

## **ANNEX 1 TO ISO/TMB 58/2003 Rev.1**

### **GLOBAL RELEVANCE OF ISO TECHNICAL WORK AND PUBLICATIONS**

#### **1 Introduction**

The formation of the WTO and the subsequent adoption of the WTO Technical Barriers to Trade Agreement (WTO/TBT), placed an obligation on ISO to ensure that the International Standards it develops, adopts and publishes are globally relevant. In Annex 4, paragraph 10 of the Agreement, the following criteria state that a globally relevant standard should:

- Effectively respond to regulatory and market needs (in the global marketplace)
- Respond to scientific and technical developments in various countries
- Not distort the market
- Have no adverse effects on fair competition
- Not stifle innovation and technological development
- Not give preference to characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions
- Be performance based as opposed to design prescriptive

Hence the development and adoption of an International Standard that fails to meet these requirements is open to being challenged as creating a barrier to free trade.

Noting the need to provide fuller advice to committees on global relevance, and following a request from the ISO Council, the ISO/TMB established a Global Relevance Task Force. This task force and, subsequently, the ISO/TMB have agreed on the set of principles and guidance that follows.

#### **2 Definitions**

##### **standard**

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 2:1996, ISO/IEC Directives, Part 2: 2001)

##### **international standard**

standard that is adopted by an international standardizing/standards organization and made available to the public.

(ISO/IEC Guide 2 :1996, ISO/IEC Directives, Part 2:2001)

##### **International Standard**

international standard where the international standards organization is ISO or IEC.

(ISO/IEC Guide 2:1996, ISO/IEC Directives, Part 2:2001)

## **global relevance**

required characteristic of an International Standard that it can be used/implemented as broadly as possible by affected industries and other stakeholders in markets around the world.

(TMB agreed definition)

## **3 Principles**

### **3.1 The status and meaning of an International Standard shall be respected.**

Any International Standard shall respect the above definitions and shall to the extent possible represent a unique international solution. In cases where unique international solutions are not possible for specific provisions of an International Standard at the current time due to legitimate market and essential differences, International Standards may present options to accommodate these differences where justified (see principles 3.4 and 3.5 below).

### **3.2 The commitment to participate in the development of and the feasibility of preparing International Standards shall be demonstrated at the outset of a standards development project.**

It is recognized that in some instances various solutions exist to meet unique aspects of the local markets in different regions and countries. With globalization and the unification of markets, these market differences should be minimized over time and evolve into one global market. But simply projecting one solution that accommodates one market (but not others) as the International Standard will not force markets to evolve and coalesce. In such cases, the markets and their related industries will look elsewhere for standards that better accommodate their needs, and ISO will lose its relevance for those markets and industries. Rather than force such a situation, ISO committees should ascertain at the outset of a project whether:

- a) a globally relevant International Standard presenting one unique international solution in all of its provisions is feasible;
- b) an International Standard is feasible that presents options in specific provisions to accommodate existing and legitimate market differences where justified; or
- c) the preparation of a globally relevant International Standard is not feasible and work should not be undertaken in such circumstances.

When evaluating proposals for new work, committees shall identify the stakeholders involved and shall ensure their commitment to participate in the development of an international standard consistent with the definitions in Clause 2 above. Committees shall also identify any factors which may impact the feasibility of reaching agreement on an International Standard that is globally relevant and shall carefully evaluate such factors before deciding to undertake new work.

Furthermore, proposers and committees should take advantage of the option to propose preliminary work items, registered at stage 0, in order to work within the committee to evaluate the feasibility of global relevance and to identify stakeholders and ensure their commitment to participate prior to formal submittal and voting on a new work item proposal.

In order to support effective new work item proposal submittals and voting to support these global relevance principles, the ISO/TMB is currently considering the further development of ISO Form 4 (New Work Item Proposal) and ISO Form 5 (Vote on a New Work Item Proposal) as well as the acceptance criteria for new work item proposals that are presented in Clause 2.3.5 of the ISO/IEC Directives, Part 1.

In cases of doubt, or if a P-member of a committee believes that a committee has taken decisions which will render a particular ISO publication inappropriate for use in certain markets, and this concern cannot be resolved within the committee the Technical Management Board may be asked to review the details of these cases in order to provide advice/direction to the committee concerned.

### **3.3 Preference shall be given to preparing performance rather than prescriptive standards.**

Please note the following:

Annex 3 of the WTO/TBT Agreement

“I. Wherever appropriate, the standardizing body shall specify standards based on product requirements in terms of performance rather than design or descriptive characteristics.”

ISO/IEC Directives, Part 2, Clause 4.2 Performance approach (Excerpt)

“Whenever possible, requirements shall be expressed in terms of performance rather than design or descriptive characteristics. This approach leaves maximum freedom to technical development. Primarily those characteristics shall be included that are suitable for world wide (universal) acceptance. Where necessary, owing to differences in legislation, climate, environment, economies, social conditions, trade patterns, etc., several opinions may be indicated.”

Given these quotations, the use of the performance-based approach is widely recognized as supporting the development of globally relevant ISO standards. In the case of design-based standards, the freedom for further technical innovation is most limited, while performance-based standards provide for maximum freedom for further innovation. However, in practice, there may be cases where inclusion of design requirements for some provisions within a performance-based standard is appropriate. There may also be other cases where development of a completely design-based standard may be appropriate and will result in a globally relevant ISO standard. Thus, which approach is most appropriate depends on the technical matter in question. Additional guidance on when to use each approach is under consideration by the ISO/TMB.

If the performance approach is adopted, care is necessary to ensure that important features are not inadvertently omitted from the performance requirements.

In the case of materials, if it is impossible to determine the necessary performance characteristics, the material may be specified but preferably with inclusion of the words "or other material which has been proved to be not less suitable".

Requirements concerning the manufacturing process shall usually be omitted in favour of tests to be made on the final product. There are, nevertheless, some fields in which reference to the manufacturing process is needed (for example, hot rolling, extrusion) or even in which an inspection of the manufacturing process is necessary (for example, pressure vessels).

### **3.4 Given existing and legitimate market differences, an International Standard may pass through an evolutionary process, with the ultimate objective being to publish, at a later point, an International Standard that presents one unique international solution in all of its provisions.**

Under this principle, a committee may wish to consider how it addresses current and potentially changeable differences in markets (based on factors such as legislation, economies, social conditions, trade patterns, market needs, scientific theories, design philosophies, etc.) in the ISO deliverables it produces, using the following approaches:

**3.4.1** A committee may wish to publish an ISO deliverable that relates regional or national distinctive aspects to respective regional or national standards that address those aspects, thereby “cataloguing” those differences and standards. This approach does not merit publication as International Standard and should be pursued as an ISO TS or TR as an interim step to understand differences in the evolution toward an International Standard providing one unique international solution.

**3.4.2** Where an International Standard for a global market is not achievable from the outset, a committee may wish to publish a performance-based International Standard supported by regional or national standards. If a design is carried out using a national or regional standard supporting such an International Standard, the design may be deemed to satisfy the performance requirements of the International Standard. One could generalize the issue by noting that the principle of verifiability means that every performance requirement has to be testable and, in particular, countries and regions may use their own national and regional standards to do the testing. Provided the results are considered to be equivalent, the fact that the test methods may be different should not be an issue. Under this approach, the concerned committee must ensure the International Standard does provides performance-based requirements and cannot be regarded as an “empty shell”. International Standards developed under this approach will support technical innovation by not imposing specific design solutions on the manufacturers, but will leave the market open to different possible solutions. Over time, it may be expected that one solution will emerge as the global solution to the set of performance requirements. In this way, this approach would contribute to an ongoing effort and commitment by the committee to narrow the differences and work towards one International Standard providing one unique international solution.

**3.4.3** A committee may wish to provide options for specific provisions within an International Standard due to market differences around the world. It is the ISO/TMB’s expectation that international agreement on as many of the provisions as possible would be captured in the International Standard in the form of performance-based requirements. When the committee agrees that options (e.g. different classes; tests) need to be presented for specific provisions of the International Standard, the number of options should be as few as possible. The intent is to capture and accommodate market dynamics, not regional or national differences. As a market may cross borders and encompass a region or a number of countries, consolidation of market dynamics is desirable to reduce redundancy in the document and confusion in the use of it. The options to address different market dynamic s may take the form of (a) parallel normative clauses in the main body text, (b) parallel clauses in normative annexes, or (c) parallel sub-parts (with each sub-part representing a specific market). Whichever form the options take, the committee will ensure that all options are treated equitably. Over time, it may be expected that markets will evolve and one global market will be established. In this way, this approach would contribute to an ongoing effort and commitment by the committee to work towards one International Standard providing one unique international solution.

**3.4.4** When there is clear commitment to harmonize competing national and regional solutions towards one International Standard, committees may also consider publication of competing national and regional solutions as Technical Specifications or Publicly Available Specifications. This should only proceed when there is ongoing effort and commitment by the committee to work towards one International Standard providing one unique international solution.

**3.5 Essential differences consistent with Annex 3 to the WTO Agreement on Technical Barriers to Trade can be included in International Standards, but specific rules shall be applied if a committee wishes to introduce such differences and special authorization needs to be given by the TMB in instances not covered by these rules.**

Under this principle, a committee may wish to consider how it addresses essential differences in markets around the world, that is, factors that are not expected to change over time, such as imbedded technological infrastructures, climatic, geographical or anthropological differences. Please see Annex 1 to this document for specific details regarding the inclusion of essential differences in ISO standards.

**3.6 Committees can only ensure the global relevance of the International Standards they produce if they are aware of all the factors that may affect a particular standard's global relevance.**

For this reason, please note the following:

1. The ISO Council has approved a comprehensive report and set of recommendations to enhance the participation of developing countries in ISO technical work. The specific projects recommended in this report will be pursued within the ISO system in the coming years, including a series of projects that the ISO/TMB will advance.
2. The ISO/TMB has developed and issued guidance for twinning arrangements in ISO technical work so that the needs of developing countries in particular can be taken into account during the ISO standards development process.
3. All member bodies should take the opportunity of DIS voting to submit votes and comments on standards relevant to their national economies to help committees ensure their global relevance.
4. The ISO/TMB has agreed to issue an implementation survey to all ISO members following publication of ISO standards in order to gather input to support better-informed decisions on the systematic review of ISO standards. This implementation survey will enable the committee to consider relevant input from ISO members that do not participate on the committee.
5. While experts from certain countries that use the ISO standards or the related products may not participate for any number of reasons, it could be expected that the participating committee leaders, delegates and experts should be aware of the specific market needs of non-participating countries. Certainly, manufacturers of products are very aware of their market needs, in all markets where they sell their products. Therefore, representatives of these manufacturers that do participate as leaders, delegates and experts have a particular responsibility to bring this knowledge into the process.
6. Information on the specific needs of markets should be documented in the sections of a technical committee's business plan on description of the market environment, objectives of the committee and strategies to address the objectives, and risk assessment or consideration of factors affecting the completion of the committee's standards or their implementation and adoption world-wide. This information captured in the committee's business plan will be valuable to guide future standards development efforts.

## **ANNEX 1**

### **IMPLEMENTATION OF ESSENTIAL DIFFERENCES IN ISO STANDARDS**

#### **A.1 General**

Essential differences, based on factors that are not expected to change over time, such as imbedded technological infrastructures, climatic, geographical or anthropological differences, may be included in the normative elements of an International Standard.

NOTE Essential differences based on alternative sizing can also be included in a standard according to Annex E of the ISO/IEC Directives, Part 2.

The meaning of essential differences in requirements does not imply different side-by-side standards and the procedure is to be applied only in those cases where the TC/SC agrees on the achievement of a substantial degree of harmonization with most of the other requirements in the ISO existing and under development standards.

As a general rule, essential differences shall be specified in the context of the specific conditions that make them necessary (e.g. in countries in which the electricity supply is 60 Hz, in regions in which the average daytime temperature is less than  $x$  °C, in tropical countries etc.), rather than making specific provisions for particular countries.

#### **A.2 Proposing the inclusion of essential differences in ISO standards**

All proposals to reflect essential differences in International Standards must be requested by a P member of the concerned committee, and this request must be presented to the P members of the committee for approval.

If a P member is not pleased with the decision of the committee on including the requested essential difference, the ISO appeal procedure will apply (ISO/IEC Directives, Part 1, Clause 5).

Each proposal for essential differences in requirements, including its technical and market justification, shall be submitted at the earliest possible stage (NWIP) and at the latest at the CD stage, for inclusion in the DIS.

#### **A.3 Voting on DIS or FDIS**

When voting on a DIS or FDIS containing essential differences in requirements in the normative part of the standard, ISO members shall not take the inclusion itself of such differences as the sole reason for a negative vote. All negative votes related to essential differences in requirements, at any stage (NWIP, DIS, FDIS), must be accompanied by a technical /market justification.

#### **A.4 Revisions of existing ISO standards**

For a revision of an existing standard a proposal for including essential differences, with justification, shall be sent by a P member to the relevant TC/SC Secretary, who will then present this request to the P members of the committee for consideration.

## **A.5 Implementation issues**

The ISO/TMB shall establish a system for monitoring the inclusion of essential differences in requirements in ISO standards.

A review of this procedure should take place two years after its introduction for implementation.

The TMB/DMT shall review the existing procedures in order to accommodate the above.

An extensive training and information programme should be implemented for TC/SC officers, not just on essentially differences, but on global relevance overall.