

ISO Policy on Global Relevance

Resources related to ISO's Policy on Global Relevance include:

[ISO/TMB Policy and Principles Statement](#) – A brief introduction to ISO's Policy on Global Relevance and the set of principles agreed upon by the ISO/TMB and the ISO/TBM Global Relevance Task Force.

[ISO/TMB Implementation Guidance](#) – A Question and Answer document, issued by the ISO/TMB, intended to give practical and easy-to-understand guidance to ISO Committee Leaders and Participants in relation to ISO's Policy on Global Relevance.

[Key Messages for Committee Leaders and Participants](#) – A summarization of ISO's Policy on Global Relevance for ISO Committee Leaders and Participants.

[Guidance on the Implementation for CEN Standardization](#) – An informational copy of the guidance provided to CEN/TC Secretaries and European experts regarding Global Relevance.

[Presentation: ISO Policy on Global Relevance](#) – An ISO Presentation, including related speaker notes, elaborating on the background and implementation of ISO's Policy on Global Relevance.



ISO/TMB POLICY AND PRINCIPLES STATEMENT

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 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 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 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.

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. 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 globally relevant International Standard presenting one unique international solution in all of its provisions is feasible;

an International Standard is feasible that presents options in specific provisions to accommodate existing and legitimate market differences where justified; or

the preparation of a globally relevant International Standard is not feasible and work should not be undertaken in such circumstances.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB's Global Relevance Implementation Guidance document.

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 practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB’s Global Relevance Implementation Guidance document.

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.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB’s Global Relevance Implementation Guidance document.

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.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB’s Global Relevance Implementation Guidance document.

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.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB’s Global Relevance Implementation Guidance document.



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

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

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.

KSO 1.6: ISO'S GLOBAL RELEVANCE POLICY

KEY MESSAGES FOR COMMITTEE LEADERS AND PARTICIPANTS

- **ISO's Global Relevance Policy is vital to ISO's international credibility.**

The WTO/TBT Committee has detailed the following criteria for 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.

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. As a result, the ISO Technical Management Board developed ISO's Global Relevance policy and related implementation guidance to assist committees in their work.

- **First and foremost, recognize the ultimate goal of producing a globally relevant International Standard.**

Any International Standard 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, in a limited number, to accommodate these differences where justified.

- **Understand the distinctions between market differences and essential differences.**

Market differences result from those factors affecting international consensus that are regarded as potentially changeable (such as legislation, economies, social conditions, trade patterns, market needs, scientific theories, design philosophies, etc.). Essential differences result from those factors that are not expected to change over time, such as imbedded technological infrastructures, climatic, geographical or anthropometric considerations. Options in ISO International Standards may accommodate either market or essential differences.

- **Seek to achieve global relevance in the same way you achieve consensus.**

The ISO Global Relevance policy compels each committee to more carefully consider the value of the standards that it provides, and while voting, members of committees have to consider that value from the perspective of all concerned parties. "One standard, one test, accepted worldwide" is a laudable goal, but it is only achievable if another element exists as a precursor: one global market. Evolving dynamics mean that a single global market does not yet exist in all cases. All committee leaders and participants must keep at the forefront of their considerations the commitment to global relevance in the course of taking consensus decisions within the committee.

- **Demonstrate the commitment and feasibility of preparing a globally relevant International Standard at the outset of the project.**

Providing one solution that accommodates one market (but not others) as the International Standard will not force markets to evolve and coalesce. This may cause markets and industries to look elsewhere for standards that better accommodate their needs. ISO will lose its relevance for those markets and industries. Therefore, ISO committees should determine at the outset of a project whether:

- a globally relevant International Standard presenting one unique international solution in all of its provisions is feasible;
- an International Standard is feasible that presents options in specific provisions to accommodate existing and legitimate market or essential differences where justified;
- an interim ISO deliverable (ISO/TS or ISO/TR) is feasible when there is no immediate likelihood of reaching agreement on an International Standard, but an International Standard is considered feasible at a future time; or
- the preparation of a globally relevant International Standard is not feasible and work should not be undertaken in such circumstances.

Committees are encouraged to form TC-level new work item review groups to explore proposals for new ISO standards at a very preliminary stage to investigate, understand and document the global relevance feasibility of new work item proposals before they are advanced for voting. Further guidance on TC new work item review groups is provided in a separate ISO/TMB guidance document.

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

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.

Be active in recruiting participation from unrepresented parts of the world where the committee's work has a significant national commercial impact. Find opportunities for twinning and partnering between developed and developing countries to support effective participation. All ISO members, even those that are not participating members of the committee, may submit positions during DIS and FDIS voting as well as during systematic review to bolster the global relevance of the ISO standards.

Furthermore, it can 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 a duty to bring this knowledge into the committee's deliberations.

- **Limit options and treat them all equally.**

As the ultimate goal is to produce as much as possible a unique international solution, or to evolve to one over time, the number of options in a standard should be as few as possible and constitute only a minority of the requirements in an ISO International Standard. The intent is to capture and accommodate market dynamics and essential differences, not regional or national differences, as a market may cross borders and encompass a region or a number of countries. 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 of International Standards (with each sub-part representing a specific market).

Whichever form the options take, the committee will ensure that all options are treated equally.

- **To understand the real global relevance of International Standards on an ongoing basis, we must understand where and how they are used.**

According to the PDCA method, it would be valuable for ISO's stakeholders that the ISO system make optimal use of the systematic review process to document the real worldwide acceptance and use of International Standards. Through improvements to the systematic review process and promotion of effective implementation of it:

- TC/SCs shall take the information resulting from the ear systematic review as input for the next revision of the standard; and
- If an ISO standard is accepted as useable (that is, there is no impediment to its use at the national level), each member body should make its best efforts to withdraw and/or modify conflicting national standards.

Furthermore, a world mapping of where each International Standard has been accepted would be useful information to industry, and this could be easily provided by ISO on its web site.

Further information and guidance is provided in the ISO/TMB Global Relevance Policy Implementation Guidance document.

**Guidance on the implications of the ISO Global Relevance policy
for CEN standardization**

Edition 2 - 25th August 2006

This document is intended to provide guidance to CEN/TC secretaries and European experts taking part in CEN and ISO activities. It has been prepared by CEN/BT WG 152 "Global relevance", under the Convenorship of UNI (Italy), and its principles were discussed within the ISO Technical Management Board and agreed by ISO/CEN Joint Co-ordination Group before its approval by the CEN Technical Board (Resolution BT 59/2005).

This is Edition 2 of the guidance. Paragraphs where text has been modified (added, changed or deleted) from the previous edition are shown by a vertical mark in the left margin.

1. ISO Global Relevance policy

ISO/TMB Resolution 1/2003 committed ISO to ensuring the "Global relevance" of its standards.

Global Relevance is the characteristic of an ISO standard through which "it can be used/implemented as broadly as possible by affected industries and other stakeholders in markets around the world". Ideally, an ISO standard should represent a single international solution that applies to all countries and can be applied by all countries. At European level, the application of the Global Relevance approach is intended to lead to ISO standards which can be adopted as identical European standards. This is in line with the commitment of CEN to adopt common EN ISO standards whenever possible.

If a single international solution cannot be found for certain elements of the ISO standard at the time of drafting, the ISO policy allows an ISO/TC or SC to include 'options' in the standard in order to achieve its global relevance. These 'options' are intended to reflect market differences. However, such differences should not be permanent and so should be expected to disappear over time. If the elimination of market differences cannot be foreseen at the start of drafting, the ISO/TC or SC should not attempt to develop an ISO standard but should use another deliverable instead (such as the ISO Technical Specification).

ISO/TMB has drafted a policy document (see Annex 1), a guidance as a collection of FAQs and a presentation, which explain the implementation of the "global relevance of standards" principles and the involvement of P-Members in the handling of market differences¹ and essential differences² in the procedure for new work item proposals and standards drafting. ISO also recommends recurring to other deliverables as an interim step, rather than definitely giving up the publication of an ISO standard.

2. Europe in the global market

Acknowledging that, in the global market, the impact of European standardisation and its relationship to European Union legislation can become a source of market differences, the CEN/BT accepted the need to study the effects of the ISO Global Relevance policy on the CEN system and the European market. CEN acknowledges that, in the past, it has not always been possible for the European members of ISO to support the parallel development of EN ISO standards which were not in line with the requirements of European legislation (i.e. New Approach directives).

Hence CEN/BT WG 152 examined the possibilities that could be explored in cases where the existence of European legislation does not allow a single technical solution in an ISO standard to be applicable to Europe. The evaluation of the possibilities was carried out taking into account the following elements:

- the application of ISO Global Relevance policy;
- the simplicity for the CEN and ISO parties involved in the drafting process;
- the clarity and transparency for the standard user;
- the user-friendliness for the market;
- the reference to conformity assessment;
- the risk of proliferation of national exemptions.

¹ Defined by ISO as "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".

² Defined by ISO as the "differences that are not expected to change over time, such as imbedded technological infrastructures, climatic, geographical or anthropological differences".

3. General application of ISO Global Relevance policy

In developing an ISO standard, consideration should be given as to whether the single technical solution proposed is applicable to all countries and can be applied by all countries. Committees are encouraged whenever possible to use a performance-based approach in the development of the standard and to ensure that all interested parties have opportunity to contribute to its development.

Where a single technical solution is not possible because of market differences, options can be included in the ISO standard, with a note specifying the market for which the options are intended. These options can appear:

- either in the main body of the standard;
- or in normative Annex A.

If this is not possible, the largest common denominators should be reflected in an ISO standard with the market differences addressed through two or more ISO/TSs.

If the market differences are believed to be permanent, an ISO standard should not be developed. The ISO committee should instead consider developing an alternative deliverable (e.g. ISO/TS).

4 Consequences for CEN

4.1 Principles

The opportunities to apply ISO Global Relevance policy at CEN level should be a matter of discussion within the CEN Technical Committees, in order to allow the European market to express its needs. If the choice is to pursue the development of a common CEN and ISO standard in parallel under the Vienna Agreement, whenever possible, the aim should be to prepare a common ISO/CEN standard representing a single technical solution (Route A).

If this is not possible due to existing market differences at European level, options can be included in the ISO standard, with a note specifying the market(s) to which the options apply (i.e. Europe). The EN ISO standard should also draw the attention of the user to the option that is applicable in Europe through explanation in the European foreword.

These options can appear:

- either in the main body of the standard (Route B1);
- or in normative Annex A (Route B2).

If this is not possible, the largest common denominators should be reflected in the ISO standard and an ISO/TS developed to address the European market difference. This ISO/TS could be adopted as an EN in the CEN collection in order to support the core EN ISO standard (Route C).

Alternatively, an EN could be developed in CEN to support the core EN ISO standard (Route D).

The CEN Technical Committee should pay careful attention to those cases where the EN ISO standard is intended to support European legislation. In addition to the guidance in this document, CEN/TCs are advised to seek the help of the CEN Consultant(s).

4.2 The Routes to follow

See also the flowchart attached as Annex 2.

Route A

Single technical solution

Every effort shall be made to develop a globally relevant ISO standard representing a single technical solution in order for the EN ISO standard to be identical to the ISO standard in content and application.

If this result is not possible, the following Routes may be considered.

The order in which the Routes appear reflects the order in which they should be considered.

Route B1

Diverging requirements addressed through different normative clauses

In this case, the text of the ISO standard addresses the diverging requirements through parallel normative clauses. Each clause should be accompanied by a note specifying the market(s) to which the clause applies (e.g. Europe).

This will allow the adoption by CEN of an EN standard identical to the ISO standard (i.e. an EN ISO standard), either after publication of the ISO standard or in parallel with the adoption of the ISO standard.

WARNING - the European Commission will not recognise an EN ISO standard containing options as a harmonized standard, providing a presumption of conformity, unless ALL options comply with the essential requirements of the related Directive(s).

Unless there is absolute certainty during the DRAFTING of the ISO standard that ALL options do comply, it is recommended that Route C is considered as the first alternative to Route A if the EN ISO standard is intended to support a New Approach Directive.

>

Route B2

Additional requirements addressed through a normative Annex

In this case, the text of the ISO standard addresses the additional requirements through the use of a normative Annex. Reference to the Annex is made in a normative clause in the main text of the standard using the following wording: *“In some markets, the additional requirements listed in the normative Annex X apply.”*

This will allow the adoption by CEN of an EN identical to the ISO standard (i.e. an EN ISO standard), either after publication of the ISO standard or in parallel with the adoption of the ISO standard.

WARNING - the European Commission will not recognise an EN ISO standard containing options as a harmonized standard, providing a presumption of conformity, unless ALL options comply with the essential requirements of the related Directive(s).

Unless there is absolute certainty during the DRAFTING of the ISO standard that ALL options do comply, it is recommended that Route C is considered as the first alternative to Route A if the EN ISO standard is intended to support a New Approach Directive.

>

Route C

Diverging requirements addressed through separate ISO Technical Specifications

In this case, the text of the ISO standard contains only core requirements that are applicable to all regions.

Diverging market requirements are dealt with in separate ISO Technical Specifications (ISO/TSs). One ISO/TS should address the particular requirements of the European market.

In cases where the EN ISO standard is intended to support European legislation, the ISO/TS addressing the particular requirements of the European market should be adopted as an EN to complement the core EN ISO standard.

Note: the ISO/TSs should add few requirements to the core ISO standard. Hence the ISO standard must not be an “empty shell”, acting simply as a ‘bridge’ for the different ISO/TSs.

Route D

Additional requirements addressed through a separate EN

If particular European requirements cannot be addressed in ISO in accordance with Route C, it is possible to publish a separate EN in support of the core ISO standard. But, noting the commitment of CEN to the primacy of international standardisation, this Route is not preferred or recommended.

4.3 Failure to agree at ISO level

If, after all alternatives have been considered and after exhaustive efforts, no agreement is possible at the ISO level on the development of an ISO standard that is globally relevant, the ISO/TC should abandon development of an ISO standard and consider the development of an alternative deliverable (e.g. ISO/TS, ISO/TR).

If development of an ISO alternative deliverable is not pursued – or if it does not meet the needs of the European market - CEN is free to pursue the development of its own deliverable (EN, CEN/TS, CEN/TR or – in the case of a CEN Workshop – a CWA).

However, the CEN technical body should keep developments at the ISO level under regular review in order to use future opportunities that may be presented to achieve a common ISO and CEN deliverable.

The primacy of international standardization must be respected at all times.

ANNEX 1

1. ISO/TMB POLICY AND PRINCIPLES STATEMENT

2. GLOBAL RELEVANCE OF ISO TECHNICAL WORK AND PUBLICATIONS

2.1 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 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 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 that follows.

2.2 2 Definitions

2.2.1.1 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)

2.2.1.2 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)

2.2.1.3 International Standard

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

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

2.2.1.4 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)

2.3 3 Principles

2.3.1.1 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.

2.3.1.2 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. 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 globally relevant International Standard presenting one unique international solution in all of its provisions is feasible;

an International Standard is feasible that presents options in specific provisions to accommodate existing and legitimate market differences where justified; or

the preparation of a globally relevant International Standard is not feasible and work should not be undertaken in such circumstances.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB's Global Relevance Implementation Guidance document.

2.3.1.3 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 practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB's Global Relevance Implementation Guidance document.

2.3.1.4 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.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB's Global Relevance Implementation Guidance document.

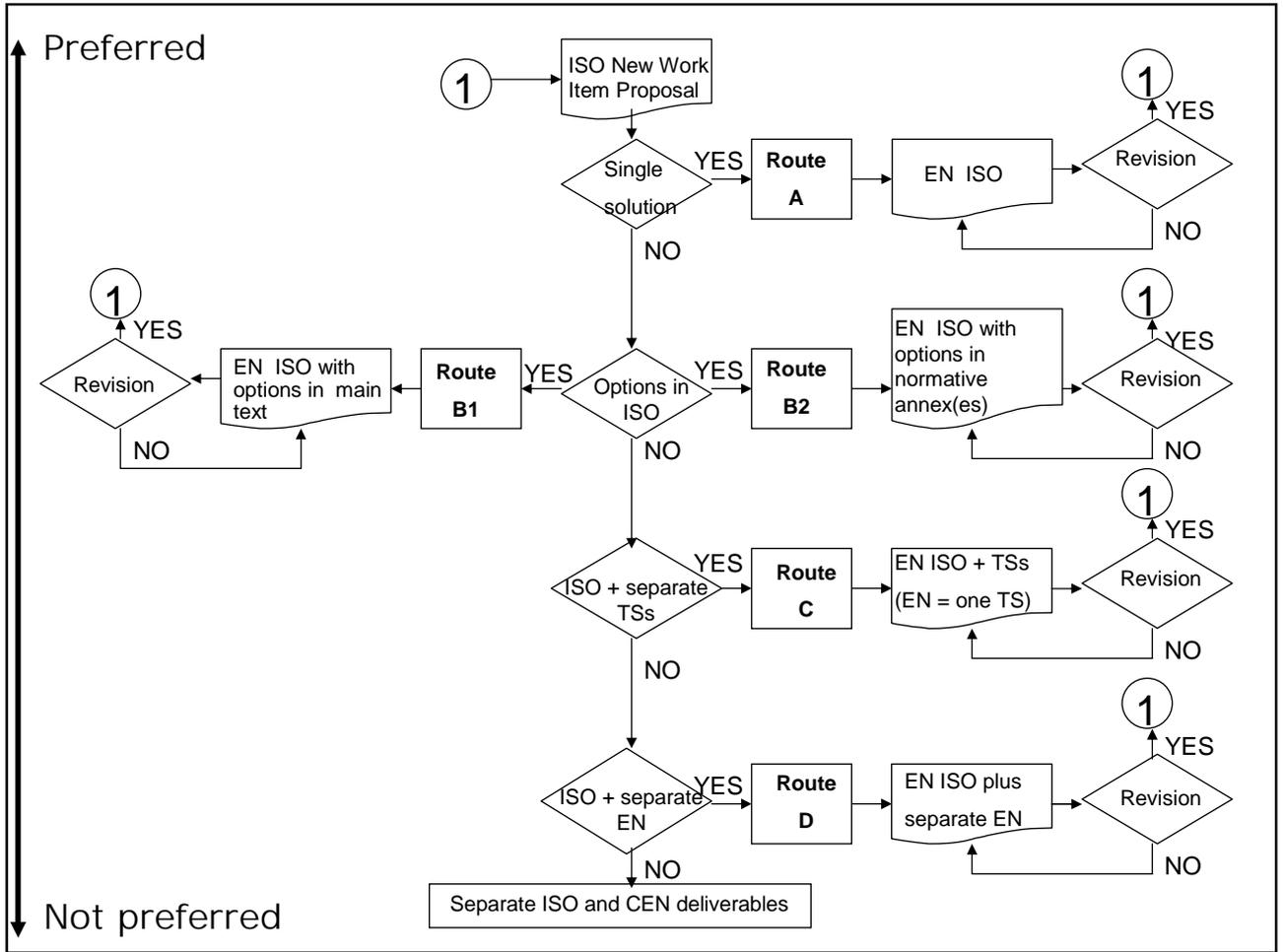
2.3.1.5 3.5 Essential differences consistent with Annex 3 to the WTO Agreement on Technical Barriers to Trade can be included in International Standards, but specific rules shall be applied if a committee wishes to introduce such differences and special authorization needs to be given by the TMB in instances 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.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB's Global Relevance Implementation Guidance document.

2.3.1.6 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.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB's Global Relevance Implementation Guidance document.





ISO Policy on global relevance

What is global relevance?

Strive to achieve a unique solution

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

TMB resolution 1/2003

TMB policy statement and implementation guidelines

During a conference several years ago, it was reported that a number of International Standards dealing with ergonomics were not suitable for use in South Eastern Asia because the International Standards were based on anthropometric parameters appropriate to the populations in Europe and North America.

After thorough debates and discussions on the subject, the ISO Technical Management Board (ISO TMB) approved a resolution in 2003 giving a definition of global relevance.

The TMB has defined 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 in markets around the world"*. A lofty characteristic of standards but one the TMB is implementing through the introduction of certain checks and balances within the development process. The aim is ultimately to improve the use and applicability of resulting ISO deliverables in world markets.

In the TMB policy statement, the first principle indicates that "the status and meaning of an International Standard shall be respected". This recalls that the first and most preferable objective of any standardization effort should be to develop a single international solution to the problem.

The ISO TMB global relevance policy details principles consistent with WTO principles, along with implementation guidelines, to ensure that ISO standards:

- respond effectively to global regulatory requirements, market needs and scientific/technical developments;
- do not distort markets nor have adverse effects on fair competition;
- do not stifle innovation or technological development;
- do not give preference to the requirements of specific countries or regions; and
- are performance-based rather than design-prescriptive.

Why is global relevance important ?

- **Growth in international trade**
 - USD 2 000 billion (1980) to USD 6 500 billion (2000)
- **Regional initiatives**
 - European Union, APEC...
- **ISO standards**
 - More than 15 600 published in 59 years
 - 20 countries vote on average
- **Developing countries**
- **And WTO/TBT**

Why is global Relevance important?

First of all, we need to keep in mind the huge increase in international trade since 1980. The biggest growth in history. There is some caution that the benefits of international trade could be compromised by regional initiatives such as those pursued by the European Union and the Asia-Pacific Economic Co-operation (APEC). It seems also interesting to recall that ISO has published more than 15 600 standards in its 59 year history. But, bearing in mind the fact that only 20 countries on average vote on the adoption of an ISO standard, how many are actually globally relevant? And how many can be used, particularly in the developing countries?

Global relevance and WTO

In order to serve the interests of the WTO [...] in facilitating international trade and preventing unnecessary trade barriers, international standards need to be relevant and to :

- Effectively respond to regulatory and market needs
- Respond to scientific and technological developments in various countries

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 second Triennial review of the operation and implementation of the Agreement, dated 13 November 2000, the following criteria state that an international standard needs to be, in order to serve the interests of the WTO membership in facilitating international trade and preventing unnecessary trade barriers, relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries.

Global relevance and WTO (cont.)

- Not stifle innovation and technological development
- Not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions
- Be performance-based rather than based on design or descriptive characteristics
- Not distort the global market
- Have no adverse effects on fair competition

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.

Who needs to be aware of this policy ?

- Bodies proposing new work items
- ISO committee chairs, secretaries, delegates and WG experts
- The TMB

Primary targets of this new policy are:

- Bodies proposing new work items;
- ISO committee chairs and secretaries responsible for the management and progression of their work programmes;
- Delegates to ISO committees presenting national positions on issues and seeking to ensure that the standards they support are relevant to their country, their region and to the global market;
- Working group experts in ISO committees to ensure that proposed text in draft standards has worldwide applicability and considers performance-based requirements versus design characteristics;
- the TMB itself to monitor and take action on the policy's implementation.

How do we achieve global relevance? Determine the factors that affect global relevance

- **Evaluate feasibility of global relevance:**
 - Stage 0 and feasibility study before launching a new proposal (NP) ballot
- **When voting on a NP :**
 1. Market needs are recognized
 2. No potential impediments to the development of a globally relevant standard

Committees can only ensure the global relevance of the International Standards they produce if they are aware of factors that have the greatest impact on their implementation. The TMB sees active feedback and participation from members as essential to discovering which countries have an impediment in the use of particular standards and why. To this end, the TMB has established that the first systematic review of an ISO Standard be carried out among all ISO members  years after its publication. The purpose is to determine usage and attempt to discover what modifications are necessary for the Standard to be implemented in countries that have not yet adopted or used the Standard.

In addition, ISO committees are encouraged to review and document their specific market profiles and needs in their Business Plans. These may then serve as an important reference point for their work when developing future requirements that acknowledge, address and evolve with market and essential differences in order to develop truly globally relevant ISO Standards.

The implementation paper of the policy statement on global relevance of ISO technical work and publications approved by the TMB meeting recommends:

Given the variety of approaches to adopting and implementing standards around the world, industry has options and may look elsewhere for standards that better accommodate their needs, thus compromising relevance and use of the ISO Standard on a global scale. ISO committees should therefore determine, at the outset of a project:

1. Is a globally relevant ISO Standard presenting one unique international solution in all of its provisions feasible?
2. Is an ISO Standard that presents options in specific provisions to accommodate existing and legitimate market differences (where justified) feasible?
3. That the preparation of a globally relevant International Standard is not feasible and therefore the work should not be undertaken?

To assist committees in this task, the TMB is currently revising relevant instructions for new work (Forms 4 and 5) to allow Proposers and ISO member bodies to focus on global relevance issues in their consideration of new subjects.

How do we achieve global relevance?

Gain the commitment of all interested parties from the outset!

- Manufacturers
- Users
- Test houses and conformity assessment operators
- Regulators
- Socio-economic partners
- Developed and developing countries

...and their participation

Consequently before starting any work :

Committees should ascertain the feasibility of preparing a globally relevant International Standard before work is undertaken. In case of doubt, says the paper, this can easily be done with the approval a preliminary work items at stage 0 and thus a feasibility study can be made before launching a NP ballot. (article 3 of the implementation paper)

When voting approval on a NP, member bodies, are confirming thus that :

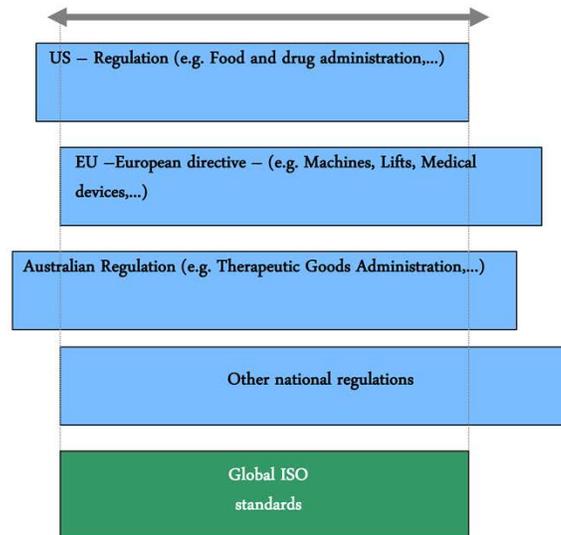
- 1.They agree **there is a market need for an International Standard on the proposed subject,**
- 2.They are **aware of NO factors** which prevent the development of a globally relevant International Standard.

How can we achieve global relevance?

The need for commitment of all interested parties **BEFORE** the work is started shall not be disregarded. Not only that, but their participation too.

How do we achieve global relevance? Governmental requirements and standards

Harmonization by cooperation outside and within ISO



How can we achieve global relevance?

Remembering that in some committees, standards do not exist in a vacuum but a legal environment, it is essential that the standards work takes account of regulations. This is particularly true in some TCs, where there is a great need to consider existing national and/or regional regulations in the work.

How do we achieve global relevance?

Performance over prescription!

- **Go the performance route**
 - Horizontal approach
 - Fewer commercial conflicts
 - Facilitates innovation
 - Standards require less frequent revision
- **Avoid “empty-shell” standards**

Performance over prescription!

This principle reinforces existing requirements in the WTO Agreement on Technical Barriers to Trade and the ISO/IEC Directives for the drafting of International Standards. The use of performance-based requirements, versus specific design requirements, may inherently improve the global acceptability of an ISO standard. Innovation and advancement can be inhibited when design criteria are locked into standards until their next revision. That's not to say design criteria should be prohibited in ISO standards. There may be cases where inclusion of design requirements for certain provisions within a performance-based standard is appropriate and universally applied. For example, when detailing materials for a product, design requirements may well be specified but consideration should also be given to including statements such as "or other materials meeting similar minimum yield strength, hardness, etc", as applicable to the desired performance of the material. This may well accommodate advances in material characteristics that may not have been available at the time the standard was written.

Preference shall be given to preparing performance rather than prescriptive standards

As recognised by the TMB in its policy statement , the message is clear. We have to go the performance route and not write prescriptive standards. This actually being in line with Annex 3 of the WTO/TBT Agreement. Some TCs are already particularly successful in pursuing horizontal standards which lead to fewer commercial conflicts, facilitate innovation and require less frequent revision. Under this approach, the concerned committee must ensure the International Standard does provide performance-based requirements and cannot be regarded as an “empty-shell”.

How do we achieve global relevance?

Performance over prescription! (cont.)

- **And what about market differences ?**
 - One option is an alternative deliverable (e.g. ISO/TS)
 - As 'stepping stones' to an ISO standard
 - If the TC is convinced of the feasibility of an International Standard



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.

There are a number of ways in which this may occur.

It is worth recalling that the ISO/IEC Directives permit competing solutions to co-exist in such interim deliverables, but they are not allowed to conflict with International Standards. It has been agreed, in cases in which practices are such that different national and regional standards exist and there is no immediate likelihood of reaching agreement on an International Standard, that such national and regional solutions may in the first instance be published as interim deliverables. A committee may wish to publish an interim 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. TMB has advocated the use of these alternative deliverables **as stepping stones to an ISO standard BUT ONLY IF an ISO standard can indeed be one day achieved.**

Options

Consider an evolutionary process to address market differences that evolve over time

- **Be flexible in approach**
 - One size does not fit all
- **Deemed to satisfy performance approach**

Options – Consider an evolutionary process to address market differences that evolve over time

There is certainly a need to be flexible in our approach. One size does not fit all. In some instances, various solutions may already exist to meet markets in different regions and countries. However, over time, factors such as increased globalization should minimize these differences and eventually evolve into more local approaches into a single market. For example, simply using a solution within an ISO Standard that accommodates only one region (but not others) does not force markets to evolve and grow together.

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.

Options (cont.)

Consider an evolutionary process to address market differences that evolve over time

- **Options in the Standard ?**
 - **if** LEGITIMATE REASONS
 - **but** limited : Optional requirement should constitute only a MINORITY of the requirements in an International Standard
 - **the intent** is to capture and accommodate market dynamics, **not regional or national differences**

Committees may also establish options for specific provisions due to market dynamics and differences, keeping in mind that only a catalogue of national and regional approaches is not intended. The TMB expects that single-approach, performance-based requirements would comprise most of a Standard and that such options would make up only a minority of requirements within the Standard. These options may be presented in parallel clauses in the Standard's main body, in normative annexes or sub-parts. It should be noted that some of these 'market' differences also reflect 'essential differences' (e.g., climate) that are less changeable over time.

It is the ISO/TMBs expectation that international agreement on as many of the provisions as possible would be captured in the International Standard in the form of a performance-based requirements.

When the committee agrees that options 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.

Over time, market evolution will enable the creation of one global market.

In this way, this approach will contribute to an ongoing effort and commitment by the committee to work towards one International Standard providing one unique solution.

Options (cont.)

Consider an evolutionary process to address market differences that evolve over time

- **How to address different market dynamics ?**
 1. Parallel normative clauses in the main body text
 2. Parallel clauses in normative annexes
 3. Parallel sub-parts

Whichever form the options take in the International Standard, the committee must ensure that all options are treated equally.

Essential differences

Apply rules for dealing with essential differences

- **Essential differences in markets = factors that are not expected to change over time:**
 - Imbedded technological infrastructures
 - Climatic differences
 - Geographical or anthropological differences

Essential differences – Apply rules for dealing with essential differences

Essential differences that are consistent with Annex 3 of the WTO Agreement on Technical Barriers to Trade can be included in International Standards (e.g., imbedded technological infrastructures, climate, geography, anthropometry) under specific rules. Such differences do not evolve much over time and so the opportunity for committees to harmonize or develop a single solution is very limited.

Essential differences

Apply rules for dealing with essential differences (cont.)

• How to include them in International standards ?

- To be requested by a P member, at the earliest possible stage
- Request submitted to the P members of the TC/SC for approval
- **To be specified in the context of the specific conditions :** “...*in countries in which the electricity supply is 60Hz, in regions in which average daytime temperature is less than x°, in tropical countries etc,...*”

Rather than specific provisions for particular countries

1. Essential differences :

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 60Hz, in regions in which average daytime temperature is less than x°, in tropical countries etc.) **rather than making specific provisions for particular countries.**

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.

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.

3. Voting on DIS and FDIS Standards containing essential differences - ISO members are not to put forward the inclusion of an essential difference itself as the sole reason for a negative vote.

4. Proposing essential differences in existing Standards - P-Members may send proposals for essential differences in existing standards, with justification, to their TC/SC secretary for circulation and consideration by the Committee.

5. Implementation issues - TMB to monitor implementation, review the procedure after two years, communicate the policy and provide for training on global relevance.