



## **ISO/TMB IMPLEMENTATION GUIDANCE GLOBAL RELEVANCE OF ISO TECHNICAL WORK AND PUBLICATIONS**

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### **INTRODUCTION**

This document is intended to provide practical and easy-to-understand guidance to ISO committee leaders as well as ISO national body delegates and experts to assist in their implementation of the concept of Global Relevance in the development of ISO International Standards.

This document is structured in a Questions and Answers format. As this is a companion document to the ISO/TMB Policy and Principles Statement on Global Relevance, the questions and answers have alphanumeric designators that indicate linkages to the appropriate provisions of the ISO/TMB Policy and Principles Statement.

### **QUESTION #1**

#### **WHY IS THE GLOBAL RELEVANCE OF ISO INTERNATIONAL STANDARDS IMPORTANT?**

##### **ANSWER #1**

The formation of the World Trade Organization (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 Second Triennial Review 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 ISO International Standard that fails to meet these requirements is open to being challenged as creating a barrier to free trade. For many years, there has been a general philosophy that an ISO International Standard represents a consensus of those who participated in its development. As a result, some ISO International Standards have been published which respond only to particular regional requirements while other countries and regions continue to use the standards that have been traditionally followed in those countries and regions. Moreover, in some instances, ISO International Standards have been published that are not appropriate for application in some countries.

### **QUESTION #2**

#### **HOW DOES ISO DEFINE “GLOBAL RELEVANCE”?**

##### **ANSWER #2A**

The ISO/TMB Policy and Principles Statement defines global relevance as "the required characteristic of an International Standard that it can be used/implemented as broadly as possible by affected industries and other stakeholders around the world".

**QUESTION #2B**

**CAN THE USE OF ISO STANDARDS DIFFER IN DIFFERING MARKETS, AND IF SO, HOW DOES THIS RELATE TO THE GLOBAL RELEVANCE OF ISO INTERNATIONAL STANDARDS?**

**ANSWER #2B**

It is important to recognize that the way ISO International Standards are used in various markets can vary considerably. In some countries, the practice is to adopt suitable ISO International Standards as national standards, while in the European Union, ISO International Standards that are approved as European Standards are not only adopted as national standards by the CEN members, but all conflicting national standards are withdrawn. In other countries and regions, ISO International Standards can be used without national adoption and can co-exist with other national and domestic standards. In these cases, the market players choose which standards to use in any particular context. In some economies in transition, where "standards" have traditionally enjoyed the status of technical regulations, it has been agreed that ISO International Standards are acceptable alternatives to those technical regulations.

The way that an ISO International Standard will be used in a particular market, country or region is not a reason to give less weight or consideration to the views of that market, country or region. The aim of the ISO/TMB is to ensure the development of globally relevant ISO International Standards that can be used in any market, country or region.

**QUESTION #3.1A**

**IS IT POSSIBLE TO ALLOW FOR OPTIONS TO BE PRESENTED IN ISO INTERNATIONAL STANDARDS AND OTHER DELIVERABLES TO SUPPORT THEIR GLOBAL RELEVANCE?**

**ANSWER #3.1A**

Yes, the use of options in ISO International Standards to address market and essential differences is possible, and further implementation guidance related to use of these options is presented later in this document.

**QUESTION #3.1B**

**COULD THE INTRODUCTION OF OPTIONS IN AN ISO INTERNATIONAL STANDARD TO SUPPORT GLOBAL RELEVANCE ACTUALLY UNDERMINE COMMITMENTS TO INTERNATIONAL STANDARDIZATION AND THE GOAL OF "ONE STANDARD, ONE TEST, ACCEPTED WORLDWIDE"?**

**ANSWER #3.1B**

The ISO/TMB's global relevance principle 3.1 states that "The status and meaning of an International Standard shall be respected". Therefore, the ISO/TMB has reconfirmed that any ISO International Standard shall to the extent possible represent a unique international solution. However, in reality, the desirable goal of "One standard, one test, accepted worldwide" is only achievable if a further element exists as a precursor: one global market or requirement. In cases where unique international solutions are not possible for specific provisions of an ISO International Standard at the current time due to legitimate market, societal and essential differences, ISO International Standards may present options to accommodate these differences where justified. 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 differences should be minimized over time and evolve into one global market. Simply projecting one solution that accommodates one area (but not others) as the ISO International Standard will not force evolution and coalescence. In such cases, affected parties will look elsewhere for

standards that better accommodate their needs, and ISO will lose its relevance for those parties.

#### **QUESTION #3.2A**

**WHEN SHOULD AN ISO COMMITTEE ASSESS WHETHER IT IS FEASIBLE AND WHETHER THE ISO COMMITTEE IS COMMITTED TO DEVELOPING A GLOBALLY RELEVANT ISO INTERNATIONAL STANDARD?**

#### **ANSWER #3.2A**

The ISO/TMB's global relevance principle 3.2 states that: "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." Therefore, when voting on new work item proposals, ISO committees should make these assessments and apply them in decisions on whether or not the projects go forward. It is understandable that ISO committees wish to produce documents; in fact, that is why such committees exist and they do wish to be seen as productive. However, rather than force a situation that results in an ISO International Standard projecting one solution that accommodates one market (but not others), ISO committees must take serious decisions at the outset of a project whether:

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

For existing standards, all ISO committees shall consider their global relevance at the next systematic review of each standard and make appropriate revisions to ensure global relevance.

#### **QUESTION #3.2B**

**WHAT PRACTICAL GUIDANCE EXISTS TO ASSIST ISO COMMITTEES AND ISO MEMBER BODIES TO ASSESS FEASIBILITY AND COMMITMENT TO GLOBAL RELEVANCE AT THE OUTSET OF A PROJECT?**

#### **ANSWER #3.2B**

The ISO/TMB Directives Maintenance Team is currently reviewing and revising the ISO forms related to new work item proposals (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. This will support proposers and ISO member bodies voting on such proposals to better focus on global relevance concerns as they address new work item proposals, and it will support the ISO committee moving forward when feasibility and commitment to global relevance is documented.

It is expected that the revised new work item proposal forms will make it explicit that:

- Proposers shall to the extent possible identify in their proposals any factors which may impact the feasibility of reaching agreement on an ISO International Standard that is globally relevant;
- The proposal should contain information to explain on strong commitment to produce a globally relevance standard will be accomplished where there are several regional or national standards in existence. Ideally, the proposal should include comment from the regional or national standards bodies with relevant standards on the proposal and any significant issues that would prevent consensus on an International Standard

- Member bodies, by voting approval on a new work item proposal understand they are confirming that:
  1. they agree there is a market need for an ISO International Standard on the proposed subject; and
  2. they are aware of no factors which prevent the development of a globally relevant ISO International Standard.

For systematic reviews/revisions of existing standards, a report should be provided that outlines progress towards one international standard since the last review and how further progress might be achieved. Again, comment from regional and national standards bodies with relevant standards regarding significant issues that would prevent consensus on an international standard. The ISO/TMB should consider and take appropriate action on any cases that show no progress being made toward one international standard.

The objective is to consider whether global relevance might be achieved within a reasonable period (say 5-10 years depending on review period) or whether the international standard is of such value that its withdrawal would materially harm trade and the other objectives of global relevance (in other words are we better off having something that is accepted widely but not universally, rather than withdrawing the international standard).

The requirement to achieve global relevance means that committee officers will in future need to exercise a lot more judgment than has been the case in the past and that the process cannot simply rely on the counting of votes.

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.

When evaluating proposals for new work, committees shall identify the stakeholders involved and shall ensure their commitment to participate in the development of an ISO International Standard.

When the NP approval criteria have been met, and no potential impediments to the achievement of global relevance have been identified, a new work item may be registered in the program of work of the committee. If the approval criteria are met, but a number of factors that may inhibit the achievement of global relevance have been identified, a further feasibility study shall be carried out. If the study shows that the factors in question can be addressed, for example, through the inclusion of options in the ISO International Standard, then the new work item may be registered in the work program of the committee and no further new work item proposal vote is needed. If on the contrary, the feasibility study shows that there are irreconcilable obstacles to the preparation of a globally relevant ISO International Standard, then the new work item proposal shall be considered to have failed.

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 ISO Technical Management Board may be asked to review the details of these cases in order to provide advice/direction to the committee concerned.

**QUESTION #3.3A**

**WHY DOES ISO/TMB GLOBAL RELEVANCE PRINCIPLE 3.3 STATE: "PREFERENCE SHALL BE GIVEN TO PREPARING PERFORMANCE RATHER THAN PRESCRIPTIVE STANDARDS"?**

**ANSWER #3.3A**

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.

**QUESTION #3.3B**

**WHAT ADDITIONAL PRACTICAL IMPLEMENTATION GUIDANCE EXISTS RELATED TO THE DEVELOPMENT OF PERFORMANCE STANDARDS?**

**ANSWER #3.3B**

Requirements for a product should be specified in terms of the performance requirements needed to ensure fitness for purpose rather than specifying the design, materials, construction etc. that will guarantee the performance of the product.

In some instances, such an approach may be the only realistic way of achieving international standardization. For example, in a number of fields, it has been recognized that, because of long-standing design traditions and philosophies, it will not be possible to harmonize existing national and regional design codes to produce an internationally accepted design code. In such cases, performance standards have been or are being developed and the national and regional codes are considered to be "deemed-to-satisfy" methods of meeting the performance requirements of the International standard.

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).

**QUESTION #3.4**

**HOW DOES THE ISO/TMB DEFINE MARKET DIFFERENCES THAT CAN BE REFLECTED IN ISO DELIVERABLES WHEN THERE IS AN EXPECTATION TO EVOLVE TO ONE INTERNATIONAL SOLUTION IN THE FUTURE?**

**ANSWER #3.4**

The ISO/TMB defines market differences as those current and potentially changeable differences in markets that are based on factors such as legislation, economies, social conditions, trade patterns, market needs, scientific theories, and design philosophies.

**QUESTION #3.4.1**

**MAY AN ISO COMMITTEE PRODUCE AN ISO DELIVERABLE THAT RECOGNIZES REGIONAL AND NATIONAL MARKET DIFFERENCES AND THE REGIONAL OR NATIONAL STANDARDS THAT ADDRESS THOSE DIFFERENCES?**

**ANSWER #3.4.1**

Yes, 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 Technical Specification (TS) or Technical Report (TR) as an interim step to understand differences in the evolution toward an International Standard providing one unique international solution.

**QUESTION #3.4.2**

**MAY AN ISO COMMITTEE DEVELOP A PERFORMANCE-BASED ISO INTERNATIONAL STANDARD SUPPORTED BY REGIONAL OR NATIONAL STANDARDS, SUCH THAT IF A DESIGN IS CARRIED OUT USING A NATIONAL OR REGIONAL STANDARD, THE DESIGN MAY BE DEEMED TO SATISFY THE PERFORMANCE REQUIREMENTS OF THE INTERNATIONAL STANDARD?**

**ANSWER #3.4.2**

Yes. 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 provide 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.

#### **QUESTION #3.4.3**

**QUESTION #3.1A ABOVE ESTABLISHED THAT AN ISO INTERNATIONAL STANDARD MAY PRESENT OPTIONS FOR SPECIFIC PROVISIONS DUE TO MARKET DIFFERENCES AROUND THE WORLD. IS THERE ANY PRACTICAL IMPLEMENTATION GUIDANCE AVAILABLE FOR ISO COMMITTEES ON HOW TO PURSUE THIS?**

#### **ANSWER #3.4.3**

Yes. However, it is the ISO/TMB's expectation that international agreement on as many of the ISO International Standard's provisions as possible would be captured 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 and constitute only a minority of the requirements in an ISO International Standard.

Such options should however be limited to the conditions set out in the policy statement and an International Standard should not be developed without there being a specific consensus about the main points to be included. 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 dynamics may take the form of:

- parallel normative clauses in the main body text;
- parallel clauses in normative annexes; or
- 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 equally.

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.

#### **QUESTION #3.4.4**

**IS IT POSSIBLE TO PUBLISH ISO DELIVERABLES REFLECTING COMPETING NATIONAL AND REGIONAL SOLUTIONS?**

#### **ANSWER #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 (TS) or Publicly Available Specifications (PAS). 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.

**QUESTION #3.5**

**WHAT ARE ESSENTIAL DIFFERENCES AND HOW MAY THEY BE IMPLEMENTED IN ISO INTERNATIONAL STANDARDS?**

**ANSWER #3.5**

The ISO/TMB Global Relevance Principle 3.5 states: "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, differences 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 implementation procedures regarding the inclusion of essential differences in ISO standards.

**QUESTION #3.6**

**REGARDING ISO/TMB GLOBAL RELEVANCE PRINCIPLE 3.6, WHAT HAS BEEN DONE, IS BEING PURSUED OR CAN BE DONE SO THAT COMMITTEES CAN BE AWARE OF ALL THE FACTORS THAT MAY AFFECT A PARTICULAR STANDARD'S GLOBAL RELEVANCE?**

**ANSWER #3.6**

The participation of all relevant ISO member bodies is seen as a major factor in supporting global relevance. However, developing countries especially have difficulty acquiring the capability, expertise and resources to participate, even when an ISO committee's work is important to their national commercial interests. 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 are being pursued within the ISO system in the coming years, including a series of projects under the ISO/TMB.

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.

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.

It is recognized that in some instances, impediments to the implementation of an ISO International Standard by a country or region will only be recognized during the process for adoption of the International Standard as a national or regional standard. To cater for such cases, the ISO/TMB has agreed that the first systematic review of any ISO International Standard should be carried out among all ISO member bodies three years after its publication. The purpose of this review is inter alia to receive feedback from the member bodies as to whether an ISO International Standard is being used in their country and if so whether it has been found necessary to modify the ISO International Standard. All such modifications will be referred back to the responsible committee so that it can determine what course of action needs to be taken to improve the global relevance of the next edition of the ISO International Standard. For example, during a conference several years ago, it was reported that a number of ISO International Standards dealing with ergonomics were not suitable for use in Southeast Asia because the ISO International Standards were based on anthropometric parameters appropriate to the populations in Europe and North America but not appropriate to the populations in Southeast Asia.

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 and perhaps even an ethical duty under the ISO Code of Ethics to bring this knowledge into the process.

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**

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### **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.