



American National Standards Institute

A large globe is mounted on a white, cylindrical pedestal in a park-like setting. The globe is illuminated from below, casting a warm glow. In the background, a city skyline is visible under a blue sky with white clouds. The foreground is a green lawn with a path leading towards the globe.

**American  
Access  
to the  
European  
Standardization  
Process**

The American National Standards Institute, a nonprofit, privately funded membership organization, coordinates the development of U.S. voluntary national standards and represents the U.S. in international standards organizations. Founded in 1918, the Institute serves a diverse membership of over 1300 companies, 250 professional, technical, trade, labor and consumer organizations and some 30 government agencies. ANSI facilitates and promotes interaction between peers and competitors for mutual benefit. ANSI is well-recognized as a neutral forum with established procedures to ensure openness, due process and consensus, including mechanisms for appeals and challenges. Consensus requires that all views and objections be considered and that an effort be made toward their resolution; consensus also indicates that substantial agreement has been reached by all directly and materially affected parties.

First edition - December 1996

Published by  
American National Standards Institute  
11 West 42<sup>nd</sup> Street  
New York, NY 10036

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*Work must become a continual process of learning  
how to create our future rather than react to our past.*

-- Peter Senge  
Excerpt from "*The Fifth Discipline*"



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## Foreword

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As U.S.-based companies expand into new international markets, including countries of the European Union, they recognize that their primary concern is not traditional trade barriers – which to a large extent have been reduced, if not eliminated, through years of successful trade negotiations – but a lack of knowledge and understanding of how to successfully access and influence the European Standards Process.

The European Union's efforts toward market unification present positive opportunities for the international community because the essential objectives of international standardization at the world level and of European standardization at the regional level are the same, namely:

- to facilitate the international exchange of goods and services through the preparation of internationally harmonized (or better, identical) national standards,
- the strict implementation of such standards at a national level, and
- the withdrawal of conflicting standards.

This publication provides an overview of how U.S.-based interested parties can effectively influence and have impact upon European standardization activities. Through a series of questions and answers and examples of actual situations played out in the standards arena, this document illustrates how the U.S., via the American National Standards Institute (ANSI) and its U.S. National Committee (USNC) of the International Electrotechnical Commission (IEC), can gain enhanced access to the European standards process while promoting understanding between U.S. and European interests.

The focus of this publication will be CEN, the European Committee for Standardization, and CENELEC, the European Committee for Electrotechnical Standardization. A third European standards body, ETSI, the European Telecommunications Standards Institute, will also be discussed.





# AMERICAN ACCESS TO THE EUROPEAN STANDARDIZATION PROCESS

## Chapter 1: Introduction

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### ***Single European Market***

Recognizing the importance of free trade amongst the peoples of Europe, the member states of the European Union (EU)<sup>1</sup> approved, in 1985, a proposal to form a "Single European Market" that would remove all barriers to the circulation of goods, services, capital and labor within the European Community.

In the following years nearly 300 European Commission (EC) "Directives" have been approved to support implementation of a unified internal market. These directives are not detailed, but rather contain information regarding general "essential requirements." European regional standards setting bodies are responsible for establishing the voluntary standards, which elaborate on the essential requirements.

Standards serve as an essential component in ensuring the complete freedom of trade in merchandise across national borders. Standards bodies in the member states are obliged to adopt European standards and withdraw conflicting national standards. Harmonized, European-wide standards in key product sectors are now replacing the thousands of differing national standards that existed in member states. Today, the European standardization system has almost 5,000 standards and produces approximately five new standards per working day.

### ***"New Approach" Directives***

In the period up to 1992, and subsequently, the European Parliament has enacted a series of measures intended to put the Single Market into practice. Some of these directives have been aimed at removing barriers of a purely customs/excise nature, others have concentrated on transport arrangements to ensure the free movement of goods, while a series of directives (produced under the heading of "New Approach" Directives) are

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<sup>1</sup> The European Union was known as the European Community until the Maastricht Treaty took effect in 1993. Present members include Austria, Belgium, Denmark, France, Finland, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. In 1994, the Agreement on a European Economic Area (EEA) took effect, adding Iceland, Liechtenstein and Norway to the Single Market (although they did not join the EU). These 18 EEA countries comprise a market about the same size as the North American Free Trade Agreement (NAFTA) (United States, Canada and Mexico).

intended to provide controls on product design, with the principal objective being to provide a level playing field for product safety requirements across the European Union.

The primary function of the New Approach directives is to ensure that products are sufficiently well designed and built to be fit for the purpose for which they are sold, and that reasonable precautions are taken to protect the user against injury while the product is being used.

The New Approach directives cover a very wide range of product areas. One of the first to be implemented concerned the safety of children's toys. Subsequent directives have included provisions for machinery, electromagnetic compatibility (EMC), personal protective equipment, medical devices, gas appliances and explosives, among others<sup>2</sup>.

In the past, the EU relied on harmonized legislation to enforce common production standards, without reference to voluntary standards or a marking system. Under this "Old Approach," directives contained such a high degree of detail on the technical specifications of products, it sometimes required a decade or more to complete the technical work.

Now, the New Approach directives specify only the "essential requirements" to be met by products and that the technical specifications governing the production and marketing of products meeting the essential requirements be laid down by the relevant European Standardization Bodies.

### ***European Standardization Bodies***

Under the New Approach, the European Commission mandated that the private sector be responsible for development of European technical standards. Three regional standards organizations were assigned the task:

**CEN** the European Committee for Standardization, produces European standards in all areas except for electrotechnical and telecommunications;

**CENELEC** the European Committee for Electrotechnical Standardization, works to produce a single set of harmonized electrotechnical standards in Europe; and

**ETSI** the European Telecommunications Standards Institute, determines and produces telecommunications standards.

CEN, CENELEC and ETSI constitute a European forum for standardization that organizes participation of all parties concerned in the development and standardization programs. These parties include national government authorities, the Commission of European Communities (commonly known as the European Commission, or the EC), the European Free Trade Association (EFTA), public bodies, manufacturers, trade unions,

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<sup>2</sup> Reference Annex 1 for a list of approved New Approach Directives.

users and consumers. These parties come together in hundreds of technical groups to prepare European standards through procedures that guarantee respect for the principles of openness and transparency, consensus, national commitment, technical coherence at the national and European level, and correct integration with other international work.

Consequently, development of standards within the national bodies of the European Union essentially ceased and work was transferred into the European standards organizations. Today some development is still done nationally for those areas not European in scope.

### ***Global Markets – Global Relationships***

In a paper entitled "European Standards to build the Common Market" (1995), Mr. Jacques Repussard, Secretary General of CEN stated "standardization is one of the lesser known tools for the strengthening of economic efficiency. Standardization . . . is an instrument through which the access of new products to the European market may be accelerated, production costs reduced, and quality levels better related to the actual needs of society."

The European Economic Area (EEA), consisting of 18 member states, represents a trading partner responsible for more than 210 billion export dollars annually. U.S. organizations, then, are presented with a tempting array of global markets in which to expand their businesses. By taking an active role whenever and wherever possible, the U.S. can work to influence the development of European product and service standards so that U.S. interests are not disenfranchised from these markets.

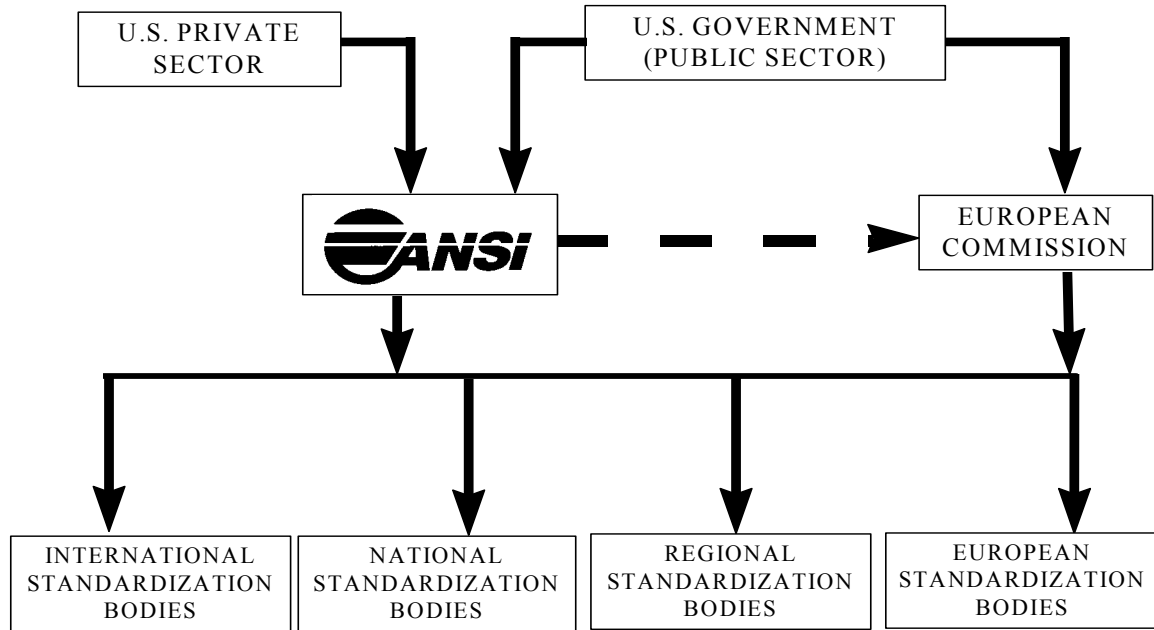
Through the American National Standards Institute (ANSI) and its U.S. National Committee (USNC) of the International Electrotechnical Commission (IEC), the U.S. has established relationships with the European standards bodies so that our domestic interests might have access to timely information and improved coordination with the European Union, effectively input to European standards development activities, and receive due consideration of U.S.-submitted contributions.

In conjunction with the efforts of ANSI, the U.S. Government, in particular the Office of European Union and Regional Affairs and the National Center for Standards and Certification Information<sup>3</sup>, ensures U.S. interests have access to information regarding activities underway in the European standards setting bodies. Through these cooperative

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<sup>3</sup> The National Center for Standards and Certification Information (NCSCI) provides information on U.S., foreign, and international voluntary standards; government regulations; and rules of conformity assessment for non-agricultural products. The Center is located at the National Institute of Standards and Technology (NIST) in the Office of Standards Services (OSS). NCSCI staff respond to inquiries, maintain a reference collection of standards and standards-related documents, and serve as the U.S. inquiry point for information to and from foreign countries. For additional information contact the National Center for Standards and Certification Information, National Institute of Standards and Technology, Bldg. 820, Room 164, Gaithersburg, MD 20899 (Telephone: 301 975-4040; Telefax: (301) 926-1559; Email: joanne.overman@nist.gov).

efforts, U.S. interested parties may work to effectively influence most international and regional standards development activities.



**Figure 1: Global Relationships**

For U.S. companies that market abroad, standards and conformity assessment are critical to survival and prosperity. Exported products and services must be accepted and function in differing cultures, value systems, and environments.

Through the "*Quick Answer*" and the "*Action Scenario*" sections discussed in the next chapters, U.S. interested parties will review opportunities and strategies for U.S. access to the European standards process. While these examples do not reflect all situations affecting U.S.-based entities, they do identify frequently raised issues and offer possible options for issue resolution.

## Chapter 2: Quick Answers

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NOTE: Most of the text in this chapter will address issues of the "Vienna Agreement" and the ISO-CEN relationships. Partly due to the success of the "Right of First Refusal" contained within the IEC-CENELEC "Dresden Agreement," IEC and CENELEC have fewer conflicts. Supporting documentation for these questions may be found in Chapters 4 and 5.

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### ***Question 1:***

*The Vienna Agreement says that my ISO Technical Committee should be receiving all relevant information distributed by the parallel CEN committee. In fact, the secretariat of the ISO committee is the same as the CEN committee (therefore, European), but I never see anything. What can I do?*

### **Answer 1:**

Write a letter to ANSI's Standards Facilitation Department (or the specific ANSI staff person with whom you regularly work) explaining what is happening (or not happening, as the case may be), and ANSI will investigate directly with the ISO Central Secretariat and the other relevant parties.

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### ***Question 2:***

*I have attended ISO committee meetings for years, and all was fine until a few years ago when CEN began receiving its direction from the European Commission. Now the Europeans have nearly disappeared from the ISO activity, saying that they can only spend their time in one place, and as they will be obliged to adopt their output as national standards, they have little choice but to work within the CEN committee. What can be done about this?*

### **Answer 2:**

Has the ISO committee consciously made a decision to move the work to CEN? If not, there is no real reason for European members of parallel ISO-CEN committees to go to CEN alone if the ISO committee is meeting European needs of timeliness (particularly when a directive is concerned). If you can't get the information you need from your ISO committee secretariat, contact ANSI's Standards Facilitation Department (or the specific ANSI staff person with whom you regularly work) and we'll investigate with ISO.

In order for work to be led by either CEN or ISO, the committees concerned must vote by ballot or resolve the matter at a meeting. The Secretariat or Chairman, particularly if it's one and the same for both ISO and CEN, cannot just stop the ISO work unilaterally. If this happens, then the ISO-CEN Joint Coordination Group (JCG) of the Technical Boards needs to be made aware of the issue so that an effort can be made towards its resolution.

ANSI's representative on the JCG would raise such issues at the ISO Technical Management Board (TMB) for inclusion on a JCG agenda.

If a similar issue arises between an IEC and CENELEC committee, the U.S. representative to the IEC-CENELEC Management Coordination Group (MCG) will raise the issue for discussion at a meeting of the MCG.

(See also Chapter 3: Safety of Toys)

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**Question 3:**

*We're constantly outvoted in our ISO committee by the Europeans. They have eight (8) Participating (P) members (i.e., votes) on the committee, and the U.S. is only one country (with one vote). This isn't fair. What can we do to level the playing field?*

**Answer 3:**

Persuade other non-Europeans with an interest in the TC/SC to become more active. There are 120 members of ISO and 95 of them have the power to vote -- only 14 are members of the European Union.

Remember, ANSI is also a member of both the Pan American Standards Commission (COPANT) and the Pacific Area Standards Congress (PASC), and has successfully convinced many former Observer or non-members of a TC/SC that it would be in their best interests to become an active member of the activity. This persuasion is usually done on two fronts:

- the technical front, where the U.S. industry sector contacts its counterparts in other countries explaining why they should be involved in the ISO technical activity, and
- the political front, where U.S. industry encourages its counterparts to contact their ISO member body, encouraging the organization to declare membership in the subject TC/SC. Concurrently, ANSI would contact its counterpart ISO member bodies with a similar message.

(Again, see Chapter 3: Safety of Toys)

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**Question 4:**

*We're a U.S. manufacturing company that exports a product to Europe. We've done this for many years. There is no American National Standard, no national standard, and no international standard. There isn't even an ISO or IEC committee working in this subject area. However, CEN has formed a technical committee which is now writing a standard that is design-based, not performance based. If approved and then adopted by the Europeans, we could be blocked out of the marketplace. Is there anything my company, or the U.S., can do?*

**Answer 4:**

In this type of situation, the only access is through ANSI into CEN. There may be strong resistance by European members (companies) of the CEN/TC to allow any participation other than written comments (which is part of the Vienna Agreement). However, ANSI can certainly raise a concern of this type with the leadership of CEN as part of the annual U.S.-European bilateral meetings. We can also use ANSI's networks to contact European members of CEN in a variety of ways (informal communications, formal written letters with technical arguments, etc.).

Please know, however, that it is difficult to get an American without a European operation a presence on a CEN working group without an ISO counterpart committee. Normally great pressure must build up before such access is given. Access is granted via the chairman of the WG, not the CEN Central Secretariat in Brussels (though CEN/CS can be instrumental in convincing a chairman of the need). ANSI has found CEN staff in Brussels to be very helpful in trying to settle problems of this type -- but it is still the CEN/TC that needs to be convinced.

Good advice for any U.S. interest facing this situation is to stay away from the "shotgun approach" – i.e., don't use too many avenues of communication to get the message across. Certainly letters to Congressional representatives, Administration officials, other government agencies, trade associations, professional societies, and ANSI will alert many of the problem, but all these entities need to be aware of the other's activities and must be coordinated in their approach<sup>4</sup>. If the U.S. industry sector agrees, ANSI could also work with that sector to form an ISO activity to do the work.

(See also - Chapter 3: Steel Drum Closures)

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**Question 5:**

*There has been an ISO committee for years, and now CEN is organizing a committee on the same subject. Why doesn't CEN just use the ISO committee?*

**Answer 5:**

This probably isn't a problem. In order for CEN or CENELEC to adopt an ISO or IEC standard directly, it must have a technical committee organized to ballot the international document. In many cases these are regional European committees that simply process the international work, and do little, if any, development work on their own.

An alternative situation is when CEN or CENELEC create a committee because there is no parallel international committee, nor interest in the international arena, to establish an activity in that subject area.

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<sup>4</sup> It should be noted that ANSI does have excellent working relations with U.S. government bodies and that ANSI coordinates regularly with the U.S. Mission to the European Union in Brussels, the International Trade Administration of the U.S. Dept. of Commerce, the National Institute for Standards and Technology, and the Office of the U.S. Trade Representative.

***Question 6:***

*My company apparently needs to get a CE Mark to legally sell its product in a European country. How do I go about getting one?*

**Answer 6:**

As this is a very sector specific subject relating to a specific European directive (e.g., Safety of Machinery, Safety of Toys, Electromagnetic Compatibility, etc.), you should go to your industry's trade association for more specific direction, or to the U.S. Government's Office of European Union and Regional Affairs (a part of the U.S. Department of Commerce). See address shown below:

Office of European Union and Regional Affairs  
U.S. Department of Commerce  
14<sup>th</sup> and Constitution Ave., NW, Room 3036  
Washington, DC 20230

Telephone: 202-492-5276

Telefax: 202-482-2155

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***Question 7:***

*How can I obtain a copy of a European Directive?*

**Answer 7:**

European directives deal with many different subjects. You could go to the trade association in your industry sector and most likely they will have a copy. You can also obtain European directives from the Office of European Union and Regional Affairs (see Answer 6 for address).

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***Question 8:***

*I understand that an ANSI delegation annually meets with several European entities. Who does ANSI meet with, and how can I participate in these meetings?*

**Answer 8:**

The annual meetings with the Europeans began in the summer of 1989 and are usually held in Brussels, Belgium. ANSI meets with the staff and/or elected executives of CEN, CENELEC, ETSI, EOTC, and officials in the European Commission that deal with standards and conformity assessment matters.

All ANSI members are welcome to join the U.S. delegation. The U.S. group is normally led by the Chairman of ANSI's Board of Directors, with company, organizational and government members in attendance as well. ANSI's President is also a part of the delegation.



Interested parties are encouraged to first participate in the U.S. public preparatory meeting before participating as part of the delegation to the bilateral meetings. Notice of the public meeting is announced in ANSI's *Standards Action* during the August/September timeframe. The dates will also appear in the Calendar of Events section of ANSI's home page on the World Wide Web (<http://www.ansi.org>).

ANSI members can always contact ANSI Standards Facilitation staff if they have unanswered questions in these areas.

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## **Chapter 3: Action Scenarios**

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This chapter contains three "Action Scenarios," i.e., examples illustrative of situations that arise from time to time.

1. The first example illustrates what can be done when European countries dominate the ISO technical committee, and do the work in CEN without direct third country input.
2. The second example tells of the experience of setting up an ISO technical committee when a CEN committee is already on the way towards developing European Standards.
3. Finally, the third example concerns the problems a U.S. company might have when CEN is developing a design-based standard that would effectively block exporting of a product to Europe, and there is no ISO or American National Standard.

As of this writing (December 1996), the second example is complete in that the ISO committee has been formed and is operating; the first and third examples are ongoing with the final outcome not yet known.

## **Safety of Toys**

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This is a case where both CEN and ISO have technical committees entitled "Safety of Toys." Denmark holds the Secretariat and Chairmanship of both CEN/TC 52 and ISO/TC 181.

Within Europe, a general Safety of Toys Directive (88/378/EEC) went into effect on January 1, 1990 which mandates that technical standards be written to support the requirements in the Directive. The CEN toy safety standards were in development prior to ISO/TC 181 being formed in 1980.

The U.S. toy industry, through Toy Manufacturers of America (TMA), was opposed to the formation of an ISO toy committee. ANSI therefore participated as an Observer member when TC 181 was formed. The toy industries in the U.S., Europe, Japan and elsewhere were concerned because the Committee was being dominated by non-toy manufacturing countries that politicized the process. They did not feel another toy safety standard was needed and the standards being developed were considered unacceptable to consumer countries as they were not based on injury data and hazard analysis.

The CEN toy safety standards were first made available in December 1988. In 1991, the Agreement on Technical Cooperation between ISO and CEN (the Vienna Agreement) officially linked CEN and ISO work, and toy safety standards being developed by CEN/TC 52 were forwarded to ISO for voting -- but not under the parallel voting process. While agreements were made in TC 181 for CEN to take the lead in ISO work on toy safety, TC 181 members never made a decision to do all the work in CEN or determined how to process the CEN output.

ANSI and the U.S. TAG become actively involved in TC 181 when the U.S. was confronted with the fact that all drafting of ISO toy standards was being done in CEN, but non-European countries had no formal status or input. The U.S. could only obtain Observer status in CEN, through ANSI's participation in ISO, although European subsidiaries of U.S. toy manufacturers were key members of the toy industry in Europe. In 1992, ANSI became a Participating member of ISO/TC 181 and the U.S. TAG was established with TMA as Administrator. U.S. manufacturers also encouraged their European subsidiaries to become more involved in CEN.

In 1995 ANSI staff met with TMA officials and planned a detailed two-prong strategy for the re-activation of ISO/TC 181. Working together, a list of ISO member bodies in TC 181 was developed and non-European countries with significant toy manufacturing facilities were identified. Based on their current status, these countries were encouraged to become Participating (voting) members or, if they already had such status, were informed of the issues and encouraged to actively participate. TMA delegations contacted their industry counterparts in these countries; ANSI concurrently contacted the standards bodies. Actual visits to several countries also took place to encourage national standards bodies and toy associations to participate. ANSI also used fora such as the Pacific Area Standards Congress (PASC) and the Pan American Standards Commission (COPANT) to raise this subject at their respective meetings, asking that interested

countries become involved in the ISO work as Participating members. As a result of all of these efforts, numerous countries changed their status or became more active.

By this time, two CEN-based toy standards had already been approved in ISO without world input at the drafting level. A third standard was then rejected in CEN, but the corresponding ISO draft International Standard was approved by a narrow margin in ISO. A new Chairman was also being proposed for ISO/TC 181 -- again a Chairman from Denmark and the same person as the Chairman of CEN/TC 52, which the U.S. found inappropriate, considering the need for more non-European input in ISO.

ANSI raised all of the U.S. concerns at the September 1995 meeting of the ISO Technical Management Board (TMB). The U.S. pointed out that ISO/TC 181 had not met in more than 12 years, and that, with increasing interest in toy safety standards from outside Europe, it was time for a meeting. While the TMB did approve the new European Chairman, it passed a resolution encouraging ISO/TC 181 to hold a meeting and to reconsider the decision that CEN/TC 52 take the lead in this field. Key toy manufacturing representatives in the U.S. and Europe then began drafting a global toy safety standard on mechanical and physical properties of toys, based on a combination of U.S. and European requirements.

During this process, ANSI, in close cooperation with TMA, wrote to the Danish Secretariat inviting ISO/TC 181 to hold its meeting in the United States. The TC 181 Secretariat accepted this invitation, and the meeting was held during November 1996 in Miami, Florida. As a result of the country-by-country outreach to encourage international participation, it was attended by a total of 49 people representing more than 17 countries.

At the meeting, the proposed global standard was approved as a Committee work item to supersede the draft international standard that originated in CEN. Another significant development was the approval of a resolution that officially broke the link between CEN and ISO in current toy safety work. The approved work item will now be edited based on input at the Miami meeting and will be further discussed at the next ISO TC 181 meeting scheduled for June 1997 in Thailand. Then, after several mandatory balloting stages, the proposed ISO standard should be finalized by the beginning of 1999.

This example shows that if a member body takes the lead in informing other non-European countries that a sector's standards are being driven by one region of the world even though the industry is global, the playing field can be leveled. There are avenues to bring the work back into ISO and, with ANSI and its members working together, the development of standards can be brought back to the international level.

If other sectors are experiencing a problem such as the one described in this case study, ANSI members should contact ANSI's Standards Facilitation Department and the Institute staff will work with you in trying to make the system work as it should.

## ***Sterilization of Health Care Products***

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The Association for the Advancement of Medical Instrumentation (AAMI) sterilization standards committee was established in 1974 to write standards, technical reports and recommended practices for industrial sterilization, hospital sterilization, and sterilization equipment. AAMI's standards were used throughout the world because of their quality, market dominance of the U.S. medical device industry, and the absence of competing international or foreign standards.

Within CEN there are two technical committees organized in this subject area, CEN/TC 102 on Sterilizers for Medical Purposes (formed in 1982), and CEN/TC 204 on Sterilization Process (formed in 1989). AAMI, through ANSI, had submitted technical comments on draft European Standards in this field, which were taken into consideration by CEN.

With increasing output from the CEN committees, the membership of AAMI felt that it was appropriate for the standardization of this field to take place in ISO, with participation from all interested countries. ANSI submitted a proposal for a new ISO technical committee to ISO, which was approved in 1990 by the then ISO Technical Board (now known as the Technical Management Board, or TMB).

This was not an open and shut case. Much persuasion had taken place by AAMI and its members around the world to gain support for this proposal, and ANSI had also spoken to many of its counterparts in ISO as well, including the Europeans. This was a case of witnessing whether the European countries would follow the oft-quoted statement "Do it once, do it right, and do it internationally."

Upon approval of the international TC, the Secretariat was assigned to ANSI, and delegated by ANSI to AAMI. One positive aspect for the U.S. was that Europe itself was divided on many key issues, and that there was support for many U.S. positions among some European nations and other ISO/TC 198 P-members. U.S. participation and leadership were welcomed by some European countries, and U.S. manufacturers often were allied with European manufacturers.

ISO/TC 198 has not been without its share of obstacles. As it was established after the CEN committees, the ISO committee was perceived as a "hijacker" or "competitor" of CEN/TC 102 and CEN/TC 204. Some interests argued that ISO/TC 198 should only adopt completed CEN standards, without change, as International Standards, other countries refused to approve ISO committee drafts that differed at all from corresponding CEN drafts.

Today, much of the standards activity in sterilization of health care products is taking place within ISO/TC 198. AAMI, early on, took an aggressive approach in getting the new ISO/TC 198 up and running, holding the first meeting only five months after the committee was officially approved by ISO, with several subsequent meetings taking

place. In only six years there are fifteen active work items and thirteen published standards.

The summary of this example is that U.S. industry can take the lead in an international standards activity, even if there is an already existing European standards activity. The homework must be done in advance of any international proposal, and the leader within the U.S. must fully commit its resources to tackle the work immediately and keep it on track. Otherwise, if CEN requires standards to meet a directive, and the ISO committee is slow to complete its tasks, CEN will simply do its work and there will be two sets of standards -- which does not constitute an ultimate international solution.

## ***Steel Drum Closures***

This is a study concerning the Rieke Corporation, a U.S. manufacturer of steel drum closures. In this example, there was no ISO committee, nor was there an American National Standard, nor a national standard in the United States.

In 1990, a CEN technical committee (CEN/TC 261 on Packaging) was formed to look at packaging standards; France was assigned both the Secretariat and Chairmanship. Some 30 working groups were formed under the parent TC, including a plastic drum group, a steel drum group, and a working group on closures for steel drums.

In 1994, the Rieke Corporation (Rieke) learned of the formation of the steel drum closure working group, and that it was close to having a prEN prepared for CEN public enquiry. Although Rieke does not export directly into the European market, the organization sells its closures to U.S. drum manufacturers, who in turn mechanically insert the closures into finished drums. The drum is then sold to a "filler"<sup>5</sup>.

Rieke's first action was to write to its representatives in Congress explaining the potential problem and asking for help. Their request for assistance was relayed to the U.S. Department of Commerce International Trade Administration, which asked the U.S. Mission to the European Union in Brussels to investigate. At this time, the U.S. Mission brought this matter to the attention of ANSI. Both the U.S. Department of Commerce and ANSI have worked closely on this case ever since.

As there was, and is, no ISO activity in this field, the only official avenue into CEN being through ANSI's commenting on the prEN when it was sent out for six-month public enquiry. As time went on, direct contact was also made between Rieke and the CEN working group convenor, through ANSI, and Rieke's comments were submitted prior to the prEN being circulated. ANSI continued to raise issues with CEN in Brussels both by correspondence and by personal meetings. ANSI also provided the U.S. Mission with CEN contacts in several European countries, and in October 1995 a Rieke representative and a DoC representative(s) visited several European standards bodies to re-enforce the message that if CEN/TC 261 proceeded with development of a design-based standard, it could have serious consequences.

At the November 1995 meeting between the ANSI delegation and CEN leaders, in Brussels, the Rieke case was raised with the ANSI delegation making it clear that the value of these bilateral meetings was to look for solutions to difficult problems, not to just follow the procedures to their ultimate conclusion. This was the case of a small company being directly, and possibly fatally, impacted by a European Standard that it had no part in developing. Clearly, this was a case of a design-based standard being written, rather than the preferred performance based standard. As a result of the December 1995 meeting, Rieke's representative was invited to the January 1996 meeting

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<sup>5</sup> A "filler" is any company using a 55 gallon steel drum to transport its liquid product. These are companies exporting into the European market through the utilization of the steel drum package with the Rieke steel closure.

of the CEN working group where he was able to make a direct contribution to the work. Consequently, the CEN working group has developed a broader standard that includes Rieke within its annexes of design examples. If the draft proceeds in this manner, Rieke will be able to continue with its business without having a European Standard blocking the way.

In summary, there are avenues, both public and private sector, to assisting companies in the United States that face this type of problem. The key is to be aware of potential standards projects in your sector through contacts in Europe and/or the United States, and to react not only with an objection, but also with a solution.



## Chapter 4: Structure of the European Standardization Bodies and Avenues for U.S. Access

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### ***CEN - The European Committee for Standardization***

CEN, established in 1961, is a non-profit regional association producing European standards in all areas except electrotechnical and telecommunication. The aim of CEN is to eliminate internal European trade barriers resulting from differing national technical standards to stimulate industry and trade and promote safety, economy, and efficiency through the creation, harmonization, and promotion of European standards.

CEN develops voluntary European Standards (EN) for mechanical engineering, building and civil engineering, health technology, information technology, biology and biotechnology, quality, certification and testing, environment, health and safety at the workplace, gas and other energies, transport and packaging, consumer goods, sports, leisure, food, materials (iron and steel), and chemistry.

The Vienna Agreement, formally known as the Agreement on Technical Cooperation between the International Organization for Standardization (ISO) and CEN, went into effect in 1991. The Vienna Agreement (VA) allows CEN to decide, case by case and according to precise conditions, to transfer the execution of European standards to ISO. CEN national member bodies, with the exception of Luxembourg, are also members of the ISO. CEN affiliate members<sup>6</sup> are national standards organizations of Central and Eastern Europe, along with Turkey. The organization also has liaison with more than 125 various European organizations.

At the end of 1996, 40% of all European Standards approved by CEN are identical to ISO standards, up from 30% in 1990.

### **Access to CEN via the Vienna Agreement**

While the predecessor of the Vienna Agreement, the Lisbon Agreement of 1989, primarily allowed an exchange of general information between ISO and CEN, the VA increased the level of exchange to include the sharing of information between ISO and CEN technical committees (TCs) and subcommittees (SCs), as well as mutual representation at committee meetings.

#### ***a. Exchange of Information***

At the administrative level, both ISO and CEN regularly exchange their Mementos and Catalogues. ISO provides the work programs of ISO/TCs, including status of progress

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<sup>6</sup> “Affiliate Members” are National Standards Bodies (NSBs) of countries likely to become EU or EFTA members. Affiliates have rights and obligations, notably participation in technical work and payment of an annual subscription fee.

and target dates, information concerning proposals for new fields of technical activity, new work item proposals (NPs), working drafts (WDs), committee drafts (CDs), texts of Draft International Standards (DIS) and final Draft International Standards (FDIS), draft technical reports (DTR) and technical reports (TR). CEN submits its General Technical Report (which is the work program of the CEN/TCs with states of progress, target dates), proposals for new studies, and texts of preliminary European standards (prEN), preliminary harmonized documents (prHD), and preliminary European Prestandards (prENV).

Both the ISO and CEN Central Secretariats have established lists of ISO/TCs (or SCs) and CEN/TCs, which have technical activities of common interest. This list indicates the name of the person in charge of the ISO/CEN reporting secretariat, the names of the ISO and CEN committee secretaries, and the relevant program managers of both Central Secretariats.

Under the Vienna Agreement, CEN can adopt ISO projects as European standards, with or without any technical change. CEN may also submit projects to ISO for inclusion on the program of work of an appropriate ISO TC or SC; upon approval as an international standard, the project might then be adopted as a CEN standard.

However, the VA does not mandate that CEN use ISO work in all cases – it also does not stipulate that CEN give primacy to ISO work. Similarly, sometimes there are specific European needs and ISO has little or no interest in initiating work, so CEN will proceed with its own standards development activities.

In some cases the European Commission (the Executive arm of the European Union) mandates that certain standards be written, and by a specific target date. CEN is obliged to follow through, either by developing its own standard(s) or by adopting an appropriate international standard. In either case, the Commission deadline must be met. In these instances the CEN Central Secretariat (CEN/CS) will provide to the ISO Central Secretariat (ISO/CS) information regarding CEN priorities and expectations concerning subjects belonging to the scope of ISO/TCs and on target dates for work items of ISO/TCs of special interest to CEN.

### ***b. Mutual Representation***

The Vienna Agreement provides for designated representatives (the preference being chairmen, secretaries, conveners or project leaders) to be present at respective ISO/TC<sup>7</sup> (ISO/TC includes subcommittees in this publication) and CEN/TC meetings as observers. This must be done by resolution of the ISO/TC or CEN/TC.

The Vienna Agreement requests that ISO representation be limited to, preferably, no more than two ISO persons. Previously ISO/TCs were restricted to appointment of only chairmen, secretaries, project leaders and working group conveners as liaisons to

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<sup>7</sup> Participation at working group meetings is subject to invitation by the parent body and/or chairman of the working group.

CEN/TCs. Though this remains the preference, at its meeting in London in September 1996, the ISO Technical Management Board approved a proposal from ANSI that, when appropriate, ISO committees should give preference to including at least one non-European member in its representation at meetings of CEN committees (reference ISO Circular Letter dated 22 October, 1996). If the United States is an active, participating member of the ISO committee, then it can use its influence to receive the appointment. The observers from the ISO/TC represent the interests of the specific ISO/TC, but nonetheless, if an American is the liaison person, the U.S. has achieved direct access to the CEN committee.

Further to the Vienna Agreement, CEN recognizes as “third countries” ISO member bodies from outside the EU. ANSI serves as the U.S. member body to the ISO. In this case, ANSI has been successful in having American representatives present, upon request, at CEN/TC and working group meetings, sometimes for selected items only. This gives U.S. interests a direct presence at CEN technical meetings to work toward harmonized standards. Such representation is only permitted if an invitation is offered by the applicable CEN technical group.

Under the right conditions Europe may be influenced to adopt a relevant international standard, encouraging "one global standard accepted by all." If the U.S. has played a leading role in the development of the international document, then the European standards process, too, has been influenced.

### ***c. Maintenance of the Vienna Agreement***

To initiate and to achieve the objectives of the Vienna Agreement, a Joint ISO/CEN Coordinating Group (JCG) of the Technical Boards has been established with the task of proposing and monitoring the appropriate operating methods and systems, on the understanding that the day to day processing shall be handled by both Central Secretariats. The Group comprises three members appointed by each Technical Board and the respective Secretaries, Chairmen, with the Secretaries and Chairmen alternating each year. ANSI is one of three members appointed by the ISO Technical Management Board (TMB) to this group.

The JCG of ISO and CEN Technical Boards has the following tasks:

- to monitor the general implementation of the Vienna Agreement;
- to review and, where necessary, propose revisions to the existing procedures, mechanisms and bases for information exchange, and to achieve the objectives of mutual visibility and understanding or work programs;
- to advise the Technical Boards of any direct involvement required of them for improving the performance of secretaries and experts appointed by member bodies;
- to maintain working linkages with the technical management bodies of both organizations;
- to review coordination issues on questions of common interest with a view to deciding on work allocation.

The JCG normally meets annually. In recent years no specific coordination issues have been brought forward to it.

The Vienna Agreement itself was up for review during 1995. ANSI, through the ANSI International Advisory Committee (IAC) Forum (AIF), sought comments from its members for improvement of the VA. No comments came forward of a specific nature; therefore, the VA approved in 1991 was essentially reaffirmed at the 1995 meeting of the ISO General Assembly (GA).

Guidelines for the VA also came up for review during 1995, and ANSI, via the AIF, provided many comments, as did many other ISO member bodies. Nearly all the ANSI comments were accepted, and the guidelines have been improved significantly in both clarity and substance. The revised guidelines were approved by the ISO/TMB at the end of June 1996.

Any U.S. entity identifying specific problems with a CEN/TC should contact staff in ANSI's Standards Facilitation Department and supply documentation that can be brought forward to the JCG by the U.S. representative. Unfortunately, though the perception can be a reality, feelings and hearsay are not sufficient evidence on which to bring to the group coordination problems or perceived/real departure from the VA by a CEN/TC. Aggrieved U.S. interests should document the problems (resolutions by the CEN or ISO/TC, minutes, correspondence) as much as possible, so that the JCG can address and resolve the issue.

#### ***d. "Corresponding" Membership***

In January 1996, the CEN Board of Administration approved the creation of the status of "CEN Corresponding Organization", in order to provide an appropriate institutional framework for requests for access to information and contacts being received from countries outside of Europe, in particular those that have concluded technical assistance programs with EC/EFTA. Corresponding members have no rights of participation in CEN bodies, but they do have access to documentation.

A "CEN Corresponding Organization" is defined as an organization:

- being a NSB of ISO, or a regional association of NSBs recognized by ISO;
- not fulfilling the statutory requirements to become a CEN National Member or a CEN Affiliate;
- having accepted the WTO (World Trade Organization) agreement on standards;
- whose National Authorities have concluded agreements with EU/EFTA or with whom CEN is interested in creating links and exchanging information;
- being ready to enter into reciprocal exchange of information with CEN on an open basis.

### ***CENELEC - The European Committee for Electrotechnical Standardization***

Established in 1972, CENELEC is a non-profit regional association that produces a single set of electrotechnical and electronic engineering standards. CENELEC operates under the same internal regulations as CEN; therefore, the process of developing European Standards within CENELEC is the same as CEN.

The Dresden Agreement between CENELEC and the International Electrotechnical Commission (IEC) is similar to the CEN/ISO agreement noted earlier. The major difference between the two agreements is that the Dresden Agreement gives IEC the "Right of First Refusal" for work proposed in CENELEC. CENELEC initiates development work only in areas where international work is so unlikely to reach a satisfactory conclusion within a reasonable timeframe that the work should be tackled, instead, at the European level. Such exceptional cases might also include subjects for which international work has not been (or cannot be expected to be) successful because of inherent technical, legislative, or commercial differences between regions.

In actuality, most IEC projects are automatically considered for adoption as CENELEC standards – over 70% of CENELEC standards are identical to IEC standards; an additional 15% of CENELEC standards are based on IEC standards.

CENELEC national member bodies, with the exception of Luxembourg and Iceland, are also members of the IEC. CENELEC has nine affiliate members from Eastern and Central Europe and has a formal agreement with 17 major European industry associations.

### **Access to CENELEC via the Dresden Agreement**

The Dresden Agreement (DA), an agreement on technical cooperation between the International Electrotechnical Commission (IEC) and CENELEC, went into effect in September 1996. The Dresden Agreement supersedes the Lugano Agreement of 1991. Similar to the Vienna Agreement, these documents established a mechanism for exchange of general information and mutual representation on activities of general interest between IEC and CENELEC.

The Dresden Agreement gives IEC the "Right of First Refusal" for work proposed in CENELEC. When planning new work, CENELEC will first offer the work to IEC. If IEC accepts the new work item then CENELEC will cease working on the project within Europe. If IEC is not interested in the work item, CENELEC will then undertake the standards development. In such situations, IEC will be kept informed of progress and its non-European members will have the opportunity to comment at the CENELEC public enquiry stage. Final drafts will, in every case, be offered to the IEC as Committee Drafts for Vote (CDVs), although the final decision on the content of the EN must remain with CENELEC.

CENELEC committees are not generally open to bodies outside of Europe. U.S. parties may formally request meetings with the chairs of CENELEC technical committees via ANSI's USNC. ISO and IEC may also nominate representatives to participate in CENELEC committees when there are related working proceedings at both the European and the international levels.

### ***ETSI - European Telecommunications Standards Institute***

The youngest of the three European standards making bodies, ETSI was set up in 1988 to set standards for Europe in telecommunications and, in cooperation with the European Broadcasting Union (EBU) and CEN/CENELEC respectively, the related fields of broadcasting and office information technology. ETSI is a non-profit, self-funding organization and relies on the subscriptions of its members for financial resources.

Membership is open to any company or organization with an interest in the creation of European telecommunications standards. To qualify for full membership, applicants must be active in one of the countries of the European Conference of Postal and Telecommunications Administrations (CEPT) and agree to contribute to ETSI's work and to use the standards it produces. There are currently over 360 members with a recent increase in new members from Eastern Europe.

The working methods of ETSI are somewhat different from the rules of CEN and CENELEC. Project teams that are tied to technical committees are included in the work. Consortia may join directly as members, as may individual enterprises and economic operators.

The principal role of the Institute is technical pre-standardization and standardization at the European level in the following fields:

- Areas common to telecommunications and information technology in coordination with CEN and CENELEC, and
- Areas common to telecommunications and broadcasting (especially audio-visual and multimedia matters) in coordination with CEN, CENELEC and the EBU.

In addition, ETSI is open to cooperation with other organizations when appropriate.

The activities of the Institute contribute to the production and the promotion of new harmonized world-wide standards and, furthermore, build upon world-wide standards, existing or in preparation.

### **Access to ETSI**

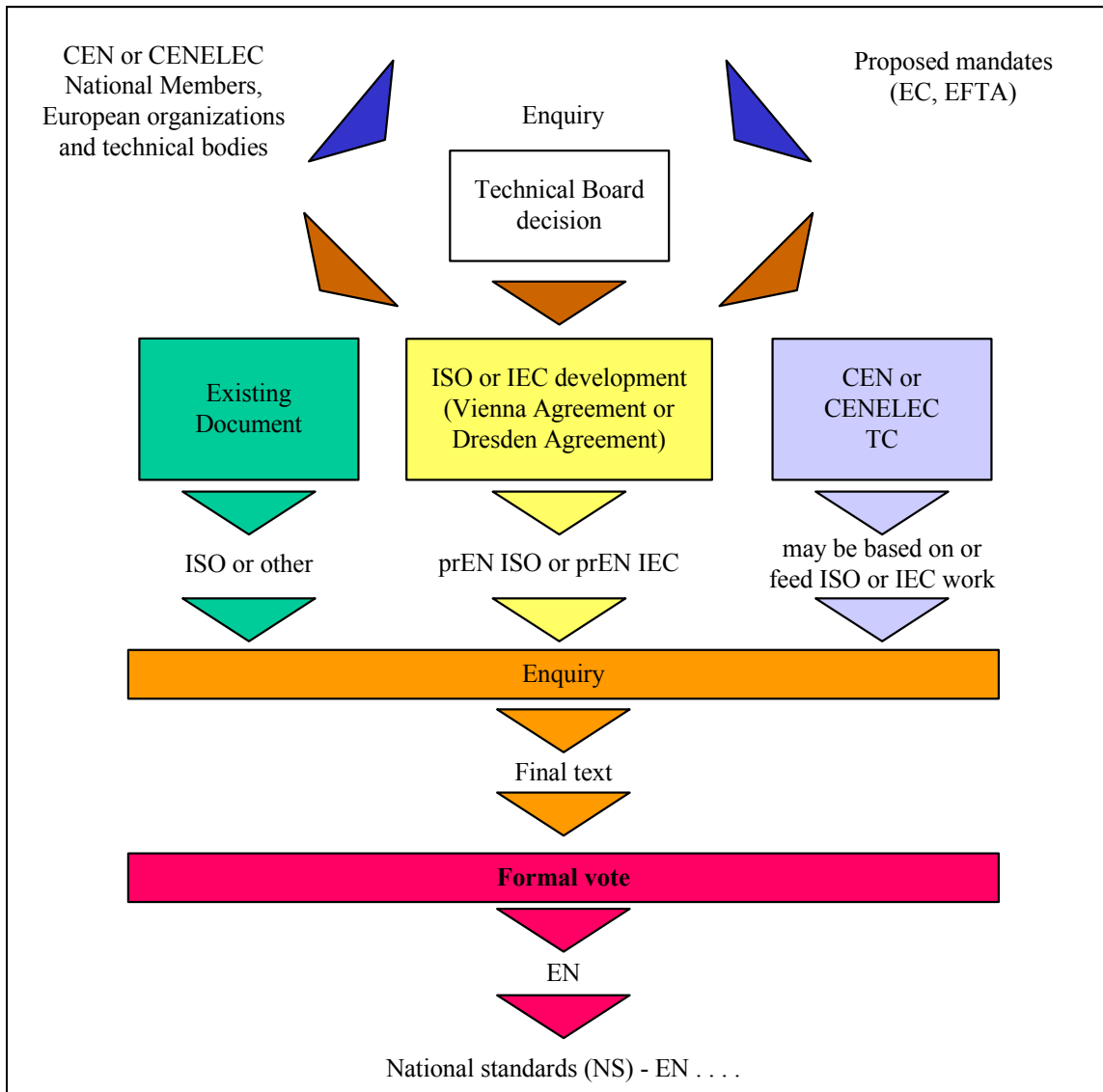
ETSI is different from CEN and CENELEC in that it offers membership not only to member states, but to individual members and associate members. Thus, American

industry has direct access to the ETSI process, from development through the General Assembly. There are both member state votes, and individual weighted voting.

ETSI has granted ANSI guest observer status. In addition, as part of its policy of openness and its ultimate aim of harmonizing standards on a global scale, representatives from other bodies involved in telecommunications, including those from U.S.-based companies, may join as Associate Members and participate in the technical work.

## Chapter 5: European Standards Development Process

Through their standardization work, CEN, CENELEC, and ETSI aim to remove any differences of a technical nature, either between the national standards of the member states or between measures applied at the national level to certify conformity, that could give rise to technical barriers to trade. In the areas of technology, European Standards are prepared following specific requests from the European Commission (EC) and the European Free Trade Association (EFTA).



**Figure 2: How European Standards Are Developed**



## ***Terminology***

### **European Standard**

The fundamental instrument of European regional standardization is the "European Standard." In CEN and CENELEC, and recently within ETSI, this is known as an "EN". The EN must be implemented at the national level by being given the status of a national standard and by the withdrawal of any conflicting national standard. Such implementation may be done by the issuance of an endorsement notice declaring that the EN is the national standard. No alteration to the content or layout of the EN is permitted in the corresponding national standard.

### **Harmonization Document**

A Harmonization Document (HD) must be implemented at the national level either by the issuance of a corresponding national standard or, as a minimum, by the public announcement of the HD number and title, and in both cases no conflicting national standard may continue to exist after the date fixed by the Technical Board for the withdrawal of such requirements. Harmonization Documents have a slightly less rigorous national transposition requirement than the EN. The absence of a corresponding national standard is not deemed to present an obstacle to harmonization.

### **European Prestandard**

A European Prestandard (ENV) may be established as a prospective standard for provisional application in all technical fields where the innovation rate is high or where there is an urgent need for technical advice. Member states are required to make the ENV available at the national level in an appropriate form and to announce their existence in the same way as for ENs and HDs. However, any conflicting national standards may be kept in force until the ENV is converted into an EN.

EN/HD/ENVs once agreed upon, are uniformly implemented by member states at the national level in compliance with the rules of the European Standardization organizations.

## ***Stages of Development***

ANSI's national and international relationships and activities offer unique opportunities for U.S. organizations to confront the changes taking place in the international and regional standards arenas. ANSI works to facilitate active U.S access to the European processes.

However, it does become more difficult to gain American access to the European standardization bodies when no ISO or IEC counterpart committee exists. Normally, access is granted via the chairman of the CEN or CENELEC working group, not the offices of the Central Secretariat (though the CS can be instrumental in convincing a WG convener of the need for participation from outside the EU). Typically great pressure must build before such access is granted.

## **New Work**

The Dresden Agreement between CENELEC and the International Electrotechnical Commission (IEC) gives IEC the "Right of First Refusal" for work proposed in CENELEC (see Chapter 4 - CENELEC).

According to the Vienna Agreement, CEN must determine whether it is possible to give preference to ISO to develop the new project, noting that a completed standards project must be available within specific timeframes. ISO has three months to respond to any such request received from CEN.

CEN must consider its various procedural options and, if the CEN/TC decides to propose the work item to ISO, work will commence following the normal procedures for one of the following scenarios:

- New work falling within the scope of an existing ISO/TC/SC;
- New work requiring an extension of the scope of an existing ISO/TC; or
- New work proposed that falls into a field(s) not yet covered in ISO.

## **Development**

Most European Standards not taken from one of the international standardization organizations are developed in working groups reporting to technical committees or subcommittees of the regional European standards organizations. Access to this process by U.S. interests has been acquired in four ways:

- Under the Vienna and Dresden Agreements, the relevant ISO or IEC/TCs or SCs can appoint a representative, preferably no more than two, to the parallel European activity, including working groups;
- ANSI can officially request that an American be allowed to attend a working group meeting(s) as an observer;
- Interests with representatives in Europe can become members of a European country's delegation and participate directly;
- Informal agreements between U.S. interests and their counterparts on CEN or CENELEC working groups allow participation. (This type of access works very well in most cases, and is usually not reported formally. Formal agreements could disrupt this method of interaction by instituting a centrally controlled aspect to this method of interaction.)

## **Enquiry**

This public enquiry is a six-month time period during which the European members can offer national body comments. This is not a voting stage.

Under the Vienna and Dresden Agreements, CEN and CENELEC have agreed to accept comments on preliminary European Standards (prEN) and preliminary Harmonized Documents (prHD) from ISO and IEC member bodies. ANSI, as the U.S. member body, announces availability of all prENs and prHDs in ANSI's *Standards Action* and via our site on the World Wide Web (<http://www.ansi.org>). Enquiry drafts can be purchased from ANSI's Customer Services Department, and comments submitted via staff in ANSI's Standards Facilitation Department<sup>8</sup>.

U.S. comments are sent to the offices of the respective Central Secretariat in Brussels and are referred to the applicable technical committee for response. Replies to U.S. comments are received in due course by ANSI and referred back to the originator in the United States.

### **Formal vote**

CEN, CENELEC, and ETSI are populated at the formal vote stage by member countries, not by individuals. National delegations have weighted votes, applied for by the national body and confirmed by the General Assemblies of the respective organizations.

The United States, as a non-member nation, does not have a vote. If ANSI were to be a member and have a vote in these organizations, the U.S. would be obligated by the respective Operating Procedures<sup>9</sup> to adopt and implement approved ENs at the national level and to withdraw any conflicting national standard. U.S. interests have indicated that they are unwilling to accept as a matter of course, the outright adoption as national standards of all documents developed and approved by the European standardization bodies.

Further, within the European regional bodies the U.S. would have only one vote, even if weighted to some extent. Through ANSI, the U.S. has considerably more options in lining up support for issues arising under the purview of the ISO and IEC. In the international arena, even though it is still "one country – one vote," ANSI can call upon allies in the Pan American Standards Commission (COPANT)<sup>10</sup> and the Pacific Area Standards Congress (PASC)<sup>11</sup> for supporting votes from outside Europe.

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<sup>8</sup> On average, ANSI submits comments on 8-12 European drafts per year.

<sup>9</sup> Clause 5.2 of the CEN/CENELEC Internal Regulations, Part 2: Common rules for standards work states, "If an EN or HD has been approved in accordance with [procedures] all members shall be bound to implement it." The exception is if a member is prevented from implementing a decision by regulations or conditions outside its competence to alter. However, the member "shall nevertheless do everything in its power to bring about the necessary changes." Similar text appears in Clause 13.7 of the ETSI Rules of Procedure.

<sup>10</sup> COPANT, the Pan American Standards Commission, was created in the 1940s to coordinate South America, parts of Central America and several Caribbean Islands. U.S. membership helps to promote trade and investment. Though COPANT does develop standards, members recently voted to use international standards in lieu of its standards wherever possible.

<sup>11</sup> PASC, the Pacific Area Standards Congress was created in 1973 by the Pacific Rim nations. PASC does not develop standards, but has brought the national standards bodies of the Pacific Rim closer to agreement

ANSI does, however, publish notice of the two month formal vote stage in *Standards Action*. The formal vote documents, which in most cases become the approved European Standard, are available for sale through ANSI's Customer Services Department.

## **Publication**

ETSI publishes its final documents following approval by its constituents.

Member countries are responsible for publishing European Standards approved by CEN and CENELEC.

ANSI obtains and sells ENs upon request.

## **Other Considerations**

### **a. Primary Questionnaire**

In order to test the market need for a standard, the Primary Questionnaire (PQ) has been developed. The PQ procedure permits CEN or CENELEC to find out whether enough interest exists in harmonization on the subject proposed, the existing degree of national harmonization on the reference document in question, and whether the document would be acceptable as an EN, HD, or ENV. The PQ procedure serves the same purpose as the six-month enquiry procedure. The PQ procedure concerns entirely new documents being offered to CEN or CENELEC. ETSI does not have the Primary Questionnaire procedure.

### **b. Dual regional and international work**

If European regional activities are already underway and the international community attempts to begin a similar activity, the Europeans may resist the suggestion for a new international committee. As an alternative, the European regional body may suggest that they will "fast-track" their work into ISO or IEC (as appropriate) at the enquiry (DIS in ISO, CDV in IEC) stage, thereby providing non-Europeans with an opportunity to cast a national body position during the fast-track DIS or CDV ballot. The problem, however, is that comments will be forwarded back to the regional body for response; this scenario provides relatively little input for non-Europeans to participate in the development of the project.

When faced with this situation, the affected U.S. industry sector, normally working through a trade association or a professional society and via ANSI, must actively persuade other non-European countries of the necessity of doing the work in an international organization like ISO or IEC. The U.S. should be extremely confident that it has the required number of allies guaranteed to support the formation of a new ISO or

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on common goals and objectives. PASC works actively with the Asian Pacific Economic Cooperation (APEC) on standards related matters.

IEC TC or SC prior to an ANSI or USNC submission of the proposal for a new area of technical work (TSP).

***c. Parallel voting***

According to the Lugano Agreement, only DIS (Draft International Standards) were processed for parallel voting both within IEC and within CENELEC. Now, with approval of the Dresden Agreement, IEC working drafts will also be sent to CENELEC for parallel review and comment. This procedure makes it more likely that the draft standard will be accepted not only internationally, but also as an identical European standard.

The Vienna Agreement also provides for parallel voting at the Draft International Standard level (DIS) and Final Draft International Standard level (FDIS). If mutual agreement is reached, the International Standard (IS) and EN would be published concurrently. The submitting organization is responsible for responding to comments during voting.

***d. Unique Acceptance Procedure (UAP)***

The UAP may be applied to any type of document, whatever its origin, in order to achieve rapid approval of an EN or HD, if it is reasonable to suppose that the document is acceptable at the European level. For a reference document, the UAP combines the questionnaire procedure and the formal vote.

If CEN or CENELEC modify an international standard, ISO or IEC must either agree to incorporate the changes into a new international standard, or the regional bodies shall adopt the revised text as a regional, but not international standard.

***Annual U.S. - European Dialogue***

The American National Standards Institute sends a delegation to annual high-level policy meetings with staff and/or elected executives of CEN, CENELEC, ETSI, the European Organization for Testing and Certification (EOTC), and officials in the European Commission that deal with standards and conformity assessment matters. The primary thrust of the initial discussions was access and transparency, both from the United States to Europe and vice versa. However, the ongoing dialogues have resulted in a number of agreements, both formal and informal. Both parties have agreed that these meetings are important for continuing an open dialogue.

ANSI delegations are comprised of both private and public sector representatives. The delegation is normally led by the ANSI Chairman of the Board, with company, organizational, and government member representation. The ANSI President is also part of the delegation. All ANSI members are welcome to join the U.S. delegation.

Notice of the annual public preparatory meeting will be placed in ANSI's bi-weekly publication *Standards Action* during the August/September timeframe. The dates will also be posted in the Calendar section of ANSI's home page on the World Wide Web (<http://www.ansi.org>).

The annual policy level meetings, which began in the summer of 1989, are normally held in Brussels, though two have been held in the United States.

## Chapter 6: Conformity Assessment and Testing

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The European Commission has supported its program of directives for the elimination of technical barriers to trade with a selection of harmonized conformity modules and with the use of a harmonized European mark, CE marking.

The purpose of the directives is not to ban any products from the European Union single market, unless the product is very poorly made or is unsafe. For most reputable manufacturers, complying with the essential protection requirements of the directives is not particularly onerous and companies that have always taken a responsible attitude to the performance and design of their products will have few problems complying with the New Approach directives.

Additional information regarding conformity assessment programs is available through ANSI's Director of Conformity Assessment at the Institute's Washington, D.C. office (Telephone: 202 639 4090; Telefax: 202 628 1886).

### ***The CE Mark***



CE marking does not indicate conformity to a standard, but rather indicates conformity to the legal requirements of EU directives. Many of the EU directives require manufacturers to have a Certified Quality system to ISO 9000 in operation and to use the assistance of a Notified Body in order that the manufacturer can legitimately apply the CE marking to their product.

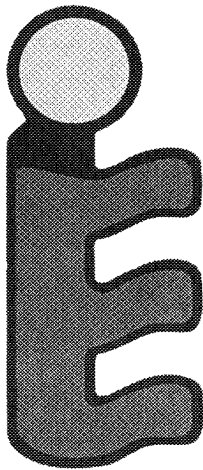
**Figure 3: The CE Mark**

As there may be difficulties in the administrative requirements, a new way of working for some manufacturers and suppliers, particularly small businesses, may be required. Manufacturers may well find it cost effective to seek outside help in the early stages of complying with the directives, in order to save time and prevent expensive mistakes. However, it is important to be aware that it is rarely necessary to commit to an expensive program of testing and certification. Unless the directives applying to the product specifically require the involvement of a third party for product approval or quality system assessment, the manufacturer can affix the mark without having to involve a test house, consultant, or anyone else.

The CE mark must be affixed to the product, its instruction manual, or to its packaging. It must be at least 5mm high. It is not intended to be a mark of quality - rather it is intended to indicate to the authorities responsible for enforcing the directives that the product's manufacturer claims compliance with the directives that apply to the product.

The act of fixing the mark to the product, and signing the Declaration of Conformity, constitutes a declaration by the manufacturer that the product meets the requirements of all the directives that apply to it. The onus is very much on the manufacturer to take responsibility for this actually being true. Marking a product which is not fully in accordance with the requirements of the applicable directives is an offense in its own right, and would also contravene related consumer safety and trades descriptions legislation.

### **The Keymark**



**Figure 4:  
The Keymark**

The purpose of the “Keymark” is to make available to European industry a voluntary harmonized service that provides for the independent third-party testing of products and to ensure compliance with the requirements of the relevant European Standards (ENs) developed by CEN or CENELEC. The Keymark also requires confirmation of the manufacturers’ quality management system. To ensure that quality is maintained, both the manufacturer and the product will be subject to regular assessment.

Contrary to the mandatory “CE” mark, use of the Keymark is voluntary.

The Keymark may replace many, if not all, of the numerous national certification marks for products which are sold throughout Europe. It is expected that there will be a reduction in costs related to certification, which will impact the consumer at another level.

As of early 1996 no Keymarks had been assigned. The U.S. will monitor use of the mark to ensure that it does not become *de facto* mandatory as, for example, in procurements.

### **EOTC - European Organization for Testing and Certification**

The European Organization for Testing and Certification was established in April 1990 by the European Commission, the European Free Trade Association (EFTA), and the European Standards Bodies. Articles of Association were signed by 22 founder members on 3 December 1992 and the EOTC attained a legal status under Belgian Law in April 1993.

The EOTC members are testing and calibration laboratories with help and input from certification bodies, manufacturers, trade associations, etc.



The customer base of the EOTC is composed of suppliers, manufacturers, purchasers and users of goods and services and all those who benefit from the development of mutual recognition in any sector.

The EOTC acts as a focal point for conformity assessment issues in Europe but does not itself test or certify products or services. Testing is performed by recognized Agreement Groups consisting of test laboratories of certification bodies.

### ***The "NVCASE" Program***

The U.S. has been actively negotiating with the EU to develop a Mutual Recognition Agreement (MRA) concerning the acceptance of mutual conformity assessment programs. The National Institute of Standards and Technology (NIST), through its Office of Standards Services, has established a fee-for-service, voluntary program entitled NVCASE (the National Voluntary Conformity Assessment System Evaluation). NVCASE evaluates and recognizes organizations which support conformity assessment activities.

The U.S. has proposed that NVCASE recognition be one means of acceptance by the EU, of U.S. bodies as equivalent to EU notified bodies, to approve products for entry to the EU marketplace. The National Voluntary Conformity Assessment Systems Evaluation Program includes activities related to laboratory testing, product certification, and quality system registration. After NVCASE evaluation, NIST provides recognition to qualified U.S. organizations that effectively demonstrate conformance with established criteria. The ultimate goal is to help U.S. manufacturers satisfy applicable product requirements mandated by other countries through conformity assessment procedures conducted in this country prior to export.

Conformity assessment activities may be considered to be conducted on three levels:

- (1) the conformity level (e.g., product testing, product certification and quality system registration);
- (2) the accreditation level (e.g., the actions of accreditors of bodies operating at the conformity level); and
- (3) the recognition of accreditors.

NVCASE recognition:

- (1) provides other governments with a basis for having confidence in the face that qualifying U.S. conformity assessment bodies are competent; and
- (2) facilitates the acceptance of U.S. products in foreign regulated markets based on U.S. conformity assessment results.

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## **ANNEXES**

## **ANNEX 1: Approved "New Approach" Directives**

European directives currently adopted under the New Approach are listed below. Copies are available through your industry's trade association or from the:

Office of European Union and Regional Affairs  
U.S. Department of Commerce  
14th and Constitution Ave., NW, Room 3036  
Washington, DC 20230

Telephone: 202-492-5276  
Telefax: 202-482-2155

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Low Voltage Directive (73/23/EEC)  
Safety of all electrical equipment operating between 50 and 1000V  
Published in Official Journal L77 (26/3/73)  
In force as of: 21/8/74  
Amended by 93/68/EEC to require CE marking of compliant items.

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Simple Pressure Vessels Directive (87/404/EEC)  
Safety requirements for pressure vessels containing air or nitrogen  
Published in Official Journal L220 (8/8/87)  
In force as of 1/7/90  
Amended by 90/488/EEC (Official Journal L270, 2/10/90) to give a transitional period ending 1/7/92

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Toy Safety Directive (88/378/EEC)  
Safety of toys for children under 14 years of age  
Published in Official Journal L187 (16/7/88)  
In force as of 1/1/90  
Corrigenda in Official Journal L281 (14/10/88)

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Construction Products Directive (89/106/EEC)  
Safety and performance of building products including requirements for mechanical stability, fire resistance, hygiene, noise and energy efficiency.  
Published in Official Journal L40, 11/2/89  
In force as of 27/6/91

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Electromagnetic Compatibility Directive (89/336/EEC)  
Noise immunity and emissions performance of electrical equipment

Published in Official Journal L139 (23/5/89)  
In force 1/1/92 (transition ends 31/12/95)  
Amended by Directive 92/31/EEC (Official Journal L126, 12/5/92)

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Machinery Safety Directive (89/392/EEC)  
Safety of all machines with moving parts  
Published in Official Journal L183 (29/6/89)  
In force 1/1/93 (transition ends 31/12/94)

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Personal Protective Equipment Directive (89/686/EEC)  
Performance of equipment designed to protect the user from injury  
Published in Official Journal L399 (30/12/89)  
In force as of 1/7/92 (transition ends 30/6/95)  
Amended by 93/95/EEC (Official Journal L276, 9/11/93)

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Non-Automatic Weighing Instruments Directive (90/384/EEC)  
Performance and calibration procedures for commercial weigh-scales  
Published in Official Journal L189 (20/7/90)  
In force 1/1/93 (transition ends 31/12/2002)  
Corrigenda in Official Journal L258 (22/9/90)

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Active Implantable Medical Devices Directive 90/385/EEC  
Safety and performance requirements for electrically operated medical devices intended for implantation in the human body.  
Published in Official Journal L189 (20/7/90)  
In force 1/1/93 (transition ends 31/12/94)

---

Gas Appliances Directive (90/396/EEC)  
Safety of all appliances burning gaseous fuels  
Published in Official Journal L196 (26/7/90)  
In force 1/1/92 (transition ends 21/12/95)

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Telecommunications Terminal Equipment Directive (91/263/EEC)  
Requirements for testing to ensure the mutual recognition of type approval of telecoms apparatus.  
Published in Official Journal L128 (23/5/91)

In force 6/11/92

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Hot Water Boilers Directive (92/42/EEC)  
Efficiency requirements for hot water boilers of 4 to 400kW output  
Published in Official Journal L167 (22/6/92)  
In force 1/1/94 (transition ends 31/12/97)  
Implemented in the UK by The Boiler (Efficiency) Regulations 1993 (SI 1993:3083)

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Medical Devices Directive (93/42/EEC)  
Safety of all medical equipment not covered by directives on In-Vitro fertilization or active implantable devices  
Published in Official Journal L169 (12/7/93)  
In force 1/1/95 (transition ends 13/6/98)

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Satellite Earth Station Equipment Directive (93/97/EEC)  
Extension of the Telecommunications Terminal Equipment Directive to cover satellite transmitting and receiving equipment.  
Published in Official Journal L290 (24/11/93)  
In force 1/5/95

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Explosive Atmospheres Directive (94/9/EEC)  
Safety requirements for control systems and equipment for use in explosive atmospheres (e.g. coal mines).  
Published in Official Journal L100 (19/4/94)  
In force 1/3/96 (transition ends 30/6/2003)

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Recreational Craft Directive (94/25/EEC)  
Design and construction of boats of 2.5 to 24m, plus specified components, excluding hydrofoils and hover craft, and craft for charter.  
Published in Official Journal L164 (30/6/94)  
In force 16/6/96 (transition ends 15/6/98)

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Civil Uses Directive (93/15/EEC)  
Performance and safety of commercial explosives excluding ammunition and pyrotechnics  
Published in Official Journal L121 (15/5/93)  
In force 30/9/93 (transition ends 31/12/2002)

Implemented in the UK by the Placing on the Market and Supervision of Transfers of Explosives Regulations 1993 (SI 1993/2714)

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Energy Efficiency Directive (96/57/EEC)  
Energy efficiency performance of domestic refrigerators and freezers  
Published in Official Journal L236 (18/9/96)  
Transition ends 31/12/1999

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Other Directives have been proposed but not yet enacted to cover:

- Lifts
- Pressure equipment
- Marine safety equipment

## **ANNEX 2: The Dresden Agreement**

### **Revised IEC/CENELEC cooperation agreement**

#### **Preamble**

This is a revision of the IEC/CENELEC Agreement approved in October 1991. This new version was approved by IEC and CENELEC in September 1996.

#### **1 Objectives**

This agreement is intended:

- to expedite the publication and common adoption of International Standards;
- to ensure rational use of available resources. Full technical consideration of the content of the standard should therefore preferably take place at international level;
- to accelerate the standards preparation process in response to market demands.

To achieve the desired results, the active support of everybody involved in the IEC and CENELEC activities and flexibility in the working methods, are necessary.

#### **2 Common planning of new work**

NOTE: CENELEC members are directly involved in the planning of new work in the IEC in their capacity as IEC members. Therefore, the following covers only cases where the need for new work arises within CENELEC.

##### **2.1 Categories of new work proposals in CENELEC**

When identifying its requirements for new work (including the revision of existing standards), it is the policy of CENELEC to ascertain first whether the IEC can undertake this work.

New work items may arise from decisions at meetings:

- of the CENELEC AG;
- of the BT (on the basis of proposals from Technical Committees, National Committees or other bodies, including the notifications under the Vilamoura procedure or under Directive 83/189).

They are categorized as follows:

##### **2.1.1 *Work of European origin***

- a) A proposal for such new work, (which would usually be undertaken in an existing or new technical body of CENELEC and lead to the publication of an EN) is accepted in CENELEC if at least 5 National Committees are willing to participate actively in that work. Normally, such a proposal shall then be submitted to the IEC and taken up by the latter unless the IEC's timescale exceeds CENELEC's planning requirements. "Normally" implies that the BT (in

consultation with the relevant TC/SR, if any) may come to the conclusion that the IEC is unlikely to meet the required timescale. If so, the reasons for this conclusion must be properly recorded in the CENELEC BT files and made known to the IEC/CO.

- b) If there is not sufficient support by CENELEC members (less than 5), a BT Working Group (in case of the Vilamoura procedure, under the Convenorship of the notifying National Committee), may be invited to prepare a prEN with the active participation of representatives of one or more countries. In such cases the IEC shall be so advised under the procedure for the exchange of technical information, and the relevant IEC TC/SC informed by the CO.

### 2.1.2 *Common modifications to IEC standards*

When the preparation of new Common Modifications is considered necessary by CENELEC in order to supplement or modify an existing international standard, the subject will be considered by the CENELEC BT, on a case by case basis, for possible submission as a new work item to the IEC. If the BT decides not to submit a new work item, the IEC shall be so advised.

NOTE: Common Modifications concerning only the selection of European alternatives from “in some countries” clauses in IEC texts do not need further action.

### 2.1.3 *Need for revision of an IEC Standard*

When an IEC standard is being considered by CENELEC and it emerges that revision is considered necessary, this shall be offered to IEC as a new work item. In this case, CENELEC may decide:

- to adopt the IEC standard if necessary with common modifications;
- 
- to postpone adoption while awaiting the results of its proposal to IEC for revision.

## **2.2 Procedures for submission to IEC**

The proposal for new work falling under the categories 2.1.1 a), 2.1.2 or 2.1.3 above for which at least 5 National Committees of CENELEC have agreed to participate shall be submitted by CENELEC/CS to the IEC/CO in accordance with the IEC/ISO Directives, Part I “Procedures for the technical work” as follows:

### 2.2.1 *For new work within the Scope of an existing IEC/TC*

Information shall be given as required under subclause 2.2 of the Procedures (form on page 47/48) and shall include, in addition to the names of the five supporting National Committees, the nomination of a project leader and the requested target date for the circulation of the CDV.

*Note for internal CENELEC use:*

In preparing the information required, CS may call for assistance from the relevant TC/SC Secretariat, Reporting Secretariat or notifying NC (in the case of a Vilamoura notifications).

### 2.2.2 *Widening of the Scope of an existing IEC/TC*



If the request implies a widening of the present scope of the IEC/TC concerned, the proposed revised scope shall be submitted to the IEC by the CENELEC/CS at the same time as the request to undertake a new work item. The additional information shall be given as in 2.2.1 above and in accordance with the IEC/ISO directives, Part 1, 1.5.12

### 2.2.3 *For new work in fields not covered so far in IEC*

Formal proposals shall be submitted by the CENELEC/CS to the IEC/CO according to the IEC/ISO Directives, Part 1, 1.5.3 and 1.5.4 (form on page 31/ 32).

NOTE: In cases of doubt, the best procedure to be adopted shall be agreed in consultation between the two General Secretaries and may include the setting-up of an Ad hoc Group to draft firm proposals for consideration by the IEC/CA and Council. This does not prevent the application of 2.3.1 below.

## 2.3 **Implementation of the procedure**

2.3.1 Work shall start at CENELEC level in parallel with the IEC consultation.

The IEC undertakes to advise, as quickly as possible, at the latest within 6 months, whether the work can be incorporated in the current programme of work with a target date as indicated by CENELEC. If the proposal is accepted by IEC, the work is "promoted" to IEC level.

2.3.2 Work shall be continued at CENELEC level only if the new work proposal is rejected by the IEC or if the IEC's timescale exceeds CENELEC's planning requirements. The resulting prEN shall be sent to the IEC in accordance with clause 4 below.

2.3.3 Information about progress of work on projects submitted by CENELEC to the IEC in accordance with 2.2 will be sent by the IEC/CO to the CENELEC/CS on a monthly basis. Difficulties and delays which cannot be resolved by the IEC, or by negotiation between the IEC and CENELEC General Secretaries, will be reported to the MCG, which will act managerially according to its terms of reference in order to obtain the necessary support from the relevant National Committees.

2.3.4 Should it become evident that IEC work is not proceeding in accordance with the agreed target dates, the CENELEC BT will reassess the matter, taking into account all information provided by the IEC.

## 3 **Parallel voting on draft international standards**

### 3.1 **Applicability**

3.1.1 All CDV and FDIS circulated for vote in IEC are automatically submitted for enquiry and vote respectively as prEN within CENELEC, with the following exceptions:

- Those emanating from certain IEC Technical Committees and Sub-Committees nominated by the CENELEC Technical Board as outside CENELEC requirements. However, a specific draft from these TCs or SCs may be considered for parallel voting;

- Draft amendments to IEC standards which have not yet been harmonized by CENELEC as EN or HD, shall not be submitted to parallel voting.

Such cases shall be detected by the CENELEC/CS and the IEC/CO shall be informed accordingly.

NOTE: Drafts for IEC publications other than standards are not circulated for parallel voting.

*Note for internal CENELEC use:*

It is emphasized that qualifying drafts are automatically submitted to parallel voting, i.e. there is no requirement for prior approval by BT or a TC/SC.

3.1.2 The FDIS submitted to voting must be of a quality consistent with the ISO/IEC Directives, in particular clauses 1.1 to 1.4 of Part 3 (objective, style, homogeneity, coherence).

3.1.3 In view of the existence of an additional official language in CENELEC, an expert of German mother tongue shall be permitted to attend meetings of IEC Editing Committees as observer.

*Notes for internal CENELEC use:*

i. The German National Committee, in cooperation with those of Austria and Switzerland, shall be responsible for nominating experts of German mother tongue and shall inform the relevant IEC TC/SC Secretariat(s) accordingly.

ii. It shall also, again in cooperation with those from Austria and Switzerland, be responsible for ensuring that the German language texts of the CDV and FDIS are available in time, where possible on the basis of a translation made at an earlier stage of the work.

3.1.4 A draft submitted for parallel voting shall cover the entire scope in accordance with the ISO/IEC Directives.

Submission of fragments of text of the same draft in separate voting documents is not permitted.

## **3.2 Implementation of the procedures**

3.2.1 The IEC/CO shall send the CDV and the voting paper to IEC members and, in addition, a copy of the CDV only will be forwarded to the CENELEC National Committee of Iceland. All such documentation will indicate that the CDV is being submitted for parallel enquiry.

The five-months enquiry period is valid for both IEC and CENELEC and shall be timed to start from the date indicated on the voting paper.

Simultaneously, the CENELEC/CS will send to its members the voting forms, which will refer to the relevant CDV being dispatched by the IEC/CO. A copy will also be sent by the CENELEC/CS to the Reporting Secretariat (SR) or CENELEC/TC/SC when relevant.

The National Committees send their comments and votes on the respective voting forms to IEC and as appropriate to CENELEC. The IEC/TC is obliged to take note of the comments received

and to explain its decision on each of them in the voting report. This provision normally takes account of any possible need for CENELEC Common Modifications.

3.2.2 In order to facilitate translation into non-official languages, the IEC/CO shall send the voting report on the CDV to the CENELEC/CS as early as possible, and not later than 2 months before the circulation of the FDIS.

The IEC/CO shall send the FDIS and the voting paper to IEC members and, in addition, a copy of the FDIS only will be forwarded to the CENELEC National Committee of Iceland. All such documentation will indicate that the FDIS is being submitted for parallel voting.

The two-months voting period is valid for both IEC and CENELEC and shall be timed to start from the date indicated on the voting paper.

*Notes for internal CENELEC use:*

- i. The CENELEC/CS is responsible for circulating the German language text of the FDIS at the same time, having received the text from the German National Committee.
- ii. Before voting, the CENELEC National Committees should have completed the public enquiry according to relevant national procedures which should be initiated, whenever possible, at the CD stage.

Simultaneously, the CENELEC/CS will send to its members the voting forms, which will refer to the relevant FDIS being dispatched by the IEC/CO. A copy will also be sent by the CENELEC/CS to the Reporting Secretariat (SR) or CENELEC/TC/SC when relevant.

The National Committees shall send their votes on the respective voting forms to IEC and as appropriate to CENELEC. In case of different votes in IEC and CENELEC, a detailed technical justification must be given to IEC/CO and CENELEC/CS, together with the voting form.

### **3.3 Ratification stage**

3.3 The IEC voting report on the FDIS shall be circulated to the IEC National Committees and the CENELEC/CS by the IEC/CO not later than two weeks after the end of the voting period.

The CENELEC voting report on the prEN shall be circulated immediately thereafter to the CENELEC National Committees and to the IEC/CO by the CENELEC/CS.

3.3.2 If the IEC and the CENELEC results are both positive, the FDIS is published as an IEC standard by IEC and it is formally ratified as an EN by the BT. The ratification is normally carried out by correspondence and implies the BT notes the approval demonstrated by the voting result and establishes the dates for national implementation.

3.3.3 In the case of a negative CENELEC result, but positive IEC result, IEC shall proceed to publish the IEC standard. CENELEC BT shall decide what action to take (e.g. a proposal for Common Modifications as given under 2.1.2)

NOTE: Such a case may occur in view of the different status of an IEC standard and an EN and hence the different significance to the two votes, i.e.

*Within IEC:* An IEC standard is based on worldwide consensus, and has the status of a “recommendation”, without obligation to implement.

*Within CENELEC:* An EN is based on European consensus, and each member is obliged-to implement the EN unchanged as a national standard.

3.3.4 Should the IEC result be negative, CENELEC BT will in due time consider what action to take within CENELEC. This could imply, for example, implementation of the FDIS as EN if the CENELEC result is positive, or the start of independent European work or the submission of a new proposal to the IEC.

## **4 Conversion of European Standards and drafts into International Standards**

### **4.1 Published EN and HD**

In the case of already published EN and HD, the CENELEC BT shall decide to submit such texts to IEC for voting as CDV and subsequent handling as FDIS.

### **4.2 Voting on prEN**

**4.2.1** This applies to work of European origin intended to lead to the publication of EN. This could be a draft developed by a technical body of CENELEC or a national standard or other document approved for final voting by the CENELEC BT.

NOTE: prENV (Draft European Prestandards) are not covered by this procedure.

4.2.2 The English and French texts of the prEN shall be sent by the CENELEC/CS to the IEC/CO for voting as CDV, and subsequent handling as FDIS.

4.2.3 National Committees that are not members of CENELEC shall be allowed to submit a positive vote on the CDV accompanied by a request for inclusion of an "in some countries" clause, which shall then be referred to the relevant IEC/TC.

To avoid the need for the frequent use of this provision, CENELEC/TCs shall be encouraged, as far as possible, to refer, for example, to rated supply voltage and frequency rather than to specific numerical values thereof.

4.2.4 In the event of divergence between the FDIS and the, (by then published) EN, full information shall be provided by IEC/CO to CENELEC/CS for consideration by the responsible CENELEC technical body.

## Abbreviations

### CENELEC

AG = General Assembly  
CS = Central Secretariat  
BT = Technical Board  
SR = Reporting Secretariat  
prENV = Draft European Prestandard  
ENV = European Prestandard  
prEN = Draft European Standard  
HD = Harmonization Document  
EN = European Standard

### IEC

TC/SC = Technical Committee/  
Sub-Committee  
CA = Committee of Action  
CO = Central Office  
CD = Committee Draft  
CDV = Committee Draft with Vote  
FDIS = Final Draft International Standard

MCG Management Co-ordination Group (of IEC and CENELEC)

## **ANNEX 3: The Vienna Agreement**

### **AGREEMENT ON TECHNICAL COOPERATION BETWEEN ISO AND CEN**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)  
EUROPEAN COMMITTEE FOR STANDARDIZATION (CEN)

#### **1. Basis for cooperation**

Agreement on exchange of technical information between ISO and CEN approved by the CEN Administrative Board in January 1989 in Lisbon as further development of ISO/Council resolution 11/1987 (so-called Lisbon Agreement).

ISO Council resolution 18/1990 and CEN General Assembly resolution CEN/AG 3/1990 appear in the annex.

#### **2. General exchange of information at Central Secretariat (CS) level**

The ISO/CS shall regularly issue to the CEN/CS:

- Memento, Catalogue
- Work programme of the ISO/TCs with state of progress, target dates
- For work items proposed by CEN: working drafts and committee drafts
- Resolutions of the ISO Technical Board linked to technical activities and in any case all decisions having an interest for the other party
- Proposals for new fields of technical activity (TS/P)
- Texts of DIS, International Standards and technical reports in English and French

The CEN/CS shall regularly issue to the ISO/CS:

- Memento, Catalogue
- CEN General Technical Report (work programme of the CEN/TCs with state of progress, target dates)
- Resolutions of CEN Technical Board linked to technical activities and in any case all decisions having an interest for the other party
- Proposals for new studies (form A)
- Texts of prEN/prHD/prENV, at enquiry and formal voting stages, and approved European documents in English and French

Further exchange of available general information shall be possible subject to special agreement between the two CSs.

### **3. Cooperation on standards drafting between ISO and CEN**

#### **3.1 Cooperation by correspondence**

The ISO/CS and the CEN/CS shall establish a list of ISO/TCs (or SCs) and CEN/TCs, including CEN sectors, which have technical activities of common interest. The list shall also indicate the name of the person in charge of the ISO/CEN reporting secretariat, the names of the ISO and CEN committee secretaries and the relevant technical officers of both CSs. The list shall be notified to the respective Technical Boards.

##### **3.1.1 Reporting on ISO work to CEN**

ISO/CEN reporting secretariats (according to clause 2.5 of the CEN/CENELEC Common Rules for Standards Work part 2) shall provide information to:

- a) the CEN Technical Board on any ISO work which may be of concern to CEN
- b) the CEN Central Secretariat upon request for preparing investigation reports in areas not covered by CEN technical committees and for which ISO is active
- c) the CEN/TC secretariats according to the CEN/CENELEC internal regulations
  - on the progress of the technical work of relevant ISO/TCs with copy to both the ISO and CEN CSs
  - on ISO new work items circulated for voting.

##### **3.1.2 Reporting on CEN work to ISO**

- a) CEN/TC secretariats shall provide information to the ISO/TC secretariat concerned, with copy to both the ISO and CEN CSs, on their programme of technical work, including:
  - state of progress
  - current work schedule

insofar as such information is not covered by that mentioned under 2.

- b) The CEN/CS shall provide information to ISO/TC secretariats with copy to the ISO/CS on the programme\_of technical work of sub-sectors not covered by CEN/TCs concerning:
  - state of progress
  - current work schedule

insofar as such information is not covered by that mentioned under 2.

- c) The CEN/CS shall provide information to the ISO/CS on CEN priorities and expectations concerning subjects belonging to the scope of ISO/TCs and on target dates for work items of ISO/TCs of special interest to CEN, insofar as such information is not covered by that

mentioned under 2. Every effort will be made to meet requests initiated by CEN within the framework of available resources.

### **3.1.3 Written Contribution**

The passive involvement in the work of CEN and ISO by way of sending written contribution is well accepted by the two organizations as a contribution towards a more open process of standardization and promotion of harmonization on the European and international level. Written contributions may emanate from TCs, Reporting Secretariats (SR) or CSs and are directly addressed to the secretariat of the technical body concerned.

## **3.2 Cooperation through mutual representation at meetings**

Appropriate designated representatives of ISO/TC/SC/WGs, who may be chairmen, secretaries, conveners, project leaders, or Central Secretariat technical officers, may have direct contact with relevant CEN/TC/SC/WGs, and up to two representatives may attend meetings of these committees as observers, and of WGs at the invitation of the parent body.

Appropriate designated representatives of CEN/TC/SC/WGs, who may be chairmen, secretaries, conveners, project leaders, or Central Secretariat technical officers, may have direct contact with relevant ISO/TC/SC/WGs, and up to two representatives may attend meetings of these committees as observers, and of WGs at the invitation of the parent body.

## **3.3 Cooperation by transfer from CEN to ISO**

### **3.3.1 Initiative**

Whenever the need to undertake new work (including the revision of existing standards) is identified in CEN, it is in accordance with its general policy to determine whether it is possible to give preference to the undertaking and completion of this work in time within ISO.

Once the decision has been taken in CEN to transfer the agreed work item to ISO and provided that at least five CEN member bodies have committed themselves to participate, the CEN proposal shall be submitted by the CEN/CS to the ISO/CS and the following procedure, in accordance with the EEC/ISO Directives part I: "*Procedures for the technical work*" shall be applied:

#### **a) For new work within the scope of an existing ISO/TC**

Information shall be provided in accordance with 2.2 of the IEC/ISO Directives, part 1 (form on pages 71/72).



**b) Widening of the scope of an existing ISO/TC**

If the request implies a widening of the current scope of the TC/SC concerned, the proposed revised scope shall be submitted to the ISO Technical Board at the same time as the request to undertake a new work item. The additional information shall be given as in a) above.

**c) For new work in fields not yet covered in ISO**

Information shall be provided in accordance with 1.5.3 and 1.5.4 of the IEC/ISO Directives, part 1 (form on pages 35/36).

In the above cases, CEN shall be entitled to nominate a Project Leader and to set a target date for the circulation of the ISO/DIS.

For cases **a)** and **b)**, ISO shall commence work immediately in parallel with the circulation of the proposal to the member bodies under the normal acceptance procedure.

For case **c)** the work in ISO shall start following the establishment of the appropriate technical committee, to which any possible CEN work on the matter shall be transferred.

**3.3.2 ISO response and further actions**

ISO shall normally respond within three months to new work proposals submitted to ISO by CEN in accordance with clause 3.3.1 above. CEN shall then draw conclusions regarding its further processing of the work.

Progress of work on such projects shall be checked by the ISO/CS on a monthly basis. Any difficulties or delays shall be reported to the Joint Coordinating Group of the Technical Boards acting as a management body in accordance with its terms of reference set out in clause 6.2 below, to obtain the necessary support from the relevant member bodies and the ISO/CS.

**3.3.3 Saving clause**

If at any time during the procedure, CEN can no longer accept the ISO results (e.g. for technical, procedural or timing reasons) CEN shall notify ISO of its decision and shall process the project separately as a CEN work item. ISO would then decide whether or not to continue to process the ISO version.

**4. Adoption of existing International Standards as European Standards**

**4.1 General**

International Standards may be adopted by CEN as European Standards under the PQ (primary questionnaire procedure) or the Unique Acceptance Procedure (UAP). When an ISO standard is proposed for adoption under one of these procedures, the CEN/CS shall send copies of the documentation to the ISO/CS, which shall inform the relevant ISO committee secretariat (if this is not held by a CEN member body) of the proposal. The result of the procedure may be :

- 1) that the ISO standard is adopted by CEN without change (4.2)
- 2) that the ISO standard is proposed for adoption by CEN subject to modification (4.3)

## **4.2 ISO Standard adopted without change**

No special provisions are required, but the ISO committee shall be notified of the adoption by ISO/CS and will take this into account when reviewing proposals for revision, confirmation or withdrawal.

## **4.3 ISO standard proposed for adoption with modifications**

All comments received under the PQ or UAP procedure shall be conveyed by the CEN/CS to the ISO/CS. The latter shall forward the comments to the secretariat of the relevant ISO committee which shall arrange for them to be reviewed by the ISO committee. Within two months, the ISO committee secretariat shall inform ISO/CS and the CEN Technical Secretariat or the CEN Reporting Secretariat of the intended action, which may be, in suggested order of priority:

- a) to consider revision of the ISO standard to incorporate the comments received as a result of the PQ or UAP procedure. In this case, the ISO committee secretariat shall inform the CEN Technical Secretariat or Reporting Secretariat of the tentative schedule for preparation of the revision. The CEN Technical Secretariat or Reporting Secretariat, after appropriate consultations within CEN, shall inform the ISO committee secretariat whether the proposed schedule is acceptable.
  - i) If so, the revised ISO standard shall be prepared and may be adopted as a European Standard according to 5.1 below.
  - ii) If the ISO committee cannot or prefers not to prepare a revision of the ISO standard within required European target dates, or for other reasons, the European Standard may be finalized in CEN according to 5.2 below. The amendments agreed within CEN will be offered to ISO by the CEN/CS for further harmonization (for instance, under the fast-track procedure);
- b) to maintain the ISO standard, and accept that the European Standard will deviate from the ISO standard.

## **5. Parallel approval of Standards**

NOTE - This clause is subject to adjustment to comply with forthcoming amendments of the IEC/ISO Directives.

### **5.1 Standards under development within ISO**

With reference to work items defined in clauses 3.3 and 4.3 above for which CEN has accepted to wait for the results from the ISO/TC/SCs, “parallel voting” shall be carried out in ISO and CEN.

Furthermore, CEN shall use the same method in other appropriate cases.

#### **a) Main elements of the procedure for parallel voting**

Once an ISO/TC has approved a draft for circulation as a DIS, the ISO/CS shall inform the CEN/CS of the reference assigned to the DIS, including the intended final number of the publication. The CEN/CS shall circulate the voting form to its members, announcing the document to arrive from the ISO/CS under the reference indicated. A copy shall be sent, if relevant, to the SR or CEN/TC/SC Secretariat.

The ISO/CS, after checking the DIS in accordance with 3.3 above and within the maximum permitted processing time, shall send the DIS to the ISO member bodies (and, on behalf of CEN, to the CEN member bodies for Iceland and Luxemburg).

The member bodies shall return their votes on the respective voting forms to ISO and CEN. Should the vote returned to CEN differ from that returned to ISO, a detailed technical justification shall be given to CEN, with a copy to ISO, together with the voting papers.

*NOTE* - Such a case may arise in view of the different backgrounds and significance of the two votes. ISO: worldwide compromise, not mandatory for national implementation; CEN: European solution, implementation as National Standard mandatory for CEN members.

If the voting results in ISO are positive and no valid technical reasons have been expressed which justify a further vote, the ISO/CS shall inform the CEN/CS immediately and proceed to publishing the DIS unaltered as an International Standard.

If the voting results in CEN are also positive, the DIS (IS) shall be formally ratified as an EN and implemented by CEN members.

In the case of a negative outcome in CEN but positive outcome in ISO, CEN shall proceed to adopting common modifications which shall be communicated to ISO.

In the event of other results, further processing shall be considered jointly by both sides on a case by case basis.

#### **b) Quality of DIS submitted to member body vote**

In order to achieve a DIS which, from the standpoint of technical content and editorial presentation, is deemed suitable for parallel voting, the relevant committee draft may (within ISO) be submitted to a “three-month voting procedure” preceding the Six Months' Rule.

At the close of the six months' voting, the results shall be communicated by the ISO/CS to the secretariat and Chairman of the ISO committee and to the CEN/CS.

Depending on the voting results, the Chairman and secretariat of the ISO committee may decide:

- to publish the International Standard with editorial modifications only;
- or
- to refer the DIS back to the committee.

## **5.2 Standards under development within CEN**

The Technical Secretariat or Reporting Secretariat shall ensure that copies of drafts are made available to the ISO committee so that it may comment as such on the successive European drafts. According to circumstances, the ISO committee may decide to await completion of the European Standards, which may then be submitted to ISO (for example, under the fast-track procedure), or may decide that parallel voting be conducted as follows:

Once consensus has been obtained within the CEN committee, the final text shall be supplied by the TC Secretariat to the CEN/CS, which shall forward the document to the ISO/CS, informing the secretariat of the ISO committee of this action. The ISO/CS shall circulate the document for DIS voting, which will also serve as the enquiry within CEN, as in 5.1. The CEN ballot paper, however, shall be issued by the CEN/CS. At the end of the voting period, the ISO/CS shall submit the result to the CEN/CS and, for information, to the secretariat of the ISO committee and its Chairman. A final text shall be agreed within CEN which shall be submitted to the CEN/CS for formal voting and to the ISO/CS for voting as a second DIS. If the voting outcome is positive both in ISO and in CEN, the ISO/CS and CEN/CS shall both proceed with publication, incorporating agreed editorial changes. If the results are not positive in both organizations, further processing shall be subject to negotiation.

## **6. Monitoring**

### **6.1 Joint coordination meetings**

Where ISO and CEN committees already exist and deal with the same subject matter but have not yet reached working arrangements to avoid duplication, the Central Secretariat of each organization should inform the TC/SC secretariats of the need to appoint delegates with a view to allocating work. Joint coordination meetings of ISO and CEN committees should be held to allocate work where necessary and to deal with comments submitted by members as a result of parallel voting on the ISO/DIS and the CEN enquiry.

### **6.2 Joint ISO/CEN Coordinating Group of the Technical Boards**

To initiate and to achieve the above objectives, a Joint ISO/CEN Coordinating Group of the Technical Boards has been established with the task of proposing and monitoring the appropriate operating methods and systems, on the understanding that the day to day processing shall be handled by both Central Secretariats. The Group comprises three members appointed by each Technical Board and the respective Secretaries, the Chairman and Secretary alternating for each meeting.

The joint tasks are as follows:

- to monitor the general implementation of the "Agreement on technical cooperation between ISO and CEN" (Vienna Agreement);
- to review and, where necessary, propose revisions to the existing procedures, mechanisms and bases for information exchange, to achieve the objectives of mutual visibility and understanding of work programmes;
- to monitor the progress of projects of mutual interest and take whatever action may be required to ensure progress towards the completion of projects within planned timescales;

- to advise the Technical Boards of any direct involvement required of them for improving the performance of Secretaries and Experts appointed by member bodies;
- to maintain working linkages with the technical management bodies of both organizations;
- to review coordination issues on questions of common interest with a view to deciding on work allocation.

#### **7. Follow-up of comments from ISO member bodies**

CEN agrees to accept comments on prEN and prHD from ISO member bodies outside CEN. These comments should be sent directly to the CEN/CS, with copy to the ISO/CS. The CEN/CS shall forward such comments to the appropriate CEN technical body.

This body shall report back to the CEN/CS. The CEN/CS shall in turn inform the ISO member body of the action taken, with copy to the ISO/CS.

Valuable new ideas which might help support CEN work could also emanate from outside of Western Europe and, if appropriate, could be usefully incorporated in the documents prepared by the CEN committee. Such contributions shall be handled in the same way as above.

#### **8. Implementation of the Agreement**

The ISO and CEN Secretaries-General shall take the necessary steps to develop appropriate mechanisms for the practical implementation of the Agreement.

In the event of difficulties arising in the performance of this Agreement, the ISO/TCs, CEN/TCs and CEN Reporting Secretariats shall report to their respective Secretaries-General who shall decide on the necessary corrective measures.

NOTE - The implementation of the Agreement is to be considered as being within the framework of ISO and CEN procedures and their possible future amendments.

#### **9. Duration of the Agreement**

This Agreement shall remain in force until such time that ISO or CEN request its revision or its termination giving one year's notice.

## ISO AND CEN RESOLUTIONS

### ISO Council resolution 18/1990

#### Council

reaffirms the urgent need for ISO member bodies to recognize the primacy of international standardization and to commit themselves fully to the pursuit of this objective,

underlines the necessity to make maximum use of ISO's possibilities, under the Lisbon Agreement, to have direct contact or attendance vis-à-vis CEN technical committees, and to further develop the Lisbon agreement on exchange of information between ISO and CEN, and requests the Secretary-General to ensure that appropriate mechanisms are put in place to achieve non-duplication of efforts, that ISO involvement in the planning process start at as early a stage as possible, and that reports on all relevant developments within CEN be available,

welcomes the proposal to establish an ad hoc group of the ISO and CEN technical boards as a means to achieve these objectives and decides that this manner be continuously held under review and periodically reported by the Secretary-General to the Executive Board and Council.

### CEN General Assembly Resolution CEN/AG 3/1990

#### CEN/AG 3 1990

having **fully considered** ISO Council resolution 18/1990 concerning the need to strengthen and expand CEN/ISO cooperation vis-à-vis the Lisbon Agreement, and having fully supported the resolution CA 8/1990 aiming at strong links with international standardization,

concur with the ISO Council's view that appropriate mechanisms need to be put in place to ensure nonduplication of efforts, ISO involvement in the CEN technical planning process at the earliest possible stages, and that reports on all relevant developments within CEN be available to ISO.

**decides** that, in principle, the operation of the Lisbon Agreement and its subsequent refinements includes the possibility that appropriately designated representatives of ISO TC/CSs have direct contact with relevant CEN TC/SCs,

**welcomes and approves** the proposal of ISO to establish an ad hoc group of the ISO and CEN Technical Boards to achieve these objectives, and decides to keep this matter continuously under review and asks the Secretary-General to report to the CEN/CA and AG.

## **ANNEX 4: Guidelines for Implementation of the Vienna Agreement**

June 1996

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)  
EUROPEAN COMMITTEE FOR STANDARDIZATION (CEN)

### ***Guidelines for TC/SC Chairmen and Secretariats for implementation of the Agreement on technical cooperation between ISO and CEN (Vienna Agreement)***

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#### **0. Introduction**

The Agreement on technical cooperation between ISO and CEN (Vienna Agreement) was formally approved on 27 June 1991 in Vienna by the CEN Administrative Board following its approval by the ISO Executive Board at its meeting on 16 and 17 May 1991 in Geneva.

The Agreement replaced the “Agreement on exchange of technical information between ISO and CEN” (Lisbon Agreement) concluded in 1989.

The text of the Agreement was distributed to TC/SC chairmen and secretaries

- by ISO, under cover of a circular letter dated 11 July 1991;
  - by CEN, under cover of a circular letter dated 3 September 1991;
- together with guidelines for the implementation of the Agreement.

Common ISO/CEN guidelines were subsequently issued to replace those issued with the above circular letters and this new issue of the guidelines incorporates a number of improvements which have been found necessary to facilitate implementation of the Vienna Agreement, together with changes required following issue of the third edition of Part 1 of the ISO/IEC Directives. The guidelines are structured to reflect the various modes of cooperation between ISO and CEN, as follows:

- cooperation by correspondence (section 1);
- cooperation by mutual representation at meetings (section 2);
- adoption of existing International Standards as European Standards (section 3);
- cooperation by transfer of work and parallel approval of standards (section 4).

Detailed considerations concerning application of CEN/CENELEC internal regulations in the framework of the agreement are given in Annex 1;

Annex 2 provides details of the procedures by which ISO may adopt European Standards.

The guidelines are accompanied by flow charts summarizing the procedures to be followed in the case when a work item of interest to CEN is to be developed by ISO (figure 1) and vice versa (figure 2).

NOTE : In order to avoid confusion, subdivisions of these implementation guidelines are referred to as "sections" to distinguish them from the subdivisions of the Vienna Agreement which are referred to as "clauses".

## **1. Cooperation by correspondence (clause 2 and subclause 3.1)**

The provisions for cooperation by correspondence include the exchange of information between the ISO and CEN Central Secretariats, for ISO/CEN reporting secretariats (SRs) to provide information to the CEN Technical Board, CEN Central Secretariat and CEN committee secretariats as appropriate, and for CEN and ISO committee (TC and SC) secretariats to exchange information, with copies to both the ISO and the CEN Central Secretariats.

Written contributions 1) may emanate from TCs, SCs, SRs or CSs, 2) are expected to reflect a consolidated CEN or ISO view, and 3) are, in principle, comments on work programmes and/or draft standards.

## **2 Cooperation through mutual representation at meetings (subclause 3.2) and joint coordination meetings (subclause 6.1)**

**2.1** Questions of common interest to both ISO and CEN technical bodies can call for mutual representation at meetings. This mutual representation should occur as early in the process as possible. In principle, only two representatives (not including interpreters) will be permitted and should be formally appointed by the ISO or CEN committee nominating them by a TC or SC resolution. Preference should be given to appointing chairmen, secretaries, conveners or project leaders within the committee which nominates. These representatives shall actively represent the views of the committee that nominated them. Participation in WG meetings is subject to invitation by the parent body of the WG.

The secretariat of the ISO or CEN committee which nominates shall advise the secretariat of the committee of the other organization, with copy to the ISO and CEN Central Secretariats, of the committee resolution as well as the names, addresses and functions in the committee which nominates, of liaison representatives to the committee of the other organization. The Central Secretariats of both ISO and CEN shall ensure relevant and adequate communication between them as well as to and from the committees concerned.

Proposals are deemed to be accepted if no reaction is received within two months.

Representation need not always be mutual. The possibility exists for any committee to seek representation of its interests in committees of the other organization, through nomination as well as by invitation. The same procedure as above applies for nomination of liaison representatives.

**2.2** Where ISO and CEN committees already exist and have overlapping programmes of work, the ISO and/or CEN Central Secretariat, following consultation between them, will organize joint coordination meetings of appropriate representatives (see 2.1) to reach agreement on allocation of work and, if necessary, to resolve comments received following parallel voting on DIS and prEN. The same principles as in 2.1 apply for representatives to such meetings.



### **3. Adoption of existing International Standards as European Standards (clause 4)**

#### **3.1 ISO standards adopted without change**

If an ISO standard is adopted by CEN without change, the ISO/TC/SC secretariats will be informed by the ISO Central Secretariat that the ISO standard has been approved as a European Standard and will be invited to take this into account when reviewing proposals for revision, confirmation or withdrawal.

#### **3.2 ISO standard proposed for adoption with modifications**

When the CEN PQ (primary questionnaire) procedure generates comments, these shall be sent by CEN/CS, after appropriate decision of the CEN/BT, to the ISO/TC/SC secretariat concerned, with a copy to ISO/CS. The ISO/TC/SC secretary shall consult via letter ballot the members of the TC/SC and within five months shall inform ISO/CS, CEN/CS and the CEN/TC secretariat (or CEN Reporting Secretariat) if the ISO/TC/SC has agreed to revise the ISO standard or not, within the proposed time schedule and with rationale.

a) If the response is positive, the ISO standard shall be revised to incorporate the comments received from CEN and shall be processed as a revised International Standard and as a European Standard using the parallel approval procedure within ISO and CEN (section 4).

b) If the response is negative, CEN must review the rationale for ISO not agreeing to undertake the revision and is free to adopt the ISO standard with modifications, under the normal CEN procedure. In such circumstances, it may be desirable to draw attention to the differences between the EN and ISO standard and the rationale for the differences.

### **4. Cooperation by mutually agreed allocation of work with parallel approval of standards in ISO and CEN (clause 5.1)**

There are two possible cases of parallel approval:

i) agreement that work be carried out in ISO with parallel approval conducted in ISO and in CEN (see section 4.1 below and Annex 1); or

ii) agreement that work be carried out in CEN with parallel approval conducted in CEN and in ISO (see section 4.2 below);

NOTE - When the time factor is not considered to be critical it will be possible to complete the work in ISO and submit it to CEN for approval through the PQ and Formal Vote or UAP (Unique Acceptance Procedure) procedure (see section 3 above). It will also be possible to propose that an approved EN standard be submitted to ISO under the fast-track procedure (see annex 2 and clause G.2 of Part 1 of the ISO/IEC Directives).

#### **4.1 Agreed allocation of work from CEN to ISO (subclause 3.3) with parallel approval of standards in ISO and CEN**

##### **4.1.1 Transfer of work from CEN to ISO**

As indicated in Annex 1, for each new work item, CEN will consider its various procedural options and if its TC decides to propose the work item to ISO, one of the following cases may arise:

###### **4.1.1.1 New work within the scope of an existing ISO/TC/SC**

Following the approval of the new work item within CEN and provided that five CEN members that are P-members of the ISO committee commit themselves to participate, work can be transferred to ISO and shall commence immediately within the relevant ISO committee, the secretariat of which shall simultaneously circulate the proposal for new work<sup>12</sup> in accordance with subclause 2.3 of Part 1 of the ISO/IEC Directives together with the list of the ISO member bodies belonging to CEN ready to participate in the work and the proposed target date. Should the conditions for acceptance by ISO be fulfilled, CEN is entitled to propose a project leader to initiate the work and take responsibility for ensuring the timely advancement of the project, and to set a target date (compatible with Part 1 of the ISO/IEC Directives) for circulation of the ISO/DIS.

Immediately at the end of the three month NP (new work item proposal) voting period, the ISO committee secretariat shall inform the ISO and CEN Central Secretariats as to whether the committee has ratified the proposal for new work and whether the work can be completed by the proposed target date (or shall propose a new target date; CEN will then decide whether the work should proceed in ISO or not).

New work item proposals for which less than five CEN/ISO member bodies commit themselves to participate in the work will be handled in accordance with clause 2.3 of Part 1 of the ISO/IEC Directives.

###### **4.1.1.2 New work requiring extension of the scope of an existing ISO/TC**

The same procedure as under 4.1.1 shall apply, provided that the chairman and secretary of the ISO technical committee concerned agree to recommend the extension of the scope of the TC. Simultaneously with consultation on the CEN/NWI proposal, they shall seek agreement of the TC P-members on the proposed extension of the scope and the Technical Management Board secretariat will similarly seek the approval of the Technical Management Board of the extended scope.

If the TC chairman and secretary are opposed to the extension of the scope of the TC, they shall inform the secretariat of the ISO Technical Management Board without delay. The latter will include this information on the Technical Management Board ballot paper concerning the proposal to extend the scope of the TC.

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<sup>12</sup> CEN form A will, in this case, serve as the form to be used in ISO for the proposal of the new work item.

#### **4.1.1.3 New work in fields not yet covered in ISO**

Upon decision in CEN to transfer the work to ISO, the procedure described in the ISO/IEC Directives for establishment of a new TC will be applied.

#### **4.1.2 Allocation of work to ISO**

In cases where CEN proposes to transfer work covered by an existing ISO work item, no special action is required.

The ISO committee secretariat shall ensure that copies of drafts are made available to the corresponding CEN committee so that it may comment on the successive committee drafts.

#### **4.1.3 Progress of work - Preparatory stage and Committee stage**

If CEN has agreed to transfer work to ISO by means of one of the procedures described above, or if as a result of a joint coordination meeting (see section 2.2) work has been allocated to ISO, work during the preparatory stage and committee stage shall be carried out in accordance with Part 1 of the ISO/IEC Directives.

#### **4.1.4 Parallel approval in ISO and CEN of standards developed in ISO (clause 5.1)**

The ISO and CEN approval processes comprise two stages - an enquiry and a formal vote. For parallel approval

- the ISO/DIS procedure is equated with the CEN enquiry;
- the two-month ISO/FDIS vote (YES/NO) is equated with the CEN formal vote (YES/NO).

The procedure shall be as follows:

When consensus has been reached in the ISO committee, the committee secretariat shall send copies of the committee draft in English and French to the ISO/Central Secretariat (ISO/CS) with the usual explanatory report for distribution as a draft International Standard (DIS). ISO/CS will distribute the DIS to all ISO member bodies and also to the CEN member body for Luxembourg indicating on the cover page that the DIS covers a subject of interest to European standardization and that consultation of ISO-CEN member bodies on the DIS has the same effect as the CEN enquiry on a draft European Standard.

Therefore, CEN/CS will confirm in parallel this status and circulate the German text.

Five months will be allowed for voting and commenting on this text. (See annex 1 for provisions concerning German versions of prEN).

ISO member bodies shall return their votes and comments to ISO/CS and ISO/CS will send a copy of the table of replies to CEN/CS. CEN member bodies shall return their comments also to CEN/CS, and CEN/CS will forward a copy to ISO/CS.

At the end of this period, the votes and comments will be sent by the ISO/CS to the ISO committee secretariat for consideration by the committee and the table of replies to CEN/CS for information. Once a final text has been agreed upon, this shall be sent, again in English and French, to the ISO/CS, together with a full report of voting, for issue as a FDIS.

ISO/CS will distribute this text for a two month YES/NO vote (distribution as FDIS). Simultaneously, CEN/CS will notify the CEN members of the issuance of the document for formal vote in CEN. (See Annex 1 for provisions concerning German versions of prEN).

ISO member bodies shall return their votes to ISO/CS and CEN member bodies shall also return their votes to CEN/CS. Should the vote returned to CEN differ from that returned to ISO, a detailed technical justification shall be given to CEN, with a copy to ISO, together with the voting paper.

The results of the formal vote will be interpreted as follows:

Result of vote in ISO	Yes	Yes	No	No
Result of vote in CEN	Yes	No	Yes	No
Decision	Standard ISO xxxx Standard EN ISO xxxx	Consultation between ISO and CEN Standard ISO xxxx	Consultation between ISO and CEN Standard EN yyyy	Consultation between ISO and CEN and return of document to the committee

If it is decided to publish the International and/or European Standard, further processing will be, in ISO, in accordance with the ISO/IEC Directives and, in CEN, in accordance with the CEN/CENELEC Internal Regulations.

#### **4.2 CEN work of interest to ISO, allocation of work to CEN with parallel approval of standards in CEN and ISO (clause 5.2)**

##### **4.2.1 Progress of work**

If an ISO committee has decided to defer the development of an approved work item via letter ballot or during a meeting to permit its development within CEN, or if as a result of a joint coordination meeting (see section 2.2) it has been agreed to allocate a work item to CEN, work shall proceed in CEN in accordance Part 2 of the CEN/CENELEC Internal Regulations up to and including the decision to submit a text for CEN enquiry. The CEN technical secretariat or reporting Secretariat shall ensure that copies of drafts are made available to the corresponding ISO committee so that it may comment on the successive CEN drafts.

##### **4.2.2 Parallel approval in CEN and ISO of standards developed in CEN (clause 5.2)**

The CEN and ISO approval processes comprise two stages - an enquiry and a formal vote. For parallel approval

- the CEN enquiry is equated with the ISO/DIS procedure;
- the CEN formal vote (YES/NO) is equated with the two month ISO/FDIS vote (YES/NO).

The procedure shall be as follows:

Once a decision has been reached in the CEN committee to proceed with the enquiry, the text shall be supplied by the CEN/TC secretariat to the CEN/CS, which will forward the document to the ISO/CS, informing the ISO committee secretariat of this action. The CEN/TC will conduct its

five month enquiry, according to the CEN rules, for comment by CEN members, including on the German version. Specific non-CEN-members, with which CEN has formal agreements, will receive the drafts, on which they may send comments to the CEN committee secretariat, with a copy to CEN/CS.

ISO/CS will distribute this document in parallel as a draft International Standard to all ISO member bodies indicating on the cover page that the text is being distributed for enquiry in CEN and simultaneously for voting as an ISO/DIS. The text itself shall not be distributed by ISO/CS to the CEN members and CEN affiliate members. Five months will be allowed for voting and commenting on this text.

ISO member bodies shall return their votes and comments to ISO/CS and copy their comments to the CEN/TC Secretariat. CEN members shall return their comments also to CEN/TC and CEN/CS.

At the end of this period, the comments will be considered by the CEN committee, and shall be sent by the CEN committee secretariat for information to the secretariat of the ISO committee and its chairman. A final text shall be agreed within CEN which shall be submitted to the CEN/CS for formal voting. The text will be circulated by CEN/CS for formal vote in CEN according to its rules.

CEN/CS shall transmit this text to ISO/CS for a simultaneous FDIS vote (YES/NO). The text itself shall not be distributed by ISO/CS to the CEN members and CEN affiliate members.

ISO member bodies shall return their votes to ISO/CS and CEN member bodies shall also return their votes to CEN/CS. Should the vote returned to CEN differ from that returned to ISO, a detailed technical justification shall be given to CEN, with a copy to ISO, together with the voting paper.

The results of the formal vote will be interpreted as follows:

Result of vote in ISO	Yes	Yes	No	No
Result of vote in CEN	Yes	No	Yes	No
Decision	Standard ISO xxxx Standard EN ISO xxxx	Consultation between ISO and CEN Standard ISO xxxx	Consultation between ISO and CEN Standard EN yyyy	Consultation between ISO and CEN and return of document to the committee

If it is decided to publish the International and/or European Standard, further processing will be, in ISO, in accordance with the ISO/IEC Directives and, in CEN, in accordance with the CEN/CENELEC Internal Regulations.

### 4.3 Synchronization of ISO and CEN work

#### 4.3.1 Synchronization of new work item approval

One of the major difficulties in implementation of the Vienna Agreement so far has been caused by the failure to synchronize the work in ISO and CEN, for example requests have been received

to submit texts for parallel processing without there being relevant work items in both ISO and CEN. In such circumstances, either the work must be delayed while the other organization fulfill its procedural requirements for approval of a new work item, or the work will be continued independently in the lead organization, although the procedures may be synchronized at a later stage.

It is by far preferable that the whole parallel approval process be synchronized. For this purpose, the ISO and CEN committee secretariats should ensure that the required steps have been taken in both organizations well in advance of the submission of the text of a standard for enquiry. (In the case of a standard being developed under ISO leadership, the CEN committee secretariat shall ensure that the relevant WI has been approved by the CEN/BT which shall have also authorized that the work be carried out under ISO leadership. In the case of a standard being developed under CEN leadership, the ISO committee secretariat shall ensure that the relevant WI has been approved and that the ISO committee has decided, either by letter ballot or at a meeting, that the work should be carried out under CEN leadership.) Furthermore, it is essential that both the CEN and ISO Central Secretariats are kept fully informed of the relevant decisions of the CEN and ISO committees.

#### **4.3.2 Synchronization of the approval process**

It is recognized that, in some cases, work may be well advanced in one of the organizations, before the other agrees the need for a standard on a particular topic. If the second organization approves such a work item before the lead organization has carried out its enquiry, then the whole approval process may be carried out in parallel. If the lead organization has already initiated, or has carried out, its enquiry, the second organization has the choice either of carrying out its own enquiry independently following which a parallel formal vote may be carried out in ISO and CEN, or of awaiting finalization of the standard in the lead organization and submitting the approved standard for adoption (by the PQ and formal vote, or UAP, procedures in CEN, or for example, by the fast-track procedure in ISO). Again, it is essential that the CEN and ISO Central Secretariats are fully informed of relevant decisions.

Any ISO/DIS which fails to meet the criteria for acceptance in the ISO/IEC Directives, Part 1, must be re-issued for enquiry. Provision also exists within CEN to re-issue prENs for enquiry. It is accordingly possible, even if one of the organizations has already carried out an enquiry, to carry out a second enquiry in the lead organization in parallel with a first enquiry in the second organization. However, the desire to synchronize procedures should be weighed against the need to make the standard available on a timely basis, particularly in the case of mandated work in CEN.

Finally, it should be noted that for much mandated work in CEN, the final texts of a European Standard needs to be reviewed by experts to ensure that the standard fulfills the provision and intent of relevant European legislation before the final vote is conducted. The CEN Central Secretariat should ensure that the relevant ISO and CEN committees are informed of this requirement and the lead committee secretariat should ensure that the proposed text of the FDIS or of the prEN for formal vote is submitted for review and confirmation before the text is sent to the Central Secretariats for issue for the formal vote.

#### **5. Joint ISO/CEN Coordinating Group of the Technical (Management) Boards (Clause 6.2)**

To monitor progress in the implementation of the Vienna Agreement and to ensure progress towards the completion of projects within planned time scales, the ISO and CEN Technical (Management) Boards have appointed a Joint ISO/CEN Coordinating Group (JCG) with terms of reference specified in clause 6.2 of the Agreement.

ISO/TC/SC and CEN/TC/SC secretariats are invited to inform this JCG, through the ISO/CS or CEN/CS, of any difficulty encountered in implementing these Guidelines.

ANNEX I  
to Guidelines

**Application of CEN/CENELEC internal regulations in the framework of the Vienna Agreement**

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CEN reaffirms the primacy of international standardization work, of avoidance of duplication of activities and of the use of international results wherever possible, however, it is to be acknowledged that CEN duly considers each request for standardization and chooses, according to the advice of its interested parties, amongst the following possibilities:

**a)** the submission of an existing document (e.g. originating from ISO) as a draft European standard through the implementation procedures (PQ plus Formal Vote, UAP) as defined in its Internal Regulations (see section 3);

NOTE - UAP is equivalent, but not identical, to the ISO “fast-track” procedure.

NOTE - As a result of these procedures, modifications to ISO documents by ISO/TCs can be requested by CEN in accordance with clause 4.3.

**b)** the request to ISO to prepare a standard on a specific subject (the transfer of work to ISO) as reflected in the Vienna Agreement (clause 3.3) to be implemented in accordance with section 4:

**c)** the use of an Associated Body (ASB) as defined in its Internal Regulations;

NOTE - This permits the introduction of documents prepared by a “recognized standardizing body” as draft European standards. The CEN concept is equivalent, but not identical, to the ISO concept.

**d)** the preparation of standards by the use of its own technical bodies (TC, SC, WG) as defined in its Internal Regulations.

However, the choice of the appropriate route to achieve the preparation of European standards (EN, HD, ENV) shall be made after careful consideration of the CEN Internal Regulations for technical work, and of the possibilities and limits of the options available.

In the CEN structure such an assessment and the relevant decision are made by the CEN Technical Board (CEN/BT) - or a CEN Technical Sector Board (CEN/BTS) by delegation - on the basis of the replies (form B) received from the CEN members on any proposals for new work items (form A).

In deciding on the way to handle the work, several elements have to be considered by the CEN/BT - or CEN/BTS by delegation - and CEN members when sending their replies by means of form B, such as :

- major commercial needs;

- importance of international trade;



- existence of ISO/TC or CEN/TC with competence in the area concerned;
- insertion in or completion of the existing documentation in the European catalogue;
- involvement of industry at international and European level;
- regulatory requirements resulting or anticipated from the European Commission;
- demonstrated technical barriers to trade (international and European);
- required or proposed timetable for the preparation of standards.

However, special attention is to be paid to the following arguments when envisaging the transfer of work to ISO:

- the CEN work item is mandated or not.

The Vienna Agreement does not exclude the transfer of mandated work items to ISO. Nevertheless, in principle the mandated work items are related to European Requirements reflected in EC Directives and are linked to a very tight target dates and obligations to be reflected in European standards that are to be recognized as “Harmonized Standards”, suitable for the implementation of the relevant Directive.

- CEN members are prepared to participate in ISO work.

At the end of work in ISO, parallel voting in CEN and ISO will be conducted. In order to be successful at this level, it is necessary that CEN members participate in the ISO work from the very beginning. Provision has been made that if at least 5 CEN P-members commit themselves to participate actively in ISO/TC work, CEN/BT can decide to transfer the work to ISO, the preparation of standards can begin without delay and CEN is entitled to nominate a project leader.

- the ISO rules allow the nomination of a project leader by CEN for conducting a given project<sup>13</sup>.

It is highly recommended that a CEN work item transferred to ISO be followed by a “European project leader”. Such a possibility permits a better link with ISO work in case of failure in ISO and the need to continue work in CEN. It is to be noted that the project leader has particular role in the editing of the prEN submitted to parallel vote.

- respect of the final control of CEN

While accepting the transfer of given work to ISO, CEN keeps open the option (see subclause 3.3.3) to withdraw at any time the transfer of work to ISO, should ISO not respond to the requirements made (respecting of EC Directives, target dates, etc.). This is particularly true for the mandated EC/EFTA work.

In that case, CEN will notify ISO of its to process the project separately as a CEN work item. The ISO/TC/SC shall then decide whether or not to continue to process work in ISO. (It is hoped that such an occurrence will be quite exceptional.)

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<sup>13</sup> This corresponds to the usual practice that the proposer of a work item offers a project leader.

### **Provisions for German versions of prENs**

ISO/DIS are normally available in English and French. In CEN, prEN shall be prepared in English, French and German, unless otherwise decided by CEN/BT. It is the responsibility of the CEN German speaking members to prepare, during the ISO/TC work, the German version of the future prEN so that CEN/CS can release this German version at the same time as the ISO/CS sends the French and English version for DIS or for FDIS vote. If at the DIS stage, the German version is still missing, one of the German speaking members shall be prepared to provide a translation of the ISO text within the first three months of the vote.

### **CEN STANDSTILL:**

Once the work item has been approved by the CEN/BT, general dispositions to impose or release standstill apply to CEN members according to the second alternative of the CEN/CENELEC Internal Regulations clause 6.2.1 (date decided by CEN/BT).

### Adoption by ISO of European Standards

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The CEN procedures for adoption of ISO standards are designed to allow the standards to be adopted without change as much as possible, on the basis that all CEN members, with the exception of Luxembourg, have had the possibility to contribute to the work in ISO.

It needs to be recalled that ISO member bodies, other than the CEN members and affiliates, will not have had the opportunity to contribute to the development of a particular European standard. If an EN is accordingly proposed to ISO for adoption, there is the possibility that there will be substantial comments on the document which may result in the ISO Standard being more or less substantially changed and hence in the ISO standard and EN being different. Whenever possible, therefore, preference should be given to parallel processing of a standard according to clause 5.2 of the Vienna Agreement.

There is no objection in principle, however, to an ISO committee deciding to submit an approved EN as a DIS, the following procedural options being available :

- 1) If the EN corresponds to an approved ISO work item, the responsible committee may decide by letter ballot, or by resolution at a meeting, that the text of the EN should be submitted for DIS ballot. In this case, once the committee has taken the decision, the secretariat should forward the English and French texts of the EN to the Central Secretariat accompanied by the usual explanatory report.
- 2 If the EN does not correspond to an approved ISO work item, two procedural options are available:
  - a) A NP ballot, during which P-members should be invited to approve the submission of the EN as a DIS;
  - b) implementation of the fast-track procedure, in which case a P-member or category A-liaison organization may propose that an EN be submitted for adoption under the fast-track procedure. All fast-track proposals (except those falling within the scope of ISO/IEC JTC 1 and ISO/TC 184) are referred to the ISO Technical Management Board for acceptance.

NOTE 1 - Procedural options 1) and 2a) above do not require that the subject document be a published European Standard. They can accordingly be used for prEN in order to synchronize the ISO and procedures.

NOTE 2 - The fast-track procedure applies only to published standards for which there is no corresponding approved work item in ISO. It cannot be used to introduce prENs into ISO. Procedural option 2a) should be used in preference to the fast-track procedure.

## **ANNEX 5: Other Information Resources**

The following publications are available from the sources indicated:

### **NIST Special Publication 891**

*Standards Setting in the European Union-Standards Organizations and Officials in EU Standards Activities (issued September 1995, updated December 1996)*

This guide includes a brief history of the role of standards in the European Union and the latest information on the EU's harmonization directives for implementing the "New Approach" and the "Global Approach" for harmonizing technical regulations and standards to reduce barriers to trade. The guide also contains information on CEN, CENELEC, and ETSI; information on European testing and certification activities; and a list of EU officials with standards-related responsibilities. The appendices include a bibliography, an extensive list of standards-related publications and directories that are available from NIST, and sources for ordering U.S. and European standards information in the United States and Europe, as well as contact points for standards-related information on the European Union in the United States.

*Available from:*

*Superintendent of Documents  
U.S. Government Printing Office  
Washington, DC 20402*

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### **The EU Information Handbook 1997**

This is a comprehensive guide that presents key information on the function, structure and staff of each of the Community institutions, and also includes details on governmental and nongovernmental organizations and research sources within and outside the European Union. The Handbook is published annually by the EU Committee of the American Chamber of Commerce.

### **Guide to the European Parliament 1994-1999**

This guide contains contact details for all 626 Members of the European Parliament (MEPs), their committees, delegations, and party membership.

### **Countdown 2000**

This is a guide to draft European legislation, published three times per year.

## **Business Guide to EU Initiatives**

A profile of more than 100 pieces of legislation currently going through the decision-making process.

## **EU Environment Guide**

Highlights of the 1996 edition include the contents and business impact of over 80 new and adopted EU environmental regulations; the latest information on the full structure and responsibilities of the European Commission's DG XI on Environment; environmental contacts within other EU institutions; and an extensive listing of world organizations and nongovernmental organizations involved in environmental affairs.

*All above available from:*

*American Chamber of Commerce  
EU Committee  
Ave. des Arts, 50  
1050 Brussels  
Belgium*

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## **Drafts and Publications of the EU Standardization Bodies**

Preliminary European Standards (prENs)	Approved European Standards (ENs)
Preliminary harmonized documents (prHDs)	Approved Harmonized Documents (HDs)
Preliminary draft European standards (prENVs)	European Prestandards (ENVs)

Administrative Documents (upon request)

*Available from:*

*American National Standards Institute  
Customer Service Department  
11 West 42<sup>nd</sup> Street  
New York, NY 10036  
Tel: 212-642-4900  
Fax: 212-302-1286  
E-mail: [info@ansi.org](mailto:info@ansi.org)*

Availability is listed twice monthly in *ANSI Standards Action*

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## **ANNEX 6: Abbreviations and Acronyms**

<b>AG</b>	CEN General Assembly
<b>AIF</b>	ANSI's International Advisory Committee Forum
<b>ANSI</b>	American National Standards Institute
<b>BT</b>	Technical Board
<b>BTS</b>	Technical Sector Boards
<b>CD</b>	Committee Draft
<b>CDV</b>	Committee Draft for Vote
<b>CE Mark</b>	Harmonized European mark for indicating conformance to relevant EU Directives
<b>CEC</b>	Commission of European Communities
<b>CEN</b>	European Committee for Standardization
<b>CENELEC</b>	European Committee for Electrotechnical Standardization
<b>CEPT</b>	European Conference of Postal and Telecommunications Administrations
<b>COPANT</b>	Pan American Standards Commission
<b>CS</b>	Central Secretariat
<b>DIS</b>	Draft International Standard
<b>EBU</b>	European Broadcasting Union
<b>EC</b>	European Commission
<b>EEA</b>	European Economic Area
<b>EETIS</b>	Electrical, Electronic, Telecommunication, Information Technology Sectors
<b>EFTA</b>	European Free Trade Association
<b>EG</b>	ETSI Guides
<b>EN</b>	European Standard (i.e., European Norm)
<b>ENV</b>	European Prestandard
<b>EOTC</b>	European Organization for Testing and Certification
<b>ES</b>	ETSI Standard
<b>ETSI</b>	European Telecommunications Standards Institute
<b>EU</b>	European Union
<b>EWOS</b>	European Workshop for Open Systems
<b>FDIS</b>	Final Draft International Standard
<b>GA</b>	ISO General Assembly
<b>HD</b>	Harmonization Document
<b>IAC</b>	ANSI's International Advisory Committee
<b>IEC</b>	International Electrotechnical Commission
<b>ISO</b>	International Organization for Standardization
<b>ITU</b>	International Telecommunications Union
<b>JCG</b>	Joint ISO/CEN Coordinating Group (JCG) of the Technical Boards
<b>JCP</b>	The Joint Presidents group, i.e. the presidents and chief executive officers of CEN, CENELEC and ETSI.
<b>MCG</b>	IEC/CENELEC Management Coordination Group
<b>MRA</b>	Mutual Recognition Agreement
<b>NC</b>	National Committee
<b>NIST</b>	National Institute of Standards and Technology
<b>NSB</b>	National Standards Body
<b>NVCASE</b>	National Voluntary Conformity Assessment System Evaluation
<b>PASC</b>	Pacific Area Standards Congress
<b>PC</b>	Programming Committee

<b>PQ</b>	Primary Questionnaire
<b>prEN</b>	Preliminary European Standard
<b>prHD</b>	Preliminary Harmonization Document
<b>SC</b>	Subcommittee
<b>TC</b>	Technical Committee
<b>TMB</b>	ISO Technical Management Board
<b>TSP</b>	Technical Study Proposal (i.e., proposal for a new area of technical work in either ISO or IEC)
<b>UAP</b>	Unique Acceptance Procedure
<b>USNC</b>	U.S. National Committee of the International Electrotechnical Commission
<b>VA</b>	Vienna Agreement
<b>WD</b>	Working Draft
<b>WG</b>	Working Group
<b>WTO</b>	World Trade Organization

## NOTES

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