



Supplement

august 1998

Introduction

In December 1996 ANSI produced a publication entitled "*American Access to the European Standardization Process*." This document provides an overview of how interested parties in the United States can effectively influence and have an impact upon European standardization activities. Through a series of questions and answers and examples of actual situations played out in the standards arena, the document illustrates how the U.S., via ANSI and the USNC/IEC, can gain enhanced access to the European standards process while promoting understanding between U.S. and European interests.

The focus of "*American Access*" is primarily on access to CEN, the European Committee for Standardization, though there are sections on

CENELEC and ETSI as well. The document contains brief mentions of the entities of the European Union, followed by the questions and answers and three case studies. The publication also describes the structure of the European standardization process and the various stages of standards development in CEN, CENELEC, and ETSI. Included are sections on conformity assessment, contacts, a list of the New Approach Directives, and text of the Vienna and Dresden Agreements. Also included are the Guidelines for Implementation of the Vienna Agreement.

The document is freely available from ANSI Online (www.ansi.org/public/library/eu_access/default.htm) or available for purchase in hard-copy format.

Supplement to *American Access*

Since the publication of "*American Access*," ANSI has learned that many U.S. delegates to ISO technical committee (TC) and subcommittee (SC) meetings still do not have a complete understanding of the Vienna Agreement (VA) for technical cooperation between ISO and CEN.

Problems regarding implementation of the VA are often a combination of technical and political issues. ANSI, with a seat on the ISO Technical Management Board (TMB) and on a Joint Coordinating Group of the ISO/TMB and the CEN Technical Board (CEN/BT), is able to help those in need. But knowledge of the Vienna Agreement and how it is implemented can stave off many problems that might be avoided before they reach the political stage.

Therefore, this supplement will further explain:

- what the Vienna Agreement is and what it is not;
- how it is being implemented;
- what work is actually being done under the terms of the VA (and who has the lead); and
- options U.S. delegates may pursue if the European members of an ISO committee want standards development work done in CEN, but the non-European members of the committee do not agree.

Please note that ANSI cannot do its work alone; industry must actively participate in the ISO process, garner support worldwide for its positions, and be committed to globally relevant standards.

Statistics

ANSI constituents frequently say that it appears the Vienna Agreement is in effect for nearly the entire ISO work program. In fact, only a small minority of the total ISO work program actually is affected by VA implementation. Let's look at a few simple statistics.

As of July 1, 1998:

- The total number of active work items in ISO was 6,431;
- The total number of active work items covered by the VA was 1,054;
- The total number of these work items covered under ISO lead was 756;
- The total number of these work items covered under CEN lead was 298;
 - Less than 5% of the entire active ISO active work program is under CEN lead.
 - More than 83% of the entire ISO active work program (not including published ISO standards not under current revision), is not affected by the Vienna Agreement*.

*NOTE: This work is being done in ISO, not CEN, or in ISO and CEN together. It might be that CEN has a parallel activity, but this may very well be because CEN plans to adopt the ISO standards as European Standards (ENs), and must have a technical committee structure in place to do so.

ANSI International Forum (AIF)

Several years ago the ANSI International Committee formed what has become known as the *ANSI International Forum* (AIF). The AIF is composed of all U.S. TAG Administrators and Chairmen, and all the Secretaries and Chairmen of ISO TCs and SCs where ANSI has the secretariat — about 350 people. The AIF meets three times per year, just prior to meetings of the ISO Technical Management Board.

Why have an AIF? To provide opportunities for members to share experiences about ISO (and related CEN) activities. Further, over the past several years more and more “horizontal” issues are coming before the TMB. The AIF provides a forum to develop

ANSI has since been investigating all 298 CEN-led work items to determine whether the United States was opposed to the CEN lead, and to inquire whether the relevant U.S. Technical Advisory Groups (TAGs) are satisfied with CEN's performance.

At the time of this publication, early results are mixed, with nearly a 60/40 split as to those U.S. TAGs that freely voted in their ISO committee to give the lead to CEN, and those who didn't. In many cases the U.S. TAG is reasonably content with how the process is working. ANSI will strive to work with the others to ensure the VA is actually implemented correctly, or to work with them to make the case in ISO (with good technical arguments) that the standards development work, perhaps at the time of next revision, should be done within ISO.

Though statistics show that there are actually relatively few problematic issues regarding implementation, ANSI recognizes that if you or your industry sector are among those who experience a difficulty, or if the VA is being misused in your arena, then all these favorable statistics are meaningless.

ANSI is responsive to its membership, and stands ready and willing to assist its members in resolving problems so that all sides feel successful. This is not always an easy assignment, but it can be, and has been, done.

coordinated, consensus-based U.S. positions on issues being addressed by the TMB.

The TMB has, by ISO statute, become much more involved in the management of the ISO work program: by trying to streamline the standards development process; by providing options that used to be available only to one or two TCs; by offering alternative procedures and deliverables; and by reviewing the work programs to rid them of very old work items. (During the past two years, approximately 1,200 work items have been deleted by the TMB as being woefully out of date — some items were more than 25 years old with a standard never published!)

Presentations made to AIF have enlightened those in attendance regarding these horizontal and management issues. The sharing of these experiences can go a long way towards making the entire system work better.

The AIF also reviews ISO/TMB agendas, offering recommendations to the International Committee on items affecting policy and to ANSI's representative on the TMB for technical issues.

Unfortunately, only a small percentage of its 350 members actually attend AIF meetings, thus losing an opportunity to share experiences and learn from the experiences of others.

Educational Opportunities

ISO instituted a Service Agreement in 1998 between ISO and its member bodies holding secretariats. The ANSI Federation has over 100 ISO TC and SC secretariats, and has revised its own Memorandum of Agreement with delegated secretariats to ensure all secretaries and chairmen have been trained, as now required by the TMB. If the TMB determines, based on substantiated complaints or data indicating poor performance, that a secretariat should be withdrawn, it will do so. (As an example, 30 secretariats formerly held by the Russian Federation were recently made available for other member bodies to assume.) All ISO member bodies, including ANSI, will be scrutinized over time to ensure the individuals serving as secretariats are moving the work program forward to meet real market needs. If there is no market need for a standard, then the work should stop.

ANSI's Information and Education Services Department has developed training seminars designed to help U.S. participants understand and effectively

influence the workings of ISO, including interaction with CEN, CENELEC, and ETSI.

Taking the Secret Out of Secretariat (Course No. 40-205) and *Author, Artisan and Statesman* (Course No. 40-206) are comprehensive training seminars for ISO TC and SC Secretariats and Project Leaders.

Seminars for committee participants, *Participate Effectively! - Strategies for Success in Standards* (Course No. 40-209) and *American Access to the Regional Standardization Bodies -- An Introductory Course* (Course No. 40-210), are especially well received. Both courses help participants learn how their organization can effectively influence and have impact upon standardization activities by strengthening their understanding of the organizations and procedures involved.

For more information visit the Education and Training Services page on ANSI Online (www.ansi.org/public/services/edu/edu_blue.htm).

Access to European Draft Standards

ANSI has a paid subscription to receive copies of all draft European standards (prENs) that go out to CEN and CENELEC members for the six-month enquiry, and for the subsequent two-month formal vote. All enquiry drafts are available to anyone wanting them. Notice of the drafts is shown in ANSI *Standards Action*, not only in paper for ANSI members, but on ANSI Online (www.ansi.org/rooms/room_14/) for those choosing to order the drafts electronically. Industry is able to acquire such drafts, but it must first regularly look to *Standards Action* to see if there are any drafts in which they have an interest.

The *NSSN: A National Resource for Global Standards* (www.nssn.org), an online database of standards information, provides an automated, e-mail-based standards alerting service that conducts a regular search and notifies customers when standards development projects of interest are initiated, reviewed, revised or approved. The NSSN tracks draft European standards through the enquiry and formal votes stages and into publication. Access to development data provides a distinct advantage to those concerned with the content of a developing standard.

Questions, Answers & Facts

Though some of these questions and answers appear in the “American Access” publication, they are presented here to reinforce what is fact, and to dispel what is myth.

1. If five or more CEN members vote affirmatively on a new work item ballot in an ISO TC or SC, does the lead automatically go to CEN?

There is absolutely no requirement anywhere in the *ISO/IEC Harmonized Directives* or the Vienna Agreement that states that when a new work item is voted upon in ISO, and at least five European members vote affirmative, the lead for the work automatically goes to CEN.

Let us be clear. The ISO process for approving new work items is an *ISO* process. It has nothing to do with CEN or the Vienna Agreement. The decision on whether or not an ISO/TC or SC approves a new work item has nothing at all to do with who takes the lead on the item, ISO or CEN.

2. Then how is the lead determined?

The Vienna Agreement cannot be implemented in any way, shape or form unless both the ISO/TC or SC and the CEN/TC concerned agree. This decision to implement is completely separate from any other decision regarding new work item approval or technical content.

If a majority of the ISO/TC or SC Participating ("P") members, either at a meeting or by letter ballot, vote that the VA be implemented, the next decision to be taken is to decide which organization shall take the lead.

The vote may be to have:

- ISO take the lead (as is the case in 95% of all VA implementations today), with parallel voting in CEN. All comments will be dealt with in the ISO committee, or
- CEN take the lead, with parallel voting of drafts in ISO. All comments will be dealt with in the CEN committee.

Therefore, for CEN to receive the lead, a conscious decision must be made by the ISO/TC or SC concerned to (1) implement the VA, and (2) assign the lead to CEN.

Again, a majority vote of the P-members is necessary. ANSI recommends that a letter ballot be issued so that all P-members of the TC or SC have a chance to vote, not only those sitting at the meeting.

Please be reminded that NP approval and VA implementation are two separate votes with no requirement that they be linked. No conditions regarding implementation of the VA are acceptable during the NP ballot (e.g., no CEN member should submit a conditional vote on a new work item stating that they will approve the new work item in ISO only on condition that the VA be implemented and CEN get the lead).

3. When the lead is assigned to either ISO or CEN under the ISO/CEN Vienna agreement, what does this assignment mean for the participating members of the ISO and CEN committees?

When a new ISO project or the revision of an existing ISO project is initiated and there is a related CEN committee, a proposal may be made to the ISO committee that the project should be developed for future ISO/CEN parallel voting. Voting would be harmonized at the ISO/DIS and CEN prEN stages, leading to concurrent approval in both organizations.

At this time a related proposal may be made that project development proceed to the ISO/DIS stage under ISO lead, or proceed to the CEN prEN stage under CEN lead, and then parallel voting will occur.

If specific requirements of European regulations and/or directives must be reflected in the standard, if specific completion deadlines are specified for Europe, or if the affected business sector is largely European-based, it may be proposed that the lead be assigned to CEN. However, a European mandate does not mean it is mandatory for CEN to take the lead or do the standards development work – it simply means that, if ISO takes on the work, the project must be completed in time to meet the European requirements.

If ISO assumes the lead for a project, ISO member countries from both Europe and elsewhere may participate directly in the committees and working groups responsible for the development work. If lead for the project is assigned to CEN, only CEN member countries may participate directly in the project's development. However, the related ISO committee may nominate two liaison representatives to attend the responsible CEN committees. It is recommended that these liaison representatives be from non-European countries. Please note that (1) these representatives do not have voting powers in the CEN meetings and (2) they are expected to represent the ISO committee – not their individual countries.

If lead is assigned to CEN, the ISO committee may review this documentation and provide the consensus input of the ISO committee to the CEN committee or working group through the liaison representatives.

Under the ISO/CEN Vienna Agreement, all documentation related to a project under development should be provided by the ISO committee to the related CEN committee and vice versa, depending on assignment of lead.

The ISO committee and the CEN committee must come to the same decision on assignment of lead; if they do not, the matter may be raised to the ISO/TMB and the CEN/BT for resolution. ANSI can work with other ISO/TMB members to gain support for the U.S. position on assignment of lead.

The Joint Coordination Group (JCG) of the CEN and ISO Technical Boards would have to reach consensus on the best approach. To date, whenever a matter has come before the JCG, it

has been resolved with the lead usually being assigned to ISO. If there is no concurrence of views between the two Technical Boards, then ISO and CEN will most likely go their separate ways on the technical work for the standard(s) in question.

4. If CEN proposes to assume the lead for the future revision of an ISO standard, but the non-European participants disagree, what should U.S. participants in the ISO/TC or SC do to ensure the lead remains with ISO?

The following is recommended:

1. The U.S. TAG should diligently monitor the work of the ISO/TC or SC in order to anticipate when initiation of the next revision of the ISO standard may be proposed.
2. The U.S. TAG should establish technical contacts in Europe that can advise the U.S. TAG when CEN may take, or has taken, actions in relation to the ISO standard.

Such actions could include:

- CEN/TC proposing to the ISO/TC that the next revision of the ISO standard be initiated;
 - CEN approving a proposal that CEN take the lead on the ISO standard;
 - CEN proposing to the ISO/TC or SC that CEN take the lead on the ISO standard.
3. U.S. TAG members should work with their associates in European countries to get them actively involved in the CEN TC. This contact will help to ensure that the CEN standard stays consistent with the ISO standard and that CEN will agree to keep the lead in ISO.
 4. In anticipation of a proposal from CEN to move an existing ISO standard to CEN lead, the U.S. TAG to the ISO TC or SC should develop a rationale for keeping the standard under ISO lead. The U.S. TAG should then interface with other non-European participating countries of the ISO TC or SC to gather support for the U.S. position. If necessary, the U.S. TAG should work to encourage non-European countries not currently participating in the ISO committee to become involved.

ANSI can assist the U.S. TAG by communicating with its contacts in other national standards bodies at the same time U.S. TAG members are contacting their fellow technical experts in the same countries. ANSI's relationships with regional standards organizations such as the Pacific Area Standards Congress (PASC) and the Pan American Standards Commission (COPANT) can be utilized to encourage stronger non-European participation.

5. As noted earlier, both the CEN/TC and the ISO/TC or SC must come to the same conclusion on assignment of the lead. If the two committees do not agree, the CEN/TC

may ask the CEN Technical Board (CEN/BT) to take higher level action with the ISO Technical Management Board (ISO/TMB) to assign the lead to CEN. If such is the case, ANSI will work with other members of the ISO/TMB to gain support for the U.S. TAG position and to further the best interests of ISO.

5. *When a decision has been previously made to give CEN the lead on a project under the ISO/CEN Vienna agreement, how can the lead assignment on the project be changed to ISO?*

The following is recommended:

1. The U.S. TAG should develop a statement of rationale on why the lead should be transferred to ISO for the project; this statement should be specific about how an ISO lead would be of greater benefit to both the project and world-wide users of the standard. An argument noting that the standard is not only regionally, but *globally*, relevant should be made.
2. The U.S. TAG should interface with other non-European participating countries of the ISO TC or SC to gather support for the U.S. position. If necessary, U.S. TAG members may work to encourage involvement of additional non-European countries in the ISO committee. ANSI will work with the U.S. TAG to garner increased levels of participation by approaching other ISO member bodies to increase their awareness of the specific activity, and to urge they become Participating members of the ISO/TC or SC concerned. Again, ANSI's relationships with regional standards organizations such as the Pacific Area Standards Congress (PASC) and the Pan American Standards Commission (COPANT) can be utilized to encourage stronger non-European participation.
3. When it is certain that a substantial amount of support exists from other countries, the U.S. should propose that the ISO TC or SC consider the question of reassigning lead to ISO. If the outcome is favorable in the ISO committee, the CEN committee must come to the same decision on assignment of lead. If the CEN committee does not immediately agree, the matter may be raised to the ISO/TMB and the CEN/BT for resolution. ANSI can work with other ISO/TMB members to gain support for the U.S. position on assignment of lead. If the CEN and ISO technical boards disagree, or the JCG doesn't reach consensus, then it is likely that CEN and ISO will go their own ways. This is a rare event, normally caused when European and ISO requirements differ.

6. What criteria/requirements must be met for an action to be taken at an ISO/TC or SC meeting, and what recourse does a delegation have if an action is proposed that does not meet these criteria or requirements?

According to Clause 3 of the *ISO/IEC Directives, Part 1* (1997 Edition), all agendas for meetings and all basic supporting documents must be circulated four months prior to a meeting. Only those drafts circulated at least four months prior to a meeting may be included on the agenda and discussed at a meeting, unless a majority of the meeting's participants decide otherwise. All other working documents to support business and actions of a meeting must reach member countries not less than six weeks before a meeting. A revised agenda and supporting documentation for any new action items may be circulated, as long as the material reaches member countries not less than six weeks before the meeting.

If an action is proposed at a meeting (such as assigning the lead on a project to CEN), and this action was not previously communicated to the committee on the original agenda (issued four months before the meeting) or on the revised agenda with supporting documentation (issued six weeks before the meeting), the following is recommended:

1. A member country at the meeting should make a motion that the action is out of order according to the *ISO/IEC Directives* and a decision on the action should be taken by correspondence of all committee member countries following the meeting.

Delegations present at the meeting may be unprepared to take such actions without the benefit of consultation with other constituents at home or with other countries. Delaying action will benefit countries not present that may be affected by the decision(s).

2. If the committee does not agree with the motion suggested under item #1 above, the same member country should then request that the vote taken be regarded as unofficial until confirmed by all of the committee's member countries via correspondence following the meeting.

Some ISO TCs and SCs have noted the appearance of CEN consultants funded by the European Commission (EC). During its annual meeting with the European Commission in November 1997, the ANSI delegation asked about this CEN consultant process, noting that a CEN consultant could hold up work nearly completed, thus denying industry the standards needed in a timely manner.

The Commission first stated that it does not control the three European standards bodies – these are independent bodies, closely linked through their efforts to implement work from the EC. Financial support is given by the EC to the standards bodies because the work they are doing is very important to the European Union (a collection of many member states working for consensus agreements). The EC confirmed plans to continue this method of operation.

However, the EC, as a regulator, sets legal requirements without setting technical solutions. There is a presumption of conformity. The New Approach responsibilities rest with the European standards bodies, not with the European Commission. Defining the harmonized standards lies entirely with the European Standards Organizations (ESOs).

As to consultants, the EC considers it useful to have independent voices in the European standards committees, thus ensuring that legal requirements of the Directives will be met. In many cases, these consultants are former national experts. Their role is

to ensure that requirements in standards meet mandates in the Directives. The Commission doesn't care who develops the European standard, so long as the requirements are the same. It is left to the ESOs as to "who does what."

At the November 1997 meeting, the ANSI delegation noted that consultants are interfering in the standards process. They frequently bring their own technical and monetary prejudices with them. The system ends up with confusion in both ISO and CEN when consultants become involved late in the process.

The Commission responded by noting that there is an extremely strong link in Europe between standards experts and regulators. The EC cannot blindly accept what a voluntary system produces, i.e., that the standards will automatically verify the legal system. Because of accountability, the EC can't depart from its present position.

The EC did recognize that considerable disruption to the standards process may arise if a consultant arrives at committee meetings when the standard in question is nearly completed, and agreed that consultants need to be involved as early as possible during the process.

NOTE: The EC also noted that, at the international level, where the commitment and the legal consequences are different, ISO results can be accepted as meeting their necessary legal requirements.

Parallel Voting & the Fast Track Process ***The role of U.S. standards developers and participants***

Parallel voting is in the best interests of non-European ISO members in that it helps to ensure the resulting CEN and ISO standards will be identical at the conclusion of the approval process. Both ISO and CEN must agree to initiate a parallel voting process.

The ISO/TC or SC involved must agree to a parallel vote. ANSI is involved in decisions regarding parallel voting at the TC/SC level if the U.S. is a Participating member of the committee.

Neither organization may initiate the parallel voting procedure on its own.

Alternatively, the Fast Track procedure may be initiated at any time. Fast track processing allows an ISO or IEC member body (such as ANSI) or Category A liaison member (such as CEN) to introduce a document at Stage 4 - Draft International Standard ballot.

A U.S. standards developer has the right to introduce a standard for parallel voting or the fast track process so long as (1) the developer agrees to abide by the resulting commitments and (2) the relevant U.S. TAG supports the developer functioning in this way. In fact, the Institute of Electrical and Electronics Engineers (IEEE) has done parallel voting of IEEE

standards and information technology standards in the ISO/IEC JTC 1 arena.

If there is any imbalance between what the U.S. can do and what CEN can do, the U.S. cannot, under the Vienna Agreement, officially take the lead on a work item as CEN can.

In practice, though, the U.S. often does take the lead; for example, organizations such as SAE, ITI, API, AAMI and probably ASTM have done so with many of their standards. Nothing stops the U.S. from

submitting a proposed standard with the condition that it go straight to the Draft International Standard (DIS) stage. The questions are, will the ISO TC or SC accept the proposal and does the U.S. have support for it? Equally, the question is: will the ISO TC or SC accept CEN taking the lead on a work item?

Remember, *parallel voting* and the *fast track procedure* are not the same thing – nor can they be done in combination.

European Chairmen and Secretariats

One additional, though infrequent, problem with implementation of the Vienna Agreement results from undue influence of European chairmen and secretariats that have responsibility for *both* the CEN and ISO work. Occasionally, such a committee officer may give undue preference to the CEN work.

ANSI and its accredited U.S. TAGs need to identify these cases and take action using the CEN/ISO TMB JCG. If the abuse is evident and goes without correction, it is possible to have the ISO TC chairman or secretariat withdrawn and reassigned.

Conclusions

Clearly, the most important issues identified in this paper are "*Who has the lead on any given item under the Vienna Agreement, and what has the U.S. done to ensure that the lead remains at ISO?*"

A problem faced too often by the U.S. is that our delegations and participants do not recognize the importance of building support for our positions within other P-member nations. Delegations may incorrectly assume that the rest of a committee will automatically support the U.S. position.

To be truly effective, the U.S. delegation's efforts must include a concerted effort to build the support of its participating member counterparts, including the Europeans. Further, the delegation must recognize that differences of opinion amongst the Europeans can be used to significant American advantage.

Finally, U.S. participants often complain about "block voting" by European participants. Realistically, "block voting" is what the voting process is all about – the politics of building support for your position until you have enough allies to win. U.S. participants can utilize the Vienna Agreement as one of the best

tools available to avoid "block" voting by the Europeans, especially if the lead for a project remains in ISO; but this requires that the U.S. ensure it has enough support from other ISO/TC or SC participating members to "lock in" an ISO lead. It is now obvious that the U.S. is not well served by standing alone in an ISO committee.

The truth is ... the U.S. is successful in ISO deliberations more often than not; successful because U.S. participants, along with ANSI, have worked to build support from other countries (including the Europeans). Success does not just happen. Similar to the members of U.S. standards committees, participants in ISO TCs or SCs have to build support for their positions if they wish to prevail.

In summary, strong channels of communication, coordination and cooperation will ensure strong U.S. influence in interactions with the Europe Standards Organizations. With the assistance of the U.S. participants, ANSI is working to identify and fix any problems or issues with CEN and the Vienna Agreement.

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