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STANDARDS SETTING IN THE EUROPEAN UNION---

Standards Organizations and Officials in EU Standards Activities

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In April 1995, when European Commission Vice President Sir Leon Brittan, Commissioner Martin Bangemann, and the late 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
U.S. Representative to the European Union
September 1993--April 1996

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

---Florence Nicolas, *Common Standards for Enterprises*

For most U.S. businesses operating 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.

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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. Although this guide does not address technical regulations, exporters need to be aware of regulations that affect products in both the EU and member countries.

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*, NIST Special Publication 891, second edition, 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.

Special Publication 891, 1997 Edition, contains the latest information from the Commission of the European Union on the CE Mark for export products entering the EU market, declaration of conformity, constructing a technical file on product conformity, and the placement of a product on the Community market.

Information in the directory was obtained from interviews and documents provided by the EU Commission and major 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 deemed competent to develop or adopt the harmonized standards needed technically to achieve conformity to the EU "New Approach" and "Global Approach" Directives. The lists of CEN National Members and CENELEC Member National Committees have been updated and expanded with new information.

The European Organization for Testing and Certification (EOTC) 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

In 1957, the ratification of the two Treaties of Rome added two new institutions to the European Coal and Steel Community established by the Treaty of Paris in 1951: the European Atomic Energy Community (EURATOM) and the European Economic Community (EEC). Under a 1965 treaty, the Member States of Belgium, Germany, France, Italy, Luxembourg and the Netherlands were merged in 1967 into a single entity, referred to as the European Community or European Communities (EC).

The European Community was joined by Denmark, Ireland and the United Kingdom in 1973, by Greece in 1981, and by Spain and Portugal in 1986. Austria, Finland, and Sweden became the newest members when they joined on January 1, 1995.

After the Maastricht Treaty of 1991 was ratified in 1993 by all 12 of the member nations at that time, the European Community changed its name to the European Union (EU). The thrust of this treaty, which became known as the Treaty on the European Union, 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."

EUROPEAN UNIFICATION

European Community--1967

Belgium, Germany, France, Italy, Luxembourg
and the Netherlands

Denmark, Ireland and the United Kingdom--1973

Greece--1981

Spain and Portugal--1986

European Union--1993

Belgium, Denmark, Germany, Greece, France,
Ireland, Italy, Luxembourg, the Netherlands, Portugal,
Spain, and the United Kingdom

European Union--1995

Austria, Belgium, Denmark, Germany, Greece,
Finland, France, Ireland, Italy, Luxembourg,
the Netherlands, Portugal, Sweden, Spain, and
the United Kingdom

The Union adopted provisions in its treaty to create three "pillars": justice and home affairs policy; a common foreign and security policy; and the goal of economic and monetary union, including a central bank and single currency.

In 1985, the EU Member States adopted Commission measures that outlined 282 legislative proposals in order 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.

The EU is governed by three institutions: the European Commission, the Council of Ministers, and the European Parliament. The European Commission, a body of Commissioners from the Member States, proposes legislation and is responsible for ensuring its implementation; the Council of Ministers, the supreme legislative body comprised of the national leaders of the Member States, enacts legislation, sometimes in co-decision with the European Parliament; and the European Parliament, which has final approval of the EU budget, approves Commission appointees, and has powers of co-decision in certain areas. The European Parliament has been a democratically elected body since 1979.

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. In cases of non-compliance, the Commission has the power to levy fines or take recalcitrant Member States to the European Court of Justice if necessary.

The European Union is the largest trading partner of the United States with a total two-way trade of approximately \$256 billion in 1995. U.S. exports to the EU in 1995 amounted to approximately \$124 billion and U.S. imports from the EU were approximately \$132 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 \$60 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. For the uninitiated, the EU can still be a little surprising because of the harmonization effort. 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 product requirements 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, describes detailed requirements in legislation without reference to additional voluntary standards, and does not rely on any system of 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 Lugano Agreement was revised in 1996 in light of experience gained and is now known as the Dresden Agreement.

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 chairs 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 established the National Voluntary Conformity Assessment System Evaluation (NVCASE) program to recognize the competence of qualified accreditation bodies where such recognition

is required for the acceptance of U.S. conformity assessment results by foreign governments such as the European Union. The NVCASE program enables the U.S. Department of Commerce, acting through NIST, to evaluate and recognize competently conducted conformity assessment activities.

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.

EFTA was created in the 1950s when the EC and other western European countries made an attempt to establish a free trade area. Even though this effort failed, Austria, Denmark, Norway, Portugal, Sweden, Switzerland and the United Kingdom strengthened their ties and founded EFTA in 1960. Following the departure of Austria, Denmark, Finland, Portugal, Sweden and the United Kingdom to the EU, EFTA's membership now includes Iceland, Liechtenstein, Norway and Switzerland. Relations with other countries have been expanded and EFTA now has formal agreements or declarations of cooperation with 17 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 working towards a bilateral agreement on testing and calibration with the European cooperation for Accreditation of 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 provisions 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 Directives 88/182/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.

It is important to note that the European Community and its member states are members of the World Trade Organization. The WTO Agreement on Technical Barriers to Trade (TBT) also requires notification of proposed technical regulations to other WTO members including the United States.

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 6 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.

The EEA was established in 1989. The president of the EU Commission had invited EFTA countries to consider different ways to strengthen relations with the European Community. This resulted in an agreement between the EC and EFTA to consider cooperation through the establishment of an 18 member European Economic Area in which all goods, capital, services and people would be allowed to move freely.

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. Both U.S. and European 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. A directive is authorized when it has been published in the *Official Journal of the European Communities*. 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 including 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 (surveillance) 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. (See Appendix B for information on conformity assessment procedures under EU Community legislation).

The Commission has developed several standard modules for these procedures to test products by the manufacturer or to have them tested by a third party. Each directive will indicate which module or modules (manufacturers can have a choice) are applicable. Information on the "Rules for Affixing and Use of the CE Conformity Marking" are in Appendix A--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. The CE mark become mandatory under a related directive for low voltage on January 1, 1997.

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.

Before the CE mark can be affixed to the product, the manufacturer must follow certain procedures. These procedures may differ for each directive and each product. The following procedures may be applicable: declaration of conformity (manufacturer's declaration); compiling a technical construction file; applying for and filing an EC Type-examination certificate; compiling a user manual; and affixing the CE mark.

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 representative established in the EU. This detailed information should appear not next to the CE mark, but rather on the declaration (or certificate) of conformity, also known as the "manufacturer's declaration," which the manufacturer or authorized representative or importer 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.

The declaration of conformity must contain the following information: product identification; the European Union directives complied with; standards used to verify compliance with the directives; name of notified body if required by the directive; be signed by or on behalf of the manufacturer or the authorized representative and identify that signatory; and the manufacturer's name and address.

Technical File-Product Construction and Design

Most of the New Approach Directives impose an obligation for the manufacturer to draw up and to provide a technical file containing the technical basis to demonstrate the conformity of the product to the requirements of the directive. The file is intended essentially for national inspection authorities. The European Commission proposes that national inspection authorities accept the subdivision of the technical file into two parts:

1. The first part (A) consists of a summary of the essential technical data relevant to the conformity assessment procedures, including:
 - the name and the address of the manufacturer and the identification of the product;
 - the list of harmonized standards followed by the manufacturer and/or the solutions adopted to satisfy the essential requirements;
 - a description of the product;
 - the operating instructions, if any; and
 - the overall plan of the product, if any.
2. The second part (B) consists of a full file containing all of the test reports, information concerning the quality manual, plans, descriptions of the products and processes, standards applied, testing results, etc.

The technical construction file must be kept at the disposal of the national authorities for inspection and control purposes. This obligation to keep at least one technical file within the Community starts at the time of placing the product on the Community market whatever the geographical origin of the product. If the manufacturer is not established in the Community and has no representative in the Community, the person who places the product on the Community market must take on this obligation. The file must be stored for at least 10 years. Any person responsible for placing a product on the Community market but not in possession of the technical construction file must be capable of (1) stating where the file is situated inside the Community; and (2) presenting the file as soon as possible on request from national authorities.

If national inspection authorities request the technical construction file, the first part (A) should be available immediately, allowing a reasonable time for transmission. Extra time should be granted for submission, if required, of the second part (B) of the file. Member States must ensure that everyone involved in the assessments, inspections and surveillance and who has knowledge of the contents of the technical construction file is bound to professional secrecy.

EC Type-Examination Certificate and 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.**" After approval, the notified body issues an EC Type-Examination Certificate.

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." A list of notified bodies also is available in the United States from the Office of European Union and Regional Affairs (see Appendix C).

Manufacturer, Authorized Representative, Importer or Person Responsible for Placing Product on the Market

Manufacturer:

The manufacturer is the person responsible for designing and manufacturing a product covered by the directive, with a view to placing it on the Community market on his own behalf. The manufacturer may be based in the Community or elsewhere. In either case, the manufacturer may appoint an authorized representative, who must be established in the Community, to act on his behalf.

The manufacturer is responsible for designing and manufacturing the product in accordance with the essential requirements laid down by the directive and following the procedures for certification of conformity of the product with the requirements of the directive in questions.

The manufacturer may subcontract some of these operations, including the design, if he physically manufactures the product, or the manufacture, if he designs it, provided he retains overall control and responsibility.

In principle, the manufacturer may employ ready-made parts or components in the product, without affecting his status as manufacturer.

Any maker of a new finished product from existing finished products is regarded as the manufacturer of the new product.

Anyone who changes the intended use of a product is regarded as the manufacturer of that product and, as such, remains subject to the requirements which the directive in question places on manufacturers and assumes responsibility accordingly.

Anyone who imports a used product from a third country with a view to bringing it into line with the essential requirements of the directive in question must comply with the requirements imposed on manufacturers by that directive and assumes responsibility accordingly.

Authorized Representative:

The authorized representative is a person appointed by the manufacturer to act on his behalf in carrying out certain tasks required by the directive, which have been delegated to him by the manufacturer. All authorized representatives appointed by the manufacturer must be established in the Community in order to be able to act on the manufacturer's behalf under the terms of the directives. The manufacturer delegates these tasks in writing to the authorized representative, spelling out the manufacturer's obligations under the directives for which he is delegating responsibility to his authorized representative. Responsibility for actions lies with the manufacturer and not with the authorized representative.

The importer or person responsible for placing on the market is any person who places on the Community market a product from a third country, which is covered by the directive. Unlike the authorized representative, the importer has no preferential relationship with a manufacturer in a third country. Therefore, if neither the manufacturer nor his authorized representative is based in the Community, the directive may stipulate which tasks are to be carried out by the importer. In that case the importer is responsible under the terms of the directives for placing the product he imports on the Community market. In this capacity he must keep the technical file and the manufacturer's declaration of conformity available for examination by the supervisory authorities.

Placing a Product on the Market:

The initial action of making a product available on the Community market, for payment or free of charge, is covered by the directive, with a view to distribution and/or use in the Community. "Placing on the market" means the moment when the product first passes from the stage of manufacture within the Community to the stage of distribution and/or use on the Community market. Since placing on the market refers only to the first time that the product is made available on the Community market for distribution or use in the Community, the directives apply only to new or refurbished products manufactured in the Community and to new or refurbished or used products imported from a third country.

Products may be placed on the Community market by the manufacturer, his authorized representative in the Community or by the importer of the product.

“Making a product available” means either:

- transfer of a product, that is, either the transfer of ownership, or physical hand-over of the product by the manufacturer, his authorized representative in the Community or the importer to the person responsible for distributing the product on the Community market or the passing of the product to the final consumer or user in a commercial transaction, for payment or free of charge, regardless of the legal requirement on which the transfer is based (sale, loan, hire, leasing, gift, or any other type of commercial legal instrument). The product must comply with the directive at the moment of transfer; and
- the offer of transfer, in cases where the manufacturer, his authorized representative in the Community or the importer, makes a product available; in his own commercial distribution chain with a view to direct transfer to the final consumer or user. The product must comply with the directive from this point onwards.

The following are not considered placing a product on the market:

- transfer of the product from a manufacturer in a third country to his authorized representative in the Community whom the manufacturer has made responsible for completing the procedures required to ensure that the product conforms in the directive in order to place it on the Community market;
- import into the Community with a view to re-export, for example, under processing arrangements;
- transfer of a product manufactured within the Community with a view to export to a third country; and
- display of the product at fairs and exhibitions.

In the absence of express rules on inventories in the directive in question, the storage of a product by the manufacturer or the importer does not constitute placing a product on the market.

Placing a product on the market refers to each individual product which is covered by the directive in question and which exists physically and in finished form, regardless of when and where it was manufactured, and whether it was produced individually or as part of a batch. The directives may contain express rules concerning components or products designed to be assembled or incorporated in a product covered by the directives.

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)**

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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. 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) 550 08 11, Fax: (32 2) 550 08 19.

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Technical Commission: Mr. John Goodall
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Fax: (32 2) 511 02 76
Internet: FIEC_BRU@MCR1.POPTEL.ORG.UK

Note: The role of the Technical Commission within FIEC is essentially three fold: (1) to monitor developments related to the Construction Products Directive (CPD) and its implementation; (2) to follow up activities in the field of standardization, especially in the European Committee for Standardization (CEN) and the European Organization for Technical Approvals (EOTA), and; (3) monitor developments in the field of Quality Assurance and Quality Management Systems (which are themselves also based on standards) in so far as they affect the construction industry.

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

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Vice President: Mr Emilio Gabaglio

Director: Mr. Marc Sapir

Standards Research Officer: Mr. Vicente Verde Peleato

Information Officer: Ms. Janine Delahaut

Tel: (32 2) 224 05 52

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

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

Standards Information:

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Fax: (32 2) 519 69 19
e-mail: cenelec@cenclcbel.be

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 has been linked to the IEC since the Lugano Agreement was ratified by CENELEC's General Assembly in 1991. This agreement was revised in light of experience gained and is now known as the Dresden Agreement. It was approved by IEC and CENELEC in September 1996. The agreement is intended:

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

It is important to note that CENELEC members are directly involved in the planning of new work in the IEC in their capacity as IEC members. Both parties are committed to exchange information aimed at harmonizing European and international standards. 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 is 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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c/o Oesterreichischen Verband fur Elektrotechnik
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Fax: (43 1) 586 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)
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B-1070 BRUSSELS
Tel: (32 2) 556 01 10
Fax: (32 2) 556 01 20
President: Mr. R. Laurent
Administrateur Delegee
NOVA Electro International
Secretary-General: Mr. J. Papier

Denmark

Dansk Standard(DS)/(Danish Standards Association)
Electrotechnical Sector
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Managing Director: Mr. Jacob Erik Holmblad
Standardization and Head of Sales and Information Department:
Mr. Henrik Hougs
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
Section Manager Mechanical Engineering: Mr. Jorgen Hageland
Certification Manager: Mr. Egon Hansen

Finland

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Sarkiniementie 3

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Vice President: Mr. Otso Kuusisto

Director: Mr. Tuomo Ilomaki

Information and Documentation Officer: Mrs. Pirkko Taavitsainen

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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

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Director: Dipl. -Ing. Karl-Ludwig Orth

Note: Within DKE, two National Committees assure collaboration with IEC and CENELEC, respectively:

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Secretary: Dipl. -Ing. Karl-Ludwig Orth

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Metrology: Mr. Vasja Hrovat, Director

Accreditation: Dr. Samo Kopac, Assistant Director

Type Approval Road Veh.: Mr. Miha Luckmann, Assistant Director

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

Director-General: Karl Heinz Rosenbrock
650 route des Lucioles
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FRANCE

Standards Information:

Tel: (33) 4 92 94 42 00
Fax: (33) 4 93 65 47 16
e-mail: secretariat@etsi.fr

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 or funded work programs. There are 11 technical committees and approximately 60 technical subcommittees and more than 140 working groups and rapporteur or reporting 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) 4 92 94 42 00, Fax: (33) 4 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
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Information:

Tel: (32 2) 502 41 41
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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 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 programs. In 1995, the EOTC Secretariat 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. There was 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. After careful review, it now can be reported that the TICQA database currently includes 2024 entries representing operators from all 19 member states. The database will be expanded after a review of potential entrants. Information on the TICQA database is available via e-mail: ticqa@eotc.be. General information on EOTC is available on the World Wide Web via the Internet at <http://www.eotc.be/>.

EOTC is also 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 Commission officials responsible for the New Approach Directives are listed in Appendix A.

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; 2) to exercise its powers of decision; 3) to act as guardian of the EU treaties by investigating treaty breaches and by summoning offenders before the European Court of Justice; and 4), 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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VIII United States Mission to the European Union

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The U.S. Mission to the European Union is headed by the U.S. Representative to the EU. The representative is responsible for the conduct of relations between the United States and the Institutions of the European Union, including the European Commission, the European Council, the European Parliament, and the Court of Justice.

The staff of the U.S. Mission to the European Union includes representatives from the Departments of State, Agriculture, Treasury, the Office of the U.S. Trade Representative, the U.S. Information Agency, the U.S. Customs Service, the Department of Justice, the U.S. Agency for International Development, and the Department of Commerce which is represented through its U.S. and Foreign Commercial Service.

The Commercial Service at the U.S. Mission (CS/USEU) is part of a cohesive team of domestic and overseas offices working for U.S. business. CS/USEU counsels U.S. businesses on a variety of EU regulatory issues including standards, testing and certification. CS/USEU assists in identifying European and international product standards applicable to prospective U.S. exports and raises issues of standards incompatibility with appropriate EU officials and European and international standards, testing and certification bodies.

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IX Non-Member International Standards Organizations

NAME OF THE ORGANIZATION: **International Organization for Standardization (ISO)**

Secretary General: Lawrence D. Eicher
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CH-1202 Geneva, SWITZERLAND

ISO/IEC Information Center:

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e-mail: central@isocs.iso.ch

Background: ISO is a non-governmental international organization established in 1947. It is made up of national standards organizations of 120 countries (84 members, 27 corresponding members, and nine subscribers). The mission 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 spheres 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) is a network of standards information centers, usually located in the national standards body member of ISO. This network also includes the ISO/IEC Information Center. The centers have agreed to make information on standards, technical regulations and related matters readily available to interested parties. They also provide a means for the exchange of standards-related information. 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/IEC Information Center in Geneva, Switzerland.

NAME OF ORGANIZATION: International Electrotechnical Commission (IEC)

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ISO/IEC Information Center:

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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.

Under IEC procedures, each member country of the International Electrotechnical Commission must be represented by a national committee that represents all of the major electrical and electronic interests in the country. Within the United States, the U.S. National Committee of the IEC (USNC/IEC) is the national body responsible for U.S. participation in IEC. Since 1931, the USNC/IEC has been affiliated with the American National Standards Institute. The USNC/IEC is a standing committee of ANSI reporting to the ANSI Board of Directors.

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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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 the CE Marking is optional for manufacturers.

Note that the particular Directorate-Generals and Commission Officials responsible for these directives are listed as contact points.

The following "New Approach Directives" have been adopted:

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

Jean-Yves Boeswillwald, DG III/D/1 Tel: (32 2) 296.52.60 Fax: (32 2) 296.62.73

<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.

Rainer Manfred Schwemmler, DG III/D/2 Tel: (32 2) 295.53.05
Alick Morris, DG III/D/2 Tel: (32 2) 296.18.00 Fax: (32 2) 296.62.73

<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.

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Christiane Specht, DG XXIV/04 Tel: (32 2) 295.79.84 Fax: (32 2) 299.18.56

<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 products.

Philippe Jean, DG III/D/3

Tel: (32 2) 295.05.39/ 295.59.93
Fax: (32 2) 296.10.65

<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.

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<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.

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<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.

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<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.

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<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
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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.

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

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

Alain Jaume, DG XIII/A/02

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

Armand Colling, DG XVII/C/2

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

Eduardo Martinez-Rivero, DG III/C/4

Tel: (32 2) 296.49.77
Fax: (32 2) 295.02.81

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
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93/15/EEC	OJ L 121 of 15.5.1993, p.20	5.4.1993	1.1.1995	31.12.2002
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14) **Medical Devices**- Council Directive of 14.06.93 concerning medical devices.

Norbert Anselmann, DG III/D/2
Robert Virefleau, DG III/D/2

Tel: (32 2) 295.93.39
Tel: (32 2) 295.36.34 Fax: (32 2) 296.62.73

<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.

Jaap Verraes, DG III/B/4

Tel: (32 2) 295.71.64 Fax: (32 2) 295.38.77

<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.

Michel Kyriakidis, DG III/D/1
Dany van Brempt, DG III/D/1

Tel: (32 2) 296.45.51/ 295.86.86
Tel: (32 2) 295.94.07 Fax: (32 2) 296.62.73

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
94/9/EEC	OJ L 100,1994	1.03.1996	30.06.2002	NA

17) Recreational Craft- Council Directive of 16.06.94 on the approximation of the laws of the Member States concerning recreational craft.

Costa Andropoulos, DG III/D/4
John Cowley, DG III/D/4

Tel: (32 2) 295.66.01 Fax: (32 2) 296.70.14
Tel: (32 2) 295.09.04 Fax: (32 2) 296.70.14

<u>Reference</u>	<u>Official Jour. Pub.</u>	<u>Adopt. Date</u>	<u>Entry Date</u>	<u>Trans End</u>
94/25/EEC	OJL 164 of 30.06.94	16.06.94	16.06.96	16.06.98

Appendix B

30.8.93 Official Journal of European Communities No. L 220/39

Conformity Assessment Procedures in Community Legislation

A. (Internal control of production)	B. (type examination)	G. (unit verification)	H. (full quality assurance)
<p>Manufacturer</p> <ul style="list-style-type: none"> Keeps technical documentation at the disposal of national authorities <p>Aa</p> <p>Intervention of notified body</p>	<p>Manufacturer submits to notified body</p> <ul style="list-style-type: none"> Technical documentation Type <p>Notified body</p> <ul style="list-style-type: none"> Ascertains conformity with essential requirements Carries out tests, if necessary Issues EC type-examination certificate 	<p>Manufacturer</p> <ul style="list-style-type: none"> Submits technical documentation 	<p>EN 29001</p> <p>Manufacturer</p> <ul style="list-style-type: none"> Operates an approved quality system (QS) for design <p>Notified body</p> <ul style="list-style-type: none"> Carries out surveillance of the QS Verifies conformity of the design (!) Issues EC design examination certificate (!)
<p>A</p> <p>Manufacturer</p> <ul style="list-style-type: none"> Declares conformity with essential requirements Affixes the CE marking <p>Aa</p> <p>Notified body</p> <ul style="list-style-type: none"> Tests on specific aspects of the product (!) Product checks at random intervals (!) 	<p>C. (conformity to type)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> Declares conformity with approved type Affixes the CE marking <p>Notified body</p> <ul style="list-style-type: none"> Tests on specific aspects of the product (!) Product checks at random intervals (!) 	<p>Manufacturer</p> <ul style="list-style-type: none"> Submits product Declares conformity Affixes the CE marking <p>Notified body</p> <ul style="list-style-type: none"> Verifies conformity with essential requirements Issues certificate of conformity 	<p>Manufacturer</p> <ul style="list-style-type: none"> Operates an approved QS for production and testing Declares conformity Affixes the CE marking <p>Notified body</p> <ul style="list-style-type: none"> Carries out surveillance of the QS
<p>D. (production quality assurance)</p> <p>EN 29002</p> <p>Manufacturer</p> <ul style="list-style-type: none"> Operates an approved quality system (QS) for production and testing Declares conformity with approved type Affixes the CE marking <p>Notified body</p> <ul style="list-style-type: none"> Approves the QS Carries out surveillance of the QS 	<p>E. (product quality assurance)</p> <p>EN 29003</p> <p>Manufacturer</p> <ul style="list-style-type: none"> Operates an approved quality system (QS) for inspection and testing Declares conformity with approved type, or to essential requirements Affixes the CE marking <p>Notified body</p> <ul style="list-style-type: none"> Approves the QS Carries out surveillance of the QS 	<p>F. (product verification)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> Declares conformity with approved type, or with essential requirements Affixes the CE marking <p>Notified body</p> <ul style="list-style-type: none"> Verifies conformity Issues certificate at conformity 	

(!) Supplementary requirements which may be used in specific Directives.

D E S I G N

P R O D U C T I O N

Appendix C

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, DC 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 conclude an MRA with the EU under which U.S. products can 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. 820, Room A164
Gaithersburg, MD 20899
(301) 975-4040
Fax: (301) 926-1559
e-mail: joanne.overman@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, DC 20037-1434

Information:

Tel: (202) 862-9500
Fax: (202) 429-1766
Internet: <http://www.eurunion.org>

The Delegation represents the Commission in its dealings with the U.S. Government for all matters within EU competence. It reports on U.S. developments to headquarters in Brussels, and acts as a liaison with other international institutions in Washington, DC.

The Delegation functions like an embassy and includes the following sections: Agriculture and Fisheries; Political Affairs and Congressional Liaison; Commerce and Trade; Development; Economic and Financial Affairs; Press and Public Affairs; Science; Technology and Education; Transport, Energy and Environment; and Personnel and Administration.

Officials from these sections represent the Commission at government, business, press, academic and other meetings throughout the United States.

Public Inquiries, Documentation and Library Services: The Public Inquiries Section answers mail, fax and telephone inquiries about the EU, its legislation, statistics and publications. The Delegation Library has the most complete collection of official EU publications in the United States. The library maintains approximately 1,000 chronological subject files on EU activities and policies. The library is open to the public by appointment only.

Other Information: Much of the information generated by the EU is now available electronically. The Commission's EUROPA server on the World Wide Web (WWW) provides up-to-date information on the aims, institutions, and policies of the EU. The server can be accessed on the WWW at <http://www.cec.lu>

Publication Sales: EU official publications can be purchased from the following:

Bernan Associates
4611-F Assembly Drive
Lanham, MD 20706-4391
Tel: (301) 459-7666 or (800) 274-4888
Fax: (301) 459-0056

Appendix D

Publications by the NIST Office of Standards Services National Institute of Standards and Technology Gaithersburg, Maryland 20899

(See last page for ordering information)

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 from NTIS by #PB 87-224309.

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 from NTIS by #PB 88-239793.

o Laboratory Accreditation in the United States (NISTIR 4576)

This report, a companion 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 from NTIS by #PB 91-194495.

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 from NTIS by #PB 93-152080/AS.

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 and identifies sources for further help in this area. Order from NTIS by #PB 93-140689.

o Survey on the Implementation of ISO/IEC Guide 25 by National Laboratory Accreditation Programs (NISTIR 5473)

ISO/IEC Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories, has been used by many laboratory accreditation programs worldwide to establish accreditation requirements designed to promote confidence in the calibrations and testing results of laboratories. National delegations to the International Laboratory Accreditation Conference (ILAC) were surveyed to collect information on the implementation and supplementation of the requirements of ISO/IEC Guide 25 within the context of their countries' laboratory accreditation programs. This report summarizes the results of that survey and includes a bibliographic list of publications

concerned with ISO/IEC Guide 25 implementation compiled from the information by the national delegations. Order from NIST by #PB 94-210150.

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 from NTIS by #PB 89-221147 or Global Engineering Documents by Order #Cat. SP767.

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 from NTIS by #PB 91-107599 or Global Engineering Documents by Order #Cat. 0258-3.

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. Contact NTIS for order information.

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 from NTIS by #PB 88-201512.

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 from NTIS by #PB 91-167379.

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 from NTIS by #PB 92-108968.

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 from NTIS by #PB 92-181940.

o ISO Environmental Management Standardization Efforts (NISTIR 5638-1)

This report describes the development of planned "environmental management" standards by the International Organization for Standardization (ISO). These standards address management systems and the environmental aspects of products in the areas of life cycle assessment and labeling. The report outlines the current status of the ISO standards and also covers developments relating to third party certification of environmental management systems. Order from NTIS by #PB 96-158662.

o U.S. Private Sector Product Certification Programs (NIST SP 903)

This report lists 178 organizations that provide product certification services in the United States. NIST Special Publication 903 is designed to meet the needs of federal agencies and standards writers as well as manufacturers, engineers, purchasing agents, distributors and others concerned with product-related certification procedures. Entries describe the type and purpose of each organization, the nature of the activity, a pictorial representation of the organization's mark (if available), products certified, standards used, certification requirements, any accreditation or recognition by a U.S. or foreign private sector or governmental agency, availability of services, methods of cost determination, and other relevant details. Order from NTIS by #PB96-215074.

To Order Publications, Contact

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5285 Port Royal Road
Springfield, VA 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) 397-7956
Fax: (303) 397-2740

Appendix E

Sources for U.S. and European Standards

The following U.S. organizations can provide copies of European standards. This list is not endorsed or supported by the authors.

American National Standards Institute (ANSI)

11 West 42nd Street, 13th Floor
New York, NY 10036
Tel: (212) 642-4900
Fax: (212) 302-1286 (Orders Only)
(212) 398-0023
e-mail: info@ansi.org
Internet: <http://www.ansi.org>

British/American Chamber of Commerce

41 Sutter Street, #303
San Francisco, CA 94104
Tel: (415) 296-8645
Fax: (415) 296-9649
e-mail: info@baccsf.org
Internet: <http://www.baccsf.org>

Custom Standards Services, Inc.

802 Oakland Avenue, Suite 5
Ann Arbor, MI 48104
Tel: (800) 699-9277 or (313) 930-9277
Fax: (313) 930-9088
e-mail: service@cssinfo.com
Internet: <http://www.cssinfo.com>

Document Center

1504 Industrial Way, Unit 9
Belmont, CA 94002
Tel: (415) 591-7600
Fax: (415) 591-7617
e-mail: info@doccenter.com
Internet: <http://www.doccenter.com/doccenter>

Document Engineering Co., Inc.

15210 Stagg Street
Van Nuys, CA 91405
Tel: (800) 645-7732 or (818) 782-1010
Fax: (818) 782-2374
e-mail: doceng@doceng.com
Internet: <http://www.doceng.com/doceng>

Euroconsult Inc.

P.O. Box 243
Manchester, MA 01944
Tel: (508) 526-1687
Fax: (508) 526-7118

e-mail: euroconsult@shore.net
Internet: <http://www.shore.net/~eurocnslt/euroconsult>

Global Engineering Documents

15 Inverness Way East
Englewood, CO 80112-5704
Tel: (800) 854-7179 or (303) 397-7956
Fax: (303) 397-2740
e-mail: global@ihs.com
Internet: <http://www.ihs.com/global>

ILI Infodisk, Inc.

The Plaza Building
14-25 Plaza Road
Fair Lawn, NJ 07410
Tel: (201) 703-8418
Fax: (201) 703-8390

Simcom, Inc.

6111 Peachtree Dunwoody Road
Bldg. E, Suite 200
Atlanta, GA 30328
Tel: (770) 730-9980
Fax: (770) 9976
e-mail: simcom@cemark.com
Internet: <http://www.eurocom.com>

Standards Sales Group

15885 Main Street, Unit 250
Hesperia, CA 92345-3403
Tel: (619) 947-6100
Fax: (619) 947-2899

QSI - Qualified Specialists Inc.

13231 Champion Forest Drive
Suite 104
Houston, TX 77069
Tel: (800) 856-5366 or (713) 444-5366
Fax: (713) 444-6127
e-mail: qsi@sccsi.com
Internet: <http://www.sccsi.com/qsi/index.htm>