

# **Report from the Informal Working Group on ANSI/European Cooperation**

## **Introduction**

Since 1989, the annual meetings between ANSI and the European standards organizations have proved invaluable in promoting a bilateral dialogue on the issues dominating the contemporary standards agenda. The initial focus of the dialogue was on the creation of a Single European Market and the role of the European standards bodies in supporting the New Approach. More recently, the focus has moved on to the differences in the approaches of Europe and the United States to standardization and technical regulation, particularly within the context of the WTO/TBT Agreement.

At the 17<sup>th</sup> meeting, held in Washington DC in November 2002, the discussion evolved to encompass the Global Relevance of International Standards.

Although the meetings are not intended to achieve a common position on particular issues, or even a common understanding, the importance of a dialogue between interests from the two most significant trading areas in the world is clear. Both the United States and Europe have a commitment to fostering international trade between all regions of the globe. But it is a fact that the well-being of international trade is dependent to a large extent upon the relationship between Europe and the United States.

The same holds true of international standardization.

It was with this thought in mind that Jacob Holmblad, as Vice-President Technical of CEN and Chairman of the CEN Technical Board, wrote to Mark Hurwitz, the President and CEO of ANSI, shortly after the 17<sup>th</sup> meeting in Washington DC. Reflecting on the tensions that are at times apparent between the United States and Europe in international standardization, and particularly those that affect CEN and its national members, he proposed the creation of a small group to explore the causes. Dr Hurwitz welcomed the proposal and so the informal working group was born.

The informal working group met twice during 2003: 3 & 4 April in Brussels and 26 & 27 June in Washington DC. This dialogue was continued through correspondence. In its talks and in developing its recommendations, the informal working group has been informal and acted as a 'think tank'.

Its members have not carried briefs from the ANSI or CEN management committees and have acted as individual experts. Most importantly, its work has been done with a view to complementing discussions within the ISO framework, most notably on Global Relevance.

Its recommendations are now presented to CEN and ANSI ahead of the 18<sup>th</sup> meeting between ANSI and the ESOs in January 2004.

## **Overview**

A century ago, standards were tools which aided the construction of national infrastructures. Today, common standards are a recognized means through which trade across international and regional boundaries can be facilitated.

Two notable examples are the New Approach to technical harmonization and standardization, one of the foundations upon which the Single European Market is built, and the use of international standards in aiding the implementation of the WTO/TBT Agreement. As a consequence, standardization has become politicized.

Two particular factors are considered by the informal working group to influence the relationship between Europe and the United States: 'misconception, misperception and myth' and Global Relevance. The informal working group also considered communications and opportunities for common work in the future.

### 1. 'Misconception, misperception and myth'

The politicization of standardization and the increasing importance of standards in supporting international trade have encouraged a mistrust between different international players. There is a fear that each side is out to best the others in the international debate; an expectation that some will find reasons not to accept what is accepted by the rest.

Such mistrust is evident in the relationship between the United States and Europe, breeding misconception, misperception and myth.

For instance, although the achievement of a Single European Market is viewed by European countries as an historic step forward in the liberalization of trade, some in the United States see it as the creation of an inward-facing trading bloc. The misconception is that the bloc is founded upon European standards from which non-European involvement is excluded.

Similarly, there is a perception in Europe that the failure of the United States to commit to the adoption of ISO standards reflects a failure to commit to ISO when the United States, through ANSI, is actually the largest single contributor to ISO and its work.

Hence the informal working group considered it important to develop a 'perceptions document'. The document lists the most common charges made against the United States by Europe, and against Europe by the United States. In each case, an answer to the charge has been made. The informal working group believes that the document should be further developed and made available by CEN and ISO as a means of dispelling some of the more persistent myths which tarnish the relationship between the United States and Europe. It is appended as Annex 1.

Of course, some issues raised by Europe or the United States cannot be explained in terms of misunderstanding or misconception. There are concerns which arise from genuine grievance. These are issues that have to be addressed through the CEN and ISO management bodies. Indeed, the informal working group would welcome the introduction of an early dispute resolution mechanism in both ISO and CEN to resolve such issues as quickly as possible. Too often, positions become entrenched later in the process leading to the inevitability of a formal appeal.

And sometimes the perception is indeed true, although it may well prove to be outside the power or the competence of the standardizers to change or challenge the cause.

## 2. Global Relevance

Much of the informal working group discussion focused on the debate initiated in ISO and IEC on the meaning and intent of Global Relevance. The informal working group confirmed Global Relevance to be a tangible issue and not one of perception. And it is one within the competence of standardizers to address.

The past President of ISO, Mario Cortopassi, defined his term of office with the 1:1:1 dream: one standard, one test, one conformity assessment procedure – accepted everywhere. The informal working group believes a further element should be added as a precursor – one global market.

Although the achievement of a global market may be the goal of business and government alike, markets at both regional and national level sometimes feature unique aspects to meet specific local needs. These needs can arise from historical economic, social or

infrastructural causes or from the local environment (e.g. climatic conditions). Whatever the cause, the key commonality is that it cannot be removed easily over time.

In the push towards globalization, the existence of legitimate market and essential differences has perhaps been overlooked by those active in the international standardization community.

But the consequence is stark. Standards must reflect and respect the market infrastructure. Standards cannot dictate the market infrastructure. The imposition of one solution through an International Standard will not force a global market to form where it does not exist. Instead, market interests will find the solutions needed to respond to their local needs elsewhere. And international standardization will become less market relevant.

The informal working group welcomes the decision of the ISO Technical Management Board at its Buenos Aires meeting to define principles for the implementation of Global Relevance (TMB Resolution 65/2003 endorsing Annex 1 to document 58/2003 Rev 1). These principles accord with the thinking of the informal working group. Indeed, the informal working group hopes that its discussions contributed in some way to the agreement that was achieved in Buenos Aires and hence does not hesitate to reproduce the TMB document as Annex 2 to this report. The informal working group notes the acknowledgement of ISO that:

- ISO should only embark on the development of a normative document if an ISO standard representing one solution is considered feasible over time;
- performance standards should be developed in preference to prescriptive standards;
- the progression to an ISO standard representing one solution can be facilitated through:
  - the use of regional (or national) standards to support an (interim) ISO standard (for example, such regional or national standards defining design may support an ISO standard which defines performance);
  - the use of options or classes within an (interim) ISO standard;
  - the use of 'competing' ISO Technical Specifications as 'stepping stones' to an ISO standard.

The informal working group believes the decision of TMB to represent a more holistic approach to standardization within ISO which can only benefit all regions of the world and aid the inclusion of the needs of developing countries within the responses of the international standards community. Hence the informal working group urges that the

clearest guidance is given to the experts who participate in ISO committees and working groups on the implementation of the principles agreed by TMB.

The informal working group welcomes the contribution made by the Vienna Agreement to the common objectives of ISO and CEN since its inception in 1991. The informal working group recognizes, however, that CEN needs to advise its committees and working groups on the implications of the TMB decision for items being developed in parallel under the Vienna Agreement, particularly those under CEN lead. Common problems need common solutions. It therefore welcomes the decision of the CEN Technical Board (in Resolution BT 10/2003) to establish CEN/BT WG 152 in order to give guidance to CEN technical committees. The informal working group further welcomes the decision of CEN to base this guidance on that being prepared in ISO for ISO committees (which it understands will be submitted for approval to TMB on 27 & 28 January 2004).

Of course, the informal working group recognizes that guidance alone will not be sufficient to answer all issues related to Global Relevance but it does consider that the initiative taken by the ISO and CEN management bodies will free the ISO Central Secretariat and the CEN Management Centre to address problems of particular complexity.

### 3. Communication

Discussions within the informal working group confirmed the well-known understanding of those closely involved in the formal standardization community that communication between the central secretariats of the international and European standards organizations and their members on the one hand, and those who participate in the technical committees on the other, needs to be strengthened. Too often, the significant decisions of the management bodies are either not communicated to the leaders and experts at the 'grass roots' or not understood in a way that permits consistent implementation.

For example, the informal working group notes that the value of the so-called 'new deliverables' (such as the ISO Technical Specification and the International Workshop Agreement) as alternative solutions to the formal standard is often unappreciated. Certainly within ISO, use of new deliverables appears to have been limited. Of course, the opposite could also be true. Leaders and experts might well understand the limitations of new deliverables and be reluctant to use them but, if so, this is not being communicated back to the management bodies.

Similarly, if the introduction of timeframes for ISO standards is to be successful in driving down development times further, leaders and committee members must be alert to manage their work programs according to the resources available.

There must also be a discipline which ensures that work is only adopted when a committee is confident that it is market relevant and has the resources behind it which will allow it to be delivered within the chosen timeframe.

The same need for awareness applies to Global Relevance.

The informal working group appreciates that both ISO and CEN have taken great steps within their management bodies to provide committees with the strategic tools needed to work faster and better. But, without encouraging a cultural change, these tools will not deliver all that might be expected. And cultural change cannot be achieved without clear and precise communication. Sadly, the informal working group believes such communication is not present for the moment.

The informal working group has no elixir to address the problem of communication. As acknowledged earlier, it has been something of an eternal challenge to all in the standardization community. But, in a modern age of ever-increasing expectation, and of both wired and wireless technologies, it is a challenge which needs to be faced once more. The informal working group therefore recommends that ISO and CEN consider how best to ensure an efficient and effective means of communication between their management bodies and those who serve in their committees can be established. This consideration should cover what could be achieved through training as well as communiqué.

#### 4. Working together

As the informal working group confirmed during its work, the United States and Europe are each striving for the common objectives of timelier and more market relevant standards, both together in ISO and separately at regional and national level. But, despite such common objectives, there remains some distrust and fear, part of which arises from the different systems of regulation and standardization employed, part from 'misconception, misperception and myth'.

There is no better way of building trust than through working together.

Hence, in the final stage of its discussions, the informal working group focused on new areas of co-operation that might benefit the United States and Europe. In doing so, and in accordance with the rest of its work, the informal working group did not intend that its discussions should undermine collaboration with other countries. Quite the contrary. The informal working group intended that its reflection should permit a foundation to be built on which future ISO and CEN collaboration might be possible.

The informal working group therefore welcomes the development since its June meeting of a consideration in both ISO and CEN of what is termed 'homeland security' or 'security of the citizen'.

The informal working group does not claim that its dialogue was responsible for promoting this new debate, but it believes it to be an ideal example of the new areas which the United States and Europe can both promote in advancing the welfare of all citizens of the world.

### **Conclusion**

The informal working group was established as an informal group to review the cause of some of the tensions between the United States and Europe. Its recommendations, listed in Appendix, have yet to be considered by the management bodies of ISO and CEN. But the dialogue has already proved of value.

It is not unreasonable to assert that, at the start of 2003, the United States and Europe did not share an understanding of Global Relevance or the principles through which it might be achieved. It was THE issue which dominated the agenda of the informal working group. Now a set of principles are in place which achieved the support of the European and non-European members of the ISO/TMB. TMB is developing guidelines for the implementation of these principles among its TCs. CEN will follow the ISO guidance through its BT WG 152 and adapt it as needed for CEN. Of course, individual issues related to Global Relevance will still arise, but these should be managed by ISO Central Secretariat and CEN Management Centre, taking the advice of ISO/TMB and CEN/BT as needed.

The challenge related to communication, which must include 'misconception, misperception and myth', is harder to answer. But it is one which needs to be pursued with all vigor.

In modern business language, weaknesses are said to be opportunities. If, in addressing the tensions between the United States and Europe, the informal working group has

founded a platform for future collaboration that can benefit all in the global society that will be opportunity taken. In an ever smaller world, with increasing competition for limited resource, effort must be focused on avoiding duplication and finding common solutions.



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## Recommendations

1. A document explaining the principles of the standardization systems of the United States and Europe should be developed for circulation among the ISO and CEN memberships. Its principal audience should be the participants in the technical committees and working groups of the organizations. It should focus on addressing the perceptions held by each of the standardization communities. A model is appended as Annex 1.
2. An early dispute resolution mechanism should be introduced in ISO and CEN to reduce the need for formal appeals. Its aim should be to enable concerns to be investigated as early as practicable in the process and for solutions to be established quickly as needed.
3. ISO should ensure that guidance to technical committees and working groups on the implementation of the principles of Global Relevance is made available as soon as possible. CEN should base guidance to its technical committees and working groups on the ISO model.
4. ISO and CEN should review their communication mechanisms (including training as well as communiqué) to ensure that the decisions of their management bodies, and the rationale for those decisions, are cascaded effectively to those who participate in their technical committees and working groups.
5. The United States and Europe should explore the possibilities for collaboration on new areas of work as a tool to encourage the building of trust and to facilitate the proposal of new work within ISO and/or CEN as appropriate.

## **Perceptions**

### **Part 1: Europe – Perceptions from the United States**

#### **1. The CEN members bloc vote in ISO**

This is a popular perception but one which has been disproved.

An ISO Council study of voting patterns at DIS and FDIS for votes conducted in the period 1998 to 2001 showed there was no discernable regional pattern in the 112/3563 votes (3.1%) which failed DIS or 7/2883 votes (0.24%) which failed FDIS. In other words, CEN members voted with other ISO members in the approval of drafts or were split when opposing drafts.

Similarly, ANSI studies of voting patterns at DIS and FDIS for votes conducted in the years 2002 and 2003 showed no discernable widespread regional pattern. The trend was for the European and non-European members of ISO to vote in unison, either for or against a draft standard.

Of course, similar (but not identical) practices in the CEN member countries may lead to delegates from those countries taking a common view in some ISO committees. This is understandable and not wrong.

What is wrong is for delegates from CEN member countries to insist that an ISO standard includes requirements needed solely to achieve compliance with certain European legal obligations. In such cases, the global relevance of the ISO standard may be compromised. In support of the decision of the September 2003 meeting of the ISO Technical Management Board (ISO/TMB) on the principles of global relevance, CEN will be developing advice for its members on the meaning of global relevance within ISO and the implications for CEN.

#### **2. The CEN member countries dominate ISO**

A survey conducted for ISO/TMB in 1999 showed that the CEN members held 63% of the ISO/TC secretariats, 69% of the ISO/SC secretariats and that 59% of the work program was under secretariats held by CEN members. Most of these secretariats are held by AFNOR (France), BSI (United Kingdom) and DIN (Germany). The biggest stakeholder among the ISO members is ANSI (United States) which holds 140 secretariats (DIN is next biggest with 114 secretariats). However, within the past five years, the ISO/TMB has not detected that any ISO secretariat is being managed in favor of a national or regional interest. Hence, whatever the national or regional identity of a secretariat, there is no evidence to say that any is not committed to the primacy of international standardization.

#### **3. The concept of one vote per country in ISO gives Europe an advantage**

An often heard claim is that it is unfair for the United States (275m population (2000); GNP \$7.9 trillion (1998)) to have one vote in ISO while CEN members from the European Union (373m population (2000); GNP \$8.3 trillion (1998)) have 15 votes collectively.

This presumes that the CEN members (or at least those from the EU countries) bloc vote, something which has been disproved (See above). Even within the EU, there are significant economic, cultural and infrastructure differences between countries which lead to different votes being returned (in CEN as well as ISO).

Moreover, it must be remembered that ISO is established on the United Nations principle of collective participation without favor to a single country, region or interest group. Hence its TCs and SCs are formed on the basis of representation of all interests with each country being accorded equal status. A 'weighted vote' in ISO could actually undermine the principle of global relevance which the ISO Council and ISO/TMB are now working to reinforce. In addition, successful implementation of the ISO/TMB decision on the principles of global relevance would be expected to make the possibility of dominance through voting numbers redundant. The inclusiveness of ISO standards would not be assured by weighted voting which might advantage the developed countries to the disadvantage of developing countries.

#### **4. CEN is part of the European Commission**

CEN is not part of the European Commission.

It is an independent international association established under Belgian law. Information on CEN and the CEN membership can be viewed at [www.cenorm.be](http://www.cenorm.be).

CEN presently comprises the national standards bodies from 22 countries, all of which are members of ISO. 15 of these countries are presently members of the European Union (EU) and 3 are members of the European Free Trade Association (EFTA).

The perception of CEN being part of the European Commission may arise from the issue of 'mandates' from the Commission to CEN. These invite CEN to develop European standards to support European legislation. The EFTA Secretariat may also mandate CEN.

#### **5. The use of European standards in Europe is compulsory**

Under the 'New Approach to technical harmonization and standardization', adopted in 1985, compliance with a mandated European standard (known as a 'harmonized standard') confers a 'presumption of conformity' of a product with the 'essential requirements' of the legislation (represented by a 'directive'). A product that conforms to the essential requirements may be legally sold throughout the European Economic Area (EEA), a territory comprising the EU countries and EFTA countries with the exception of Switzerland. About 15% of products in the EEA are subject to one or more directives. A list of the directives in force with lists of the harmonized standards adopted can be found at [www.newapproach.org](http://www.newapproach.org).

However, this does not mean that the use of European standards is compulsory. With one exception (the Construction Products Directive), manufacturers can demonstrate that their products conform to the essential requirements in other ways. And even in the case of the Construction Products Directive, alternative solutions to European standards are possible.

So why have harmonized standards? Quite simply, compliance with a harmonized standard should be the easiest and most cost-effective means for a manufacturer to demonstrate the conformity of a product to the essential requirements.

Use of standards in this way is not unique to Europe – the National Technology Transfer and Advancement Act of 1996 seeks to make greater use of voluntary standards in federal and state agencies within the United States.

#### **6. The European Commission funds the development of European standards**

True – in part.

Mandates are usually accompanied by ‘Order Vouchers’ which provide seed corn funding to encourage the development of the European standards. In addition to these Order Vouchers, the European Commission and EFTA Secretariat together meet 45% of the costs of CEN Management Centre (the Central Secretariat in Brussels). This funding sometimes gives non-Europeans the impression that CEN and its standardization activities are owned and funded by the EU and EFTA. However, an independent financial study, conducted in 1999, showed that EU and EFTA funding met only 2% of total costs, with over 90% being met by industry.

## **7. The European Commission drives the CEN work program**

Only about 20% of the CEN work program is mandated at any one time.

Hence 80% of the CEN work program is industry-driven and CEN regrets that many, even within Europe, do not recognize this.

## **8. CEN Consultants slow the progress of ISO work**

CEN/TCs drafting standards under mandate are advised by ‘CEN Consultants’. The task of the Consultant is to determine whether a draft standard adequately meets the requirements of a directive. CEN has made great efforts in recent years to ensure that the assessments made by Consultants do not slow progress of projects, particularly those being developed in parallel with ISO under the Vienna Agreement. But CEN acknowledges that delays do sometimes occur, particularly where the draft is complex or where more than one Consultant is involved in the assessment (as the draft is intended to support more than one directive).

## **9. The Vienna Agreement allows Europe an unfair advantage**

When the New Approach was adopted in 1985, the fear was that European industry would gradually abandon its efforts in ISO and concentrate its resources in CEN on the development of mandated European standards. It is doubtful whether ISO could have continued had such a withdrawal of resource been allowed to happen. The Vienna Agreement, adopted by ISO and CEN in 1991, was a natural and necessary response.

The Vienna Agreement, and particularly its option for the parallel development of standards in the two organizations, not only maintained the commitment of Europe to ISO but allowed ISO access to and even leadership of projects which would otherwise have been undertaken solely in CEN. The key benefit of the Vienna Agreement is that it seeks to achieve the same standard approved in both CEN and ISO (provided it is globally relevant), for the benefit of those that do business in Europe and in other parts of the world. Non-Europeans have an equal range of options under the ISO Directives to propose their standards to become ISO standards, and the newly approved ISO global relevance principles should ensure that proposals from any region or country for ISO standards pass the test of global relevance. It should also be remembered that non-European members of ISO have the right to comment on any draft European standard at the public enquiry stage (‘CEN Enquiry’).

The ‘consolidated’ Vienna Agreement, agreed by CEN and ISO in 2001, offers even more safeguards on the part of CEN to the primacy of international standardization. Up to four observers from ISO may now attend any CEN/TC or WG meeting without being required to seek agreement from CEN. And all standards developed under the Vienna Agreement are now revised in ISO, even if the original was developed under CEN lead.

## **Part 2: The United States – Perceptions from Europe**

### **1. The United States is not committed to ISO**

Not true. ANSI is the biggest single contributor to ISO and its work.

Although ANSI does not routinely adopt ISO standards as American National Standards, a great many ISO standards are used in the USA, and many ISO standards are derived from standards developed in the USA.

Just because the United States does not routinely adopt ISO standards as national standards, as Europe does for its internal market needs, does not mean ISO standards are not used. Many standards fields - such as petroleum products and lubricants, plastics, heavy equipment, mechanical contraceptives and informational technology - are actively worked on by US participants in ISO, and the deliverables are widely used by the US industry.

### **2. The United States is not committed to the withdrawal of conflicting standards**

Use and adoption of ISO standards are considered separate issues in the US. There is no broad-ranging U.S. national policy to seek adoption of as many ISO standards as possible. Within the USA, a sector-based approach allows the industry sector to determine what standards it will use. Where an industry sector chooses ISO standards, these may be nationally adopted and replace conflicting national standards or they may simply be used by industry without the need for national adoption.

Indeed most countries outside Europe have no practical need to adopt the library of ISO standards and withdraw conflicting national standards. This is because these countries do not exist in a treaty-based common market where there is a political necessity to harmonize conflicting national standards.

What works for Europe does not necessarily work for the rest of the world.

### **3. The United States wants to run or circumvent ISO**

The US wants to add value to and ensure the credibility and global relevance of the international standards system, as there are many in the US that do rely on ISO standards. ISO standards are used in the US. But the US believes that other long-established standards developers have a role which complements that of ISO in certain fields. An accommodation among the various international standards developers around the world must be reached to benefit the users of the standards.

By virtue of its extensive level of participation in ISO committees, and at the policy level, it is clear that the U.S. does not want to circumvent ISO. But the US does want to make ISO a more inclusive organization, able to increase the market relevance of its deliverables.

### **4. The United States promotes the US SDOs ahead of ISO**

As noted earlier, the United States acts on a sector-based approach and believes that other long-established standards developers have a role which complements that of ISO in certain fields. ANSI promotes the use of market relevant international standards from wherever they may originate – ISO or elsewhere.

The US features a decentralized system. ANSI accredits over 260 or so entities. Many of these have existed for well over 50 years and some for over 100 years. By comparison, ISO was formed in 1947. It is not surprising therefore that some of the US SDOs were serving an international market before ISO was established.

#### **5. The standards system in the United States is fragmented**

The US system is *decentralized* - not fragmented - as it is well-coordinated and duplication of voluntary standards in the USA rarely occurs. In the very small number of cases where duplicate efforts may be started, mechanisms exist to resolve them. In the end, given limited resources to support standardization activities, stakeholders will not provide the financial and expert support for duplicate initiatives, and they will choose one into which they will pour their support.

For the United States, a decentralized system brings many strengths, not weakness. Sectors that need standards immediately can write them; others that can wait 5 years can write them in 5 years. This decentralized standards system has served the United States, and the world, very well for over 100 years.

#### **6. The United States features differing state requirements**

True. A fact arising from the US Constitution. Different sectors are affected differently and use different strategies to address this concern. For example, in the petroleum field, the American Petroleum Institute has some 30 state offices to assist with compliance with state regulations. Also in this same field, in the case of marketing operations (gas stations, etc.) the regulations/issues are mostly local, while in other areas (pipeline transportation, exploration and production) the regulations are mostly federal.

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## 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 operation and implementation of the Agreement, dated 13 November 2000, the following criteria state that a globally relevant standard should:

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

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

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

### 2 Definitions

#### **standard**

document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

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

#### **international standard**

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

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

#### **International Standard**



international standard where the international standards organization is ISO or IEC.  
(ISO/IEC Guide 2:1996, ISO/IEC Directives, Part 2:2001)

### **global relevance**

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

(TMB agreed definition)

## **3 Principles**

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

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

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

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

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

When evaluating proposals for new work, committees shall identify the stakeholders involved and shall ensure their commitment to participate in the development of an international standard consistent with the definitions in Clause 2 above. Committees

shall also identify any factors which may impact the feasibility of reaching agreement on an International Standard that is globally relevant and shall carefully evaluate such factors before deciding to undertake new work.

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

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

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

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

Please note the following:

Annex 3 of the WTO/TBT Agreement

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

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

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

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

consideration by the ISO/TMB.

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

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

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

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

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

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

**3.4.2** Where an International Standard for a global market is not achievable from the outset, a committee may wish to publish a performance-based International Standard supported by regional or national standards. If a design is carried out using a national or regional standard supporting such an International Standard, the design may be deemed to satisfy the performance requirements of the International Standard. One could generalize the issue by noting that the principle of verifiability means that every performance requirement has to be testable and, in particular, countries and regions may use their own national and regional standards to do the testing. Provided the results are considered to be equivalent, the fact that the test methods may be different should not be an issue. Under this approach, the concerned committee must ensure the International Standard does 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.

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

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

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

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

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

For this reason, please note the following:

1. The ISO Council has approved a comprehensive report and set of recommendations to enhance the participation of developing countries in ISO technical work. The specific projects recommended in this report will be pursued

within the ISO system in the coming years, including a series of projects that the ISO/TMB will advance.

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

## **ANNEX 1**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### **A.5 Implementation issues**

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

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

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

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