development process. Furthermore, the national body should examine its governance structure, which should support neutrality with respect to the representation of specific private or public interests across all its relevant governing bodies.

4.4.3 The national body should have a standardization process that remains collaborative and consensus-based, and that takes into account all views expressed and brings together diverging opinions.

4.4.4 The national body should assist its participants and those in leadership positions (such as the committee chair) in building consensus. For this, the good practices below are recommended.

a) Promoting the right attitude

The national body should invite the participants involved to cooperate fully and in good faith in the standardization work.

b) Dealing with objections

In the process of reaching consensus, many different points of views will be expressed and addressed as the document evolves. However, "sustained opposition" constitutes views expressed and maintained by an important part of the stakeholders and which are incompatible with the committee decision. Those expressing sustained opposition have a right to be heard and the following approach is recommended when sustained opposition is declared.

- The leadership should first assess whether the opposition constitutes sustained opposition, If this is not the case, the leadership may register the opposition (e.g. in the minutes) and continue to lead the work on the document.
- If the leadership determines that there is sustained opposition, it should try to resolve it in good faith. However, sustained opposition cannot be interpreted as a right to veto. The obligation to address the sustained opposition does not imply an obligation to successfully resolve it. The responsibility for assessing whether or not consensus has been reached rests with the leadership. This includes assessing whether there is sustained opposition or whether any sustained opposition can be resolved without compromising the existing level of consensus on the rest of the document. In such cases, the leadership will register the opposition and continue the work.

- In all cases, the national body is expected to demonstrate efforts to identify solutions that resolve any sustained opposition, while considering the interests of all participants.
- Those maintaining sustained opposition and who are dissatisfied with the process or the outcome may make use of appeals mechanisms (see <u>5.12</u>).
- c) Achieving consensus rather than voting

The national body should take decisions in accordance with the consensus principle to the extent possible. Formal voting should only be used under specific conditions and when the voting process has been detailed in established procedures.

d) Documenting decisions

It is good practice to document the standpoints expressed with rationales, including any sustained opposition, the decisions taken, the actions launched and, if necessary, the initiatives taken to reach consensus.

4.4.5 The national body should protect the standards development process, ensuring its integrity, avoiding taking a technical position on the standards under consideration, and keeping an impartial and independent position by providing the opportunity for representation by an appropriate balance of interests in the standards development process.

It is good practice to categorize stakeholders and participants according to broad areas of interest. Annex B gives an example of the participant categories. The relevance of the various participant categories should be assessed taking account of the standard under development. Not all categories are relevant to all standards projects.

The national body's rules should grant the same rights to all participants in the standardization work to express their opinions and to have them duly taken into account. It is good practice for the national body's rules to state that all timely and relevant contributions submitted in accordance with established procedures are duly considered, without favouring or ignoring any of them.

For this, it is good practice for the national body 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 record their commitment. The rules and procedures of the national body should be communicated to those leading the standards development process who are responsible for ensuring that they and the participants follow these rules and procedures.

With respect to the representation of industry and commerce, it is good practice to pay particular attention to the representation of small businesses, as recommended in ISO/IEC Guide 17.

4.4.6 The national body should maintain a governance structure that is neutral, impartial and independent with respect to the specific interests of the participants. The national body should focus on behavioural independence, as reflected in:

- a) the ability of its governing bodies and staff to behave independently from those that finance the standard development activity;
- b) the possibility for all stakeholders and participants to express themselves;
- c) the diversity of those who are participating.

4.4.7 Each national body should have a documented complaints and appeals resolution process (e.g. the process described in the ISO/IEC Directives, Part 1).

4.5 Effectiveness and relevance

4.5.1 The national body should take account of relevant regulatory or market needs, as well as of societal, scientific and technological advances in the development of standards.

4.5.2 The national body should develop new standards that:

- support open and fair markets;
- support cross-border movement of products, services, innovation or solutions that are fit for purpose in an intended application or use;
- support fair competition;
- support innovation and technological development;
- consider their effects on the environment;
- comply with Sustainable Development Goals (SDGs);
- are designed to be applicable for the benefit of all users of products and services based on standards.

4.5.3 The national body should put in place procedures aimed at identifying and reviewing standards that have become obsolete, inappropriate or ineffective for various reasons. All standards should be reviewed on a periodic basis and revised in a timely manner, to be relevant in the context of changing market or regulatory needs and new scientific and technological developments.

4.5.4 Proposals for the development of new or revised standards, when submitted according to appropriate procedures by any materially and directly affected stakeholder, wherever located, should be given prompt consideration. For basic standards, the modification or withdrawal can impact other projects and stakeholders. Therefore, in relation to modification or withdrawal of basic standards, the committee should consider the use of current and historical versions. Special attention should be given to other standards making normative reference to basic standards. It is good practice for the national body to make historical versions of standards available, when applicable. If historical versions are available, the status of the standard should be clearly stated, e.g. if it is a withdrawn standard or a superseded standard.

4.5.5 The national body should develop standards that express requirements in terms of performance rather than design or descriptive characteristics, whenever possible, so that the standards do not create unnecessary obstacles to trade, development and innovation. This allows maximum freedom for technical development and reduces the risk of undesirable market impacts (e.g. restriction of innovative solutions). The choice between specifying by description or by performance should include the input of knowledgeable experts to decide on the best approach.

NOTE See the ISO/IEC Directives, Part 2.

4.5.6 The national body should develop standards to meet the needs of the marketplace and contribute to advancing trade in the broadest geographical and economic contexts.

4.5.7 The national body should focus on user-friendliness and simple language and should limit the use of normative references to those that are essential for meeting the standard's requirements.

4.5.8 There is no objection in principle to drafting standards in terms that require the use of a patented item, when the use of such an item is justifiable for technical reasons and the patent holder agrees to negotiate licenses with interested applicants, wherever located, under fair and reasonable terms and conditions. If it is possible that patented items are included in a standard, the patent policy should be clearly described in a publicly available document.

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4.6 Coherence

4.6.1 For standards to be mutually consistent and free from contradiction for the benefit of the users, standardization activities should be actively and voluntarily coordinated:

- a) among different national bodies;
- b) within each country or region;
- c) within each national body.

Such coordination will also benefit the application of limited resources of experts participating in standardization.

4.6.2 Coordination responsibility among standardization activities should rest with each national body to work directly with other relevant national bodies, where work programmes can result in overlapping or duplicative work.

4.6.3 As early as possible, each national body should provide information publicly via suitable methods regarding its work programme, especially for new projects, to assist in understanding where overlaps and duplications can occur and to support early engagement and participation of stakeholders.

4.6.4 All national bodies should conduct a thorough study before starting new projects to understand if and where there are complementary, overlapping or duplicative projects or existing standards. Ideally, this check should be carried out and the results should be reflected in any proposal to start new work.

- a) When it is known that an international or regional standard is being developed, national bodies should consider with their participants the opportunity of adopting the international or regional standard, to avoid duplicative or conflicting efforts.
- b) For standards to be mutually consistent and free from contradiction for the largest possible audience, standardization activities should be actively, and voluntarily, coordinated at and between international and regional levels and within each country. At the international and regional levels, this is accommodated by the national delegation principle.

4.6.5 All national bodies should strive to resolve potential conflicts and to coordinate standardization activities. In such cases, there should be a demonstration of substantial, thorough and comprehensive efforts, and national bodies should retain documentation of the efforts made.

4.6.6 For the development of national standards, all national bodies are encouraged to adopt policies and procedures that are flexible enough to support effective coordination and cooperation with other national bodies to develop national standards, while respecting each other's values, objectives and membership. For example, this can be achieved by using one or more of the following:

- maintaining clear delineation of the scope, purpose and intended application of each standard;
- early public notice of standardization activities;
- organization of an independent but representative body acceptable to the concerned standards bodies to coordinate their efforts, where appropriate;
- establishment of formal agreements to document the terms of cooperation and coordination;
- joint and cooperative development of standards, where appropriate;
- liaison relationships between organizations.

4.6.7 The national body should have in place a system that allows identification of the possible role of standardization in support of legislation or relevant regulation. In this context, the involvement of

public bodies and officials is also essential, especially in the case of those standards that are aimed at supporting legislation.

4.7 Development dimension

4.7.1 At the national level, national bodies should make efforts to engage potentially under-represented stakeholders in the development of national standards and to consider appropriate means to enhance their participation. The national body should consider the scope and intended application of the standard and the impact it can have on relevant groups in the country. Working effectively with a diverse group of participants is an essential component of successful standards development work. National bodies should promote a culture of fair and ethical behaviour without prejudice against any participant on any basis.

4.7.2 To improve the accessibility of information regarding standardization activities for those who are potentially under-represented, the national body should also consider how drafts and finalized documents are disseminated, e.g. whether these outputs are provided by the most appropriate media and means, such as screen readers for visually impaired, provided in the local language or provided in hardcopy format where electronic means are not available.

5 Guidance with respect to the implementation of the WTO TBT Agreement's Code of Good Practice for the Preparation, Adoption and Application of Standards

5.1 General

This clause provides guidance to support the application of Annex 3 of the 1995 WTO TBT Agreement, which is the Code of Good Practice for the Preparation, Adoption and Application of Standards.

5.2 Notification of acceptance of/withdrawal from the Code of Good Practice

- a) National bodies should accept this Code of Good Practice and take the necessary measures to implement it.
- b) National bodies should signify formally their acceptance of Annex 3 of the 1995 WTO TBT Agreement and notify the WTO ISO Standards Information Gateway accordingly. They should also signify if they no longer intend to comply with Annex 3 of the 1995 WTO TBT Agreement (see Annex C).

5.3 Non-discrimination principle

The national body should develop standards that do not discriminate against foreign products (in favour of domestic producers), or between foreign producers (e.g. by favouring one country over another). Products imported from the territory of any WTO member should be accorded "treatment no less favourable" than that accorded to "like products" of national origin and to like products originating in any other country.

5.4 Avoidance of unnecessary barriers to trade

- a) When developing national standards, the national body should allow for the participation of all stakeholders and it should take into account comments received, including those from outside its country or region. The purpose of this broader participation and input is to help the national body understand the global trade implications of the standards that it develops and to avoid the creation of unnecessary obstacles to international trade.
- b) Where appropriate, relevant opportunities for effective and meaningful contributions from other countries can be organized under the auspices of the national bodies of those countries.

5.5 Using ISO and IEC standards as a basis for national standards

ISO and IEC standards are widely adopted at regional or national level and applied by manufacturers, trade organizations, purchasers, consumers, testing laboratories, authorities and other stakeholders. Since these standards reflect a consensus of performance levels for a product, system or service and cover common needs in a variety of countries, they constitute an important basis for the removal of technical barriers to trade.

- a) The national body should base its national standards on ISO and IEC standards as far as is possible. The adoption of an approved ISO or IEC standard is the responsibility of the national body and should be carried out in accordance with ISO/IEC Guide 21-1. Most importantly, the level of correspondence to the ISO or IEC standard should be immediately apparent to the reader (identical or modified). Identical adoptions ensure alignment and transparency, which is fundamental to the facilitation of trade. Efforts should be made to minimize national variations, and any variations should be clearly indicated and explained.
- b) When a relevant International Standard exists or is being developed, national bodies should adopt the International Standard or relevant parts of it unless the International Standard would not be effective or appropriate due to divergent national preferences and circumstances (e.g. climatic, geographical, societal or technological reasons). It is possible that national bodies decide against using a standard if it is an ineffective or inappropriate way of fulfilling the public policy objective that is being pursued.
- c) When an ISO or IEC standard is adopted as a national standard, attention should be drawn to the requirements for copyright, copyright exploitation rights and sales of international publications stated in relevant ISO and IEC rules and policy documents.

5.6 Playing a full part in the development of ISO and IEC standards

Widespread participation in ISO and IEC can ensure that ISO and IEC standards reflect country-specific interests. The national bodies should participate, within the limits of their resources, in the work of ISO and IEC for the development of standards.

- a) At the international level, national participation in the standardization process is organized under the authority of the national body that is the member of ISO or IEC. In accordance with <u>4.4.5</u>, the participation of national bodies should reflect a balance of national interests as far as is possible.
- b) The national body should provide the opportunity for the participation of national stakeholders in the development of ISO or IEC standards. Appropriate guides or procedures should be developed by the national body to manage the participation of the country in ISO or IEC standardization activities and to coordinate the national position. Any groups convened by the national body should mirror the ISO or IEC technical body in such a way as to allow them to make effective contributions and comments.
- c) When collaborating at the regional level, national bodies should consider the promotion and adoption of ISO and IEC standards when this is relevant.

5.7 Avoiding duplication of work

To avoid the development of conflicting or duplicative standards, a national body should:

- have appropriate processes in place to facilitate coherence of its own standards and the work programmes of its committees;
- coordinate the standardization efforts in its country to avoid duplication or overlap (see <u>4.6</u>).

5.8 Specifying standards based on performance requirements

Whenever possible, requirements should be expressed in terms of performance, rather than design or descriptive characteristics (see <u>4.5.5</u>).

5.9 Standards work programme

- a) The national body should make available its complete work programme on an on-going basis. The work programme should contain the following, if available:
 - the titles of published and draft standards for the previous six months, in English, French or Spanish;

NOTE English, French and Russian are the official languages of ISO and IEC. English, French and Spanish are the official languages of the WTO.

- classification relevant to the subject matter;
- the stage reached in the standards development process;
- references to any standards used as a basis for the national standard.
- b) The agreed format for notification of the work programme to the WTO ISO Standards Information Gateway is included in Annex C. The national body that communicates its work programmes via the internet should specify in the notification form the exact web pages where the information on work programmes is located. Such work programmes should also be made available on request.
- c) Transparency is a fundamental principle of the WTO TBT Agreement. The national body should respond to any reasonable requests emanating from stakeholders, in particular regarding the work programme or the standards that it developed.

5.10 Submission of comments on the draft standard by stakeholders

- a) Once it is determined that a draft standard is ready for open consultation, the national body should make the draft available to stakeholders (see <u>4.2.5</u>). An announcement of the start and the end of the commenting period should contain the following:
 - the title and scope of the draft standard published for comment, and the reason for its development;
 - information on how to access or obtain a copy of the draft standard;
 - information on whether the draft standard is based on, or is a complete adoption of, another standard;
 - an overview of any differences between the draft standard and the standard used as a basis for the draft standard.
- b) Upon request, the national body should provide a copy of the draft standard to any stakeholder in a timely manner, so that it has the opportunity to make comments. The national body may charge a fee for providing the draft standard, provided that the national body charges the same fee to all stakeholders.
- c) Once the comment period is over, all comments should be collated and properly considered by the committee. The committee leadership should provide recommendations for the disposition of the comments for consideration by the committee. It is good practice to respond in a timely manner to each person who comments (if requested) on the disposition of their comments and to provide adequate explanation if the comments were not accepted. A national body can consider inviting commenters to the comments resolution meeting. Commenters can be encouraged to have their comments represented by a member of the committee.

5.11 Publishing of standards

Once the standard has been approved [see <u>4.4.4</u> c)], the national body should publish the standard promptly and list it in its standards catalogue. The standard should be made available for purchase as a hard copy or digitally.

5.12 Procedure for appeals

The national body should have a procedure for responding to enquiries, hearing complaints and handling appeals arising from its standards development process and its implementation of the Code of Good Practice (e.g. the process described in the ISO/IEC Directives, Part 1).

Annex A

(informative)

Principles for the development of international standards, guides and recommendations

The text below is reproduced from annex 4 to the 2nd Triennial review of the operation and implementation of the Agreement on Technical Barriers to Trade, "Decision of the committee on principles for the development of international standards, guides and recommendations with relation to articles 2, 5 and Annex 3 of the agreement", G/TBT/9, 13 November 2000.

- 1. The following principles and procedures should be observed, when international standards, guides and recommendations (as mentioned under Articles 2, 5 and Annex 3 of the TBT Agreement for the preparation of mandatory technical regulations, conformity assessment procedures and voluntary standards) are elaborated, to ensure transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and to address the concerns of developing countries.
- The same principles should also be observed when technical work or a part of the international standard development is delegated under agreements or contracts by international standardizing bodies to other relevant organizations, including regional bodies. TRANSPARENCY
- 3. All essential information regarding current work programmes, as well as on proposals for standards, guides and recommendations under consideration and on the final results should be made easily accessible to at least all interested parties in the territories of at least all WTO Members. Procedures should be established so that adequate time and opportunities are provided for written comments. The information on these procedures should be effectively disseminated.
- 4. In providing the essential information, the transparency procedures should, at a minimum, include:
 - The 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;
 - the 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;
 - the 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;
 - the prompt publication of a standard upon adoption; and
 - to publish periodically a work programme containing information on the standards currently being prepared and adopted.

- 5. It is recognized that the publication and communication of notices, notifications, draft standards, comments, adopted standards or work programmes electronically, via the internet, where feasible, 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 with respect to developing countries. Accordingly, it is important that procedures are in place to enable hard copies of such documents to be made available upon request. OPENNESS
- 6. 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 taken into account;
 - reviewing existing standards;
 - voting and adoption of standards; and
 - dissemination of the adopted standards.
- 7. Any interested member of the international standardizing body, including especially developing country members, with an interest in a specific standardization activity should be provided with meaningful opportunities to participate at all stages of standard 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 expected to adopt, standards for the subject-matter to which the international standardization activity relates. This is illustrative of the importance of participation in the international standardizing process accommodating all relevant interests.

IMPARTIALITY AND CONSENSUS

- 8. All relevant bodies of WTO Members should be provided with meaningful opportunities to contribute to the elaboration of an international standard so that the standard development process will not give privilege to, or favour the interests of, a particular supplier/s, country/ies or region/s. Consensus procedures should be established that seek to take into account the views of all parties concerned and to reconcile any conflicting arguments.
- 9. Impartiality should be accorded throughout all the standards development process with respect to, among 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;
- right to transpose the international standard into a regional or national standard; and
- revision of the international standard.

EFFECTIVENESS AND RELEVANCE

- 10. In order to serve the interests of the WTO membership in facilitating international trade and preventing unnecessary trade barriers, international standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries. They should not distort the global market, have adverse effects on fair competition, or stifle innovation and technological development. In addition, they 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. Whenever possible, international standards should be performance based rather than based on design or descriptive characteristics.
- 11. Accordingly, it is important that international standardizing bodies:
 - take account of relevant regulatory or market needs, as feasible and appropriate, as well as scientific and technological developments in the elaboration of standards;
 - put in place procedures aimed at identifying and reviewing standards that have become obsolete, inappropriate or ineffective for various reasons; and
 - put in place procedures aimed at improving communication with the World Trade Organization.
 COHERENCE
- 12. In order to avoid the development of conflicting international standards, it is important that international standardizing bodies avoid duplication of, or overlap with, the work of other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential.

DEVELOPMENT DIMENSION

13. 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 international standards development 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 TBT Agreement. Provisions for capacity building and technical assistance within international standardizing bodies are important in this context.

Annex B

(informative)

Participant categories

The ISO Technical Management Board adopted seven categories for the classification of experts nominated to working groups in TMB Resolution 75/2012. <u>Table B.1</u> provides the categories and classifications for each of the experts.

Category		Classification		
А	Industry and commerce	Manufacturers — Producers — Designers — Service industries — Distri- bution, warehousing and transport undertakings — Retailers — Insurers — Banks and financial institutions — Business and trade associations		
В	Government	International and regional treaty organizations and agencies — National government and local government departments and agencies — All bodies that have a legally recognized regulatory function		
С	Consumers	National, regional and international consumer representation bodies independent of any organization that would fall into the "industry and commerce" category — Individual experts engaged from a consumer perspective		
D	Labour ^a	International, regional, national and local trades unions and federations of trades unions and similar bodies, the main purpose of which is to promote or safeguard the collective interests of employees in respect of their relationship with their employers		
Е	Academic and research bodies	Universities and other higher educational bodies or professional educators associated with them — Professional associations — Research institutions		
F	Standards application ^b	Testing, certification and accreditation bodies — Organizations primarily devoted to promoting or assessing the use of standards.		
G	Non-governmental organ- ization (NGO) ^c	Organizations that usually operate on a charitable, not-for-profit or non-profit distributing basis and that have a public interest objective relat- ed to social or environmental concerns.		
^a Th	^a This does not include professional associations, which are regarded as:			

Table B.1 — Participant categories

associations of individuals practising, or being closely associated with the practice of, specific professional skills or sets
of closely related skills;

having a purpose, at least in part, to advance the development of those skills and the understanding of the arts, sciences
and technologies to which they relate.

^b Accreditation refers to the accreditation of testing and certification bodies.

^c This category does not include political parties or other bodies whose main purpose is to achieve representation in government or governmental bodies.

Annex C

(informative)

Forms related to the WTO TBT Agreement's Code of Good Practice for the Preparation, Adoption and Application of Standards

- Notification of acceptance of the Code of Good Practice:
 <u>go.iso.org/tbtforma</u>
- Notification of withdrawal from the Code of Good Practice:
 <u>go.iso.org/tbtformb</u>
- Notification of existence of work programme:
 <u>go.iso.org/tbtformc</u>

Bibliography

- [1] World Trade Organization *Agreement on Technical Barriers to Trade*, TBT, 1995
- [2] World Trade Organization, Annex 4 to the 2nd Triennial review of the operation and implementation of the Agreement on Technical Barriers to Trade, "Decision of the committee on principles for the development of international standards, guides and recommendations with relation to articles 2, 5 and Annex 3 of the agreement", G/TBT/9, 13 November 2000
- [3] ISO/IEC Guide 17, Guide for writing standards taking into account the needs of micro, small and medium-sized enterprises
- [4] ISO/IEC Guide 21-1, Regional or national adoption of International Standards and other International Deliverables Part 1: Adoption of International Standards
- [5] Competition Law Guidelines for Participants in the ISO Standards Development Process

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