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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 http://patents.iec.ch).

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 www.iso.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;

— Clauses 4 and 5 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 www.iso.org/members.html.

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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 Annex A). 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 https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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]

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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* (3.6) 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]

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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 Annex A).

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.

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