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*Standards Setting in the European Union—
Standards Organizations and Officials
in EU Standards Activities*

Roger A. Rensberger and Rene van de Zande



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Standards Setting in the European Union— Standards Organization and Officials in EU Standards Activities

Roger A. Rensberger
Standards Officer, USEU

Rene van de Zande
Commercial Specialist, USEU

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The Honorable Stuart E. Eizenstat
United States Representative to the European
Union



U.S. Department of Commerce
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Technology Administration
Mary L. Good, *Under Secretary for Technology*

National Institute of Standards and Technology
Arati Prabhakar, *Director*

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In April 1995, when European Commission Vice President Sir Leon Brittan, Commissioner Martin Bangemann, and U.S. Secretary of Commerce Ronald H. Brown jointly asked more than 1,400 U.S. and European businesses and associations how the Commission and the U.S. Administration could improve and deepen the transatlantic business relationship, the issue area cited most often by far, was standards.

I am pleased that the Commercial Service at the U.S. Mission to the European Union prepared a guide that will be an important resource for U.S. manufacturers and exporters seeking information on standards in the EU, on key EU standards developing organizations and officials in the Commission with standards responsibilities.

The purpose of the guide, "Standards Setting in the European Union," is to bring U.S. industry closer to the EU standards community to enhance trade between the European Union and the United States. I hope that all its users find it informative, and they should feel free to suggest improvements or additions to our Commercial Service staff.

Ambassador Stuart E. Eizenstat
United States Representative to the European
Union

"Standardization, the best way of organizing economic relations."

--Florence Nicolas, Common Standards for Enterprises

For most U.S. businesses in Europe today, tariffs, quotas, even financing are not issues. Years of multilateral trade negotiations have reduced most of the traditional barriers to negligible levels. The key to competitiveness in the European Union countries is the timely availability of information. It is very appropriate to paraphrase the adage and say that for Europe "Knowledge is Exports." This is especially true in the field of standards, testing and certification. With tariff barriers virtually gone, advance warning and real insights into the issues of transparency of standards development, ISO 9000, CE marking, environmental management and ecolabelling are key to successful marketing and reducing the cost of doing business.

This document is a real "Baedeker" to the standards and regulatory community in Europe that directly affects doing business and can be used to find just the right information to avoid costly mistakes in a very complex and slippery field of play.

Charles Ludolph, Director
Office of European Union and Regional Affairs
U.S. Department of Commerce
Chairman, U.S. interagency Working Group on EU
Standards and Regulatory Issues

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Christopher Ginther, CS USEU, assisted in preparing the guide to EU officials.

The cooperation of officials at the Commission of the European Union and non-governmental organizations who have provided information and reviewed their respective sections is sincerely appreciated.

Brussels, Belgium 1995

ABSTRACT

Standards are a principal element of trade in general and a vital focus of the European Union's Single Market Program. The single market is one of the cornerstones of trade in the EU. This is an area without internal frontiers in which the free movement of goods, people, services and capital inside the European Community is ensured. The free movement of goods is covered by Articles 30 to 36 in the 1957 Treaty of Rome that established the European Economic Community.

The EU is creating harmonized, European-wide standards in key product sectors to replace the many thousands of differing national standards in member countries. The guide Standards Setting in the European Union, Standards Organizations and Officials in EU Standards Activities is designed to help U.S. manufacturers, exporters, government and private-sector standards interests locate contact points for important information on the development of standards and conformity assessment issues.

The guide includes a brief history of the role of standards in the European Union and the latest information on the EU's harmonization directives for implementing the "New Approach" and the "Global Approach" for harmonizing technical regulations and standards to reduce barriers to trade. The harmonization of standards is expected to lead to expanded trade within Europe as well as with other key markets, including the United States.

The standards guide also contains information on the three key European standards organizations that are mandated by the EU Commission to draft European technical standards; information on European testing and certification activities; and a list of EU officials with standards-related responsibilities. The appendices include a bibliography, an extensive list of standards-related publications and directories that are available from the National Institute of Standards and Technology (NIST); sources for ordering U.S. and European standards information in the United States and Europe; and contact points for standards-related information on the European Union in the United States.

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INTRODUCTION

The guide to Standards Setting in the European Union: Standards Organizations and Officials in EU Standards Activities provides information on the harmonization of standards in the European Union for U.S. manufacturers, exporters, government and private-sector officials and others with standards interests. The publication is a joint effort by the Commerce Department's Foreign Commercial Service at the U.S. Mission to the European Union, Brussels, and the National Institute of Standards and Technology, Gaithersburg, Md.

Information in the directory was obtained from interviews and documents provided by the EU Commission and major, key standards developing organizations in the EU: the European Committee on Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). These three organizations develop standards primarily to serve their members, but when mandated by the EU Commission, they are those competent to develop or adopt the harmonized standards needed technically to achieve conformity to the EU "New Approach" and "Global Approach" Directives.

The European Organization for Testing and Certification is listed in view of its prominent role in carrying out the EU Global Approach of 1989 to harmonize testing and certification procedures in the Single European Market.

Information also is included on the major organizations that develop the international standards which are promoted or adopted by EU standards organizations. These organizations are the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). The American National Standards Institute (ANSI) is the U.S. member of ISO, and ANSI sponsors the U.S. National Committee for the IEC.

The appendices include a list of EU New Approach Directives, a compilation of standards-related publications and information available from NIST, Gaithersburg, Md., a list of sources for ordering standards in the United States and Europe, and contact points for obtaining standards-related information on the European Union in the United States.

I Standards in the European Union

The European Economic Community (EEC) was created by the signing of two Treaties of Rome in 1957 that added two new communities to the European Coal and Steel Community established by the Treaty of Paris in 1951: the European Atomic Energy Community (EURATOM) and the EEC. Under a 1965 treaty, the communities were merged in 1967 into a single entity, referred to as the European Community or European Communities (EC).

After the Maastricht Treaty of 1991 was ratified in 1993 by all of the member nations, the European Community changed its name to the European Union (EU). The thrust of this treaty is "to promote a harmonious and balanced development of economic activities, sustainable and non-inflationary growth respecting the environment, a high-degree of convergence of economic performance, and to create an ever closer union among the peoples of Europe, where decisions are taken as closely as possible to the citizens."

The Union adopted provisions in its treaty to create EU citizenship, establish a common foreign and security policy, and set the goal of economic and monetary union, including a central bank and single currency.

The EU member countries in 1985 approved a plan that outlined 282 legislative proposals to create a "single market" by the end of 1992. This internal market is defined in the treaty as an area without borders, where people, merchandise, services and capital are free to circulate. The Single European Act of 1987 committed government leaders to adhere to the timetable and made passage of legislation easier.

At the end of 1993, 266 EU directives had been adopted by the EU Council of Ministers, the supreme legislative body. Over the course of years, the original 282 measures have been changed often. They now amount to 271 because some became obsolete and were abandoned or replaced, and still others were consolidated. By the end of November 1994, the EU member states had adopted 90 percent of the national measures required to implement the internal market legislation.

The European Commission, a body of Commissioners from the member states, will continue to monitor, enforce and assess the implementation of the internal market during its second phase. As the largest executive body of the EU, the Commission serves as guardian of the Treaty and sees to it that provisions of the Treaty and decisions of the institutions are correctly applied.

The European Union is the largest trading partner of the United States at more than \$210 billion annually. U.S. exports to the EU in 1994 amounted to approximately \$102.8 billion and U.S. imports from the EU were approximately \$110.8 billion.

Standards that describe the quality and performance of goods and services are critical in the development of the global marketplace. They provide a framework and common language for commerce and economic development worldwide.

Standards are a principal element of the European Union's Single Market Program. The EU is creating harmonized, European-wide standards in key product sectors to replace the many thousands of differing national standards. The goal of the EU legislative program is to free up the flow of goods, services, capital and people throughout the EU by eliminating differing national requirements among EU member states.

The European Union's Single Market is widely considered to be an opportunity for U.S. business. The U.S. Department of Commerce has made product standards, testing and certification a top priority with the EU in recognition of U.S. industry's concerns that the harmonization of several thousand EU product standards could become EU-wide non-tariff barriers to trade.

It is estimated that close to 50 percent, or \$50 billion, of U.S. exports to the EU are subject to harmonization requirements for regulated products. The International Trade Administration of the U.S. Department of Commerce recommends that businesses be aware of the layers of business law that coexist in the European Union as a result of new legislation for the EU Single Market that was created in 1992. But for the uninitiated, the EU can still be a little surprising. As in the United States, not all products are "regulated" in the sense that government intervenes to mandate how products are designed. Many products enjoy free circulation throughout Europe because governments have no requirements, and national voluntary product standards are increasingly giving way to European standards as the means for describing buyer requirements throughout the EU.

For regulated products, the EU Commission has set out the guidelines for harmonized European-wide standards in a number of directives, commonly known as "New Approach Directives." The harmonization of technical standards for regulated products is centered on the health and safety aspects of these products, and is intended to produce minimum safety and health levels throughout the Union.

Not all product requirements are "harmonized" -- as defined on an EU-wide basis. Non-harmonized products and sectors still exist where member state regulations remain as mandatory requirements. Gas connectors and analogue type telecommunications terminal equipment are examples of products

that still require national approvals. However, most products are harmonized.

The EU's Single Market successfully completed an 8-year program to eliminate most of the EU's 15 member states' technical barriers to trade by harmonizing the bulk of technical requirements and preempting any member state regulations for which an EU rule existed. For most regulated products, such as gas appliances, electrical applications, and telecommunications attachment equipment, the European Union created harmonized requirements.

The EU's Single Market is well known for the "New Approach" that includes harmonized directives, reference to voluntary European-wide standards and the CE mark. This is one of the key areas where the standards bodies described in this guide are pivotal in describing the detailed performance requirements for products. But in areas such as foods, drugs, automobiles and airplanes, the EU has relied on the "Old Approach." This is a form of harmonized legislation at the EU level that preempts some aspects of local member state authority, and describes detailed requirements in legislation without reference to additional voluntary standards and does not rely on any system of mark or marking.

The harmonized standards of the EU will be an important condition of sale and, in some cases, a legal requirement in Europe throughout the 1990's and beyond. The standards will reduce technical barriers to trade. Manufacturers will have to meet only one European-wide standard, rather than making costly changes to a product to meet 15 different national standards. The harmonization of standards is expected to lead to expanded trade within Europe as well as with other key markets, including the United States. Information on requirements for product testing is provided in the chapter on "European Union Harmonization Directives: the New Approach and the Global Approach."

Under the New Approach, the EU Commission mandates three key, regional European standards organizations to draft European technical standards. These organizations are the European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). Information on these organizations is in the chapter on "European Standards Organizations."

CEN, CENELEC and ETSI not only draft standards for the EU, they also develop standards to serve their European national member organizations. In addition, the European Organization for Technical Approvals (EOTA) provides technical assessments of the fitness of construction products.

The EU Commission, CEN and CENELEC have stated their intention to adopt and, wherever possible, implement the international standards of the International Organization for

Standardization (ISO) and the International Electrotechnical Commission (IEC). The EU wants to avoid duplicating efforts and use international standards to meet deadlines for EU standards development. The Commission has stated that CEN and CENELEC will develop their own standards only when international standards do not exist and are unlikely to emerge to meet EU needs.

The adoption of existing international standards by CEN and CENELEC is carried out under two agreements for technical cooperation between the European standards organizations and ISO and IEC. Under the Vienna Agreement of 1991, CEN and ISO agreed on the general exchange of information, cooperation on standards drafting between the two organizations, and the adoption of existing international standards as European standards.

The Lugano Agreement of 1991 between CENELEC and IEC, based on a 1989 formal collaboration on the exchange of information, emphasizes prompt adoption and publication of standards to meet the demands of industry. This agreement also has some of the same objectives as the Vienna Agreement between CEN and ISO.

The notion of "standstill" applies to European standardization when no new standards work will be initiated in the member states in areas where the EU Commission had identified an EU directive and the European standards bodies have begun developing EU-wide standards.

Under the new approach, CEN and CENELEC develop, in general, EU-wide standards for both the regulated and unregulated sectors. These standards are developed in various technical committees. Standards for products not regulated by the EU may still be developed at the national level; for unregulated products, mutual recognition of national standards applies.

In 1989, the Commerce Department and the Commission initiated a series of dialogues that increased the transparency of the European standards-making process and U.S. awareness of it. U.S. industry had argued that European manufacturers had an advantage over producers in other countries in obtaining information on standards development activities in the EU through their state standards bodies, which are members of CEN, CENELEC and ETSI.

Both CEN and CENELEC took steps to make better information available to everyone, for example, through the "CEN/CENELEC/ETSI Bulletin." The total work program of the standards organizations is transparent. If a U.S. company is based in Europe and is a member of a European trade federation or a national standards body, it may take an active role as part of the national delegation or federation to these bodies. It should also be noted that associate members of CEN, for example the European Computer Manufacturers Federation, have

rights of participation in both policy-making and technical committees.

For U.S. business, representation to CEN and CENELEC can be made by the American National Standards Institute (ANSI). ANSI is the U.S. member body to ISO and sponsors the U.S. National Committee for the IEC. U.S. parties may formally request meetings with the chair of CEN and CENELEC technical committees through ANSI. ISO and IEC may also nominate representatives to sit in CEN and CENELEC committees when there are working proceedings at both the European and ISO level.

Differences in testing and certification requirements in other countries frequently pose obstacles to U.S. exports. To help U.S. industry become more competitive, the U.S. Department of Commerce's International Trade Administration is conducting negotiations to conclude mutual recognition agreements (MRAs) with the EU in areas where the U.S. private sector has expressed interest.

The National Institute of Standards and Technology recently established the National Voluntary Conformity Assessment System Evaluation (NVCASE) program to facilitate the acceptance of U.S. products in international markets, such as the European Union, based on U.S. government recognition of the competence of qualifying U.S. conformity assessment bodies.

The NVCASE program may be applied to activities related to laboratory testing, product certification or quality system registration. NVCASE will evaluate and provide official recognition to bodies in the United States that effectively demonstrate that they satisfy established criteria and the applicable regulatory requirements of other countries. Acceptance by other governments of NVCASE recognition of a notified body will be subject to the terms of an MRA between the United States and the other government.

The European Union is also promoting the harmonization of testing and certification requirements. The EU Commission established the European Organization for Testing and Certification (EOTC) in 1990 under a memorandum of understanding (MOU) with CEN, CENELEC and the European Free Trade Association (EFTA) countries.

EOTC was formally established in 1992 as an independent, non-profit, international association. As mandated in the MOU, EOTC is to provide: "The appropriate framework for the non-regulatory sphere with regard to conformity assessment issues, whilst operating in such a manner as to give technical support to legislation of the Commission of the European Communities and EFTA countries regarding conformity assessment in the regulatory sphere." In 1992 the EFTA countries were Austria, Finland, Iceland, Liechtenstein, Norway, Sweden and Switzerland.

Recent MRA negotiations between the EU Commission and the United States, Canada, Australia and New Zealand have resulted in an increase in third country representatives inquiring how they may be more formally associated with EOTC. The U.S. National Voluntary Laboratory Accreditation Program at NIST is negotiating a multilateral agreement on testing with the European Cooperation for Accreditation Laboratories (EAL), a European member of EOTC.

II European Union Harmonization Directives:

The New Approach and the Global Approach

New Attitude to the Elimination of Trade Barriers

The single market is one of the cornerstones of the European Union. This is a geographic area without internal frontiers and where the free movement of goods, people, services and capital inside the European community is ensured. The free movement of goods is covered by Articles 30 to 36 in the 1957 Treaty of Rome that established the European Economic Community.

Article 30 states:

Quantitative restrictions on imports and all measures having equivalent effect shall, without prejudice to the following provisions, be prohibited between the Member States.

Article 36 provides ground for exemption from the obligation contained in Article 30:

The provisions of articles 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

The justification by member states for national regulations that created barriers to trade based on Article 36 has led to many legal cases before the European Court of Justice. The "Cassis de Dijon" (Case 120/78, judgement of 20-20-1979), is well known for its far reaching implications of the interpretation of Articles 30 to 36. The case involved an attempt by Germany to restrict French currant liqueur from entering its market.

The Court of Justice's decision stated:

- a) products legally manufactured or marketed in one country of the Community can in principle freely

circulate throughout the Community. Products manufactured in third countries and legally put on the market in one EU country, benefit from the same principle; and

b) barriers to trade which result from differences between national legislation can only be accepted if there is an overriding health, safety or environmental reason to prevent such trade circulation, and no alternative exists that would create less barriers to trade. Even then the regulations shall satisfy the requirement that there shall be causal relationship between the measure and its objective, and the regulation shall be "proportional" to the objective pursued.

Where national regulations, accepted on the grounds of the foregoing interpretation of Articles 30 to 36 give rise to barriers to intra-community trade, the barriers can only be eliminated by means of harmonization of the national regulations or "technical harmonization." Even in the absence of diverging national regulations, barriers to trade can exist due to the adoption of technical specifications by public authorities or independent standards bodies.

However, in order to overcome trade barriers, Article 100a of the Treaty of Rome states that if, after the adoption of a harmonization measure by the Council acting by a qualified majority, a member state deems it necessary to apply national provision on grounds of major needs referred to in Article 36, or relating to protection of the environment or the working environment, it shall notify the Commission of these provisions. In turn, the Commission shall confirm the provisions involved after having verified that they are not a means of arbitrary discrimination or a disguised restriction on trade between member states. The Commission or any member state may bring the matter directly before the Court of Justice if it considers that another member state is making improper use of the powers provided in Article 36.

In order to prevent the erection of new barriers to trade, the EU adopted Directive 83/189/EEC on March 23, 1983 (amended by Directive 88/189/EEC and 94/10/EEC), laying down two information procedures, one for standards and the other for technical regulations (mandatory standards) on industrial, agriculture, pharmaceutical, cosmetic and food products.

The standards information procedure requires each national standards body to inform the EU Commission and all other member state standardization bodies of its proposed draft standards or amendments to existing ones, except in the case of a transposition of an international (ISO/IEC) or European standard (EN). Each national standards-developing body publishes copies of its draft standards. In addition, each national standards body may take an active or passive role in the standardization work of another national standards

entity and is entitled to receive copies of drafts and learn what action is taken on the comments to the drafts, if any.

The technical regulations information procedure also obliges the member states to notify the EU Commission about any draft regulation and subsequent amendments, unless the regulation is an integral transposition of an international or European standard, in which case a simple note on the regulation is sufficient. This procedure gives the EU Commission and other member states an opportunity to study the proposed regulations and comment on their compliance with the principles in Articles 30-36 of the Treaty.

Under this procedure, a member state is required to refrain from adopting any draft technical regulation earlier than 3 months after the date of receipt by the EU Commission and the other member states. This procedure introduces the concept of "standstill."

If the other member states or the EU Commission deliver comments, the member state concerned may not adopt the draft regulation before the end of the 3-month standstill period. Other procedures require a member state to postpone the adoption of a draft by 4 months (draft in the form of a voluntary agreement) or six months (any other draft).

If the EU Commission wishes to propose or adopt a directive regulation or decision in the same area, or if the draft concerns a subject already covered by an EU Commission proposal, the member state concerned must suspend adoption of the draft for 12 months. If the Council adopts a common position during this period, the standstill period is extended by 6 months for a total of 18 months.

In absence of one of these responses, member states can adopt the draft legislation after the 3-month standstill period.

Directive 83/189/EEC also marked the beginning of a new attitude towards eliminating technical barriers to trade and the important role of standards. This led to the adoption of a resolution by the Council of the European Union, May 7, 1985, on "A New Approach to Technical Harmonization and Standardization."

In addition to the 15 EU member states, the provisions of the New Approach and the Global Approach also apply to signatory states of the European Economic Area (EEA), Iceland, Liechtenstein and Norway. The EEA Agreement was initiated in 1993 by six out of the seven countries of the European Free Trade Association (EFTA). The nations were Austria, Finland, Iceland, Liechtenstein, Norway and Sweden. Switzerland rejected the EEA Agreement in a referendum because it feared loss of its national identity. Austria, Finland and Sweden joined the EU in 1995.

New Approach to Technical Harmonization

The goal of the European Union's standardization program under the "New Approach" is to streamline technical harmonization and the development of standards for certain product groups. The program is called the "New Approach" because it differs significantly from the way European standards were drafted in the past. Under the "Old Approach," directives for the harmonization of standards by the member states contained such a high degree of detail on the technical specifications of products that it sometimes required 10 to 15 years to develop a standard. This harmonization process was so time-consuming and tedious that it allowed the member states to introduce national regulations and standards at a greater pace than the European Commission could handle, with an ever-increasing backlog of harmonization work.

Under the New Approach, directives are limited to essential safety or other performance requirements in the general public interest. The technical details of how to meet these requirements are left to manufacturers who self-certify products, the three regional European standards organizations, CEN, CENELEC, ETSI, and government appointed product certification bodies. The EU Commission gives mandates to these standards organizations to develop technical standards that are consistent with the essential safety and performance requirements of EU directives.

Products that meet the essential technical standards outlined by CEN, CENELEC and ETSI are presumed to conform to the requirements of EU directives and allowed to circulate freely within the European Union. For many products, a manufacturer can choose not to comply with the CEN/CENELEC/ETSI standards, but then must demonstrate that the product meets the essential safety and performance requirements of the directives. As a result of the new approach, a product manufactured in conformity with EU legislation in one member state will be guaranteed automatic access to the markets of all the other member states. U.S. manufacturers who comply with health and safety requirements in the New Approach Directives may affix the "CE Mark." The mark signifies that a product meets essential conformity assessment requirements and guarantees its legal access to all of the markets in the member states of the European Union. A discussion on the CE mark follows and a list of the adopted New Approach Directives is in Appendix A.

It is important to note that the "New Approach" deals with large families of products--machinery, gas appliances, pressure equipment, toys, and construction products--or "horizontal" risks such as those addressed in the EU's Electromagnetic Compatibility Directive, rather than being product-based as under the old approach. Some products may be governed by more than one directive because different risks may be dealt with under separate directives. The manufacturer

is responsible for ensuring the product meets the requirements for all applicable New Approach Directives.

EU directives are addressed to the member states, who then must transpose them into national law. The directives define a schedule for adopting and publishing national provisions to implement each directive. Directives also define when national provisions must be applied. New Approach Directives also recognize a transitional period during which existing national provisions and new legislation will co-exist. In such cases, the manufacturer may choose to following either of these series of conditions.

As noted, the "Old Approach" still remains in effect and covers a range of products covering automobiles, pharmaceuticals, foods, and aircraft. These products do not require the CE mark.

CE Mark

The European Commission describes the CE mark as a "passport" that allows manufacturers to circulate industrial products freely within the internal market of the EU. The letters, "CE"--French for "Conformite Europeene," indicate that the manufacturer has undergone all assessment procedures required for the product. Although consumers may perceive the CE mark as a quality mark, it is not. The CE mark addresses itself primarily to the national enforcement authorities of the member states, and its use simplifies the task of market surveillance of regulated products.

Products covered by New Approach Directives must bear a CE mark before they can be sold in the EU. Details on the use and affixing of the CE mark are spelled out in each of the New Approach directives. In 1993, in an effort to harmonize CE marking requirements across all of the New Approach Directives, the EU published Council Directive 93/68/EEC and Council Decision 93/465/EEC of July 22 1993 (OJ L 220, August 1993). Directive 93/68/EEC provides a consistent and harmonized approach to affixing and using the CE mark, while Decision 93/465/EEC lists the procedures for conformity assessment that are to be used in certifying compliance with the New Approach Directives.

The CE mark must be affixed to the product, to its data plate or, where this is not possible or not warranted on account of the nature of the product, to its packaging, if any, and to the accompanying documents by the manufacturer, the authorized representative in the community or, in exceptional cases, by those responsible for placing the product on the market. The CE mark must be affixed visibly, legibly and indelibly. Where special provisions do not impose specific dimensions, the CE mark must have a height of at least 5 millimeters. Depending upon the directive, in some cases the CE mark is followed by the identification number of

a notified body if such a body is involved in the production control phase of the product.

Currently, CE marking is only required under the New Approach Directives. In cases where more than one directive may apply (for example, machinery that is electrically operated), the CE mark can be affixed only if the product complies with the appropriate provisions of all applicable directives that have become mandatory. For instance, electrically operated machinery sold in the EU in 1996 would have to meet the requirements of the machinery and the electromagnetic compatibility directives, under which CE marking then will have become mandatory. Because the CE marking does not become mandatory under a related directive for low voltage until January 1, 1997, the CE mark on the product would not necessarily reflect compliance with that directive.

Just looking at the CE mark will not tell surveillance authorities to which directive a given product complies. Rather, it is the declaration of conformity that contains the details on the directives to which the product complies and the standards that were relied upon in assuring compliance.

Declaration of Conformity

The CE mark is not intended to include detailed technical information on the product, but there must be enough information to enable the inspector to trace the product back to the manufacturer or the authorized agent established in the EU. This detailed information should appear not next to the CE mark, but rather on the declaration (or certificate) of conformity, which the manufacturer or authorized agent must be able to provide at any time, along with the product's technical file. New approach legislation provides for the issue of a declaration of conformity by the manufacturer or sometimes it requires a certificate of conformity by an independent certification body.

Notified Bodies

Each New Approach Directive sets forth procedures to be followed for assessing conformity with its essential requirements. Generally, the method of compliance with the New Approach Directive is voluntary. This means that the manufacturer can choose how to comply with the conformity assessment options available with each directive. Many new approach directives require third-party certification before a manufacturer can affix a CE mark to a product; those third-parties must be **"Notified Bodies"**.

Notified bodies are independent testing houses or laboratories authorized by their governments to perform the conformity assessment tasks specified in directives. A notified body is appointed by a member state and must have the necessary qualifications to meet the testing requirements set

forth in a directive. The Commission and other member states must be informed about the authorization. Notified bodies may be private organizations or public entities. Manufacturers may choose a notified body in any EU member state. Lists of notified bodies are published by the European Commission in the "Official Journal of the European Communities."

Global Approach to Certification and Testing

The European Commission complemented the new approach to technical harmonization and standardization with a policy on harmonized rules and procedures for conformity assessment, "The Global Approach to Certification and Testing." Its objectives are contained in a Council Resolution of December 12, 1989 (OJ C 267, 1989). This policy also aims to establish conditions whereby mutual recognition agreements (MRAs) can be implemented that will permit the recognition of test results from a notified body by all of the member states or the acceptance of test results between two governments, such as between the United States and the European Union. The aim of such agreements is to enhance market access on a reciprocal basis by reducing the costs associated with demonstrating product conformity to regulations, testing and certification. The global approach can also be applied to conformity testing of non-regulated products.

III European Standards Organizations:

NAME OF ORGANIZATION: **European Committee for Standardization (CEN)**

Secretary General: Jacques Repussard
rue de Stassart 36
B-1050 Brussels, BELGIUM

Information and Communications Services:

Tel: (32 2) 519 6811

Fax: (32 2) 519 6819

Please note: CEN can be consulted for standards information. See Chapter V for information on EU legislation.

Background: The European Committee for Standardization (CEN), established in 1961, is a non-profit international association. CEN is responsible for creating European standards (ENs) in all areas except for electrotechnical and telecommunications. Standards in these areas are the responsibility of CENELEC and ETSI respectively. The aim of CEN is to eliminate trade barriers resulting from differing national technical standards to stimulate industry and trade and promote safety, economy and efficiency through the creation, harmonization and promotion of European standards.

Role in the harmonization of standards in the European Union: CEN is one of three officially recognized European standards organizations that can write standards for the Commission of the European Union under "New Approach Directives" that are the basis for the harmonization of standards in the EU's single market program as well as programs for research and development, transport, public procurement and others. The other recognized European standards developing organizations are CENELEC and ETSI. CEN also develops standards to serve its member organizations, trade, industry and European society in general.

Standardization Activities: CEN develops voluntary European Standards (EN) for mechanical engineering, building and civil engineering, health technology, information technology, biology and biotechnology, quality, certification and testing, environment, health and safety at the work place, gas and other energies,

transport and packaging, consumer goods, sports, leisure, food, materials (iron and steel), and chemistry.

CEN's administrative board concluded a technical cooperation agreement in 1991 with the International Organization for Standardization (ISO) that is aimed at securing the highest possible degree of identity between European and international standards to avoid the duplication of standardization work. Under the 1991 Vienna Agreement, CEN will work with its international partner to harmonize European and international standards to reduce technical barriers to trade within its sector. ISO may appoint representatives to CEN technical committees and vice versa.

Membership: The membership of CEN is made up of the national standards bodies of the EU member states and the EFTA countries. The member countries are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN affiliate members are the national standards organizations of Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Lithuania, Poland, Romania, Slovenia, and Turkey. The associate members are the European Trade Union Technical Bureau for Health and Safety (TUTB) and the European Construction Industry Federation (FIEC).

The 18 full members of CEN are obliged to issue the adopted European standards as national standards without modification and withdraw any conflicting national standards. Affiliate members are encouraged to adopt ENs as national standards but without the obligation to withdraw their conflicting national standards. However, affiliates are not allowed to modify an EN.

U.S. Access: CEN committees are not in general open to bodies outside of Europe. U.S. parties may formally request meetings with the chairs of CEN technical committees through ANSI. ISO and IEC also may nominate representatives to sit in CEN technical committees when there are working proceedings at both the European and ISO level.

Other Information: CEN normally issues its work as European standards (ENs), and it also issues Harmonization Documents (HDs), European Prestandards (ENVs) and CEN reports (HDs). CEN European standards are prepared in English, French and German. They also are translated into the national languages of CEN members as they are issued as national standards by member organizations.

CEN's technical publications may be purchased from its member organizations and from some ISO members outside of Europe such as ANSI in the United States. Draft European standards (prENs) are available normally in English, French and German at different stages of their preparation and are available from CEN member organizations as well as a number of ISO members outside of Europe such as the American National Standards Institute (ANSI) in the United States.

Copies of CEN Central Secretariat publications such as catalogs and the English language "CEN/CENELEC/ETSI Bulletin," which lists adopted standards and drafts, main decisions of principal policy-making bodies, mandates received and official citations, can be ordered from the Distribution and Sales Unit, CEN--Central Secretariat, rue de Stassart 36, B-1050 Brussels, Tel: (32 2) 519 6811,
Fax: (32 2) 519 6819.

CEN National Members

Austria

Osterreichisches Normungsinstitut/Austrian Standards Institute
(ON)

Postfach 130

Heinestrasse 38

A-1021 VIENNA

Tel: (43 1) 222 213 00

Fax: (43 1) 222 213 00 818

President: Dr. Karl Korinek

Managing Director: Dr. Ing. Gerhard Hartmann

Deputy Managing Director: Mr. Hans G. Stoklasek

Head PR and Communications: Dr. Johannes Stern

Tel: (43 1) 213 00 317

Fax: (43 1) 213 00 327

Belgium

Institut Belge de Normalisation/Belgisch

Instituut voor Normalisatie (IBN/BIN)

Avenue de la Brabanconne 29/ Brabanconnelaan 29

B-1040 BRUXELLES/BRUSSEL

Tel: (32-2) 734 9205

Fax: (32-2) 733 4264

Head: Mr. P. M. Croon

Denmark

Dansk Standard (DS)

Baunegaardsvej 73

DK-2900 HELLERUP

Tel: (45) 39 77 0101

Fax: (45) 39 77 0202

Managing Director: Mr. Jacob Erik Holmblad

Standardization and Head of Sales and Information Department:

Mr. Mogens Winther

Section Manager Electrical Engineering: Mr. Jan Roed

Section Manager Healthcare: Mr. Lars Brogaard

Section Manager Information, Technology and Logistics: Mr.
Hans Jorn Reuss

Section Manager Building, and Civil Engineering: Mr. Jorgen
Riis-Jensen

Certification Manager: Mr. Egon Hansen

Finland

Suomen Standardisoimisliitto/Finnish Standards Association
(SFS)

PO Box 116 (Maistraatinportti 2)

FIN-00241 HELSINKI

Tel: (358 0) 149 9331

Fax: (358 0) 146 4925

Internet: given name.surname@sfs.fi

Managing Director: Kari Kaartama

Director Standardization: Raija Relander

Director Certification: Eeva Parviainen
Chief Marketing: Satu Simula
Head System Certification: Stefan Fagerstrom
Public Relations Officer: Jyrki Alanko
Library: Seija Koskimaa
Environmental Labelling Expert: Matti Jarvi

France

Association Francaise de Normalisation (AFNOR)
Tour Europe
F-92049 PARIS-LA DEFENSE Cedex 7
Tel: (33 1) 42 91 5555
Fax: (33 1) 42 91 5656
President: Mr. Henri Marte
General Manager: Mr. Bernard Vaucelle
Deputy: Mr. Alain Durand
Public Relations/Communication: Mrs. Ghyslaine Pertusot
Manager Internat. and European Affairs: Mrs. Florence Nicolas
Manager Personnel and Human Resources: Mr. Gabriel Bacq
Manager Finance and Logistics: Mr. Daniel Geronimi
Manager Quality and Strategic Marketing: Mrs. Claude Merle
Manager Standards/Normative Strategy: Mr. Etienne Dupont
Manager Certification: Mr. Jacques Beslin
Manager Products/Services/Consulting: Mr. Bruno Dusollier

Germany

Deutsches Institut fur Normung (DIN)
Burggrafenstrasse 6
D-10787 BERLIN
Tel: (49 30) 26 010
Fax: (49 30) 26 01 1231
President: Mr. Eberhard Mollmann
Vice President: Gottfried Kremer
Director: Dr. Ing. Sc.D Helmut Reihlen
Deputy Director: Mr. Klaus Gunther Krieg
Technical Director for International Cooperation:
Mr. Ernst-Peter Ziethen
Technical Director for Technical Coordination and Planning:
Mr. Peter Kiehl

DIN's German Information Center for Technical Rules (DITR)
Information Inquiries: Tel: (49) 30 2601 2600
Euro-Info-Center: Tel: (49) 30 2601 2505

Greece

Hellenic Organization for Standardization (ELOT)
Acharnon Street 313
GR-111 45 ATHENS
Tel: (30 1) 2015 025
Fax: (30 1) 2020 776
President: Prof. G. Varoufakis
Tel: (30 1) 2234 966
Managing Director: N. Malagardis
Tel: (30 1) 2234 966
Promotion and Information: V.A. Filopoulos, Manager
Tel: (30 1) 2013 778

Standardization: D. Agapalidis, Manager
Tel: (30 1) 2019 891
Electrotechnical Standardization: Dr. P. Theofanopoulos,
Manager
Tel: (30 1) 2029 367
Testing Laboratories: K. Ionas, Manager
Tel: (30 1) 5247 117
Directive. 83/189/EEC and GATT: E. Melagrakis, Manager
Tel: (30 1) 2019 890

Iceland

The Icelandic Council for Standardization (STRI)
Technological Institute of Iceland
Keldnaholt
IS-112 REYKJAVIK
Tel: (354) 587 7000
Fax (354) 587 7409
Internet: stri@iti.is
Chairman: Mr. T. Karlsson
Secretary: Mr. J. Thorsteinsson

Ireland

National Standards Authority of Ireland (NSAI)
Glasnevin
Ireland DUBLIN 9
Tel: (353 1) 837 0101
Fax: (353 1) 836 9821
Head: Mr. E. Paterson

Italy

Ente Nazionale Italiano di Unificazione (UNI)
Via Battistotti Sassi, 11b
I-20133 MILANO
Tel: (39 2) 70 02 41
Fax: (39 2) 70 10 6106
Head: Dr. E. Martinotti

Luxembourg

Inspection du Travail et des Mines (ITM)
Boite postale 27
26, rue Ste Zithe
L-2010 LUXEMBOURG
Tel: (35 2) 478 6154
Fax: (35 2) 49 1447
Head: Mr. P. Weber

ITM's main role is to ensure the implementation of all legislative aspects related to the working conditions and contracts, health and safety at the workplace, etc. Due to the size of the country and owing to some industrial reasons, Luxembourg does not develop National Standards. For the implementation of European Standards, the procedure is executed by ITM.

The Netherlands

Nederlands Normalisatie-Instituut (NNI)
Postbus 5059
Kalfjeslaan 2
NL 2600 GB DELFT
Tel: (31 15) 690 255
Fax: (31 15) 690 130
Head: Mr. C. De Visser

Portugal

Instituto Portugues da Qualidade (IPQ)
Rua Jose Estevao, no. 83-A
P-1199 LISBON Codex
Tel: (351 1) 52 3978
Fax: (351 1) 353 0033
Head: Mr. C. dos Santos

Norway

Norges Standardiseringsforbund (NSF)
Postboks 7020
Homansbyen
N-0306 OSLO
Tel: (47 22) 46 6094
Fax: (47 22) 46 4457
Managing Director: Ivar Jachwitz
Technical Director: Liv Solhjell
Support/Services: Odd Bjornstad, Assistant Director
Assistant Director Information: Sidsel Aarnaes Arbo
Assistant Director Standards: Anne Kristoffersen
Assistant Director Marketing: Frederik Hilsen
Assistant Director Certification: Kirsten Svindahl

Spain

Asociacion Espanola de Normalizacion y Certificacion (AENOR)
Calle Fernandez de la Hoz, 52
E-28010 MADRID
Tel: (34 1) 310 4851
Fax: (34 1) 310 4976
Head: Mr. R. Naz Pajares

Sweden

Standardiseringskommissionen I Sverige (SIS)
PO Box 3295
Tegnergatan 11
S-103 66 STOCKHOLM
Tel: (46 8) 613 5200
Fax: (46 8) 411 7035
Director: Dr. L. Wallin
Head Technical Department: Mr. Anders Skold
Head Certification Department: Mr. Ivar Paljak
Head PR and Communications: Ms. Jannecke Schulman
Tel. (46 8) 613 5227
Fax (46 8) 10 8464

Switzerland

Schweizerische Normen-Vereinigung (SNV)

Muhlebachstrasse 54

CH-8008 ZURICH

Tel: (41 1) 254 5454

Fax: (41 1) 254 5474

Director: Dr. H.C. Zurrer

Information/Communication Manager: Mr. Heinz Kull

United Kingdom

British Standards Institution (BSI)

2, Park Street

UK LONDON W1A 2BS

Tel: (44 71) 629 9000

Fax: (44 71) 629 0506

Head: Sir Neville Purvis

Affiliate Members

Bulgaria

Committee for Standardization and Metrology
21, rue de 6 Septembre
BG-1000 SOFIA
Head: Mr. Y. Yordanov
Tel: (359) 2 85 91
Fax: (359) 2 80 1402

Czech Republic

Czech Office for Standards, Measurement, and Testing
Vaclavske Namesti 19
113 47 PRAGUE 1
Tel: (42 2) 242 247 34
Fax: (42 2) 242 247 26
President: Mr. Michal Tosovsky
Tel: (42 2) 242 166 88
Fax: (42 2) 242 282 90
Department of International Relations
Vice President: Mrs. Vaclava Horakova
Tel: (42 2) 236 57 06
Fax: (42 2) 242 297 54
Department of State Testing
Director: Mr. Vojtech Petrik
Tel: (42 2) 248 109 39
Fax: (42 2) 248 109 64
Department of Metrology
Director: Mr. Jiri Kraus
Tel: (42 2) 248 109 39
Fax: (42 2) 248 109 64

Cyprus

Cyprus Organization for Standards and Control of Quality (CYS)
Ministry of Commerce and Industry
CY-NICOSIA
Tel: (357 2) 30 3441/(357 2) 36 6185
Fax: (357 2) 36 6120
Chairman: Dr. G. Christodoulides
Director: Dr. I.G. Karis
Secretary: Mrs. Katherina Photiadou

Hungary

Hungarian Office for Standardization (MSZH)
25 Ulloi Ut
H-1450 BUDAPEST 9PF 24
Tel: (36 1) 118 3011
Fax: (36 1) 118 5125
Head: Mr. G. Ponyai

Lithuania

Lietuvos Standartizacijos/Luthianian Standardization Office
(LST)
A. Jaksto g. 1/25

2600 VILNIUS
Tel: (370 2) 226 962
Fax: (370 2) 226 252
Director: Mr. Brunonas Sickus
Tel: (370 2) 226 962
Deputy Director: Mr. Stasys Brencius
Tel: (370 2) 224 944

Poland

Polski Komitet Normalizacji/Polish Committee for
Standardization (PKNMIJ)
PO Box 10
PL-00-950 WARSAW
Tel: (48 2) 620 5434
Fax: (48 2) 620 5434
President: Mr. Marian Lukaszewicz
Tel: (48 2) 620 29 16
Fax: (48 2) 620 07 41
Vice-President: Mr. Andrzej Kocznorowski
Tel: (48 2) 620 6621
Fax: (48 2) 620 0741
Secretary: Mr. Krzysztof Trzcinski
Tel: (48 2) 620 2914
Fax: (48 2) 620 0741
Foreign Relations: Mr. Zygmunt Niechoda, Director
Tel/Fax: (48 2) 620 5434
Information and Documentation: Mrs. Jadwiga Bochinska,
Director
Tel/Fax: (48 2) 247 122

Romania

Institutul Roman de Standardizare
13, rue Jean-Louis Calderon
RO-70201 BUCAREST 2
Director General: Mihail Ciocodeica
Tel: (401) 611 40 43
Fax: (401) 312 08 23
Division of Standardization
Director: Mircea Petcu
Tel: (401) 615 58 70
Fax: (401) 210 08 33
Division of Certification, Accreditation, Notification of
bodies, Quality
Director: Claudiu Stefanescu
Tel: (401) 222 38 50
Fax: (401) 210 08 33
Division of Services, Consulting, Communication, International
Relations (ISO, CEN, CENELEC, ETSI, IEC, TERMNET)
Director: Daniela Moga
Tel: (401) 615 58 70
Fax: (401) 312 47 44
Division of Human resources, Finances, Accounting, Logistics,
Marketing
Director: Clementina Enciu
Tel: (401) 615 58 70
Fax: (401) 312 47 44

Division of the Secretariat of the National Center for
Training, Consultancy and Management in Quality Assurance
Director: Gabriela Anghelescu
Tel: (401) 222 38 60
Fax: (401) 210 08 33

Slovakia

Slovak Office of Standards, Metrology and Testing (UNMS)
Stefanovicova 3
81439 BRATISLAVA
Tel: (42 7) 491 085
Fax: (42 7) 491 050
President: Mr. Lubomir Sutek
Tel: (42 7) 491 085
Standards: Mrs. Kvetoslava Steinlova, Director
Tel: (42 7) 493 521
International Relations: Mr. Andrej Svatik, Director
Tel: (42 7) 494 728

Slovenia

Standards and Metrology Institute (SMIS)
Ministry of Science and Technology
Kotnikova 6
SI-61000 LJUBLJANA
Tel: (386 61) 131 23 22
Fax: (386 61) 314 882
Internet: ic@usm.mzt.si
Director: Mr. Bogdan Topic
Admin. and Legal Advice: Mr. Vitomir Fister, Assistant
Director
Standardization: Mr. Tone Pogacnik, Assistant Director
Metrology: Mr. Vasja Hrovat, Director
Accreditation: Mr. Bogdan Topic, Director
Type Approval Road Veh.: Mr. Miha Luckmann, Assistant
Director
Information Center: Mr. Dusan Zuzic, Advisor to the Director

Turkey

Turkish Standards Institution (TSE)
Necatibey Cad 112
TR-06100 ANKARA BAKANLIKAR
Tel: (90 4) 417 83 30
Fax: (90 4) 425 43 99
Head: Mr. M.Y. Ariyoruk

Associate Members

European Trade Union Technical Bureau for Health and Safety (TUTB)

Blvd. Emile Jacqmain 155
B-1210 BRUSSELS
BELGIUM

Tel: (32 2) 224 0560

Fax: (32 2) 224 0561

President: Mr. Fritz Verzetnitsch

Vice President: Mr Emilio Gabaglio

Director: Mr. Marc Sapir

Standards Research Officer: Mr. Jean-Jacques Gueant

Standards Research Officer: Mr. Vicente Verde Peleato

Information Officer: Ms. Janine Delahaut

Tel: (32 2) 224 0552

European Construction Industry Federation (FIEC)

avenue Louise 66

B-1050 BRUSSELS

BELGIUM

Tel: (32 2) 514 5535

Fax: (32 2) 511 0276

President: Dr. Ing Thomas Rogge

Director General: Mr. Ulrich Paetzold

Technical Affairs: Mr. John Goodall

NAME OF THE ORGANIZATION: **European Committee for
Electrotechnical Standardization (CENELEC)**

Secretary General: Stephen Marriott
rue de Stassart 35
B-1050 Brussels, BELGIUM

Standards Information:
Tel: (32 2) 519 6871
Fax: (32 2) 519 6919

Please note: CENELEC can be consulted for standards information. See Chapter V for information on EU legislation.

Background: CENELEC is a non-profit making international association established in 1972. The aim of CENELEC is to produce a single set of harmonized electrotechnical standards in Europe including those that support EU directives.

Role in the harmonization of standards in the European Union: CENELEC is one of three officially recognized European standards organizations that write standards for the Commission of the European Union under the "New Approach Directive" that is the guide for the harmonization of standards in the EU's single market program. The other organizations appointed by the Commission are CEN and ETSI.

Standardization Activities: CENELEC develops standards for the whole field of electrotechnical and electronic engineering where no International Electrotechnical Commission (IEC) standards are available. CENELEC works very closely with the Geneva-based IEC at the international level and transposes IEC documents with or without modification. CENELEC is linked to the IEC by the Lugano Agreement that was ratified by CENELEC's General Assembly in 1991. Under the agreement, CENELEC and IEC have agreed to exchange information aimed at harmonizing European and international standardization. In turn, some CENELEC standards have been adopted by the IEC.

Membership: The member countries of CENELEC are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. CENELEC has affiliate members from Poland, Romania, Slovakia and Slovenia.

U.S. Access: CENELEC committees are not open in general to bodies outside of Europe. U.S. parties may formally request meetings with the chairs of CENELEC technical committees through the American National Standards Institute (ANSI). ISO and IEC also may nominate representatives to sit in CENELEC committees when there are working proceedings at both the European and ISO level.

Other Information: CENELEC standards may be purchased from CENELEC members within their countries. The official versions of the standards are available in English, French and German, and in the relevant national languages of the member states. CENELEC standards also are available through IEC members outside of Europe such as the American National Standards Institute (ANSI) in the United States.

Information on CENELEC's activities, catalogs, and annual report are available from the CENELEC Central Secretariat, rue de Stassart 35, B-1050 Brussels, Tel: (32 2) 519 68 71, Fax: (32 2) 519 69 19.

CENELEC Member National Committees

Austria

Osterreichisches Elektrotechnisches Komitee (OEK)
beim Osterreichischen Verband fur Electro
Eschenbachgasse 9
A-1010 VIENNA
Tel: (43 1) 587 6373
Fax: (43 1) 56 7408
President: Dipl.-Ing. Helmut Hainitz
Gen. Sec.: Dipl.-Ing. Dr. H. Starker
Exec. Sec.: Mr. P. Rausch

Belgium

Comite Electrotechnique Belge (CEB)
Belgisch Elektrotechnisch Comite
(BEC)
Avenue Fr. Van Kalken 9
B-1070 BRUSSELS
Tel: (32 2) 556 0110
Fax: (32 2) 556 0120
President: M.R. Laurent
Administrateur delegue
NOVA Electro International
Overhamlaan 44
B-3700 TONGEREN
Tel: (32 12) 23 2986
Fax: (32 12) 26 2056
Secretary-General: M.J. Papier

Denmark

Dansk Standard(DS)/(Danish Standards Association)
Electrotechnical Sector
Baunegaardsvej 73
DK-2900 HELLERUP
Tel: (45) 39 77 0101
Fax: (45) 39 77 0202
Pres.: Mr. Niels W. Holm
Managing Director: Mr. Jacob Erik Holmblad
Standardization and Head of Sales and Information Department:
Mr. Mogens Winther
Section Manager Electrical Engineering: Mr. Jan Roed
Section Manager Healthcare: Mr. Lars Brogaard
Section Manager Information, Technology and Logistics: Mr.
Hans Jorn Reuss
Section Manager Building, and Civil Engineering: Mr. Jorgen
Riis-Jensen
Certification Manager: Mr. Egon Hansen

Finland

Finnish Electrotechnical Standards Association (SESKO)

Sarkiniementie 3
PO Box 134
FIN-00211 HELSINKI
Tel: (358 0) 696 391
Fax: (358 0) 677 059
President: Mr. Kalervo Rudanko
Vice President: Mr. Otso Kuusisto
Director: Mr. Tuomo Ilomaki
Information and Documentation Officer: Mrs. Pirkko
Taavitsaien

France

Union Technique de l'Electricite (UTE)
Location Address:
Immeuble Lavoisier
4, place des Vosges
La Defense 5-COURBEVOIE
Mailing Address:
UTE-Cedex 64
F-92052 PARIS-LA DEFENSE
Tel: (33 1) 46 91 1111
President: M.P.R. Sallebert
Director-General: M.J. Benoist
UTE, Approval Department, Tel: (33 1) 47 89 4587
UTE, All Services, Tel: (33 1) 47 89 4775
UTE, Standardization Department, Tel: (33 1) 46 91 1265

Germany

Deutsche Elektrotechnische Kommission im DIN und VDE (DKE)
Stresemannallee 15
D-60596 FRANKFURT/MAIN
Tel: (49) 69 630 80
Fax: (49) 69 631 2925
President: Mr. Gunter G. Seip
Direktor, Siemens AG
ASI 3 GWR
Siemenstrasse 10
D-93055 REGENSBURG
Tel: (49) 941 790 2252
Fax: (49) 941 790 2700
Teletex: 2627-9418128=Sie IBJR
Secretary: Dipl.-Ing. K. Orth

Greece

Hellenic Organization for Standardization (ELOT)
Acharnon Street 313
GR-111 45 ATHENS
Tel: (30 1) 2015 025
Fax: (30 1) 2020 776
President: Prof. G. Varoufakis
Tel: (30 1) 2234 966
Managing Director: N. Malagardis
Tel: (30 1) 2234 966
Promotion and Information: V.A. Filopoulos, Manager
Tel: (30 1) 2013 778
Standardization: D. Agapalidis, Manager

Tel: (30 1) 2019 891
Electrotechnical Standardization: Dr. P. Theofanopoulos,
Manager
Tel: (30 1) 2029 367
Testing Laboratories: K. Ionas, Manager
Tel: (30 1) 5247 117
Dir: 83/189/EEC and GATT: E. Melagrakis, Manager
Tel: (30 1) 2019 890

Iceland

The Icelandic Council for Standardization (STRI)
Technological Institute of Iceland
Keldnaholt
IS-112 REYKJAVIK
Tel: (354) 587 7000
Fax: (354) 587 7409
Internet: stri@iti.is
Chairman: Mr. T. Karlsson
Secretary: Mr. J. Thorsteinsson

Ireland

Electro-Technical Council of Ireland (ETCI)
ESB Office
Parnell Avenue
Harold's Cross
Ireland DUBLIN 12
Tel: (353 1) 454 5819/454 5820
Fax: (353 1) 454 5821
Chairman: Mr. S. Elmore
Personal Assistant: Ms. Lucie Quesnel-Brady
Admin.: Mr. J.P. Sheehan
Ballymun Road
Tel: (353 1) 837 6773
Fax: (353 1) 836 9821
Head Secretary: Mr. D. O'Regan

Luxembourg

Service de l'énergie de l'Etat
34, avenue de la Porte-Neuve
L-2227 LUXEMBOURG
Tel: (352) 46 9746-1
Fax: (352) 22 2507
Postal Address:
c/o Service de l'Energie de l'Etat
BP 10
L-2010 LUXEMBOURG
Director: M. Jean-Paul Hoffmann

The Netherlands

Nederlands Elektrotechnisch Comité (NEC)
Kalfjeslaan 2
Postbus 5059
NL-2600 GB DELFT
Tel: (31 15) 690 255
Fax: (31 15) 690 130

President: Mr. E. Ribberink,
Vice President, Euro Affairs
Holec Systems and Components BV
PO Box 23
NL-7550 AA HENGELLO
Tel: (31 74) 46 4880
Fax: (31 74) 46 42208

Vice-Presidents:
Prof. Ir. J.L. de Kroes
Mr. C. Ch. Smit
Director: Mr. T.D. Roodbergen
Tel: (31 15) 690 208
Fax: (31 15) 690 242

Norway

Norsk Elektroteknisk Komite (NEK)
Harbitzalleen 2A, Sky yen
Postboks 280
N-0212 OSLO 2
Tel: (47 22) 52 6950
Fax: (47 22) 52 6961
Telegrams NORWELCOM
Pres.: Mr. Knut Herstad
Tel: (47 7) 59 7200
Fax: (47 7) 59 7250
Director: Mr. B.I. Odegard

Portugal

Instituto Portugues da Qualidade (IPQ)
Rua Jose Estevao, no. 83-A
P-1199 LISBON Codex
Tel: (351 1) 52 3978
Telex: (404) 13042 QUALIT P
Fax: (351 1) 353 0033
Pres.: Mr. Candido dos Santos

Spain

Asociacion Espanola de Normalizacion y Certificacion (AENOR)
Comite Electrotecnico Espanol
Calle Fernandez de la Hoz 52
E-28010 MADRID
Tel: (34 1) 310 4851
Fax: (34 1) 310 4976
Chairman: Mr. I Tornos
IBERDROLA
Calle Claudio Coello 53
E-28010 MADRID
Tel: (34 1) 577 6565
Fax: (34 1) 577 0848
General Director: Mr. R. Naz
Secretary: Mr. V. Ruiz de Valbuena

Sweden

Svenska Elektriska Kommissionen (SEK)
Kistagangen 19

Box 1284
S-16428 KISTA STOCKHOLM
Tel: (46 8) 750 7820
Fax: (46 8) 751 8470
Chairman: Mr. M. Setterwall
Sveriges Elektroindustriforening
Box 5501
S-11485 STOCKHOLM
Tel: (46 8) 783 8164
Fax: (46 8) 663 6323
Vice Presidents:
Mr. G. Sandqvist
Mr. J. Nou
Managing Director and Secretary of the Swedish Committee of
IEC and CENELEC committees: Mr. Hans Erik Rundqvist

Switzerland

Swiss Electrotechnical Committee (CES)
Luppenstrasse 1
CH-8320 FEHRALTORF
Tel: (41 1) 956 1170
Fax: (41 1) 956 1190
President: Dr. Ing. Paul W. Kleiner
AWK Engineering AG
Leutschenbachstrasse 45
CH-8050 ZURICH
Tel: (41 1) 305 9511
Fax: (41 1) 305 9519
Secretary-General: Mr. R.E. Spaar

United Kingdom

British Electrotechnical Committee (BEC)
British Standards Institution (BSI)
2, Park Street
UK LONDON W1A 2BS
Tel: (44 71) 629 9000
Fax: (44 71) 629 0506
Chairman: Mr. Norman J.A. Holland
Consultant: Standards & Directives
Pinehaven, 94 Hiltingbury Road
Chandler's Ford, Hampshire SO5 1NZ
Tel: (44 0703) 27 0605
Fax: (44 0703) 27 0605
Secretary: Mr. I. Campbell

Affiliate Members

Poland

Polski Komitet Normalizacji/Polish Committee for
Standardization (PKNMiJ)
PO Box 10
PL-00-950 WARSAW
Tel: (48 2) 620 50434
Fax: (48 2) 620 5434
President: Mr. Marian Lukaszewicz
Tel: (48 2) 620 2916
Fax: (48 2) 620 0741
Vice-President: Mr. Andrzej Kocznorowski
Tel: (48 2) 620 6621
Fax: (48 2) 620 0741
Secretary: Mr. Krzysztof Trzcinski
Tel: (48 2) 620 2914
Fax: (48 2) 620 0741
Foreign Relations: Mr. Zygmunt Niechoda, Director
Tel/Fax: (48 2) 620 5434
Information and Documentation: Mrs. Jadwiga Bochinska,
Director
Tel/Fax: (48 2) 247 122

Romania

Institutul Roman de Standardizare
13, rue Jean-Louis Calderon
RO-70201 BUCAREST 2
Director General: Mihail Ciocodeica
Tel: (401) 611 4043
Fax: (401) 312 0823

Division of Standardization

Director: Mircea Petcu
Tel: (401) 615 5870
Fax: (401) 210 0833

Division of Certification, Accreditation, Notification of bodies, Quality

Director: Claudiu Stefanescu
Tel: (401) 222 3850
Fax: (401) 210 0833

Division of Services, Consulting, Communication, International Relations (ISO, CEN, CENELEC, ETSI, IEC, TERMNET)

Director: Daniela Moga
Tel: (401) 615 5870
Fax: (401) 312 4744

Division of Human resources, Finances, Accounting, Logistics, Marketing

Director: Clementina Enciu
Tel: (401) 615 5870
Fax: (401) 312 4744

Division of the Secretariat of the National Center for
Training, Consultancy and Management in Quality Assurance
Director: Gabriela Anghelescu
Tel: (401) 222 3860
Fax: (401) 210 0833

Slovakia

Slovak Electrotechnical Committee (SEV)/Slovak Office of
Standards, Metrology and Testing (UNMS)
Stefanovicova 3
81439 BRATISLAVA
Tel: (42) 7 491 085
Fax: (42) 7 491 050
President: Mr. Vladimir Adamec
Tel: (42) 7 496 847

Slovenia

Standards and Metrology Institute (SMIS)
Ministry of Science and Technology
Kotnikova 6
SI-61000 LJUBLJANA
SMIS is an affiliate of CEN, CENELEC and a member of ETSI
Director: Mr. Bogdan Topic
Admin. and Legal Advice: Mr. Vitomir Fister, Assistant
Director
Standardization: Mr. Tone Pogacnik, Assistant Director
Metrology: Mr. Vasja Hrovat, Director
Accreditation: Mr. Bogdan Topic, Director
Type Approval Road Veh.: Mr. Miha Luckmann, Assistant
Director
Information Center: Mr. Dusan Zuzic, Advisor to the Director
Tel: (386) 61 131 2322
Fax: (386) 61 314 882
Internet ic@usm.mzt.si

NAME OF THE ORGANIZATION: **European Telecommunications
Standards Institute (ETSI)**

Director: Karl Heinz Rosenbrock
650 route des Lucioles
F-06921 Sophia Antipolis CEDEX
FRANCE

Standards Information:
Tel: (33) 92 94 4200
Fax: (33) 93 65 4716

Please note: ETSI can be consulted for standards information. See Chapter V for information on EU legislation.

Background: ETSI is a non-profit organization whose mission is to determine and produce telecommunications standards for improving communications between the member countries of the European Union. It was established in March of 1988 to assume the standards writing activities of the European Conference of Postal and Telecommunications Administration (CEPT) to prepare for the European unified market. ETSI represents one of the largest international technical associations in the field of telecommunications and brings together an impressive array of expertise, all working together towards the ultimate goal of a universal information network.

Role in the harmonization of standards in the European Union: ETSI is one of three officially recognized European standards organizations that write standards for the Commission of the European Union under the "New Approach Directive" that is the guide for the harmonization of standards in the EU's single market program. The other organizations are the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC).

Standardization Activities: ETSI standards are produced under voluntary work programs and costed work programs. There are 11 technical committees and approximately 60 technical subcommittees and more than 140 working groups and rapporteur groups. These committees deal with standards for public and private telecommunications systems and equipment, local area networks, and other electronics equipment for government and consumers. By relating its work to developments on the global scene, ETSI also is helping to work towards establishing telecommunications standards worldwide.

ETSI has produced more than 4,000 voluntary standards since it was established. Many of these have been adopted by the Commission of the European Union as the technical basis for directives and regulations.

Membership: ETSI is an open forum that brings together 373 full members, 14 associate members and 71 observers from 30 European countries. ETSI members are from EU member national telecommunications administrations, manufacturers, public network operators, users and counsellors, and firms established within ETSI member states, albeit of foreign origin, are also ETSI members.

ETSI members are currently from Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom. Australia and Israel are associate members.

U.S. Access: ETSI has granted the United States and U.S. companies observer status.

Other Information: ETSI Standards are available in English, and global dissemination of its standards has been one of ETSI's top priorities. At the European level, ETSI has reached agreement with the national standards organizations of the European Standards Committee (CEN) and the European Electrotechnical Standards Committee (CENELEC) for the sale and distribution of documents. For information on ETSI standards, contact the ETSI Secretariat, 650 route des Lucioles, F-06921 Sophia Antipolis CEDEX, FRANCE, Tel: (33) 92 94 42 00, Fax: (33) 93 65 47 16.

IV Testing and Certification in the Single European Market

NAME OF THE ORGANIZATION: **European Organization for Testing and Certification (EOTC)**

Secretary General: David H. Stanger
Egmont House
rue d'Egmontstraat 15
B-1050 Brussels, BELGIUM

Information:

Tel: (32 2) 502 4141
Fax: (32 2) 502 4239

Background: The European Organization for Testing and Certification (EOTC) was established in 1990 under a memorandum of understanding (MOU) signed by the Commission of the European Union, the European Free Trade Association (EFTA), the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) to serve as the focal point in Europe for all issues relating to conformity assessment.

EOTC, as mandated by the MOU, is to provide the appropriate framework for the non-regulatory sphere with regard to conformity assessment issues, while operating in such a manner as to give technical support to legislation of the Commission of the European Communities and the EFTA countries regarding conformity assessment in the regulatory sphere.

EOTC is a non-profit organization which attained legal status under Belgian law in April 1993. EOTC operates under a General Assembly composed of an increasing number of representatives of all relevant interests from both the public and private sectors.

Role in Conformity Assessment: The role of EOTC as the focal point for conformity assessment in Europe is being achieved by actively encouraging the formation of Sectorial Committees through which it gives recognition to Agreement Groups composed of calibration or testing laboratories or certification bodies that operate in accordance with the internal regulations and relevant guidelines established by EOTC over the past 4 years.

Members: EOTC has 32 members, including 16 representatives of national conformity assessment communities and 16 European organizations. Each national member has documented rules of operation that demonstrate it is open to representation from all parties concerned with conformity assessment at the national level, notably

manufacturers, suppliers, users and consumers, conformity assessment practitioners, and public authorities. The national members are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Other Information: EOTC disseminates information on European testing and certification activities. It also coordinates pre-standardization work to complement or service EU Commission program. The EOTC Secretariat recently took over the management of the Testing, Inspection, Calibration, Certification and Quality Assurance database (TICQA Project) that was launched by Directorate General--III, Industrial Affairs of the European Commission in 1991. The database is an inventory of more than 10,000 entities, public and private, working in the areas of testing, inspection, calibration, certification and quality assurance in each member state of the European Union.

The TICQA Database is being updated and will be made public by the end of 1995 to those who have an interest in doing business in the single market. EOTC also is involved in the Conformance Testing Services Program to provide funding for suitable projects. EOTC has signed a Five-Year Framework Contract (1995-99 with the European Commission and the European Free Trade Association (EFTA).

V The European Commission:

Officials with Standards Responsibilities

Please note: European Commission Officials can be consulted for information on EU legislation. For standards information see Chapter III.

The European Commission is the executive body of the European Union which has, generally speaking, four main tasks: 1) to carry out the detailed implementation of decisions reached by the Council of Ministers; to exercise its powers of decision; to act as guardian of the EU treaties by investigating treaty breaches and by summoning offenders before the European Court of Justice; and to serve as the sole initiator of EU policies by making policy proposals to the Council of Ministers. In this chapter the names are listed of staff members responsible for standards related activities within the European Commission.

Directorate General (DG) III: Industrial Affairs

Postal Address:
rue de la Loi 200
1049 Brussels

Directorate A - Industrial Policy

Director: N/A

Advisors

Peter Lennon Tel: (32 2) 295 1226
 Fax: (32 2) 296 9852

Piero Squartini Tel: (32 2) 295 1486
 Fax: (32 2) 296 9852

1. Industrial Relations and International Technologies

Jean Michel Corre Tel: (32 2) 295 8822/296 5738
 Fax: (32 2) 296 6026

2. Industrial Cooperation

Petro Paolo Merolla Tel: (32 2) 295 7756/296 32 30
 Fax: (32 2) 296 9853

3. Competitiveness and Industrial Policy

Jean-Francois Marchipont Tel: (32 2) 295 7965/295 7928
 Fax: (32 2) 296 3028

4. Industrial Aspects of Structural Assistance (PEDIP)

N/A

5. Info Technologies and Telecoms Equipment

Michel Catinet Tel: (32 2) 296 9529

Fax: (32 2) 296 8867

**Directorate B
Regulatory Policies and Standards for Telematic Networks**

Evangelos Vardakas Tel: (32 2) 295 0296/295 0245
Fax: (32 2) 296 2893

1. Technical Legislation

David White Tel: (32 2) 295 5724/296 2877
Fax: (32 2) 296 0851

2. Standardization

Michel Audoux Tel: (32 2) 296 9539/296 9540
Fax: (32 2) 296 9500

3. Quality Policy, Certification, and Conformity Marking

Jacques McMillan Tel: (32 2) 295 2475
Fax: (32 2) 295 3877

4. Industrial Problems related to Environmental Regulations

Jaques Soenens Tel: (32 2) 295 1267/295 7716
Fax: (32 2) 296 0916

5. Networks and European Telematic Systems

Emile Peeters Tel: (32 2) 299 2246/299 22 47
Fax: (32 2) 299 0286

Directorate C - Industrial Affairs I

Pedro Ortun Silvan Tel: (32 2) 296 0391/295 2084
Fax: (32 2) 295 6515

Advisor

Reginald Spence Tel: (32 2) 295 5831
Fax: (32 2) 295 6515

1. Steel, Internal Market and Sectoral Structures

Giacomo Giacomello Tel: (32 2) 295 1268/295 1279
Fax: (32 2) 295 9800

2. Steel, External Measures

Jacobus Aarts Tel: (32 2) 295 4492/ 295 2267
Fax: (32 2) 295 6515

3. Raw and Advanced Materials

Vicente Leoz Arguelles Tel: (32 2) 295 1225/295 2511
Fax: (32 2) 295 6515

4. Chemicals, Plastics, Rubber

Gyorgy von O'Svath Tel: (32 2) 295 7074/295 2258
Fax: (32 2) 295 6515

Directorate D - Industrial Affairs III

Paul Weissenberg Tel: (32 2) 296 3358/295 3363
 Fax: (32 2) 296 1125

1. Mechanical and Electrotechnical Engineering

Luis Montoya Moron Tel: (32 2) 296 2592/295 4242
 Fax: (32 2) 296 6273

2. Pressure and Medical Devices, Metrology

Joseph Putzeys Tel: (32 2) 295 5956/295 1890
 Fax: (32 2) 296 1125

3. Construction

Karlheinz Zachmann Tel: (32 2) 295 4816/ 295 5718
 Fax: (32 2) 296 1065

4. Industry of Means of Transportation

Abraao Carvalho Tel: (32 2) 295 7397/295 7048
 Fax: (32 2) 295 6851

Directorate E - Industrial Affairs III

Guy Crauser Tel: (32 2) 295 5572/295 3049
 Fax: (32 2) 296 1027

1. Foodstuffs Legislation

Egon Gaerner Tel: (32 2) 295 3126/295 4661
 Fax: (32 2) 295 1735

2. Food-Processing Ind., Biotechnology

Kirtikumar Mehta Tel: (32 2) 295 7389/295 2871
 Fax: (32 2) 296 6265

3. Pharmaceuticals

N/A

4. Textiles and Clothing, Leather & Shoes, Furniture

Fabrizio Barbaso Tel: (32 2) 2295 6739/295 3940
 Fax: (32 2) 296 1027

5. Automobiles and other Road Transport

Richard Wright Tel: (32 2) 295 3397/295 6499
 Fax: (32 2) 296 9930

6. Public Electronics

Galway Johnson Tel: (32 2) 296 2342
 Fax: (32 2) 296 1027

Directorate F - RTD Actions: Information Technologies

George Metakides Tel: (32 2) 296 8067/296 8076
 Fax: (32 2) 296 8363

Principal Advisor

Attilio Stajano Tel: (32 2) 296 8067/296 8076
 Fax: (32 2) 296 8363

General Aspects & Coordination of Info. Technologies Programs

Claude Ouannes Tel: (32 2) 296 8048/296 8044
 Fax: (32 2) 296 8597

1. Coordination and Execution of Information Technology Programs

Bernard Libertalis Tel: (32 2) 296 8952/296 8953
 Fax: (32 2) 296 8597

2. Basic Research & Scientific Relations in the Info. Tech. Field

Simon Bensasson Tel: (32 2) 296 8066
 Fax: (32 2) 296 8390

3. Micro-Electronics

Horst Forster Tel: (32 2) 296 8057/296 8061
 Fax: (32 2) 296 1692

4. Logistics & Advanced Treatment of Information

David Edward Talbot Tel: (32 2) 296 8103/296 8102
 Fax: (32 2) 296 8364

5. Informatics Distributed at High Performance

Thierry Van Der Pijl Tel: (32 2) 296 8405/296 8105
 Fax: (32 2) 296 1692

6. Multimedia Systems & Application of Micro Processors

Rosalie Zobel Tel: (32 2) 296 8168/296 8144
 Fax: (32 2) 296 8387

7. Industry Technology

Patricia MacConaill Tel: (32 2) 296 8127/296 8121
 Fax: (32 2) 296 8365

Library/Documentation Center

Roger Prosperpio Tel: (32 2) 295 4930
 Fax: (32 2) 296 8597

Directorate General--V: Employment, Industrial Relations & Social Affairs

Directorate F - Health and Safety

William Hunter Tel: (352) 43 013 27 19/2708
 Fax: (352) 43 013 45 11

Directorate General--XII: Science, Research, and Development

Directorate C - R & TD Actions:

Industrial Technologies and Materials

Arturo Garcia Arroyo Tel: (32 2) 295 0013/296 1985
 Fax: (32 2) 295 8046

Joint Research Centre

Institute for Reference Materials and Measurements

Steenweg op Retie
B-2240 Geel
Belgium
Tel: (32 14) 57 1211
Fax: (32 14) 58 4273
Director: Werner Muller

Institutes of the Joint Research Centre:

Institute for Advanced Materials

Westerduinweg 3, Postbus 2
NL-1775 ZG Petten
The Netherlands
Tel: (31 22) 46 5656
Fax: (31 22) 46 1002
Director:

also:

I-21020 Ispra (VA)
Italy
Tel: (39 322) 78 9111
(39 322) 78 9889
Fax: (39 322) 78 90 01
Director: (N/A)

Environment Institute

I-21020 Ispra (VA)
Italy
Tel: (39 322) 78 9111
(39 322) 78 9889
Fax: (39 322) 78 90 01
Director: Bruno Versino (acting)

Institute for Safety Technology

I-21020 Ispra (VA)
Italy
Tel: (39 322) 78 9111
(39 322) 78 9889
Fax: (39 322) 78 9001
Director: Helmut Holtbecker

VI EU Member State Missions and Delegations to
the European Union, Brussels, Belgium

Austria

Industrial/Products: Alfred Komaz, Tel: (32 2) 741 21 51
Environment: George Rebernig, Tel: (32 2) 741 21 96

Belgium

Industry: Francois De Vleeschouwer, Tel: (32 2) 233 21 63
Standards: Chris Vanden Bilcke, Tel: (32 2) 233 21 11
Fax: (32 2) 231 10 75

Denmark

Industry: Leif Thomassen, Tel: (32 2) 233 08 22
Environment: Jeff Huntington/ Kim Christiansen,
Tel: (32 2) 233 08 22

Finland

Industry: Pakka Lindroos, Tel: (32 2) 287 84 11
Environment: Satu Nurmi, Tel: (32 2) 287 84 46
Tuiga Talsi, Tel: (32 2) 287 84 77

France

Industry: Jean-Francois Corallo/Henry Breuil,
Tel: (32 2) 229 84 04
Environment: Mme Laurence Auer, Tel: (32 2) 229 82 74

Germany

Industry: Hartwig Burghart, Tel: (32 2) 238 18 55
Environment: F. Petermann, Tel: (32 2) 238 18 58

Greece

Industry: Zachary Mavroukas, Tel: (32 2) 739 56 80
Environment: Athena Mourmouri, Tel: (32 2) 739 56 79
Fax: (32 2) 735 59 79, or (32 2) 739 56 71

Ireland

Industry: Paul Farrell, Tel: (32 2) 218 06 05, ext 242,
Fax: (32 2) 218 46 19
Environment: Mary O'Donoghue, Tel: (32 2) 218 06 05, ext 242,
Fax: (32 2) 219 43 36

Italy

Industry: Corrado Buresti, Tel: (32 2) 220 04 86
Fax: (32 2) 219 34 49
Environment: Clara-Maria Bisegna, Tel: (32 2) 220 04 96
Fax: (32 2) 220 04 94

Luxembourg

Industry: Jean-Marc Hoscheit
Environment: Jean Graff
Tel: (32 2) 735 20 60
Fax: (32 2) 736 14 29

Netherlands

Industry: Walter van Ditmars, Tel: (32 2) 679 15 16
Fax: (32 2) 679 17 92
Environment: Robert Milders, Tel: (32 2) 679 15 19
Fax: (32 2) 679 17 93

Portugal

Industry: Sergio de Fonseca, Tel: (32 2) 211 12 24
Environment: Jose' Carvalho, Tel: (32 2) 211 12 89
Fax: (32 2) 218 15 42 or (32 2) 218 14 59

Spain

Industry: Miguel Perez-Zarco, Tel: (32 2) 509 86 97
Environment: Carlos Emeno-Sanz, Tel: (32 2) 509 86 96
Fax: (32 2) 511 10 23

Sweden

Industry: Lennart Lindeborg, Tel: (32 2) 289 56 77
Environment: Suzanne Frigren, Tel: (32 2) 289 56 75

United Kingdom

Industry: Tom Davy, Tel: (32 2) 287 82 95
Adam Jackson, Tel: (32 2) 287 82 78
Environment: James Humphries, Tel: (32 2) 287 82 01
Fax: (32 2) 287 83 98

VII Other Country Missions and Delegations to the
European Union, Brussels, Belgium

Iceland

Industry: Harald Aspelund, Tel: (32 2) 219 90 90

Environment: Johann Benediktsson, Tel: (32 2) 219 90 90

Norway

Industry: Andreas Mortensen, Tel: (32 2) 234 11 65

Environment: Kiell Glomnes, Tel: (32 2) 234 11 48

Switzerland

Industry: Alois Ochsner

Environment: Michael Ambuhl

Tel: (32 2) 286 13 11

Fax: (32 2) 289 56 00

United States Mission to the European Union

40 Blvd. du Regent

B-1000 Brussels, Belgium

Tel: (32 2) 508 27 46

Fax: (32 2) 513 12 28

CS USEU PERSONNEL

Stephen C. Arlinghaus

Minister Counselor

Tel: (32 2) 508-2747

Gill Huyghe

Secretary

Tel: (32 2) 508-2746

Margaret A. Keshishian

Commercial Attache

Tel: (32 2) 508-2755

Helen Davis Delaney

Standards Officer

Tel: (32 2) 508-2674

Rene van de Zande

Commercial Specialist

Tel: (32 2) 508-2676

Eric Fleury

Commercial Specialist (Fisheries)

Tel: (32 2) 508-2769

Sylvia Mohr

Commercial Assistant

Tel: (32 2) 508-2675

Carol Proven

EC Tender Reporter

Tel. (32 2) 508-2677

VIII Non-Member International Standards Organizations

International Organization for Standardization (ISO)

rue de Varembe 1
CH-1202 Geneva
Switzerland
Tel: (41 22) 749 01 11
Fax: (41 22) 733 34 30

ISO/IEC Information Center:

Tel: (41 22) 749 02 22

ISO is a non-governmental international organization established in 1947. It is made up of national standards organizations of 90 countries (71 members and 19 corresponding members). The main function of ISO and its member bodies is to provide a forum for the standards making process, to approve standards by a set of procedures that ensure their validation and to publish them. This effort is aimed at facilitating the international exchange of goods and services and to develop cooperation in the sphere of intellectual, scientific, technological, and economic activity.

Membership: Participation is restricted to official representatives of members. There is only one member per country. The American National Standards Institute (ANSI) is the official U.S. member of ISO.

Other Information: ISO has published more than 7,500 international standards drafted by approximately 2,600 technical committees. The standards are available in English. The scope of these standards cover all fields except electrical and electronics engineering that are the responsibility of the International Electrotechnical Commission (IEC).

The ISO Information Network (ISONET) coordinates and systematizes the exchange of information on standards and standards-type documents by linking the information centers of ISO members and the information center of the General Secretariat. As the U.S. member of ISONET, the National Institute of Standards and Technology has access to information through the other ISONET members and the ISO information center in Geneva, Switzerland.

International Electrotechnical Commission (IEC)

rue de Varembe 3
CH-1211 Geneva
Switzerland
Tel: (41 22) 34 01 50
Fax: (41 22) 33 38 43

ISO/IEC Information Center:

Tel: (41 22) 749 02 22

Founded in 1906, IEC develops technical standards in the electrical and electronic engineering fields to promote international understanding. IEC standards are developed and promoted with the national committees from more than 50 countries. IEC and ISO form together the world's largest non-governmental system for voluntary industrial and technical collaboration at the international level.

Membership: The American National Standards Institute (ANSI) provides support to the U.S. National Committee for the IEC.

Other Information: IEC standards are available in English and French from IEC distributors such as the IEC National Committees.

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- Common Standards for Enterprises, Florence Nicolas with the Cooperation of Jacques Repussard, 1995, Office for Official Publications of the European Communities, L-2985 Luxembourg.

- Compliance Manual for Trade, The European Union Machinery Directive, James W. Kolka and Bruce McIntosh, Simcon, Inc., 1995.

Appendix A

New Approach Directives

The Official Jour. Pub. column refers to the date the adopted legislation was published in the Commission's Official Journal. The Adopt. Date column indicates date of adoption by the Council. The Entry Date column refers to the date by which the Member States of the European Union are supposed to have implemented the legislation (and thus is "in force"). The Trans. End (Transitional Period) column refers to the date until which CE Marking is optional for manufacturers.

The following "New Approach Directives" have been adopted:

1) **Low Voltage** - concerns electrical equipment designed for use within certain voltage limits.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
73/23/EEC	OJ L 77 of 26.3.1973, p.29	19.2.1973	18.8.1974	NA

2) **Simple Pressure Vessels** - first is Council Directive of 25.06.87 on the harmonization of the laws of the Member States relating to simple pressure vessels; second is Council Directive of 17.09.90 amending Directive 87/404/CEE on the harmonization of the laws of the Member States relating to simple pressure vessels.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
87/404/EEC	OJ L 220 of 8.8.1987, p.48	25.6.1987	1.7.1990	1.7.1992
90/488/EEC	OJ L 270 of 2.10.1990, p.25	17.9.1990	1.7.1991	NA

3) **Safety of Toys** - Council Directive of 03.05.88 on the approximation of the laws of the Member States concerning the safety of toys.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
87/378/EEC	OJ L 187 of 16.7.1988, p. 1	3.5.1988	1.1.1990	NA

4) **Construction Products** - Council directive of 21.12.88 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction projects.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
89/106/EEC	OJ L 40 of 11.2.1989, p.12	21.12.1988	27.6.1991	not fixed

5) **Electromagnetic Compatibility (EMC)** - first is Council Directive of 03.05.89 on the approximation of the laws of the Member States relating to electromagnetic compatibility; second is Council Directive of 28.04.92

amending Directive 89/336/CEE on the approximation of the laws of the Member States relating to electromagnetic compatibility.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
89/336/EEC	OJ L 139 of 23.5.1989, p.19	3.5.1989	1.1.1992	31.12.1995
92/31/EEC	OJ L 126 of 12.2.1992, p.11	12.7.1992	12.11.1992	NA

6) **Safety of Machines** - first is Council Directive of 14.06.89 on the approximation of the laws of the Member States relating to machinery; second is Council Directive of 20.06.91 amending Directive 89/392/CEE on the approximation of the laws of the Member States relating to machinery; third is Council Directive of 14.06.93 amending Directive of 14.06.93 amending Directive 83/392/EEC on the approximation of the laws of the Member States relating to machinery.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
89/392/EEC	OJ L 183 of 29.6.1989, p.9	14.6.1989	31.12.1992	31.12.1994
91/368/EEC	OJ L 198 of 22.7.1991, p.16	20.6.1991	1.1.1993	NA
93/44/EEC	OJ L 175 of 19.7.1993, p.12	14.6.1993	1.1.1995	31.12.1996

7) **Personal Protection Equipment** - Council Directive of 21.12.89 on the approximation of the laws of the Member States relating to personal protective equipment.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
89/686/EEC	OJ L 399 of 30.12.1989, p.18	21.12.1989	1.7.1992	30.6.1995
93/95/EEC	OJ L 276 of 9.11.1993, p.11	29.10.1993	29.1.1994	NA

8) **Non-automatic Weighing Machines** - Council Directive of 20.06.90 on the harmonization of the laws of the Member States relating to non-automatic weighing machines.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
90/384/EEC	OJ L 189 of 20.7.1990, p.1	20.6.1990	1.1.1993	1.1.2003

9) **Active Implantable Medical Devices** - Council Directive of 20.06.90 on the approximation of the laws of the Member States relating to active implantable medical devices.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
90/385/EEC	OJ L 189 of 20.7.1990, p.17	20.6.1990	1.1.1993	31.12.1994

10) **Appliances Burning Gaseous Fuels** - Council Directive of 29.06.90 on the approximation of the laws of Member States relating to appliances burning gaseous fuels.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
90/396/EEC	OJ L 196 of 26.6.1990, p.15	29.6.1990	1.1.1992	31.12.1995

11) **Telecommunications Terminal Equipment** - Council Directive of 29.04.91 on the approximation of the laws of the Member States concerning Telecommunication equipment, including the mutual recognition of their

conformity; second is Council Directive 29.10.93 supplementing Directive 91/263/CEE in respect to satellite earth station equipment.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
91/263/EEC	OJ L 128 of 23.5.1991, p.1	29.4.1991	6.11.1992	NA
93/97/EE	OJ L 290 of 24.11.1993, p.1	29.10.1993	1.5.1995	NA

12) **New hot-water boilers fired with liquid or gaseous fuels** - Council Directive of 21.05.92 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
92/42/EEC	OJ L 167 of 22.6.1992, p.17	21.5.1992	1.1.1994	31.12.1997

13) **Explosives for Civil Uses** - Council Directive of 5.4.93 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
93/15/EEC	OJ L 121 of 15.5.1993, p.20	5.4.1993	1.1.1995	31.12.2002

14) **Medical Devices** - Council Directive of 14.06.93 concerning medical devices.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
93/42/EEC	OJ L 169 of 12.7.1993, p.1	14.6.1993	1.1.1995	13.6.1998

15) **Rules for the affixing and use of the CE conformity marking** - Council Directive of 22.07.93 amending Directives: 87/404/EEC - simple pressure vessels, 88/378/EEC - safety of toys, 89/106/EEC - construction products, 89/336/EEC - electromagnetic compatibility, 83/392/EEC - machinery 889/686/EEC - personal protective equipment, 90/384/EEC - non-automatic weighing instruments, 90/385/EEC - active implantable medicinal devices, 90/396/EEC - appliances burning gaseous fuels, 91/263/EEC - telecommunications terminal equipment, 92/42/EEC - new-hot-water boilers fired with liquid or gaseous fuels, 73/23/EEC - electrical equipment designed for use within certain voltage limits, 93/68/EEC.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
93/68/EEC	OJ L 220 of 30.8.1993, p.1	22.7.1993	1.1.1995	NA

16) **Equipment for Explosive Atmospheres** - Council Directive of 23.03.94 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres.

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
	OJ L 100,1994		1.03.1996	30.06.2002

Appendix B

Contacts in the United States for Information on European Union Standards and Standards-Related Activities

Office of European Union and Regional Affairs

U.S. Department of Commerce
14th and Constitution Avenue, N.W., Room 3036
Washington, D.C. 20230
Tel: (202) 482-5276
Fax: (202) 482-2155

The Office of European Union and Regional Affairs (OEURA), part of the U.S. Department of Commerce's International Trade Administration, works to ensure that U.S. exporters maintain access to the West European market and to improve market access wherever possible. In carrying out this mission, OEURA develops policy, participates in negotiations, and provides information to U.S. businesses regarding legislative, regulatory and policy matters in Western Europe which might have an impact on U.S. exports to that region.

U.S. exporters have indicated that an important determinant of market access in Western Europe is access to timely information on European product standards, testing and certification requirements. Consequently, a significant portion of business counseling by OEURA staff involves providing the latest information on CE mark requirements, the New Approach directives and related standards, product certification under the "old approach," as well as other EU legislation and regulation. OEURA also serves as coordinator of the U.S. government effort to be tested and certified in the United States to European requirements, and vice versa.

OEURA staff members provide copies of directives, information on the availability of standards, lists of notified bodies, and interpretive guides, as well as information on tariffs, value added and other taxation requirements, and trade and economic data analysis. In addition to these general information services, OEURA also assists U.S. companies in overcoming specific trade barriers encountered in exporting to Europe, by serving as a link to contacts and resources in the EU and, where necessary, engaging in consultations or negotiations with EU officials.

National Center for Standards and Certification Information
(NCSCI)

National Institute of Standards and Technology
Bldg. 411, Room A163
Gaithersburg, MD 20899
(301) 975-4040
Fax: (301) 926-1559
e-mail: overman@micf.nist.gov

The Center, part of the Office of Standards Services, National Institute of Standards and Technology, serves as a referral service and focal point for standards-related information in the United States. NCSCI staff respond to inquiries concerning U.S., foreign, and international standards, technical regulations and conformity assessment procedures. There is no charge for the services.

The Center maintains an extensive reference collection of standards, specifications, test methods, codes and recommended practices as well as indexes, directories and other resource material. NCSCI has a comprehensive standards bibliographic CD-ROM database containing EU standards (CEN, CENELEC and ETSI) and directives. Copies of these documents are available on CD-ROM for review only (NCSCI does not provide copies of standards). The Center also subscribes to the Official Journal of the European Communities and maintains various EU-related publications.

NCSCI serves as the U.S. inquiry point in response to obligations resulting from the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement), the North American Free Trade Agreement (NAFTA), and the ISO Information Network (ISONET). The Center, with other national inquiry points, form networks - for WTO and ISO - that regularly exchange standards-related information. These networks also provide NCSCI with access to foreign trade-related technical standards, regulations and conformity assessment procedures.

Two hotlines are maintained by NCSCI to provide the latest information on proposed foreign technical regulations notified under the TBT Agreement (GATT Hotline - (301) 975-4041) and draft CEN and CENELEC standards (EC Hotline - (301) 921-4164). The recorded messages are updated weekly and are available 24 hours a day, 7 days a week.

An annual report and newsletter concerning NCSCI's TBT Agreement activities are published and are available upon request.

Delegation of the European Commission
2300 M Street, N.W.
Washington, D.C. 20037-1434

Tel: (202) 862-9500
Fax: (202) 429-1766

Information:

Tel: (202) 862-9539

Appendix C

PUBLICATIONS

Applications and Assistance Program
Office of Standards Services
National Institute of Standards and Technology
Gaithersburg, MD 20899

o 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.

o 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.

o 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'S 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.

o 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 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.

Order as PB 93-152080/AS from NTIS.

o More Questions and Answers on the ISO 9000 Standard Series and Related Issues (NISTIR 5122)

This report, a sequel to NISTIR 4721, provides additional information on the ISO 9000 standards and related issues to readers unfamiliar with some of the new developments in this area. It attempts to answer additional questions on ISO 9000 standards related issues which NIST has received since the publication of NISTIR 4721. It also identifies sources for further help in this area.

Order as PB 93-140689 from NTIS.

o 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 PB 89-221147 from NTIS or order as Cat. #SP767 from Global Engineering Documents.

o 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 PB 91-107599 from NTIS or order as Cat. #0258-3 from Global Engineering Documents.

o 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. NIST SP 806, a revision of NBS SP 681, covers activities related to both mandatory and voluntary U.S. standards. SP 806 also contains a subject index and related listings that cover acronyms and initials, defunct bodies and organizations with name changes. Order as PB 91-177774 from NTIS or order as Cat. #SP806 from Global Engineering Documents.

o 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. Order as PB 90-161712 from NTIS.

o 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 PB 88-201512 from NTIS.

o 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 PB 91-167379 from NTIS.

o 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 as PB 92-108968 from NTIS.

o Directory of Professional/Trade Organization Laboratory Accreditation/Designation Programs (NIST SP 831)

This directory is a guide to laboratory accreditation and similar types of programs conducted by professional and trade organizations. These programs accredit or designate laboratories or other entities to assist private sector professional societies, trade associations, related certification bodies, their membership, as well as government agencies, in carrying out their responsibilities. This accreditation or designation is based on an assessment of the capability of the laboratory to conduct the testing. However, the nature of the assessment varies considerably by organization and program.

Order as PB 92-181940 from NTIS.

To order publications contact:

National Technical Information Service (NTIS)

5285 Port Royal Road
Springfield, Virginia 22161, USA
Telephone: (703) 487-4650
Orders Only: (800) 553-6847
Fax: (703) 321-8547

Global Engineering Documents

15 Inverness Way East
Englewood, CO 80112-5704
Telephone: (800) 854-7179
(303) 792-2181
Fax: (303) 792-2192

Appendix D

Sources for U.S. and European Standards

The following U.S. organizations can provide copies of European standards.

<u>Organization</u>	<u>Information</u>
American National Standards Institute (ANSI) (the U.S. member body for ISO and IEC) Standards 11 West 42nd Street, 13th Floor New York, New York 10036, USA Telephone: (212) 642-4900 Fax: (212) 302-1286 (Orders Only) (212) 398-0023 Internet: http://www.ansi.org/home.html	ANSI and ANSI approved U.S. Industry International (ISO and IEC) and Foreign Standards and Draft ISO, CENELEC and CEN Standards
Global Engineering Documents (and Global Information Centers) 15 Inverness Way East Englewood, Colorado 80112-5704, USA Telephone: (800) 854-7179 (303) 792-2181 (202) 492-2860 (Washington, DC) Fax: (202) 331-0960 (303) 792-2192	U.S. Industry Standards Federal (FED), Military (MIL) and Department of Defense (DOD) Specifications and Standards/Handbooks International/Foreign/ European Standards and Documents Historical standards
Standards Sales Group (SSG) 20025 Highway 18 Apple Valley, California 92307-2639, USA Telephone: (619) 946-0500 Fax: (619) 946-2999	International and Foreign Standards, Publications and Other Reference Materials Select U.S. and Foreign Regulatory Compliance Information Translation Services
Document Center 1504 Industrial Way, Unit 9 Regulations 94002, USA Telephone: (415) 591-7600 Fax: (415) 591-7617 Internet: http://www.doccenter.com/doccenter and e-mail: doc@netcom.com	U.S. Industry Standards U.S. Federal Belmont, California DOD/MIL/FEDERAL standards/ specifications EC/International/ standards and documents

Note: The National Center for Standards and Certification Information, National Institute of Standards and Technology can provide additional sources for obtaining standards in the United States (see Appendix B).





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National Institute of Standards and Technology
Gaithersburg, MD 20899

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