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

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

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U.S. Department of Commerce Ronald H. Brown, Secretary

**Technology Administration**Mary L. Good, *Under Secretary for Technology* 

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The Honorable Stuart E. Eizenstat United States Representative to the European Union National Institute of Standards and Technology Special Publication 891 Natl. Inst. Stand. Technol. Spec. Publ. 891 72 pages (Sept. 1995) CODEN: NSPUE2 U.S. Government Printing Office Washington: 1995

For sale by the Superintendent of Documents U.S. Government Printing Office Washington, DC 20402 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, <u>Common Standards for Enterprises</u>

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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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 <u>Standards Setting in the European Union</u>, <u>Standards Organizations and Officials in EU Standards Activities</u> 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 it's 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 coexist. 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.

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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.

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Director General: Mr. Ulrich Paetzold Technical Affairs: Mr. John Goodall NAME OF THE ORGANIZATION: European Committee for Electrotechnical Standardization (CENELEC)

Secretary General: Stephen Marriott

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Standards Information:

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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 affilate 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.

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Director: Karl Heinz Rosenbrock

650 route des Lucioles

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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:

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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 quidelines 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.

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Environment: Mme Laurence Auer, Tel: (32 2) 229 82 74

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# 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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  Standardization, Certification and Mutual Recognition,
  Egide Jongen, European Commission DG III, January 1991.
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- o <u>EC Testing and Certification Procedures Under the</u>
  <u>International Market Program</u>, International Trade
  Administration, U.S. Department of Commerce, April 1993.
- o <u>Business Guide to EU Initiatives</u>, EU Committee of the American Chamber in Commerce, Winter/Spring 1994.
- o <u>EC Information Handbook, 1994/95</u>, The EC Committee of the American Chamber of Commerce in Belgium, April 1994.
- O <u>Product Standards Under the Internal Market Program</u>, International Trade Administration, U.S. Department of Commerce, March 1994.
- O <u>European Technical Legislation and Standardization</u>. A <u>Guide for Foreign Businessmen</u>, European Commission 1994.
- O <u>Guide to the Implementation of Community Harmonization</u>
  <u>Directives Based on the New Approach and the Global</u>
  <u>Approach</u>, First Version, European Commission 1994.

- o <u>EOTC Directory</u>, Subscriber Update, January 1995.
- o <u>US-EC Facts and Figures</u>, U.S. Mission to the European Union, 1995, Brussels, Belgium.
- O <u>Common Standards for Enterprises</u>, Florence Nicolas with the Cooperation of Jacques Repussard, 1995, Office for Official Publications of the European Communities, L-2985 Luxembourg.
- O 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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End
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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End 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.

  Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

  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.

  Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Official Jour. Pub.

Reference

Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End
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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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.

Reference Official Jour. Pub. Adopt. Date Entry Date Trans End

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 tarde 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 <u>Directory of International and Regional Organizations</u>
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 <u>Directory of European Regional Standards-Related Organizations</u> (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 <u>or</u> 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 <u>Directory of Private Sector Product Certification Programs</u> (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 <u>Directory of Federal Government Certification Programs</u> (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 <u>Directory of Federal Government Laboratory Accreditation/</u>
<u>Designation Programs</u> (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 <u>Directory of State and Local Government Laboratory</u> <u>Accreditation/ Designation Programs</u> (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 <u>Directory of Professional/Trade Organization Laboratory Accreditation/Designation Programs</u> (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.

# Organization

# Information

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

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

Standards Sales Group (SSG)

20025 Highway 18

Apple Valley, California 92307-2639, USA

Telephone: (619) 946-0500 Fax: (619) 946-2999

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

ANSI and ANSI approved U.S. Industry

International (ISO and IEC) and Foreign

Standards and Draft ISO, CENELEC and

CEN Standards

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

International and Foreign Standards, Publications and Other Reference Materials

Select U.S. and Foreign Regulatory Compliance Information

Translation Services

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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