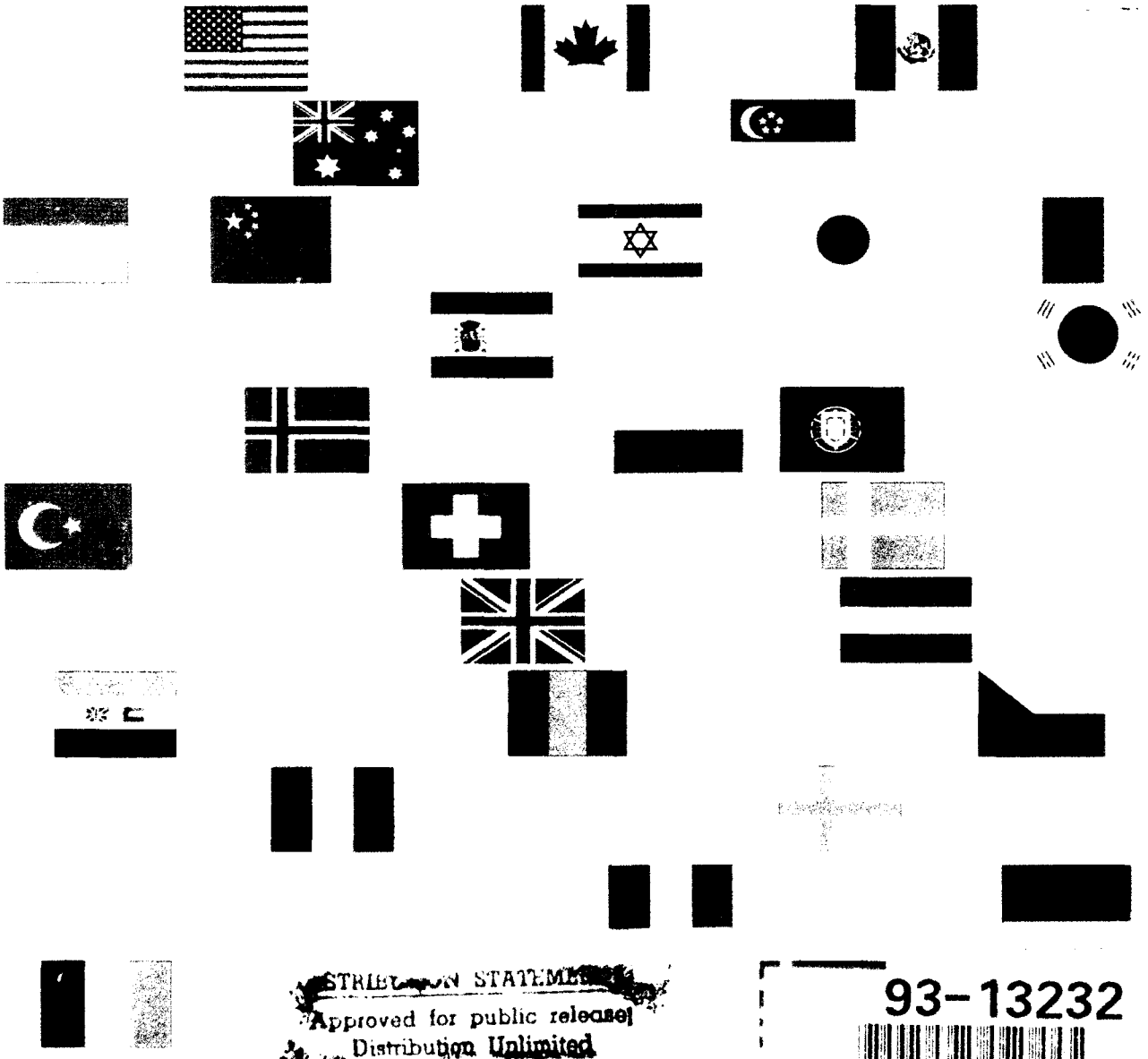
STANDARDS AND TRADE IN THE 1990s

A Source Book for
Department of Defense
Acquisition and Standardization Management
and their Industrial Counterparts



STANDARDS AND TRADE IN THE 1990s

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FOREWORD

This report, initiated by the Defense Systems Management College (DSMC), recognizes the importance of standards in the area of military acquisition and cooperation within NATO.

Standards, in various forms, are dynamic. New product development and standards development are progressing together. Hence, no report on standards can be final; it only can be a report on the present situation.

Fortunately, some basic concepts and types of standards are quite stable. Those basics are summarized in the appendix, "The ABC's of Standards-Related Activities in the United States," by Maureen A. Breitenberg of the National Bureau of Standards.

I wish to thank all members of the steering committees for their contributions. I regret that the late Professor Dave Acker, who started the project jointly with Professor Franz Frisch, was not able to enjoy the results.

I recommend this document as a basis for discussing and studying standards in acquisition and as a guide to stimulate future actions. Comments regarding this guide may be referred to the DSMC point of contact:

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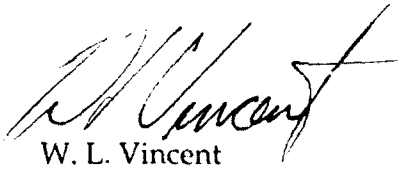

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Mr. Samuel Miller, Department of Defense
Mr. Lyn Mohler, United States Army Materials Command
Mr. Jay Myer, Society of Automotive Engineers
Mr. Peter Yurcisin, American National Standards Institute

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Executive Summary

Acquisition is a vital function of national and multilateral defense programs. Its efficient operation and sound management depend on the availability and application of standards and the assessment of conformity of goods and services to those standards.

The Defense Systems Management College (DSMC) is facing new challenges and a rapidly changing world environment that will alter its operations, including downsizing in budgets, and new responsibilities for the armed forces.

Of particular concern are the emerging programs of the European Community (EC) for standards and conformity assessment. How these will affect world trade and industrial competitiveness needed to be studied, analyzed, and acted upon.

DSMC and the Defense Supply Service invited proposals for a study and development of baseline information on which the United States can develop acquisition policies, standards, and conformity assessment programs to help American industry remain competitive in world markets.

The contract was awarded to the American Society of Mechanical Engineers (ASME), which in turn engaged two principal investigators to conduct the study and prepare the final report. They are Donald L. Peyton, President, Peyton Associates of White Plains, New York, and Charles W. Hyer, President of the Marley Organization, Ridgefield, Connecticut.

This source book, Standards and Trade in the 1990's, is the product of the contract.

The reader will find important background information on the evolution of standards and conformity assessment in the United States and Europe. Included is the genesis of the International Organization for Standardization standard—ISO 9000—the quintessential quality control standard.

Military-federal and industrial-voluntary, are the twin elements of the U.S. standards scene. How they operate to develop of national and international standards will interest acquisition and standards personnel. U.S. leadership is emphasized. Special attention is paid to the Defense Standards System, North Atlantic Treaty Organization (NATO), and case histories of U.S. successes.

The authors set the U.S. standards scene, with all of its uniqueness, problems, challenges, and fantastic strength derived from the U.S. competitive market system and our free society. Some may feel that we have not adequately covered the government's role in the voluntary system.

After a quarter-century of personal involvement and commitment — some of it critical but always supportive and devoted — it is difficult to suggest a role for the government other than the ones it now enjoys:

- by far, the largest user of standards
- protector and exponent of government missions and responsibility
- negotiator of international treaties and trade agreements
- guardian of public health, safety, and environment

• watchman against trust, monopoly, and fraud in the marketplace that U.S. voluntary standards have served well for almost a century

What the standards community wants from government is largely contained in three words — participation, encouragement, and support. A working partnership between the private and public sectors would enhance and strengthen the position of the U.S. in the current and foreseeable global standards scene.

To provide information and better understanding of the European scene, the source book includes sections on (a) the European standards system, (b) European Committee for Standardization (CEN), (c) European Committee for Electrotechnical Standardization (CENELEC), and (d) European Telecommunications Standards Institute (ETSI). It also describes how these systems and groups interface with the United States and international standards organizations.

Conformity assessment (CA) in the United States and in the Department of Defense, the NATO Standardization Agreement STANAG 4093, accreditation, and an introduction to the European Organization for Testing and Certification (EOTC) round out the essential elements of the acquisition process by which management can verify adherence to its judgments regarding use of standards.

The report ends with conclusions and recommendations for further action, and a series of annexes that are included for those who want or need further information. A glossary of acronyms is also provided.

1

INTRODUCTION-PROLOGUE

1.1 Introduction - Prologue

During the 20 years of its existence, the Defense Systems Management College (DSMC) has earned a well-deserved, worldwide reputation in government and industry for quality education, research, and information dissemination programs.

The college's vision statement is as follows: "The Defense Systems Management College will improve its ability to serve as the national center of excellence for defense acquisition management education, research, consulting and publications. We will lead efforts throughout DOD, industry and Congress to continuously improve defense acquisition management processes."

The DSMC faces many new challenges in the 1990s and a changing environment that will alter its operation. Reduction in the military budgets of the United States and its allies, and the sizes of U.S. armed forces will affect the acquisition system and its work force.

Of particular concern are the emerging programs, policies, and legal requirements of the Commission of the European Communities (CEC) and its EC-92 goal of establishing a unified, barrier-free internal market with common standards and programs of conformity assessment. Included in the goal are testing, certification, attestation, registration of quality assurance schemes, and access to those schemes by third party countries (non-European Community (EC) and European Free Trade Agreement (EFTA)). The impact of European Community (EC) programs and policies on collective mutual security pacts (e.g., NATO) in which the United States is a major participant will also be considered.

The DSMC has a number of key research efforts, including an analysis of potential dependence on foreign products and processes, and a review of the effect that using international standards as a basis for manufacturing may have on U.S. competitiveness.

To analyze current and foreseeable actions by the European Community and the impact of those actions on free trade, DSMC and the Defense Supply Service awarded a study contract to the American Society of Mechanical Engineers (ASME). The ASME hired two principal investigators to conduct the study and prepare a final report. This source book, *Standards and Trade in the 1990s*, is the result.

The book contains a number of sections that together provide acquisition and standardization management techniques along with background information and recommendations for strengthening the acquisition and standardization functions of national defense. Industrial implementation of these recommendations can help assure U.S. competitiveness in world markets.

1.2 Background and Events Leading to EC-92

The history of European and U.S. involvement of Europe and the United States in international standards development can be traced to the economic development and industrialization of the two regions. Following World War II, and until the mid-1960s, the United States had little incentive to be seriously concerned with international standards. Our industry, the world's largest and most diversified, was the supplier of the world. The U.S. standards were de facto international standards. Europe soon realized that there was little value in having 15 to 20 fractured national standards bodies working independently or in small groups that lacked the capacity to produce international standards. European standards bodies joined and became very active in the major international standards organizations: the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). They accepted leadership positions (secretariats) on key industrial product committees and exerted strong influence.

At the European level, they formed a regional group, the European Committee for Standardization (CEN), and an electrotechnical counterpart, the European Committee for Electrotechnical Standardization (CENELEC).

In 1985, the Commission of the European Community (CEC) created a new approach to technical barriers to trade, which stated that technical specifications (standards) should be the responsibility of CEN, CENELEC, and the European Telecommunications Standards Institute (ETSI). This new approach began the formal relationship between the EC and the standards groups.

The CEN and CENELEC, which are composed of Europe's national standards groups—*Deutsces Institut fur Normung*, DIN (Germany), Association *francaise de normalisation*, AFNOR (France), British Standards Institution, (BSI) (United Kingdom), and the other European Community and European Free Trade area standards organizations—had as their initial motivation the preservation of European standards development in national organizations. As time went on, these bodies became, and still are, the developers of Europe's standards and the central source of input to ISO and IEC. They can control input from outside countries because their technical committees are not always open to outsiders. Lack of accessibility to EC's standards development process was listed as a major concern in surveys of U.S. international standards participants.

Because members of CEN and CENELEC are the official members of ISO and IEC, the United States at times finds itself at a disadvantage.[1] The United States national standards body, the American National Standards Institute (ANSI), has made yeoman efforts to keep American influence strong and effective. The ANSI provides U. S. comments and suggestions to both CEN and CENELEC and arranges for technical representation where circumstances permit. It has an office in Brussels for liaison with CEN, CENELEC, ETSI, and the European Community. The ANSI-Brussels also supports ISO and IEC activities.

There is little question that EC-92 did a lot to alert U.S. industry—as well as private sector trade, technical, and professional groups, and the US. Government—to the advantages and the potential threats of European market unification. The United States has maintained a close and effective relationship with the EC and has access to virtually all of its plans, programs,

priorities, regulations, and directives. Government-to-government liaisons have been reasonably effective. The work goes on. Some of the more important directives are still under discussion.

On the private side, the United States, through ANSI, appears to have had the greatest success. ANSI liaison and cooperation with individual European standards bodies have been nurtured for some 75 years. Access to CEN and CENELEC documents and the acceptance of comments go back to about 1970. Both European and U.S. standards communities have given a strong priority to developing and adopting international standards. In ISO and IEC, the United States will be working with its counterpart CEN/CENELEC members. The best way to avoid technical barriers to trade in standards is to adopt international standards. Strong participation and cooperation within ISO and IEC is the key.

The other side of the standards coin (some say the only side) is conformity assessment (CA). The military has had quality-control programs for years. International standards in the ISO 9000 series are quite comparable. The EC is still considering directives for conformity assessment. This topic will be covered in a later section of the source book. At this point, however, it is important to mention that, in addition to the EC, the United States also interfaces with another regional, private group — the European Organization for Testing and Certification (EOTC).

1.3 Conformity Assessment and ISO 9000

It should be the goal of the defense acquisition and standards communities to encourage development of a single set of sound, accepted, international quality standards for both government and nongovernment applications. This uniform system is already emerging. It is largely the adoption phase that remains.

It may surprise some that quality control is an American innovation and that the path to the ISO 9000 series probably began in U.S. defense and space programs, where a number of unique concepts in contracting and conformity assessment succeeded. As is common practice among allied countries, the British learned from us, developed their highly successful BS 5750 Quality Management Systems, which eventually became internationalized as ISO 9000.

Historically, U.S. Department of Defense (DOD) standards and specifications have been adopted in NATO documents for acquisition and interoperability of products. There is no record of NATO adoption of nongovernment standards. Hence, DOD experience with international standards has been largely through NATO and based on military specifications.

Many suppliers of products conforming to voluntary standards have no experience with or interest in qualifying for DOD contracts. The ISO 9000, which offers a path toward consolidation of military and commercially based quality system review, becomes of interest. And, while the newly revised *Office of Management and Budget (OMB) Circular A-119* promotes government adoption and use of international standards, the only current, highly visible U.S. used international quality control standard is ISO 9000.

The U.S. standards community should support the efforts of BSI, ANSI, and other participants in ISO technical committees who have worked to develop and improve global quality control standards. Their adoption and judicious use will help enhance international trade.

As 1992 continues, the U.S. standards community appears in a good position with respect to its European counterparts. But 1992 is only prologue for the future. Both sides have a lot of work to do. Both must continue to strengthen infrastructure while realizing that the best that can be achieved for the time is a cooperative working relationship. The United States is not Europe. Europe is not the United States Both have extremely productive and effective means of obtaining standards, even international ones. Both sides must commit to the goal of developing standards that do not become trade barriers.

It is also important to appreciate the viability of strong standards systems, such as those of the United States and Europe. These systems are essential to the adoption and application of standards to the economic, social, and environmental well-being of our individual societies, all of which are unique and different. Attempting to force one community's standards systems to mirror others is unrealistic. Throughout the long and proud history of voluntary standardization, the harmonization and consensus acceptance of standards have been most effective when conflicting views and differing methodology have come together to find global solutions to problems.

1.4 References

1. *U. S. Voluntary Standardization System: Meeting the Global Challenge*, p. 19, published by American National Standards Institute, New York, NY.

2

THE U. S. STANDARDS SCENE

2.1 Background

For the purposes of this source book, it is necessary to view the U.S. standards scene from two perspectives: one military-federal, and the other industrial, or voluntary.

The Defense Establishment is encompassed by a large, complex, closed cocoon of 41,000 specifications and standards on which it bases its acquisition decisions. Some 34,000 of these standards have been developed by 120 separate military units or taken from Federal Supply Service. There are 5,100 nongovernment standards and 1,620 international ones. In addition, there are 4,300 DOD-prepared Commercial Item Descriptions, which serve as procurement specifications for off-the-shelf products.[1] The primary source of information on DOD specifications and standards is the *Defense Department Index of Specifications and Standards* (DODISS). As of now, there is only scant documentation on how many specifications, standards, or Commercial Item Descriptions have been adopted by the DOD.

Steps are being taken to encourage government adoption of nongovernment standards and gradual elimination of costly, duplicative government programs. The ANSI and a number of voluntary organizations have cosponsored four annual sessions entitled Industry-Government Standards Partnership—An Equal Partner Conference.

The history and future of the defense system, of international trade implications, and of suggested alternatives will be explored in a following section of this book.

2.2 The Voluntary System

The U.S. voluntary standards system is precisely what the private sector industrial community—and its scientific, technical, professional, trade, and labor organizations that supply standards and conformity assessment services—want it to be. It is unique in all the world, but then so is the competitive enterprise market system that drives the voluntary standardization process.

In the world of trade and enterprise, no two national standards bodies are the same. There are, however, a rapidly growing number of important similarities between the United States and Europe because of their interdependence on each other's markets and trade. Still, the principles of openness, due process, accessibility, flexibility, and freedom of entry are the linchpins of commitment to the voluntary system.

2.3 American National Standards Institute

The ANSI federation began 75 years ago when a group of engineering organizations with the common goal of eliminating duplication and conflict in standards formed a coordinating committee that later evolved into the American National Standards Institute. The founders, with one exception, remain active in standards.

The American Society for Testing and Materials (ASTM), American Society of Mechanical Engineers (ASME), Institute of Electrical and Electronic Engineers (IEEE), Society of Automotive Engineers (SAE), Underwriters Laboratories (UL), and ANSI are among the 20 major, private sector standards bodies responsible for 75 percent of nongovernment standards.

Figure 2-1 lists major voluntary standards organizations and the number of nongovernment standards for which each is responsible.

In the standards community, developers are organized and operate independent of one another, except for common-purpose projects. With the exception of ASTM, few groups were organized for the sole purpose of developing standards. Virtually every group's program evolved from the root cause of its establishment.

2.4 Standards Developing Organizations

The different types of organizations developing standards include the following:

Trade Associations. These groups are created to specifically address their industries' needs. They are considered among the most exclusive bodies and are the most likely to replicate market forces. Examples: National Association of Electrical Manufacturers, American Petroleum Institute, American Bankers Association.

Professional Societies. These individual membership groups advance the theory, practice, and applications of their technical fields. They carry considerable public trust responsibility and are often funded from publication sales or direct services to industry and public. Examples: Society of Automotive Engineers, American Society of Mechanical Engineers, Institute of Electrical and Electronics Engineers

General Membership Organizations. These groups are broadest based of all standards developers. They are individual membership organizations that pride themselves on fair and open processes. Every effort is made to represent all interests. Their procedures most closely approximate formal due process. Examples: American Society for Testing and Materials, National Fire Protection Association.

Third party Certifiers. These independent organizations test products to assure that they meet standards or regulatory requirements. They often develop the standards against which they test. They have a strong engineering orientation and perform other conformity assessment functions such as quality assurance registration. They have joint programs and agreements with foreign laboratories and a major stake in outcome of European decisions on conformity assessment. Examples: Underwriters Laboratories, American Gas Association.

The *National Institute for Standards and Technology* (NIST) Special Publication 806 lists the standards activities of 750 organizations. This number can be misleading when compared with ANSI's organization membership of 250.

2.5 National Standards Development

Membership is important to voluntary organizations, but it is not a requirement for participation in the voluntary system. The ANSI is a coordinating organization. It identifies a single, consistent set of standards for consideration as American National Standards. These, in turn, are generally regarded by the marketplace as warranting national recognition. More than 40

percent of all the standards developed by the 10 largest private standards developing organizations (SDO) have been approved as American National Standards.

Submittal of standards for approval as American National Standards is voluntary and is the decision of developers. The direction taken in managing a particular standardization effort is dependent on the needs expressed by the interested parties. For example, the strategy of choice in many industry sectors is to develop a national standard prior to submission to the international processes. Others are concerned with the timing of submittal and approval by ANSI.

As coordinator of the voluntary system, ANSI has the unique distinction of not developing standards. It helps facilitate standards development and verification of consensus (based on evidence supplied by the developer). It should be noted that all major standards developers are members of ANSI and that 97 percent of the standards developed in the United States originate within the membership of the federation.

The ANSI approval provides value-added verification that the principles of due process and openness have been adhered to and that a consensus of directly and materially affected interest has been achieved. This factor is particularly important for consideration in military acquisition.

With the emphasis on voluntary programs, one must not lose sight of the fact that the government plays a continuing and important role in the national standards system. Since its inception, ANSI has enjoyed a cooperative relationship with government at all levels. At the federal, state, and local levels, many departments and agencies have chosen to become members. In the field of acquisition, both the Department of Defense and General Services Administration (GSA) belong and take an active role in the governance of ANSI as participating members of the institute's Government Member Council. Government members also serve on the institutes board of directors.

The voluntary system is never completely satisfied with its progress; nor is ANSI, which faces a growing number of challenges from both increasing demands and financial limitations. However, progress and improvements continue to be made. The ANSI membership numbers more than 1,300 individual companies, 250 organizations, and 30 government agencies. Publication sales reached $8 million in 1991 and served an ever-expanding world market. As a broker and occasional publisher, ANSI buys its inventory of standards and then markets them. Publishers share in the revenues. The number of ANSI-approved American National Standards continues to grow and is now close to 10,000. There is also encouraging growth in ISO/IEC international standards.

Critical growth opportunities lie in the area of international standards administration and participation. The institute's allocation of resources to international standardization programs has grown from 25 percent to 64 percent of its funds. The ANSI's total budget has increased by 50 percent since 1988.

2.6 References

1. *NIST Special Publication 806, Standards Activities of Organizations in the United States.*

20 Major Nongovernment Standards Developers

	Number of Standards
Aerospace Industries Association	3,000
American Association of Cereal Chemists	370
American Association of State Highway and Transportation Officials	1,100
American Conference of Governmental Industrial Hygienists	700
American National Standards Institute	1,400
American Oil Chemists Society	365
American Petroleum Institute	880
American Railway Engineers Association	300
American Society of Mechanical Engineers	745
American Society for Testing and Materials	8,500
Association of American Railroads	1,350
Association of Official Analytical Chemists	1,900
Costmetic, Toiletry and Fragrance Association	800
Electronic Industries Association	600
Institute of Electrical and Electronics Engineers	575
National Fire Protection Association	275
Society of Automotive Engineers	5,100
Technical Association of the Pulp and Paper Industry	270
Underwriters Laboratories	630
United States Pharmacopeia	4,450

Figure 2-1

3

INTERNATIONAL STANDARDS

3.1 Background

Defense Acquisition and Standards Management personnel are aware that there are literally hundreds of international bodies developing standards. A large portion of these are treaty organizations that the United States Government supports. In some instances, such as with NATO, the United States Government is a major contributor. The NATO standardization will be covered in a separate section of the source book.

This publication limits its scope to the two major, nongovernmental voluntary groups and one intergovernmental group that promote most of the standards with which Military Acquisition deals in its normal, non-classified areas. The ISO and IEC are the nongovernmental groups. The intergovernmental group is the International Telecommunications Union (ITU).

As mentioned earlier, ISO and its electrical counterpart, IEC, are the prime sources of international voluntary standards and the nongovernment organizations to which ANSI and the United States National Committee of IEC are dedicated.

Through increasing technical participation and international leadership (particularly the acceptance of key secretariats and administrative responsibilities), ANSI has emerged as one of the leading partners in international industrial standards development and application. The United States is in a similarly favorable position in the field of telecommunication standards.

In less than a decade, telecommunications has turned from a government-dominated technical area to one that is fast approaching complete privatization. Standards are developed within a series of national institutions and are eventually approved by the International Telegraph and Telephone Consultative Committee (CCITT) and the International Radio Consultative Committee (CCIR) or the ITU. As the international treaty organization, ITU continues to assert preeminence in setting international telecommunications standards.

A variety of U.S. private entities have memberships in the committees of ITU, but the functions are administered by the State Department through U.S. national committees (e.g., USNC-CCITT). When national representation is required, the United States is represented by the State Department.

In this country, following the divestiture of AT&T, the ANSI Accredited Standards Committee on Telecommunications (T1) was formed to develop the network standards previously undertaken by the Bell System. (The sponsor of this committee is the Exchange Carrier Standards Association, which also provides the secretariat functions.) Committee T1 develops in excess of 90 percent of the United States technical contributions to ITU through the Department of State. Together with the Telecommunications Industries Association (TIA), another ANSI-accredited orga-

nization, T1 constitutes the standards development process for telecommunications in the United States.

3.2 U.S. Participation in International Technical Activities

The United States positions in ISO technical committees and subcommittees are formulated by U.S. Technical Advisory Groups (TAGs). These groups are organized and administered under ANSI due process procedures. When possible, TAGs are assigned to organizations developing national standards in the same or compatible fields. The ANSI depends on its standards developing members for administration of these groups.

The TAG activities are coordinated by U.S. TAG administrators appointed by ANSI ensure procedural compliance. Figure 3-1 contains the approved functions of U.S. Technical Advisory Groups.

The ANSI can provide Defense Acquisition and Standards personnel with current lists of U.S. Technical Advisory Groups and their administrators and topics covered. The ANSI can also arrange liaison meetings, if necessary.

3.3 Standardization and U.S. Global Competitiveness

Changes in the political structure of Europe, the virtual collapse of traditional collective alliances, the rapid growth in independent economies, and the emergence of regional economic rivalries have created a more competitive standards environment. Awareness of these factors has been sharpened by the European Community's development of a single, internal market with new systems of standards and conformity assessment.

This development has, in turn, brought about a significant increase in international standardization. Emergence of a global marketplace presents new challenges to the U.S. standards community and especially to its international interface organization, ANSI.

3.4 ANSI - Key to International Participation

The ANSI has the global relationships and programs to offer unique opportunities to handle changes taking place throughout the world—in emerging, unified Europe and other important geographic regions, Pacific Area Standards Congress (PASC) in the Pacific Ocean area and Pan American Standards Commission (COPANT) in Latin America. While still under development, the North American Free Trade area is another important region in which ANSI has been actively involved (ANSI's global relationships and relations are shown in Figure 3-2.).

The ANSI is the U.S. member of ISO and IEC. The IEC was formed before ANSI, in 1906, and a national committee (USNC-IEC) was formed to carry on activities. In 1931, USNC-IEC was placed under ANSI. The ANSI has borne full responsibility for IEC dues and for the administration of the USNC. IEC is composed of more than 40 national electrotechnical committees that are heavily involved in industrial standardization.

The ANSI helped found ISO in 1946, and is solely responsible for the U.S. share of its dues. The ISO has grown to a worldwide federation of 86 countries. It is devoted to producing standards that facilitate international exchange of goods and services, and it cooperates in myriad scientific, technological, and economic activities. Its work

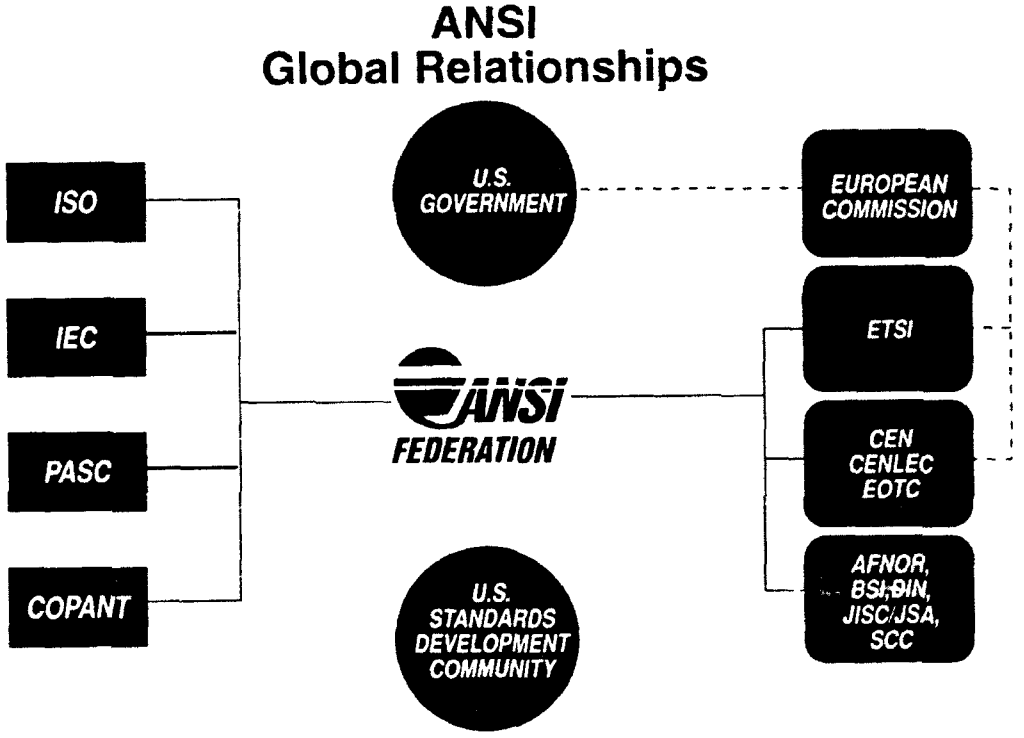


Figure 3-2 shows the unique global coverage of ANSI to all geographical areas of trade and regional standards interests.

Figure 3-2

covers all areas of technology, except those handled by IEC.

3.5 U.S. Leadership and Participation in International Standards

The ANSI holds participating or observer status on 95 percent of ISO's technical committees and 100 percent of IEC's. As shown in Figures 3-3, 3-4, and 3-5, the United States does not hold the greatest number of international technical committee secretariats; however, it is clearly superior in producing standards and is the lead producer of pages of technical text. By personal example and leadership, ANSI secretariats built a record of having the shortest elapsed time in developing and delivering ISO standards.

The ANSI is deeply involved in many international standards activities essential to military as well as nongovernment sectors of society. In the top 10 U.S. import and export trade areas identified by the U.S. Department of Commerce, the United States has a strong degree of influence and provides creative leadership.[1] By administering secretariats and chairing ISO and IEC technical committees and subcommittees, the United States helps drive standards activities in such important industry sectors as civilian aircraft, engines and parts, computers, and peripherals and parts.

The United States has a strong, proactive influence in the development of standards in the economically important areas of plastics, automobiles, petroleum, fuels and lubricants, electric machinery, and telecommunications.

Figures 3-6 and 3-7 show U.S. leadership positions in major export/import categories of importance to global commerce, as well as to America's global competitiveness.

3.6 Adoption of International Standards

In accordance with its due process and consensus principles, ANSI must take additional steps before deciding to adopt an international standard. International products result from agreements between the member bodies of ISO or the national committees of IEC. Following approval at the international level, a standard may be submitted to ANSI for approval as an American National Standard. International standards may also serve as the basis of national standards. Adoption by reference, in whole or in part, is acceptable procedure and accepted practice. Concurrent national-international review and processing is also possible in certain high-tech fields. The prime consideration, as in all areas of standardization, is ANSI's objective of achieving consensus approval of all known and materially affected or concerned interests.

In the practical world of standards application, it is important to determine the degree of equivalency between specific U.S. and ISO/IEC/CCITT standards. This factor is critical when international standards are proposed for military acquisition action. The international (ISO) definitions of categories of equivalency of national and international standards are as follows:

(a) Identical. The United States standard corresponds to the international standard exactly as an authentic translation with identical content and presentation.

(b) Technically Equivalent.The United States standard corresponds to the international standard so that what is acceptable to one standard is acceptable to the other, and vice versa.

(c) Partially Equivalent.TheUnited States standard is technicallyt equivalent in part to the international standard.

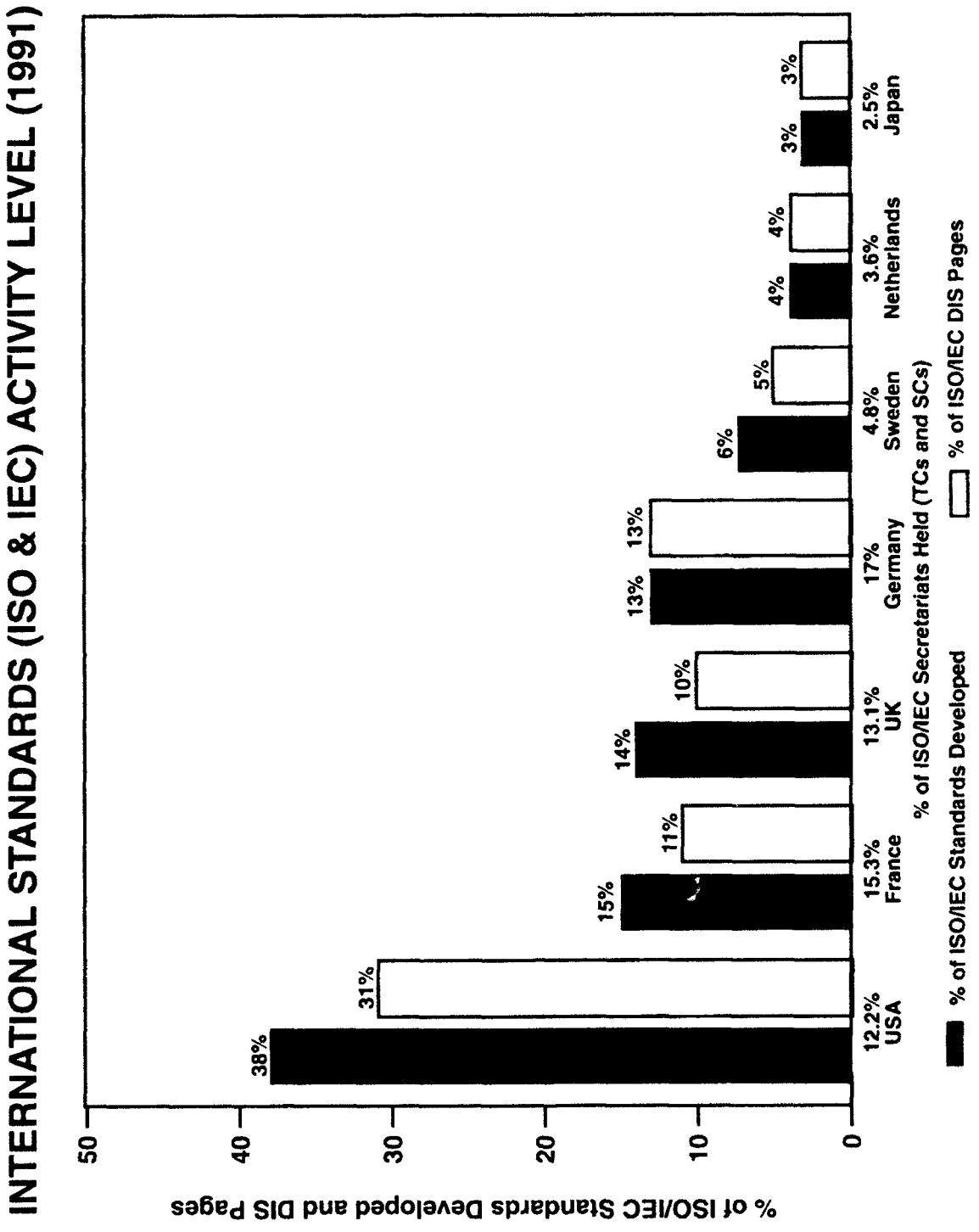

INTERNATIONAL STANDARDS (ISO & IEC) ACTIVITY LEVEL (1991)
% of ISO/IEC Standards Developed and DIS Pages
50
40
30
20
10
0
38%
31%
15%
11%
14%
10%
13%
13%
6%
5%
4%
4%
3%
3%
12.2% USA
15.3% France
13.1% UK
17% Germany
4.8% Sweden
3.6% Netherlands
2.5% Japan
% of ISO/IEC Secretariats Held (TCs and SCs)
% of ISO/IEC Standards Developed
% of ISO/IEC DIS Pages

Figure 3-3

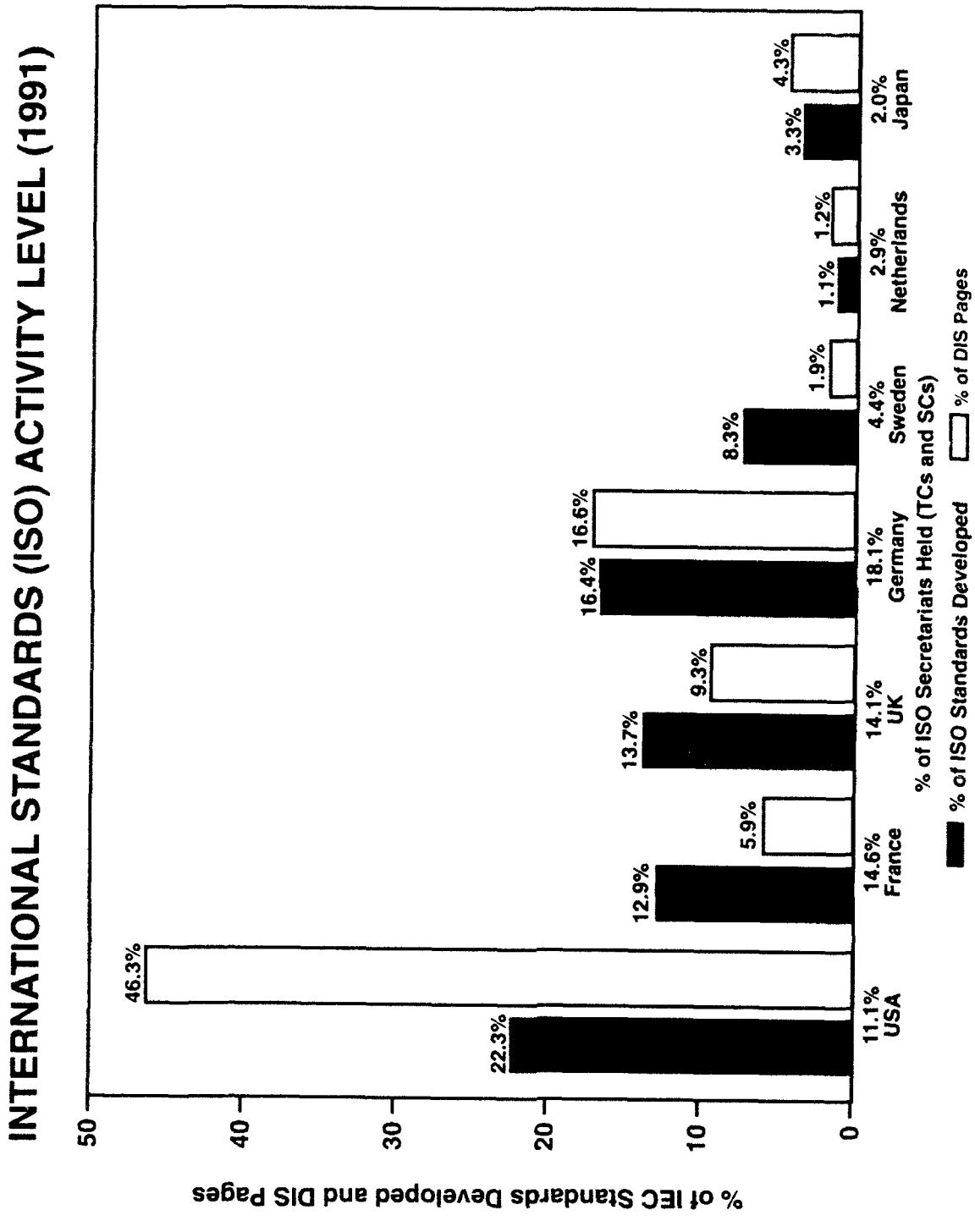

INTERNATIONAL STANDARDS (ISO) ACTIVITY LEVEL (1991)
% of IEC Standards Developed and DIS Pages
50
40
30
20
10
0
11.1% USA
22.3%
46.3%
14.6% France
12.9%
5.9%
14.1% UK
13.7%
9.3%
18.1% Germany
16.4%
16.6%
4.4% Sweden
8.3%
1.9%
2.9% Netherlands
1.1%
1.2%
2.0% Japan
3.3%
4.3%
% of ISO Secretariats Held (TCs and SCs)
% of ISO Standards Developed
% of DIS Pages

Figure 3-4

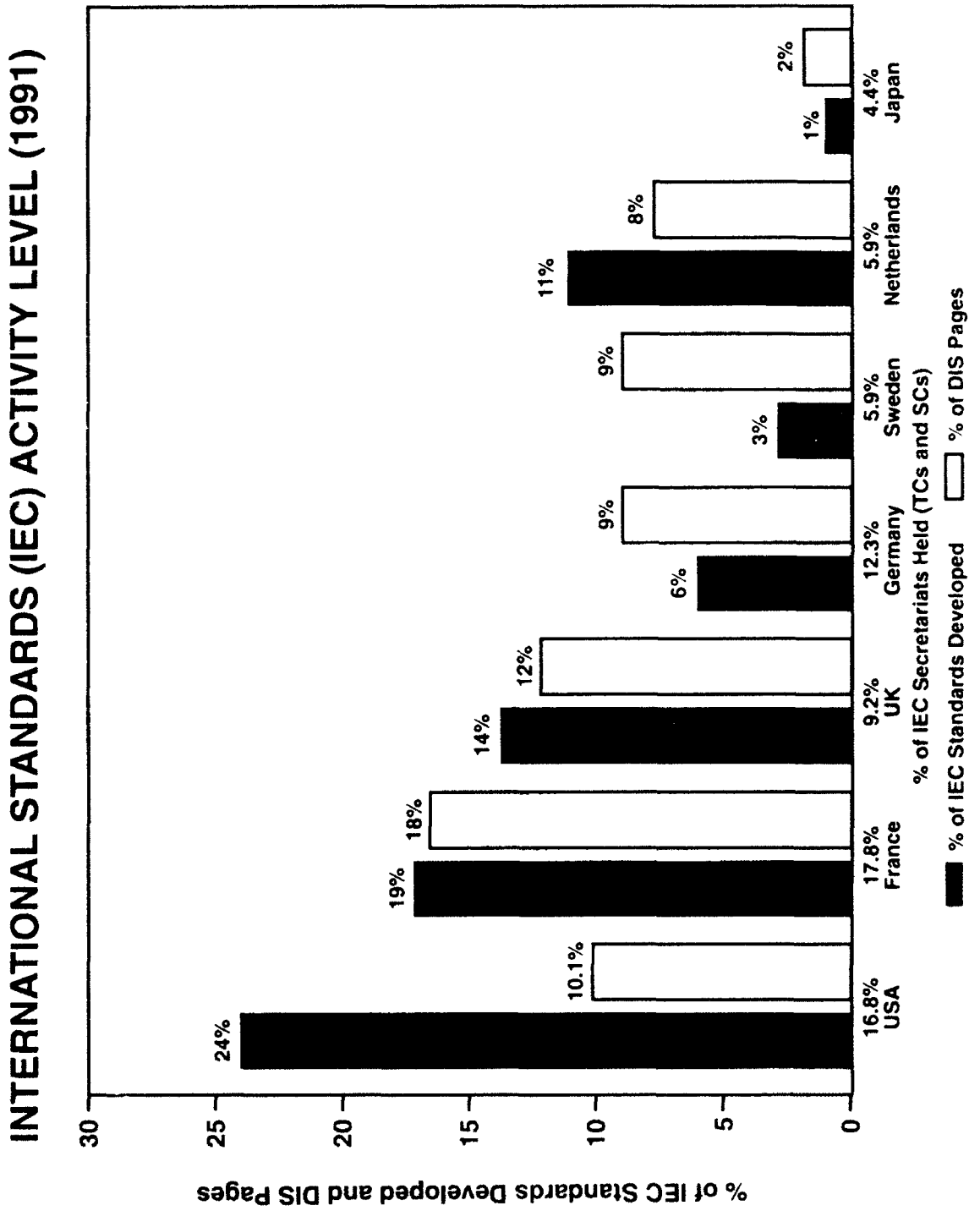

INTERNATIONAL STANDARDS (IEC) ACTIVITY LEVEL (1991)
% of IEC Standards Developed and DIS Pages
30
25
20
15
10
5
0
24%
10.1%
19%
18%
14%
12%
6%
9%
3%
9%
11%
8%
1%
2%
16.8% USA
17.8% France
9.2% UK
12.3% Germany
5.9% Sweden
5.9% Netherlands
4.4% Japan
% of IEC Secretariats Held (TCs and SCs)
% of IEC Standards Developed
% of DIS Pages

Figure 3-5

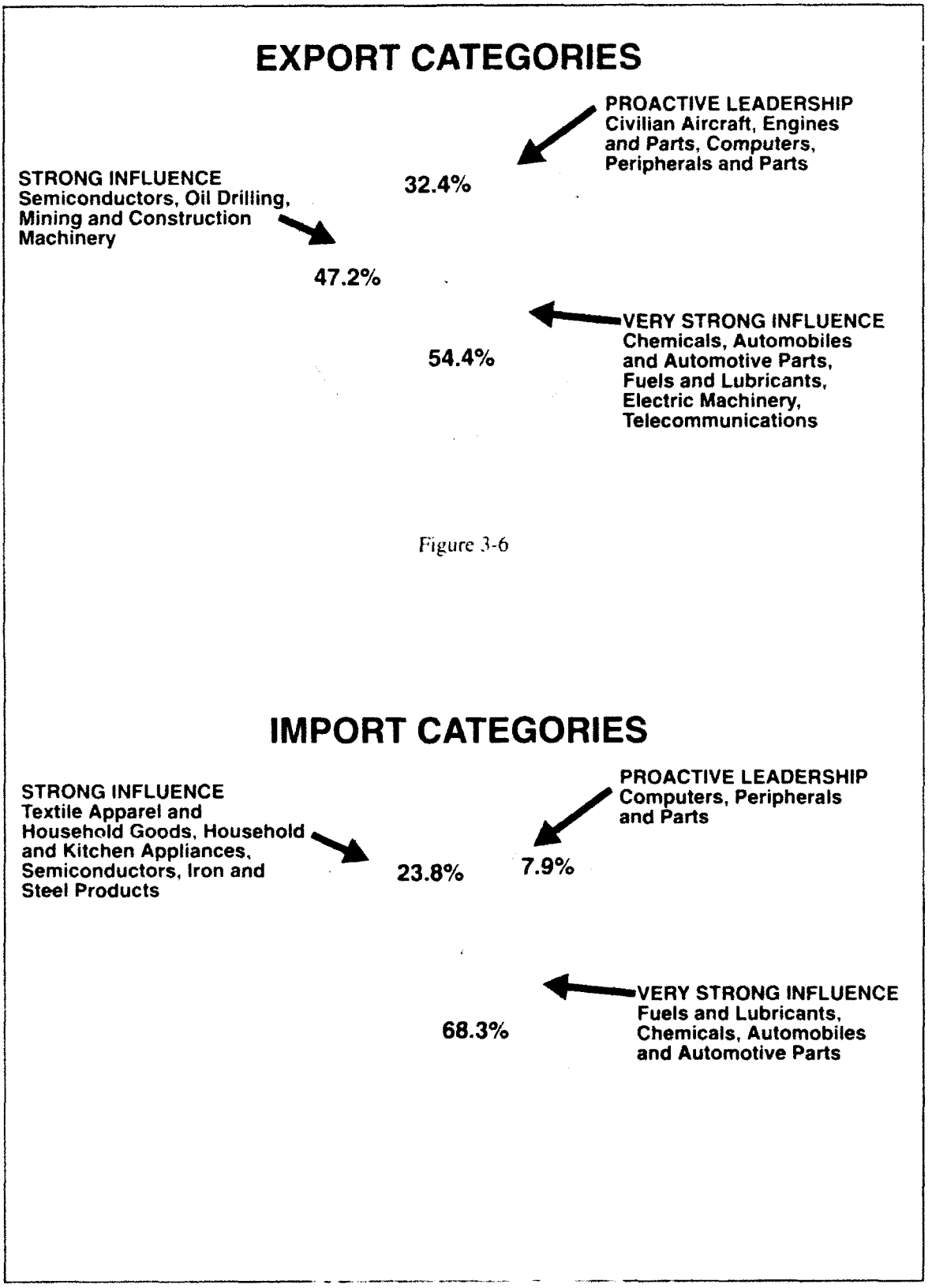


Figure 3-6

Figure 3-7

(d) Related. The United States standard is related but not equivalent to the corresponding international standard.

The ANSI technical analysis of approximately 7,800 ISO and IEC standards, while not completed, indicated the following sample study results:

- 22 percent are identical or technically equivalent to U.S. standards.
- 33 percent are partially equivalent or related to U.S. standards.
- 45 percent are not equivalent.

These numbers will change as the drive toward international standards becomes more universal and as voluntary regulatory adoption methods become more equivalent. It is presumed that U.S. equivalency figures will, in time, be similar to those of other highly industrialized countries.

3.7 Acceptance of U.S. Standards Technology

Prior to EC-92, the path to international standards success was largely dependent on the motivation of U.S. industry and the standards community to participate and, even as today, on the availability of technical and financial resources. The ANSI had much more control over America's standards destiny. It dealt with nongovernmental international standards organizations in which the United States had a strong voice in policy, procedures, and overall governance.

The European goals of economic unification and establishment of a single market, commonly known as EC-92, brought added attention to international standards and significantly changed the way the process will be carried out. In 1989, ANSI launched its own EC-92 program to provide its constituency, the United States voluntary system, with the means to compete in the changing global marketplace and to ensure access to timely information and improved coordination with Europe.

The European Community acted to refer the task of developing European standards to its prime regional bodies—CEN, CENELEC, and ETSI. These bodies are the key sources of European recommendations to ISO, IEC, and the technical arms of ITU. The U.S. input and access to these groups is limited because they are not completely open to outside standards bodies. With the advent of these new European initiatives, their subsequent impact on relations between ANSI and European national standards bodies, and the opportunity to negotiate standards issues on a one-to-one basis, the American battle cry became "Fortress Europe-Need for Transparency-Trade Barriers."

How have things progressed? Are we in trouble dealing with our counterparts in Europe? Will U.S. industry be disadvantaged or become less competitive? Answers to these questions are encouraging. In fact, a good bit of progress is being made because of a climate of cooperation and a series of helpful conferences between ANSI and European private sector organizations.

To provide an independent evaluation, the authors surveyed a representative group of U.S. international standards participants, both from organizations and from industry. They also questioned ANSI on submittal of comments on proposed EC standards and questioned the NIST Office of Standards Information regarding standards disputes under the General Agreement on Tariffs and Trade (GATT) Standards Code. The results were as follows:

(a) The United States international participants believed there should be access to the EC's standards development process at working levels. The ultimate goal should be to have all regional bodies that develop standards work under ISO, IEC, or ITU, or under their procedural guidelines.

(b) Respondents were active in a number of international forums. The ITU and the UN Economic Commission for Europe (ECE) were most often cited in addition to ISO and IEC. Coordination of activities was accomplished under procedures of the United States State Department, USTR, NIST, and ANSI.

(c) Respondents indicated that access was improving and that they had little difficulty making their views known to European groups. Some indicated that direct participation had been granted in specific instances. While many had participated or presented comments, they preferred international and opposed regional programs.

During the period of a year, only 12 formal comments on European standards had been received by ANSI and submitted to CEN and CENELEC. This record is not one of dissatisfaction. Additionally, during the 13-year life of the GATT Standards Code, only three standards cases were brought before the GATT Committee on Technical Barriers to Trade. None of these cases went through the formal dispute settlement. There are no cases pending.

Collecting information on work in progress and on the status of standards under development is a prime difficulty for smaller groups and companies without European subsidiaries or trade association connections. Information gathering, analysis, and follow up is expensive. Little evidence of networking was presented. The most often voiced need was for development of a single, electronic data base of information on standards and work in progress. Some indicated this service might be provided by government, especially if military and industrial data bases are consolidated.

The survey and personal interviews in Europe demonstrated that working agreements do exist between IEC/CENELEC and ISO/CEN to focus standards development internationally rather than regionally. These agreements are under review to strengthen internationalization.

3.7.1 Air-Conditioning and Refrigeration Institute (ARI) Case Study - A Response to the EC-92 Challenge

The ARI is a national industry trade association representing the producers of more than 90 percent of U.S.-made central air-conditioning and commercial refrigeration equipment. The ARI is a standards-developing organizational member of ANSI, having published more than 60 industry standards relating to the performance testing and rating of specific products. The ARI administers more than 20 product-rating and labeling-certification programs that provide, through independent testing organizations, verification of the performance ratings determined by the manufacturers of products conforming to ARI standards.

Early in 1989, the ARI board of directors decided that it was necessary to become actively involved in the international standards development activities of both ISO and IEC. It provided the resources to hire an international standards manager to expedite the development of proposed international standards. The ARI realized that an effective way to impact the development of foreign national and regional standards was to actively participate and contribute to the development of international standards in ISO and IEC.

The development of the European Community's single market and the consequent need for implementing standards and conformity assessment procedures created a significant demand for new standards in Europe. The European standards organizations, CEN and CENELEC, responded to the initial challenge. When the United States realized that the standards of these bodies would be developed behind closed doors, with no opportunity for U.S. participation, it firmly promoted the development of those standards and the adoption of international standards by the Europeans. Subsequently, the European Commission agreed to rely on international standards and to develop European standards only if international standards were nonexistent and could not be developed in a timely manner.

The ARI was aware of several standards development projects in CEN committees when it began to accelerate its participation in ISO subcommittees. The ARI proposed 29 new projects to the ISO technical committee to develop international standards for refrigeration and air-conditioning equipment. The ARI also identified 12 projects for priority development and offered to draft proposed standards for those 12 product categories in order to expedite the development of international standards. To date, five draft documents are under development in ISO subcommittees and seven drafts have been prepared for subsequent international work.

The Europeans recognize that they do not have the resources to participate in both ISO and CEN standards activities and they are in many cases satisfied with the progress being made in ISO. Therefore, the EC appears to be relying on the ISO standards development process for the standards it will need to implement its directives.

In the electrical safety area, ARI is actively participating in the appropriate subcommittee of IEC and has guided the development of a safety standard covering air-conditioners, heat pumps, and dehumidifiers through the approval process. This standard, based on requirements from a U.S.-Canadian binational standard, had been modified to meet the demands of the CENELEC committee that was developing a similar standard. The CENELEC will adopt the IEC standard and thus accept the provisions that were based both on the United States-Canadian requirements and on those that had already been developed by CENELEC.

The United States took a leadership role in ISO and IEC to accomplish these objectives. The United States holds the secretariat for the IEC subcommittee and expeditiously carried out the administrative work required for the development of the standard.

The standardization activities of ARI have been planned to support its current certification activities. The ARI is proposing to have its programs based on conformity with ISO international standards rather than its current ANSI-approved standards. In Europe, a conformity assessment program based on international standards is also being formulated. The United States program is expected to work out a mutual recognition agreement with Europe, which will make the ARI certification program acceptable for the European marketplace. The international IEC safety standard is expected to be adopted by the EC Common Market. The international IECEE certification scheme—discussed in Annex G—in which both the United States and Canada have membership, is expected to become the accepted program for worldwide safety

conformity. This acceptance will allow continued use of the current product safety certification arrangements of ARI members.

The ARI case demonstrates how an industry sector can and has worked to prevent potential barriers to trade resulting from EC-92 plans, and how industry can work to integrate current U.S. conformity assessment procedures into internationally accepted certification systems.

3.7.2 Association for the Advancement of Medical Instrumentation (AAMI) Case Study

The AAMI is a voluntary association composed of more 3,000 individual members, 175 manufacturing members, and 250 hospitals and other nonprofit health care facilities. In its total membership structure, the organization represents 2,000 hospitals and roughly 500 manufacturers. It includes agencies of government bodies; for example, the federal Food and Drug Administration, and medical societies. Leadership and initiative in a complex, competitive technical area by AAMI has brought the United States to a strong competitive leadership position in international medical device standards.

Standards are important to AAMI because of its applications in communicating medical device information, its role in domestic and international trade, and its contributions to the European Community plans for a single, integrated market by the end of 1992.

The AAMI has developed a proactive program of participation and administrative leadership in international standards. It is keenly aware that the European Community has an especially strong influence in world standards through CEN. First, CEN is composed of the European members of ISO and IEC, the lead international standards developers. They can, and at times do, act in consort in ISO technical activities, providing a convenient block of influence. Second, CEN receives mandates from the EC to draw up European standards for use in the context of harmonized technical directives. In medical devices, CEN has a target of completing 36 mandated standards by the end of 1992 and has 12 drafts at the final step of the procedure.

The AAMI's international program is intended to make sure that U.S. interests have a strong voice in ISO and IEC standards and have access to and influence over CEN and CENELEC standards. Because of the overriding priority for international (as contrasted with regional) standards and the close-working relationships between CEN/ISO and CENELEC/IEC, the AAMI program is succeeding. The common goal in harmonization of standards is to make it possible for a manufacturer to design a product for all markets according to one standard or regulation. The goal of AAMI is to harmonize standards in all markets of the world.

The AAMI has succeeded in influencing standards at ISO, IEC, and CEN/CENELEC levels. Its national programs are well grounded, well supported, and active at the international level. The AAMI is involved with two ISO committees that have been successful in their relations with corresponding CEN committees:

(1) The ISO/TC 194 on biocompatibility, for which AAMI is U.S. Technical Advisory Group administrator, was formed in 1989 and predates its CEN counterpart. The CEN committee to date simply monitors

ISO work and ballots ISO documents for CEN adoption. The AAMI provided the convener for the key working group that developed the overall TC 194 standard on selection of biocompatibility tests.

(2) The ISO/TC 198 on sterilization, for which AAMI provides the international secretariat, was formed in 1990, after its CEN counterparts. Coming along after the CEN work had begun has made the U.S. task more difficult. While there will probably be separate ISO and CEN standards for sterilization, they are closely harmonized. There is no question that the CEN standards have been influenced by the work of TC 198. In addition, AAMI has been able to send U.S. experts to virtually all CEN working-group meetings, either as representatives of ISO/TC 198 or as U.S. representatives.

The AAMI case represents success in gaining access to CEN technical meetings and in influencing development of harmonized medical device standards free of technical trade barriers. Information on the AAMI standards program and its interface with European regional and international groups (ISO/IEC) may be obtained from the Association for Advancement of Medical Instrumentation, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201. Phone: 703-525-4890. Fax: 703-276-0793.

3.8 Conclusions

It is apparent from discussions on both sides of the Atlantic that, in the minds of professionals, voluntary standards participation in ISO and IEC is the key to U.S. interests in influencing the European standards process, and in strengthening American competitiveness in world markets. Defense Acquisition and Standards personnel should encourage industrial participation in ISO/IEC to ensure further development and availability of sound international standards that meet military requirements. Acquisition personnel should avail themselves of opportunities to serve on ANSI and USNC-IEC technical advisory groups to voluntary international bodies.

3.9 Trouble Spots

While cooperation and accord with CEN and CENELEC improves and the United States strengthens its overall position in Europe, it would be misleading to assume that there are no existing programs that are, in fact, creating technical trade barriers either through standards or conformity assessment requirements. A prominent group that is causing a problem is a subset of CENELEC, located in Frankfurt, Germany. It is known as the CENELEC Electronic Component Committee (CECC).[2] It bills itself as the CECC System for Electronic Components of Assessed Quality. Among the services it promotes are the following:

The CECC also promotes a series of active advisory groups to meet the growing demand of aerospace, telecommunications, and information technology; defense; household equipment; and automotive industries.

Participation in CENELEC and CECC is limited to members of the European Community. A company cannot qualify its products unless its manufacturing facilities are located in an EC country. The U.S. input to component standards — developed for European application — is not possible under CECC procedures.

Steps have been taken in CENELEC-CECC by the Electronics Industries Association (EIA) to integrate CECC standards and programs under the auspices of IEC and to

open CECC approval and Quality Product Lists to non-European manufacturers and products. The EIA has presented its case to the U.S. trade representative for a solution to the problems under GATT. Details on CECC are provided in Annex C.

3.10 Aerospace Industries

A recent entry into the dialogue about technical trade barriers and EC-92 is the Aerospace Industries Association (AIA). The AIA is a leading producer of voluntary standards and conducts the secretariat of the International Committee for Aerospace Standards, ISO/TC 20.

The AIA recently published a report entitled *Impact of International Standardization and Certification on the U.S. Aerospace Industry.*

The executive summary states:

"Today, in standardization as in other fields, the U.S. is no longer the unquestioned world leader, but a strong player among strong rivals. Standards developed outside of the United States — particularly in Europe or in international standards organizations — are gaining credibility and acceptance. Key examples are the Joint Aviation Regulations (JARs) developed in Europe, and the ISO 9000 series on quality systems developed by the International Organization for Standardization. To the extent that these standards diverge from or conflict with U.S. standards and practices, the U.S. can be at a disadvantage in the world marketplace."

The study recommends the following:

- Increased industry support for active participation in international standardization/certification arenas.

- Closer dialogue with European industry on standards and certification issues.

- Harmonization of U.S. and international technical requirements.

- Resolution of regulatory and contractual issues related to ISO 9000 quality system assessment.

- Communication of aerospace industry concerns to appropriate U.S. Government agencies, and professional and trade associations.

- Enhanced industry awareness through gathering and dissemination of information by AIA.

The AIA report is a strong call to action by a leading trade association. Support from AIA's underlying membership will strengthen the U.S. competitive position in the international aerospace market. The AIA report is found in Annex F.

3.11 References

1. *U.S. Voluntary Standardization System: Meeting the Global Challenge*, published by American National Standards Institute, New York, NY.

2. *The CECC System for Electronic Components of Assessed Quality - Introduction to the System*, CECC - Annex C.

4

THE DEFENSE STANDARDS SYSTEM

4.1 Historical Perspective

Some people contend that the Department of Defense Standards System just grew into the monolith it now is. This belief is not the case. There were good reasons for almost every major change and increase in size. The DOD, unlike many federal departments, has always had a strong mission orientation. There is no other department that contends with all the debate, congressional authorization, and subsequent appropriations for its resources. The legislative branch receives the same heavy scrutiny that Defense receives from everyone, and especially the press. In times of trouble, DOD defends and protects us, and we respond favorably to its budgets. In hard economic times, we turn away and appear to expect the defense establishment to fend off the enemies.

For proper support, for the acquisition of goods and services, and for the health and welfare of its personnel, we look to Defense Acquisition and Standards Management activities to be carried out in an open and honest way, making the best use of the tools at hand. We expect standards that determine performance, quality and fitness for purpose. We expect conformity assessment that assures constituents that professional judgments are sound and will stand proper review.

The DOD standards effort probably began with development of joint Army-Navy (JAN) specifications and standards some 50 years ago. The JAN documents were intended to institutionalize standardization of items and materials in order to improve effectiveness through economies of scale. Under Public Law 82-435, The Cataloging and Standardization Act of 1952, the Defense Department acknowledged the need to establish, develop, and maintain a system of technical documentation "in support of design, development, engineering, acquisition, manufacturing, maintenance and supply management which would (1) increase efficiency and effectiveness of logistical support and operational readiness of the military services, and (2) conserve resources and money."

Since 1952, to comply with federal law, all material (hardware) products and support services purchased for use by military departments and defense agencies must be described in sufficient detail to solicit multiple supply sources and competitive bids from established, capable defense industries and commercial producers. Standards are usually referenced in a contract's end-item product specification.

4.2 Military Specifications and Standards

During the years, DOD has developed or adapted more than 41,000 specifications and standards documents to meet its acquisition needs. These are categorized by document type as follows:

- Military Specifications (Mil Specs)

- Military Standards
- Federal Specifications and Standards
- Nongovernment Standards
- International Standards and Commercial Item Descriptions

Mil Specs and military standards are written and validated in DOD standards management facilities. Military departments and Defense agencies function as lead standardization activities, participating activity, user activity, or departmental custodian, depending upon their authority. Suffice it to say that a thorough yet cumbersome series of checks, balances, and review is actively engaged in the Defense Standardization System.

4.3 Nongovernmental Standards

Nongovernmental standards are used in accordance with provisions of Office of Management and Budget (OMB) Circular A-119, which covers federal participation in and use of voluntary standards. The DOD personnel participate in more than 200 voluntary organizations. The DOD is also heavily involved in the work of technical advisory groups to international standards organizations that are administered by nongovernment groups under the procedures of ANSI. The DOD lists 1,600 international standards as having been adapted for use in defense procurement.

5

NORTH ATLANTIC TREATY ORGANIZATION (NATO)

5.1 Introduction

The DOD standards activities are also conducted in support of the NATO Standardization Program. The NATO consists of 14 European countries, the United States, and Canada. There are more than 320 multinational working groups and committees sponsored by NATO to develop STANAGs (standardization agreements) and APs (allied publications). There are around 1,900 NATO documents, many compatible with U. S. Mil Specs and military standards. Many refer to national standards and specs for military-use products issued by various NATO members. The U.S. Mil Specs and military standards are often referenced in NATO documents. Therefore, many U.S. military-use products are acceptable in NATO countries.

5.2 Historical Background

In the early 1960s, the NATO nations developed and ratified STANAG 4093 on "mutual acceptance by NATO member countries of Electronic and Electrical components for military use." Edition 4 of the 4093 document, which is in the final stages of ratification, specifies a procedure that includes both product qualification and acceptance. It also sets forth necessary conditions for products to be on reciprocal qualified product lists. Among the results of mutually executed agreements under STANAG 4093 will be the elimination of nontechnical requirements, the compatibility of assessment procedures and test methods, and the avoidance of redundant surveys and audits. The basic concept and procedures established by STANAG, as currently applied to military-use products, can be readily applied to non-military-use products.

5.3 Future Considerations

Much more could be written about this collective security arrangement that has served North America and Europe very well. However, standards and virtually every aspect of NATO largely in limbo because of changes in Europe and the former Warsaw Pact countries. If NATO continues with a collective peacekeeping role or some other accepted mission, there will be little need for acquisition and standards requirements as we know them today. The U.S. Department of Defense should monitor these developments closely and be prepared to offer strong leadership in setting the future course of action.

6

INTERNATIONAL TELECOMMUNICATIONS SATELLITE ORGANIZATION (Intelsat)

6.1 Overview

Intelsat is the not-for-profit commercial international cooperative that owns and operates global satellite systems servicing the entire world.

Intelsat membership totals 124 countries. Through its network of 19 satellites, it links more than 170 countries around the world.

There are in excess of 760 earth stations connected to this global system that are owned and operated by individual private companies and government organizations. The United States is the largest shareholder. The COMSAT Corporation is the U.S. signatory and represents U.S. interests at Intelsat meetings.

The management of Intelsat, which has a staff of approximately 700, is headquartered in Washington, D.C.

Representatives of member countries jointly develop standards for the system in advisory committees. These standards are followed at both U. S. and foreign earth stations.

The Department of Defense and many foreign governments utilize the Intelsat system for day-to-day voice, data, and facsimile telecommunications services, and for specialized governmental communications. The activities of this international standards-setting organization are of importance to DOD Acquisition and Standards.

7

THE EUROPEAN SCENE

7.1 Background

In the continuing quest for a harmonized European market economy, a key issue is Pan-European competitiveness. As commercial trade barriers continue to fall, attention turns to the practical aspects of expanding into neighboring markets and leads to discovery of new and complex technical barriers.

Europe has progressed from a series of fragmented markets toward a new, harmonized market. In reality, technical incompatibility lingers as a major obstacle for companies that aspire to European and worldwide success.

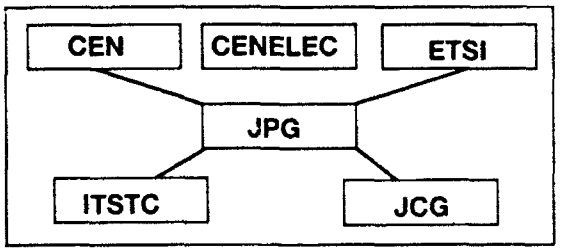
Standardization is key to overcoming these problems, boosting competition, and enabling European harmonization to become a practical reality.

7.2 The European Standardization System

The 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 the European Communities, the European Free Trade Association, public bodies, manufacturers, trade unions, users and consumers. These parties come together in 1,500 technical groups to prepare European standards.

The three groups established a high-level coordination body called the Joint Presidents Group (JPG) to achieve the coherence necessary for agreement on key policy orientations; to prevent duplication of work; and to allow a coordinated dialogue with CEC, EFTA and others. The Joint Presidents Group is supported in its work by two subordinate bodies, the Joint Coordination Group (JCG) and the Information Technology Steering Committee (ITSTC)

THE EUROPEAN STANDARDIZATION SYSTEM

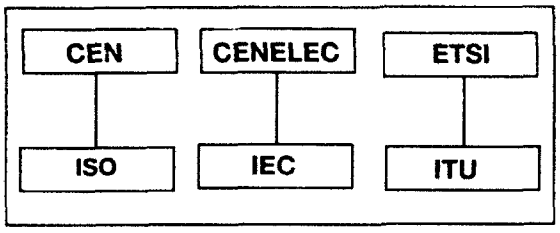


Within the Joint Presidents Group, CEN, CENELEC and ETSI have adopted a five-mode working approach that lays the ground rules for technical cooperation in the production of standards. Depending on the nature of the project, the three select a working relationship that can range from an information relationship to an integrated relationship under which a joint working group is established.

7.3 Worldwide Cooperation

The CEN, CENELEC and ETSI are committed to promoting worldwide standards

whenever practicable. The European structure broadly mirrors the worldwide structure. On the worldwide level, each European standards organization has its corresponding international organization.



The JPG also serves as a coordinating mechanism enabling the three European bodies to define common policies and establish, when necessary, joint delegations to cooperate with similar groups in other regions or worldwide.

7.4 CEN—European Committee for Standardization

The CEN was established in 1961. In 1975, it moved to Brussels. Its statutes were published on 29 January 1976. The CEN is composed of the ISO members of the 12 EC and 6 EFTA countries.

The CEN encompasses all areas of technical standardization other than electrotechnical and telecommunications. In the field of information technology, it works cooperatively with CENELEC and ETSI under coordination of the Information Technology Steering Committee.

The CEN and CENELEC are closely related, and their programs are complementary. With the development of the ETSI program, the three bodies are now referred to as the the European Standardization System. All three cooperate with the official member of ISO and IEC. The ANSI cooperates with ETSI primarily through its underlying membership and its accreditation of the Accredited Standards Committee on Telecommunications (T1).

The CEN members are at the grass roots of standards development. This organization allows all parties to meet and formulate standards, and contribute to European and international standards. Standards reflect the state of the art. Members seek to promote the practical application of their standards, and the state of the art can only be reflected if those who contribute to technical progress at the grass-roots level have access to the various bodies responsible for standardization.

The basic objectives of CEN standardization activities are as follows:

(a) To harmonize the national standards and technical documents of its members by promoting implementation of international standards prepared by ISO, avoiding as far as possible any duplication of work at the European level; and by preparing new European standards when no suitable international standard exists.

(b) To create and implement procedures for the mutual recognition of test results and certification systems.

The CEN Central Secretariat serves the central management structures. The CEN also has four Associated Standards Bodies to which the drafting of standards in specialized areas has been delegated. They are AECMA—European Aerospace Industry Association; ECISS—European Committee for Iron and Steel Standards; WE/EB—Western European Edifact Board; and EWOPS—European Workshop for Open Systems.

The administration of CEN is financed by the national members, through contractual relations linked to the preparation of mandated standards, by the Commission of the European Communities, and the EFTA Secretariat. Additional information on CEN is in Annex A, *CEN Annual Report 1991*.

7.5 CENELEC—European Committee for Electrotechnical Standards

The CENELEC, composed of the 18 national electrotechnical committees of EC and EFTA countries, is the bridge to IEC. It is responsible for European standardization and conformity assessment in the electrical, electronic and allied fields. The CENELEC enjoys an active industrial support base in a technology heavily standardized and regulated in public utility applications. The CENELEC was in existence in the late 1950's and legally formed in its present statutes in 1973. It is located in Brussels.

The work of CENELEC closely parallels that of CEN, with the addition of a strong, well-organized European body—the Electronic Components Committee (see 3.9, Trouble Spots). CENELEC and CEN are mandated by the EC and EFTA to develop standards needed in their respective regulations and mandatory programs.

It is important to recognize the legal and highly institutionalized liaison that exists between the European Community and CEN/CENELEC. The standardization policy followed by the EC since 1983 is based on three fundamental documents with which Defense Acquisition and Standards Management should be familiar:

• Directive 83/189 laying down a procedure for the provision of information in the field of technical standards and regulations.

• The conclusions of the EC Council on 16 July 1984 setting out the broad lines of Community standardization policy for future years, and containing this important sentence:

"The Council believes that standardization goes a long way toward ensuring that industrial products can be marketed freely and also toward creating a standard technical environment for undertakings in all countries, which improve competitiveness...."

• The Council resolution of 7 May 1985 recommending reference to standards in Community harmonization and describing the methods to be followed. (The complete text of Council documents, plus an excellent history of the European Standardization System may be found in the CEC Document, Common Standards for Enterprise, by Florence Nicolas and Jacques Repussard, Office for Official Publications of the European Communities L-2985 Luxembourg.)

The most comprehensive information on the structure, programs, financing and future outlook for CENELEC is contained in its 1991 annual report (see Annex B).

A particularly significant user group developed and supported by CECC is the Military Usage and Harmonization Advisory Group (MUAHAG). The MUAHAG is designed to ensure maximum utilization of the CECC system in specifying and assessing electronic components for military usage in member countries. This group, along with the use of preferred product lists (PPL) of components to which U.S. manufacturers are excluded, constitutes a very effective technical barrier to trade.

The MUAHAG receives guidance and support from two subsets of NATO—the Independent European Program Group (IPEG) and the European Defense Industry Group (EDIG). (The United States is excluded from participating in these groups.) The user-group influence on NATO, along with recommendations for corrective actions that may be presented to the Defense Department follow in a separate section of this

book. Figure 7-1 gives a summary of MUAHAG.

7.6 ETSI—European Telecommunications Standards Institute

At first glance, ETSI may seem like the new kid on the block, having been created in 1988. In reality, the technology it serves has been highly organized since 1872 when the International Telecommunications Union was formed as an independent body. The ITU became a part of the United Nations after World War II. When one talks telecommunications standards it is necessary to introduce the International Telegraph and Telephone Consultative Committee, ITU's technical arm. The CCITT and JTC 1, the ISO/IEC joint technical committee on information technology, are commonly recognized by telecommunications standards participants as the most significant organizations for development of global industry standards.

In 1947, the European Commission issued a paper on developing the Common Market for telecommunications services and equipment. It recommended establishing an organization to set telecom standards for the whole of Europe and to accelerate the process of technical harmonization. In 1988, ETSI was established and located in the South of France.

The ETSI has pioneered a new approach to standards making. Whereas traditionally standards were developed and promulgated in Europe by Government Postal and Telecommunications Administrations, the ETSI membership is open equally to public network operators, manufacturers, users, private service providers and researchers.

The ETSI has a membership of 300 European-based manufacturers and telecommunications service companies. It has associate members and regularly invites interested parties from around the world to its assemblies. From the United States, for example, the following are included: Telecommunications Industries Association, ANSI-USA, T1-USA, CBEMA-USA, and ECSA-USA.

General information on ETSI is provided in Annex D. An in-depth report prepared by the U.S. Organization for CCITT, entitled CCITT Interactions with other Standards Organizations, appears Annex E.

What Is MUAHAG?

The Military Usage and Harmonization Advisory Group (MUAHAG) is subsidiary to CECC CD (Comite' Directeur) the system's management committee. The main functions of MUAHAG may be summarized as:

(1) Ensure the maximum utilization of the CECC system in the specification and assessment of electronic components for military usage in member countries.

(2) Agree to a common "Preferred Products List" (PPL) if CECC-qualified components for use in current and future collaborative and single-country military equipment.

(3) Ensure, firstly, the maximum usage of components listed in the MUAHAG PPL Volumes, in military equipment under development and/or in production, under both international collaborative and national projects. Secondly, in any applications where no preferred component is suitable, ensure maximum usage of other CECC-qualified components.

(4) Agree on specific components, or ranges of components, to be recommended to member countries as suitable for future equipment projects and for qualification approval against current or potential future CECC specifications.

(5) Develop, with the guidance and support of the Independent European Programme Group (IEPG) and European Defence Industry Group (EDIG), methods of ensuring effective use of the PPLs, e.g., harmonized component selection procedures for project usage and logistic support.

(6) Advise CECC CD and its technical Working Groups on matters relating to utilization of the CECC system by Western European military authorities.

The MUAHAG has existed since 1980, in which time it has completed the task of producing the common PPL for most classes of components in current use, and is also achieving very considerable agreement in the area of future component requirements.

It is encouraging to note that the IEPG (comprising representation from all European national governments who participate in NATO project procurement and logistic planning) and EDIG (representing the defence industries of the same countries) fully endorse and support the MUAHAG objectives.

The MUAHAG comprises national representatives from the military standardization agencies in Denmark, France, Germany, Italy, Netherlands, Norway, Sweden, and United Kingdom, together with liaison members from the European Space Agency (ESA) and the CECC Telecommunications Group, and correspondence members in Switzerland.

Component family volumes of the PPL are being published and updated progressively, and their availability is reported elsewhere in this leaflet.

Members of the equipment industry and component industry involved in defence projects are invited to use the PPL and to send any comments on the list or on the scheme, in general, to their national representatives.

Figure 7-1

Why is MUAHAG Publishing a PPL?

(1) It saves time and money as well as making good logistic sense for the designers and manufacturers of European Military equipment to use electronic components that are readily available from European Component Manufacturers.

(2) It is equally good logistic sense for European military authorities to procure the electronic components that they require to service their equipment from European sources.

(3) It is good quality and reliability sense for both manufacturers and military users to buy qualified and assessed CECC specified components.

(4) Maximizing the military usage demand for the preferred products should lead to economics of scale in manufacture, increasing user pressure for price reductions.

Who Needs to Know About and Use the PPL?

(1) Military procurement authorities.

(2) Military equipment designers, production engineers, and component-buying departments.

(3) Engineers and buyers having similar responsibilities for equipment that normally incorporates military-grade electronic components.

(4) The component industry's marketing organization because it will indicate likely military preferences in new technologies.

Is the PPL Available?

(1) The PPL is being published in separate volumes for each major component family.

(2) The following volumes have been published:

Vol 0. Introduction
Vol 1. Capacitors
Vol 2. Resistors
Vol 3. Connectors
Vol 4. Magnetic Components
Vol 5. Relays
Vol 6. Piezo-Electric Devices
Vol 7. Integrated Circuits
Vol 8. Switches
Vol 9. Discrete Semiconductors
Vol 10. Opto-Electronic Devices
Vol 11. Filters
Vol 12. Microwave Components

These volumes may be purchased from the General Secretary, CECC, or from the Support Services (PPL) (See membership list for addresses and telephone numbers.)

(3) The following volumes are being prepared:

Vol 13. Servo Components
Vol 14. Sensors
Vol 15. Batteries
Vol 16. Printed Wiring Boards

Figure 7-1

8

CONFORMITY ASSESSMENT

8.1 Conformity Assessment: Philosophy and Terminology in the United States and Other Countries

In many countries, certifying the conformity of products and services to a set of one or more standards improves the flow of product- or service-related information between the manufacturer/supplier and the buyer/consumer. Certification can also enable exporting countries to secure access to foreign markets. Certification can have a major impact on trade.

Certification systems, in most parts of the world, are operated directly or indirectly under the auspices of the national standards body, which is generally also the member body of ISO. In the United States, standards development took a different path, and the U.S. system is structured very differently from most other countries. As a partial result, the term certification has, until very recently, had a different meaning in the United States, as has the term conformity assessment.

The term conformity assessment was developed by the ISO Committee on Certification (CERTICO), which was later restructured as the ISO Council Committee on Conformity Assessment (CASCO). The term was developed to better describe the expanding activities that now comprise what was known internationally as certification. Conformity assessment includes such activities as testing; inspection; calibration; certification; quality system management evaluation and registration; and the related accreditation of laboratories, certification programs, and quality system registration programs.

To appreciate the extent of conformity assessment, it is helpful to review a bit of history in order to better understand the differences between the earlier definition and use of the term certification by the United States and other countries.

In 1946, the American Standards Association (ASA), ANSI's predecessor, established an autonomous sectional Committee Z34 in accordance with ASA board policy. In 1947, Committee Z34 stated in its Z34.1 standard, American National Standard Practice for Certification Procedures, that

> "certification is employed in this document broadly to include any representation of approval, endorsement, recommendation or listing. This American Standards Practice sets forth the approved procedure to be followed in certifications to the public representing by any means or terminology conformance of a product, article, commodity, or service with applicable standards based on adequate and independent sampling and examination by an impartial and competent agency."

By introducing the concept of an impartial and competent agency other than the buyer or seller, the Z34.1 standard established a role for an impartial third party in certification. This role included (1) testing or inspection to ascertain initial conformity to a standard(s); and (2) periodic sampling and retesting to assure continued product conformity.

Recently, industry and others have come to formally recognize that assurance of continued product conformity depends not only on periodic sampling and retesting. It also depends on the effectiveness of a supplier's quality management system. Among the more recent international standards have been those in the ISO 9000 series for quality management. These generic standards could ultimately replace the U.S. industry interpretation of the current ANSI standards that address quality system requirements. This topic is discussed in more detail later.

In 1969, a reactivated Z34 Committee further defined certification in the United States with the publication of American National Standard Practice for Certification by Producer or Supplier, Z34.2. This standard defines a procedure whereby certification of a product's or service's conformity to designated specifications or other criteria can be administered by the supplier or producer of the product or service (a procedure often known as self-certification). This standard defines certification as "the procedure by which a product or service is certified." Initial testing or inspection is left to the supplier; and continuing evidence of product conformity is based on a required, but mostly undefined or generic, quality control/assurance system. As noted above, however, industry may come to use the ISO 9000 standards to interpret such quality system requirements.

In October 1982, OMB issued Circular A-119, Federal Participation in the Development and Use of Voluntary Standards. Under its term, the Secretary of Commerce is charged with coordinating and implementing the circular's terms. The Federal Interagency Committee on Standards Policy (ICSP) is the coordinating mechanism to advise the Secretary in implementing policy. In 1987, at the urging of ICSP, ANSI Z34.1, American National Standards for Certification—Third Party Certification Program, was revised. The purpose of the revision was to harmonize the standard with the 1984 Guidelines for Federal Use of Private Sector Third Party Certification Programs developed by ICSP. The later document was published in response to certain obligations that the U.S. Government undertook in signing the international Agreement on Technical Barriers to Trade. This agreement,[1] popularly known as the GATT Standards Code, or just the Standards Code is administered under the Secretariat of the General Agreement on Tariffs and Trade. The 1984 guidelines define certification as "the procedure by which written assurance is given that a product or service conforms to a standard specification."

The 1987 version of Z34.1 represents the current U.S. private-sector definition of certification. However, GATT defines certification in Annex 1 Terms and Their Definition for the Purpose of This Agreement differently. The GATT definition is based upon the 1991 edition of the ISO/IEC Guide 2 - General Terms and Their Definitions Concerning Standardization and Related Activities. Section 13.5.2 in the guide defines certification as the "procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements."

However, there are certain differences between the ISO/IEC Guide 2 definition and

that used in GATT. As defined in ISO/IEC Guide 2, certification covers products, processes, and services. GATT deals only with technical regulations, standards, and conformity assessment procedures pertaining to products or related processes and production methods. Standards, as defined by ISO/IEC Guide 2, may be mandatory or voluntary. For the purpose of GATT, standards are defined as voluntary, and technical regulations as mandatory. Standards prepared by the international standards community (particularly ISO/IEC and ITU) are based on the principle of achieving consensus among all interested parties on the requirements contained in a standard. However, GATT also covers international standards and related documents not based on consensus. Potential differences in the meaning of such terms as certification and conformity assessment as used in various documents and requirements should be carefully considered, as such differences can seriously affect the interpretation of a document. For example, CERTIFICAT—Product Certification European Directory, published by AFNOR (the French standardization body), lists more than 5,000 certified products, 300 certification systems, and 700 certification bodies related to existing mandatory or voluntary certification in Europe alone.

As noted above, ISO/IEC Guide 2 defines certification as the "procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements." The ISO/IEC Guide 2, therefore, defines certification as a third party (not a supplier or buyer) function. Further, the self-certification process described in ANSI Z34.2 is defined in section 13.5.1 of ISO/IEC Guide 2 as "supplier's declaration: Procedure by which a supplier gives written assurance that a product, process or service conforms to specified requirements." To avoid misinterpretation, ISO/IEC Guide 2 added the following note to this definition: "In order to avoid any confusion, the expression 'self-certification' should not be used."

For purposes of GATT, conformity assessment procedures consist of any method used (directly or indirectly) to determine that the relevant requirements in technical regulations or standards are fulfilled. As so defined, conformity assessment procedures would include procedures for sampling, testing, and inspection; evaluation; verification and assurance of conformity; accreditation; quality system evaluation and registration; and various possible combinations of these procedures.

The overall challenge to the United States—to align its definitions and thinking in conformity assessment with current international concepts—remains. The latest revision of ANSI Z34.1 has been harmonized with international documentation, including the 1991 version of ISO/IEC Guide 2. If approved, the term certification will mean action by a third party defined in the annex to ISO/CASCO 179 as a "person or body that is recognized as being independent of the parties involved, as concerns the issue in question. Note - Parties involved are usually, supplier ('first party') and purchaser ('second party')." This definition will require a change in the U.S. view of what certification means. It will also modify the long-held U.S. philosophy, largely based on ultimate legal responsibility, that certification can be performed by a supplier or a buyer.

8.2 Conformity Assessment in the United States

An overview of conformity assessment in the United States reveals that it is much like the pluralistic standards development system. The U.S. process for providing assur-

ances of conformity with standards and specifications has been based largely on agreements. Agreements between first and second parties or on regulatory definitions of what constitutes an acceptable method of certification have been the norm.

Unlike most other countries, the regulation of various aspects of public health and safety in the United States is a function left by the U.S. Constitution to individual state governments. Only when specific aspects of health or safety are the subject of federal preemption legislation does the federal government assume responsibility. When this situation occurs, safety and health requirements become national in scope. Even when such requirements are nationally regulated, states sometimes can and do impose additional requirements. When regulations address safety and health-related products and services, both federal and individual state requirements must be met.

State adoption of voluntarily developed safety and health standards and codes is commonplace. States also frequently require that, when appropriate, evidence of product, article, commodity, or service compliance to a standard be established by third party certification programs. Often, certification programs conforming to ANSI Z34.1 criteria are mandated. State-mandated reliance on independent third party certification programs to assure initial and ongoing compliance of products and services has been common among the states, and through state delegations to local governments. While state governments have relied on third party certification, evidence of conformity on the national level (in both regulated and non-regulated areas) has been dominated by the acceptance of (1) supplier declarations of conformity (self-certification); (2) acquisition programs designed to duplicate, in whole or part, thirdparty certification programs; or (3) evaluations conducted by federal agencies.

Until recently, third party certification was primarily used in the United States to demonstrate compliance with state and local government-mandated use of voluntary codes. State and local adoption of the National Electrical Code is the paramount example. More recently, mandatory use of a third party in various facets of conformity assessment is increasing as a requirement for participation in bilateral or international trade. Such participation requirements may in the near future require U.S. third parties to gain some form of international acceptance, even for those third parties that are recognized by state and local government mandated programs. Such challenges to generally accepted U.S. conformity assessment procedures created by international trade demands must be considered in light of their effect on the U.S. industrial system's competitiveness.

8.3 Notes

1. The United States is one of many signatories to this internationally binding agreement, which covers most product areas, though it currently excludes services.

2. The Standards Code requires that each signatory provide an inquiry point to answer all requests for information about technical regulations, standards, and rules of conformity assessment. The U.S. inquiry point is the Standards Code and Information Program of the NIST Office of Standards Services. An annual GATT Standards Code Activities is published by the Department of Commerce.

3. This is a Draft - Rearrangement of ISO/IEC Guide 2 Sections Concerning Conformity Assessment, prepared by CASCO Working Group 5, which is to be reviewed

for possible incorporation into the overall revision of Guide 2.

4. See NBSIR 87-3608, Index of Products Regulated by Each State, Maureen Breitenberg, Editor, U. S. Department of Commerce, NIST, Office of Standard Code and Information, Gaithersburg, MD 20899.

5. See NBS 739, Directory of Federal Government Certification Programs and NBS 744, Directory of Private Sector Product Certification Programs, Maureen Breitenberg, Editor, U. S. Department of Commerce, NIST, Office of Standard Code and Information, Gaithersburg, MD 20899.

9

CONFORMITY ASSESSMENT IN THE DEPARTMENT OF DEFENSE

9.1 Introduction

Every conformity assessment procedure, including those described in international documentation, has been or is being used by DOD in its procurement functions. The DOD is the world's largest buyer (second party) of products and services. Requirements for all DOD-procured products and services are developed either directly by DOD or are adopted from the vast number of technical specifications and standards documents developed by the private sector. In addition to developing its own product qualification and certification process, DOD has also adopted national and international conformity assessment documents, such as ANSI Z34.1 and ISO 9000, for appropriate contractual application use.

The DOD certification process is carried out under the quality assurance functions of DOD's Defense Logistics Agency (DLA). The DLA performs such functions for itself, the National Aeronautics and Space Administration (NASA), other federal agencies, and foreign governments. Its work force of 8,000 quality assurance personnel covers some 17,000 contractor facilities that have contracts requiring DLA certification.

Based on many years of quality assurance experience, DLA has developed conformity assessment methods that mitigate the repetitive use (with attendant costs) of such procedures as sampling, testing, and inspection. The development of the Qualified Product List (QPL) is an example. Once the DOD certification process is complete, products can be purchased from those listed on a QPL without need for further certification procedures. The Qualified Manufacturers List (QML), another quality assurance procedure, involves auditing a supplier's quality management system to determine if it adequately maintains the standard. Once a manufacturer has been placed on a QML, its products may be purchased without further certification.

Programmatic innovations like the QPL and QML allow DOD components, such as the Defense Electronics Supply Center (DESC), to develop unique programs. The DESC's Standardized Military Drawing Program (SMDP) is an example. The SMDP is a standardized document described in DOD STD-1000. It is used to describe and procure highly reliable commercial electronic parts as they are introduced into military systems. At present, it is limited to Federal Supply Class (FSC) 5962 (microcircuits). The SMDs eliminate the need for original equipment manufacturer (OEM) source/specification control drawings (SCDs). As the second party or purchaser, DOD establishes the conformity assessment requirements and bears much, if not all, of the costs associated with such certification. However, in the case of DESC's electronic products, DLA has established an annual administration fee for all manufacturers

and laboratories participating in the DOD Product Certification and Qualification Program. The administration fee will recover DLA costs associated with this program.

Internationally, when certification is defined as a third-party function, many conformity assessment procedures are identical to, or comparable with, those developed with and adopted by DOD. The exception is that the procedures be conducted by an independent third party.

For instance, the ISO 9000 Standard Series on quality management and systems has evolved from standards initially developed by DOD. A certification of conformance (registration) to one of the three quality system models defined in the ISO 9000 series is issued by a third party that registers (certifies) the conformity of a manufacturer's quality system. The quality system models in the ISO 9000 Standard Series are not product specific. They apply to all types of manufacturers and service industries.

Comparable DOD QMLs are more product specific, but the two major differences between these conformity assessment processes are as follows:

(1) The auditors or assessors using the ISO 9000 standards are impartial professionals chosen by the conformity assessment body. Under the QML process, the auditors or assessors are DOD quality assurance personnel or other specialists acceptable to DOD.

(2) The cost of ISO 9000 certification is borne by the manufacturer whose costs are then shared by customers. The DOD bears most of the cost associated with the QML process.

The rapid development of European and international standards, and perhaps more importantly, the associated conformity assessment requirement and procedures, such as testing and quality system registration programs, are focusing attention on the challenges presented by the varying certification approaches of the United States and the European community.

In his book, *The Engineering Standard: A Most Useful Tool*, Albert L. Batik writes: "The last element of quality is the conformance to specifications. It is the degree to which the product meets the predetermined standard for this performance, manufacture, and design. Under traditional methods of quality control, it is the inspection of the product that focuses attention to this one element alone. Because there exists the concept that the more inspections the better the quality, executives assume that better quality means higher costs. Not so! In fact, the higher the level of quality, generally speaking, the lower the cost of production; provided it is done correctly. It definitely does not mean more inspections."[1]

For DOD, the challenge will be greater because of the need to maintain an industrial base capable of providing quality products while acquisition requirements are declining. This decline may make the concept of harmonizing appropriate DOD quality system assessment requirements with international systems of quality assessment extremely attractive to many DOD contractors. Harmonizing quality system requirements can provide entry to foreign markets and can reduce the cost of producing products that currently must meet multiple sets of requirements and undergo an assortment of assessment processes. Harmonization can also enhance the use of diminishing DOD acquisition personnel and resources.

The challenge of harmonization and mutual recognition of product qualification and certification processes between the United States and the European Community (particularly in DOD product acquisition areas) has reached a critical stage.

9.2 References

1. *The Engineering Standard: A Most Useful Tool*, Albert L. Batik, BookMaster/El Rancho Publishers, P.O. Box 159, Ashland, OH 44805.

10

NATO STANDARDIZATION AGREEMENT, STANAG 4093

Introduction

For 10 years, NATO has fielded complaints that protectionistic requirements from U.S., Canadian, and European industries are being included in local standards and specifications.

As a result of work of the NATO AC 301 standards group, a NATO procedure for product qualification and certification was developed. Its full title is NATO Military Agency for Standardization—Standardization Agreement 4093, commonly known as STANAG 4093. The agreement covers the Mutual Acceptance by NATO Member Countries of Qualifications of Electrical and Electronic Components for Military Use. In effect, it may be a model for reciprocal agreements among trading partners in other areas as well. Actions required by the STANAG include the following:

- Use of technically identical specifications and standards by both nations involved in a reciprocal agreement on products to be listed in qualified products lists (QPLs).

- Elimination of discriminatory technical requirements written into national specifications and standards and QPLs in a manner that constitutes technical barriers to trade.

- Compatibility of quality assessment procedures and test methods applied in various countries for product qualification and certification.

- Avoidance of excessive, redundant, repetitive plant surveys and audits and product retesting for qualification acceptance of foreign-made products in some nations.

- Fair cost charges for technical experts sent to NATO countries to conduct required initial audits of production and test facilities and to assess quality assurance processes employed by foreign manufacturers seeking qualification of their products.

- Reciprocal posting of the QPLs in both countries of all products conforming with the same national specification and standards.[1]

If a foreign company's product conforms with a U.S. specification and is listed on the U.S. QPL, all U.S.-made products listed on that same QPL must then be listed on the QPL of the foreign national. The applicable U.S. specification must be accepted by the Foreign National Qualification Authority as an approved specification for defense supply procurement purposes. Products conforming to that specification will be approved for inclusion in the national preferred parts list.

This listing or acceptance process is mutual; that is, when a U.S.-made product is qualified to a foreign national specification and listed on the foreign QPL, all foreign-made products listed on that same QPL must then be listed on the applicable U.S.

QPL. The applicable foreign specification must be accepted by DOD as an approved specification for defense supply procurement purposes. A recent example of such an agreement is the Novation of Standardization Agreement Between EOLAS - The Irish Science and Technology Agency and the Department of Defense of the United States of America for Reciprocal Qualification of Products Manufactured in Either Country, Ireland or United States.[2]

While STANAG 4093 was developed to apply to military-use products procured by NATO nations, its concept and procedures may suggest some basic conditions that could be negotiated bilaterally or internationally to reach similar agreements in nonmilitary-use product areas. Other NATO standardization agreements and allied publications have been developed to establish acceptable levels of uniformity in industrial quality assurance methods practiced in the various NATO nations. These documents may prove useful if they are adopted and implemented by EC members of NATO in a manner that minimizes EC-92 standardization and conformity assessment challenges. In any event, the NATO experience provides important guidance on the complex issues raised by the assessment and certification of conformity.

10.2 Notes and References

1. DOD Response to the EC-92 Standards Challenge, by S.P. Miller, OSASD(PR) MM-SPD, 9 October 1991.

2. Prepared by S.P. Miller, OASD (P&L) PR-MM-SPD, 19 June 1992.

11

ACCREDITATION

11.1 Introduction

While the subject of accreditation is often included in discussions of testing/inspection, product certification, and quality system assessment, the challenges of EC-92 to the U.S. industrial base and through it to DOD's acquisition program, warrants a separate discussion. As defined in section 13.7 of ISO/IEC Guide 2, accreditation is a "procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks." One such procedure is laboratory accreditation.

In the 1980 ISO report, Principles and Practice of Certification, eight types of third party, product certification systems in world-use were identified. Section 14.1 of ISO/IEC Guide 2 defines a certification system as a system that has its own rules of procedure and management for carrying out certification of conformity.

In the 1980 ISO report, all certification systems involved an element of testing as a necessary means of proving a product's compliance with the specification. The report noted that it is "fundamental to the integrity of any of these systems that the testing laboratories be competent."

The ISO/IEC Guide 2 uses the term laboratory to mean testing laboratory and, in section 16.1, defines laboratory accreditation as the formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests.

The formal means by which a testing laboratory may be judged competent is through laboratory accreditation. Accreditation of other types of conformity assessment bodies or systems (such as quality system registration) provides similar types of authoritative assurance that those bodies are competent to carry out specific conformity assessment tasks.

The importance that the European Community (and most of the world) places on accreditation is indicated by the establishment of the European Organization for Testing and Certification, which will be discussed in more detail later. The EOTC is the focal point in Europe for all nonregulatory questions relating to conformity assessment. The EOTC is composed of suppliers, purchasers, and users of goods and services whose goal is to establish mutual confidence among parties concerned with conformity assessment issues. They seek to realize this goal by (1) promoting and implementing of mutually acceptable criteria and procedures for assessing the technical capabilities of conformity assessment organizations; and (2) using criteria and procedures that assure the continued performance and competence of these organizations. The EOTC and its private sector counterparts in the United States, as well as the EC and U.S. Governments, will be expected, by the nature of testing and certification, to use accreditation as a tool to promote mutual confidence in each other's conformity assessment systems.

This process will ultimately lead to the development of mutual recognition agreements between the European community and the United States.

Throughout the history of laboratory accreditation and, to a lesser extent, the accreditation of certification bodies and programs, a considerable amount of national and international documentation has developed on which to base mutual recognition agreements. The quality system registration and the accreditation of its registrars as competent to assess the conformity of a manufacturer's quality system with ISO 9000 standards and related requirements is not as well established.

Section 13.6 of ISO/IEC Guide 2 defines registration as a procedure by which a body indicates relevant characteristics of a product, process or service, or particulars of a body or person, in an appropriate, publicly available list.

Procedures for the registration of quality systems and for the accreditation of registrars are rapidly developing at both national and regional levels. Quality system registrars (and, to a lesser extent, the accreditors of those registrars) are making extensive use of the memorandum of understanding (MOU). Because of growing interest in ISO 9000 quality systems management registration, international documentation that can be used as the basis for establishing mutual recognition agreements is likely to be developed in the near future.

11.2 European Organization for Testing and Certification (EOTC)

The EOTC is an example of the importance Europe, and most of the world, places on accreditation by an authoritative body. Founded in 1990, it is the focal point in Europe for all nonregulatory questions relating to conformity assessment. It was created by a memorandum of understanding between the European Community, the European Free Trade Association, and CEN/CENELEC.

The EOTC is also an example of the complex and multiple aspects of testing and certification accreditation. As the Product Certification European Directory records, there are some 300 certification systems and 700 certification bodies currently operating in one or more of the 18 countries of the EC/EFTA.

The EOTC is composed of suppliers, purchasers, and users of goods and services. Its goal is to establish mutual confidence between parties. These parties are concerned with conformity assessment issues relating to the facilitation of free circulation, throughout Europe, of goods and services that conform with technical capabilities, operational performance and maintenance of competent operators.

The ultimate effect of EOTC is to enable industry to secure from one source the testing or certification needed for accredited entry to the whole European market. Once technical specifications, such as international or European standards, have been agreed upon, a product or service will only need to be tested or assessed once to be accepted in the wider European market.

The EOTC's governing structure consists of the following:

- A council.

- Specialized committees that are discipline-oriented such as calibration, testing, certification, quality assurance and inspection. (Areas not covered by EC directives,

are managed by the MOU-created European Committee for Quality System Assessment and Certification, which is responsible for input on ISO 9000 standards.)

- Sectoral committees such as the European Committee for Information Technology Certification.

- Agreement groups such as CECC Calibration Laboratory Accreditation System, European Fire and Security Group, and International Instrumentation Evaluation Group.

- A supporting administrative infrastructure.

The EOTC council establishes overall policy and business strategy; specialized committees provide advice for implementing basic CEN/CENELEC technical instruments; sectoral committees define their field of competence; agreement groups design and maintain rules for mutual recognition agreements or for European certification systems. Each committee fosters mutual recognition agreements in nonregulated areas through its agreement groups.

Other European bodies have developed documents and agreements in conformity assessment that support or supplement EOTC activities. The European Accreditation of Certification (EAC) organization is one such agreement. It is based on an MOU signed in May 1991. The EAC membership is open to one national accreditation body from each European country, or one coordinating committee representing the country in which more than one national body exists. The objectives of EAC are to strengthen market confidence in programs operated by accredited bodies; to foster collaboration in pursuit of a European system of assessment and accreditation; and to promote harmonization of the operations of participating bodies based on relevant standards. The EAC is obligated to identify for CEN/CENELEC the updating needs of the EN 45000 series—certification criteria standards.

The EOTC and other bodies and agreements are essentially aimed at harmonizing different, unregulated national product requirements. For regulated products, the EC Commission is developing a series of technical harmonization directives. Notified bodies are the qualified organizations designated by EC members to carry out conformity assessment procedures set out in the directives. Notified bodies are themselves in conformity with EN 45000 standards and other requirements set out by the EC.

The European Community is also developing a document entitled Mutual Recognition of Tests and Certificates, Inside and Outside the EEC, which will become the basis for negotiating agreements. A Working Document on Negotiations with Third Countries Concerning the Mutual Recognition of Conformity Assessment is an EC Commission document providing mutual recognition criteria. Notified bodies status and mutual recognition agreements are the linchpins for product and service imports to Europe after 1992.

There are a few international certification and approval schemes that allow one country's tests or certification to be recognized in Europe and worldwide. These schemes are in the electrotechnical area. The two principal ones, the Scheme of the IECEE for Recognition of Results of Testing to Standards for Safety of Electrical Equipment (CB Scheme) and The Worldwide Electronic Component Certification System (IECQ), are discussed in 11.3.

11.3 The IECQ System and the CB Scheme - International Conformity Assessment

The ICEQ is a third party certification system for electronic components. It is supported by 25 member countries of the IEC. Each country has a national organization consisting of a National Authorized Institution (NAI) and a National Standards Organization (NSO). Each must operate within the IECQ rules and agree to recognize all IECQ approvals of manufacturers, distributers and test laboratories, and IECQ component certification.

Currently, 20 countries have either a National Supervising Inspectorate (NSI) approved under IECQ or use the NSI of another participating country. Certifying countries are responsible for all approvals and the implementation of procedures that have been established to certify individual component types. The approval of manufacturing facilities is a prerequisite for component certification.

An IECQ-approved manufacturer or independent test laboratory is one that has demonstrated that its organization and facilities are adequate to meet the requirements of the system. It also complies with the requirements of ISO 9001 or 9002, or ISO/IEC Guide 25 for test laboratories. (Currently, the requirement is to have a quality management system that complies with ISO 9001 or 9002 subject to IECQ verification audit, as opposed to certification by a third party registrar.The IECQ, which became operational in 1982, is available to manufacturers and users of electronic components worldwide. Once a manufacturer holding an approval has demonstrated that a component has achieved the prescribed quality, quality conformance is established and the relevant products may be delivered under an IECQ Certificate of Conformity.

An internationally available Qualified Product List (QPL), which also lists all approved companies, is provided by CODUS.[2] The CODUS also provides a reliability prediction facility for all component types U.S. Military Handbook 217, Issues D and E and HRD 4. Additionally, all IECQ specifications can be accessed from the specifications list and in microfilm (see IECQ publication entitled *A Guide to the Worldwide Electronic Component Certification System*). The IECQ system has the same purpose as NATO's STANAG 4093.

The CB Scheme was originally operated by the International Commission for Conformity Certification of Electrical Equipment (CEE). It was integrated into IEC in 1985 as the Scheme of the IECEE for Recognition of Results of Testing to Standards for Safety of Electrical Equipment (CB Scheme). It is administered by the Committee of Certification Bodies. (See IEC publication IECEE 02, second edition 1992-05, Rules and Procedures of the Scheme of the IECEE for Recognition of Results of Testing to Standards for Safety of Electrical Equipment CB Scheme).

The CB Scheme is based on mutual recognition (reciprocal acceptance) by its members of test results for obtaining certification or approval at the national level by the various national certification bodies. It is intended to reduce obstacles to international trade arising from different national certification or approval criteria. Participation of the various certification bodies within the scheme is intended to facilitate certification or approval according to IEC standards.

When national safety standards are not yet completely based on IEC standards,

declared national differences are taken into account. However, the operation of the scheme presupposes that national safety standards are reasonably harmonized with corresponding IEC standards. Use of the scheme is intended to promote the exchange of information necessary to help manufacturers around the world obtain certification or approval at the national level.

The operating units of the scheme are the accepted national certification bodies. They run CB testing laboratories and are accepted according to scheme rules. The scheme is based on the use of CB test certificates, which provide evidence that representative specimens of the product have successfully passed tests to show compliance with the relevant IEC standard. A supplementary report providing evidence of compliance with declared national differences in order to obtain national certification or approval may also be attached to the CB test certificate. The certification body must be prepared to recognize CB test certificates as a basis for approval at the national level for one or more categories of products.

These two systems, both intended to result in the acceptance of products for national distribution, have vast differences. The IECQ system qualifies electronic components to be equally acceptable within the participating countries of the system without further review or discrimination. The CB Scheme provides regulated product safety test results that must be accepted as the basis for an application for national product safety approval. The scheme may, therefore, be more accurately described as an international testing laboratory accreditation program rather than a product certification program.

Notes

1. Close cooperation between IECQ and the European system of CECC, under the authority of IEC and CENELEC respectively, has the ultimate objective of a single, worldwide system for quality-assessed electronic components. The avoidance of duplication, exchange of information, parallel voting, and joint development of new standards are principal interests.

2. For more information, contact CODUS Ltd., 196-198 West Street, Sheffield, S1 4ET, Great Britain.

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CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Research into the potential impact of EC-92 standards and conformity assessment programs on U.S. defense acquisition and industrial competitiveness has been conducted. Based on knowledge of current European planning, operating practices, and regulations and on comparisons with similar U.S. systems, it has been generally concluded that the objective of global standardization is more readily attainable.

Europe and the United States have been engaged in an inseparable, multinational, competitive program of technical standards development and the application of these standards to trade and commerce since the end of World War II. Both sides have held important but temporary advantages depending on the strength and viability of various industrial sectors.

During the years, the growing importance of barrier-free trade and the advent of strong consensus systems for international standards development have evened out the advantages and brought the competitors to the negotiating tables of the world's leading international standards forums.

Three organizations lead the way: ISO, IEC, and one largely intergovernmental group—ITU with its International Telephone and Telegraph Consultative Committee (CCITT). There are many more groups but none have developed the strong infrastructure and appeal to both government and industry to seriously challenge these three. Europe and the United States have evolved systems for developing standards to meet national, regional, and international requirements. In Europe, it is the tripartite European Standardization System, compring CEN, CENELEC, and ETSI. In the United States, it is the decentralized voluntary standards system that operates internationally through the programs and structure of ANSI.

Both regional groups have concluded from 40 or more years of standards participation that it should be their common goal to develop standards that do not become technical barriers to trade. They have also concluded that harmonization and consensus acceptance of standards have been most effective when conflicting views and differing methodologies have come together to find global solutions to problems.

Conformity assessment—the process by which a party may determine whether a product or service meets the requirements of standards that, in turn, have proved effective in regulatory as well as voluntary application—constitutes the major challenge to defense acquisition management. National security, environmental protection, public health and welfare, and all forms of safety (personal and product) are at stake.

It is important to realize that quality assessment is highly complex and controversial,

with less likelihood that differences between the U.S. system, which relies to a great extent on manufacturers' declarations of conformity, and the European system, where the prevailing mode is third party assessment, will soon be resolved. The review of conformity assessment in general, its application in the United States and in the Department of Defense have led to several conclusions:

- A better understanding and appreciation of the basis and application of conformity assessment in Europe and the United States is needed.

- National standards bodies, the military, and all standards participants should be encouraged to develop and improve global quality standards. Their adoption and judicious use will enhance international trade.

- A major boost to unification and advancement of quality management standards would occur if the Defense Department and other federal acquisition systems would adopt and mandate use of the ISO 9000 standards.

The final conclusion of the investigation is that the United States is competitive with Europe. It has assumed its rightful leadership in participation and support and is encouraging U.S. adoption of international standards.

The EC-92 is but a prologue to the future of global standards and conformity assessment. The United States appreciates what Europe has done to unify its markets. This effort should be encouraging to everyone engaged or interested in international trade. Defense Acquisition and Management will play a key role in the development of global standards and conformity assessment. This source book will ease entry into the field.

Recommendations

The study of the CEC's standards and conformity assessment programs in support of its EC-92 integrated market has naturally led to comparison with U.S. systems. The critical question becomes: Why can the two not get together and adopt a global approach? This question is important in the field of standards for acquisition, and absolutely critical in conformity assessment.

Chapter nine, Conformity Assessment in the Department of Defense, clearly states the functions and requirements of DOD's traditional approaches and compares the rapid acceptance of the ISO 9000 Quality Management Standards. Also introduced are the challenges presented (to trade) by the varying certification approaches taken by the United States and the European community.

For DOD, the challenge is even greater. It must have an adequate industrial base to supply future needs, even as acquisition requirements are declining. This decline will make the concept of harmonizing DOD quality system assessment requirements with international systems (which can provide entry into foreign marketplaces) extremely attractive to DOD contractors. Such harmonization can result in lower costs and more effective use of diminishing resources.

It is recommended that the research and consulting resources of the Defense Systems Management College bring together the Defense Logistics Agency's quality assurance functions with those of ISO 9000 Quality Management Systems to begin harmonizing quality requirements.

It became apparent from the research that a critical point has been reached in develop-

ing and utilizing an electronic data base on standards and standards development efforts. Unfortunately, the existing data base developments are split between the military and voluntary systems in the United States. Neither sector has the financial resources to put in place a system to interface with others, such as the European Communities Commission.

Proposals have been made, the latest in a report by the Congressional Office of Technology Assessment, that federal financial support might be proper. Data are needed by all sectors. The private sector is cautious about this approach.

It is recommended that the Defense Systems Management College conduct studies and seminars with interested and affected parties in an effort to develop consensus approaches to electronic data base development and use.

Glossary of Acronyms

AAMI	Association for the Advancement of Medical Instrumentation
AATCC	American Association of Textile Chemists and Colorists
ACEC	IEC Advisory Committee on Electromagnetic Compatibility
ACET	IEC Advisory Committee on Electronics and Telecommunications
ACOS	IEC Advisory Committee on Safety
ACTPN	Advisory Committee for Trade Policy and Negotiations
ADA	American Dental Association
AFBMA	Anti-friction Bearing Manufacturers Association
AFNOR	Association francaise de normalisation
AHAM	Association of Home Appliance Manufacturers
AIA	Aerospace Industries Association
ANSI	American National Standards Institute
AP	Allied Publications
ARI	Air-Conditioning and Refrigeration Institute
ASA	Acoustical Society of America
ASHRAE	American Society of Heating, Refrigerating & Air-Conditioning Engineers
ASME	American Society of Mechanical Engineers
ASQC	American Society for Quality Control
ASTM	ASTM (formerly the American Society for Testing and Materials)
AWS	American Welding Society
BSI	British Standards Institution
BSR	Board of Standards Review
CA	Conformity Assessment
CASCO	ISO Council Committee on Conformity Assessment
CBEMA	Computer Business Equipment Manufacturers Association
CCITT	International Telephone and Telegraph Consultative Committee
CEC	Commission of the European Communities
CECC	CENELEC Electronic Component Committee
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CERTICO	ISO Specialized Committee on Certification
CGA	Compressed Gas Association
CIC	Consumer Interest Council
COPANT	Pan American Standards Commission
COPOLCO	ISO Council Committee on Consumer Policy
CPSC	Consumer Product Safety Commission
DESC	Defense Electronics Supply Center
DIN	Deutsces Institut fur Normung
DLA	Defense Logistics Agency
DOC	Department of Commerce
DOD	Department of Defense
DSMC	Defense Systems Management College
EAC	European Accreditation of Certification

EC	European Community
ECE	Economic Commission for Europe
ECSA	Exchange Carriers Standards Association
EDIG	European Defense Industry Group
EEC	European Economic Community
EFTA	European Free Trade Association
EIA	Electronic Industries Association
EOTC	European Organization for Testing and Certification
ETSI	European Telecommunications Standards Institute
ExSC	Executive Standards Council
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FSC	Federal Supply Class
GAMA	Gas Appliance Manufacturers Association
GATT	General Agreement on Tariffs and Trade
GSA	General Services Administration
HFS	Human Factors Society
HIMA	Health Industry Manufacturers Association
HUD	U.S. Department of Housing and Urban Development
IAC	International Advisory Committee
ICSP	Interagency Committee on Standards Policy
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
INFCO	ISO Council on Information
INTELSAT	International Telecommunications Satellite Organization
IPEG	Independent European Program Group
ISA	Instrument Society of America
ISO	International Organization for Standardization
ISONET	ISO Information Network
ITSTC	Information Technology Steering Committee
ITU	International Telecommunications Union
JAR	Joint Aviation Regulation
JSG	Joint Coordination Group
JISC	Japanese Industrial Standards Committee
JPG	Joint Presidents Group
JSA	Japan Standards Association
JTC-1	ISO/IEC Joint Technical Committee 1-Information Technology
MOU	Memorandum of Understanding
MUAHAG	Military Usage and Harmonization Advisory Group
NAPM	National Association of Photographic Manufacturers
NASA	National Aeronautics and Space Administration
NATO	North Atlantic Treaty Organization
NBBPVI	National Board of Boiler and Pressure Vessel Inspectors
NEMA	National Electrical Manufacturers Association
NFPA	National Fire Protection Association
NFPA	National Fluid Power Association

NISO	National Information Standards Organization
NIST	National Institute of Standards and Technology
NSWMA	National Solid Waste Management Association
OEM	Original Equipment Manufacturer
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PASC	Pacific Area Standards Congress
PPL	Preferred Product List
QC	Quality Control
QML	Qualified Manufacturers List
QPL	Qualified Product List
REMCO	ISO Council on Reference Materials
RMA	Rubber Manufacturers Association
SAE	Society of Automotive Engineers
SC	Subcommittee
SCD	Source/Specification Control Drawings
SDO	Standards Developing Organizations
SEIA	Solar Energy Industries Association
SMDP	Standardization Military Drawing Program
SMPTE	Society of Motion Picture and Television Engineers
STANG	Standardization Agreements (NATO)
TC	Technical Committee
TIA	Telecommunications Industries Association
T1	Accredited Standards Committee on Telecommunications
USDA	United States Department of Agriculture
UL	Underwriters Laboratories
USNC	United States National Committee
US TAG	United States Technical Advisory Group

ANNEX A
CEN
ANNUAL REPORT 1991

President's Foreword

Last year was crucial in the development of CEN and the evolution of European Standardization. During 1991, CEN announced a strategy for the future designed not only to meet the high expectations of the market place for timely, quality standards, but also to provide a basis for trade between members of the Single Market and its trading partners worldwide.

Significant progress has been made in increasing efficiency and output and in ensuring that all sectors of industry play a major and strategic role in determining the content and priorities of a standardization programme fully integrated within the international framework. The year also marked the first wider-based CEN General Assembly where many interested parties were represented, including our partners from Central and Eastern Europe whom we welcomed for the first time as Affiliates of CEN.

Altogether, I believe that this annual report demonstrates CEN's commitment to transparency of information, at the service of the new Europe of the nineties. My sincere thanks to all CEN members, Central Secretariat staff, and the many thousands of experts whose contributions have made this possible.

The Role of CEN

Technical specifications ensuring compatibility between products, appropriate levels for their safety, quality or efficiency and the test methods needed to establish conformity to these specifications have so far been set by National Standard Bodies, sometimes very differently from one country to another, sometimes in an equivalent manner thanks to international cooperation, notably within the framework of ISO, the International Organization for Standardization.

However, a major part of these national documents is gradually being replaced by a unique set of several thousand European standards forming a coherent technical background for the internal market, to the benefit of all involved in the European economic area.

The CEN is the European organization responsible for the planning, drafting and adoption of these standards (with the exception of those pertaining to the two sectors of lectrotechnology and telecommunications), through procedures which guarantee respect for the following principles:

- Openness and transparency: all interested concerns take part in the work programme;

- Consensus: standards are developed on the basis of voluntary agreement between the interested parties;

- National commitment: formal adoption of European Standards is decided by a

majority vote of CEN National Members binding on all of them;

• Technical coherence at the European and national level: standards form a collection, which ensures its own continuity for the benefit of users.

1. Development of European Standards in these areas is entrusted respectively to CENELEC - The European Committee for Electro-technical Standardization and ETSI - The European Telecommunica-tions Standards Institute.

1991: A Year of Change for CEN

Last year was in many aspects the beginning of a new era for CEN:

• Output of approved documents more than doubled compared to the same period in 1990, with 219 publications and, even more significant, 759 documents entering the enquiry stage of procedure, a figure for the first time consistent with the total size of the work programme, which reached 6553 items by the end of the year;

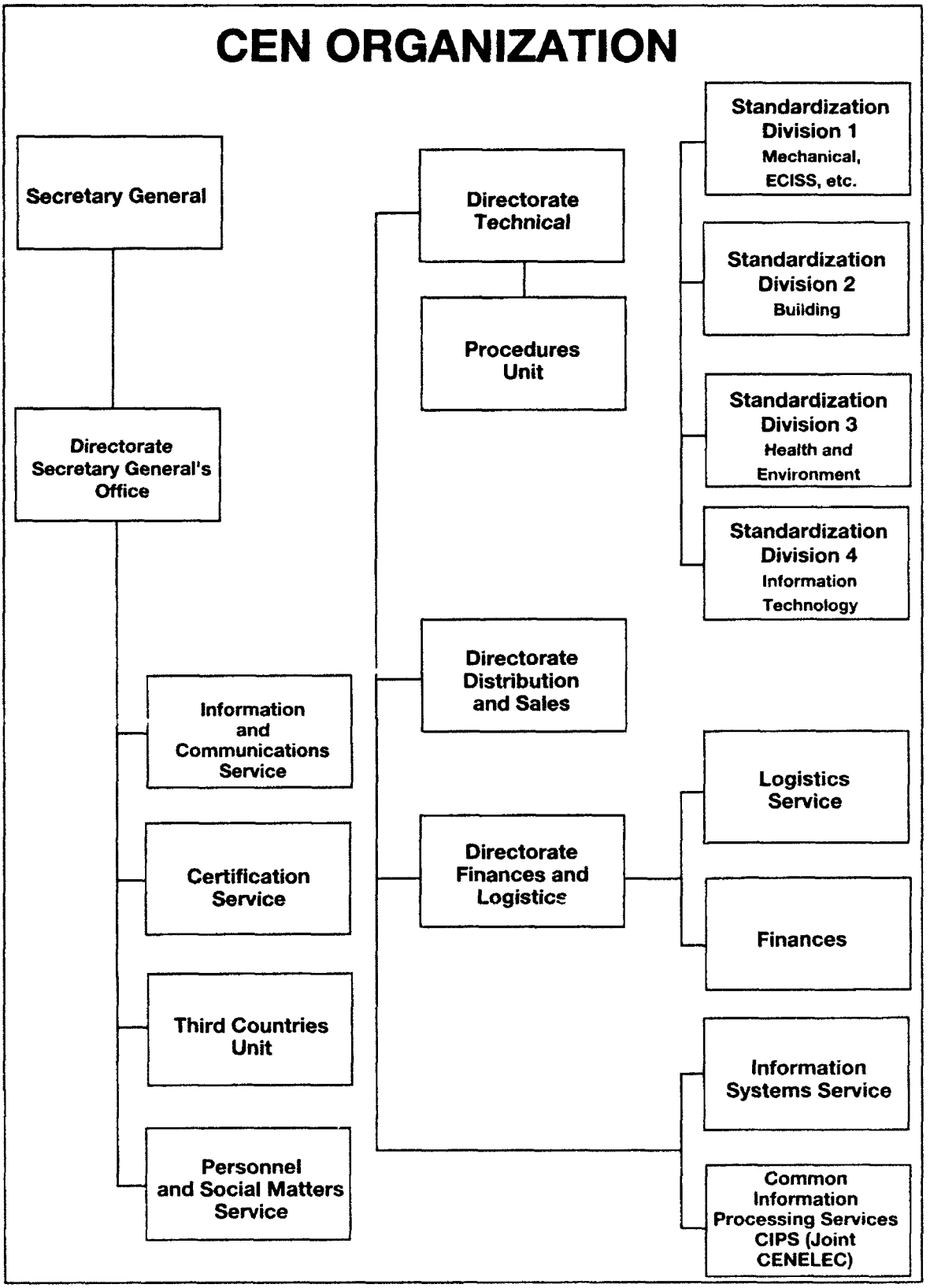
• The central role of CEN for voluntary technical harmonization in Europe was highlighted in the debate which followed the publication by the Commission of the European Communities of its Green Paper on standardization;

• As a regional standardization organization, CEN found its place in the international arena, demonstrated by the signature in Vienna of a wide-ranging cooperation agreement with ISO, the International Organization for Standardization, and the constitution within the Central Secretariat of a Third Countries Unit for the management of cooperation programmes agreed between the EC and EFTA and a number of countries in the field of standardization, quality, certifica-tion and metrology;

• A new structure for the Central Secretariat was adopted in 1991 to reinforce the priority given to the management of the technical programme, whilst strengthening the appropriate infrastructure for improving transparency of information and availability of publications.

I would like to thank all the staff of the Central Secretariat for their efforts which achieved significant progress in productivity during the year.

Jacques Repussard
Secretary General


CEN ORGANIZATION
Secretary General
Directorate Secretary General's Office
Information and Communications Service
Certification Service
Third Countries Unit
Personnel and Social Matters Service
Directorate Technical
Procedures Unit
Directorate Distribution and Sales
Directorate Finances and Logistics
Standardization Division 1 Mechanical, ECISS, etc.
Standardization Division 2 Building
Standardization Division 3 Health and Environment
Standardization Division 4 Information Technology
Logistics Service
Finances
Information Systems Service
Common Information Processing Services CIPS (Joint CENELEC)

Overall Management of the CEN Technical Programme for Standardization

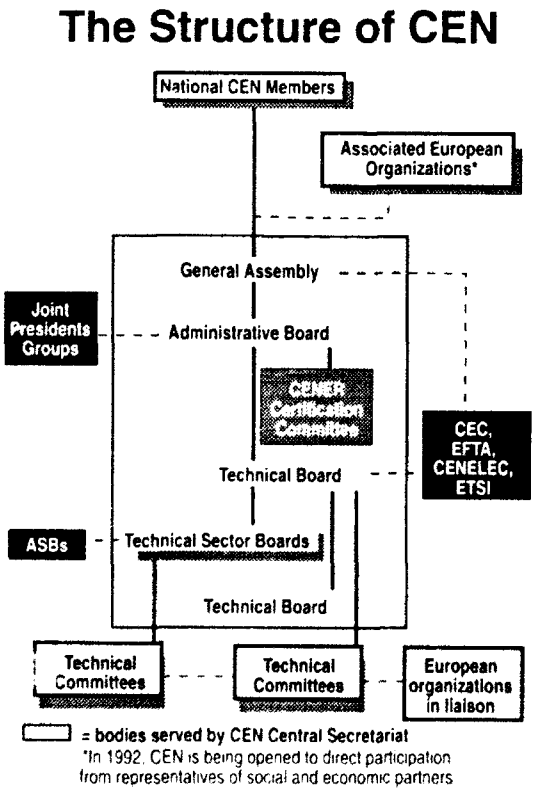
On 25 April 1991 the Administrative Board of CEN approved a *Strategy for the Development of European Standardization*, making a clear commitment to achieve a style of management which would fulfill the expectations of the economy (including public authorities) in terms of quality and rapid availability of standards, transparency of procedure–particularly at the programming level, and rationality in the use of scarse expert resources, taking also into consideration standards activity at the international level.

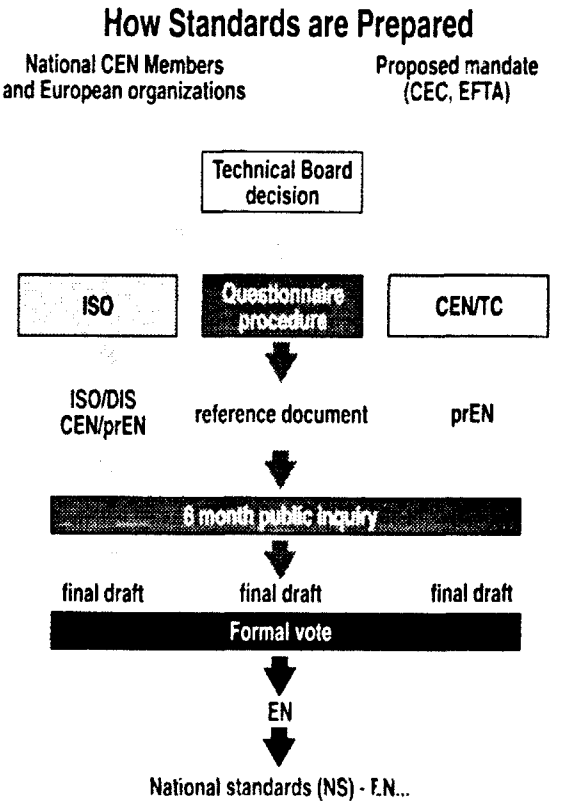
Major decisions toward the implementation of this strategy were adopted in the course of 1991, although their full effect will only appear from 1992 onward:

- the management of programmes, sector by sector, will be very largely delegated to Technical Sector Boards (or rogramming Committees), composed of national delegations including representatives from manufacturers and users/consumers, and delegations of representative interests of the economy at the European level;

- the conditions of cooperation between CEN and ISO at the international level were significantly upgraded by the signature, in June 1991, of the Vienna Agreement, now gradually coming into force, with the promise of much shorter delays for the uniform implementation in Europe of those international standards that the European economy sees fit for its own use;

- coordination with CENELEC and ETSI for the management of 'grey zones' be-





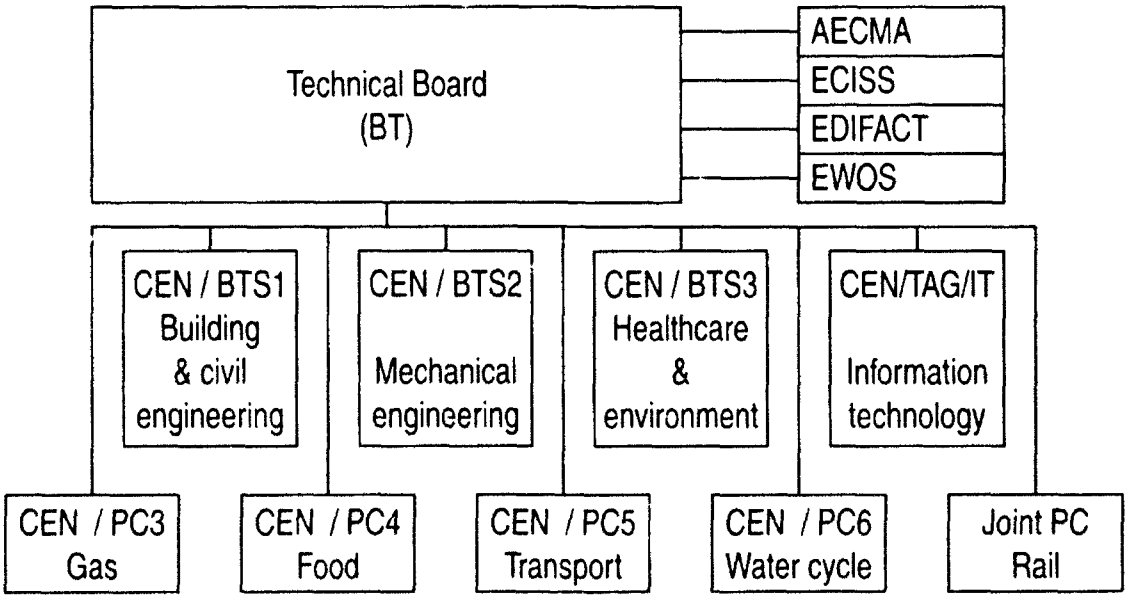
tween the three organizations was strengthened through the adoption of the principle of the 'five modes approach' clarifying in different possible configurations the respective responsibilities of the three bodies;

• following an audit early in 1991, measures were introduced to improve the quality and efficiency of the administration of the standards programme: a Technical Directorate was created to coordinate administration at the Central Secretariat level; a system of 'progress sheets' was introduced to improve the reliability of information exchanged between Central Secretariat and technical secretariats in the Member countries; the number of technical officers responsible for the different sectors in the Central Secretariat under the authority of the four Heads of Division was increased from 11 to 15. Training seminars were organized in several sectors in order to improve the awareness of participants in CEN work about the facts, doctrine and rules of European standardization;

• several actions aimed at developing electronic communication of data and texts between the Central Secretariat and the National Members of CEN were launched, some of them in cooperation with ETSI and CENELEC (the RISE project for text communication via satellite);

• measures, to be effective from April 1992, were taken to ensure that the official text of European Standards would be effectively made available, in the three language versions, from the Central Secretariat and from the National Members no later than three weeks after the date of ratification. In addition, actions were taken by most National Members to ensure the proper operation of timely procedures for national publication transposing the European Standard in accordance with CEN's rules of procedure.

CEN Sectorial Organization (end 1991)



Standards in the Mandated Programme

A mandate is a procedure whereby CEN agrees to draw up a European Standard, generally for use in the context of EC harmonized technical legislation (directives) at the request of the Commission of the European Communities and EFTA who also usually offer financial support for the work. The number of standards currently being developed under this procedure represents 20 percent of the total work programme of CEN. The table shows the rate of execution, at the end of 1991, of the specific programme linked to community legislation.

	Number of standards and main target dates	Adopted standards	Draft at final step of the procedure
Pressure vessels	42 by end 1993	12	12
Safety of toys	5 by end 1992	4	1
Construction	753 by end 1995	7	127
Safety of machinery	107 by end 1994	2	19
Personal protective equipment	98 by end 1992	16	72
Medical devices	36 by end 1992	0	12
Gas appliances	54 by end 1993	6	7
Iron and steel	126 by end 1994	45	13

Mechanical Engineering

Safety of Machinery

1991 saw a slow but steady increase in the publication of draft standards in the field of machinery safety in support of the EEC Directive.

Some fundamental European standards were adopted, the most important being:

EN 292-1 *Safety of machinery - Basic concepts, general principles for design*

Part 1: *Basic terminology, methodology*

Part 2: *Technical principles and specifications*

Both are 'type A' standards, namely fundamental safety standards that can be applied to all machinery. They are essential for designers and manufacturers of machines giving an overall framework and guidance to enable them to make machines that are safe for their intended use and conform to European legislation.

Pressure vessels and tanks

Two standards were adopted in support of the related Directive: EN 286 *Simple unfired pressure vessels designed to contain air or nitrogen*

Part 1: *Design, manufacture and testing*

Part 2: *Pressure vessels for air braking and auxiliary systems for motor-vehicles and their trailers*

Related areas have seen several supporting standards adopted in the fields of welding (about 20) and non-destructive testing, some of them mandated.

Iron and Steel

The European Committee for Iron and Steel Standardization (ECISS) adopted 16 mandated European standards out of a total of 42, most of them being already implemented by the majority of Members. A fourth CEC/EFTA mandate was granted to the Committee covering 32 items out of a programme of 40.

Gas Appliances

The gas appliances mandate (60 items) saw progress with the publication of three standards and numerous drafts.

Packaging

Through the disbandment of five Technical Committees in the field of packaging and the creation of TC 261, *Packaging*, an important and wide-ranging activity was reorganized covering both primary packaging and distribution and transport packaging in all materials including aspects related to environment such as recycling and degradability.

Transport

There was a huge development of activities in CEN/TC 256 *Railway applications* in good cooperation with CENELEC and other European professional bodies within the Joint Programming Committee *Rail-ways*. Two new technical committees were created which dealt with the transport of dangerous goods.

Aerospace

24 new European Standards were ratified in the aeronautical field (originating from AECMA - European Aerospace Industry Association) and mandates signed with the

Engineering	TCs	Work items	ENs adopted
Technical Sector Board 2 : Engineering			
Machinery	32	408	8
Pressure vessels and tanks	11	119	1
General engineering	3	122	39
Iron and steel	23	247	45
Gas	18	150	4
Transport	7	75	2
Non-ferrous metals	4	128	4
Others	41	589	10
AECMA		1872	139

Commission for a second programme of standardization for products, materials, testing methods and procedures for the construction, maintenance and use of aircraft and space vehicles, including engines and equipment.

Building and Civil Engineering

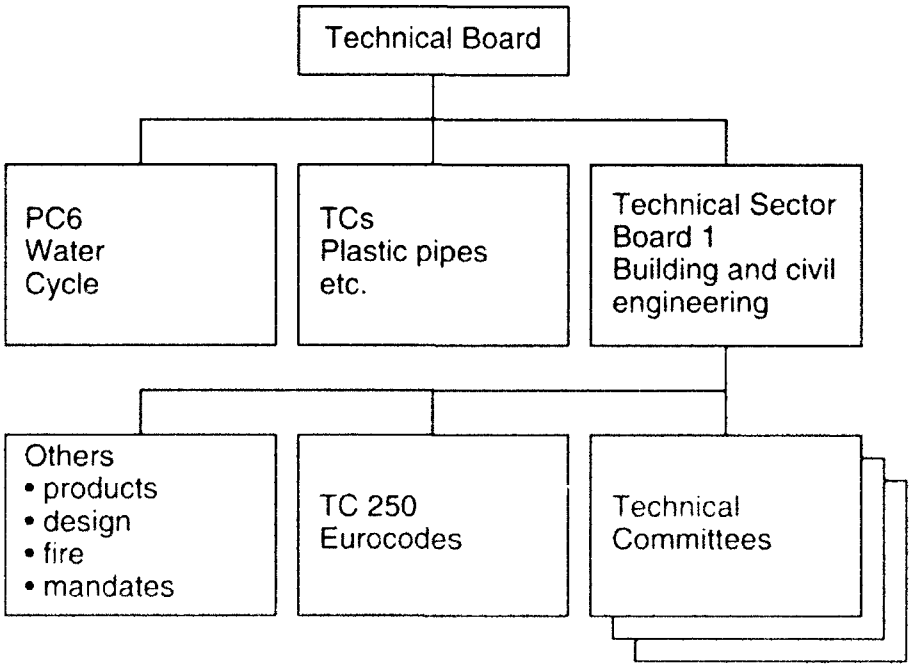
The CEN's Construction sector covers 60 Technical Committees in which 2,500 work items are being developed as ENs, 80 percent of which are test methods, the rest being technical specifications for building products.

Technical Sector Board 1 *Building and Civil Engineering* (formerly PC1) controls the majority of the committees and the Technical Board work on generic materials (plastics, textiles, pipes). The activities related to water supply and waste water are under the responsibility of the Programming Committee *Water Cycle*, PC6.

1) 1991 saw significant progress in the field of EUROCODES (design rules for structures). The combination of efforts of CEN/TC 250, the Commission, EFTA and the Central Secretariat led to the conclusion of the first part of the mandated programme. Part 1 of EUROCODES 2 and 3, dealing with the design of concrete and steel structures were circulated to CEN Members.

2) Another major development was the issue of 23 prENs (draft standards) prepared by CEN/TC 104 *Concrete*. These documents are intended to provide support the EUROCODE 2 and will help designers and contractors in the drafting and execution of projects for construction works. The CEN enquiry procedure will allow the ENs to be adopted by the end of 1992.

Standardization is mostly developed in the context of the recent Construction Products Directive, covering the products/materials/ equipment installed in buildings



and civil engineering works. The scope of the directive reaches far beyond conventional construction products.

Future ENs conforming to mandates agreed between CEN and the CEC/EFTA in this area will be recognized as 'Harmonized Standards,' allowing products to bear the 'ce' mark. So far 13 mandates cover work on general test methods for acoustics, resistance to fire, and thermal properties of construction products and components. Further mandates are being negotiated on floor coverings, glass in buildings and roofing membranes.

Healthcare, Environment, Personal Protective Equipment and Food

Healthcare

1991 saw increased growth in CEN's healthcare sector in response to the adoption or development of several EEC directives in the medical devices area.

A number of important 'horizontal' standards were issued under mandate as prENs or using the primary questionnaire procedure. These included draft standards for quality systems for medical devices, methods and guidance on the validation routine control of sterilization procedures, a specification for medical alarm signals, clinical investigation of medical devices, and biological testing of materials and devices. As a part of the fight against the spread of AIDS, the CEC/EFTA issued a mandate to CEN to prepare European standards for condoms. In response, prEN enquiries were launched in December 1991 on a standard in nine parts covering a specification for latex rubber condoms for consumer use with seven supporting test methods and a specification for packaging and labeling.

16 TCs 345 work items 33 ENS

Environment

Two mandates were signed between CEN and the CEC. The first related to a standardized method of measurement for dioxins and porous emission in exhaust gases and the second a reference method for the calibration of automatic measuring equipment for HCl.

3 TCs 99 work items 16 ENs

The CEN Technical Board created a Working Group on Environment with an advisory role to assess the needs for future European standardization.

The groups 'programme' covers two main types of possible CEN activity, one directly related to the standardization process itself and the second to a more general impact.

Personal Protective Equipment (PPE)

An important package of prENs was launched in 1991 for personal protective equipment which covers approximately 78 percent of the standards foreseen by the first group of mandates which cover the following: respiratory protective devices, eye protective equipment, head protection, hearing protectors, protection against falls from heights, foot and leg protectors and protective clothing.

7 TCs 174 work items 31 ENs

Food

A Programming Committee (PC4) was created to investigate needs for standardization in three different areas: methods of analysis, codes of practice, and definitions and specifications. A preliminary questionnaire was launched on a document published by the European organization of fruit and vegetable processing industries (OEITFL) which gives definitions and specifications for canned fruits and vegetables.

2 TCs 31 work items 0 ENs

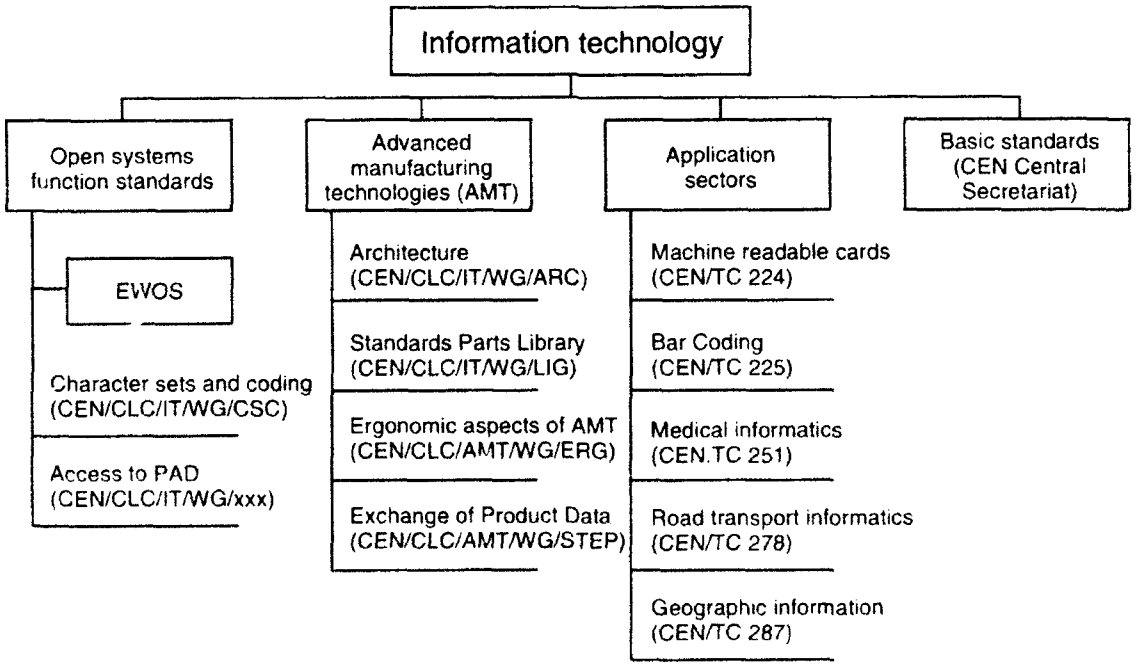
Information Technology

Following the work done at international level on base standards and progress in functional standardization, programmes aimed at satisfying the needs of important user sectors were launched in:

Healthcare
Banking
Transport
Geographic information

Notable progress in 1991 was achieved in the area of healthcare informatics. The Technical Board approved a work programme of 51 items guided by CEN/TC 251 *Medical informatics*. Contracts providing funds for the development of standards were issued by the CEC/EFTA in the shape of 15 order vouchers, proving their support for the selected priority items.

TCs	5
	(with 120 work items)
Total number of work items	300
ENs and ENVs	90



This Technical Committee decided to work on ENs and ENVs for, among others, a vocabulary of health-care informatics, interchange of clinical laboratory information, medical imaging and related data and computerized electrocardiography.

Out of the standards published in 1991, EN 28583 adopts a common interface which enables the interchange between two private systems of messages for financial transactions originated from a bank card. It exemplifies the worldwide harmonization which makes life easier for users of the banking system.

The ENV 41204 is a prestandard which enables two electronic systems to make file transfers using the open systems interconnection (OSI) connection-mode.

In functional standardization for information system interconnection, the alignment efforts made by EWOS (European Workshop for Open Systems) with the North American and Asian workshops bore fruit with a first set of commonly approved texts directed to both the ISO/IEC process and CEN formal adoption mechanism.

For users, standardization in road transport informatics was initiated (CEN/TC 278), and a work programme drafted in cooperation between CEN, CENELEC and ETSI. Standardization in geographic information was also launched (CEN/TC 287) and will impact on numerous domains; e.g., cartography, transport, and resource and urban planning.

Sales and distribution

In 1991 the CEN Central Secretariat established a new directorate to manage the sales and distribution of CEN publications, the governance of CEN copyright and in-

Statistics for 1991

Info Pro

National work programme	:	7798 notifications *
European work programme	:	5846 notifications *
International work programme	:	in the second part of 1991 CEN began to set up a new database to host the ISO work programme. This is expected to be operational in early 1992.

* not including figures for the electrotechnical sector

ICONE

National standards inplementing European standards	:	4974 (including 390 implementing CENELEC and CECC standards)
National standards implementing international standards	:	4195 (including 703 implementing IEC standards)
Total	:	9169 entries

tellectual property rights, as well as the development of conferences on European standardization.

Sales and distribution in 1991 embraced the traditional CEN publications; i.e., *Catalogue, General Technical Report, Catalogue of National Implementations of European Standards, List of Draft Standards, Memento* and the *CEN/CENELEC Review*. A new publication, *The CEN Technical Programme* was developed, with the participation of the Information Unit, and launched during the year to a good reception in most of the CEN member countries and abroad.

This publication, which will be issued again in 1992 in an improved format, helped CEN more than double its sales revenue.

In the field of intellectual property rights (IPR), a new document, CEN/CENELEC Memorandum No. 8, was adopted by CEN and CENELEC to offer more detailed guidance to technical committees in particular, the doctrine itself remaining identical to that followed by ISO/IEC.

After the decision of CEN to improve the availability of European standards, measures have been introduced, both at the National and Central Secretariat level, to reduce to three weeks the delay between the formal adoption of an EN and its actual commercial availability.

Preparatory actions have also been carried out to make, from 1992, the European Standard available from the Central Secretariat, (for European or international organizations only, since CEN does not intend to develop in its Central Secretariat a costly commercial infrastructure, which would duplicate those existing at each National member body level).

Finally, generous copyright arrangements were agreed with the new Affiliates standards organizations of eastern Europe, in order to encourage the diffusion and implementation of European standards in the countries concerned.

The Information Procedure and ICONE

The Information Procedure (InfoPro). Directive 83/189 lays down a procedure for the provision of information in the field of technical standards and regulations.

The aim is transparency from the beginning of the standardization process in order to curb the development of nonharmonized national standards liable to lead to trade barriers, and to promote a concerted effort at the European and international level.

For this purpose, a Central Unit in CEN/CENELEC set up in 1985 a bibliographic database, compiled from the work programmes of international (ISO, IEC), European (CEN, CENELEC) and national standardization organizations. Maintenance of the database is ensured through a notification procedure from standards organizations to the Central Unit. The ICONE (*Index Comparatif des Normes en Europe*) is a database listing all European and international standards along with information about their implementation at the national level.

This project, also started in 1985, was designed to help small and medium enterprises (SMEs) to overcome the obstacles posed by the existence of more than 50,000 national standards, and became part of the SPRINT initiative. The costs of these two systems are partly covered by Community and EFTA funding.

However, in 1991 the Commission explained its wish to revise Directive 83/189 to achieve a lightened procedure focusing on new work initiatives and more open participation in the national standardization process. The CEN and CENELEC were invited to think about this matter, including the consequences as far as funding of the system was involved.

The Third Countries Unit of CEN

As Europe with the arrival of 1993 attracts a growing amount of interest, it goes without saying that if standardization is important to the western European economy, it is no less important to other economies interested in trading with the EC/EFTA.

The CEN, answering the growing number of enquiries and requests for technical assistance about European standardization and related matters from third countries, especially central and eastern Europe, and the need to coordinate such activities, set up at the end of 1990 a special Unit in its Central Secretariat in order to:

- Act as a point of contact for enquiries about European standardization;

- Provide basic information for countries not within CEN, including matters related to international standardization;

- Launch calls for tender for projects of technical cooperation instigated by the CEC, EFTA, or any potentially interested institution, and further organize a pre-selection of candidates according to procedures guaranteeing openness and transparency.

This Unit works in close cooperation with the EC/EFTA services, the standardization organizations, CENELEC, ETSI, and the European Organization for Testing and Certification (EOTC). It has started to establish a database of experts qualified in standardization, certification, metrology and quality assurance (EN 29000 - EN 45000).

In 1991, the Third Countries unit provided expertise for EC/EFTA sponsored technical assistance programmes, notably the PHARE programme, in the following countries:

Algeria
Programme for technical assistance in the field of quality assurance

Bulgaria, Czechoslovakia, Hungary, Poland, Romania
Regional programme on quality assurance

Hungary, Poland
Assistance with the implementation of standardization and certification programmes

Israel
Cooperation project on standardization

Malta
Upgrading of standards laboratories

Mexico
Programme for strengthening standards and certification system, and product quality improvement

Tunisia
Programme for technical assistance in the field of standardization

Together with the creation of the status of Affiliate (for Central and Eastern Europe countries), the Unit's activities demonstrate the will of CEN and its partners in standardization and linked disciplines to help all countries better understand the contribution of these systems to the European economy, improve their knowledge and upgrade national systems to the European level, now recognized worldwide.

Certification and Conformity of European Standards

The Development of the CENCER Certification System

CEN operates a European system of certification of product conformity to European standards, which includes the European CENCER mark.

This system can be implemented in those areas where industry shows an interest for such voluntary operational procedures. Until 1990, the main applications were limited to language programs in the IT area and to thermostatic valves for central heating equipment. 1991 saw further developments of this certification system, when new agreements were reached between interested parties in the building/construction sector for the setting up of the CENCER scheme for vitrified clay pipes, glue-laminated timber, heat exchangers, radiators, concrete pipes and ceramic tiles (although the system for tiles will be restricted to mutual recognition of test results).

CEN policy on certification and conformity to European Standards

- The very large increase in the production of European Standards needed for the implementation of EC Directives, which includes specifications for the assessment of conformity in view of 'ce' marking, led CEN to decide in 1991 to establish a new policy for the drafting of these specifications, hitherto under the responsibility of the specialized 'CCC' groups, this task will in the future be given to Technical Committees and new guidelines to this effect have been prepared.

- With regard to the general role of CEN in voluntary certification, the situation is as follows:

- CEN will seek the formal recognition by the European Organization for Testing and Certification Agreement groups it operates in the CENCER system;

- A strategic study has been launched to investigate the following question:

What policy should CEN adopt in the field of product marking and certification, beyond the existing CENCER approach, in order to promote European Standardization, and to answer the emerging market needs for marks of conformity to standards that can operate throughout the European market?

Finance

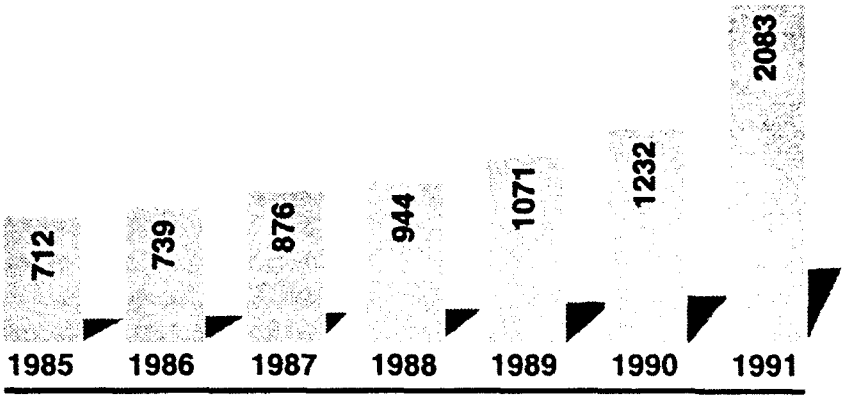
The largest part of the costs of European standardization is borne directly by the employers of the experts who prepare and participate in the consensus-forming process of technical committees, working groups, task forces, etc. However, there is no true record of such costs and to date no comprehensive European-based study of them.

A further element of the costs is that incurred directly by the national standards organizations, which provide the secretariat for most of the technical committees and their subordinate working structures and which operate the CEN procedures (enquiries, votes, implementation and translation where needed of adopted European standards). A fraction of these costs is covered by contracts between CEN, the Commission of the European Communities and the EFTA Secretariat for work corresponding to the execution of 'mandates'; i.e., mostly preparation of standards for use in the framework of Community legislation.

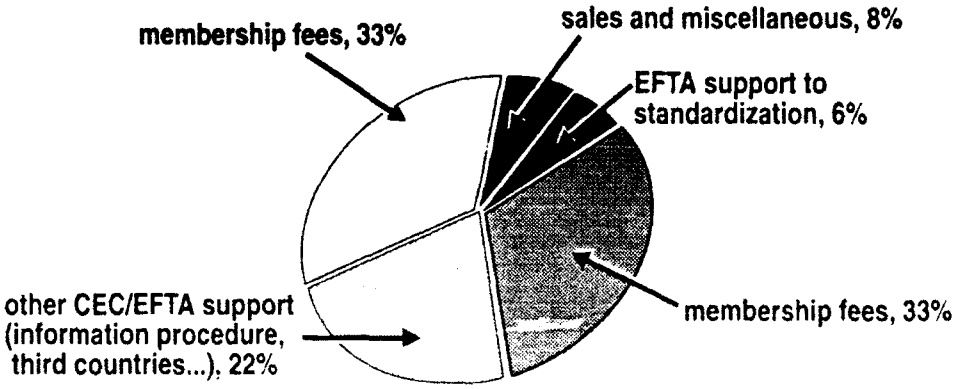
The smallest part of the costs is incurred in the form of the operation of the Central Secretariat of CEN, amounting in total to 5 M ecu (not including EWOS).

These costs are covered as shown in the figures on the next page.

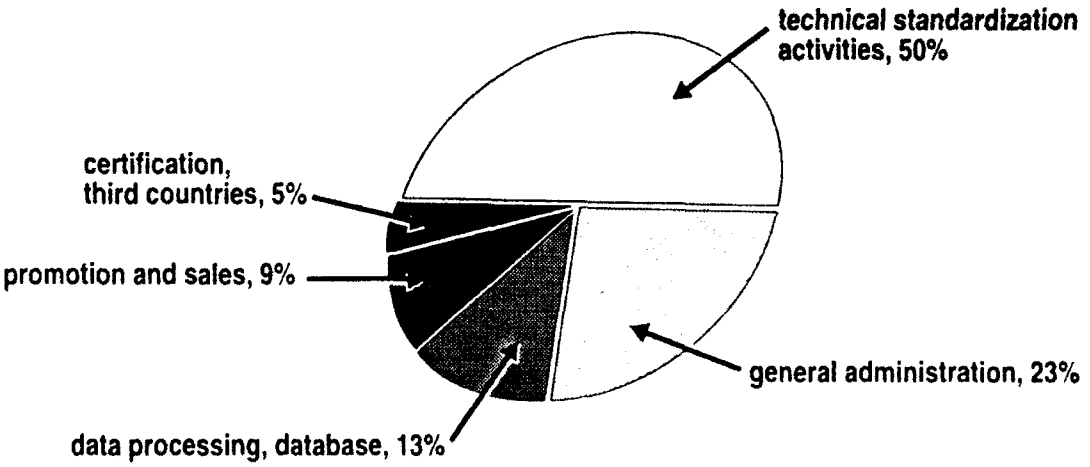
CEN MEMBERSHIP FEES (1985 - 1991) k ecu



REPARTITION OF THE FINANCING OF THE CENTRAL SECRETARIAT (1991)



REPARTITION OF THE COSTS OF THE CENTRAL SECRETARIAT (1991)



INFORMATION

CEN's Main Publications

CEN's European Standards	Documents adopted by CEN are mainly given the status of European standard, recognizable by the designation EN....CEN also publishes pres ndards (ENV), harmonization documents (HD) and reports (CR). These documents are available, as transposed national standards, from National CEN Members. European, international or foreign organizations may also obtain European standards and the publications listed below from the CEN Central Secretariat.
Newsletter	Every two months
Catalogue	List of approved documents
List of Draft Standards	Annual
Memento	*Information on Members*, Technical Sector Boards, Technical Committees, etc., Associated Bodies and organizations in liaison. Annual
Document N525	National implementation of approved documents. Annual
General Technical Report	Lists, for each technical committee, documents issued and work items in progress. Annual
The Technical Programme	Comprehensive survey of CEN's work programme by sector with background information. Annual
CEN/CENELEC/ETSI Bulletin	Lists of standards adopted, drafts issued, principle decisions of main policy-making bodies, mandates received, and citations in the Official Journal of the European Communities. Monthly (except August)
Memoranda and Internal Regulations	Standing documents concerning policy, principles and procedures

How to Take Part in CEN's Work

The programme of CEN is public and can be found from available documents. Requests for further information or participation in the work must be addressed to the Member of CEN which is the National Standards Body of the country concerned or CEN Central Secretariat.

In addition, more than 125 European organizations (listed in the Memento) have been granted a liaison status with CEN in order to help the mutual exchange of information between CEN and professional bodies or associations also interested in standardization. Finally, draft standards are always submitted to a public enquiry stage and announced in the official Bulletins of CEN and all national CEN Members. Resulting comments are sent to the responsible technical body of CEN for the preparation of the final text submitted to formal vote.

ANNEX B
CENELEC
ANNUAL REPORT 1991

What is CENELEC?

CENELEC is the European Committee for Electrotechnical Standardization, a non-profit-making international organization made up from the National Electrotechnical Committees of 18 countries in western Europe. Sixteen of these national committees are also members of the International Electrotechnical Commission (IEC), with which CENELEC has a close, working relationship. The CENELEC, which has been established under Belgian law, has three official languages: English, French and German.

Although CENELEC itself was formed in 1973, National Electrotechnical Committees (NECs) had been grouping together in the interests of European standardization since the late fifties, developing alongside the European Economic Community. In 1959, two years after the Treaty of Rome was signed, the NECs of Belgium, France, Germany, Italy and the Netherlands grouped together to form CENELCOM, the European Committee for the Coordination of Electrical Standards in the Common Market countries.

During the 1960s, CENELCOM collaborated with CENEL, the European Committee for the Coordination of Electrical Standards, which consisted of the NECs of the UK, Austria, Denmark, Norway, Portugal, Sweden, Switzerland, and the two organizations worked side by side until the end of 1972, when CENEL was disbanded and its members joined CENELCOM to form a new organization with the name of CENELEC.

Words From A Parting President...

"Last year was a year of both consolidation and change - and I do not see this as a paradox.

"Consolidation related to resources and agreements. A new Secretary General settled in, staff responsibilities were more clearly defined and we occupied more practical offices in Brussels which represent real value for money. New agreements with our standards partners, the International Electrotechnical Commission (IEC), the Committee for European Standarization (CEN) and the European Telecommunications Standards Institute (ETSI), were made to work.

"We made major internal changes to welcome affiliates from "third" countries, the emerging democracies of Central and Eastern Europe. We made timely progress to involve our European economic and social partners more closely in our work. We established the European Electrotechnical Sectoral Committee (ELSECOM) for certification and testing. And we improved public relations and document circulation.

"Such changes were made possible by consolidation within CENELEC some years ago, through the sound administration of our predecessors and those loyal servants still working in the organization. To be successful, agents for change must build on tried and tested formulae of the past.

"The role of these agents is to assess the present, to interpret and forecast the needs of the future, and, through strategy and plan-ning, to harness resources to make progress through change.

"I hope I do not appear complacent, as someone who has had many sleepless hours of worry in the service of CENELEC, when I say that I think CENELEC is now clearly demonstrating its relevance.

"Over the past year we have developed a sound strategy and business plans. They have been warmly welcomed by our members, partners and staff and will be implemented next year as indicative documents for the future, the results of which will be judged subjectively and through published efficiency indicators.

"I hope that the reader of this annual report will conclude that CENELEC has had a year of both effective consolidation and major change, and that we have been an open-minded and adaptive institution. For if the reader should draw such a conclusion, it would be a fitting end to my two-and-a-quarter years as president of CENELEC. Of course, everything has been made possible by all the hard-working members and our staff, and I thank them warmly for their work, which has been dedicated and relevant.

"Finally, all the modern technology that supports the standardization process is useless without people. An individual in work can facilitate or hold back.

"As a system involving thousands of experts both professional and voluntary, we face possibilities for incomprehension, obduracy, willful misunderstanding and misreporting. These can delay, frustrate and cause uncertainty and anxiery, and we need to counter such negative influences.

"My personal answers are to be certain as to what we have to do, to be determined to do it, to be prepared to work for it in an open way through teams of people and always to try to find fun in our work–even at times when that seems impossible!

"With my best wishes to you all for the future, I leave you in the excellent hands of Dr. Enrico Comellini. He will have my fullest support and friendship during the next two years."

— Gordon Gaddes.

Standardization

Excitement is running high throughout CENELEC and its 250-plus technical bodies as the organization approaches a superb milestone thanks to more than 30 years of dedicated cooperation between the National Electrotechnical Committees of western Europe.

Early in 1992, perhaps even in January before this 1991 Annual Report reaches the desks of standardizers, manufacturers, engineers, consumers and users alike, CENELEC will have published more than 1000 European electrotechnical standards –a major contribution to the development of the internal market which becomes a reality at the end of this year. But, of course, 1000 is not enough! Our work continues unabated, a pursuit of uniformity and excellence within that uniformity.

Last year saw some major steps forward in electrotechnical standardization. Perhaps the most important development in recent years came to fruition in 1991 with the introduction and success of the two new IEC/CENELEC Cooperation Agreements. They came into operation at the start of last year, although the final texts were only ratified in October by both the IEC and CENELEC. By the time of the 70th Technical Board (BT), in Brussels in December, their implementation was highly visible.

The two agreements concern "parallel voting," a system of concurrent IEC/CENELEC action designed to speed up and make more efficient the standardization process without affecting the ethos of consensus, and the common planning of new work, designed to encourage the publication and adoption of international standards, prevent work overlap and ensure the rational use of resources.

There was swift and significant progress concerning the agreements during 1991. By the end of the year, 10 European Standards (ENs) had been ratified at the same time as the corresponding International Standards were accepted at worldwide level, thanks to the new parallel voting procedure. As far as the common planning of new work was concerned, CENELEC had introduced 17 new work–item proposals with a view to transferring them to the international forum if IEC can undertake the work in the required time period.

At an earlier BT, the 69th in London in September, the key decision was taken to start the conversion of CENELEC's existing Harmonization Documents (HDs) into ENs as quickly as possible. The ENs are more suitable to the demands of the internal market as their texts, unchanged, have the status of national standards in member states. As CENELEC currently has 695 HDs, compared with 290 ENs, this conversion is an important step.

Further steps were taken to enhance the decentralization of the standards-making process, allowing national committees to participate more in the work of other countries, through modification of the Vilamoura Procedure. This Procedure has been refined on the basis of a full year's experience, to enhance efficiency and take into account the IEC/CENELEC Co-operation Agreements.

Following the 68th BT in Brussels in June, the Procedure was split into two. Part One pertains to new work, Part Two to revisions of existing national standards. The notification procedure for new work is now more thor ugh, with additional questions and involvement of the relevant CENELEC Technical Committee during the ational committees' three-month reply pe-

riod, while revisions have been markedly simplified.

The first BT of 1991, again in Brussels in March, was dominated by an indepth analysis of the problems encountered in the electromagnetic compatibility (EMC) standardization area. The discussions led to a clearly defined policy on the standards that need to be prepared, relating to the mandates concerning the implementation of the EMC Directive from the Commission of the European communities.

The difficulty with EMC standardization cannot be performed in isolation in one technical committee or Sub-committee for instance. A large number of parties are involved: manufacturers of a very different nature, users, generation and distribution entities, laboratories, public authorities and scientific consultants. Their backgrounds and economic interests are quite different, and they rarely act in a coherent manner at international level.

A large number of organizations, especially concerned with standardization or prestandardization, are involved in addition to CENELEC, CEN and ETSI, and inside these organizations often exist different technical bodies with their own views and concepts.

These differences are manifest at a time when there are very strong legal implications and financial consequences of noncompliance with standards covered by the EMC Directive. Thus, it was deemed vital to lay out a clear synopsis, for the benefit of all these different parties and organizations, of the principles by which this work should be carried out; through cooperation with the IEC and (in the information technology field) ETSI, using parallel voting as much as possible, with flexible application of the different types of EMC standards where appropriate.

The World Context

Under no circumstances can CENELEC tolerate, as we fast head into 1992 setting the foundations for the internal market, a "Fortress Europe" i.e. a Europe only for European manufacturers, distributors and traders. The philosophy of CENELEC [illegible]

Through the IEC/CENELEC Cooperation Agreements, more of which can be read elsewhere on these pages, we believe the international dimension to CENELEC's work in electrotechnical standardization has never been stronger. Through our regular meetings, information exchange system and correspondence with, for example, ANSI, the American National Standards Institute, and the Japanese standards institutes, we keep non-European competitors well informed on developments in European electrotechnical standardization.

In Brussels in November, last year, we held the fifth in a series of meetings between US and European interests. Leading figures in CENELEC and CEN met some 25 representatives of American organizations under ANSI leadership. These friendly discussions reinforced a common understanding of the primacy of international standardization and there was a general satisfaction with the transparency of European standardization processes to the rest of the world.

Our results speak volumes for our intent. Eighty-nine per cent of the electrotechnical

standards produced by CENELEC by the end of 1991 were identical to, or based heavily on, IEC results. This compares with 85 per cent at the end of the previous year — a small but significant increase.

So why base our work in a world context, rather than focus solely on rapidly developing a comprehensive network of "home-grown" standards tailor-made to favour European designers, engineers and producers in an increasingly competitive marketplace?

The answer lies with European customers and manufacturers themselves. According to the basic law of the market, European customers will demand access to products and services of the right quality at the right price, whatever their origin. European manufacturers also are plainly realizing that they can maximize their profitability only by competing in world markets.

The CENELEC's European members can make an important contribution to worldwide standardization by convincing their non-European colleagues around the IEC table to incorporate IEC results in their national standards portfolios.

Western Europe

While mindful of the absolute necessity to fight any attempt to create a protectionist "Fortress Europe," it is necessary for the three European standardization bodies, CENELEC, CEN and ETSI, to commit themselves to the strongest possible relationship of consultation, cooperation and agreement on the way forward in establishing the European Standardization System.

An important step in this direction was the conference, "Present and Future Developments in European Standardization," in Luxembourg in December. Some 140 people, widely representative of western European interests, attended this constructive event at which the three standards organizations were able to demonstrate major changes they had made to adapt to market demands.

It is necessary for all three bodies to continue to demonstrate their policies of openness, including the processes of regular consultation with their economic and social partners, and to show that they are cooperating together in a loose form of tripartite alliance, bearing in mind the international dimension mentioned earlier.

The CENELEC, CEN and ETSI have established useful coordinating mechanisms to prevent the overlapping of their work and, as new work occurs, to allocate it where necessary in a fair and technically logical way.

These mechanisms include three joint committees: the Joint Presidents' Group for coordinating common key policy orientations, defining basic principles and allowing a coordinated dialogue with the CEC and EFTA; the Joint Coordination Group, a "court of last resort" where issues of work overlap between the three organizations still await solution; and the Information Technology Steering Committee, which identifies relevant parts of complex standardization in the information technology field and assigns them accordingly.

The CENELEC, for its part, is committed to openness within western Europe as well as concerned enough to improve its transparency to the rest of the world. Consultation should also be with consumers and users and one of the joys of the Luxembourg conference was to see representatives of these groups stand up, be counted and speak from the floor.

The participants in the Luxembourg conference, which included senior officials from the CEC and EFTA, stressed that industrialists should be thoroughly involved in the development of standardization strategies and that decision-making should be kept close to the market.

Eastern Europe

Last year saw CENELEC open its arms to National Electrotechnical Committees from the emerging Central and Eastern European democracies, an historic step. We have acted swiftly, but judiciously, in this respect, although it must be stressed that our western European member committees have been working for decades with these new affiliates in the context of the IEC.

The first three of our five new affiliates– Czechoslavakia, Hungary and Poland– were present as observers at the CENELEC General Assembly at Toulouse in October, their applications having been accepted at Copenhagen six months earlier. They contributed to the Toulouse Assembly immediately by making official statements to the 18 CENELEC member committees. However, as yet, as affiliates they have no voting power.

The Toulouse Assembly accepted a further two applications for affiliate status with CENELEC, from Romania and Turkey. No doubt we will be receiving more applications in the immediate future as the face of Europe changes and CENELEC, as an international standardization body, continues to embrace and react to these changes without any unnecessary delay.

With CENELEC Memoranda 16 and 17, on "third" countries and affiliate status, ratified by the General Assembly in Copenhagen, we now have the machinery and criteria in place to assess quickly all future applications on their respective merits as they arise.

Certification

Monumental and radical progress was made in the field of testing and certification during 1991, the climax being the creation by CENELEC of a sectoral committee for electrotechnology.

The ELSECOM (the European ELectro-technical SEctoral COMmittee for testing and certification) was finally given the green light at our General Assembly in Toulouse in November.

Such was the market need for coordination of existing and future mutual recognition arrangements, in the field of electrotechnology and electronics, that special sessions were devoted to certification matters at both 1991 General Assembly meetings.

The constitution of the new sector committee has been specially designed to reflect the interests of manufacturers, users and third parties such as certifying bodies and testing laboratories. It will respond to perceived market needs for conformity assessment and mutual recognition in the whole field of electrotechnology, including electronics.

CENELEC has applied to the Council of the European Organization for Testing and Certification (EOTC) for recognition of ELSECOM, and has the intention of working very closely with the EOTC in the future with respect to the work of our new offspring.

If ELSECOM was the cream of the year, there also was plenty to enjoy in the milk. The work of the CENELEC Marks Committee is becoming increasingly successful. Coverage of the CENELEC Certification

CENELEC IN FIGURES

THANKS to its skillful team of tec[h] experts, standardizers and admini[s]tors, CENELEC can display on these p[ages] a record of impressive success.

We are nearly at an important landmark - European standards! It should be reached e[arly] 1992. At the time of writing, we have 22.717 of standards. In 1991, CENELEC completed a [record] year. We published nearly 3,500 new pag[es] magnificent achievement!

DURING THE YEAR

Contributions and Expenditure
- CENELEC Central Secretariat expenditure
- CENELEC member contributions
- CECC General Secretariat expenditure
- CECC member contributions

Standards
- New and revised CENELEC standards made av[ailable]
- Total new pages of CENELEC standards made
- New and revised CECC specifications published
- Total pages of CECC specifications published

Meetings
- CENELEC technical meetings held
  in Brussels
- CECC technical meetings held

AT THE YEAR END

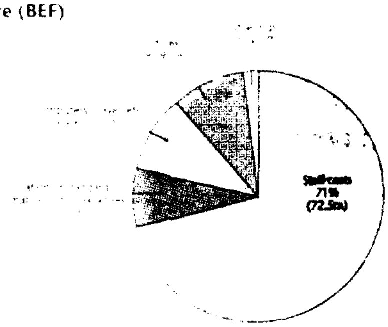
Staff numbers
- CENELEC Central Secretariat staff
- CECC General Secretariat staff

Standards
- Valid European standards, total
  - ENs
  - HDs
  - ENVs
- Total pages of valid CENELEC European stan[dards]
  - number based on IEC publications
- CECC European Standards
- Valid CECC specifications
- Total pages of valid CECC specifications

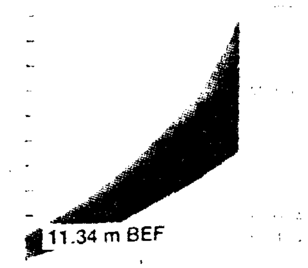
Technical Bodies
- Number of CENELEC technical bodies, total
  - Technical Committees/Sub Committees
  - TC/SC Working Groups
  - BT Task Forces/Working Groups
- Number of CECC Technical Working Groups

CECC Approvals
- CECC ECQAC approvals, total
  - qualifications approvals
  - capability approvals

CENELEC Central Secretariat Expenditure (BEF)

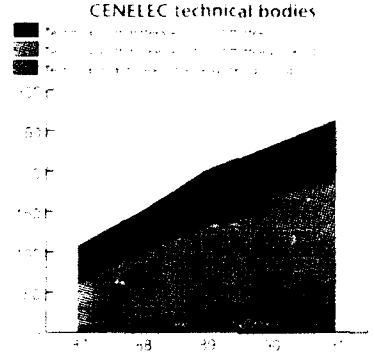


CENELEC Central Secretariat Income



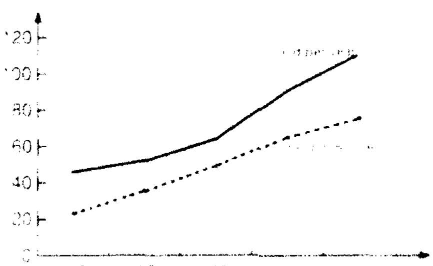
Over the next five years contributions from CENELEC members will increase as we become less reliant on funding ultimately from the taxpayer. CENELEC has decided to reduce annual contributions from the EC and EFTA in percentage terms from more than 40 per cent of the total budget in 1991 to around 18 per cent by 1996.

CENELEC technical bodies



As CENELEC's workload continued to expand and intensify last year, the number of dedicated technical bodies under its umbrella grew to record levels. At the year end, there were some 269 in operation Europe wide.

CENELEC Technical meetings



The number of CENELEC technical meetings has risen sharply over the past two or three years [illegible] 1992 and the establishment of the European internal market. As many of the meetings as possible have been held in Brussels, so that Technical Committees, Sub Committees, Working Groups and Task Forces have the full assistance of Central Secretariat.

CENELEC
IN FIGURES

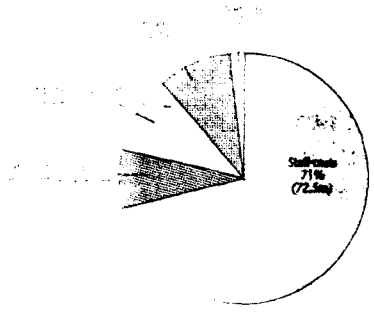
THANKS to its skillful team of technical experts, standardizers and administrators, CENELEC can display on these pages a record of impressive success.

We are nearly at an important landmark - 1000 European standards! It should be reached early in 1992. At the time of writing, we have 22,717 pages of standards. In 1991, CENELEC completed a record year. We published nearly 3,500 new pages - a *magnificent achievement!*

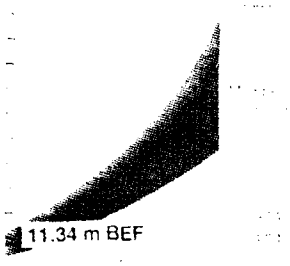
CENELEC is a standardization body consis European members. But we believe that ou *should be firmly set in a worldwide tradi* text. For that reason, we are delighted to that 89 per cent of our output is now ident or heavily based upon, IEC results.

An important future trend concerns contri to our finances. We will become less ar reliant on taxpayers' money via the EC and Instead the large majority of our funds will plied by our own members, the 1? Na *Electrotechnical Committees of Western Euro*

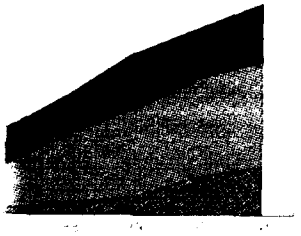
il Secretariat
(BEF)

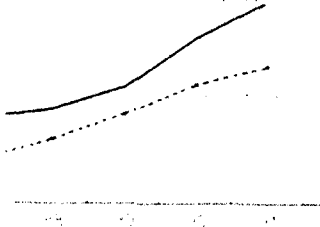


CENELEC Central Secretariat Income



CENELEC technical bodies





EC Technical meetings

DURING THE YEAR	1991	1990
Contributions and Expenditure		
• CENELEC Central Secretariat expenditure	[illegible]	[illegible]
• CENELEC member contributions	[illegible]	[illegible]
• CECC General Secretariat expenditure	[illegible]	[illegible]
• CECC member contributions	[illegible]	[illegible]
Standards		
• New and revised CENELEC standards made available	168	[illegible]
• Total new pages of CENELEC standards made available	3139	[illegible]
• New and revised CECC specifications published	[illegible]	[illegible]
• Total pages of CECC specifications published	[illegible]	[illegible]
Meetings		
• CENELEC technical meetings held in Brussels	[illegible]	[illegible]
• CECC technical meetings held	[illegible]	[illegible]

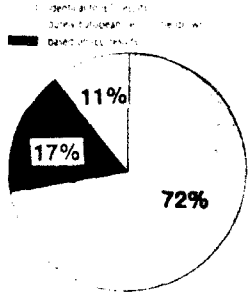
AT THE YEAR END		
Staff numbers		
• CENELEC Central Secretariat staff	[illegible]	[illegible]
• CECC General Secretariat staff	[illegible]	[illegible]
Standards		
• Valid European standards, total	490	469
ENs	[illegible]	[illegible]
HDs	[illegible]	[illegible]
ENVs	[illegible]	[illegible]
• Total pages of valid CENELEC European standards	[illegible]	21 000
number based on IEC publications	18 878	[illegible]
• CECC European Standards	4	
• Valid CECC specifications	195	152
• Total pages of valid CECC specifications	8 150	6415
Technical Bodies		
• Number of CENELEC technical bodies, total	269	231
Technical Committees/Sub-Committees	71	63
TC/SC Working Groups	138	121
BT Task Forces/Working Groups	60	47
• Number of CECC Technical Working Groups	26	24
CECC Approvals		
• CECC/ECQAC approvals, total	[illegible]	[illegible]
qualifications approvals	2642	2580
capability approvals	[illegible]	[illegible]

CENELEC is a standardization body consisting of European members. But we believe that our work should be firmly set in a worldwide trading context. For that reason, we are delighted to report that 89 per cent of our output is now identical to, or heavily based upon, IEC results.

An important future trend concerns contributions to our finances. We will become less and less reliant on taxpayers' money via the EC and EFTA. Instead the large majority of our funds will be supplied by our own members, the 18 National Electrotechnical Committees of Western Europe.

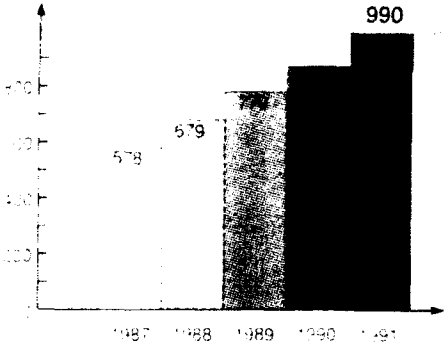
	1991	1990
BF millions	102	96
BF millions	58	50
DM Thousands	1855	1706
DM Thousands	996	765
	158	191
	3439	3037
	72	47
	1335	2390
	111	91
	75	65
	42	40
	36	33
	13	15
	990	869
	290	217
	695	647
	5	5
	22 717	21 000
	18 878	17 700
	4	—
	495	452
	9750	7415
	269	231
	71	63
	138	121
	60	47
	26	24
	2799	2734
	2642	2590
	157	144

CENELEC European standards



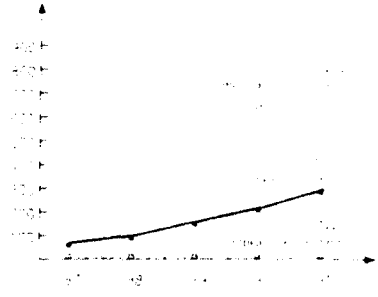
CENELEC has always sought to stress the importance of the worldwide nature of its work. By the end of last year, it could be said with some pride that 89 per cent of electrotechnical European standards were truly international. This compares with 85 per cent at the end of 1990.

Total valid CENELEC European standards



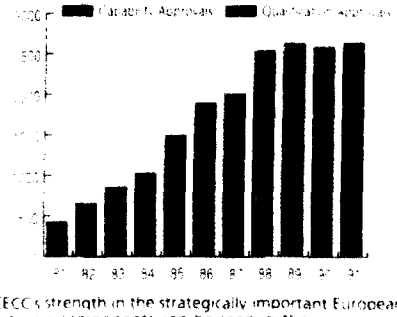
By early 1992 there will be 1000 European Standards in the CENELEC catalogue, representing a total of 24 000 pages of text, per annum.

Breakdown of CENELEC European standards



Following a key decision at September's Technical Board meeting in London, CENELEC has decided that most new work should be aimed towards European Standards. This continues the trend shown above to rely less on Harmonization Documents and to increase the number of ENs which are more useful to the Internal Market and require the publication of an identical national standard by each CENELEC member.

CECC Approvals



Evidence of CECC's strength in the strategically important European marketplace for electronic components can be seen in the encouraging rise in Qualification Approvals, up to 2642 by the end of 1991. And CECC national authorities have already issued 157 Capability Approvals – a considerable step forward in the acceptance of the CECC system.

Coverage of the CENELEC Certification Agreement was extended to three new participants–in Luxembourg, Spain and the United Kingdom–and the Marks Committee is currently discussing two further new draft certification agreements, on electrical components for household appliances and lighting fittings.

The three new participants to the CENELEC Certification Agreement mean it now has 20 signatories, from 17 countries. The success of the CCA in industry also is shown by a steady growth in the number of notifications of test results delivered. More than 4,000 have been delivered to date and over 6,000 recognized. A similar steady increase occurred in the number of licences issued to European cable manufacturers through the HAR Agreement for low voltage cables and cords.

New initiatives for mutual recognition of certificates and test reports for electrical products expanded under the CENELEC umbrella throughout Europe. The certification agreement on active medical devices, EMEDCA, settled its basic rules of procedure and made a first attempt at a common test report form on the basis of the harmonized European Standard (EN).

Two key new agreements were signed: for low-voltage industrial equipment (LOVAG) and for high voltage electrical power equipment (STLA). And the coordinating committee for testing and certification in Electromagnetic Compatibility (EMC) set up an important working group to study the possiblities of preparing a common report form for EMC testing of all electrical equipment.

Finally, CENELEC, as a signatory to the Memorandum of Understanding that established the EOTC, helped with the formation of the EOTC Council and its Advisory Committee. We gave special assistance in preparation of the Rules of Operation of the Council, the Guidelines for the Recognition and Publication of Agreement Groups and the Guidelines for EOTC Sectoral Committ

CECC's Year

Crucial progress has been made by the CENELEC Electronic Components Committee (CECC) in tackling the challenging task of documenting and specifying characteristics, and technical requirements, for the rapidly expanding range of electronic components.

April was a month worth celebrating at CECC's Frankfurt offices, when it issued its first European Standard, EN 123 000, a generic specification for printed boards. We expect all existing, higher-order CECC Specifications to become ENs by the end of next year and, further, that all new ones will be issued as ENs from now on.

The CECC cemented ties with manufacturers and users last year, with the creation of several new working forums. A Joint Automotive Working Group was established in June in conjunction with the European component manufacturers' technical body, CEMEC. The group which consists of representatives of the European car manufacturers, equipment manufacturers and electronic component manufacturers, will probably become a new CECC User Group in due course.

Long-standing and successful contacts between the European Organization for Civil Aviation Electronics (EUROCAE) and CECC bore fruit with the setting up of the Civil Aviation Users Group (CAUG). This new body will benefit, in terms of economy in costs and resources, civil avionics equip-

ment manufacturers and users, as well as the electronic components industry.

Another important CECC liaison which continues to grow stronger by the day is with the European Association of Aerospace Equipment Manufacturers (AECMA), the body that represents the interests of constructors of aircraft and aerospace vehicle constructors. A joint forum has prepared a draft Memorandum of Understanding (MOU), which will be the basis for common activities in the standardization of electronic components for aerospace applications.

Recognizing their common interest in electronic components standardization, CECC and ETSI have held discussions to ensure adequate liaison takes place between their respective technical committees. A cooperation agreement on fibre optics has already emerged from these discussions.

Other progress in CECC's standardization field included the setting up of a special task force to develop new specification methods which will be simpler, more flexible and more closely aligned to current industrial practice.

And, in October, CECC published what is likely to become the first global standard in the important area of protection of electrostatic-sensitive devices, Basic Specification CECC 00 015.

The worldwide interest being shown in this specification (orders have already exceeded even very optimistic expectations) indicates the strength of demand for international standards in this field and confirms that CECC is once again leading the way. It is intended that this standard should become the basis of a new IEC publication in the near future.

Last year, CECC clearly strengthened its position in the strategically important European marketplace for electronic components. Evidence of this progress can be seen in the encouraging rise in Qualification Approvals, up to 2642 by the end of 1991.

The CECC national authorities have already issued 157 Capability Approval Certificates throughout Europe–a considerable step forward in the acknowledgement and acceptance of the CECC system, and a compliment to this more modern approach to product assessment.

There is a growing interest in the CECC system, especially among equipment manufacturers and small and medium-sized component manufacturers. This is shown by the enormous increase in enquiries about CECC, more than 150 percent, received by the General Secretariat. Between January and November, more than 260 companies, asking for detailed information on the European Standardization and Quality Assessment System and the procedures for CECC approval, were replied to worldwide.

Responding to this growing demand from users and manufacturers, CECC is also pursuing an alternative method of approval incorporating the latest and most modern principles and techniques in quality development. "Technology Approval" will allow continuous product release through rapid technology extension and swift introduction to the marketplace.

General Assembly

The important decisions in CENELEC are made at the twice-yearly General Assembly (AG), where delegations from the members vote on recommendations and proposals drafted by Central Secretariat under their instruction. Last year, the two General

held in Toulouse, at the end of October, and Copenhagen, in May.

Nearly 100 items were processed in the plenary sessions at Toulouse, in less than two days. As time progresses, our General Assembly meetings seem to become more and more efficient. It is difficult to know how Toulouse can be bettered in future in this respect, but of course we will certainly be trying!

However, a CENELEC General Assembly is no longer a purely internal matter. Observer status has been granted to a range of interested organizations, from the International Electrotechnical Commission to the EC and EFTA, and European-level representatives of manufacturers, users and consumers. In addition, at Toulouse, CENELEC members welcomed statements during the plenary session from colleagues in the other two main European standardization organizations CEN and ETSI, from the IEC, from representatives of our new affiliates in Czechoslavakia, Hungary and Poland, and from the European Commission and the EFTA Secretariat.

Virtually all the decisions we make on these occasions seem so important, that it is difficult to give any priority of order to those listed on these pages. One of the first steps taken at Toulouse was to add two new affiliates, the National Electro-technical Committees of Romania and Turkey. Dr. Enrico Comellini of Italy was elected president to succeed Gordon Gaddes on 1 January 1992 for a period of two years. A similar term of office was given to Edward Johnston of Ireland elected vice president to replace Dr. Comellini. It is impossible to thank Rudolph Winckler enough for his years of wonderful work in the service of CENELEC. He has left the CENELEC adminstrative board now, replaced automatically by Mr. Gaddes as immediate past president.
As far as standardization was concerned, the General Assembly agreed on a crucial statement regarding the international context of CENELEC's work; European standardization in the electrotechnical field should be identical to IEC work, thus implying the implementation of IEC results as the only National Standard for a given subject. The systematic conversion of all existing HDs into ENs was endorsed. An important new CENELEC Memorandum, No. 18, on Standardization and Intellectual Property Rights was approved, as were the basic principles and procedures for the establishment of cooperation agreements between CENELEC and potential feeder organizations.

A monumental decision was taken during the Certification Session of the Assembly, probably the last special session on certification to appear on an AG agenda as a result, when members decided to establish, within CENELEC, the European Electrotechnical Sectoral Committee for Testing and Certification (ELSECOM). The new committee will perform the necessary coordinating functions in the field of testing and certification for electrotechnology, including electronics, and is currently seeking recognition from the European Organization for Testing and Certification (EOTC). Gordon Gaddes was appointed acting chairman of ELSECOM.

The AG in COPENHAGEN followed hot on the heels of a CENELEC/IEC Seminar in Berlin in March, at which the principle of affiliation to CENELEC of so-called "third countries" was jointly accepted. Thus, the Copenhagen AG undertook to do all that was necessary to accommodate future affiliates as rapidly as possible. A draft Memorandum, No. 16, on third countries was ratified, providing access to CENELEC, and a second draft Memorandum, No. 17, defined the conditions which had to be met

for affiliation to CENELEC. Once these draft Memoranda had been accepted, the AG immediately agreed applications for affiliation from the Czechoslovakian, Hungarian and Polish committees for electrotechnical standardization.

Important changes in our Articles of Association and Internal Regulations were made affecting the election and terms of office of president and vice presidents, the tasks of the secretary general, the payment and ratio of members' contributions, the change in the registered office of CENELEC and a widening of attendance at future AGs.

A substational part of the Copenhagen plenary session was given over to discussing relations between CENELEC and the CEC and EFTA. The CEC representatives talked frankly about the "post-Green Paper" period, in particular the theme of the new partnership between regulators and standardizers aiming at closer cooperation in setting priorities and more openness, particularly in the certification domain.

The New President

"I would like to thank the whole CENELEC community for electing me as President; it will be both a great honour and a demanding task.

"I am receiving, from my predecessor and friend Gordon Gaddes, the responsibility of a healthy and vital organization, the activity and efficiency of which must be expanded and increased yet further in the future.

"This need to expand is due to the demands of European industry, the social sector, governments and the forces at the basis of our constituency the National Electrotechnical Committees of the member countries. All these bodies demand fresh standards, a key factor in promoting trade, technical and economic progress in the exciting years ahead.

"Standards are needed urgently and, whenever possible, internationally because European industry wishes to compete fairly in the international market. They have to be of a good quality and based on the largest possible consensus, which is the best guarantee of their widespread implementation.

"These are very demanding requirements, but the thousands of earnest people who work in the CENELEC Technical Committees, Sub-Committees, Task Forces, Working Groups and in the Central Secretariat are just the kind of people able to meet the most difficult challenges, as our history clearly shows.

"In achieving these objectives, we are open to cooperation from the other European standard bodies, with whom we relate on a permanent basis in the framework of the Joint Presidents Group and other forums such as the Joint Coordination Group.

"We also cooperate with other European organizations, who are able to contribute to the standardization process by setting priorities and preparing standards. We are open as always to the most fruitful cooperation with the IEC.

"The CENELEC is considered an important partner by the Commission of the European Communities, which, through our cooperation, is able to establish essential requirements in the Directives, relying on voluntary standards for detailed technical requirements. We have the capacity and ambition to work even more with the CEC in the future.

"Proud of our past, we look forward to the future, confident of reaching all our fundamentally-necessary and expected goals.

"To a successful and exciting 1992!"

— **Dr. Enrico Comellini**

A Final Word

"I predicted, in my contribution to the 1990 Annual Report, that 1991 would be an exciting year for CENELEC. It has certainly proved to be so!

"Many highlights are recorded elsewhere in this Report, but two of them have been, for me personally, particularly significant. The first was the remarkable speed with which we were able to put into effect our agreements with our worldwide partner, the IEC, through close cooperation between the secretariats of the two organizations in overcoming the inevitable teething-troubles. The second experience, the memory of which I shall long treasure, was the readiness with which we welcomed our new affiliates from Central and Eastern Europe into the CENELEC family. It will be a pleasure and a privilege to work with them.

"During the year, CENELEC has built upon and developed its contacts with other organizations and institutions. This has given me the pleasant opportunity to strengthen friendships with members of the Commission services and EFTA secretariat and with my fellow-standardizers, in particular those in the secretariats of the IEC, CECC, CEN and ETSI.

"As well as these "external" events, 1991 saw a continuation of the solid success of our standards production—more pages published and more drafts circulated than in any previous year. The thousands of contributors to this process—chairmen, secretaries, convenors, delegates and experts, and their National Committees–can be justifiably proud of this achievement. All who benefit from electrotechnical standardization, that is all the citizens of Europe, owe them a debt of gratitude for their labours.

"Turning to the Central Secretariat, I can state with confidence that my colleagues have, without exception, worked enthusiastically and hard - some of them, indeed, harder than it is reasonable to expect. They have the real satisfaction of doing a worthwhile job, and of doing it well. There is a high level of morale and (almost always!) a lively sense of humour. It is an honour to lead such a outstanding team, and I thank them sincerely for their loyalty and unstinting support. Towards the end of the year, we were joined by a highly-qualified PR and Information Officer. It will be his task to work, with the National Committees, to increase awareness of CENELEC its capabilities and achievements. We welcome him and wish him well in his work, of which this Annual Report is an early example.

"A last, personal remark. My first full year as Secretary General seems to have passed very quickly. It has been challenging and exciting and, above all, enjoyable. This is due, in particular to the friendship and guidance of the President and to the understanding and support of my wife. My grateful thanks are humbly offered to both of my bosses."

— Stephen P.A. Marriott

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ANNEX C
THE CECC SYSTEM FOR ELECTRONIC COMPONENTS OF ASSESSED QUALITY

Introduction to the System

The CENELEC Electronic Components Committee (CECC) System for electronic components of assessed quality became operational in 1973 following discussions which were instituted in 1970. Its object is to facilitate international trade by the harmonization of the specifications and quality assessment procedures for electronic components and by the grant of an internationally recognized Mark, and/or Certificate of Conformity. The components produced under the CECC System are accepted by all member countries without further testing.

This object is achieved through two separate but closely associated organizations:

- the CECC, being a committee of the *Forderverein fur Elektrotechnische Normung* (FEN) e. V.*
- the ECQAC (Electronic Components Quality Assurance Committee).

There are currently 15 countries participating in the CECC System (see list at the end of this publication).

Approvals

Under the CECC System any company which meets a specified set of stringent requirements may be approved to manufacture or distribute electronic components of assessed quality in conformity with internationally recognized specifications based on IEC and ISO Standards.

These specifications may be generated jointly by international technical expert groups or may be of national origin, developed by national standards bodies or by one or more manufacturers or users of components to meet either a custom-built or volume market demand.

Distributors who are recognized as fit to stock and distribute components produced and released under the CECC System may be granted Distributor Approval.

Independent test laboratories with appropriate facilities and procedures may also be granted approval within the System to carry out tests on components.

The Product

All electronic components supplied with a registered Mark or Certificate of Conformity have been subject to rigid inspection for quality conformance and a comprehensive schedule of tests and acceptance requirements, under the surveillance of an independent inspectorate.

The Advantages of the CECC System

The CECC System provides a wider quality components market for vendors and pur-

* Association for the promotion of electrotechnical standardization.

chasers alike, but there are many other benefits, for example:

•the assurance of a component of consistent quality

• the scope for multisourcing from similarly qualified suppliers in different countries

• Certified release of each delivery

• Improved traceability

• Reduced vendor appraisal and goods inwards inspection

• Improved reliability

• Reduced total life costs

• Simpler purchasing and contractual requirements

• Increased confidence in supplier and product

• The availability of qualified components in small quantities from approved distributors.

A range of over a million individual CECC approved component types, covering many different technologies, from resistors to connectors, and from integrated circuits to printed boards, ensures that the System can satisfy the demands for availability, quality, reliability and cost effectiveness of industries dealing with widely varied applications, including such divergent requirements as those of aerospace and telecommunications, defence and household equipment.

The Customer

A potential customer has ready access to information on all CECC approved companies, all published specifications and every approved electronic component in production under the System through

• Published documents (especially the Qualified Products List, CECC 00 200)

• The CODUS Databank

• The Technical Indexes Ltd Microfile.

Additional Benefits for Component Manufacturers

The manufacturer of components also benefits through economies of scale and independent third party surveillance, ensuring recognition in all member countries. He can be confident that his CECC-certified components will be acceptable to the growing quality-conscious market for the application of electronics technology.

The Flexibility of the CECC System

An important aspect of the CECC System is its ability to respond rapidly to the requirements of customers. It enables equipment makers to negotiate with their suppliers the manufacture of components to agreed specifications which precisely meet their needs. There are presently two types of quality assessment procedure in use:

• Qualification Approval which is the approval granted to an individual component or range of components which meets the requirements given in a Detail Specification published within the System

• Capability Approval whereby a component manufacturer obtains approval for a technology of which the boundaries have been precisely defined. Such approval is valid for all components produced within that technology and is applicable to custom-built products, devices made in short

production runs and standard catalogue items.

The CECC System also includes specialized methods for quantifying the manufactured quality, Assessed Process Average (APA) (see CECC 00 014) and the Parts Per Million approach (see CECC 00 800), which have been introduced in response to industrial demand.

The System's flexibility is designed to allow it to keep in step with technology and developing concepts and techniques.

System Organization

The CECC System is governed by a Management Committee (CD), which is constituted of representatives of the National Authorized Institutions (ONH) and of Users' Advisory Groups, and is regulated by Rules of Procedure administered through national bodies by the General Secretariat in Frankfurt.

Implementation of the System's rules is the responsibility of member countries, each represented by an ONH.

Inspection and surveillance is undertaken by the relevant National Supervising Inspectorate (ONS).

The international coordination of ONS activities is undertaken by the independent body ECQAC.

Information

Detailed information on any aspect of the CECC System is obtainable from either your ONH or ONS or from the CECC General Secretariat (see list hereafter).

CD = *Comite Directeur du CECC*/CECC Management Committee
ONH = Organisme National Habilite/National Authorized Institution
ONS = *Organisme National de Surveillance*/National Supervising Inspectorate

CECC Press Release

EN STATUS FOR CECC ELECTRONIC COMPONENT SPECIFICATIONS

JUNE 1991

Recognizing the urgent need for the harmonization of European technical requirements as an essential element of the Single European Market of 1992 and beyond, the CENELEC Electronic Components Committee (CECC) has initiated action to establish its electronic component specifications as European Standards (ENs).

In consequence, it is intended that existing higher-order CECC Specifications will become ENs by the end of 1992. Most new CECC draft specifications will in future be submitted automatically for voting as proposed ENs.

The issue of ENs by CECC will place an obligation on all CENELEC countries (i. e., all 18 EC and EFTA members) to recognize them as national standards and to withdraw conflicting national specifications.

> CECC has thus taken a vital step toward 1992 by paving the way for full European harmonization in the field of Electronic Components

• Existing CECC Specifications: Subject to the agreement of CENELEC member countries, all basic, generic, sectional, blank detail and some detail specifications will be progressively republished as ENs.

• New draft CECC Specifications: These will be treated as draft European standards from the outset and published as ENs.

• CECC Specifications accorded EN status will be prefixed with the digit 1 without the appellation 'CECC'. And these are listed in CECC 00 300: CECC Publications and their related National Documents.

viz | EN 123 000 | : Generic Specification: Printed Boards, to be published shortly, which is identical with CECC 23 000.

• To avoid delay in the publication of ENs, some specifications will be issued in only two languages (usually English and French) to begin with. In this case the English version will be implemented in Germany as the national standard. If necessary, drafts may also be circulated in two languages only during preparation of the specification.

For further information please consult:

CECC 00 200: Qualified Products List

CECC 00 300: CECC Publications and their related National Documents

CECC 00 301. List of CECC Specifications and Related Detail Specifications

or contact: CECC General Secretariat,
Gartenstrasse 179,
D-6000 Frankfurt 70,
Tel.: Int.+(49) 69 63 91 71
Fax.: Int.+(49) 69 63 94 27

CECC 00 200: *"Qualified Products List"* An essential tool for purchasers of electronic components

The CECC (CENELEC Electronic Components Committee) has recently issued its "Qualified Products List"–CECC 00 200 Issue 1/1992. Once again, this document contains essential information for purchasers of electronic components. For example:

- A list of all electronic components granted qualification approval (2,622 entries) together with product and manufacturer codes and assessment levels

- A list of all capability approvals granted under the CECC System (161 entries) with statements of the approved limits of capability

- A cross reference index between component type numbers and respective CECC specification numbers to which they are approved

- A list of all European manufacturers approved under the CECC System (255 entries)

- A list of all European distributors approved under the CECC System who distribute the components listed in this QPL (125 entries)

- A list of all European test laboratories approved under the CECC System which have tested, or are testing, components listed in this QPL (36 entries).

The CECC 00 200 is published three times a year and can be obtained, also on a subscription basis, from the National Authorized Institutions of the CECC. For further information please contact:

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D - 6000 Frankfurt/Main 70
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Cenelec Electronic Components Committee

Forderverein fur Elektrotechnische Normung e.V.

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New Spanish Member
to be determined

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CECC Press Release

CECC EMBRACES ISO 9000/ EN 29 000

October 1990

The CECC (CENELEC Electronic Components Committee) has taken an important step to harmonize its requirements with the procedures of the ISO 9000 (EN 29 000) and EN 45 000 worldwide and European standards. These standards–described in full in the annex to this Press Release–are now widely accepted as the fundamental method for the assessment of quality systems in respect of industry and services. They have been implemented in the United Kingdom in BS 5750.

The decision of the CECC to publish a new CECC Rule of Procedure, CECC 00114 Part I*, covering the relevant requirements of ISO 9000/EN 29 000 and EN 45 000 means that:

- CECC approvals will in future be fully compatible with the agreed international and European approach to quality systems assessment

- There will be a significant reduction in the duplication resulting from similar assessments carried out by various agencies against equivalent requirements

- The achievement of CECC approval will be greatly simplified for companies already holding appropriate approval against relevant ISO 9000/EN 29 000 requirements.

CECC 00 114 Part I*, also identified as CECC Rule of Procedure 14 Part I, is already published. With immediate effect, it is available for use in granting new or revised approvals under the CECC System. In consequence, all CECC approvals will be aligned with this new Rule of Procedure by 1 January 1993, to coincide with the establishment of the Single European Market.

*CECC 00 114 Part I: "Quality Assessment Procedures–Approval of Manufacturers and Other Organizations." For further information on this publication and its important consequences, please contact:

CECC General Secretariat, *Gartenstrasse* 179, D - 6000 Frankfurt 70, Germany Tel.: Int.+(49) 69 63 91 71 or Fax.: Int.+(49) 69 63 94 27

Additional general information on the CECC System may be obtained from the

enclosed copy of CECC 00 500: "Introduction to the System."

The ISO 9000 series of international standards has been published with identical content as the EN 29000 series of European stand-ards, with the following titles:

EN 29 000 (ISO 9000) Quality management and quality assurance standards–Guidelines for selection and use

EN 29 001 (ISO 9001) Quality Systems–Model for quality assurance in design/development, production, installation and servicing

EN 29 002 (ISO 9002) Quality Systems–Model for quality assurance in production and installation

EN 29 003 (ISO 9003) Quality Systems–Model for quality assurance in final inspection and test

EN 29 004 (ISO 9004) Quality management and quality elements–Guidelines

The EN 45 000 series of European standards establishes the requirements for certifying bodies, testing laboratories, and suppliers, and consists at present of the following publications:

EN 45 001, General criteria for the operation of testing laboratories

EN 45 002, General criteria for the asssessment of testing laboratories

EN 45 003, General criteria for laboratory accreditation bodies

EN 45 011, General criteria for certification bodies operating product certification

EN 45 012, General criteria for certification bodies operating quality system certification

EN 45 013, General criteria for certification bodies operating certification of personnel

EN 45 014, General criteria for suppliers' declaration of conformity

CECC Press Release

PROTECTION OF ELECTROSTATIC SENSITIVE DEVICES. WORLDWIDE RECOGNITION FOR NEW CECC SPECIFICATION

October 1991

The CECC (CENELEC Electronic Components Committee) has recently published the new Basic Specification CECC 00 015: Protection of Electrostatic Sensitive Devices - Part I: General Requirements, which is likely to become the first global standard in this important area. A wide range of interests throughout the electronics industry has already adopted the draft version of CECC 00 015 and orders and enquiries from Europe, North America, Asia and Australia for the standard have exceeded all expectations. The interest being shown in CECC 00 015 indicates the strength of demand for international standards in this field and confirms once again that CECC is leading the way.

The CECC Basic Specification 00 015 defines those precautions which are necessary for product protection, describes how to incorporate these precautions into work areas and products, and provides recommended work practices. The Basic Specification also addresses design considerations and various quality issues including checking and auditing. Further specialized topics and areas will be added to the Specification in the next few months. Part II will cover protection in low humidity areas; Part III will address clean room conditions; and Part IV will cover protection in high voltage areas.

For further information please contact:

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Mr. Frank Graichen
Gartenstrasse 179,
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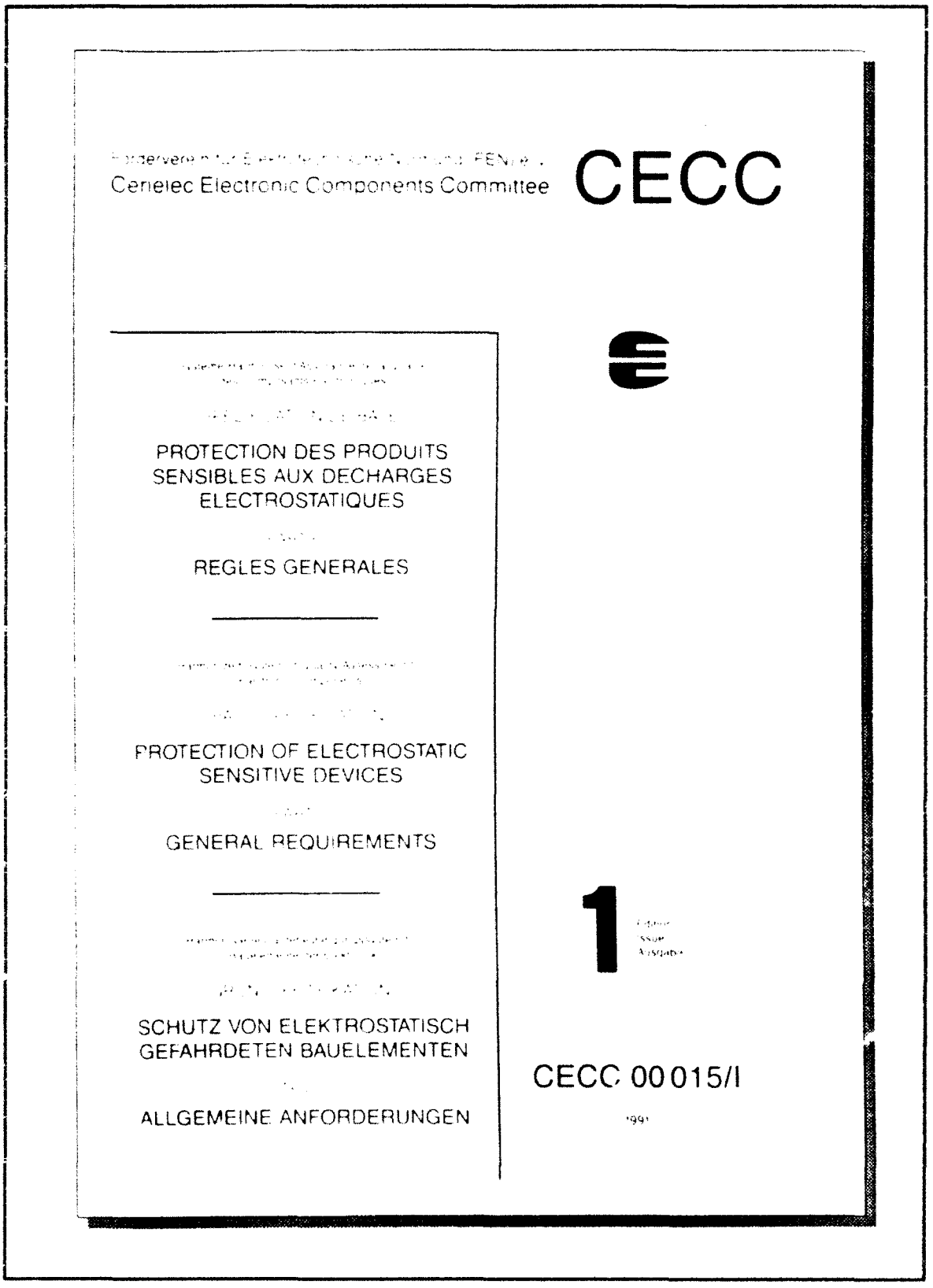


Cenelec Electronic Components Committee

CECC

PROTECTION DES PRODUITS SENSIBLES AUX DECHARGES ELECTROSTATIQUES

REGLES GENERALES

PROTECTION OF ELECTROSTATIC SENSITIVE DEVICES

GENERAL REQUIREMENTS

SCHUTZ VON ELEKTROSTATISCH GEFAHRDETEN BAUELEMENTEN

ALLGEMEINE ANFORDERUNGEN

1

CECC 00015/I

CECC Press Release

CEC/EFTA JOIN FORCES IN CECC IT AND TELECOMS STANDARDIZATION

The Commission of the European Communities (CEC) STANDARDIZATION and representatives of CEN/CENELEC in Brussels recently signed a Standardization Mandate in Brussels for CECC (CENELEC Electronic Components Committee) projects. This mandate has the full support of the EFTA Secretariat.

It covers the preparation of a set of European Specifications within the CECC System for electronic components of assessed quality intended for use within equipments for information technology and telecommunications applications.

CEC and EFTA see information technology and telecommunications as an area of growing importance to the whole European Economic scene.

Information technology and telecommunications equipment incorporate a wide variety of electronic components for which manufacturers demand a quality assured source.
Harmonized specifications avoid technical divergences and permit the interchangeability of equipment.

This Mandate is already being applied in the following areas of CECC Work and gives prominence to Capability Approval:

3 - Fixed Capacitors
4 - Resistors
9 - Integrated Circuits
16 - Relays
17 - Piezoelectric Devices
20 - Semiconductor and Liquid Crystal Optoelectronic Devices
24 - Electromechanical Switches
26 - Fibre Optic and Hybrid Connectors

For further information see Crystal Optoelectronic attached information brochure Devices CECC 00 500: "Guide to the System" or contact the CECC 17th D-6000 Frankfurt, Tel. Int (49) 69 63 91 71; Telex: 40 32 175 cecc d; Fax: (069) 63 94 27

CECC - Working Groups

CECC WG 3:	Capacitors
CECC WG 4:	Resistors
WG 4 A:	*Fixed resistors*
WG 4 B:	*Potentiometers*
WG 4 C:	*Thermistors*
WG 4 D:	*Varistors*
CECC WG 5:	Semiconductor Diodes & Transistors
CECC WG 7:	Rectifier Diodes & Thyristors
CECC WG 9:	Semiconductor Integrated Circuits
CECC WG 11:	Electro-Optical Devices
CECC WG 12:	Magnetic Components: Magnetic Wound Components
CECC WG 12 A:	Magnetic Components: Ferrite Cores
CECC WG 14:	Space-Charge Controlled Tubes
CECC WG 16:	Relays
CECC WG 17:	Piezoelectric Devices for Frequency Control & Selection
CECC WG 18:	Microwave Devices
CECC WG 20:	Semiconductor & Liquid Crystal Opto - Electronic Devices
CECC WG 21:	Film & Hybrid Integrated Circuits
CECC WG 22:	RF Connectors
CECC WG 23:	Printed Circuits
CECC WG 24:	Switches
CECC WG 25:	LF Connectors
CECC WG 26:	Fibre Optic Connectors
CECC WG 27:	Passive components for fibre optics (excluding connectors, mechanical splices and inserts)
CECC WG 28:	Optical fibres and optical fibre cables (excluding image transmission types)
CECC WG-	CHAD
CECC WG-	Data Base
CECC WG-	Publicity Coordination
CECC WG-QAP:	Quality Assessment Procedures
CECC WG-	Reliability
CECC WG-SMT:	Surface Mount Technology
CECC WG-ESD:	Electrostatic Sensitive Devices

CECC - User Groups

CECC	Telecommunication Users Advisory Group
CECC M.U.A.H.A.G.:	Military Usage And Harmonisation Advisory Group
CECC CAUG:	Civil Aviation Users Group

ANNEX D
EUROPEAN TELECOMMUNICATIONS STANDARD INSTITUTE

In June 1987, the European Commission published its Green Paper on the Development of the Common Market for Telecommunications Services and Equipment. It argued that a pan-European telecommunication infrastructure with full interoperability was the only basis on which a community-wide market for communications equipment and services could thrive.

With the coming of the Single European Market, not just the telecommunications industry, but users in all walks of life and in all businesses were growing to depend on the development of an integrated communications network.

The CEC recommended the establishment of an organization to set telecommunications standards for the whole of Europe and to accelerate the process of technical harmonization. As a result, in 1988 the European Telecommunications Standards Institute (ETSI) was born.

Bringing Down Barriers

The ETSI is an open forum bringing together the most highly qualified experts in Europe to work on common problems. Drawing on administrations, public network operators, manufacturers, users, service providers and research bodies, the organisation involves all interested parties so that its output is technically correct and widely acceptable.

An independent, self-funding organization located in Sophia Antipolis in the south of France, it has a small, highly qualified permanent staff gathered from all parts of Europe, but throughout the continent nearly 2,000 technical experts are working on specific technical projects.

The ETSIs task is to set uniform telecommunications standards for Europe which will be adopted by each individual country, thus linking national networks and services and ensuring interoperability of equipment. Pan-European telecommunications systems are now becoming a reality, and the benefits are already being felt by manufacturers who are experiencing increased market potential and by users who are enjoying reduced costs and improvinq facilities and services.

The ETSI's remit is the whole field of telecommunications and the related areas of broadcasting and office information technology, in cooperation with the European Broadcasing Union and CEN and CENELEC respectively.

The ultimate goal is harmonised communications standards between all the countries of Europe. And by so doing, ETSI may also help establish telecommunications standards world-wide.

Benefiting Both Manufacturer and User

In the past, standards in Europe were set nationally or regionally, with the result that interoperability has been severely restricted. Each country has gone its own way with equipment development and services, producing systems that do not readily

interlink.

This has meant the communications manufacturer has been denied the economic advantages of producing for the whole European market, and the creation of new international services carried over the telephone lines has been frustrated. For the user, communication across Europe has become unnecessarily time consuming, inefficient and costly, particularly for businesses exchanging large quantities of data.

But, by setting standards that are accepted throughout Europe, ETSI is opening up new opportunities for manufacturer and user alike.

Nowhere could this have more significant effect than in the field of pan-European digital mobile telephones. The recent generation of mobile cellular telephones embraces a wide variety of equipment and transmission systems. National markets mean that, in most cases, products only work where they are made and sold, and manufacturers cannot achieve large-scale production economies.

But, when common standards have been agreed, the people of Europe will be able to telephone anywhere within the boundaries of Europe using their individual equipment. There will be a more uniform tariffing system, and equipment producers will compete on the quality of their products rather than on their geographical location.

This is just one example of an area where ETSI's work is already benefiting both manufacturers and users throughout the continent.

A Process of Wide Consultation

The ETSI has pioneered a new approach to standards making. Traditionally, telecommunications standards were set exclusively by administrations. But, recognizing the advantages of involving all interested parties, ETSI membership is open equally to public net-work operators, manufacturers, users, private service providers and research bodies.

Members may participate individually or within groups. Companies can join as parent companies or subsidiaries or both.

In addition, invited representatives from other bodies involved in telecommunications may attend the general and technical assemblies as observers with the right to speak but not to vote. The EC Commission and the EFTA Secretariat have the special status of counsellors.

By consulting those involved at every stage of telecommunications from R & D through to the end-user, ETSI ensures that standards do not enter the market already flawed. And because the consultative processes are thorough and comprehensive, once agreed within ETSI, new standards are being adopted quickly by the national standards organisations of Europe.

In this respect, ETSI foreshadowed the 1990 EC green paper on standardization which recommends wider participation by all interested parties in the standards-making process.

The green paper urges industry to give a higher priority to standardization–sound policy already recognised by ETSI Members; the growing confidence of manufacturers in ETSI's work has been reflected by their increasing percentage of the membership and by the number of manufacturers taking up the responsibility of committee chairmanship within ETSI.

Membership

The number of members has grown steadily since ETSI was established. There are now approaching 300 members representing the leading European telecommunications interests.

The geographical coverage is wide, with 23 countries currently represented:

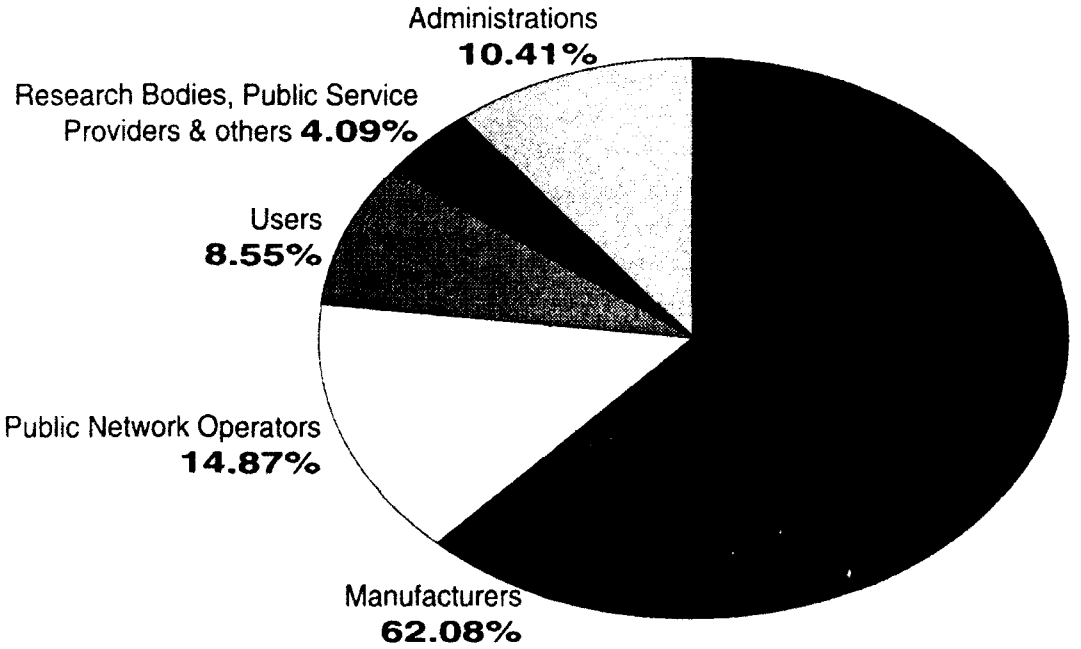
Austria	Luxembourg
Belgium	Malta
Cyprus	The Netherlands
Czechoslovakia	Norway
Denmark	Poland
Finland	Portugal
France	Spain
Germany	Sweden
Greece	Switzerland
Iceland	Turkey
Ireland	United Kingdom
Italy	

In addition, a growing number of non-European invited representatives attend ETSI assemblies; for example from Australia, Canada, Israel, Japan, Korea, New Zealand and the United States. The ETSI has created a new category of associate member to provide opportunities for the reciprocal exchange of information with organizations outside Europe; and Australia is the first to take advantage of this new mechanism. By developing these international links, ETSI will help pave the way toward world-wide standardization.

The Preparation of Standards

The Single Market in Europe will only become a complete reality when common technical standards have been developed at a European rather than a national level. Such action ensures:

- Free interaction among national networks and services



• The portability of equipment across national boundaries

• The strengthening of the position of European R & D, manufacturers and operators within world telecommunications markets.

But, the choice of the best standard is a delicate matter.

First, ETSI's Technical Assembly decides a three-year rolling work programme and sets time scales and priorities, and technical Committees, composed of the most highly qualified experts in each field, work on individual problems. Where a particular standard is especially complex or urgent, project teams can be set up to bring together the best experts from Europe to work full-time on the creation of draft standards, achieving solutions within a rapidly accelerated time scale.

Once agreed by the appropriate technical committee, each of which is responsible for a different area of telecommunications, the ETSs (European Telecommunications Standards) or, where further development is needed, I-ETSs (Interim European Telecommunications Standards) are sent out for public enquiry to the national standards organizations throughout Europe. When the standards are adopted, they become effective on a voluntary basis, but national governments may make them mandatory or the EC may issue a directive, thereby making them enforcable throughout Europe.

It is a principle of ETSI's operation that it never works in isolation. Thus, it will never set a new standard without regard to what is available internationally. Sometimes parts, or even the whole, of existing standards will be adopted if they are the best solution, thus increasing technical harmonization beyond the boundaries of Europe.

At the time of going to press, more than 50 ETSs have been adopted. About 200 more are in the pipeline, in the process of public enquiry or the subsequent technical evaluation, and an efficient production line of new standards has been created.

One of ETSI's early priorities was in the area of mobile services. In particular, the creation of more than 100 ETSs was recognized as necessary to define the pan-European Digital Cellular Network and allow the operation of mobile digital telephones throughout the continent.

In addition, experts are working on some 200 ETSs to allow the new Integrated Services Digital Network (ISDN) to operate on a commercial basis across Europe.

The potential hazards incurred in the proliferation of electronic equipment and electromagnetic compatibility have been high on the agenda. The appropriate operational structure has been agreed upon and work is underway.

All of ETSI's committees have very active calendars. Meetings are held at ETSI headquarters and throughout Europe on an almost daily basis to ensure that the tight schedules are adhered to and new standards are available to meet the market requirements.

ETSI

The headquarters of ETSI, located in the high-tech International Activities Park in Sophia Antipolis in the south of France, are home to the director, the deputy director, the staff of the Secretariat and the project teams.

Many of the Technical Committee and Sub Technical Committee meetings are held at ETSI headquarters and, at the invitation of members, in many parts of Europe.

Sophia Antipolis lies just north of the Nice-Aix motorway near Antibes and the journey from the nearest international airport, at Nice, takes about ten minutes by helicopter and about half an hour by road.

The ETSI's work load has increased significantly since its inception, as the need for new standards to meet the pressing demands of the Single Market has multiplied. As a result, ETSI was obliged to embark on a new phase of development with an extension to its headquarters, provided by France Telecom, to accommodate the additional staff now needed to fulfill its expanded role.

The Making of a European Telecommunications Standard

A standard is a document that contains technical specifications laying down the characteristics required of a product, such as levels of quality, performance, safety or dimensions.

It includes the requirements applicable to the product, regarding terminology symbols, testing and test methods, packaging, marking or labelling.

A standard must be approved by a recognized standards body for repeated, or continuous, application.

Compliance with a standard is not compulsory.

The need for a European Telecommunication Standard (ETS) is initially raised either by an individual, a company, or by one of the standards bodies, and is decided at the ETSI Technical Assembly. At this point the project becomes part of the ETSI Work Programme.

Most of the technical work in the ETSI Work Programme is carried out by one of

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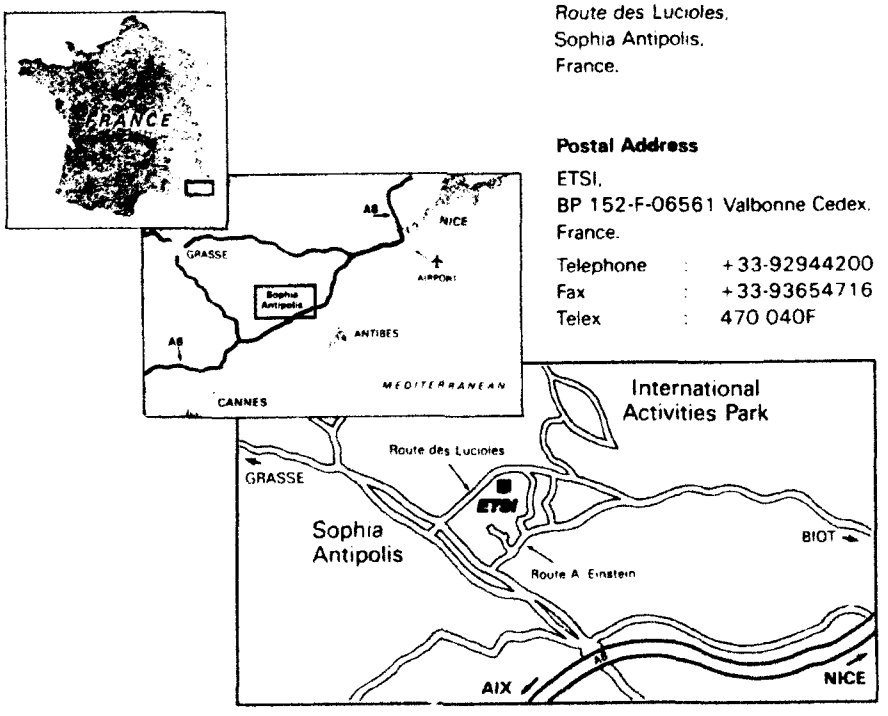


the 12 ETSI technical committees (TCs), each of which deal with a different area of the telecommunications field. They will specify the standard's scope, its exact title and delegate experts responsible for producing the draft standard. These experts usually will meet under auspices of a Sub Technical Committee, an Experts' or a Rapporteurs' group or an ETSI project team.

Once the draft of the standard has been approved by the relevant technical committee, it is sent to the ETSI Secretariat, which co-ordinates the next steps in the ETSI standards approval procedure, that is the Public Enquiry and Vote.

The ETSI Standards Approval Procedure

The following formal approval procedures are necessary to ensure that the draft standards are really acceptable to all parties concerned; that is to network operators, administrations, manufacturers, service providers and users.

The normal standards approval process takes at least 46 weeks, but in special cases this can be shortened.

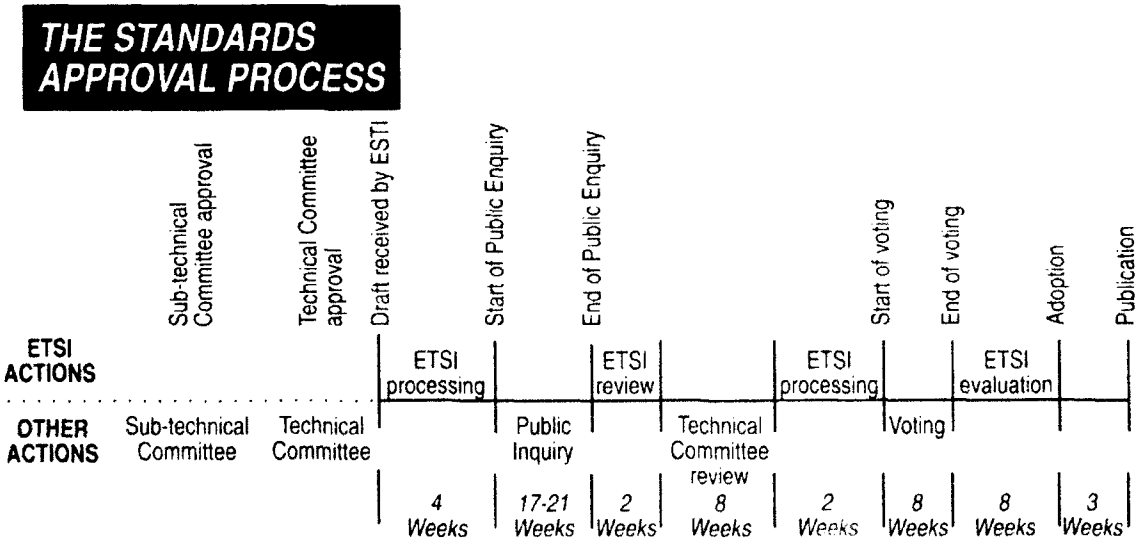
Each standard is managed within the ETSI Secretariat by a technical editor, who works in close contact with the technical committee concerned. The technical editor is responsible for the editorial aspects of the document, while the technical responsibility remains with the technical committee.

The Public Enquiry

The next phase in the ETSI standards approvals-procedure is the public enquiry. Once a draft standard has been approved by the appropriate ETSI technical committee, the ETSI Secretariat has four weeks to prepare and edit the document for this phase.

The draft standard is distributed amongst 25 National Standards Organizations (NSOs) in Europe for Public Enquiry. The NSOs, in turn, distribute the drafts within their countries to interested parties both ETSI members and non-members.

The NSOs are usually given 17 weeks to transmit their national position and proposed modifications to the draft, to the ETSI Secretariat. A public enquiry is con-



sidered valid if at least half of the NSOs replied.

At the end of a public enquiry, ETSI has two weeks to collate individual NSO comments and dispatch them to the relevant TC hairman and back to NSOs.

During the next eight weeks the modifications proposed are considered by the technical Committee. At this point technical changes may be made to the draft. The technical editor assigned to the draft standard, in turn, makes necessary editorial amendments to the document within two weeks.

The Vote

The updated standard is now ready for the next stage in the procedure, the national vote.

A weighted national vote is carried out in much the same way as a public enquiry. The procedure lasts for eight weeks, after which the NSOs notify ETSI of their national position.

The Secretariat processes and dispatches results of the vote, sending them back to the technical committee concerned and the NSOs. A vote is only considered valid if at least half of the NSOs have replied. A draft is accepted when the percentage of positive votes exceeds 71 percent.

If a document is accepted it is published by ETSI as a European telecommunication standard (ETS).

If a draft fails, the calculation is repeated for European Community members and if 71 percent of community members' votes are favorable, the standard is adopted within the European community.

In addition to ETSs, ETSI produces two other types of document. These are Interim European telecommunication standards (I-ETSs) and ETSI technical reports (ETRs).

An I-ETS is so called because the standard is a provisional solution and is to be further developed, or because it is an immature draft that requires a period of trial. In general, an I-ETS has a duration of three years. After two years members are asked for comments on the document and, following this procedure, the ETSI Technical Assembly will either convert the IETS into an ETS, extend life of the document for two years, replace the document with a new revised version, or withdraw the IETS.

An ETR provides background comment or guidance on matters pertaining to, but outside of the scope of an ETS or an I-ETS. The ETRs do not under go the above procedures of public enquiry and vote and are published after they have been approved at TC level.

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To obtain more information about ETSI, please complete this coupon or attach your business card and send it to the STSI Secretariat at the address above.

Name _____

Position _____

Organization _____

Telephone _____ Fax _____

ANNEX E
CCITT INTERACTIONS WITH OTHER STANDARDS ORGANIZATIONS

United States Department of State

Strategic Planning Group

United States Organization for the
International Telegraph and Telephone
Consultative Committee (CCITT)

Spring 1991

TASK FORCE OF THE STRATEGIC PLANNING GROUP

Introduction

This report was commissioned by the Strategic Planning Group (SPG) which provides advice to the State Department, particularly regarding some areas of responsibility assigned to the Bureau of International Communications & Information Policy. The SPG asked the task force to report on the interactions among CCITT and other standards organizations.

During the course of the task force's work, it realized that it preferred to put the interactions in the context of principles regarding standards rather than deal with the interactions in the abstract. Section I of the report identifies principles which Task Force members believe most upon people involved in standards-development activities could agree.

Sections II and III describe some of the interactions between CCITT and other standards organizations. The descriptions are based on the documentation from the various standards organizations as identified in these sections, as well as the personal experience of members of the task Force; also upon personal experience of coworkers who are/have been involved in standards development.

Section IV lists conclusions reached by comparing principles with practice. It identifies strong and weak correlation between principles.

Immediately following each conclusion, some recommendations are presented that might improve the correlation in weaker areas. The recommendations are not intended to be exhaustive and perhaps, should be supplemented with additional recommendations. The task force would welcome discussion–both on the recommendations included, and additional ones that others might like included.

The annexes include material referenced in the report and identification of the standards organizations mentioned.

Section I

Principles

The development of United States policy for dealing with the management and administration of telecommunications standards development in the international arena, and the interests of the United States telecommunications industry, are served by establishing a set of somewhat idealized objectives or principles as follows:

Principle 1: Telecommunications standards should be "global standards."

As an objective, telecommunications issues affecting international interoperability should be covered by worldwide (global) standards. This principle should be considered for all standards activities, including those within the United States designed to satisfy specific domestic applications but related to, or subject, to global standards at one or more interfaces.

Principle 2: All standards development must be open to everyone with a direct and material interest in the work.

Standards development undertaken by regional standards organizations (including those representing only one national body) must be fully open in planning and execution. This openness applies to interests external to the standards body's membership and is a prime facilitator in the achievement of Principle 1.

Principle 3: Standards development should efficiently meet user needs.

Every effort must be made to assure that standards development:

1. Be done in a manner that maximizes coordination among standards organizations to minimize redundant effort.

2. Be done in a manner that facilitates technological evolution and/or free and open marketplace competition.

3. Be done in a manner that avoids abuse and manipulation that may result in inefficient standards development.

4. Be done in a way that meets marketplace needs in a timely manner.

5. Be done in a manner that contributes to a unique global standard, while recognizing that multiple options may be necessary in some instances.

Principle 4: Standards should be voluntary.

Compliance with national and international standards should be voluntary, with exceptions such as safety noted. Unnecessary application of mandatory standards can limit technological evolution and/or competition by limiting market entry into some aspect of a field on which standards exist. This does not minimize the fact that bilateral (multilateral) agreements to interoperate should use relevant published or planned standards when appropriate.

Principle 5: Standards should support technical evolution

Continuing technological progress requires that standards development permit the introduction of new and innovative technology to meet and evolve the telecommunications capability. For example, development of new standards should not be constrained by unyielding requirements for backward compatibility. Marketplace forces should be relied on where backward compatibility is an issue.

Principle 6: Conformance testing should be based on global standards

Conformance requirements included in any certification program should be based on the technical parameters and procedures in global standards. Developers of global standards should consider such use during the development of the standards.

Principle 7: Intellectual property rights must be protected.

Whenever a technical standard is being considered which is impacted by intellectual property considerations, appropriate intellectual property rights policies should be followed. For example, when patent rights are at issue for ANSI standards, the American National Standards Institute patent policy should be followed.[1] Similar patent policies or procedures exist in ISO/IEC and CCITT.[2]

Section II

Standards Interaction: CCITT with ISO/IEC JTC1

The CCITT and the joint technical committee 1 (JTC1) of ISO/IEC are commonly recognized by telecommunications standards participants as the most significant organizations for development of global telecommunications standards. Pictorial representations of telecommunications standards development flow[3] show these two for as the nucleus of the standards development universe with significant interaction between them. In the global telecommunications standards arena, the CCITT standards interaction task force focused only on the interaction between CCIT and JTC1.[4]

To understand interactions between the two organizations, some background is helpful. The CCITT as the non-radio standards element of the ITU, a treaty organization in operation since 1867, had been the only significant global telecommunications organization until the early 1960s when terminals connected to public networks began to be more complex.

The ISO/IEC has a broader standards mission than CCITT in that it is involved in global standards in almost every facet of current interest. However, an element of ISO/IEC, labeled JTC1, is focused primarily on information-related technology and therefore, is the element this task force focused on in preparing this report.

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1. See E-12 - ANSI's Patent Policy.

2. Recently CBEMA, in its comments on the EC paper on standardization, which suggested additional burdens be put on patent holders, said "Any rule which goes beyond the ISO/IEC requirement that a patent holder provides licenses under reasonable and nondiscriminatory terms and conditions would be inappropriate.

3. See Annex "C" and "D" - Today's Information - Telecommunications Standards Making Architecture dated 13 May 1990 - A. Rutkowski of the ITU and Pictorial Representation of Telecommunications Standards Bodies.

4. There is considerable interaction between CCITT and CCIR; but, since they are both under the ITU, their interactions will be reviewed as part of the overall study of the ITU being conducted by the High Level Committee, and therefore the Task Force chose not to focus on their interactions.

In reviewing CCITT and ISO/IEC/JTC1 documentation related to their interaction, the task force found that CCITT had formulated recommendations as early as 1964, describing its area of standards preeminence and recognizing an ISO/IEC role in standards. Specifically, CCITT recommendation A.20, collaboration with other international organizations over data transmission was approved during the 1964 plenary in Geneva. In essence this recommendation identifies public network functions; e.g., transmission, signaling and transmission, as in the CCITT domain. It implies that data terminal equipment (e.g., some data processing and office equipment) is in the ISO/IEC domain and states that where these domains intersect there shall be consultation.[5]

At the 1980 plenary in Geneva, Recommendation A.21, collaboration with other international organizations on CCITT-Defined Telematic[6] Services, was adopted. This recommendation divides domains in a manner similar to A.20 and calls for similar consultation with ISO/IEC.

At the 1988 plenary in Melbourne, CCITT adopted recommendation A.22, collaboration with other international organizations on information technology. This recommendation calls for collaboration with JTC1 on information technology and identifies among the areas of mutual interest certain interworking and open systems interconnection (OSI).

The ISO/IEC/JTC1 recognizes benefits of coordination. The ISO/IEC directives include a section entitled "Cooperation with other International Organizations" which specifically mentions CCITT. The JTC1 directives also underscore the importance of cooperation. Perhaps the most tangible evidence of CCITT/JTC1 cooperation is the "Informal Guide for ISO/IEC JTC1 and CCITT Cooperation" which was developed by the Collaborative Group on Procedures for JTC1 and CCITT Cooperation during a meeting July 26-27, 1988.

From all of the above, the Task Force concludes that the interaction between CCITT and JTC1, if carried out in the spirit of these principles, would minimize duplication of effort as well as the possibility of conflicting standards.

Further, recent experiences indicate that those involved in the work of CCITT and JTC1 have identified "study questions," which have potential linkages between them, and arranged for the experts to be aware of this and interact to minimize duplication/conflict.

Although the task force concludes that the proper principles are in place, and that right-minded people will minimize unproductive work, it is aware that the roots of CCITT membership and JTC1 membership are different. There are two elements of this historical difference. First, CCITT members tend to have a telecommunications background whereas JTC1 more often have computer-oriented backgrounds. Second, since the ITU, of which CCITT is a part, is a treaty organization, official representation is through governments, while JTC1 is private sector. The ANSI provides the official representation for the United States in JTC1. These differences can cause the approaches of standards experts working in CCITT to be different from those experts in JTC1. For example, CCITT experts may

5. See specific language in CCITT recommendation A.20 sections (2) and (8).

6. "Telematic Services" include Videotex, Teletex, Facsimile.

believe that the telecommunications network should provide additional functionality to make it more generally available, whereas JTC1 experts may believe that this complicates their work in facilitating certain forms of information transfer.

It is suggested that U.S. experts, familiar with both perspectives, be encouraged to participate in both organizations or, at minimum advocate open liaison between the two organizations. The United States (and others among more liberalized nations) must take the lead in this area since there continues to be tendency to function with insufficient liaison.

Section III

Regional Network Standards Activities

Currenily two regional[7] standards organizations are preparing proposed contributions with respect to telecommunications network standards for submission to CCITT. They are the ANSI Accredited Standards Committee (ASC), Committee T1[8] - Telecommunications in the United States, and the European Telecommunications Standards Institute in Europe.

As in the case of global standards organizations, it will help the reader understand the interaction between CCITT and T1 and ETSI if some background is provided.

Before the AT&T divestiture in 1984, majority of the contributions submitted to the U.S. National Committee for CCITT were prepared by AT&T. These were, in turn submitted after discussion, modification when necessary and approval, to CCITT as U.S. contributions. It was recognized that with divestiture of the Bell System, there was a need to provide an alternative to AT&T for formulation of standards at the interfaces between local exchange carrier networks and customer premises equipment (CPE), as well as between networks. From that recognition and considerable industry discussion, Committee T1 was created and accredited following ANSI procedures.

In non-wireline network areas such as equipment performance, terminal equipment, cellular radio, and data, other U.S. standards bodies have assumed a *de facto* regional role, notably the TIA sponsored TR-8, TR-29, TR-30, TR-41, and TR-45 ASCs, and the CBEMA sponsored ASC X-3, Information Processing Committee. Another standards body, which supplements others described in this section, is difficult to classify. It is the 802 committee sponsored by IEEE, a professional society. Its standards proposals on metropolitan area networks are coupled with Broadband ISDN work in the USNC for CCITT. While some TIA bodies are more closely identified with IEC/ISO and JTC1 or CCIR, TIA committees TR-29 (facsimile) and TR-30 (data transmission) are the primary U.S. expert groups providing input in their areas to the USNC for CCITT.

Because ETSI has a broader charter than just network standards, several of these

7. Regional, as used in this context, is more of a designation related to informal influence over a region with respect to tele-communications standards, largely based on economic considerations rather than being based on multiple nation participation or any formal authority.

8. Committee T1 works in the area of network structure and services, and is a leading ISDN standards committee in North America.

organizations have information interchange agreements with ETSI. Both T1 and TIA have arranged for coordination of standards efforts with ETSI at the technical committee level.

Because of the commonality of many features of the U.S., Canadian and many Caribbean telephone networks, Committee T1 has some of the attributes of a regional standards organization, in the sense of striving to help further compatible standards. It was not conceived to serve much of North America but, rather, to replace a structure which existed prior to the AT&T divestiture. However, regardless of intent, it is actively supported by representatives of the telecommunication industry in Canada as well as the United States and is, therefore, considered regional. Representatives from Australia, Japan and Europe actively participate in T1 meetings. Committee T1 works through the U.S. CCITT National Committee in much the same manner as other organizations had prior to its formation, in flowing network contributions to CCITT. Canada and the Caribbean nations, of course, have their own voice in CCITT but, through the cooperation in Committee T1, there is a better chance that particularly U.S and Canadian positions will be coordinated by the time they reach CCITT.

The ETSI was formed largely in response to a trigger from outside the standards arena. The European economic community recognized that, if it was to operate cohesively, it would need standardized telecommunications and encouraged a focused effort to develop telecommunications standards for its members by chartering ETSI in 1988. This newly chartered standards body superseded activity which had largely coordinated European telecommunications activities previously, primarily by CEPT. Although, because of its recent formation, it has only completely approved 17 standards, it is expected that ETSI will seek approval of its work for global status via CCITT, on a case-by-case basis. The ETSI has been accepted as an International Organization member of CCITT. Currently, however, a number of concerns exist: 1) It appears that minority views within ETSI are not being expressed at CCITT meetings after ETSI reaches internal agreement; 2) In at least one instance, ETSI sought preferential treatment by submitting an untimely contribution to CCITT; 3) CCITT accepted the untimely submitted contribution; and 4) ETSI's draft intellectual property rights procedures would impose restrictions more severe than those used in other standards bodies.

Although other network standards organizations have in some cases been identified as "regional," e.g., TTC and TTA, they are, to date, only permitting membership from the country in which they are organized. However, both TTC and TTA were involved in the first Interregional Telecommunications Standards Conference at Fredericksburg in February 199011 and TTC was at a June follow-up meeting in Geneva. Further and perhaps more important, they are more users of the output of the standards process from CCITT rather than contributors.[9]

Two other European organizations should be mentioned in order to have symmetry in terms of information flow when comparing European and North American input to CCITT and ISO. They are ECMA and CEN/CENELEC which provide substantial in-

9. TTC has expressed an interest in participating in the "upstream" process, i.e., preparing contributions to CCITT.

put to JTC1. The Task Force did not focus on them since they, like X3, TR8 and TR41 and ASC X12 work more through JTC1 than CCITT and therefore this paper does not reflect heavily on their contributions to standards work.

On the other hand, from a U.S. perspective, it is fairly important to understand the relationship between T1 and other standards providers since national resource in the telecommunications field are finite and duplication and/or conflict would amplify the demands on this finite resource. Liaisons have been established among T1, TR30, TR41, X3, X12 and 802 although their effectiveness varies. No substantial duplication or conflict was identified by the task force but some overlap is recognized. However, by the time their work reaches CCITT, most of the overlap has been eliminated by the U.S. National Committee process, JTC1 or the organizations themselves. During the mid-1980s ANSI formed the Joint Telecommunications Standards Coordinating Committee (JTSCC) to help improve standards-making efficiency by reducing redundancies. However, there has not been a need for it to convene in the last few years.

Section IV

Conclusions/Recommendations

There are several conclusions that might be made regarding well interactions of CCITT with other standards organizations align with principles listed earlier in this report. For each conclusion one or more recommendations are made to strengthen U.S. support of the principles.

1. Conclusion

A possible primary weakness of standards making, as practiced by the North Americans and western Europeans, is that the standards process is a field of competition. Rather than confining competition to the production of goods and services based on agreed-upon standards, the nations of these two areas tend to compete to achieve international standardization of their own version of a standard, sometimes without regard to technical superiority. Competing efforts in various countries have resulted in attempts to stall, delay or otherwise disrupt progress of a standard, often for perceived economic rather than technical reasons.

This competition within the standards process may appear to be unfairly biased to some participants. This, in turn, tends to encourage generation of regional standards which are, in some measure, in conflict. This whole system has no technical arbiter and sometimes tends to be a political contest with the two regions seeking supporters among 166 members of the ITU.

Recommendation

Although there has been recent progress toward a more cooperative interaction among CCITT and both JTC1 and regional standards organizations, more might be done if visible recognition were given to individuals who further cooperation among standards organizations. This recognition could be in the form of an award at a joint government/industry conference. Annual selection of one or two honorees from both the private sector and the public sector would underscore U.S. commitment. Nominations might be completely open with selection made by a joint industry/government committee. Since much of the U.S. competitive position in the global marketplace is in some measure dependent upon the standards community operating according to the principles identified above, people at senior levels of industry and

government should be involved in such a conference.

2. Conclusion

There are cases where there may be confusion which organization has jurisdiction since technology inexorably overruns boundaries. As this has occurred, coordinating conferences have been scheduled to mediate differences and establish new boundaries. This type of activity has been valuable and it is desirable to continue to recognize its value. Another conclusion is that so-called regional-standards organizations have come into existence to address specific needs; for example, greater speed of standards development. These organizations are working with CCITT and its cooperating counterparts such as JTC1 to reduce duplication of effort. Here, too, written "guidelines" like "the Spirit of Fredericksburg" are generally supportive of the above principles; but continuing effort is needed to attain intended benefits.

Recommendation

A key recommendation is that the industry/government partnership continue on the course charted at Fredericksburg. This includes the encouragement of direct interactions among CCITT and regional standards bodies in activities like coordination of work plans and schedules. It means that "venue shopping" should not be encouraged. Failure to gain favorable response on proposals, over time has caused parties whose positions were not approved to seek alternative standards bodies that might treat proposals more favorably. In fact, they have encouraged formation of new support groups. This proliferation of standards-oriented organizations tends to undermine mainstream work and dilutes available resources. Therefore, we recommend that new organizations be formed only after careful research has been carried out that ensures redundant organizations are not formed.

3. Conclusion

Another conclusion as a part of this task force's work is that, in general, standards bodies, particularly those interacting directly with CCITT, have written into operating principles guidelines seeking to minimize inefficiency and jurisdictional conflict.

It therefore might be a logical conclusion that action is needed to encourage members of standards bodies to follow their own guidelines. In part, failure to do so may be lack of familiarity with their existence.

Recommendation

Regarding the observation that most standards organizations have written "rules" supporting the principles, e.g., CCITT Recommendations A.20-22, ISO directives, but that they aren't always followed, it will help if these "rules" receive greater publicity. As a step in that direction, some the rules are included as annexes to this report. Readers of this report are encouraged to distribute them to others interested in standards activities. Further, members of each standards body, as they become aware of the "rules" need to insist they are observed by other members.

4. Conclusion

With multiple standards organizations working on closely related activities, it is vital not only that they share information but to do so in a timely manner. The more open this communication becomes, the more closely practice will correlate with the principles in this report.

Recommendation

The recommendation is that improvement in communication among the interacting standards bodies must occur if the principles are to become fact. This was recognized at Fredericksburg and was agreed to among participants. However, a vital element is that all interested parties have ready and timely access to meeting schedules, working group papers, project summaries, etc. Unless this access is via electronic technology, the volume of paper, the filing of it and the searching through the paper for information, would defeat the purpose of sharing the paper. Since the CCITT is already on course to make electronic communication of its material available, the U.S. standards community should lend its full support and commit resources toward ensuring that databases and communications linkages are established.

In fact the U.S. standards communityhas demonstrated its support of these activities by actively participating in the *ad hoc* group of CCITT Resolution No. 18 studying electronic document handling.[10] Secretary General Tarjanne acknowledged that the increased use of information technology will contribute to the ITU's operations and enhance its effectiveness, and will accelerate the standardization process in a cost-effective manner. To ensure electronic communication is the rule and not the exception, the U.S. standards industry must continue to support and commit resources for these purposes.

Having all information available electronically is only part of the improvement needed. Agreement on prioritization of the information to be shared needs to be reached. The ETSI committees NA5 and NA6 are attempting to do such a prioritization with T1.

5. **Conclusion**

A final technical conclusion is that the ISO/OSI seven-level hierarchical approach to data communication can be a common denominator in all facets of telecommunications. A consistent approach to work on data, voice, image and video standards can avoid technical misalignment that may occur when attempting to develop an integrated standard.

Recommendation

Finally, we recommend that the industry/government partnership continue to encourage rapid harmonization of generalized approaches to standards development between standards bodies such as the ISO/OSI seven-layer model. These approaches can include standards for transport of information and the operations systems that directly support them, as well as generalized industry support systems. This will smooth interworking among standards bodies and also improve efficiencies.

6. **Conclusion**

The influence of the regional standards organizations has become such that, companies desiring to participate in the corresponding regional markets feel that it is necessary to participate in their activities.

With formation of ETSI, whose goal is the standardization of telecommunication

10. For example, MCI in October of 1990 agreed to supply the ITU with 3000 MCI mail mailboxes,and as a grant of $1 million to cover the ITU members' usage.

products and services across the EC, there was a heightened concern about "block voting." While the task force recognized that this could occur without ETSI's existence, it thought written rules to encourage "block voting" were too inflexible in the context of ITU standards making because of an ETSI bylaw requiring ETSI members support its standards in global standards-making bodies. It is important to see substantive changes in bylaws[11] and also in behavior that would reflect intent of the bylaw change.

Recommendation

Monitoring of ETSI procedures/actions needs to continue, and U.S. companies that are members of ETSI need to point out concerns during governance meetings. If CCITT is involved, concerns should be raised with the U.S. Government for action. Most important may be the need for timely dialogue before any "camp" makes an irreversible decision.

11. ETSI amended its bylaws in this area at its 9th General Assembly meeting in Nice on 20-21 November, 1990.

Acronyms Used in the Report

ANSI - American National Standards Institute

CBEMA - Computer and Business Equipment Manufacturers Association

CCIR - International Radio Consultative Committee

CCITT - International Telegraph & Telephone Consultative Committee

CEN/CENELEC - European Committee for Standardization / European Committee for Electrotechnical Standardization

CEPT - European Conference of Postal & Telecommunications Administrations

EC - European Community

ECSA - Exchange Carrier Standards Association

ETSI - European Telecommunications Standards Institute

IEC - International Electrotechnical Commission

IEEE - Institute of Electrical & Electronics Engineers

ISDN - Integrated Services Digital Network

ISO - International Organization for Standardization

ITU - International Telecommunications Union

JTC1 - Joint Technical Committee 1

JTSCC - Joint Telecommunications Standards Coordinating Committee

OSI - Open Systems Interconnection

SPG - Strategic Planning Group

TIA - Telecommunications Industry Association

TTA - Telecommunication Technology Association of Korea

TTC - Telecommunications Technology Committee (Japan)

USNC - United States National Committee

ANSI PROCEDURES FOR DEVELOPMENT AND COORDINATION OF AMERICAN NATIONAL STANDARDS

Appendix I – ANSIs Patent Policy

11. Inclusion of Patents in American National Standards

There is no objection in principle to drafting a proposed American national standard in terms that include the use of a patented item, if it is considered that technical reasons justify this approach.

If the Institute receives a notice that a proposed American national standard may require the use of a patented invention, the procedures in Sections I2 through I5 shall be followed.

12. Statement from Patent Holder

Before approval of such a proposed American national standard, the Institute shall receive from the patent holder (in a form approved by the Institute) either: assurance in the form of a general disclaimer to the effect that the patentee does not hold and does not anticipate holding any invention whose use would be required for compliance with the proposed American national standard or assurance that:

(1) A license will be made available without compensation to applicants desiring to utilize the license or the purpose of implementing the standard, or

(2) A license will be made available to applicants under reasonable terms and conditions that are demonstrably free of any unfair discrimination

The terms and conditions of any license shall be submitted to ANSI for review by its counsel, together with a statement of the number of independent licensees, if any, which have accepted or indicated their acceptance of terms and conditions of the license.

13. Record of Statement

A record of the patent holders statement (and a statement of the basis for considering such terms and conditions free of any unfair discrimination) shall be placed and retained in the files of the Institute.

14. Notice

When the Institute receives from a patent holder the assurance set forth in I2(1) or I2(2), the standard shall include a note as follows:

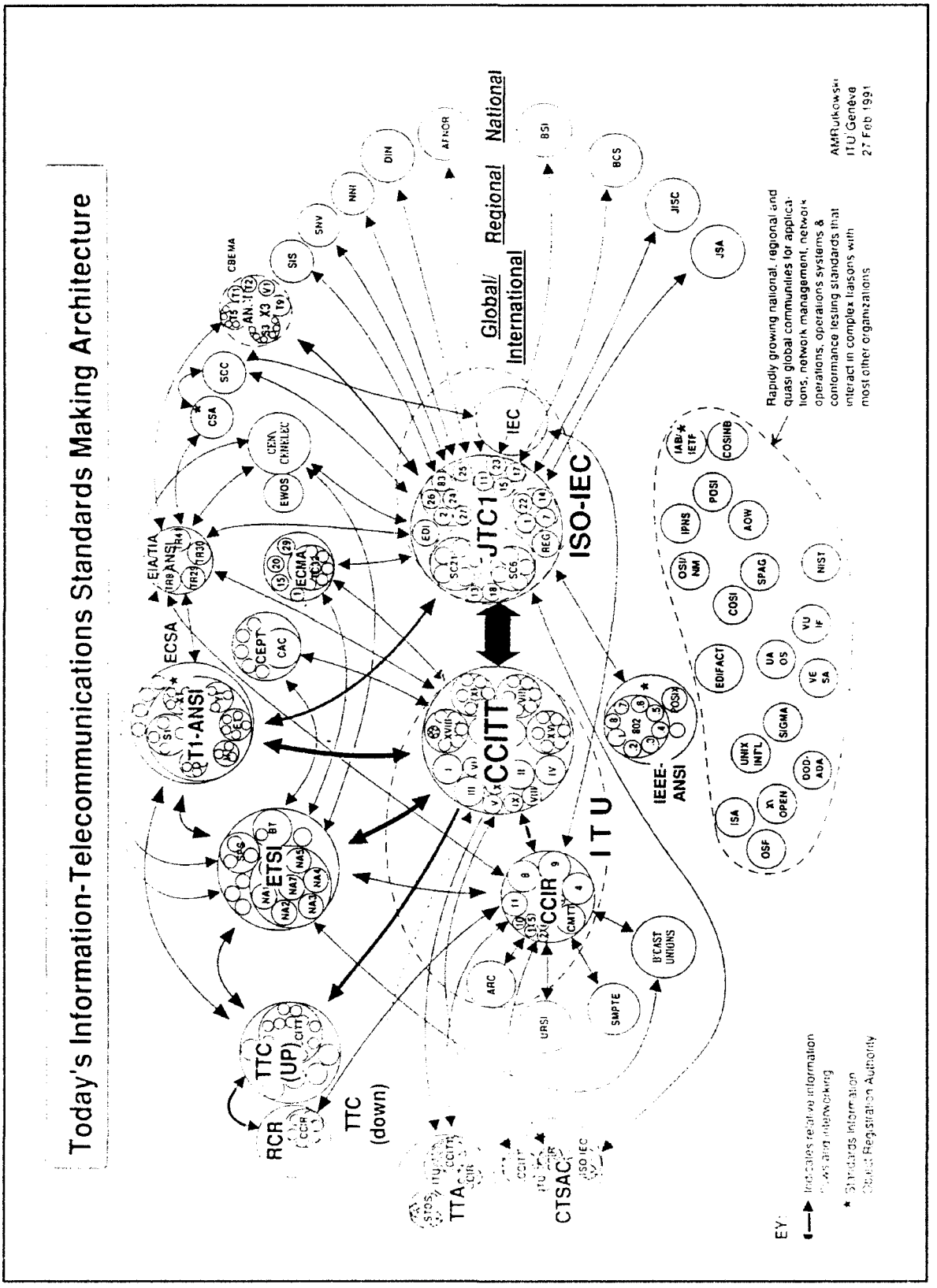
NOTE: The user's attention is called to the possibility that compliance with this standard may require use of an invention covered by patent rights.

By publication of this standard, no position is taken with respect to the validity of this claim or of any patent rights in connection

therewith. The patent holder has, however, filed a statement of willingness to grant a license under these rights on reasonable and nondiscriminatory terms, and conditions to applicants desiring to obtain such a license. Details may be obtained from the publisher.

I5. Responsibility for Identifying Patents

The Institute shall not be responsible for identifying all patents for which a license may be required by an American national standard or for conducting inquiries into the legal validity or scope of those patents that are brought to its attention.


Today's Information-Telecommunications Standards Making Architecture
Global/ International
Regional
National
ISO-IEC
IEC
JTC1
ITU
CCITT
CCIR
T1-ANSI
ECSA
ETSI
EIA/TIA
IEEE-ANSI
ANSI X3
CBEMA
CEN CENELEC
EWOS
ECMA
CEPT
CAC
SCC
CSA
SIS
SNV
NNI
DIN
AFNOR
BSI
BCS
JISC
JSA
IAB/IETF
COSINE
IPNS
POSI
AOW
OSI NM
SPAG
COSI
NIST
EDIFACT
UA OS
VU IF
VE SA
SIGMA
UNIX INT'L
DOD-ADA
ISA
X/OPEN
OSF
POSH
802
BEAST UNIONS
SMPTE
URSI
ARC
CMTT
TTC (UP)
TTC (down)
RCR
CTSAC
Rapidly growing national, regional and quasi global communities for applications, network management, network operations, operations systems & conformance testing standards that interact in complex liaisons with most other organizations
AMRutkowski
ITU Geneva
27 Feb 1991
KEY:
Indicates relative information sharing and networking
Standards Information Source/Registration Authority

Significant Organizations in the Information-Telecommunications Standards Field

Scope	Organization Name		Secretariat						General Chair				
			Name	Address	Tel	Fax	Email	Head	Name	Address	Tel	Fax	Email
Telecom systems	CCITT	International Telegraph and Telephone Consultative Committee	CCITT Secretariat	ITU, place des Nations, CH-1211 Genève 20, Switzerland	+41 22 730 5851	+41 22 730 5853		Theo Irmer, Director	[redacted]				
Information systems	[illegible]	Joint Technical Committee for Information Technology	JTC1 Secretariat	American National Standards Institute, 1430 Broadway, New York NY 10018, USA	+1 212 354 3300	+1 202 302 1286		F. Schrotter	L. J. Rankine, Chair				
General	ISO	International Organization for Standardization	Central Secretariat	Case postale 56, CH 1211 Genève 20, Switzerland	+41 22 733 3430	+41 22 734 1240		Lawrence D. Eicher, Secretary General					
Radio	CCIR	International Radio Consultative Committee	CCIR Secretariat	ITU, place des Nations, CH 1211 Genève 20, Switzerland	+41 22 7305801	+41 22 7305806		Richard Kirby, Director	[redacted]				
Electrical Equipment	IEC	International Electrotechnical Commission	IEC Central Office	Case postale 131, CH-1211 Genève 20, Switzerland	+41 22 734 0150	+41 22 733 3843		Tony Raeburn, General Secretary					
Networks, Applications	IEEE	Institute of Electrical and Electronic Engineers	IEEE Secretariat	345 East, 47th Street, New York NY 10017, USA	+1 212 705 7900	+1 212 7057589		Carleton A Bayless, President					
Radio Science	URSI	Union radioscientifique internationale	URSI Secretariat	c/o Observatoire Royal de Belgique, 3 ave Circulaire, B-1180 Bruxelles, Belgique	+32 2 3741308								
Networks - TCP/IP	IAB/ IETF	Internet Activities Board/Internet Engineering Task Force	Information Sciences Institute	University of Southern California, 4676 Admiralty Way, Marina del Rey, CA 90292 6695	+1 213 822 1511		Postel@ISI.EDU		Phill Gross, Chair of the IETF	Corp for Nat'l Research Initiatives, 1895 Preston White Dr # 100, Reston VA 22091, USA	+1 703 620 8990	+1 703 620 0913	PGross@R RI.RESTO N.VA.US
TCP/IP object registration		Internet Assigned Numbers Authority	Information Sciences Institute	University of Southern California, 4676 Admiralty Way, Marina del Rey, CA 90292 6695	+1 213 822 1511		IANA@ISI.EDU	Joyce K Reynolds					
Image Systems	SMPTE	Society of Motion Picture and Television Engineers	SMPTE	595 West Hartsdale Avenue White Plains NY 10607, USA	+1 914 761 1100	+1 914 7613115			Maurice I French, President	Canadian Broadcasting Corporation			

Applications	SA	Integrated Systems Architectures											
Networks	COSINE	Cooperation for Open Systems Interconnection Networking In Europe	COSINE Secretariat	CDC, DG XIII A2, office A25 7/13, rue de la Loi 200, B-1049 Bruxelles, Belgium	+32 2 235 5976	+32 2 235 0655	Nicholas Newman @OZCOM	Nicholas K Newman, Secretary					
Applications	EDIFACT	Western European Electronic Data Interchange for Administration, Commerce and Transportation	ECE/UNCTAD	European Commission for Europe, Palais des Nations, Geneva,	+41 22 7346011	+41 22 7349825		Shaun Kubler					
Conformance	SPAG	European Standards Promotion and Applications Group		Brussels									
Applications	EMUG	MAP/TOP Users Group		Brussels									
Applications	X/OPEN	[Unix Open Applications Group]		Apex Plaza, 4 Bury Road, Reading RG1 1AX, UK	+44 734 508311	+44 734 500110		Geoff Morris President					
Applications	EWOS	European Open Systems Workshop		rue de Stassart 36, B-1050 Brussels,	+32 2 511 7455	+32 2 511 8723							
Conformance	AOW	Asian Oceania Workshop											
Conformance	POSI	Pacific OSI Group											

Scope	Name		Secretariat						General Chair				
			Name	Address	Tel	Fax	Email	Head	Name	Address	Tel	Fax	Email
General	SAA	Standards Association of Australia		P.O. Box 458, North Sydney, NSW 2059, Australia	+61 2 9634111	+61 2 9593896		Mr. S. Horwood, Chief Executive					
Telecom	CTSAC	Canadian Telecommunication Standards Association Council							Paul Racine	Department of Communications, 300 Slater Street, Ottawa, Ontario K1A 0C8, Canada			
General	SCC	Standards Council of Canada		350 Sparks # 1200, Ottawa, ON K1P 6N7, Canada	+1 613 995 4564	+1 613 238 3222		John R Woods, Executive Director	Georges Archer, President				
General	AFNOR	Association française de normalisation		Tour Europe - Cedex 7, F-92080 Paris La Défense, France	+33 1 4291 5555			Bernard Vaucelle, Director General					
General	DIN	Deutsches Institut für Normung		Burggrafenstrasse 6, Postfach 1107, D-1000 Berlin 30, Germany	+49 30 260 11	+49 30 260 1231		Prof. Dr. H Rehlen, Director					

Applications	UNIX	Users Association for Open Systems											
Image Systems	VESA	Video Equipment Standards Association											
LAN Object Registration	IEEE	Institute of Electrical and Electronic Engineers		345 East 47th Street, New York NY 10017, USA	+1 212 705 7900	+1 212 7057589		Carleton A. Bayless, President					
PABXs	IPNS	Integrated PABX Networking Specification											
FDDI Conformance		Advanced Micro Devices Inc Network Centre		Sunnyvale, CA									
FDDI, 10BaseT Conformance		Interoperability Laboratory		Research Computing Division, University of New Hampshire, Durham, NH									

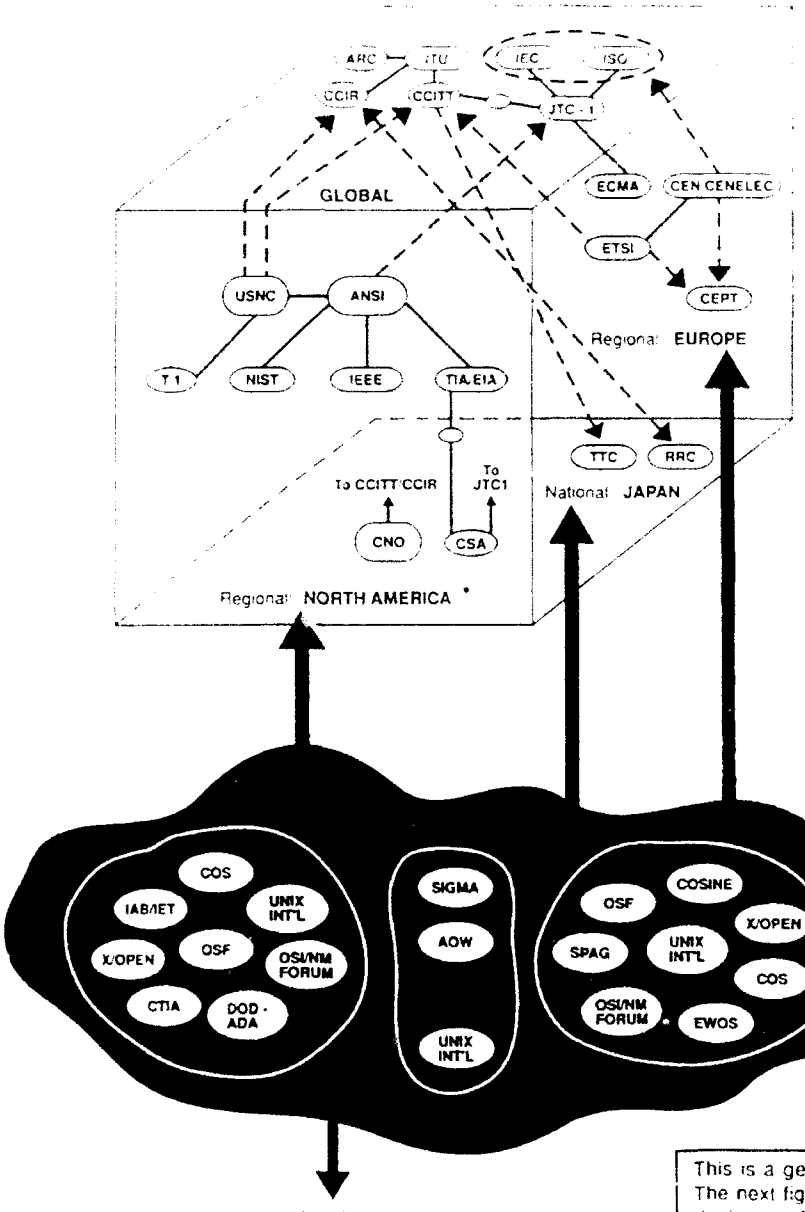
Scope	Name		Secretariat					General Chair				
			Name	Postal Address	Tel	Fax	Email	Head	Name	Address	Tel	Fax	Email
Telecom Systems	ETSI	European Telecommunication Standards Institute	ETSI Secretariat	B.P. 52-F-06561, VALBONNE Cedex, France	+33 92 944200	+33 93 654716		Karl Heinz Rosenbrock Director	Ib Loenberg, General Assembly Chairman				
Telecom Systems	T1	Standards Committee T1 - Telecommunications	T1 Secretariat	5430 Grosvenor Lane, Bethesda MD 20814-2122, USA	+1 301 564 4505	+1 301 564 4501		Alvin Li, Director	*Ivor Knight*, Chairman	*COMSAT, 950 L'Enfant Plaza, SW, Washington DC 20024 USA*	*+1 202 863 6515*	*+1 202 488 3819*	*I Knight (MCIMail)*
Telecom Systems	TTC	Telecommunications Technology Council	TTC Secretariat	Hamamatsu-cho Suzuki Building, 1-2-11, Hamamatsu-cho, Minato-ku, Tokyo 105, Japan	+81 3 432 1553	+81 3 432 1551		Tokuo Iida, Executive Managing Director	Eiji Toyoda, Chairman				
Information Standards	ECMA	European Computer Manufacturers Association	ECMA Secretariat	rue du Rhône 114, CH-1204 Gevève, Switzerland	+41 22 735 3634	+41 22 786 5231		Dara Hekim Secretary General	J. van den Beld, President				
Electronic	CEN/ Cenelec	Comite Europeene de Normalisation Electronique	CEN/CENELEC Secretariat	rue Braderode 2, Boite 5, B-1000 Brussels, Belgium	+32 2 519 6811	+32 2 519 6819							
Public Telecom Provisioning	CEPT	European Conference of Posts and Telecommunication Administrations	CEPT Secretariat	Case Postale 1283, Berne, Switzerland	+41 31 622 081	+41 31 622 078			Robert Priddle, President	Dept of Trade & Industry, Telecom & Post Div, Kingsgate House, 66-74 Victoria St, London SW1E 6SW, UK	+44 71 2158149	+44 71 9317194	

General	NEN	Nederlands Normalisatie Institut		Kalfjeslaan 2, P.O. Box 5059, 2600 GB Delft, The Netherlands	+31 15 690390		Mr. H.W. Kuipers, Director					
Electrical	JISC	Japan Industrial Standards Committee	c/o Standards Department	Agency of Industrial Science & Technology, Ministry of International Trade & Industry, 1-3-1 Kasumigaseki, Chiyoda-ku, Tokyo	+81 3 5019295	+81 3 5801418	Isamu Yamashita, President					
General	JSA	Japan Standards Association										
Conformance testing	CASS	Conference of Advanced Telecommunication Systems		Technology Policy Div., Communications Policy Bureau, Ministry of P&T, Tokyo, Japan	+81 3 3504 4947	+81 3 3503 0690						
Applications	SOSA	[Japan Open Applications Group (Japan)]										
Telecom	TTA	Telecommunication Technology Association of Korea		3rd floor, Yangjae Telephone Office Bldg. 907-7, Dokok Dong, Kangnam-ku, Seoul, Korea	+82 2 577 5101	+82 2 573 5400	Kawn Ha Lee, President	Hae Wook Rhee, Chairman	Korea Telecommunication Authority			
Telecom	NSAI	National Standards Authority of Ireland		EOLAS, Glasnevin, Dublin, Ireland	+353 137 0101	+353 137 9620						
General	SIS	Standardiseringskommissionen i Sverige		Box 3295, S-10366 Stockholm, Sweden	+46 8 230 0400	+46 8 791 8945	Lars Wallin, Director					
General	SNV	Swiss Association for Standardization		Kirchenweg 4, Postfach, 8032 Zurich, Switzerland	+41 1 3844747	+41 1 3844774	Dr. Hans C. Zurrer, Director					
Standards	BSI	British Standards Institute		2 Park Street, London W1A 2BS, United Kingdom	+44 71 6299000	+44 71 6290506	Dr. Ivan Dunstan, Director General					
Public Telecom	ECSA	Exchange Carriers Standards Association	ECSA Secretariat	5430 Grosvenor Lane, Bethesda, MD 20814-2122, USA	+1 301 564 4505	+1 301 564 4501	Gus Gusella, Director	Casimir Skrzypczak, Chairman	NYNEX, 1113 Westchester Ave., White Plains NY 10604, USA	+1 914 644 6435	+1 914 694 2670	
General	ANSI	American National Standards Institute		1430 Broadway, New York, NY 10018, USA	+1 212 3543300	+1 212 3021286	Manuel Peralta, President					
Telecom	TIA	Telecommunications Industry Associations		1722 Eye Street N.W., Washington DC 20006, USA	+1 202 457 4912	+1 202 457 4910						
OSI Object Registration	OIW	OSI Network Management Forum		Fort Lee Exec. Pk. Two, Executive Dr., Ft. Lee	+1 201 592 0040							

Conformance	COS	Corporation for Open Systems International		1750 Old Meadow Road # 400 McLean VA 22102 4306 USA	+1 703 848 2755			Lincoln D Faurer, President				
Applications	OSF	Open Software Foundation		Cambridge Mass	+1 617 6218700			Peter Tory, President				
Applications	UI	Unix International Inc		Parsippany NJ	+1 201 3639400			Peter Cunninghan, President				
Information Standards	ITRC	Information Technology Requirements Council										
Conformance	NIST OWI	National Institute for Standards and Technology - Open Interconnection Workshop										
Applications	VMUIF	Voice Messaging User Interfac Forum										
Applications	DOD ADA	U.S. Department of Defense-ADA Joint Program Office										
General	GOST	USSR State Committee for Standards		Leninsky Prospekt 9, Moscow 117049 USSR	+7 095 2364044			Prof. Dr V V Sytchev, President				

Global Information Standardization

Information Standardization "Triad"



Rapidly growing national, regional and quasi-global communities for applications, network management, operations systems and conformance testing standards that interact in complex liasions with most other organizations

This is a generalized representation only. The next figure provides a more accurate depiction of the interrelationships of the U.S. standards bodies

ANNEX F

STANDARDS AND CERTIFICATION CRITICAL TO AEROSPACE COMPETITIVENESS

Aerospace Industries Association
1250 Eye Street, N.W., Washington, D.C. 20005 (202) 371-8400
CONTACT: Alexis Allen (202) 371-8544

WASHINGTON, April 30 - Today, in standardization as in other fields, the United States is no longer the unquestioned world leader, but a strong player among strong rivals, according to an Aerospace Industries Association (AIA) report, *Impact of International Standardization and Certification on the U.S. Aerospace Industry.*

The report concludes that aerospace companies need to give international standards and certification issues a higher prioriry. If U.S. industry does not maintain an active presence in international standards and certification activities, the result will be increasingly significant differences between U.S. standards and those of Europe and the rest of the world, and an increasing likelihood that U.S. companies will be required to meet standards they had no voice in setting.

"Traditionally, U.S. aerospace marketplace leadership has been supported by worldwide acceptance of U.S. standards," said Don Fuqua, president of AIA. "Now that standards from non-U.S. sources are gaining international acceptance, the U.S. industry must act to ensure that standards, testing, and certification do not become trade barriers," Fuqua concluded.

The report is the result of a combined project by AIA's Civil Aviation, International, and Technical and Operations Councils to assess the impact of international standardization and certification on the aerospace industry, and recommend appropriate AIA actions.

Standards.../2

The immediate issues of concern identified by the report are harmonization of airworthiness requirements and certification of quality systems to international standards (ISO 9000 series). Additional concerns include supplier evaluation, international design and product standards, and European regional standardization and metrication.

The study recommends:

- Increased industry support for active participation in international standardization/certification arenas.
- Closer dialogue with European industry on standards and certification issues.
- Harmonization of U.S. and international technical requirements.
- Resolution of regulatory and contractual issues related to ISO 9000 quality system assessment.
- Communication of aerospace industry concerns to appropriate U.S. government agencies, professional and trade associations.

• Enhanced industry awareness through gathering and dissemination of information by AIA.

Founded in 1938, AIA's National Aerospace Standards Committee (NASC) establishes technical standards for items designed into aerospace products and used in their fabrication. To date, approximately 3,000 national aerospace standards have been developed by the NASC, constituting the third largest group of U. S. voluntary standards. The AIA also administers the secretariat of the international standards committee for aerospace, ISO/TC 20.

The AIA is the trade association representing the nation's manufacturers of commercial, military and business aircraft, helicopters, aircraft engines, missiles, spacecraft, and related components and equipment.

-AIA-

attachment

P.A. Rel. 92-23
04.30.92

Impact of International Standardization and Certification On the U.S. Aerospace Industry

AIA Resolution on International Standardization

Whereas, An AIA study group has identified issues in international standards and certification which can have negative impact on U.S. products in the global marketplace.

Now, therefore be it resolved: That industry participation in international standards and certification bodies should be increased to a level sufficient to promote U.S. industry interests and promote trade; and

To implement this policy, that AIA members make sufficient company resources available to support participation in international standards and certification bodies.

Aerospace Industries Association

Approved by AIA Executive Committee
April 14, 1992

IMPACT OF INTERNATIONAL STANDARDIZATION AND CERTIFICATION ON THE U.S. AEROSPACE INDUSTRY

EXECUTIVE SUMMARY

Today, in standardization as in other fields, the United States is no longer the unquestioned world leader, but a strong player among strong rivals. Standards developed outside of the United States — particularly in Europe or in international standards organizations — are gaining credibility and acceptance. Key examples are the Joint Aviation Regulations (JARS) developed in Europe, and the ISO 9000 series on quality systems developed by the International Organization for Standardization. To the extent that these standards diverge from or conflict with U.S. standards and practices, the U.S. can be at a disadvantage in the world marketplace.

AIA established an inter-council project to assess the impact of international standardization and certification on the aerospace industry, and to recommend appropriate AIA actions. Input was solicited from the Civil Aviation, International, and Technical and Operations Councils. The project group identified harmonization of airworthiness standards and certification of quality systems to international standards (i.e., the ISO 9000 series) as the immediate priority concerns for industry. Additional concerns include supplier evaluation, international design and product standards, European regional standardization, and metrication.

The study concluded that in the future, the U.S. aerospace industry will increasingly be subject to technical requirements which are determined internationally or in Europe. Lack of awareness or responsiveness could result in added costs and put U.S. products at a disadvantage. An increased level of vigilance is required to assure that standards, testing and certification do not escalate into barriers to trade.

The study recommends:

- Increased industry support for active participation in international standardiztion/certification arenas.

- Closer dialogue with European industry on standards and certification issues.

- Harmonization of U.S. and international technical requirements.

- Resolution of regulatory and contractual issues related to ISO 9000 quality system assessment.

- Communication of aerospace industry concerns to appropriate U.S. government agencies, professional and trade associations.

- Enhanced industry awareness through gathering and dissemination of information by AIA.

APRIL 1992
IMPACT OF INTERNATIONAL STANDARDIZATION AND CERTIFICATION ON THE U.S. AEROSPACE INDUSTRY

Introduction

In the past, the aerospace industry around the world has used mostly U. S. standards in the design, manufacture, certification and operation of aerospace products. This worldwide acceptance of U.S. standards as "*de facto*" international standards has permitted aerospace products to be operated, maintained and serviced around the world. Customers for civil and military aerospace products have benefitted from the resulting interchangeability, interoperability and economies of scale. The U.S. marketplace leadership has gone hand-in-hand with worldwide acceptance of U.S. standards.

For many years, international standardization has been a "back burner" issue for the United States. As long as U.S. standards were recognied and used around the world, international harmonization was not a problem.

Today, in standardization as in other fields, the United States is no longer the unquestioned world leader, but a strong player among strong rivals. Standards developed outside of the United States—particularly in Europe or in international standards organizations—are gaining credibility and acceptance. Key examples are the Joint Aviation Regulations (JARS) developed in Europe, and the ISO 9000 series on quality systems developed by the International Organization for Standardization. To the extent that these standards diverge from or conflict with U. S. standards and practices, the United States can be at a disadvantage.

Recognizing the potential impact of international standardization and certification on aerospace business, the AIA Technical and Operations Council established an intercouncil project to assess the impact and to recommend appropriate AIA actions. The scope of the project was to address concerns from civil and military sides of industry, including quality, trade and materiel management. The following councils and committees participated:

Civil Aviation Council
- Airplane Noise Control Committee
- Commercial Customer Support Committee
- Manufacturing Integrity Committee
- Propulsion Committee
- Transportation Committee

International Council

Technical & Operations Council
- Electronic Systems Committee
- International Standardization Advisory Group
- Materiel Management Committee
- Quality Assurance Committee
- Technical Management Committee

The project group met October 24, 1991, to review and validate issues identified by survey. A subsequent survey was conducted to update findings and recommen-

dations of the 1982 AIA study "Impact of International Standardization Trends on the U.S. Aerospace Industry."

The project group identified issues of concern to the aerospace industry in the areas of standards and conformity assessment (which includes quality system and supplier certification and related issues). This report provides a summary of the issues and their potential impact on industry, followed by recommendations for AIA action.

Standards Issues

International Harmonization of Airworthiness Requirements

The increasingly global nature of the civil aviation industry has caused AIA to give high priority to harmonization of airworthiness certification requirements among nations. Certifying an aircraft to national requirements unique to the country in which the aircraft is sold or operated increases certification costs without necessarily improving safety. The U.S. Federal Aviation Administration and the European Joint Aviation Authorities recognize that the current system of varying national requirements is problematic, and have intensified their efforts toward harmonization.

The AIA and its European counterpart AECMA requested that air worthiness authorities make harmonization a priority. The rapid increase in worldwide air travel, the growth of cross-border leasing, chartering and transfer of aircraft, and the general development of international cooperation in the design and production of civil transport aircraft are compelling reasons to intensify harmonization efforts. Critical to the harmonization effort are elimination of non-essential regulations and strict adherence to multilateral solutions. The FAA's Aviation Rulemaking Advisory Committee (ARAC), of which U.S. and European aviation interests are part can assume an important role in this effort.

International Design and Product Standards

There are standards activities in international bodies such as the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), which have a potential to affect the design, manufacture and operation of aerospace products. The increasing incidence of multinational aerospace programs, with U.S. companies sometimes acting as suppliers to foreign companies, and the stated preference by DoD and NATO for international standards, should accelerate the introduction of international standards in the aerospace marketplace.

The primary international body responsible for development of international standards specifically intended for aerospace applications is Technical Committee 20 of the International Organization for Standardization (ISO/TC 20). Thirteen nations (Brazil, Canada, China, Czechoslovakia, France, Germany, Italy, Japan, The Netherlands, Romania, the United Kingdom, the United States of America, and the USSR) participate actively in TC 20. AIA holds the chairmanship and the international secretariat, by delegation from ANSI, the official U.S. member body of ISO.

The standards developed by ISO/TC 20 cover a wide range of aerospace parts and materials, as well as other areas supporting interchangeability and interoperability. A new initiative currently underway is to define a program of international standardization for space applications. The U.S. companies engaged in commercial space ventures need to become actively involved to

assure that international space standards reflect their needs and interests.

The ISO standards often are based on existing standards. U.S. aerospace standards are prime candidates for adoption as ISO standards. However, European standards have an even better chance because they are metric, because the Europeans have more votes, and because of "fast-track" procedures created for processing EC standards into ISO. If U.S. companies do not participate actively, they leave the door open to the setting of international standards favoring their competitors.

Besides TC 20, there are more than 250 other ISO and IEC technical committees working on standards in a variety of areas, some of which should be of concern to the aerospace industry; for example, software and configuration management. It is difficult for individual companies to participate in or maintain awareness of this wide range of activities. Liaisons established through the aerospace technical committee, ISO/TC 20, can provide a resource-effective way of monitoring developments in many of these groups. In others, direct participation is desirable.

European Aerospace Standardization

The European community embarked on an aggressive program of developing regional standards and certification systems, as part of the "EC 92" efforts to create an integrated European market by eliminating internal technical barriers. These regional standards are emerging at the expense of traditional U.S. technical leader-ship in many areas; and, sometimes at the expense of international harmonization. The size and coherence of the EC market give EC regional standards considerable importance, and many non-EC nations are watching these developments with a view of adopting them.

In the aerospace field, European regional standardization is the province of the European aerospace industry association, AECMA. Under authority delegated by the European Community, AECMA launched an accelerated program of standardization. To date, AECMA published 1,000 standards for aerospace parts, materials and processes, and has 1,000 in work.

The U.S. Department of Commerce, the American National Standards Institute, and the International Organization for Standardization have launched major initiatives to negotiate with the EC, to provide better access to European regional standardizing processes, and to encourage the EC to work more at the international level. As a result, many export-oriented U.S. industries are focusing increased effort and resources on development of international standards, which can provide an alternative to a technical "Fortress Europe" and provide an opportunity for U.S. input.

In the aerospace sector, while AECMA representatives regularly participate in U.S. aerospace standardization committees, AECMA's committees have been closed to outsiders. Recently, AECMA concluded agreements with ISO/TC 20 to allow participation by a designated observer. However, due to the current low level of U.S. company support for international standardization, the U.S. cannot take full advantage of these agreements. Thus, despite long-term efforts at harmonization, the technical divergence between the standards used by the United States and the European aerospace industries is increasing.

Metrication

Nearly all international and European standards are metric. However, the U.S. aerospace industry has had no market motivation to take the lead in converting to metric.

Foreign government acquisitions and certification programs, and NATO programs will encourage conversion. As metric standards are required and selected, the choices are more likely to come from ISO or Europe than from the United States where metric standard parts are required (for example, on the Comanche helicopter), they often are not available in the United States or incur lead time and cost penalties.

GATT Agreement on Technical Barriers to Trade

The General Agreement on Tariffs and Trade (GATT) includes an Agreement on Technical Barriers to Trade known as the "Standards Code." Its purpose is to remove barriers to trade that exist due to differences in national technical regulations, standards, and conformity assessment systems. The GATT includes a dispute settlement procedure under which disagreements between signatory nations may be resolved. To date there have been two cases involving standards, although neither was related to the aerospace industry.

Impact on the Aerospace Industry

Increasingly, standards from international and foreign sources will come into use alongside, or in place of, the U.S.-developed standards which heretofore have dominated aerospace design, production and maintenance worldwide. In the future, it is increasingly likely that U.S. companies will be required to meet standards they have had no voice in setting.

Customer preferences increasingly are for internationally agreed standards. The Standards developed in Europe and in international bodies will have growing importance, not only for the European market but elsewhere in the world. New policies and economic pressures are pushing the DoD toward greater reliance on the private sector for standards. The existing body of MIL specs, which has dominated world aerospace procurement and maintenance for decades, will diminish in favor of voluntary standards, including those from international and regional sources. As NATO downsizes and buys in smaller quantities, the need for using standards that have achieved will increase commercial international acceptance.

To the extent that these standards diverge from or conflict with, U.S. standards and practices, the United States can be at a disadvantage. The potential for negative impact on U.S. worldwide marketing efforts in Europe and the rest of the world includes more subtle threats than outright barriers to trade. For example, U.S. companies may encounter added time and cost to comply with non-U.S. standards, to find qualified sources, or to obtain certification; additional requirements placed on subcontractors; and impediments to international cooperative efforts. In the civil-aviation field, there is a concern that certifying aircraft to standards unique to the country in which the aircraft is sold or operated increases certification costs without necessarily improving safety.

Conformity Assessment Issues

The ISO 9000 Standards on Quality Systems

In 1987, the International Organization for Standardization (ISO) published a series of five international standards (ISO 9000, 9001, 9002, 9003, and 9004), developed by ISO Technical Committee (TC) 176 on quality systems. The ISO 9000 and 9004 were intended to be advisory in nature; ISO 9001, 9002 and 9003 were developed primarily for use in two-party contractual situations.

However, the standards are being applied under a broader range of conditions. In

some cases, compliance with one of the ISO 9000 standards (or their equivalent) has been, or will be, mandated by a U.S., foreign national, or regional government body. In other instances, marketplace/customer pressures are requiring conformance to ISO 9000 standards.

To date, the ISO standard has been adopted by some 40 countries—including, most recently, Japan—and the number continues to grow. The United States equivalent is known as the ANSI/ASQC (American Society for Quality Control) Q 90 series. In Europe, the operative documents are the EN (European Norm) 29000 series. Other variants exist around the world.

The ISO 9000 series is not static; the basic standards are already in the process of review and revision. Additional standards are published, or in work, in ISO to extend the current series including supplements on software, services, quality audits and measuring equipment. To add further to a fluid situation, some national and regional standards bodies outside of ISO are developing supplemental guidance for the application of the ISO 9000 series, for general use or for specific industries.

Conformance with ISO 9000 or its variants may be demonstrated in a number of ways, including self-audit. Third-party registration (sometimes called certification) of quality systems is not required by the ISO 9000 documents, but may be called for by a regulatory agency or a customer. In response to increasing demand, third party registration schemes are being established in many countries. The problem is that registration by a given registrar may not be universally accepted. Efforts are underway to assure mutual recognition of systems within the EC, and between the EC and the U.S., but these efforts are not complete. The issue of who in the U.S. will accredit third-party auditors and registrars also must be resolved. This issue, which has implications for many industries, is being worked at the national level by the United States Department of Commerce and ANSI.

Impact on the Aerospace Industry

The impact of the ISO 9000 series on the aerospace industry is largely dependent on customer/marketplace requirements. Some RFPs from European and other foreign customers are including a requirement that potential bidders be ISO 9000-compliant. For companies with quality systems in place, changes and added costs involved in ISO 9000 compliance have not been unreasonable in the experiences to date.

However, inconsistencies in the application of standards causes confusion among U.S. suppliers. Acceptance of a self-audit or third party registration by one customer does not necessarily guarantee acceptance by another. In instances where third party registration is required, suppliers will have to ascertain what registration agency is acceptable to each customer. Until mutual recognition agreements are in place internationally, multiple registrations may be required.

The Department of Defense is considering replacing MIL-Q-9858A and MIL-I-45208A with the U.S. equivalent of the ISO 9000 series. Although the AIA position is not to encourage an immediate transition, AIA believes that an eventual transition must be closely coordinated between government and industry to avoid disruption.

NATO is revising its AQAPs to incorporate the ISO standards, with a target of release by the end of 1992. The issue of whether NATO countries will require third-party registration for U.S. supplied mate-

riel is not resolved. The AIA is commenting on the draft AQAPs.

In the civil aviation field, AIA is concerned potential requirements from European and other foreign customers for third party registration of quality systems to ISO 9000 or its equivalents, could duplicate or conflict with the existing FAA procedure, impose added costs on industry, and pose a potential non-tariff barrier to trade. The AIA believes that rules and regulations of the FAA constitute the highest standard of safety, performance and quality. The AIA position, taken jointly with the General Aviation Manufacturers Association (GAMA) and AECMA, is to encourage FAA and JAA to rule that production approval holders manufacturing products in accordance with the JAR or FAR need not be further certified or registered to ISO 9000 standards to freely interchange products and services.

No specific direction exists regarding how subcontractor service and support centers will be dealt with by OEMs or airlines.

Supplier Evaluation

Third party systems to evaluate suppliers of aerospace parts and components and certain services is a related issue being addressed in the United States and in the EC. The goal is to reduce the number and frequency of supplier audits while providing contractors with reliable information about the supplier's quality systems and/or products.

In the United States, the National Aerospace and Defense Contractors Accreditation Program (NADCAP) has been established to audit suppliers on behalf of contractors. The DoD and FAA have expressed support in principle of such schemes, but have stressed that ultimate responsibility and liability continues to rest with the prime contractor (in the case of DoD) or the production approval holder (in the case of FAA).

In Europe, AECMA has established AECMA-CERT to qualify parts and materials to European standards. The system includes a third-party quality system audit based on ISO 9002. The AECMA-CERT will be part of the European Organization for Testing and Certification (EOTC), created by the EC in April 1990 to promote mutual recognition of test results, certification procedures, and quality system assessments and registrations in nonregulated product areas. At present, the United States has no interface with the EOTC. Some overtures toward mutual recognition of U.S. and EC systems for supplier accreditation have been initiated.

For electronic components, an international system of qualification has been established under the International Electrotechnical Commission (IEC), known as IECQ. The U.S. element of the IECQ system is operated by the Electronic Industries Association.

The AIA position on third party supplier evaluation systems has been to recognize that they do not relieve prime contractors of ultimate responsibility and liability. For the civil aviation field, third party supplier evaluation must be limited to use within Part 14 of the Code of Federal Regulations. Since these systems are likely to become the accepted way of doing business in the global marketplace, and may also result in reduced costs to industry, the project group recommends that AIA continue to monitor them, and encourage mutual recognition between eventual systems in the United States and Europe.

Conclusion

Today, many export-oriented U.S. industries are focusing increased effort and resources on the development of international standards in recognition of the globalization of the marketplace. International standards provide an alternative to a technical "Fortress Europe" and provide an opportunity for U.S. input.

In the aerospace industry, however, international standards and certification issues have not been given high priority by U.S. aerospace companies. On the contrary, as aerospace companies move to reduce overhead, support for internal and external standardization activities is being reduced. This declining company support for standards participation has directly and negatively affected U.S. ability to be effective in the international standards arena.

The intercouncil project identified a range of issues which have a potential for long-term negative impact on U.S. worldwide marketing efforts in Europe and the rest of the world. Negative effects could include added costs to comply with non-U.S. standards or to obtain certification, as well as penalties to subcontractors, and impediments to international cooperative efforts.

This study revealed that the U.S. aerospace industry is largely in a reactive mode relative to international standardization and certification issues. If U.S. industry does not maintain an active presence in international standards and certification activities, the result will be increasingly significant differences between U.S. standards and those of Europe and the rest of the world, and an increasing likelihood that U.S. companies will be required to meet standards that they have had no voice in setting. An increased level of industry vigilance is required to keep pace with fast-moving developments and to assure that standards, testing and certification requirements do not escalate into barriers to U.S. trade.

Recommendations

The aerospace industry should, through the appropriate AIA committee structure:

1. Improve participation and success level of U.S. aerospace industry in key international standards committees; specifically, provide industry support for an active U.S. presence in ISO/TC 20, Aircraft and Space Vehicles and ISO/TC 176, Quality Management and Quality Assurance.

Action:
International Standardization
Advisory Group Quality Assurance
Committee

2. Pursue closer liaison with European aerospace standardization and certification activities such as JAA, AECMA, AECMA-CERT and EOTC; specifically, provide industry support to take advantage actively of the opportunity to participate in selected AECMA standardization meetings.

Action:
International Standardization
Advisory Group
Quality Assurance Committee
Civil Aviation Council

3. Systematically determine the appropriate degree of harmonization of existing U.S. standards with international standards. Specific strategies include promoting the adoption of U.S. standards internationally; periodically reassessing the pace and impact of aerospace metric conversion; and ensuring orderly implementation of international requirements where deemed appropriate.

Action:
International Standardization Advisory Group
Aerospace Sector Committee/ American National Metric Council
National Aerospace Standards Committee
Quality Assurance Committee
Civil Aviation Committee

4. Resolve contractual and regulatory issues related to ISO 9000, and increase industry awareness. Specific goals include:

a. Maintain preeminence of FAA airworthiness certification requirements.

b. Keep non-value-added, third party quality system registration from becoming a prerequisite for doing business. Promote use of self-audit and declaration of conformance.

c. Clarify the timing of industry compliance with customer-imposed ISO 9000 requirements before contractual penalties being levied.

d. Closely coordinate with DoD as it moves toward implementation of the ISO 9000 series. This involves reconciling the shortcomings of the ISO series and defining the training required for the transition.

e. Support mutual recognition between a disciplined, reliable third party supplier registration system in the United States and in Europe.

Action:
Quality Assurance Committee
Civil Aviation Committee

5. Communicate aerospace concerns to federal agencies such as the Department of Commerce, State Department, Department of Defense, and the United States Trade Representative, as part of the national dialogue on standards and certification issues. Assure consideration of aerospace issues in bilateral and multilateral agreements negotiated with foreign trading partners. Heighten the awareness among U.S. professional and trade associations such as ANSI and ASQC of specific aerospace industry issues.

Action:
AIA staff and committees

6. Heighten industry awareness of worldwide standardization and certification trends and developments affecting aerospace by gathering, disseminating and analyzing information on a timely basis. Maintain active monitoring for potential use of standards and certification as trade barriers. Retain the Intercouncil Project Group to provide an AIA-wide focal point.

Action:
Technical and Operations
Civil Aviation Committee
International Council

ANNEX F
Glossary of Standardization/Certification Terms and Acronyms

International

IEC — International Electrotechnical Commission. Sister organization of ISO which covers standardization in the electrical and electronic areas.

ISO—The International Organization for Standardization. Composed of member bodies from more than 90 nations. The official U.S. member body is ANSI.

ISO/TC 20—The international technical committee for aerospace standardization. The U.S. Technical Advisory Group (TAG) is administered by SAE. AIA is the international secretariat of ISO/TC 20.

ISO/TC 176 —The international technical committee on quality systems standards. The United States Technical Advisory Group is administered by the American Society for Quality Control.

European Regional

AECMA—Association Europeenne des Constructeurs de Materiel Aerospatial. European counterpart to AIA, consisting of aerospace industry associations of nine European nations. By delegation from CEN, responsible for preparing ENs in the aerospace field.

AECMA-CEPT—Organization established by AECMA. Performs qualification of products, and certification of suppliers' quality systems, to AECMA EN standards. Also represents the aerospace sector in the European certification system (EOTC).

CEN/CENELEC—European regional standardization bodies. Develop European Norms (ENs). Certain ENs are developed at the request of the European Commission, and will be mandatory in the European Community for regulated products.

EOTC—European Organization for Testing and Certification, created in 1990 to promote mutual recognition of conformity assessment in nonregulated product areas throughout the European Community.

JAA—Joint Aviation Authorities, established to harmonize national airworthiness, maintenance and operational rules into Europe-wide Joint Aviation Regulations (JARS).

U.S. National

AIA—Aerospace Industries Association. Trade association of U.S. aerospace companies. Standardization activities include development of U.S. National Aerospace Standards, and administration of international secretariat of ISO/TC 20.

ANSI—American National Standards Institute. Non-governmental, private sector U.S. standards coordinator. Official U.S. member body of ISO and IEC.

DOC/NIST—The U.S. Department of Commerce, and its specialized agency, the National Institute for Standards and Technology. The DOC and NIST have a primary responsibility for development of U.S. interagency policies in the area of EC 92 standards and certification and their impact on U.S. business.

NADCAP—National Aerospace and Defense Contractors Accreditation Program. Third party registration program for suppliers of aerospace products and services, organized by SAE.

SAE—Society of Automotive Engineers. Professional society active in self-propelled technologies. Standardization activities include development of AS and AMS standards, and administration of U.S. TAG for ISO/TC 20.

ANNEX G
ISO 9000 STANDARD SERIES
(QUESTIONS AND ANSWERS ON QUALITY, QUALITY SYSTEM REGISTRATION, AND RELATED ISSUES)

Abstract

This report provides information on the development, content and application of the ISO 9000 standards to readers who are unfamiliar with these aspects of the standards. It attempts to answer some of the most commonly asked questions on quality; quality systems; the content, application and revision of the ISO 9000 standards; quality system approval/registration; European Community requirements for quality system approval/registration; and sources for additional help.

Key Words: conformity assessment; EN 29000; ISO 9000; quality assurance; quality control; quality system; quality system registration

What Is Quality?

Quality improvement has now become both the corporate and international business strategy of the 1990s. Cadillac and Milliken and Company each advertise winning the Malcolm Baldrige Award for quality. Ford Motor Company publicizes a "Quality is Job 1" slogan, and many other companies are following suit. At the international level, interest has mushroomed in quality systems as a means of assuring the consistent conformity of products or services to a given set of standards or expectations.

There has, however, been little agreement among either corporate management or professionals in the field regarding the meaning of "quality." The International Organization for Standardization (ISO) Standard 8402 defines quality as: "the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs." However, there are problems with this definition. Whose needs does the service or product address? Who are its customers? In the testing services field, for example, totally erroneous test results may satisfy a client's needs quite well if the faulty test report can be used to allow him to sell his product, especially if an accurate test report would not. Nevertheless, such results are unlikely to satisfy the needs of the potential buyers of the product or of the agency responsible for regulating the product.

Customers for a product or service produced by a company can be located within or outside the company or both, depending on the product or service. A product or service may be provided by one company unit to another solely for the latter's use, or for subsequent delivery to a customer outside the organization. It has been said that most product or service defects (no matter where they occur in the service or manufacturing process) usually find their way to the point of interface between a company and its outside customers.

In an attempt to address this problem, ISO has added seven footnotes to its definition, including that: "in a contractual environment, needs are specified, whereas in other environments, implied needs should be

identified and defined" and that "needs can change with time." Needs can be defined in terms of safety, usability, availability, versatility, compatibility with other products, reliability, maintainability, overall cost (including purchase price, maintenance costs, and product life), environmental impact, or other desired characteristics.

Even if all "needs" can be identified and adequately defined (often no easy task), what about the issue of an "acceptable quality level (AQL)" — the maximum percentage of nonconforming products or service units that should be considered satisfactory as a process average? Stated in other words, how many (if any) mistakes can you make and still produce a "quality" product or service? A manufacturer's production system may be considered by his customers to produce a "quality" product if the AQL is 0.1 percent; that is, only one in 1,000 products contains defects. Yet a 1 in 1,000 error rate for nurses whose job it is to hold babies (they only drop one out of a thousand) or for containers which hold highly toxic or hazardous materials (only one serious leak gets by for every 1,000 containers produced) are obviously not acceptable. There is a belief among many quality experts and their disciples that the only acceptable quality level for any manufactured product or service is 100 percent ("zero defects"), and that any failure to "do it right" the first time is not tolerable. This is not a universally held opinion.

What Is a Quality System?

Product quality depends on many variables, such as the caliber of the components or materials used; type of equipment used in design, production, handling, installation, testing and shipping; the equipment calibration and maintenance procedures employed; the training and experience of production and supervisory personnel; the level of "workmanship" and sometimes the environmental conditions (temperature, humidity, level of dust particles) in the area where the product is produced. The process, organizational structure, procedures, and resources that manufacturers and suppliers use to control these variables to produce a product of consistent quality which meets defined specifications is called a quality system.[1] The standards that are being adopted globally for quality systems are the ISO 9000 standards.

What is ISO?

The ISO is the International Organization for Standardization, founded in 1946 to promote the development of international standards and related activities, including conformity assessment,[2] to facilitate the

[1] Note this definition is somewhat different from the ISO definitions. ISO Standard 9000-1987 defines quality system as: "the organization, structure, responsibilities, procedures, processes and resources for implementing quality management." The standard defines quality management as: "that aspect of the overall management function that determines and implements quality policy." The standard defines quality policy as: "the overall intentions and directions of an organization as regards quality, as formally expressed by top management." These ISO definitions also include several additional footnotes.

[2] Conformity assessment includes testing, inspection, laboratory accreditation, certification, quality system assessment, and other activities intended to assure the conformity of products to a set of standards and/or technical specifications.

exchange of goods and services worldwide. The ISO is composed of member bodies from over 90 countries, the United States member body being the American National Standards Institute (ANSI). The ISO's work covers all areas except those related to electrical and electronic engineering, which are covered by the International Electrotechnical Commission (IEC). The results of ISO's technical work are published as International Standards or Guides.

What Are the ISO 9000, ANSI/ASQC Q 90, and CEN/CENELEC EN 29000 Standards?

In 1987, the ISO published a series of five international standards (ISO 9000, 9001, 9002, 9003, and 9004), developed by ISO Technical Committee (TC) 176 on quality systems. This series, together with the terminology and definitions contained in ISO Standard 8402, provides guidance on the selection of an appropriate quality management program (system) for a supplier's operations.

The ISO 9000 standards were intended to be advisory in nature and were developed primarily for use in two-party contractual situations or for internal auditing. However, the standards are currently being applied under a much broader range of conditions and circumstances. In some cases, compliance with one of the ISO 9000 standards (or their equivalent) has been or will be mandated by a U. S., foreign national, or regional government body. Conformance to ISO 9000 standards also is being required in purchasing specifications with increasing frequency.

The ISO 9000 Standard Series has been adopted in the United States as the ANSI/ American Society for Quality Control (ASQC) Q 9^ Series (soon to be changed to the ANSI/ASQC Q 9000 series). In Europe, it has been adopted by the European Committee for Standardization (CEN) and the EuropeanCommittee forElectrotechnical Standardization (CENELEC) as the European Norm (EN) 29000 Series. According to a recent survey by ISO, forty-eight (48) countries have national standards that are identical or equivalent to the ISO 9000 Standard Series. Additional countries are considering their adoption.

What Sort of Information Is Contained in Each ISO 9000 Standard?

The ISO 9000 Standard Series is generic in scope. Each standard addresses a different aspect of quality assurance, depending on the needs of the user.

The ISO 9001, 9002 and 9003 describe three distinct quality system models of varying stringency for use in different applications. Common elements in ISO 9001, 9002, and 9003 include the need for: an effective quality system; ensuring that measurements are valid, that measuring and testing equipment are calibrated regularly; the use of appropriate statistical techniques; having a product identification and traceability system; maintaining an adequate record keeping system; having an adequate product handling, storage, packaging and delivery system; having an adequate inspection and testing system as well as a process for dealing with nonconforming items; and ensuring adequate personnel training and experience.

The ISO 9000 (ANSI/ASQC Q 90), *Quality Management and Quality Assurance Standards - Guidelines for Selection and Use*, explains fundamental quality concepts; defines key terms; and provides guidance on selecting, using, and tailoring ISO 9001, 9002, and 9003.

The ISO 9001 (ANSI/ASQC Q 91), *Quality Systems - Model for Quality Assurance in*

Design/Development, Production, Installation and Servicing, is the most comprehensive standard in the series. The ISO 9001 covers all elements listed in ISO 9002 and 9003. In addition, it addresses design, development, and servicing capabilities.

ISO 9002 (ANSI/ASQC Q 92), *Quality Systems - Model for Quality Assurance in Production and Installation*, addresses the prevention, detection, and correction of problems during production and installation. It is more extensive and more sophisticated than ISO 9003.

The ISO 9003 (ANSI/ASQC Q 93), *Quality Systems - Model for Quality Assurance in Final Inspection and Test*, is the least comprehensive standard. It addresses requirements for the detection and control of problems during final inspection and testing.

The ISO 9004 (ANSI/ASQC Q 94), *Quality Management and Quality System Elements - Guidelines*, provides guidance for a supplier to use in developing and implementing a quality system and in determining the extent to which each quality system element is applicable. The ISO 9004 examines each of the quality system elements (cross-referenced in the other ISO 9000 standards) in greater detail and can be used for internal and external auditing purposes.

Where Can Copies of these Standards Be Obtained?

Copies of ISO draft/final standards and European standards (ENs) can be purchased from: The American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036, Phone: (212) 642-4900, Fax: (212) 302-1286.

Are the ISO 9000 Standards Subject to Change?

According to ISO procedures, all ISO standards, including those in the ISO 9000 series, must be reviewed and revised or reafirmed at least once every five years. The ISO has begun to revise and supplement the ISO 9000 series. Some of these standards/guidelines will supplement ISO 9000 and ISO 9004, while others will be included in the new ISO 10000 series. Both series have been reserved for use by ISO TC 176.

Recently released ISO standards and guidelines in the quality area include: ISO 9000-3, *Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software*; ISO 9004-2, *Quality Management and Quality System Elements - Part 2: Guidelines for Services*; ISO 10011 Part 1, *Guidelines for Auditing Quality Systems -Auditing*; ISO 10011 Part 2, *Guidelines for Auditing Quality Systems - Qualification Criteria for Auditors*; ISO 10011 Part 3, *Guidelines for Auditing Quality Systems - Managing Audit Programs*: and ISO 10012-1, *Quality Assurance Requirements for Measuring Equipment - Part 1: Management of Measuring Equipment*.[3]

In addition, ISO/DIS (Draft International Standard) 8402-1 *Quality Systems Terminology*; and DIS 9000-2 *Addendum to 9000 on Guidelines for Implementing 9001-2-3*; DIS 9004-3 *Addendum to 9004 on Processed Materials* are under review by ISO TC 176. The ISO TC 176 is also considering committee draft (CD) 9004-4 *Addendum to 9004 on Quality Improvement*; guidance documents on project management, quality plans, quality manuals, the economics of quality, and configuration management; documents

[3]Information on drafts or proposed standards work was provided by Patricia Kopp, Standards Administrator at the American Society for Quality Control (ASQC) in Milwaukee, WI, Phone: 414-272-8575.

covering revisions to ISO 9000, 9001-2-3; and 9004; and a working draft (WD) 10012-2: *Quality Assurance Requirements for Measuring Equipment - Part 2: Measuring Equipment.*

Some national and regional standards bodies are developing supplemental guidance for the application of the ISO 9000 series to specific industries. CEN and CENELEC, for example, are developing more specific requirements for the application of the ISO 9001 to the medical device industry.[4] The U.S. Food and Drug Administration (FDA) is planning to revise its Good Manufacturing Practice (GMP) regulations for medical devices to follow ISO 9001 with appropriate additional requirements. Draft GMP regulations are expected to be issued by the end of 1992. The International Organization for Legal Metrology (OIML) is developing a document entitled: "Quality Assurance as Applied for Initial Verification of Measuring Instruments," which provides guidance on the applicability and use of the ISO 9000 Standard Series in the manufacture of measuring instruments.

Does TC 176 Have a Plan for Revising and Supplementing the ISO 9000 Standards?

Vision 2000 - *A Strategy for International Standards' Implementation in the Quality Arena During the 1990s* is a long-range plan through the year 2000 developed by an *Ad Hoc* Task Force of ISO TC 176. The plan includes providing additional guidance on how to apply the ISO 9000 series standards to four generic product categories (hardware, software, processed materials, and services), as well as providing guidance on related issues, such as quality system auditing. As noted above, these documents are in various stages of development. Minor modifications in the original ISO 9000 series are expected in 1993, with major revisions in 1997. The long-range goal, according to *Vision 2000*, is to have a single Total Quality Management Standard by the year 2000.

What Is the ISO 9000 Forum?

The ISO has established a forum to serve the needs of ISO 9000 users by: providing information (including a newsletter); facilitating international discussions on new developments and issues affecting the application of the ISO 9000 standards; promoting the exchange of experience in such areas as training, promotion and operation of relevant schemes; harmonizing practices in the application and interpretation of the ISO 9000 standards; providing advice to ISO TC 176 or the relevant ISO decision-making body.

How Do the ISO 9000 Criteria Compare With Criteria Used in the Malcolm Baldrige National Quality Award Process?

The Malcolm Baldrige National Quality Award process is designed to recognize and award those firms with outstanding records of quality performance. The purpose of the program is therefore very different from the purpose behind the development of the ISO 9000 criteria. While the use of the ISO 9000 standards may be a good starting point in establishing a quality system, the criteria used in evaluating candidates for the Baldrige Award are much more detailed and extend beyond those areas covered by the ISO 9000 series. The

[4] CEN and CENELEC have issued a draft European standard, EN 46001 - *Specific Requirements for the Application of EN 29001 to Medical Devices*. Medical device manufacturers doing business in the EC will have to comply with the quality system requirements of EN 46001.

Baldrige Award criteria are results oriented and cover all operations, processes, and work units of a company. The evaluation procedures emphasize the dynamics involved in the integration of all aspects of a firm's quality system and the firm's continuous improvements in quality.

What Is Quality System Registration?

Quality system registration or approval (sometimes misnamed "quality system certification")[5] involves the assessment and periodic audit of the adequacy of a supplier's quality system by a third party, known as a quality system registrar. When a supplier's system conforms to the registrar's interpretation of an ISO 9000 standard, the registrar issues the supplier a "certificate of registration." Interpretations of an ISO 9000 standard may not be consistent from one registrar to another.

Note that the supplier's quality *system* is registered, not an individual product. Consequently, quality system registration does not imply product conformity to any given set of requirements. Registration programs can be conducted in conjunction with or independently from a certification program.[6] Registrars may or may not concurrently operate a product certification program.

Who Evaluates Quality Systems?

A manufacturer may choose to evaluate his own quality system. Such self-audits are usually major components of the quality system itself. Such self-audits can increase the confidence of management in its production system and demonstrate to its personnel that the firm is committed to quality management.

"Second party" evaluations are also common. In these cases, it is usually the buyer who requires and conducts quality system evaluations of his suppliers. These evaluations are mandatory only for companies wishing to become suppliers to that buyer.

"Third party" quality system evaluations and registrations may be voluntary or mandatory and are conducted by persons or organizations independent of both the supplier and the buyer. According to a recent ISO survey, 31 countries reported the existence of one or more third party registration schemes in their countries.

What Is the "New Approach" for Conformity Assessment of Regulated Products?

The Government of the European Community (EC) has established a conformity assessment scheme for EC-regulated[7] products. The EC has specified conformity assessment methods in terms of eight "modules," such as self-certification (also called "manufacturer's declaration"), type testing, quality system approval, or final product verification by a third party. Each "new approach" directive specifies the alternative means (set of modules) which suppliers must use to certify their products as being in

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[5] ISO/IEC Guide 48 uses the term "register," though many Europeans continue to use the term "certify."

[6] Certification defined in ISO Guide 2-1991 as the "procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements."

[7] Regulated products are those for which the EC Commission has developed or is developing an EC-wide technical harmonization directive which provides manufacturers with a single set of requirements that must be met to place their products on the EC market.

conformance with the "essential requirements" spelled out in each directive.

When EC directives require the use of a third party in the conformity assessment process, each member country government must provide the EC government with a list of such bodies. Each member country government must determine that the bodies it notifies, referred to as a "notified bodies," are competent to declare that a regulated product is in conformity to the "essential requirements" spelled out in a particular directive. Member states notify bodies by both conformity assessment method (module) and by directive to the EC, which is then responsible for compiling a list of all such bodies.

Each EC country must accept the results of conformity assessments by notified bodies in all other EC countries unless there is cause to believe that the product was improperly tested. Each EC country is responsible for assuring that the bodies it designates as notified bodies comply with the criteria for competence of testing laboratories, certification and laboratory accreditation bodies, and quality system registrars spelled out in the European EN 45000 series of standards.

Will Quality System Approvals Be Mandatory in the EC?

Having an approved quality system will not be a blanket requirement for all products. However, for suppliers of construction products, certain classes of medical devices and personal protective equipment, telecommunications terminal equipment, gas appliances, commercial scales, and possibly other products (such as pressure equipment, recreational craft, cable ways, and lifting equipment for people), approval of a supplier's quality system will be a key component of the EC's legal requirements for certification. For most of these regulated products, ISO 9000 registration is one alternative to proving compliance, not an absolute requirement.

In other directives, such as the Council Directive dated June 14, 1989, on machinery (89/392/EEC), manufacturers of some products will be permitted to self declare that their product conforms to the requirements of the directive and to place the European Community (EC) mark on the product. However, such machinery manufacturers must maintain a file on the manufacture of those products, including information on "the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive" — in other words, on the manufacturer's quality system. It is possible that the ISO 9000 (EN 29000) Series Standards could be used within the European Community to evaluate the adequacy of such quality systems.

Manufacturers need to review all relevant EC directives for specific requirements applicable to their products.

Who Will be Able to Conduct Mandatory EC Quality System Approvals?

At the present time, notified bodies must be physically located within the geographical boundaries of the European Community. In November 1991, the EC developed a document entitled, *Working Document on Negotiations with Third Countries Concerning the Mutual Recognition of Conformity Assessment*, which provides guidance for the establishment of mutual recognition agreements with third countries. A less-detailed directive on this topic is expected sometime in June 1992. Until the directive is issued and one or more mutual recognition agreements are subsequently established between the United States and the Euro-

pean Community, there can be no notified bodies in the United States. A mutual recognition agreement would allow U.S. entities to perform all required conformity assessment procedures included within the scope of the agreement.

There remains the possibility that some conformity assessment tasks may be subcontracted by notified bodies to bodies outside the EC, including organizations in the United States. Such subcontracting would be done at the discretion of the notified body, which would continue to be responsible for the final assessment of product conformity. Subcontractors must comply with all requirements of the EN 45000 series. Guidance on subcontracting can be found in *Guiding Principles for Subcontracting by "Notified Bodies" Pursuant to the Council Resolution of 13 December 1990 Concerning the Modules for the Various Phases of the Conformity Assessment Procedures.*

Will Quality System Registration Be Required for Nonregulated Products in the EC and Elsewhere?

In the nonregulated product area, producers desiring to do business in the European Community (EC) and elsewhere may be required by procurement authorities or buyers to be audited and registered as being in compliance with an ISO 9000 standard. This is especially likely in industries such as aerospace, autos, electronic components, measuring and testing equipment or in industries where safety and liability are concerns. Such requirements will result from marketplace demands, as opposed to regulatory requirements.

It should be noted that in the United States, the U.S. Department of Defense is considering adopting the ISO 9000 standards in place of some of its military quality standards (MIL-Q-9858A and MIL-I-45208A). Other foreign government procurement authorities have already or are likely to follow suit.

What Is the EOCT and How Does It Fit into the Picture?

The European Organization for Testing and Certification (EOTC) was created by the EC in April 1990 under a memorandum of understanding with the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Free Trade Association (EFTA) countries. The EOTC was formed to promote the mutual recognition of test results, certification procedures, and quality system assessments and registrations in nonregulated product areas throughout the EC and EFTA. The EOTC will also be responsible for providing technical assistance to the EC Commission in the implementation of some EC legislation, especially in the preparation of mutual recognition agreements with non-EC countries. It is anticipated that there will be a Specialized Committee of the EOTC in the area of Quality Assurance. However, this committee will not be established until after December 31, 1992. Nevertheless the need for expert advice in this area was recognized by the EOTC in July 1991. The European Organization for Quality (EOQ) and the European Committee for Quality System Assessment and Certification (EQS) have been offered observership status in EOTC to fill this need. The EOTC is expected to be fully operational by the end of 1992. For further information on the EOTC, contact: EOTC, Rue Stassart 33, 2nd Floor, B-1050 Brussels, Belgium, Phone: 32 2 519 6969, Fax: 32 2 519 69 17/19.

Does the U. S. Have a Scheme For Quality System Registration?

Until recently, U.S. companies relied on quality system registration firms in Europe

and Canada to register their quality systems, but this is no longer the case. Today, the number of U.S.-based organizations offering consulting services, assessment and/or quality system registration is growing rapidly.

Who Evaluates the Competence Of Registrars?

In 1989, the Registration Accreditation Board (RAB) was established as an affiliate of the American Society of Quality Control (ASQC) to develop a program to evaluate the quality of services offered by registrars. The RAB issued its first approval in March 1991, and several more firms have been approved since then. The RAB and ANSI agreed to form a joint U.S. program in December 1991. In February 1992, RAB announced the establishment of an ISO 9000 auditor certification program. Information on the RAB program is available from: the RAB, 611 East Wisconsin Ave., Milwaukee, WI 53202, Phone 414-272-8575.

Programs similar to that of the RAB have been underway in Canada, in a number of European countries, and elsewhere in the world for some time.

Where Can U. S. Industry Go To Get Additional Help?

Additional information is available from:

National Center for Standards and Certification Information (NCSCI)
National Institute of Standards and Technology (NIST)
TRF Bldg. Room A163
Gaithersburg, MD 20899
Phone: (301) 975-4040 Fax: (301) 926-1559

and from:

Office of EC Affairs
International Trade Administration,
Room 3036
14th and Constitution Ave., SW
Washington, DC 20230
Phone: (202) 377-5276 Fax: (202) 377-2155

Both agencies are located in the Department of Commerce and can refer interested parties to other sources of information within and outside the federal government.

INFORMATION AND PUBLICATIONS AVAILABLE FROM

Standards Code and Information Program (SCI)
National Institute of Standards and Technology
Administration Building, Room A629
Gaithersburg, MD 20899
(301) 975-4040

The ABC's of Standards-Related Activities in the United States (NBSIR 87-3576). This report is an introduction to voluntary standardization, product certification and laboratory accreditation for readers not fully familiar with these topics. It stresses some of the more important aspects of these fields; furnishes the reader with both historical and current information on these topics; describes the importance and impact of the development and use of standards; and serves as background for using available documents and services. Order as PB 87-224309 from NTIS.

The ABC's of Certification Activities in the United States (NBSIR 88-3821). This report, a sequel to NBSIR 87-3576, *The ABC's of Standards-Related Activities in the United States*, provides an introduction to certification for readers not entirely familiar with this topic. It highlights some of the more important aspects of this field, furnishes the reader with information necessary to make informed purchases, and serves as background for using available documents and services. Order as PB 88-239793 from NTIS.

Laboratory Accreditation in the United States (NISTIR 4576). This report, a sequel to NBSIR 87-3576 *The ABC's of Standards-Related Activities in the United States* and NBSIR 88-3821 *The ABC' of Certification Activities in the United States*, is designed to provide information on laboratory accreditation to readers who are new to this field. It discusses some of the more significant facets of this topic, provides information necessary to make informed decisions on the selection and use of laboratories, and serves as background for using other available documents and services. Order as PB 91-194495 from NTIS.

Directory of International and Regional Organizations Conducting Standards-Related Activities (NIST SP 767). This directory contains information on 338 international and regional organizations which conduct standardization, certification, laboratory accreditation, or other standards-related activities. It describes their work in these areas, as well as the scope of each organization, national affiliations of members, U.S. participants, restrictions on membership, and the availability of any standards in English. Order as SN 003-003-02937-8 from GPO.

Directory of European Regional Standards-Related Organizations (NIST SP 795). This directory identifies more than 150 European regional organizations - both governmental and private-that engage in standards development, certification, laboratory accreditation and other standards-related activities, such as quality assurance. Entries describe the type and purpose of

each organization, acronyms, national affiliations of members, the nature of the standards-related activity, and other related information. Order as SN 003-003-03038-4 from GPO.

Standards Activities of Organizations in the United States (NIST SP 806). The directory identifies and describes activities of over 750 U.S. public and private sector organizations which develop, publish, and revise standards; participate in this process; or identify standards and make them available through information centers or distribution channels. The NIST SP 806, a revision of NBS SP 681, covers activities related to both mandatory and voluntary U.S. standards. The SP 806 also contains a subject index and related listings that cover acronyms and initials, defunct bodies and organizations with name changes. Copies not available from SCI. Order as SN 003-003-03070-8 from GPO.

Directory of Private Sector Product Certification Programs (NIST SP 774). This directory presents information from 132 private-sector organizations in the United States which engage in product-certification activities. Entries describe the type and purpose of each organization, the nature of the activity, product certified, standards used, certification requirements, availability and cost of services, and other relevant details. Copies not available from SCI. Order as SN 003-003-02984-0 from GPO.

Directory of Federal Government Certification Programs (NBS SP 739). This directory presents information on U.S. Government certification programs for products and services. Entries describe the scope and nature of each certification program, testing and inspection practices, standards used, methods of identification and enforcement, reciprocal recognition or acceptance of certification, and other relevant details. Order as SN 003-003-02852-5 from GPO.

Directory of Federal Government Laboratory Accreditation/Designation Programs (NIST SP 808). This directory provides updated information on 31 federal government laboratory accreditation and similar type programs conducted by the federal government. These programs, which include some type of assessment regarding laboratory capability, designate sets of laboratories or other entities to conduct testing to assist federal agencies in carrying out their responsibilities. The directory also lists 13 other federal agency programs of possible interest, including programs involving very limited laboratory assessment and programs still under development. Order as SN 003-003-03069-4 from GPO.

Directory of State and Local Government Laboratory Accreditation/Designation Programs (NIST SP 815). This directory provides updated information on 21 state and 11 local government laboratory accreditation and similar type programs. These programs, which include some type of assessment regarding laboratory capability, designate private sector laboratories or other entities to conduct testing to assist state and local government agencies in carrying out their responsibilities. Entries describe the scope and nature of each program, laboratory assessment criteria and procedures used in the program, products and fields of testing covered, program authority, and other relevant details. Order from SN 003-003-03093-7 GPO.

Barriers Encountered by U.S. Exporters of Telecommunications Equipment (NBSIR 87-3641). This report addresses the perceived institution of unreasonable technical trade barriers by major European trading partners to the export of telecom products and systems by U.S. companies. The GATT technical office, which has responsibilities to assist U.S. exporters to take advantage of

trade opportunities, informally contacted over a period of six months, telecom companies and agencies to assess the extent of unreasonableness in foreign national standards, regulations, testing and certification requirements, and accreditation procedures. Order as PB 88-153630 from NTIS.

A Review of U.S. Participation in International Standards Activities (NBSIR 88-3698). This report describes the role of international standards, their increasingly significant importance in world trade, and the extent of past and current U.S. participation in the two major international standardization bodies - ISO and IEC. The degree of U.S. participation covers the 20-year period 1966-1986. A coarse analysis of data indicates some correlation between U.S. participation and recent export performance for several major product categories. Order as PB 88-164165 from NTIS.

An Update of U.S. Participation in International Standards Activities (NISTIR 89-4124). This report presents updated information on the current level of U.S. participation in ISO and IEC (reference: NBSIR 88-3698). Order as PB 89-228282/AS from NTIS.

A Summary of the New European Community Approach to Standards Development (NBSIR 88-3793-1). This paper summarizes European Community (EC) plans to aggressively pursue its goal of achieving an "internal market" by 1992 and the standards-related implications of such a program on U.S. exporters. Order as PB 88-229489/AS from NTIS.

Trade Implications of Processes and Production Methods (PPMs) (NISTIR 90-4265). This report discusses processes and production methods (or PPM's) and their relationship to trade, the GATT Agreement on Technical Barriers to Trade, and traditional product standards used in international commerce. The report provides background information on PPM's, a suggested definition, and the possible extension of their application from the agricultural sector to industrial products. Order as PB 90-205485 from NTIS.

See Last Page for NTIS and GPO Contacts

The following documents are available upon request from OSCI.

tbt news. This news letter provides information on government programs and available services established in support of the GATT Agreement on Technical Barriers to Trade (Standards Code). *tbt news* reports on the latest notifications of proposed foreign regulations; bilateral consultations with major U.S. trade partners; programs of interest to U.S. exporters; and availability of standards and certification information. Subscription is free upon request.

Technical Barriers to Trade. This booklet explains the basic rules of the international Agreement on Technical Barriers to Trade negotiated during the Tokyo Round of the Multilateral Trade Negotiations (MTN), and describes Title IV of the U.S. Trade Agreements Act of 1979 which implements the United States' obligations under the Agreement. The Agreement, popularly known as the Standards Code, was designed to eliminate the use of standards and certification systems as barriers to trade. The booklet describes the functions of the Departments of Commerce and Agriculture, the Office of the U.S. Trade Representative, and the State Department in carrying out U.S. responsibilities.

"GATT Standards Code Activities." This brochure gives a brief description of NIST's activities in support of the Standards Code. These activities include operating the U.S.

GATT inquiry point for information on standards and certification systems; notifying the GATT Secretariat of proposed U.S. regulations; assisting U.S. industry with trade-related standards problems; responding to inquiries on foreign and U.S. proposed regulations; and preparing reports on the Standard Code.

GATT Standards Code Activities of the National Institute of Standards and Technology. This annual report describes the GATT Standards Code activities conducted by the Standards Code and Information Program for each calendar year. The NIST responsibilities include operating the GATT inquiry point, notifying the GATT Secretariat of proposed U.S. Federal Government regulations which may affect trade, assisting U.S. industry with standards-related trade problems, and responding to inquiries about proposed foreign and U.S. regulations.

Free handout material includes office activities and standards-related information such as: government sources of specifications and standards; foreign standards bodies; U.S. standards organizations; and a brochure on the National Center for Standards and Certification Information (NCSCI).

In addition to general inquiry services, the following assistance is available:

EC Hotline. This hotline reports on draft standards of the European Committee on Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). It also provides information on selected EC directives. The recorded message is updated weekly and gives the product, document number and closing date for comments. *The hotline number is (301) 921-4164 (not toll-free).*

GATT Hotline. A telephone hotline provides current information received from the GATT Secretariat in Geneva, Switzerland, on proposed foreign regulations which may significantly affect trade. The recorded message is updated weekly and gives the product, country, closing date for comments (if any) and Technical Barriers to Trade (TBT) notification number. *The hotline number is (301) 975-4041 (not toll-free).*

The NCSCI provides assistance to U.S. and foreign exporters in obtaining current standards, regulations and certification information for the manufacture of products. To aid foreign exporters, NCSCI also provides directory information of state offices prepared to respond to queries concerning conditions to be met by goods for sale in their state.

Publication Ordering Information

NTIS - National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
Telephone: (703) 487-4650
Fax: (703) 321-8547

GPO - Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402
Telephone: (202) 783-3238
Fax: (202) 275-2529

SOURCES FOR ORDERING STANDARDS
(other than directly from the respective standards-issuing organization)

Organization	Information provided
American National Standards Institute (ANSI) 11 West 42nd Street 13th Floor New York, New York 10036, USA Foreign/Domestic: (212) 642-4900 Telex: 42 42 96 ANSI UI Fax: (212) 302-1286 (212) 398-0023	ANSI and ANSI approved industry standards International and foreign standards Select draft CEN/CEMELEC standards; draft ISO standards
Global Engineering Documents 2805 McGaw Avenue, P.O. Box 19539 Irvine, California 92714, USA Telephone: (800) 854-7179 (714) 261-1455 Washington, D.C., USA (202) 429-2860 Fax: (714) 261-7892 Telex: 692 373	Industry standards Federal standards and specifications Military standards and specifications International and foreign standards
National Standards Association (NSA) 1200 Quince Orchard Boulevard Gaithersburg, Maryland 20878, USA Telephone: (800) 638-8094 (301) 590-2300 Fax: (301) 990-8378 Telex: 44 6194 NATSTA GAIT	Industry standards Federal and military standards, specification and related documents NATO standards Aerospace standards
General Services Administration (GSA) Specifications Branch Seventh and D Streets, S.W. Washington, D.C. 20407, USA Telephone: (202) 708-9205 Fax: (202) 708-9862	Federal standards and specifications

Organization	Information provided
Naval Publications and Forms Center Attn: NPODS 5801 Tabor Avenue Philadelphia, Pennsylvania 19120-5099, USA Inquiries (not for placing orders) Telephone: (215) 697-2667 Fax: 215) 697-5914	Dept. of Defense (DOD) adopted documents Naval publications Military manuals Other related forms
Standardization Document Order Desk 700 Robbins Avenue Building #4, Section D Philadelphia, Pennsylvania 19111-5094, USA Telephone: (215) 697-2179 Fax: (215) 697-5914	Military standards, specifications and handbooks Federal standards and specifications
Document Center 1504 Industrial Way, Unit 9 Belmont, California 94002, USA Telephone: (415) 591-7600 Fax: (415) 591-7617	Industry standards Federal standards and specifications Military standards and specifications International and foreign standards
Information Handling Services (IHS) P.O. Box 1154 Iverness Way East Englewood, Colorado 80150, USA Telephone: (800) 241-7824 (303) 790-0600 Fax: (303) 799-4097 Telex: 4322083 IHS UI	International and foreign standards Industry standards Federal standards and specifications Military standards and specifications Select European standards (CEN/CENELEC)
Standards Sales Group (SSG) 9420 Reseda Boulevard, Suite 800 Northridge, California 91324, USA Telephone: (818) 368-2786 Orders Only: (800) 755-2780 Fax: (818) 360-3804	International and foregin standards, publications and other reference materials Translations Service U.S./foreign general regulatory complicance information

ANNEX H
THE ABC's OF STANDARDS-RELATED ACTIVITIES IN THE UNITED STATES

Abstract

This report provides an introduction to voluntary standardization, product certification and laboratory accreditation for a reader who is not fully familiar with these topics. It highlights some of the more important aspects of these fields; furnishes the reader with both historical and current information on these topics; describes the importance and impact of the development and use of standards; and serves as background for using available documents and services.

Key Words: certification, inspection, laboratory accreditation, standardization, standards, testing

Introduction

> "The inch is a standard of measurement.
> Money is a standard of exchange.
> Words are standards of communication.
> Traffic lights are safety standards.
> Octane numbers of gasoline are quality standards.
> No more than 1% shrinkage is a performance standard."[1]

As the above indicates, standardization has a major impact on our lives, yet most people know little about the process or about the standards themselves. They know that camera film marked ISO 100 is likely to give good results in a camera with the film speed set at 100, but few understand that the ISO 100 marking on the package means that the film conforms to a standard established by the International Organization for Standardization (ISO), an international organization that writes standards. Few people question that three-holed notebook paper will align with the three rings in most notebooks, yet such confidence would not be possible without standards. While driving we are on the lookout for hexagonal, not round or square-shaped stop signs, just as we know that inverted triangles indicate where traffic should yield. These are just a few of the thousands of standards that impact on our lives.

Because standards have such an impact, it is important to have some familiarity with what they are and how they are developed and used. This paper is designed to be an introduction to some of the more significant aspects of standards development, product certification, and laboratory accreditation. It also will discuss some of the benefits and problems associated with these processes. The interested reader is encouraged to increase his knowledge of the field by taking advantage of other available publications and services described in the appendix.

Background

A standard was defined by the National Standards Policy Advisory Committee as: "A prescribed set of rules, conditions, or requirements concerning definitions of

terms; classification of components; specification of materials, performance, or operations, delineation of procedures; or measurement of quantity and quality in describing materials, products, systems, services, or practices" [2]

Though often unrecognized, standards can help to assure health and safety and to increase the quality of life. Standards are vital tools of industry and commerce. They often provide the basis for buyer-seller transactions, hence they have tremendous impact on companies and nations, and even on the economic fabric of the world market.

In the United States alone, approximately 30,000 current voluntary standards have been developed by more than 400 organizations. These do not include a much greater number of procurement specifications (developed and used by Federal, State, and local procurement authorities), as well as mandatory codes, rules and regulations containing standards developed and adopted at Federal, State, and local levels. In addition, numerous foreign national, regional and international organizations produce standards of interest and importance to U.S. manufacturers and exporters.

There are numerous international organizations that produce standards. The International Organization for Standardization (ISO) probably produces the largest number of International Standards, having issued approximately 6,000 standards. The ISO's work is carried out through some 2,300 technical bodies in which more than 20,000 experts from all over the world participate annually in the development of ISO standards.

The international General Agreement on Tariffs and Trade (GATT) has as one of its major components the Agreement on Technical Barriers to Trade (usually referred to as the Standards Code). The framers of the Standards Code recognized that standards and standards-related activities can seriously hinder the free flow of goods in international commerce. The Code established for the first time some requirements for the procedures by which standards are developed, adopted and used, and for the systems which determine conformity with such standards.

The Trade Agreements Act of 1979 implemented the Standards Code in the United States. Federal agencies are required under the Act to:

- "Not engage in standards activities that are prepared, adopted or applied to create, or have the effect of creating, unnecessary obstacles to the foreign trade of the United States;
- "Ensure that imported products are treated no less favorably than domestic products;
- "Use international standards, if appropriate, as a base for developing new standards;
- "Develop standards based on performance rather than design criteria, if appropriate; and
- "Allow foreign suppliers access to their certification systems on the same basis as access is permitted to domestic suppliers." [3]

Historical Notes on Standardization

The history of standardization is both fascinating and demonstrative of the scope and variety of such activities. A predecessor of the American National Standards Institute (ANSI) noted that one of the first known attempts at standardization in the Western

world occurred in 1120. King Henry I of England ordered that the ell, the ancient yard, should be the exact length of his forearm) and that it should be used as the standard unit of length in his kingdom.[4]

That history also notes that in 1689 the Boston city fathers recognized the need for standardization when they passed a law making it a civic crime to manufacture bricks in any size other than 9x4x4. The city had just been destroyed by fire, and the city fathers decided that standards would assure rebuilding in the most economic and fastest way possible.[5]

Eli Whitney is sometimes referred to as the "Father of Standardization" in the area of interchangeability, having originated and implemented the concept of mass production in the United States in 1780. He was awarded a contract to produce 10,000 muskets by then Vice President Thomas Jefferson. Though standardized parts had been successfully used in other parts of the world, Whitney brought the concept to this country when he divided the manufacturing process into individual steps and put different groups to work on each step of the process. All parts of the same type were copied from a model musket and were made to be interchangeable. Subsequently, when he appeared before the Congress with a collection of assorted parts and proceeded to assemble 10 working muskets by selecting the required parts at random, the Congress was convinced of the benefits of mass production made possible by standardization.[6]

Standards are known to have existed as early as 7000 B.C. when cylindrical stones were used as units of weight in Egypt. However, the great blaze in downtown Baltimore in February 1904 and other, similar catastrophes provided tragic and undeniable evidence of the importance of standards. While the fire in Baltimore burned, fire engines from as far away as New York rushed to the scene only to discover that their hoses would not fit Baltimore hydrants. Those "alien" fire engines were useless! The inferno burned for more than 30 hours, destroying 1526 buildings covering more than 70 city blocks. All electric light, telephone, telegraph, and power facilities were also razed.[7]

In contrast, 23 years later, help from 20 neighboring towns saved Fall River, Massachusetts, from destruction since hydrants and hose couplings had been standardized in these communities.[8]

As late as 1927, a color-blind motorist had as good (or as bad) a chance as anyone else when trying to interpret traffic signals. Purple, orange, green, blue, yellow, and red lights greeted him as he drove from state to state. In some states, green meant "Go," in others "Stop." Red, not yellow, lights meant caution in New York City. In 1927 a national code for colors was established through the work of the American Association of State Highway Officials, the National Bureau of Standards (now NIST) and the National Safety Council.[9] Imagine the chaos that would occur during rush hour in any major U.S. city today if newcomers and tourists did not know what traffic signals meant!

Probably the most significant standard ever developed in the United States, however, was the railroads' standard track gage. This standard, now used in Great Britain, the United States, Canada and much of continental Europe, enables railroad rolling stock to cross the country.[10]

It was the Second World War, however, that brought the urgency of extending domestic standardization to the international level. Allied supplies and facilities were

severely strained because of the incompatibility of tools, replacement parts, and equipment. The War highlighted the need for standards aimed at reducing inventories and increasing compatibility.

Types of Standards

Standards may be classified in numerous ways, some of which are described here. The ISO Draft Guide 2 differentiates eight types based on purpose.[11] A basic standard has a broad-ranging effect in a particular field, such as a standard for metal which affects a range of products from cars down to screws. Terminology standards define words permitting representatives of an industry or parties to a transaction to use a common, clearly understood language. Testing standards define the test methods to be used to assess the performance or other characteristics of a product. Product standards establish qualities or requirements for a product (or related group of products) to assure that it will serve its purpose effectively. Process standards specify requirements to be met by a process, such as an assembly line's operation, in order to function effectively. Service standards, such as for servicing or repairing a car, establish requirements to be met in order to achieve the designated purpose effectively. Interface standards, such as the point of connection between a telephone and a computer terminal, are concerned with the compatibility of products. The last type provides a listing of data requirements for a product or service for which values need to be obtained.

Standards also may be classified by the intended user group. These classifications range from company standards, meant for use by a single industrial organization, to international standards. International standards are developed and promulgated by international governmental and non-governmental organizations, such as the North Atlantic Treaty Organization's (NATO's) Military Agency for Standardization (governmental) and the ISO (non-governmental). International standards may be voluntary or mandatory in nature. A harmonized standard, on the other hand, can be either an attempt by a country to make its standard compatible with an international, regional or other standard or it can be an agreement by two or more nations on the content and application of a standard, the latter of which tends to be mandatory. Harmonized standards may also be identical in content to other standards. There are still other classifications such as industry standards, developed and promulgated by an industry for materials and products related to that industry; and military or government standards, such as those designed to be used by the Department of Defense or by the Federal Government. These should not be confused with Federal and Military Specifications, used by the Federal Supply Services in the General Services Administration and by the Department of Defense, respectively. Specifications are a set of conditions and requirements that provide a detailed description of a procedure, process, material, product, or service for use primarily in procurement and manufacturing.[12]

Another distinction among standards is the manner in which they specify requirements. Those standards that describe how a product is supposed to function are called performance standards. In contrast, design standards define characteristics or how the product is to be built. For example, a performance standard for water pipe might set requirements for the pressure per square inch that a pipe must withstand, along with a test method to determine if a specimen meets the requirement. On the other hand, the specification that a pipe be made of a given gage of copper would characterize a

given gage of copper would characterize a design standard. The distinction, however, between these two types of standards is not always clear cut. It is possible to include two different requirements within the same standard, one of which is stated in terms of performance and the other in terms of design. For example, in a standard for copper pipe, requirements for the pipe can be specified in terms of its performance (being able to withstand a given amount of pressure), but the same standard may require that the pipe's flanges or couplings meet specific design requirements.

Design standards may be appropriate, as in testing methods where the need for comparability may outweigh other considerations. In general, however, performance standards, though usually more difficult to write and enforce, tend to be less restrictive than design standards, and more likely to encourage innovation. For that reason, signatories to the Standards Code are encouraged to write technical regulations and standards in terms of performance, rather than design characteristics.

Still another classification scheme distinguishes between voluntary standards, which by themselves impose no obligations regarding use, and mandatory standards. A mandatory standard is generally published as part of a code, rule or regulation by a regulatory government body and imposes an obligation on specified parties to conform to it. However, the distinction between these two categories maybe lost when voluntary consensus standards are referenced in government regulations, effectively making them "mandatory" standards. Voluntary consensus standards also may become "quasi-mandatory" due to conditions in the marketplace. For example, the health-care industry is sensitive to the need to have available the safest products to ensure patient safety and to protect manufacturers, vendors and health care providers against lawsuits. Informed buyers of health-care products will frequently insist that products meet all appropriate voluntary consensus standards. If they wish to compete effectively, manufacturers of such products are obliged to conform to such standards.

It is clear, then, that standards cover a broad range of types and serve a wide variety of purposes.

Private Standards Organizations In the U.S.

The need for safe and economical structures, such as roads and bridges, led to the founding of the International Association for Testing and Materials in 1896. Its mission was to develop standardized test methods. Two years later, the American Section of this organization was formed and became the forerunner of the American Society for Testing and Materials, now known as ASTM. Since becoming an independent organization in 1902, ASTM has continued to grow and now produces the largest number of non-governmental, voluntary standards in the United States.

In 1918, ASTM was one of five private, technical society originators of the American Engineering Standards Committee, later to be known as the American Standards Association (ASA), and subsequently as the American National Standards Institute (ANSI). The ANSI today serves as the coordinator of voluntary standards activities in the United States and as the agency that approves standards as American National Standards. The ANSI is also the coordinator and manager of U.S. participation in the work of two non-governmental, international standards organizations, ISO and the International Electrotechnical Commission (IEC).

Another of the major private standards organizations, the American Society of Mechanical Engineering (ASME), was founded in 1880 and first issued the ASME Boiler Code in 1914. Today that Code is mandatory not only in the United States but in many countries throughout the world. In 1952, a forerunner of ANSI stated: "Probably no other single standard in America has done more for national safety than the ASME Boiler Code."[13] The ASME Boiler Code may be the most widely used voluntary standard in the world.

The founding of the Society of Automotive Engineers (SAE) in 1910 led to the pioneering efforts of the American automotive industry to achieve substantial inter-company technical standardization. Most drivers now take these efforts for granted when choosing motor oils by SAE designations (such as 10W-40) without being aware of the full significance and background of the detailed standards development process.

Most consumers also take for granted the familiar UL mark on a range of products from electrical appliances to fire extinguishers. The Underwriters Laboratories (UL), founded in 1894, is not only a major standards writer, but operates non-profit testing laboratories whose mission is to investigate products and materials with respect to hazards that might affect life or property and to list those items which appear to pose no significant hazards.

The work of other major standards organizations, although equally vital, tends to be less well known outside the standards community. For example, the National Fire Protection Association (NFPA) has for more than three quarters of a century produced the National Electrical Code, used in building construction, and many other standards affecting our safety from fires and other hazards. We accept without conscious thought the safety of aircraft unaware of the standards produced by the Aerospace Industries Association of America (AIA) for guidance and control systems and many other items. The Association of American Railroads' (AAR) standards similarly affect our railroads. Even the quality and size of paper is standardized through the work of the Technical Association of the Pulp and Paper Industry (TAPPI).

In all, more than 400 organizations develop voluntary standards of many different types for a broad range of services, products, and tests. Some organizations, such as ANSI and ASTM, are primarily concerned with standards. Others are trade associations interested in all matters affecting their members. The Electronic Industries Association, for example, has been a standards developer in the areas of electrical and electronic products and components since 1926.

Many professional and technical organizations are also standards developers. The Institute of Electrical and Electronics Engineers (IEEE), which traces back to 1884, maintains more than 500 standards with 800 more under development. The IEEE is responsible for the National Electrical Safety Code, widely used by governments and regulatory agencies for electric supply and communications installations. Still other standards developers are primarily research and testing bodies, such as the National Sanitation Foundation (NSF), which develops standards for products from a health and sanitation perspective. The Factory Mutual Research Corporation (FM), another standards developer, is a "product listing" type of organization, as is UL.

In addition, building-code organizations, such as the Building Officials and Code Administrators International (BOCA), the International Conference of Building Offi-

cials (ICBO), and the Southern Building Code Congress International (SBCCI), are involved in standards development. These organizations are composed of building, construction, zoning, and inspection officials; they have developed model building codes adopted by thousands of State and local governments.

The broad range of organizations participating in standards development reflects the impact standards have on a vast spectrum of interests and disciplines.

Standards Development Procedures

Two of the most widely used procedures for assuring consensus in the development of standards are the committee and the canvass methods.

Committee Method. Committee standards are subject to wide review and consideration by all interested parties. The requirements of this process vary among organizations. In some organizations, consensus may be defined as an agreement of at least 51 percent of the participants. Other organizations may also include requirements for due process, appeals procedures, the mandatory consideration of negative votes or comments, and for "committee balance." Balance is achieved when all parties having an interest in the outcome of a standard have an opportunity to participate, and where no single interest can dominate the outcome. Standards organizations differ widely in the emphasis placed on each of these requirements. Organizations which emphasize all four factors, in addition to the achievement of substantial agreement among participants, produce standards that are more likely to be adopted and used.

Canvass Method. The "canvass" method is frequently used by an organization that has prepared a standard under its own internal procedures. To gain greater stature and acceptance of the drafted standard, the developer may then submit it to balloting by a set of organizations representing a variety of interests, such as manufacturers, consumers, government, and others. Any objections or comments from organizations on the "canvass list" must be addressed and satisfactorily resolved. Changes in a proposed standard, as well as any unresolved objections and the developing organization's rationale for its response, must be resubmitted to the "canvass list." It is crucial that all interested groups be included on the list. Two problems sometimes arise: the response level may be low and consumers and others on the "canvass list" may have difficulty commenting on a standard because they did not participate in the initial drafting, and may not understand the reasons for, or implications of, particular provisions.

Benefits and Problems of Standardization

On the whole, the benefits of standardization far outweigh the difficulties and potential for abuse. Standards promote understanding between buyer and seller and make possible mutually beneficial commercial transactions. Product attributes cannot always be evaluated by individual purchasers by inspection or even from prior experience. However, a product's conformance to accepted standards readily provides an efficient method of conveying complex information on the product's suitability. Architects use standards in a shorthand manner when drafting plans for buildings; purchasing agents also can use standards as an easy way of communicating their needs to potential suppliers. In a host of situations, standards are, or may be, used to replace large quantities of complex information.

Standards underlie mass production methods and processes. They promote more effective and organized social interaction, such as the example of the standardized colors for traffic lights and many other widely accepted conventions. Standards are essential in efforts to improve product safety and to clean up the environment. Standardized and interchangeable parts can reduce inventory requirements and facilitate product repairs. They can also promote fair competition by facilitating the comparison of prices of standardized commodities.

In general, standards permit society to make more effective use of its resources and allow more effective communication among all parties to particular activities, transactions, or processes. Indeed, standards are crucial to every form of scientific and industrial process. Without standards, the quality of life would be significantly reduced.

No system, particularly one as complex and diverse as the U.S. voluntary standards system, is without problems. In a recent case of great significance, the United States Supreme Court on May 17, 1982, rendered its decision in favor of Hydrolevel, a manufacturer of low-water fuel cutoff devices, in the case of American Society of Mechanical Engineers (ASME) v. Hydrolevel. It found ASME liable for conspiring to restrain trade since two subcommittee officers, serving as volunteers but acting in the name of ASME, issued a misinterpretation of a standard and produced an adverse effect on the competitiveness of the plaintiff. Similarly, the Federal Trade Commission held hearings on standards and certification and uncovered "substantiated complaints of individual standards and certification actions that have, in fact, unreasonably restrained trade or deceived or otherwise injured consumers."[14]

In part, problems result from the sometimes substantial costs of participation in standards development, making it difficult (if not impossible) for small firms and nonindustry representatives to be active in the process. The standards themselves may cause problems if highly technical in nature. It is frequently difficult, if not impossible, to get qualified consumer representatives to participate actively. This seriously complicates the attempts to achieve balanced representation by all interests concerned.

Other problems may occur when a standard undergoes review and revision. Unless the original writers of the standard participate in its revision, the reviewers may not be able to understand how the document was prepared, what was eliminated from consideration, and the reasons or assumptions underlying decisions and the resultant provisions. Problems also can occur in the application of specific provisions if the intent behind them is unclear. Rationale statements, which sometimes accompany a standard, are specifically designed to define the purpose and scope of the standard, to explain the criteria used in developing its requirements and to provide all other relevant information at the disposal of the developers. However, the use of rationale statements is not yet extensive.[15]

Certification

"The first time a craftsman claimed that his product met a commonly accepted standard, the most basic form of certification came into being."[16] Today, product certification schemes range from the simple to the complex. The hallmarking of precious metals was an early form of certification. Many early attempts, most unsuccessful, also were made to certify weights and measures to provide a uniform basis for the

exchange of goods. Now there are over 100 private organizations and over 60 federal programs in the United States which certify products ranging from electrical cords to kitchen cabinets. In addition, many certification programs are operated at the state and local level. Consumers see evidence of the extensiveness of certification when they note the Underwriters' Laboratory (UL) certification mark on many products ranging from coffee pots to fire extinguishers; the U.S. Department of Agriculture (USDA) mark on meats, poultry and other agricultural products; and the International Wool Secretariat's Woolmark and Woolmark blend on wool or wood-blend textile goods. These are only a few of the many certification programs which are conducted in the United States.

Product certification is intended to confirm that a particular product conforms to one or more specified standards, thus providing the user with explicit or implicit information about the characteristics and/or performance of the product. Certification is a method for increasing a buyer's confidence in a product and for furnishing product information.

In the United States, if a manufacturer or supplier attests to the fact that his product meets one or more standards, the process is called self-certification. This process is also known as a manufacturer's declaration in other parts of the world. The manufacturer's capability, integrity, and reputation determine the degree of confidence that can be placed in self-certification.

Third party certification is the term applied to the process by which an organization, independent of either the manufacturer or supplier, assesses the product's conformance to one or more standards. A manufacturer's overall quality control program also may be examined as part of the certification process. A quality control program is a series of activities designed to assure that quality is being maintained at all phases of production. There are hundreds of third party certification programs in the United States operated by Federal, State, and local governments and by many private organizations. Third party certification programs differ greatly from one another, and the degree of confidence in the resultant certification depends on the program's type and comprehensiveness.

The methods used in third party certification programs can be classified as follows:

- Type-testing/Initial Inspection—This assures that the manufacturer's design specifications can produce a product that conforms to a particular standard. Products from a production run are not inspected or tested, and there is no information on whether products from a production run also consistently meet the specification.

- Audit-Testing—In this procedure, test samples are selected at random from the marketplace. Extensive testing is usually required to provide adequate assurance that products meet the desired standard.

- Surveillance of the Manufacturing Process—Assessment of a manufacturer's production and control processes can, at relatively low cost, provide assurance that the manufacturer's quality control procedures are adequate.

- Field Investigations—Alleged failures of products under use conditions are investigated to determine the cause of failure and to suggest appropriate corrective action.

- Batch-testing—A sample of products is selected from a production batch and tested for conformance to the standard. If the sampling procedure and the sample size

are adequate, batch-testing makes it likely that all products in that batch conform to the standard. It does not, however, ensure that a specific untested product in the batch will meet the standard nor does it furnish information on the quality of products produced in earlier or subsequent batches. Batch testing is used in many certification programs for building products, such as those for energy conservation.

• 100 Percent Testing—Each individual product is tested to determine if it meets the designated standard. If the testing procedures are adequate, the procedure provides the highest possible level of assurance that the product conforms to a particular standard. It also is usually the most expensive method and can be applied only where the test has no adverse effect on the product.[17]

Many programs apply two or more of these methods in their certification process. The choice of methods depends on the needs of both the buyer and the seller and the nature of the product. The methods chosen can greatly affect both the cost of the program and the level of confidence that can be ascribed to it. The ANSI and ISO have each developed criteria to evaluate certification programs. The ANSI also has developed a program to accredit certification schemes which meet its criteria, but only two programs have been accredited to date.

Laboratory Accreditation

Laboratory accreditation is a process for evaluating testing facilities and designating those laboratories judged competent to perform specific tests using standard test methods, where available. The National Voluntary Laboratory Accreditation Program (NVLAP) in the NIST, Department of Commerce, and the American Association for Laboratory Accreditation (AALA) are the two largest accreditation agencies in a the United States. There are many other Federal, State and local government programs, as well as many private-sector laboratory accreditation programs. Some of these include: the Department of Defense (DOD) programs for accrediting laboratories which test products which will later be sold to DOD; the State of Massachusetts programs for accrediting concrete-testing laboratories and laboratories which test solid fuel burning appliances; and the National Kitchen Cabinet Association's (NKCA) accreditation program for laboratories which test kitchen cabinets as part of the NKCA's certification program.[18]

It should be emphasized that laboratory accreditation assesses the capability of a laboratory to conduct testing, generally using standard test methods. The accreditation process should not be confused with certification or with the validation of a certification, which is "an action by a third party to assure that the producer (or certifier) is adhering to the requirements of a given certification program."[19] Laboratory accreditation neither reviews or assesses products, or does it check the tests conducted on specific products or product batches. In addition, laboratories may be accredited to conduct tests (such as EPA's accreditation program for laboratories testing drinking water) in fields where no certification program exists.

Laboratory accreditation, however, can affect the quality of certification programs by requiring evidence that a certifying laboratory has competent personnel, adequate equipment, and sufficient knowledge of the testing procedures for which accreditation is sought. Also, laboratory accreditation is assuming increased importance in trade. As countries seek acceptance of their test data by trading partners, they must assure that the data come from competent

laboratories. Laboratory accreditation can help provide that assurance.

Summary

Standardization, product certification, and laboratory accreditation are closely linked. In many developing countries, all three activities are conducted by the same organization. Certification programs are communication tools designed to reduce the cost of exchanging information between buyer and seller. The quality of the information conveyed depends on both the competence of the testing laboratory selected and the adequacy and appropriateness of the standards against which the product is to be evaluated. Certification can result in widespread consumer deception if performance characteristics or test methods contained in the standard are insufficient to assure adequate product performance, or if the testing laboratory is incompetent or has biases which affect the reporting of test results.

Considering the number of standards in existence and the variety of fields covered by private sector standards development and certification organizations, the United States has one of the most developed and complex standardization and certification systems in the world. Furthermore, the number of Federal, State, and local government standardization and certification activities and the large volume of standards, regulations, and procurement specifications that these agencies have developed, result in an immense impact of standardization and related activities on almost every aspect of life in the United States. Not only are considerable resources invested in this country in such activities every year, but purchasers (consumers) depend on standards and certification to ensure that products purchased are safe and perform satisfactorily. Recognition of the impact of standards and certification on trade, as evidenced by the Standards Code, is also increasing. Society depends on standardization and related activities for its existence

APPENDIX

The Office of Standards Code and Information
National Institute of Standards and Technology
Administration Building, Room A629
Gaithersburg, MD 20899
(301) 975-4040

• *Directory of International and Regional Organizations Conducting Standards-Related Activities* (NBS SP 649). Directory contains information on international and regional organizations which conduct standardization, certification, laboratory accreditation, or other standards-related activities. Volume describes their work in these areas, as well as the scope of each organization, national affiliations of members, U.S. participants, restrictions on membership, and the availability of any standards in English.

• *Standards Activities of Organizations in the United States* (NBS SP 681). The directory summarizes the standardization activities of organizations in the United States, including Federal and State agencies and private sector groups that develop standards. It also contains listings of State procurement offices, sources of standards documents and information, a subject index and related listings that cover acronyms and initials, defunct bodies and organizations with name changes.

• *Private Sector Product Certification Programs in the United States* (NBS SP 703). This directory presents information from private sector organizations in the United States which engage in product certification activities. Entries describe the type and purpose of each organization, the nature of the activity, products certified, standards used, certification requirements, availability and cost of services, and other relevant details.

• *Federal Government Certification Programs for Products and Services* (NBS SP 714). This directory presents information on U.S. Government certification programs for products and services. Entries describe the scope and nature of each certification program, testing and inspection practices, standards used, methods of identification and enforcement, reciprocal recognition or acceptance of certification, and other relevant details.

• *KWIC Index (Computer Output Microform* (COM) produced). The KWIC Index contains the titles of more than 25,000 U.S. voluntary product and engineering standards. A standard can be located by means of any significant or key word in the title. Key words are arranged alphabetically. A standard with five key words, for example, would therefore be listed in five different places. To purchase microfiche copies of the 1987 revision of the Index, contact the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; (703)487-4600. Use order no. PB87-133377; cost is $18.00 for purchasers in the United States.

• *tbt news*. This newsletter provides information on government programs and available services established in support of the GATT Agreement on Technical Barriers to Trade (Standards Code). tbt news reports on the latest notifications of proposed foreign regulations; bilateral consultations

with major U.S. trade partners; programs of interest to U.S. exporters; and availability of standards and certification information. Subscription is free upon request.

• *Technical Barriers to Trade.* This booklet explains the basic rules of the international Agreement on Technical Barriers to Trade negotiated during the Tokyo Round of the Multilateral Trade Negotiations (MTN), and describes Title IV of the United States Trade Agreements Act of 1979 which implements the United States' obligations under the Agreement. The Agreement, popularly known as the Standards Code, was designed to eliminate the use of standards and certification systems as barriers to trade. The booklet describes the functions of the Departments of Commerce and Agriculture, the Office of the United States Trade Representative, and the State Department in carrying out the United States's responsibilities.

• *GATT Standards Code Activities.* This brochure gives a brief description of NIST's activities in support of the Standards Code. These activities include operating the United States GATT inquiry point for information on standards and certification systems; notifying the GATT Secretariat of proposed U.S. regulations; assisting U.S. industry with trade-related standards problems; responding to inquiries on foreign and U.S. proposed regulations; and preparing reports on the Standard Code.

• *Report to the United States Congress on the Agreement on Technical Barriers to Trade - "Standards Code."* This 2nd triennial report describes the programs and activities established to implement the Standards Code in the United States by the four responsible U.S. Government agencies: Office of the United States Trade Representative; Department of Commerce (National Institute of Standards and Technology, International Trade Administration); Department of Agriculture and Department of State.

• Free handout material on the Office of Standards Services (OSS), the National Center for Standards and Certification Information's (NCSCI) and GATT activities, and standards-related information such as: Government sources of specifications and standards, use of the KWIC index, foreign and international standards bodies, U.S. standards organizations, State purchasing offices, NCSCI fact sheet and its certification rules activity, and OSS publications list (bibliography).

In addition to general inquiry services, the following assistance also is available:

• GATT Hotline

A telephone hotline provides current information received from the GATT Secretariat in Geneva, Switzerland, on proposed foreign regulations which may significantly affect trade. The recorded message is updated weekly and gives the product, country, closing date for comments (if any) and Technical Barriers to Trade (TBT) notification number. *The hotline number is (301) 975-4041 (not toll-free).*

• Assistance to U.S. and foreign exporters—Current regulations and certification information for the manufacture of products in the United States for export are obtained from foreign countries. To aid foreign exporters, NCSCI provides directory information on State offices prepared to respond to queries concerning conditions to be met by goods for sale in their state, as well as standards and certification information for export to the United States.

FOOTNOTES

1. USA Standards Institute, "What is...a Standard? the USA Standards Institute? a USA Standard?," USA Standards Institute, New York, New York, p. 1.

2. National Policy on Standards for the United States and a Recommended Implementation Plan, National Standards Policy Advisory Committee, Washington, D.C.,December, 1978. p. 6.

3. International Trade Administration, The Tokyo Round Agreements: Technical Barriers to Trade - Volume 4, Dept. of Commerce, Washington, D.C., September 1981.

4. American Standards Association, "Through History with Standards" in Rowen Glie (ed.), *Speaking of Standards*, Cahner Books, Boston, MA, 1972, p. 38.

5. *Ibid*, p. 42.

6. *Ibid*, p. 44.

7. Rexmond C. Cochrane, *Measures for Progress: A History of the National Bureau of Standards, National Bureau of Standards*, U.S. Department of Commerce, Washington, D.C., pp. 82-86,1974.

8. American Standards Association, p. 60.

9. *Ibid*, p. 68.

10. *Ibid*, p. 50.

11. International Organization for Standardization, draft revision of ISO Guide 2, "General Terms and Their Definitions Concerning Standardization, Certification and Testing Laboratory Accreditation," July 1985

12. W. E. Andrus, Jr., Draft, *NBS Glossary of Terms for Product Standardization, Product Certification and Laboratory Accreditation*, U. S. National Bureau of Standards, Dept. of Commerce, 1974.

13. American Standards Association, p. 48.

14. Bureau of Consumer Protection, Standards and Certification: Final Staff Report, April 1983, Federal Trade Commission, Washington, D.C., April, 1983, p. 2.

15. David A. Swankin, *Rationale Statements for Voluntary Standards - Issues, Techniques, and Consequences*, National Bureau of Standards, Dept. of Commerce, Gaithersburg, MD, November, 1981.

16. *International Organization for Standardization: Certification, Principles and Practice*, International Organization for Standardization, Geneva, Switzerland, 1980, p. 7.

17. Douglas B. Thomas, *NVLAP Glossary of Terms for Laboratory Accreditation, Product Certification and Standardization*, U. S. National Bureau of Standards, Washington, D.C. 1980.

18. Charles W. Hyer, *Principal Aspects of U. S. Laboratory Accreditation Programs*, National Bureau of Standards, Gaithersburg, MD 20899, October 1984.

19. *Ibid*, 21.

ANNEX I
INFORMATION AND PUBLICATIONS OF INTEREST

The ABC's of Standards-Related Activities in the United States (NBSIR 87-3576). This report is an introduction to voluntary standardization, product certification, and laboratory accreditation for readers not fully familiar with these topics. Order as PB 87-224309 from NTIS.

The ABC's of Certification Activities in the United States (NBSIR 88-3821). This report, a sequel to NBSIR 87-3576, provides an introduction to certification for readers not entirely familiar with this topic. Order as PB 88-239793 from NTIS.

Laboratory Accreditation in the United States (NISTIR 4576). This report, a sequel to NBSIR 87-3576 and NBSIR 88-3821, provides information on laboratory accreditation to readers who are new to this field. Order as PB 91-194495 from NTIS.

Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues (NISTIR 4721). This report provides information on the development, content, and application of the ISO 9000 standards to readers who are unfamiliar with these aspects of standards. Order as PB 92-126465 from NTIS.

Directory of International and Regional Organizations Conducting Standards-Related Activities (NIST SP 767). This directory contains information on 338 international and regional organizations that conduct standardization, certification, laboratory accreditation, or other standards-related activities. Order as PB 89-221147 from NTIS.

Directory of European Regional Standards-Related Organizations (NIST SP 795). This directory identifies more than 150 European regional organizations - both government and private - that engage in standards development, certification, laboratory accreditation, and other standards-related activities, such as quality assurance. Order as PB 91-107599 from NTIS.

Standards Activities of Organizations in the United States (NIST SP 806). This directory identifies and describes activities of over 750 U.S. public and private sector organizations that develop, publish, and revise standards; participate in this process; or identify standards and make them available through information centers or distribution channels. Order as PB 91-177774 from NTIS.

Directory of Private Sector Product Certification Programs (NIST SP 774). This directory presents information from 132 private sector organizations in the United States that engage in product certification activities. Order as PB 90-161712 from NTIS.

Directory of Federal Government Certification Programs (NBS SP 739). This directory presents information on U.S. Government certification programs for products and services. Order as PB 88-201512 from NTIS.

Directory of Federal Government Laboratory Accreditation/Designation Programs (NIST SP 808). This directory provides updated information on 31 federal government laboratory accreditation and similar programs conducted by the federal government. Order as PB 91-167379 from NTIS.

Directory of State and Local Government Laboratory Accreditation/Designation Programs (NIST SP 815). This directory provides updated information on 21 state and 11 local government laboratory accreditation and similar programs. Order as PB 92-108968 from NTIS.

Directory of Professional/Trade Organization Laboratory Accreditation/Designation Programs (NIST SP 831). This directory is a guide to laboratory accreditation and similar programs conducted by professional and trade organizations. Order as SN 003-003-03144-5 from GPO.

A Summary of the New European Community Approach to Standards Development (NBSIR 88-3793-1). This paper summarizes European Community plans to aggressively pursue its goal of achieving an internal market by 1992 and the standards-related implications of such a program on U.S. exporters. Order as PB 88-229489 from NTIS.

The following documents are available from SCI:

tbt news
This newsletter provides information on government programs and available services established in support of the GATT Agreement on Technical Barriers to Trade (Standards Code). Subscription is free on request.

Technical Barriers to Trade
This booklet explains the basic rules of the Agreement on Technical Barriers to Trade negotiated during the Tokyo round of the Multilateral Trade Negotiations (MTN), and describes Title IV of the U.S. Trade Agreements Act of 1979, which implements the United States' obligations under the agreement.

In addition to general inquiry services, the following assistance is also available:

EC Hotline
This hotline reports on draft standards of the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI). The hotline number is (301) 921-4164.

GATT Hotline
This hotline provides current information received from the GATT Secretariat in Geneva, Switzerland, on proposed foreign regulations that may significantly affect trade. The hotline number is (301) 975-4041.
NCSCI provides assistance to U.S. and foreign exporters in obtaining current standards, regulations, and certification information for the manufacture of products. To aid foreign exporters, NCSCI also provides directory on information state offices prepared to respond to queries concerning conditions required for the sale of goods in their state.

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161, USA
(703) 487-4650, Fax: (703) 321-8547
Orders only: (800) 336-4700

Superintendent of Documents
U.S. Government Printing Office (GPO)
Washington, DC 20402, USA
(202) 783-3238, Fax: (202) 512-2250

When requesting information from SCI, please send a self-addressed mailing label to:

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