European Technical Directives

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Dedicated to
Aza, Andrew, Elena, Marina & Charlie

PREFACE

The single European market is one of the great achievements of our time. The European Economic Community (EEC), founding by the Treaty of Rome of 1957 was based on "four freedoms: freedom of movement of goods, services, capital and people. From January 1st 2007, 27 countries are EU members. In such an globalisation environment the future engineers should have knowledge concerning the European technical legislation represented mainly by the European Technical Directives (ETD) and appropriate harmonised standards. Since 1987 some more 20 directives, adopted on the basis of the New Approach and the Global Approach, have progressively come into force. Especially important for the engineers is to be aware with the so called New Approach Directives, serving the wide range of products on the European market. The engineers have to know the requirements and procedures concerning CE marking, so that the product to be placed on the European market.

It is the purpose of this book to provide such an information in more understandable way, because the technical legislation documents language is too specific and difficult for unerstanding. The text has been written with the assumption that the reader has no prior knowledge in this area.

I hope that this book will be helpful to those who want to do business in the single market and that it will assist those whose job is to manage the market place.

Finally the book has very useful appendixes, concerning the subject.

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Contents

Acronyms

EC – European Community
ECSC – European Coal and Steel Community
EDC – European Defense Community
EEC – European Economic Community
EPC – European Political Community
CFSP – Common Foreign and Security Policy
EFTA – European Free Trade Association
EMU – Economic and Monetary Union
EMC – Electromagnetic Compatibility
EN –European Standards
EU – European Union
Euratom – European Atomic Energy Community
CE – Conformite Europeenne (French)
CEN – European Committee of Standardization
CENELEC – European Committee for Electrotechnical Standardization
GDP – Gross Domestic Product
GPSD – General Product Safety Directive
IEC – International Electrotechnical Commission
LVD – Low Voltage Directive
OJEC - Official Journal of the European Communities
R&TTE - Radio Equipment and Telecommunications Terminal Equipment
TCF – Technical Construction File

1. European Union

1.1. EU History

Attempts to unify the disparate nations of Europe precede the modern nation-states and have occurred repeatedly throughout the history of Continental Europe since the collapse of the Mediterranean-centered Roman Empire.

The Great Schism of 1054 between Orthodoxy and Catholicism rendered the idea of "Christendom" moot. George of Poderbrady, the king of Bohemia proposed the creation of Christian nations against the Turks in 1464.

In 1569, the Union of Lublin transformed the Polish-Lithuanian personal union into the Polish-Lithuanian Commonwealth, a multi-national federation and elective monarchy.

In 1728, Abbot Charles de Saint-Pierre proposed the creation of a European league of 18 sovereign states, with common treasury, no borders and an economic union.

Some suggestion of a European union can be found in Immanuel Kant's 1795 proposal for an "eternal peace congress".

The French socialist Saint-Simon and Augustin Theirry would in 1814 write the essay "De la reorganization de la society europeene", already concurring up some form of parliamentary European federation.

In the conservative reaction after Napoleon defeat in 1815, the German Confederation (German "Deutscher Bund") was established as a loose association of thirty-eight German states formed by the Congress of Vienna. The German Confederation was an association of independent, equal sovereign nation states.

In 1834 the Zollvereign (German "customs union") was formed among the states of the Confederation, in order to create better trade flow and reduce internal competition.

Italian writer and politician Giuseppe Mazzini called for the creation of a federation of European republics in 1843.

This set the stage for perhaps the best known early proposal for peaceful unification, through cooperation and equality of membership, made by the pacifist Victor Hugo in 1847.

Following the catastrophe of the First World War, some thinkers again began to float the idea of a politically unified Europe. In 1923 the Austrian Count Richard Coudenhove-Kalergi founded the Pan-Europa movement and hosted the First Paneuropean Congress, held in Vienna in 1926.

In 1929 Aristide Briand, French prime minister, gave a speech in the presence of the League of nations Assembly in which he proposed the idea of a Federation of European nations based on solidarity and the pursuit of economic prosperity and political and social co-operation. Many economists supported this view.

At the League's request Briand presented a Memorandum on the organization of a system of European Federal Union in 1930.

In 1931 the French politician Edouard Herriot published the book "The United States of Europe".

In 1943, the German ministers Joachim von Ribbentrop and Cecil von Renthe-Fink proposed the creation of a European confederacy, which would have had a single currency, a central bank in Berlin, a regional principle, a labor policy and trading agreement under the absolute German hegemony.

The founders of the post-war movements for European unity were anti-fascist and emphasized that unity must be based on democracy and partnership, not domination and conquest. One of the most influential figures in this process was Altiero Sinelli, co-author with Ernesto Rossi of the "Ventotene Manifesto" entitled "Towards a Free and United Europe".

In 1943 in Milan the Monvimento Federalista Europeo (MFE) was founded.

In 1943, Jean Monnet a member of the National Liberation Committee of the Free French government and regarded by many as the future architect of European unity, is recorded as declaring to the committee:

"There will be no peace in Europe, if the states are reconstituted on the basis of national sovereignty… The countries of Europe are too small to guarantee their peoples the necessary prosperity and social development. The European states must constitute themselves into a federation… "

Post 1945 impetus

By the end of the war, a new impetus for the founding of the European Union was the desire to rebuild Europe after the disastrous events of World War II, and to prevent Europe from ever again falling victim of war.

Winston Churchill gave a speech at the University of Zürich on September 19, 1946 calling for a "United States of Europe", similar to the United States of America. The principal result of this speech was the forming of the Council of Europe in 1949. The Council of Europe however was (and still remains) a rather restricted organization, like a regional equivalent of the United Nations.

The three communities

For centuries, Europe was the scene of frequent and bloody wars. In the period 1870 to 1945, France and Germany fought each other three times, with terrible loss of life. A number of European leaders became convinced that the only way to secure a lasting peace between their countries was to unite them economically and politically.

The European Union grew out of the European Coal and Steel Community (ECSC), created by the Treaty of Paris in 1951, had six founding members: Belgium, the Netherlands and Luxembourg (the Benelux countries), West Germany, France and Italy. The ECSC was the brainchild of Jean Monnet.

On May 9, 1950 Schuman presented his proposal for the creation of an integrated Europe, stating that it was indispensable to the maintenance of peaceful relations. This proposal, known as the "Schuman Declaration", is considered to be the beginning of the creation of what is now the European Union, which later chose to celebrate May 9 as Europe Day.

The British were invited to participate in it, but refused on grounds of national sovereignty.

Further efforts towards integration were immediately undertaken following the success of the ECSC. Encouraged by the United States, an attempt was made to create a European Defense Community (EDC) and a European Political Community (EPC). The EDC called for no less than the creation of a common European army, with joint high command. The purpose of the EPC was to establish a federation of European states - replete with a bicameral parliament, executive organ, and a European Court. These attempts proved overambitious. In 1954 the French National Assembly refused to ratify the EDC treaty, which led to its abandonment; after the failure of the EDC treaty, the EPC, too, was quietly shelved. Nonetheless, the ideas behind both institutions lived on - as testified by later developments such as European Political Co-operation (also called EPC), the Common Foreign and Security Policy (CFSP) "pillar" established by the Maastricht treaty, and the European Rapid Reaction Force currently in formation.

Despite the failure of the EDC and EPC, the six founding members soon tried again to further their integration. The next major milestone was the founding of the European Economic Community (EEC) and the European Atomic Energy Community (Euratom), both through the Treaty of Rome of 1957 (implemented January 1, 1958).

The purpose of the EEC was to establish a customs union among the six founding members, based on the "four freedoms":

1. freedom of movement of goods,
2. services,
3. capital,
4. people.

Euratom was created to pool the non-military nuclear resources of the states. Of the three institutions now extant - the ECSC, the EEC, and Euratom - the EEC was by far the most important, so much so that it was later renamed simply the European Community (EC).

In January 1960, Britain and other countries who didn't belong to the EEC formed an alternative association, the European Free Trade Association (EFTA).

EEC, ECSC and Euratom had merged into the EC in 1967.

A customs union was established in 1968.

The first direct elections for the European Parliament were held in 1979.

The elected, full-time parliament soon became a forum for ideas on reforming the Communities into a more developed Union, with a stronger role for the Parliament itself.

Indeed, the governments had in principle agreed to transform the European Communities into the European Union in the Solemn Declaration on European Union (also known as the Stuttgart Declaration), of 19 June 1983.

In 1986 the Single European Act was signed, the first step towards the single European market. At the same it formally introduced the concept of European Political Cooperation.

In 1990 – Reunification of Germany.

In 1992 the Maastricht treaty was signed, which at the same time modified the Treaty of Rome. It established the European Union, adding two further pillars of cooperation, on Common Foreign and Security Policy and on Justice and Home Affairs. At the same time it established Economic and Monetary Union (EMU) as a formal objective. The Maastricht treaty came into force in 1993.

The Copenhagen criteria are the rules that define whether a nation is eligible to join the European Union. The Criteria require that an applicant state have the institutions to forward and preserve democratic governance, human rights, a functioning coordinated market economy, and accept the obligations and intent of the EU. These membership Criteria were drawn and established at the June 1993 European Council in Copenhagen, Denmark:

"Membership requires that the candidate country has achieved stability of institutions guaranteeing democracy, the rule of law, human rights and respect for and, protection of minorities, the existence of a functioning market economy as well as the capacity to cope with competitive pressure and market forces within the Union. Membership presupposes the candidate's ability to take on the obligations of membership including adherence to the aims of political, economic and monetary union."

During the negotiations with each candidate country, progress towards meeting the *Copenhagen Criteria* is regularly monitored. On the basis of this, decisions are made as to whether and when a particular country should join, or what actions need to be taken before membership realization.

The Copenhagen Criteria are divided into three groups — geographic, political and economic.

The Criteria are held in a lengthy, eighty thousand-page document. An example of the broad over arching changes the Criteria dictates is illustrated by the fact that it will take Turkey a minimum of 10 years to implement all 80 000 pages.

The European Economic Area (EEA) was founded in 1994 in order to allow EFTA countries to participate in the Single Market without having to join the EU.

In 1997, the Treaty of Amsterdam was signed, which updated the Maastricht treaty and aimed to make the EU more democratic.

Obviously growth of these European Communities into what is currently the European Union can be said to consist of two parallel processes -- first their structural evolution and institutional change.

1. 2. Enlargement of the EU

Britain soon realized that the EEC was more successful than the EFTA and decided to apply for membership. Ireland and Denmark, both of whom being heavily reliant on British trade, decided they would go wherever Britain went, and hence also applied to join the Community. Norway also applied at this time.

- The first application occurred in August 1961 under the Conservative government of Harold Macmillan, who was more favorable to Britain joining the EEC than his predecessors. Negotiations started in November 1961 and a provisional agreement was reached in July 1962. However, Britain's membership was vetoed by French president Charles De Gaulle in January 1963 (all EEC founding members had this right). Officially, De Gaulle said that Britain was not sufficiently European-minded yet to break away from the Commonwealth and accept a common agricultural policy. But other reasons include Britain's close relationship with the US in terms of defense. De Gaulle refused an "Atlantic" Europe. As a result, the whole negotiations with the four countries broke off.
- The second application occurred under the Labour government of Harold Wilson. Wilson said in April 1966 that Britain was ready to apply for EEC membership if essential British interests were safeguarded. Negotiations started on May 1967 with the four countries but De Gaulle once again used his veto in September 1967. Officially, De Gaulle said that Britain had to improve its economy but he actually still feared that Britain would act as the US Trojan horse. The whole negotiation broke off once again, and it seemed that Britain wouldn't be able to join the EEC as long as De Gaulle was president.
- The third and last application occurred after De Gaulle resigned in 1969 and was replaced by Georges Pompidou. In October 1969, the European Commission asked for new negotiations concerning the applications of the four countries. French minister Maurice Schumann declared that France would agree to Britain's membership if questions of agricultural finance were settled first.

Negotiations started in June 1970 under the Conservative government of Edward Heath, who was one of the most strongly pro-European politicians in Britain. Britain agreed to the conditions of the EC: Britain had to accept the Merger Treaty and all decisions taken since the second application, and resolve its problem of adaptation, i.e. conflicts between the EC and the Commonwealth.

Finally, Britain joined successfully on January 1, 1973. In 1972, Ireland (application from July 1961), Denmark (application from August 1961), Norway (application from April 1962) held referenda on whether to join.

The results were:

* Ireland - 83.1% in favor (May 10)
* Norway - 46.5% in favor (September 25)
* Denmark - 63.3% in favor (October 2)

Following the rejection by the Norwegian electorate (53.5% against), Norway did not join, an event that was to be repeated again twenty years later, when the government proposed joining along with Austria, Sweden and Finland.

1973 - member states. The United Kingdom, Denmark (with Greenland but not the Faroe Islands) and Ireland join. Greenland left in 1985.

1981 - 10 member states: Greece joins

Greece submitted its membership application in June 1975 and joined on January 1, 1981, under the presidency of Constantine Caramanlis.

In 1985, Denmark's territory Greenland left the union following home rule and a referendum.

1983 – 12 member states: Spain & Portugal join.

Portugal submitted its application in March 1977 and Spain in July 1977.

On 1 January 1986, Spain and Portugal joined the union together.

In February 1986, the Single European Act was signed in Luxembourg.

1990 - Reunification of Germany had place

1995 – 15 member states: Austria, Sweden and Finland (with Åland) were admitted on January 1, 1995.

The 1994 referenda on membership were as follows:

* Austria - 66.6% in favor (June 12); application submitted in July 1989
* Finland - 56.9% in favor (October 16); application submitted in March 1992 (separate referendum held in Åland)
* Sweden - 52.8% in favor (November 13); application submitted in July 1991
* Norway - 43.1% in favor (November 28); application submitted in December 1992

As the referendum in Norway was 52.2% against joining, the proposal by the Norwegian government to join was rejected for the second time.

With the departure of Austria, Sweden and Finland to the EU, only Norway, Iceland, Switzerland and Liechtenstein remain members of the EFTA.

2004 – 25 member states

The European Commission's Strategic Report of October 9, 2002 recommended 10 candidate members for inclusion in the EU in 2004: Estonia, Latvia, Lithuania, Poland, the Czech Republic, Hungary, Slovakia, Slovenia, Malta and Cyprus. Their combined population is roughly 75 million; their combined Gross Domestic Product (GDP) was about 840 billion US dollars.

While the EU has enlarged several times in the past, never before had an enlargement round included so many countries and with such different levels of economic and domestic political development, not to mention different historical and cultural backgrounds. Many of the candidates had only just begun building democracies and had not finalized their transition to a market economy. Culturally and linguistically, this enlargement greatly increased the number of languages spoken within the EU, reflecting the increased cultural heterogeneity and level of diversity in the EU.

This could therefore be called one of the most ambitious enlargements of the European Union yet. On the side of the European Union it was partly motivated by a desire to reunite Europe after the end of the Cold War, and an effort to tie Eastern Europe firmly to the West in order to prevent it falling again into communism or dictatorship.

The first stage of negotiations took place among the then current 15 member states when they agreed upon a common negotiating position regarding the terms of accession with which to approach the candidates. The second stage of negotiations occurred between the EU and the candidate states, when these terms were discussed and revised.

Cyprus was made a candidate for admission because Greece threatened to veto the enlargement unless Cyprus was also allowed to be a part of it. The prospect of membership for the island also led to a significant (but eventually failed) push for reunification through the Annan Plan for Cyprus.

After negotiations between the candidates and the member states, the final decision to invite these nations to join was announced on December 13, 2002 in Copenhagen, with the European Parliament voting in favor of this on April 9, 2003.

On April 16, 2003 the Treaty of Accession was signed by the 10 new members and the 15 old ones in Athens.

The final remaining step was the ratification of the treaty by the current member states and by each of the candidate nations. Ratification in the former was done by the parliaments of the member states alone, whereas in the latter the ratification was first subject to a referendum, except for Cyprus where the parliament was solely responsible. The 2003 referenda dates (in four of the countries, a two-day ballot is held), and the outcomes in each of the candidate countries, are as follows:

* MaltaMalta - 54% in favor (March 8, 2003)
* SloveniaSlovenia - 90% in favor (March 23, 2003)
* HungaryHungary - 83% in favor (April 12, 2003)

* LithuaniaLithuania - 91% in favor (May 10-May 11, 2003)
* SlovakiaSlovakia - 92% in favor (May 16-May 17, 2003)
* PolandPoland - 77% in favor (June 7-June 8, 2003)
* Czech RepublicCzech Republic - 77% in favour (June 13-June 14, 2003)
* EstoniaEstonia - 67% in favor (September 14, 2003)
* LatviaLatvia - 67% in favor (September 20, 2003).

The referenda results were all in favour of joining, ratification proceeded without problems and the candidate countries became full members of the EU on May 1, 2004.

The eight countries formerly in Eastern Europe (Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, and Slovenia) are together known as the A8 countries.

Some additional restrictions were placed on A8 nationals' rights to work and claim welfare benefits.

In 2005 Croatia & Turkey were beginning membership negotiations.

2007 – 27 member states: Bulgaria & Romania join.

The EU includes now the following 27 member states (in alphabet order):
Austria, Belgium, Bulgaria, Denmark, Estland, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lthuania, Luxemburg, Malta, Poland, Portugal, Rumania, Slovakia, Slovenia, Spain, Sweden, The Netherlands, Czech Republic, UK, Cyprus.

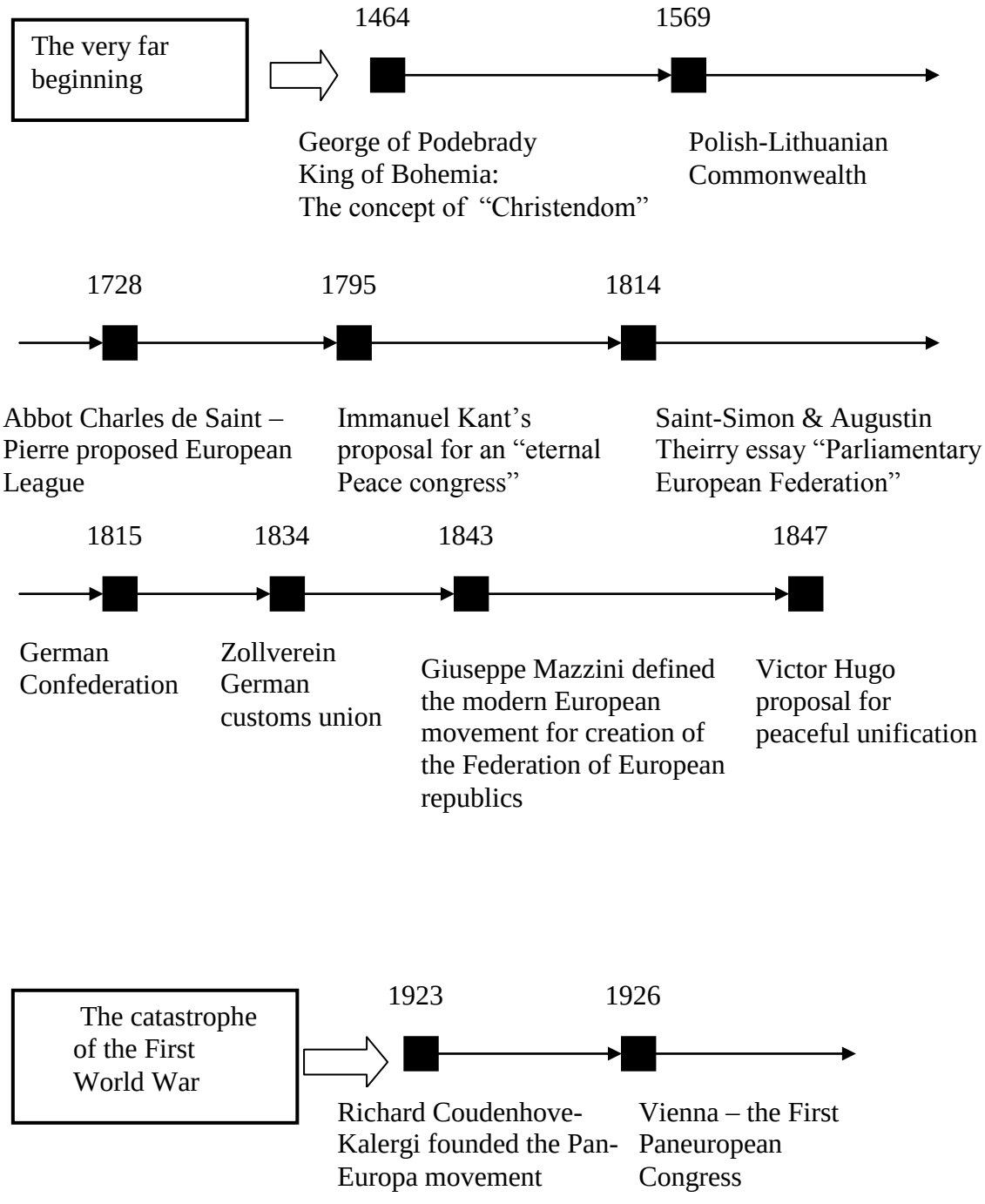
Current issues

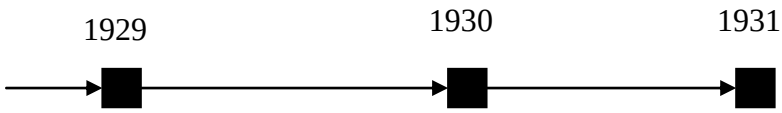
Currently, The EU is undergoing organizational difficulties, especially those dealing with the proposed European Constitution. The new constitution must be ratified by all 27 member states before it can enter into force, in some cases by national referenda.

To date, 18 countries have ratified the constitution, voters in France and the Netherlands have rejected it. The future of the constitution is now uncertain.

Another issue is the application for EU membership of Turkey. There is still significant concern about Turkey’s suitability as a member, for political, cultural and economic reasons. There’s also a question of its continuing disputes with Greece and Cyprus.

1. 3. EU history step-by-step





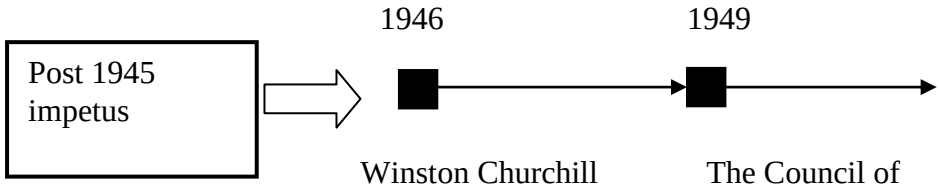
The French Prime minister Aristide Briand presented on the League of Nations Assembly the idea of a Federation of European nations

Briand's Memorandum on the European Federal Union

Edouard Herriot – book The United States of Europe

Joachim von Ribbentrop and Cecil von Renthe-Fink: proposal for the European confederacy under the absolute German hegemony.

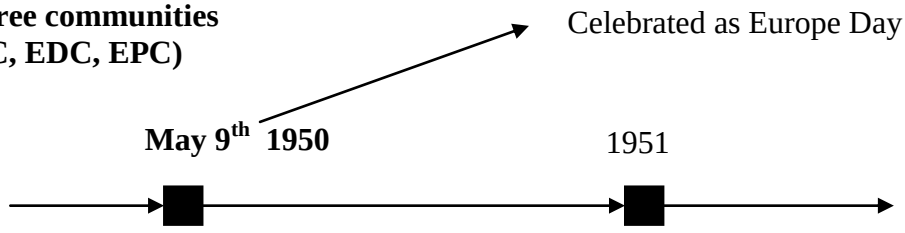
Altiero Spinelli, Ernesto Rossi. Milan, Movimento Federalista Europeo (MFE)



Winston Churchill speech "United States of Europe" in the Zurich University

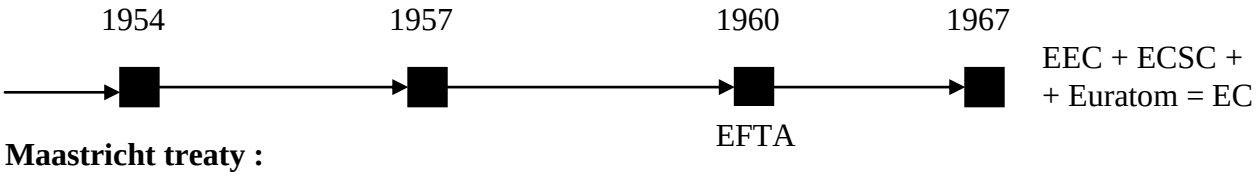
The Council of Europe

1952 – 58
The three communities
(ECSC, EDC, EPC)



French foreign minister Robert Schuman:
Schuman Declaration

Treaty of Paris
ECSC created with 6 members, Brainchild of Jean Monnet, known as an architect of European Unity



Maastricht treaty :
CFCP = EDC + EPC

Treaty of Rome
Founding of EEC and Euratom.
EEC is a custom union based on the "four freedoms":

1) freedom of movement of goods
2) freedom of movement of services
3) freedom of movement of capital
4) freedom of movement of people

Six member states: Belgium, the Netherlands, Luxembourg (the Benelux countries), West Germany, France, Italy.

1990

■ Reunification of Germany

1992

■ Maastricht treaty – created the EU
EMU was established

1993

■ Copenhagen
- European Council was established
- The Copenhagen criteria for membership was drawn, divided in three groups: geographic, political and economic (80 0000 pages)

1994

■ EEA was founded

Enlargement of the EU ⇨ 1973 ■ 9 member states
6 + UK, Denmark, Ireland

In fact Britain, Ireland, Denmark and Norway applied three times:

- First application in Aug. 1961 (UK with Harold Macmillan)
  French veto of Charles De Gaulle
- Second application in Sept. 1967 (UK with Harold Wilson)
  French veto of Charles De Gaulle
- Third application in Jan. 1973 (UK with Edward Heath)
  De Gaulle was resigned in 1969 and was replaced by Georges Pompidou.

Referenda in 1972:
- Ireland 83,1 % in favor
- Denmark 63,3 % in favor
- Norway 46,5 % in favor

So, Norway did not join EC.

1981

10 member states
9 + Greece

1985

12 member states
Spain & Portugal join
Greenland (Denmark's territory) leaves because of a negative referendum

1995

15 member states
Austria, Finland & Sweden join

Referenda in 1994:
- Austria 66,6 % in favor
- Finland 56,9 % in favor
- Sweden 52,8 % in favor
- Norway 43,1 % in favor

So, Norway was rejected for the second time.
Norway, Iceland, Switzerland and Liechtenstein remain members of EFTA.

2004

25 member states
Estonia, Latvia, Lithuania, Poland, the Czech Republic, Hungary, Slovakia, Slovenia, Malta & Cyprus join.
Note: Cyprus was made a candidate for admission because Greece threatened to veto the enlargement unless Cyprus was also allowed to be a part of it.

Referenda in 2003:
- Malta 54 % in favor
- Slovenia 90 % in favor
- Hungary 83 % in favor
- Lithuania 91 % in favor
- Slovakia 92 % in favor
- Poland 77 % in favor
- Czech republic 77 % in favor
- Estonia 67 % in favor
- Latvia 67 % in favor

A - 8 countries

2005

■ Croatia & Turkey are beginning membership negotiations

2007

■ 27 member states
Bulgaria & Rumania join

2. EU single market

It took some time for the Member States to remove all the barriers to trade between them and to turn their "common market" into a genuine single market in which goods, services, people and capital could move around freely.

The Single Market was formally completed at the end of 1992, though there is still work to be done in some areas - for example, to create a genuinely single market in financial services.

During the 1990s it became increasingly easy for people to move around in Europe, as passport and customs checks were abolished at most of the EU's internal borders. One consequence is greater mobility for EU citizens. *Since 1987, for example, more than a million young Europeans have taken study courses abroad, with support from the EU.*

Economic and political integration between the member states of the European Union means that these countries have to take joint decisions on many matters. So they have developed common policies in a very wide range of fields - from agriculture to culture, from consumer affairs to competition, from the environment and energy to transport and trade.

In the early days the focus was on a common commercial policy for coal and steel and a common agricultural policy. Other policies were added as time went by, and as the need arose.

Some key policy aims have changed in the light of changing circumstances.

For example, the aim of the agricultural policy is no longer to produce as much food as cheaply as possible but to support farming methods that produce healthy, high-quality food and protect the environment.

The need for environmental protection is now taken into account across the whole range of EU policies.

Before the creation of the European Union, each country imposed its own technical requirements. Differences *between national laws, standards, and conformity assessment procedures made trade between the countries difficult, contentious, and expensive.*

In order to eliminate these barriers, a new legislative technique and strategy was instituted. The new approach was designed to envelop, or "harmonize," the health, safety, and environmental requirements into one European-wide legislative package. The unification of 27 European countries into a European Union, and the consequent harmonization of laws, standards, and conformity assessment procedures, changed all that.

Where harmonization of legal requirements or administrative regulations is necessary, the European Commission - the executive body of the European Union - develops regulations, which after acceptance by the European Council, are called Council Directives or simply Directives.

Each directive describes the consensus that has been achieved and provides a deadline for the transposition of this consensus into the national laws of each Member State.

In 1985 a European Council Resolution on a new approach to technical harmonization and standards proposed a radical change in regulating the technical aspects of industrial products.

The new approach involves the development of legislation specifying only the essential requirements that are general and mandatory. The detailed technical specifications that may be

used to demonstrate conformity with the essential requirements are elaborated in voluntary harmonized standards.

If a product complies with the requirements of a new approach directive, the manufacturer marks it with the CE-mark.

3. New Approach

3.1. Basic principles of the New Approach

The so-called "New Approach" was conceived in the early eighties and laid down in a *"Council Resolution of 7 May 1985 on a New Approach to technical harmonization and standards"* [1].

It is based on four fundamental principles:

- legislative harmonization is limited to the adoption of the essential safety requirements (or other requirements on the general interest) with which products put on the market must conform, and which will therefore enjoy free movement throughout the territory of the European Union (EU);
- the task of drawing up the technical specifications needed for the production and placing on the market of products conforming to the essential requirements established by the directives, while taking into account the current stage of technology, is entrusted to organizations competent in the standardization area (e.g. CEN, CENELEC, ETSI, etc.);
- these technical specifications are not mandatory and maintain their status of voluntary standards;
- but at the same time national authorities are obliged to recognize that products manufactured in conformity with harmonized standards are presumed to conform to the essential requirements established by the directive. This signifies that the producer has the choice of not manufacturing in conformity with the harmonized standards but that in this event he has an obligation to prove that his products conform to the essential requirements of the directive.

In order that this system may operate, the resolution also specifies that it is necessary that:

- on the one hand, the standards offer a guarantee of quality with regard to the essential requirements established by the directives;
- on the other hand, the public authorities keep intact their responsibility for the protection of safety (or other requirements) on their territory.

There is thus a clear distinction between the methods adopted under the New Approach and those used prior to its adoption. It should be noted that the "Old Approach" is still used in some areas of EU technical legislation such as cars, food, cosmetics, etc...

The differences may briefly be summarized as follows:

- The New Approach deals with large families of products (e.g. machinery, construction products, toys, etc...), or horizontal risks (such as electromagnetic compatibility), as opposed to the product-based approach used under the Old Approach.
- The New Approach establishes close cooperation between public authorities and market operators: an important role exists for standards, and the bodies responsible for the assessment of conformity with the requirements of the directive (the so-called "notified bodies") can be private entities, notified by Member States. Under the Old Approach, technical specifications are adopted by authorities and the functions of "notified bodies" are carried out by national authorities.
- The New Approach defines the essential requirements that products must meet when they are put on the market, but, in contrast to the Old Approach, technical specifications of how to do so, are not included.

- New Approach Directives, since they do not contain technical specifications, do not necessitate regular adaptation to technical progress, in contrast to Old Approach Directives.
- New Approach Directives allow manufacturers a significant degree of flexibility. They can choose and adapt technology to meet the essential requirements. In regard to conformity assessment, normally a New Approach Directive gives various options.
- Old Approach Directives are often based on optional harmonization i.e. leaving a choice to manufacturers to follow the harmonized Community rules, assuring free movement, or to follow national legislation, without a guarantee of free movement. New Approach Directives are based on total harmonization, since they replace national legislation.

The New Approach is currently the method of harmonization used for most industrial products.

Some specific aspects of the New Approach

New Approach Directives deal with large families of products (gas appliances, toys, machinery, pressure equipment, etc.). Product-related directives define, for groups of products, the risks that have to be dealt with before such products can be put on the market.

New Approach Directives can however, also address horizontal risks such as electromagnetic compatibility (EMC).

It is quite possible that products may be governed by more than one directive. This is not a legislative error ("overlap"), but a consequence of the fact that different risks may be dealt with under various directives.

For instance, one can easily imagine the simultaneous application of the Electromagnetic Compatibility Directive and the Machinery Directive: the EMC aspects of a machine will be covered by the EMC Directive while mechanical risks may be covered by the Machinery Directive.

3.3. Harmonised standards

New Approach Directives foresee that the European Standards organizations (e.g. CEN, CENELEC etc.), following a mandate given by the Commission, will elaborate European Standards (EN), or identify existing ENs, which will offer technical solutions to meet the essential requirements.

Once reference to these standards have been published by the Commission in the Official Journal of the European Communities (OJEC), and once they have been transposed into identical national standards by the National Standardization Bodies (NSB) in the Member States, they will give a presumption of conformity with respect to the essential requirements that they deal with.
Note: It should be noted that the process of transposition by all the NSBs does not need to have taken place for such presumption of conformity, though of course the national bodies are obliged to transpose all new ENs.

Such standards are qualified in New Approach Directives as "harmonized standards".Standards remain voluntary. Therefore, under New Approach, there is no obligation to use ENs.

Where other technology is used to meet the essential requirements, or in the absence of standards, the burden of proof that the product meets the essential requirements will rest on the person affixing the CE marking (producer, his authorized representative in the Community or by the importer of the product). The Commission publishes references of harmonized standards as they are presented to the Commission by the European Standards Organizations.

4. New Approach Directives

4.1. General terms and considerations

WHAT IS THE EU's NEW APPROACH TO PRODUCT CERTIFICATION?

Essential health and safety requirements are at the heart of the New Approach Directives. They are mandatory, legally binding obligations, and they are enforced.

The European Union (EU) developed "New Approach" Directives to streamline product approvals for a broad range of goods in order to facilitate trade within the EU single internal market.

The "Old Approach" Directives contained a high degree of technical detail, and EU member states introduced national standards or regulations at a faster pace than the European Commission could finalize these "Old Approach" Directives. These national specifications often proved to be trade barriers.

The aim of most essential requirements is the elimination of risks of accident to the extent possible. New Approach Directives are limited to essential health and safety requirements for sectors such as machinery, electrical products, or medical devices. They do not cover specific products such as motor vehicles, cosmetics, or chemicals, which are still covered under the Old Approach Directives. The main difference between the New and Old Approach Directives is that under the New Approach, the technical details outlining the minimum requirements a product must meet are usually not found in the directive itself. The New Approach Directives are more general.

Obviously, not all products are governed by New Approach Directives. There are essentially three regulatory levels. Technical requirements differ for each of them :

- There are the "old approach" regulations, which have technical specifications integrated into the annexes. Some of these products are regulated on a product-by-product basis.
- The New Approach Directives make references to harmonized standards.
- In the third level, products are unregulated at the EU level, but the products may be regulated at the national level and are governed by Member State laws.

Technical details on how to meet these minimum health and safety requirements are left to the following three groups:

1) Manufacturers who self-certify products by meeting the requirements of the applicable directives, in some cases by using appropriate European standards;
2) The three regional European standards organizations (CEN, CENELEC and ETSI), which now make Europe-wide standards covering product sectors falling under the New Approach Directives;
3) Government-appointed product certification bodies (called notified bodies), which provide testing and product approvals.

Self certification

Self certification is where the manufacturer (or the person who places the product on the market) determines that the product complies with all the requirements of the relevant harmonized standard(s) and ensures compliance with all the protection requirements of the Directive. Self declaration includes production of a Declaration of Conformity which must be retained by the manufacturer for any occasion of dispute of conformance, or for spot checks by enforcement agencies. The Declaration is signed by a responsible person.

Where a Directive requires products and/or systems to be independently tested, certified, or inspected, this must be done by a "Notified Body" or "Competent Body".

Notified Body is an organization that has been nominated by a member Government and Notified by the European Commission. A Notified Body will be nominated based on designated

requirements, such as knowledge, experience, independence and resources to conduct the conformity assessments.

The primary role of a Notified Body is to provide services for conformity assessment on the conditions set out in the New Approach Directives in support of CE Marking. This normally means assessing the manufacturers conformity to the essential requirements listed in each directive.

Conformity assessment can be inspection, quality assurance, type examination or design examination, or a combination of these.

Accredited Competent Body

One form of self certification of compliance with the Directive involves the use of an accredited Competent Body in the EU to verify the documented claims of the manufacturer and issue an approved report or certificate.

This route to conformity is used when there are applicable standards which make complete provision in respect of the product, but the manufacturer has chosen not to apply all or any of the standards in part or in full, or there are no applicable standards, or there are applicable standards which the manufacturer has applied but they do not make provision in respect of the product.

The Technical Construction File is required to contain:

* a general description of the product,
* conceptual, design and manufacturing documentation,
* descriptions and explanations necessary for the understanding of the documentation and the operation of the product,
* list of standards applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the standards have not been applied,
* results of design calculations made, examinations carrier out etc.,
* test reports.

Testing by a Competent Body is often also used by manufacturers to replace or support the manufacturer's own testing to provide surety before issuing a Declaration.

The New Approach Directives are designed to facilitate product certification, to maintain a high level of consumer and workplace safety, and to expand intra-European trade.

The directives cover a very wide range of product areas including toys, medical devices and pressure equipment. Their primary objective *is to ensure that the products are well designed, and safe for the user.*

Throughout Europe, where a New Approach Directive is in force, it is necessary for the manufacturer to CE mark their product.

CE marking requirements vary from Directive to Directive, and even within Directives. Third party testing, systems assessment and technical file assessments can be mandatory, but *sometimes the manufacturer's unverified claim is all that's asked for.* But beware! *If you claim your product complies and it doesn't, you will be prosecuted.*

Having independent testing and assessments carried out is the safest way for manufacturers to proceed, whether this is mandatory or not.

There are New Approach Directives for electronic and electrical products, machinery, medical devices, radio and telecommunications terminal equipment, recreational craft, pressure equipment, equipment for use in potentially explosive atmospheres, personal protective equipment, toys, simple pressure vessels, and others.

These directives came about as a way of eliminating trade barriers and facilitating the EU Single Internal Market. New Approach Directives indicate a product has met certain health and safety requirements. A company affixes the CE mark to its product once it has met the requirements of the applicable New Approach Directive(s).

Not all products fall under the New Approach Directives.

There are essentially *three levels of regulatory control:*

Old Approach

The Old Approach Directives apply to the foodstuff, motor vehicle, chemical, cosmetic, and pharmaceutical sectors. These regulations have *technical specifications written into the annexes*.

New Approach

These directives make references to harmonized standards and apply to broad product sectors.The directives usually set down general health and safety requirements, and the specifications for meeting these general requirements are found in the standards applicable to the manufacturer's product. Conformity assessment procedures (the system and responsibilities for testing and certification which should lie with the manufacturer and, where applicable, the notified bodies) are also contained in the these directives**.**

General Product Safety Directive (GPSD) [8] covers all products not specifically covered by the CE mark directives but which do require some level of safety regulation. These products may also be regulated at the national level by member states**.**

Before placing a product on the Community market, the manufacturer must subject the product to a conformity assessment procedure provided for in the applicable directive, with the view to affixing the CE marking.

The CE marking is, in particular, an indication that the products comply with the essential requirements of applicable directives and that the products have
been subject to a conformity assessment procedure provided for in the directives.

Conformity assessment in Europe, is the process by which compliance with essential requirements is determined.

This process can be carried out with or without the use of standards.

This last principle is important to manufacturers of new or innovative products for which *standards do not yet exist*, and ensures that standards annexed to New Approach Directives (which are voluntary) do not become de jury obligatory.

4.2. Scope of the New Approach Directives

New Approach directives are generally designed to cover all hazards related to the public interest that the directive intends to protect.

Standard elements of New Approach directives

New Approach directives *are based on the following principles:*

* Harmonisation is limited to essential requirements.
* Only products fulfilling the essential requirements may be placed on the market and put into service.
* Harmonized standards, the reference numbers of which have been published in the Official Journal and which have been transposed into national standards, are presumed to conform to the corresponding essential requirements.
* Application of harmonised standards or other technical specifications remains voluntary, and manufacturers are free to choose any technical solution that provides compliance with the essential requirements.
* Manufacturers *may choose* between different conformity assessment procedures provided for in the applicable directive.

New Approach directives apply to products which are intended to be placed (or put into service) on the Community market *for the first time.*

It is the *responsibility of the manufacturer* to verify whether or not the product is within the scope of a directive.

The objects submitted to the directive are referred to, for instance, as products, equipment, apparatus, devices, appliances, instruments, material, assemblies, components or safety components, units, fittings, accessories or systems. A combination of products and parts, which

each comply with applicable directives, does not always have to comply as a whole. The decision whether a combination of products and parts needs to be considered as one finished product has to be taken by the manufacturer on a case-by-case basis.

A product, which has been subject to important changes that aim to modify its original performance, purpose or type after it has been put into service, may be considered as a new product. It must comply with the provisions of the applicable directives when it is placed on the market and put into service.

The person who carries out important changes to the product is responsible for verifying whether or not it should be considered as a new product. Products which have been repaired (for example following a defect), without changing the original performance, purpose or type, are not to be considered as new products according to New Approach directives.

Several directives may have to be taken into consideration for one product, since the placing on the market and putting into service can only take place when the product complies with all applicable provisions. This calls for a joint application of the directives.

Two or more directives can cover the same product or hazard. In such a case preference is given to the more specific directive. This usually requires a risk analysis of the product.

Consumer products outside the field of application of New Approach directives and other Community legislation come under the Directive on general product safety.

The Directive on general product safety (92/59/EEC) [8] aims to ensure that consumer products placed on the market do not present a risk under conditions of use that are normal or can be reasonably foreseen. It requires producers to place only safe products on the market. The Directive on general product safety covers new, used and reconditioned products. The Directive on general product safety contains detailed provisions on market surveillance.

The Directive on product liability (85/374/EEC) [6] , which is applicable to all products covered by New Approach directives, provides a powerful incentive to guarantee the safety of products. Consequently, New Approach directives and the Directive on product liability are complementary elements in ensuring an adequate level of protection.

4.3. List of Directives

New Approach directives (directives providing for CE marking)

1) 73/23/EEC, 93/68/EEC	Low Voltage (LVD)
2) 87/404/EEC, 90/488/EEC 93/68/EEC	Simple Pressure Vessels
3) 88/378/EEC 93/68/EEC	Safety of toys
4) 89/106/EEC, 93/68/EEC	Construction products
5) 89/336/EEC, 2004/108/EC	Electromagnetic compatibility (EMC)
6) 98/37/EC 98/79/EC	Machinery
7) 89/686/EEC, 96/58/EC	Personal protective equipment (PPE)
8) 93/68/EEC, 90/384/EEC	Non-automatic weighing instruments
9) 93/68/EEC, 90/385/EEC	Active implantable medical devices
10) 93/68/EEC, 90/396/EEC	Appliances burning gaseous fuels
11) 2004/8/EC, 2005/32/EC,92/42/EEC	Efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels
12) 93/15/EEC	Explosives for civil uses
13) 2001/104/EC, 93/42/EEC	Medical devices
14) 94/9/EC	Equipment explosive atmospheres (ATEX)
15) 2003/44/EC, 94/25/EC	Recreational craft
16) 95/16/EC	Lifts
17) 97/23/EC	Pressure equipment
18) 98/79/EC	In vitro diagnostic medical devices
19) 1999/5/EC	Radio Equipment and Telecommunication Terminal Equipment and the Mutual Recognition of their Conformity (R&ETT)

20) 2000/9/EC	Cableway installations designed to carry persons
21) 2004/22/EC	Measuring instruments (MI)

Directives based on the principles of the New Approach or the Global Approach, but which do not provide for CE marking

1) 2005/20/EC, 94/62/EC	Packaging and packaging waste
2) 2004/50/EC, 96/48/EC	Interoperability of trans-European high- speed rail system
3) 2002/84/EC , 96/98/EC	Marine equipment
4) 2004/50/EC, 2001/16/EC	Interoperability of trans-European conventional rail system

Directives based on some principles of the New Approach and the Global Approach

1) 96/57/EC	Energy efficiency requirements for household electric refrigerators, freezers and combinations thereof
2) 1999/36/EC	Transportable pressure equipment
3) 2000/14/EC	Noise emission in the environment by equipment for use outdoors
4) 2000/55/EC	Energy efficiency requirements for ballasts for fluorescent lighting

Other standards-receptive directives

1) 86/594/EEC	Airborne noise emitted by household appliances
2) 2001/95/EC	General product safety (GPS)
3) 2002/39/EC, 97/67/EC	Community postal services
4) 76/769/EEC	Restrictions on marketing and use of certain dangerous substances and preparations
5) 92/75/EC	Energy labeling of household appliances
6) 2003/108/EC,2002/96/EC	Waste electrical and electronic equipment

5. Conformity assessment. Global Approach

Conformity assessment is defined by the International Organization for Standardization/International Electrical Engineering Commission Guide 2: 1996 as: *"any activity concerned with determining directly or indirectly that relevant requirements are fulfilled."*

Typical examples of conformity assessment activities are sampling, testing and inspection, evaluation, verification and assurance of conformity (supplier's declaration), certification, registration, accreditation, and approval as well as their combinations.

Conformity assessment may also be the process by which it is determined that a product's design meets a specification or standard.

Conformity assessment may vary in levels of difficulty and complexity, depending on the level of risk associated with the product. If a Harmonized Standard is used to meet an essential requirement of a New Approach Directive, and *if the risk of injury is low* , no third party conformity assessment procedure is required. (This is true regardless of the nationality of the manufacturer.) A manufacturer or supplier may declare, after performing the necessary product evaluations (through a *Declaration of Conformity*), that the product meets the essential requirements of a directive.

As the risk of injury increases, the level of complexity of the conformity assessment process (and the cost) increases with it. The applicable directive will be the guide to the level of risk involved and the methods of conformity assessment that may be employed.

The New Approach entitled refining conformity assessment in such a way as to allow different conformity assessment mechanisms. The objective was to provide flexibility on conformity assessment over the entire manufacturing process in order for it to be adapted to the needs of each

individual operation. *The Global Approach introduced a modular approach which subdivided conformity assessment into a number of operations (modules). This modules differ according to the stage of development of the product.*

The Global Approach was completed by Council Decision 90/683/EEC, which was replaced and brought up to date by Decision 93/465/EEC [4]. These decisions lay down general guidelines and detailed procedures for conformity assessment that are to be used in New Approach directives.

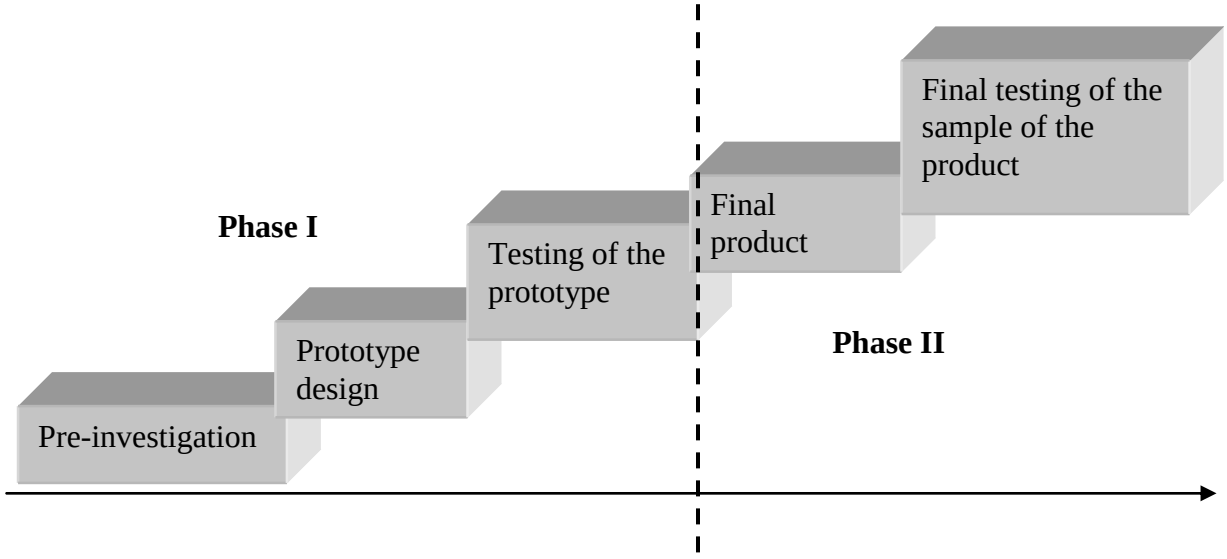
Thus, conformity assessment is based on:

- manufacturers' internal design and production control activities
- third party type examination combined with manufacturers'internal production control activities
- third party type or design examination combined with third party approval of product or production quality assurance systems, or third party product verification
- third party unit verification of design and production or
- third party approval of full quality assurance systems.

The Module Decision of Conformity Assessment

The Module Decision set out the criteria and guidelines for conformity assessment procedures to be used in the New Approach Directives. The General Guidelines are as follows and are taken directly from the document as it appeared in the Official Journal of the European Communities No. L 380/14, dated December 12, 1990:

1. The essential objective of a conformity assessment procedure is *to enable the public authorities to ensure that products placed on the market conform to the requirements* as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers.
2. Conformity assessment can be *subdivided into modules which relate to the design phase of products* and to their production phase.
3. As a general rule a product should be subject to both phases before being able to be placed on the market if the results are positive.
4. There are a variety of modules which cover the two phases in a variety of ways. The directives shall set the range of possible choices which can be considered by the Council to give the public authorities the high level of safety they seek, for a given product or product sector.



5. In setting the range of possible choices open to the manufacturer, the directives, will take into consideration, in particular, such issues as the appropriateness of the modules to the type of products, the nature of the risks involved, the economic infrastructures of the given sector (e.g., existence or non-existence of third parties), the types and importance of production, etc.

The factors that have been taken into account must be explicitly spelled out by the Commission in these directives.

6. The directives will, in setting the range of possible modules for a given product or product sector, attempt to leave as wide a choice to the manufacturer as is consistent with ensuring compliance with the requirements.
7. The directives will set out the criteria governing the conditions in which the manufacturer shall choose the most appropriate modules for his production from the modules laid down by the directives.
8. The directives should avoid imposing unnecessarily modules.
9. Notified bodies should be encouraged to apply the modules without unnecessary burden for the economic operators. The Commission, in cooperation with the Member States, shall ensure that close cooperation is organized between the notified bodies in order to ensure consistent technical application of the modules.

CEN and CENELEC's principal members are national standards bodies. ETSI's membership incorporates a wider range of interested parties . These three are *the only recognized bodies* from which European Standard (EN) can emanate. When the development of a European Standard begins in one of these organizations, development of a national standard must stop. European Standards, like European laws and European conformity assessment procedures, preempt national (Member State) standards, and replace them.

6. Placing on the market and putting into service

Placing on the market is the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community.

The concept of placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series.

The transfer of the product takes place either from the manufacturer, or the manufacturer's authorized representative in the Community, to the importer established in the Community or to the person responsible for distributing the product on the Community market. The transfer may also take place directly from the manufacturer, or authorized representative in the Community, to the final consumer or user.

Placing on the market is considered not to take place where a product is:

- transferred from the manufacturer in a third country to an authorized representative in the Community;
- transferred to a manufacturer for further measures (for example assembling, packaging, processing or labeling);
- manufactured in a Member State with a view to exporting it to a third country;
- displayed at trade fairs, exhibitions or demonstrations or
- in the stocks of the manufacturer, or the authorized representative established in the Community;

A product offered in a catalogue or by means of electronic commerce is deemed not to have been placed on the Community market until it is actually made available for the first time.

New products manufactured in the Community and all products *imported from third countries* – whether new or used – must meet the provisions of the applicable directives when made available for the first time on the Community market. Member States have an obligation to ensure this in the framework of market surveillance.

Putting into service takes place at the moment of first use within the Community by the end user. Products must comply with the provisions of the applicable New Approach directives and other Community legislation when they are put into service.

The need to verify the compliance of products should be limited, in the framework of market surveillance , to products:

- which can only be used after an assembly, an installation or other manipulation has been carried out
- whose compliance can be influenced by the distribution conditions (for example storage, transport) or
- which are not placed on the market prior to putting into service (for example products manufactured for own use).

Transitional period

The aim of the transitional period is to allow manufacturers and notified bodies to adjust gradually to the conformity assessment procedures
and the essential requirements set up by the new directive. The transitional period provides for extra time for the adoption of harmonized standards, even though this is not, in principle, a precondition for the application of New Approach directives.

Most New Approach directives provide for a transitional period. During the transitional period, products conforming to all applicable directives may be placed on the Community market and put into service in any Member State.

Each directive providing for a transitional period sets the date for freezing the national system in force.

At the end of the transitional period, Member States are obliged to terminate the national systems kept in force until then, for example to repeal the relevant regulations. As a result, the national measures implementing the new directive will be the only mandatory rules in force for the products or risks concerned in every Member State.

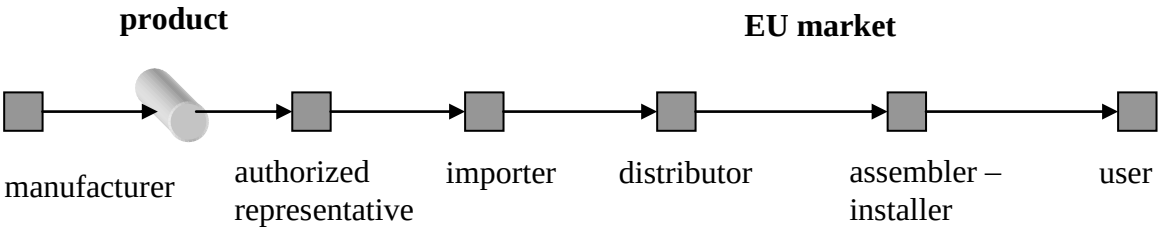
After the transitional period, products manufactured before or during this period may no longer be placed on the Community market. A product which is placed on the market before the end of the transitional period may only be put into service after that date if it fully complies with the provisions of the directive.

Only products in compliance with the applicable directive may be placed on the Community market and put into service after the transitional period.

According to the general rule, CE marking is an indication that products, which are subject to several directives providing for its affixing, conform to the provisions of all these directives. During a transitional period, the CE marking does not necessarily indicate that the product conforms to all applicable directives providing for its affixing.

Information concerning the directives applied must also be given in the EC declaration of conformity.

7. Responsibilities



Supply chain

Manufacturer

The manufacturer is any natural or legal person who is responsible for designing and manufacturing a product with a view to placing it on the Community market under his own name. The responsibilities of the manufacturer apply also to any natural or legal person who assembles, packs, processes, or labels ready-made products with a view to their being placed on the Community market under his own name.

Where subcontracting takes place, the manufacturer must retain the overall control for the product and ensure that he receives all the information that is necessary to fulfill his responsibilities according to the New Approach directives.

The manufacturer is responsible:

- for designing and manufacturing the product in accordance with essential requirements laid down by the directive
- for carrying out conformity assessment in accordance with the procedure(s) laid down by the directive.

As a general rule, the manufacture must take all measures necessary to ensure that the manufacturing process assures compliance of the products, to affix the CE marking to the product, to establish a technical documentation and to draw up the EC declaration of conformity. Depending on the directive, the manufacturer may be required to submit the product to a third party (usually a notified body) for product testing and certification, or to have the quality system certified by a notified body.

However, sometimes it is not possible to identify the person who, in reality, was in charge of designing and manufacturing the product. This does not reduce the responsibilities of the person who placed the product on the Community market.

The manufacturer must ensure that the product complies with the applicable directives, and that the appropriate conformity assessment procedure has been carried out.

A product may be put into service without prior placing on the market (such as a product manufactured for own use). In such a case the person who puts the product into service must assume the responsibilities of the manufacturer. Accordingly, he must ensure that the product complies with the directive, and that appropriate conformity assessment has been carried out.

New Approach directives do not require the manufacturer to be established in the Community. Thus, the responsibilities of a manufacturer according to the directives are equal whether he is established outside the Community or in a Member State.

The Directive on general product safety requires manufacturers to place only safe products on the market. Legal or administrative action may take place against any person in the supply or distribution chain who can be considered responsible for a non-compliant product. This may, in particular, be the case when the manufacturer is established outside the Community.

According to the Directive on general product safety, a producer is the manufacturer of the product when he is established in the Community. Any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the

person who reconditions the product, is also the producer. A producer is also the manufacturer's representative when the manufacturer is not established in the Community or if there is no representative established in the Community, the importer. Other professionals in the supply chain are producers insofar as their activities may affect the safety properties of a product on the market.

Authorized representative

The manufacturer may be based in the Community or elsewhere. In either case, the manufacturer may appoint an authorized representative in the Community.

An Authorized Representative is the person appointed by the manufacturer and delegated to act on his or her behalf in carrying out certain tasks required by a New Approach Directive. This Authorized Representative must be established inside the European Union and available to Member State Authorities. The manufacturer, however, is ultimately responsible for the actions carried out by the Authorized Representative.

Manufacturers established outside the European Union are not necessarily required to have an Authorized Representative in the European Union. There are **exceptions,** however. Manufacturers who do not have a registered place of business in a Member State and whose products are governed by the Directives for Medical Devices, Active Implantable Devices and In-vitro Diagnostic Devices, must appoint an Authorized Representative established within the European Union.

The delegation of tasks from the manufacturer to the authorized representative should be arranged by contract.

For the purposes of New Approach directives, to be able to act on behalf of the manufacturer, the authorized representative must be established inside the Community.

Depending on the conformity assessment procedure and the directive, the following tasks can be delegated to the Authorized Representative:

- to ensure and declare that the product complies with the requirements;
- to affix the CE marking and the notified body's number to the product;
- to draw up and sign the Declaration of Conformity
- to keep the Declaration and the technical documentation at the disposal of national surveillance authorities.

An authorized representative cannot modify the product on his own initiative in order to bring it into line with the applicable directives.

The authorized representative can, at the same time, act as a subcontractor. As a subcontractor he may, for instance, take part in the design and manufacture of the product, on condition that the manufacturer retains the overall control for the product.

Commercial representatives of the manufacturer (such as authorized distributors), whether or not established inside the Community, are not to be confused with the authorized representative in the meaning of New Approach directives.

The authorized representative can also at the same time act as an importer.

Importer

An importer (a person responsible for placing on the market) – in the meaning of New Approach directives – is any natural or legal person established in the Community who places a product from a third country on the Community market.

According to New Approach directives, the importer must be able to provide the surveillance authority with a copy of the EC declaration of conformity, and make the technical documentation available. This responsibility is placed on the importer only where the manufacturer is not established in the Community, and has no authorized representative in the Community.

The importer should require formal assurance in writing from the manufacture that the documents will be made available when requested by the surveillance authority.

The importer must ensure, in order to fulfill his responsibilities, that a contact with the manufacturer can be established. In some situations the person referred to as an importer shall be able to assume the responsibilities of the manufacturer.

Distributor

Provisions regarding distribution are in general *not included* in New Approach directives. A distributor is to be considered as any natural or legal person in the supply chain who takes subsequent commercial actions after the product has been placed on the Community market. The distributor shall act with due care in order not to place clearly non-compliant products on the Community market. He shall also be capable of demonstrating this to the national surveillance authority.

Retailers, wholesalers and other distributors in the supply chain do not need to have a preferential relationship with the manufacturer like the authorized representative.

The distributor should act with due care and have a basic knowledge of the applicable legal requirements. He should know, for instance, which products must bear the CE marking, what information (for example EC the declaration of conformity) has to accompany the product, what are the language requirements for users' instructions or other accompanying documents, and what is a clear indication of the product being non-compliant. Accordingly, he may not supply products that he knows or should have assumed, on the basis of information in his possession and as a professional, not to be in compliance with the legislation. Further, he should cooperate in actions taken to avoid or minimize these risks.

The distribution conditions (for example transportation or storage) may have an impact on maintaining the compliance with the provisions of the applicable directive. This may, for instance, be the case for measuring instruments and medical devices. Thus, the person in charge of the distribution conditions shall take the necessary measures to protect the compliance of the product. This is to ensure that the product complies with the essential requirements at the moment of first use within the Community.

The distribution conditions may, in the absence of Community legislation, be regulated to some extent on the national level.

New Approach directives do not foresee that the distributor would take over the responsibilities of the manufacturer. Therefore, he cannot, for instance, be requested to make a copy of the EC declaration of conformity or the technical documentation available, unless he is at the same time the authorized representative established in the Community or the importer.

He has an obligation to demonstrate to the national surveillance authority that he has acted with due care and ensured that the manufacturer, or his authorized representative in the Community, or the person who provided him with the product has taken the necessary measures required by the applicable directives. The distributor must also be able to identify the manufacturer, his authorized representative in the Community, the importer or the person who has provided him with the product in order *to assist the surveillance authority* in its efforts to receive the EC declaration of conformity and the necessary parts of the technical documentation.

According to the Directive on general product safety the distributor is defined as any professional *in the supply chain* whose activity does not affect the safety properties of a product. *The Directive requires distributors to act* with due care in order to help to ensure compliance with the general safety requirement of the Directive, in particular by not supplying products that they know or should have presumed, on the basis of the information in their possession and as professionals, not to comply with this requirement.

Assembler and installer

Some products can only be used after an assembly, an installation or other manipulation has been carried out. This may, for instance, be the case for machinery, personal protective equipment, measuring instruments, gas appliances and telecommunications terminal equipment TTE).

The person responsible for such manipulations must ensure that they do not cause a non-compliance with the essential requirements.

User (employer)

Many products covered by New Approach directives are used at the workplace.

An *employer* is considered to be any natural or legal person who has an employment relationship with a worker and has responsibility for the undertaking or establishment.

According to *the Directive 89/655/EEC* of 30 November 1989, *concerning the minimum safety and health requirements for the use of work equipment by workers at work*, the employer must take all measures necessary to ensure that the work equipment (for example machinery and apparatus) made available to the workers is suitable for the work carried out, and may be used by workers without impairment to their safety or health. The employer may only obtain or use work equipment that complies with the provisions of the applicable directives.

Further, the employer has an obligation to provide information and training for workers as regards the use of work equipment.

According to *the Directive 89/656/EEC* of 30 November 1989, *concerning the minimum health and safety requirements for the use of personal protective equipment by workers at the workplac*e, such equipment must comply with the relevant Community provisions on design and manufacture with respect to safety and health (that is the New Approach Directive relating to personal protective equipment).

The employer is required, before choosing the personal protective equipment, to assess that it satisfies the requirements.

According to *the Directive 90/270/EEC* of 29 May 1990 *on the minimum safety and health requirements for work with display screen equipment* , employers are obliged to perform an analysis of workstations in order to evaluate the safety and health conditions, particularly regarding possible risks to eyesight, physical problems and problems of mental stress. The Directive also lays down the minimum requirements for the display screen and other equipment.

In accordance with the training and the instructions given by their employer *the workers* must, for instance, make correct use of machinery, apparatus, and other means of production, and the personal protective equipment.

A user's manual is an essential safety requirement. A user's manual must contain all the information required for the correct and safe use of a product, including:

* information concerning risks;
* identification and discouragement of hazardous applications;
* instructions on how the product must be put to safe use;
* identification of those authorized to perform certain actions; and
* identification of appropriate safety precautions that have to be taken.

8. Non-compliance

What have the Europeans done to enforce the CE marking requirements and what are the penalties for non-compliance ?

Products may be placed on the market and put into service only if they are in compliance with the essential requirements.

Presumption of conformity

Products that comply with national standards transposing harmonized standards, the reference numbers of which have been published in the *Official Journal of the European Communities*, are presumed to comply with the corresponding essential requirements.

Member States are obliged to take the necessary measures to ensure that products are placed on the market and put into service only if they do not endanger the safety and health of persons, or other public interests covered by the directive, when properly installed, maintained and used for

the intended purposes. This entails an obligation for market surveillance on the part of the Member States.

European national agencies have been appointed to conduct market surveillance for CE marking. The purpose of this surveillance is to ensure that the provisions of the New Approach Directives have been met for products marketed within the European Union.

In pursuit of this goal, surveillance authorities will:

- visit commercial, industrial and storage premises on a regular basis;
- visit work places and other premises where products are put into service and used ;
- organize random checks;
- take samples of products for examination and testing.

The surveillance authority can ask for the manufacturer's *declaration of conformity* and *technical file* after making a random check.

The manufacturer, his authorized representative or the importer must be able to provide the technical file within 7 to 10 days after the surveillance authority makes the request. If the product is found to be *noncompliant,* corrective action will depend on and be appropriate to the level of noncompliance.

The surveillance authority will hold accountable the person responsible for affixing the CE mark to the non-compliant product. Others responsible for the noncompliance of the product will be held accountable as well.

Penalties, which may include imprisonment, are *determined by national law.*

Sweden (Approval March/April 1997, vol.3) has become the first country to remove product from the EU market because they do not comply with the EMC Directive. Under Article 9.1 of the directive, member states which find non-compliant products are obliged to remove them from European market and to inform the Commission. Sweden has notified the Commission, and other member states, of three products which have been tested and do not comply. All three are frequency converters used in motor drive products. The manufacturers are all said to be large multinational organizations. Products are removed from the market as soon as they have been identified as non-compliant.

In Germany (Compliance Engineering, July/August 1997) each month roughly 1500 data sheets concerning market surveillance are established and processed. For further processing, 750 sheets are forwarded to the regional offices responsible for the company which placed the equipment on the market.

The interpretation of the data sheets has led to the following results:

- Currently, testing of the equipment is restricted to visual inspections in most cases.
- Technical tests on the premises of the customer require a lot of time and effort .
- An additional problem is the fact that in some cases it is very time-consuming to find the mark of conformity (CE-label) on the product, in the equipment documents or on the packaging.
- The quality of these sheets varies to a great extent.
- The identification of the company which placed the equipment on the market using delivery notes has proven to cause the most problems.

IS ISO 9000 REQUIRED IN ORDER TO GET THE CE MARK?

ISO 9000 registration (or EN 29000 certification) is used widely in Europe *on a voluntary basis* as a condition of acceptance of a manufacturer's product or as a way of recognizing the manufacturer's credibility. While a quality system such as ISO 9000 indicates that a company has an efficient organization structure and has low failure costs, *it does not always certify conformity with the CE mark directives*. However, *some directives require use of a quality management system as part of the conformity assessment*.

For example, the Machine Directive requires manufacturers to set up a quality control system to make sure that future products coming off an assembly line meet CE mark requirements. However, the quality control system does not have to be ISO 9000, although ISO 9000 is a good choice, since it is widely recognized.

The Medical Device Directive does require ISO 9000 (EN 13485) as part of the conformity assessment process.

The Directive on product liability (DPL) 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [6].

DPL covers any product manufactured or imported into the Community, which causes damage to individuals or private property. Thus, the Directive applies also to products that fall within the scope of a New Approach directive**.**

The Directive on product liability covers all movable and electricity, as well as raw materials and components of final products. Services as such are excluded from the scope at present. The Directive applies only to defective products.

Liability, the responsibility to pay for damages, is placed on a producer. Importers placing products on the Community market from third countries are all considered to be producers according to the Directive on product liability. If the producer cannot be identified, each supplier of the product becomes liable.

When several persons are liable for the same damage, they are all liable jointly.

The producer must compensate for damages caused by the defective product to individuals (death, personal injury) and private property (goods for private use). However, the Directive does not cover any damage to property under EUR 500 for a single incident.

The Directive does not cover the destruction of the defective product itself.

The producer is not automatically liable for damages caused by the product. The injured person, whether or not he is the buyer or user of the defective product, must claim his rights to obtain compensation. The victim will be paid only if he proves that he has suffered damage, the product was defective, and this product caused the damage.

The producer will not have to pay, if he proves:

- he did not place the product on the market (for example the product was stolen)
- the product was not defective when he placed it on the market
- the product was not manufactured to be sold
- where he is a subcontractor, that the defect was due either to the design of the finished product or to defective instructions given to him by the producer of the finished product.

Ten years after the product is placed on the market, the producer is liable.

9. Compliance with Directives and with harmonised standards

Essential Requirements

Essential requirements are the requirements that products must meet to be put on the market. They are mandatory. These requirements deal in particular with the protection of health and safety of users (usually consumers and workers) and sometimes cover other fundamental requirements (for example protection of property or the environment). Essential requirements are designed to provide and ensure a high level of protection.These requirements define the results to be attained, or the risks to be dealt with, but do not specify the technical solutions for doing so. *Suppliers are free to choose how the requirements are to be met.*

Essential requirements are therefore written in such a way that *they remain valid over time* independent of technical progress. Assessment of whether requirements have been met should be based on the state of technical know-how at a given moment.

This does not mean that essential requirements are not determined. They have to be drafted in such a way as to give sufficient information to enable assessment of whether products meet them.

Several directives may be applicable to a given product at the same time, since essential requirements of different directives need to be applied simultaneously in order to cover all relevant public interests.

The flexibility allows manufacturers to choose the way to meet the requirements.

Directive 98/34/EC of 22 June 1998 [9]**,** laying down a procedure for the provision of information in the field of technical standards and regulations, defines European standards as technical specifications adopted by European standards organizations.

According to the internal rules of these organizations, European standards must be transposed at national level. This transposition means that the European standards in question must be made available as national standards in an identical way, and that all conflicting national standards must be withdrawn in a given period.

The technical contents of such standards are under the entire responsibility of the European standards organizations:

CEN (European Committee for Standardization);

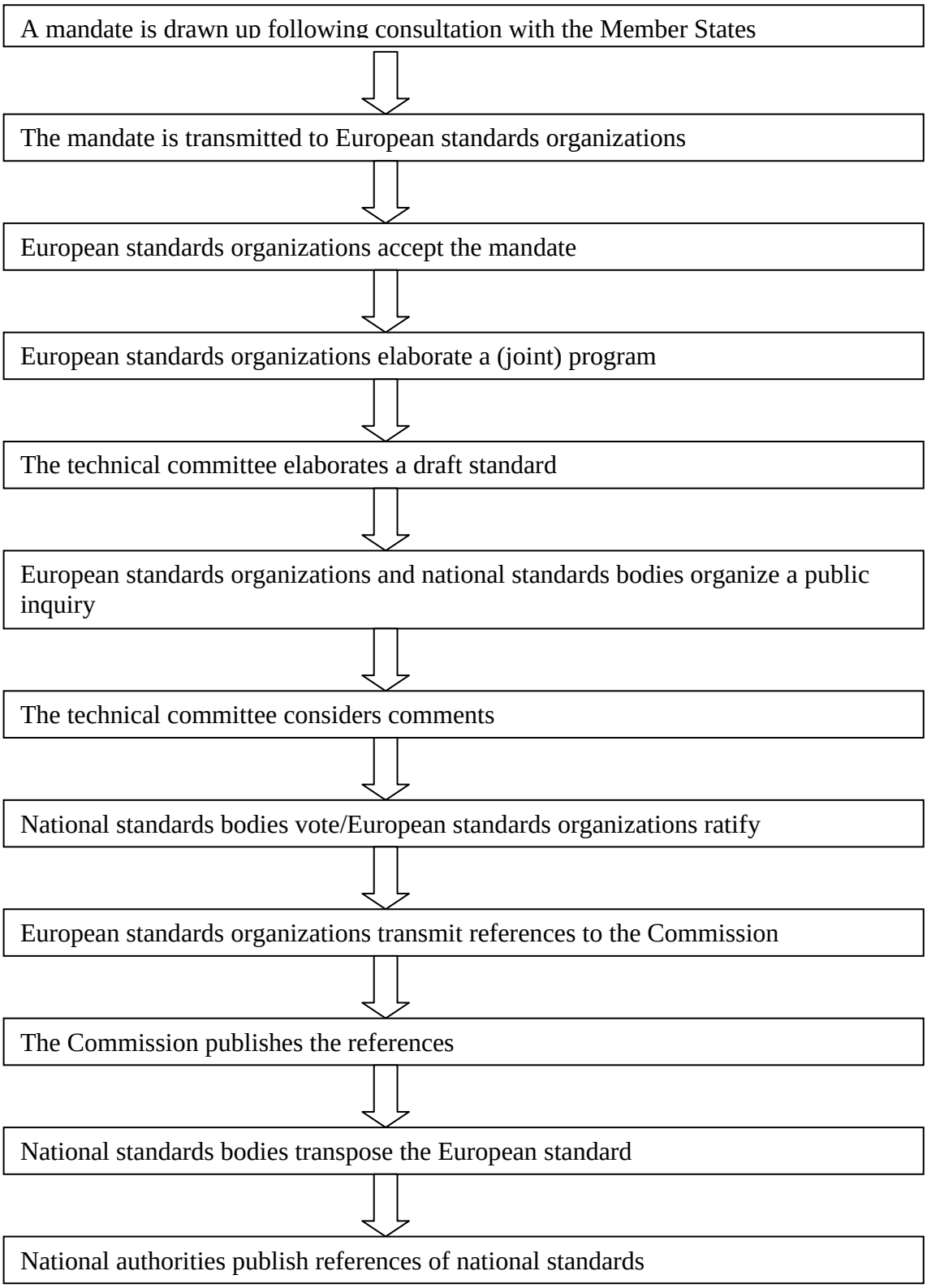
CENELEC (European Committee for Electrotechnical Standardization);

ETSI (European Telecommunication Standards Institute).

A harmonised standard must match the essential requirements of the relevant directive. A European standard may contain provisions relating not only to essential requirements but also to other provisions. The harmonised standard does not necessarily cover all essential requirements. This would oblige the manufacturer to use other relevant technical specifications in order to meet all the essential requirements of the directive.

Harmonization documents must be implemented at national level, at least by public notification of the title and number of the document, and by the withdrawal of conflicting national standards.

Standardization procedure under the New Approach



10. Conformity

10.1. Definition

Conformity assessment is defined by the International Organization for Standardization/International Electrical Engineering Commission Guide 2: 1996 as: *"any activity concerned with determining directly or indirectly that relevant requirements are fulfilled."*

Typical examples of conformity assessment activities are sampling, testing and inspection, evaluation, verification and assurance of conformity (supplier's declaration), certification, registration, accreditation, and approval as well as their combinations.

Conformity assessment may also be the process by which it is determined that a product's design meets a specification or standard.

Conformity assessment may vary in levels of difficulty and complexity, depending on the level of risk associated with the product. If a Harmonized Standard is used to meet an essential requirement of a New Approach Directive, and *if the risk of injury is low*, no third party conformity assessment procedure is required. (This is true regardless of the nationality of the manufacturer.) A manufacturer or supplier may declare, after performing the necessary product evaluations (through a *Declaration of Conformity*), that the product meets the essential requirements of a directive.

As the risk of injury increases, the level of complexity of the conformity assessment process (and the cost) increases with it. The applicable directive will be the guide to the level of risk involved and the methods of conformity assessment that may be employed.

Presumption of conformity

Conformity with a national standard that transposes a harmonized standard, whose reference has been published, confers a presumption of conformity with the essential requirements of the applicable New Approach directive that is covered by such a standard Harmonized standards provide a presumption of conformity with the essential requirements , if their reference has been published in the *Official Journal* and if they have been transposed at national level. However, it is not necessary that transposition takes place in all Member States before the presumption of conformity becomes effective.

Since European standards have to be transposed in a uniform way, a manufacturer may choose any of the corresponding national standards. The objective of publishing the reference in the *Official Journal* is to set the earliest date for the presumption of conformity to take effect.

The application of harmonized standards that give a presumption of conformity remains voluntary .The manufacturer can choose whether or not to refer to harmonized standards. Compliance with harmonized standards will, according to certain directives, determine the applicable conformity assessment procedure, which sometimes opens the possibility for conformity assessment without the intervention of a third party.

Revision of harmonized standards

The formal decision to revise a standard is, in principle, taken by the European standards organizations. The need for revision can result from the changes of the scope of the directive (such as an extension of the scope to other products or a modification of the essential requirements).

During this transitional period both harmonized standards give presumption of conformity, provided that the conditions for this are met. After this transitional period, only the revised harmonized standard gives a presumption of conformity.

10.2. Conformity assessment procedure

The directives set out the criteria governing the conditions under which the manufacturer can make a choice, if more than one option is provided for.
The factors that have been taken into account when setting the range of possible procedures are described in the directives.

As a general rule, a product is subject to conformity assessment according to a module during the design as well as the production phase.

Conformity assessment according to the modules is either based on the intervention of a first party (manufacturer) or a third party (notified body).

Should a manufacturer subcontract design or production, he still remains responsible for the execution of conformity assessment for both phases.

New Approach directives establish different procedures, according to the categories of products covered, by either leaving manufacturers no choice or by giving them the freedom of choice within the same category of products.

The Member States must transpose into their national legislation all the conformity assessment procedures established under a directive and they must guarantee the free movement of all products, which have been subject to a conformity assessment procedure according to the directive in question.

Certain directives provide for the possibility of using procedures based on quality *assurance techniques from the EN ISO 9000 series of standards.*

MODULES FOR CONFORMITY ASSESSMENT

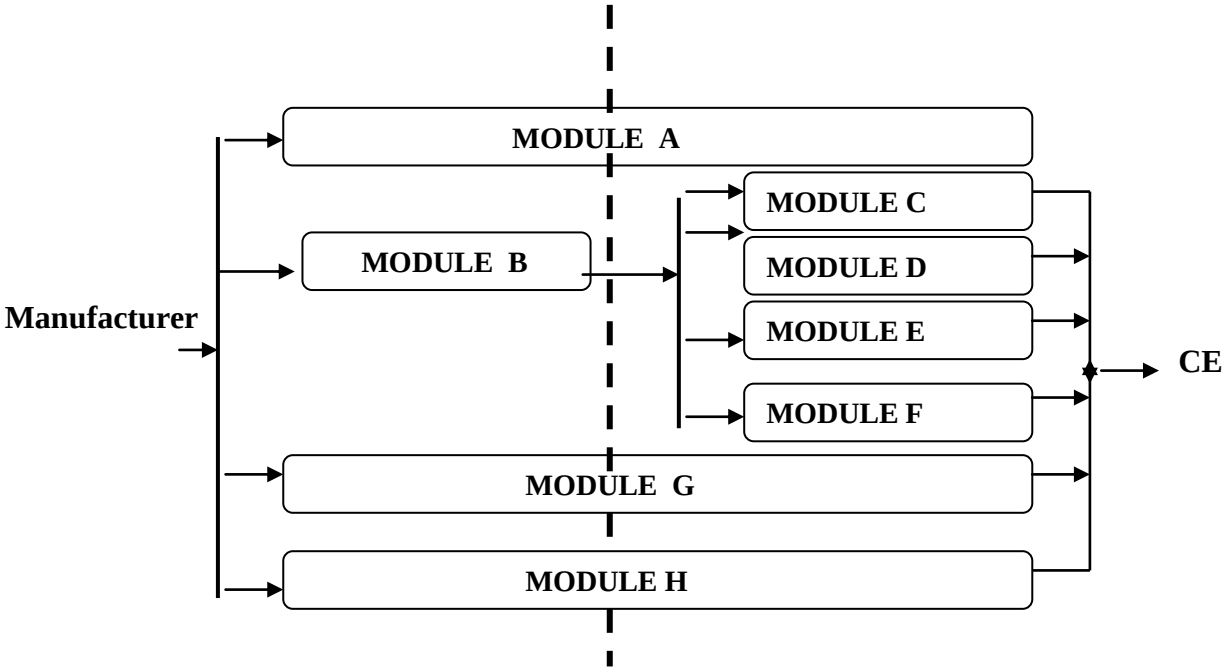
Explanatory notes

Specific directives may allow the CE marking to be affixed to the packaging or the Accompanying documentation, instead of to the product itself.

The declaration of conformity or the certificate of conformity (whichever of the two applies in the directive concerned) must cover either individual or several products and shall either accompany the product covered or be kept by the manufacturer. The appropriate solution for the directive concerned will be specified.

Specific directives may use modules A,C and H with additional provisions containing supplementary requirements which figure in the boxes. Module C is designed to be used in combination with module B (EC type-examination). Modules D, E and F will also normally be used in combination with module B; however, in special cases (for example, when dealing with certain products of very simple design and construction) the may be used on their own.

Module A (internal product control)
Module B (EC type-examination)
Module C (conformity to type)



Simplified flow chart of conformity assessment procedures

The modules based on quality assurance techniques (modules D, E, H and their variants) describe the elements a manufacturer must implement in his organization in order to demonstrate that the product fulfills the essential requirements of the applicable directive. This means that a manufacturer is given the possibility of using an approved quality system for the purpose of demonstrating compliance with the applicable essential requirements.

Module approach

A. Internal control of the production	Covers internal design and production control.
B. EC type-examination	Covers the design phase and must be followed up by a module providing for assessment in the production phase. The EC type-examination certificates issued by a notified bodies.
C. Conformity type	Covers the production phase and follows module B. Provides for conformity with the type as described in the EC type-examination certificate issued according to module B. This module does not require a notified body to take action.
D. Production quality assurance	Covers the production phase and follows module B. Derives from the quality assurance Std EN ISO 9002, with the intervention of a notified body responsible for approving and controlling the quality system for production, final inspection and testing set up by the manufacturer.
E. Product quality assurance	Covers the production phase and follows module B. Derives from the quality assurance Std EN ISO 9003, with the intervention of a notified body responsible for approving and controlling the quality system for production, final inspection and testing set up by the manufacturer.

F. Product verification	Covers the production phase and follows module B. A notified body controls conformity to the type as described in the EC type-examination certificate issued according to module B, and issues a certificate of conformity.
G. Unit verification	Covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.
H. Full quality assurance	Covers the design and product phases. Derives from quality assurance standard EN ISO 9001, with the intervention of a notified body responsible for approval and controlling the quality system for design, manufacture, final product inspection and testing set up by the manufacturer

10.3. Council Decision 93/465/EEC

COUNCIL DECISION 93/465/EEC of 22 July *1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives* [4].

GENERAL GUIDANCE

A. The principal guidelines for the use of conformity assessment procedures in technical harmonization directives.

The essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers.

Conformity assessment can be subdivided into modules which relate to the design phase of products and to their production phase.

As a general rule a product should be subject to both phases before being able to be placed on the market if the results are positive. There are a variety of modules which cover the two phases in a variety of ways. The directives must set the range of possible choices which can be considered by the Council to give the public authorities the high level of safety they seek, for a given product or product sector.

In setting the range of possible choices open to the manufacturer, the directives, will take into consideration, in particular, such issues as the appropriateness of the modules to the type of products, the nature of the risks involved, the economic infrastructures of the given sector (e.g. existence or non-existence of third parties), the types and importance of production, etc. The factors that have been taken into account must be explicitly spelled out by the Commission in these directives.

The directives will, in setting the range of possible modules for a given product or product sector, attempt to leave as wide a choice to the manufacturer as is consistent with ensuring compliance with the requirements.

The directives will set out the criteria governing the conditions in which the manufacturer chooses the most appropriate modules for his production from the modules laid down by the directives.

The directives should avoid imposing unnecessarily modules which would be too onerous relative to the objectives of the directive concerned.

Notified bodies should be encouraged to apply the modules without unnecessary burden for the economic operators. The Commission, in cooperation with the Member States, must ensure that close cooperation is organized between the notified bodies in order to ensure consistent technical application of the modules.

In order to protect the manufacturers, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessment of conformity. Legal protection of confidential information is required.

Whenever directives provide the manufacturer with the possibility of using modules based on quality assurance techniques, the manufacturer must also be able to have recourse to a combination of modules not using quality assurance, and vice versa, except where compliance with the requirements laid down by the directives requires the exclusive application of a certain procedure;

For the purposes of operating the modules, Member States must notify on their own responsibility bodies under their jurisdiction which they have chosen from the technically competent bodies complying with the requirements of the directives. This responsibility involves the obligation for the Member States to ensure that the notified bodies permanently have the technical qualifications required by the directives and that the latter keep their competent national authorities informed of the performance of their tasks. Where a Member State withdraws its notification of a body, it must take appropriate steps to ensure that the dossiers are processed by another notified body to ensure continuity;

In addition, with regard to conformity assessment, the sub-contracting of work shall be subject to certain conditions guaranteeing:

- the competence of the establishment operating as sub-contractor, on the basis of conformity with series EN 45 000 standards, and the capability of the Member State that has notified the sub-contracting body to ensure effective monitoring of such compliance,
- the ability of the body notified to exercise effective responsibility for the work carried out under sub-contract.

Notified bodies which can prove their conformity with harmonized standards (EN 45 000 series), by submitting an accreditation certificate or other documentary evidence, are presumed to conform to the requirements of the directives. Member States having notified bodies unable to prove their conformity with the harmonized standards (EN 45 000 series) may be requested to provide the Commission with the appropriate supporting documents on the basis of which notification was carried out. List of notified bodies must be published by the Commission in the Official Journal of the European Communities and constantly updated.

B. The principal guidelines for the affixing and use of the CE marking.

The CE marking symbolizes conformity to all the obligations incumbent on manufacturers for the product by virtue of the Community directives providing for its affixing.

Thus, such conformity is not limited to the essential requirements relating to safety, public health, consumer protection, etc., as certain directives may impose specific obligations not necessarily forming part of the essential requirements.

The CE marking affixed to industrial products symbolizes the fact that the natural or legal person having affixed or been responsible for the affixing of the said marking has verified that the product conforms to all the Community total harmonization provisions which apply to it and has been the subject of the appropriate conformity evaluation procedures.

Where the industrial products are subject to other directives concerning other aspects and which also provide for the affixing of the CE marking, the latter must indicate that the products are also presumed to conform to the provisions of those other directives. However, where one or more of these directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking indicates conformity to the provisions only of those directives applied by the manufacturer. In this case, particulars of the directives applied, as

published in the Official Journal of the European Communities, must be given in the documents, notices or instructions accompanying the products or, where appropriate, on the data plate.

The CE conformity marking must consist of the initials 'CE' taking the following form:

- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- Where the directive concerned does not impose specific dimensions, the CE marking must have a height of at least 5 mm.
- The CE marking must be affixed to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents.
- The CE marking must be affixed visibly, legibly and indelibly.

Any industrial product covered by the technical harmonization directives based on the principles of the global approach must bear the CE marking, save where the specific directives provide otherwise; such exceptions constitute derogations not from the marking requirement but from the administrative procedures for conformity evaluation, which may in certain cases be considered too cumbersome. Appropriate grounds must accordingly be given for any exception to or derogation from the marking requirement.

The CE marking is the only marking which certifies that the industrial products conform to the directives based on the principles of the global approach.

Member States must refrain from introducing into their national regulations any reference to a conformity marking other than the CE marking in connection with conformity to all the provisions contained in the directives on CE marking.

The CE marking must be affixed at the end of the production control phase.

The CE conformity marking must be followed by the identification number of the notified body within the meaning of paragraph I.A where the said body is involved in the production control phase within the meaning of this Decision. Such identification numbers must be assigned by the Commission as part of the body notification procedure. The Commission must publish lists of the notified bodies in the Official Journal of the European Communities; such lists must be updated regularly.

A notified body must be assigned the same number when it is notified under several directives. The Commission must ensure that each notified body receives a single identification number, however many directives it is notified under.

It is necessary to lay down provisions concerning the use of certain products. In this case, the CE marking and the identification number of the notified body may be followed by a pictogram or any other mark indicating, for example, the category of use.

The affixing for any other marking liable to deceive third parties as to the meaning and form of the CE marking must be prohibited.

A product may bear different marks, for example marks indicating conformity to national or European standards or with traditional optional directives, provided such marks are not liable to cause confusion with the CE marking. Such marks may therefore only be affixed to the product, its packaging or the documentation accompanying the product on condition that the legibility and visibility of the CE marking are not thereby reduced.

The CE marking must be affixed by the manufacturer or his agent established within the Community. In exceptional, duly warranted cases, the specific directives may provide that the CE marking can be affixed by the person responsible for placing the product on the Community market.

The identification number of the notified body must be affixed under its responsibility either by the body itself or by the manufacturer or his agent established within the Community.

Member States must take all provisions of national law necessary to exclude any possibility of confusion and to prevent abuse of the CE marking.

Without prejudice to the provisions in the directive concerned relating to the application of the safeguard clause, where a Member State establishes that the CE marking has been affixed unduly, the manufacturer, his agent or, exceptionally, where the specific directives so provide, the person responsible for placing the product in question on the Community market is obliged to make the product comply and to end the infringement under conditions imposed by the Member State. Where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in the safeguard clauses.

MODULES FOR CONFORMITY ASSESSMENT

Explanatory notes

Specific directives may allow the CE marking to be affixed to the packaging or the accompanying documentation, instead of to the product itself.

The declaration of conformity or the certificate of conformity (whichever of the two applies in the directive concerned) must cover either individual or several products and shall either accompany the product covered or be kept by the manufacturer. The appropriate solution for the directive concerned will be specified.

Specific directives may use modules A, C and H with additional provisions containing supplementary requirements which figure in the boxes in the modules. Module C is designed to be used in combination with module B (EC type-examination). Modules D, E and F will also normally be used in combination with module B; however, in special cases (for example, when dealing with certain products of very simple design and construction) they may be used on their own.

Module A (internal product control)
Module B (EC type-examination)
Module C (conformity to type)
Module D (production quality assurance)
Module E (product quality assurance)
Module F (product verification)
Module G (unit verification)
Module H (full quality assurance)

10.4. Responsibilities of the manufacturer (authorised representative) and the notified body through the modules

Module A
Manufacturer

- establishes a technical documentation as regards the design, manufacture and operation of the product
- takes all measures necessary to ensure that the manufacturing process assures compliance of the products with the technical documentation
  and with the applicable requirements (i.e. operates a quality system Manufacturer or the authorised representative).
- ensures and declares that the products concerned satisfy the requirements
- affixes the CE marking to each product
- draws up a declaration of conformity
- keeps a copy of the declaration of conformity and the technical documentation at the disposal of the surveillance authorities

Module B

Manufacturer

- establishes a technical documentation as regards the design, manufacture and operation of the product

Manufacturer or the authorised representative

- applies for the EC type-examination
- places at the disposal of the notified body one (or more) specimen(s), which is (are) representative of the production envisaged
- informs the notified body of all modifications to the approved product
- keeps the technical documentation, including a copy of the EC type-examination certificate, at the disposal of the surveillance authorities.

Notified bodies

- ascertains, by performing or having performed examinations and tests, that the specimen(s) meet(s) the applicable provisions and is manufactured in accordance with the technical documentation
- issues an EC type-examination certificate
- keeps a copy of the certificate and a record of other relevant technical information
- communicates to the other notified bodies the relevant information concerning the EC type-examination certificates (on request).

Module C

Manufacturer

- takes all measures necessary to ensure that the manufacturing process assures compliance of the products with the type as described in the EC type-examination certificate and with the applicable requirements (i.e. operates a quality system, which includes establishing the necessary documentation).

Manufacturer or the authorised representative

- ensures and declares that the products concerned are in conformity with the EC type-examination certificate and satisfy the applicable requirements
- affixes the CE marking to each product
- draws up a declaration of conformity
- keeps relevant technical information and a copy of the declaration of conformity at the disposal of the surveillance authorities.

Module D

Manufacturer

- operates an approved quality system for production, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the product category envisaged, documentation concerning the quality system and its updating, technical documentation of the approved type, a copy of the EC type-examination certificate, and the decisions and reports from the notified body) applies for the assessment of the quality system for the products concerned
- ensures and declares that the products concerned are in accordance with the EC type-examination certificate and satisfy the applicable requirements
- undertakes to fulfill the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient

  supports the action carried out by the notified body for surveillance purpose
- keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body.

Manufacturer or the authorised representative

- affixes the CE marking to each product
- affixes the notified body's identification number to follow the CE marking
- draws up a declaration of conformity
- informs the notified body of any intended updating of the quality system
- keeps a copy of the declaration of conformity at the disposal of the surveillance authorities.

Notified body

- assesses the quality system to determine whether it satisfies the applicable requirements, and accordingly takes a decision
- supervises the affixing of its identification number
- carries out surveillance of the manufacturer by means of periodic and unexpected visits
- keeps a record of relevant technical information
- communicates to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (on request).

Module E

Manufacturer - As in module D, but operates an approved quality system for final product.
Manufacturer or the authorised representative – as in module D.
Notified body - as in module D.

Module F

Manufacturer

- takes all measures necessary to ensure that the manufacturing process assures conformity of the products with the type as described in the EC type-examination certificate and with the applicable requirements (i.e. operates a quality system, which includes establishing the necessary documentation).

Where the statistical verification is used:

- presents the products in the form of homogeneous lots and takes all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.

Manufacturer or the authorised representative

- applies for certification of conformity
- checks and attests that the products are in conformity with the type as described in the EC type-examination certificate and satisfy the applicable requirements
- affixes the CE marking to each product
- affixes the notified body's identification number to follow the CE marking
- draws up a declaration of conformity
- keeps relevant technical information (e.g. the notified body's certificate of conformity) and a copy of the declaration of conformity at the disposal of the surveillance authorities.

Notified body

- carries out the appropriate examinations and tests in order to check the conformity of the product with the applicable requirements either by examination and testing of every product, or by examination and testing of products on a statistical basis
- supervises the affixing of its identification number
- draws up a certificate of conformity relating to the tests carried out
- if a lot is rejected, takes appropriate measures to prevent the putting on the market of that lot
- keeps a record of relevant technical information
- communicates to the other notified bodies relevant information (on request).

Module G

Manufacturer

- establishes a technical documentation as regards the design, manufacture and operation of the product
- ensures and declares that the product concerned conforms to the applicable requirements

Manufacturer or the authorised representative

- applies for certification of conformity
- affixes the CE marking to each product
- affixes the notified body's identification number to follow the CE marking
- draws up a declaration of conformity
- κeeps a copy of the declaration of conformity and the technical documentation at the disposal of the surveillance authorities

Notified body

- examines the individual product, and carries out the appropriate tests to ensure its conformity with the relevant requirements
- supervises the affixing of its identification number
- keeps a record of relevant information
- draws up a certificate of conformity concerning the tests carried out
- communicates to the other notified bodies relevant information (on request)

Module H

Manufacturer

- operates an approved quality system for design, manufacture, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the design, the product category envisaged, documentation concerning the quality system and its updating, and the decisions and reports from a notified body)
- applies for the assessment of the quality system for the products concerned
- ensures and declares that the products concerned satisfy the applicable requirements
- undertakes to fulfill the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient
- supports the action carried out by the notified body for surveillance purpose
- keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body.

Manufacturer or the authorised representative - as in the module D.

Notified body - as in the module D.

11.5. Application of quality system standards

Some directives require use of a quality management system as part of the conformity assessment.

Quality assurance modules : D, F and H

The modules based on quality assurance techniques describe the elements a manufacturer must implement in his organisation in order to demonstrate that the product fulfills the essential requirements of the applicable directive. This means that a manufacturer is given the possibility of using an approved quality system for the purpose of demonstrating compliance with regulatory requirements, thus having the capability to design (if applicable), manufacture and supply products that fulfill the applicable essential requirements.

A quality system implemented on the basis of the EN ISO 9001, 9002 or 9003 standard gives a presumption of conformity with the respective modules with regard to the provisions in the modules that these standards cover, and provided that the quality system enables the manufacturer to demonstrate that the products fulfill the essential requirements of the directive in question. This means that the manufacturer must specifically address regulatory needs when implementing and applying a quality system for the purpose of the New Approach directives, in particular:

- the quality objectives, quality planning, quality manual and control of documents must fully take on board the objective of delivering products that conform to the essential requirements
- the manufacturer must identify and document the essential requirements that are relevant for the product and the harmonised standards to be used or other technical solutions that will ensure fulfillment of the essential requirements
- the identified standards or other technical solutions must be used as design input, and as verification that design output ensures that the essential requirements will be met
- the measures taken by the organization to control production must ensure that the products conform to the identified safety requirements
- the organisation in its measurement and control of the production process and finished products must identify and use methods which are identified in standards or other appropriate methods to ensure that the essential requirements are met; and
- quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, must be suitable to ensure the fulfillment of the applicable essential requirements.

The manufacturer has the responsibility to implement and continuously operate the quality system in such a way that regulatory needs are respected. The notified body must ensure the compliance in its assessment, approval and continued surveillance.

Directives may lay down additional provisions for conformity assessment according to modules D, E, H, and their variants which require that compliance with standards EN ISO 9001, 9002 and 9003 is completed with supplementary elements.

12. Technical documentation

New Approach directives oblige the manufacturer to draw up technical documentation containing information to demonstrate the conformity of the product to the applicable requirements. This documentation may be part of the quality system documentation where the directive provides for a conformity assessment procedure based on a quality system (modules D, E, H and their variants).

The technical documentation must be kept for at least 10 years from the last date of manufacture of the product, unless the directive expressly provides for any other duration.

This is the responsibility of the manufacturer or the authorised representative established within the Community. In some cases the importer or the person placing the product on the Community market must take on this responsibility.

The contents of the technical documentation are laid down, directive by directive, in accordance with the products concerned. As a rule, the documentation should cover the design, manufacture and operation of the product. The details included in the documentation depend on the nature of the product and on what is considered as necessary, from the technical point of view, for demonstrating the conformity of the product to the essential requirements of the relevant directive or, if the harmonised standards have been applied, to these instead by indicating the essential requirements covered by the standards.

In order to carry out the conformity assessment procedures requiring third-party verification in a proper way, the documentation should always be in a language understood by the notified body.

EC declaration of conformity

New Approach directives impose an obligation on the manufacturer, or the authorised representative established within the Community, to draw up an EC declaration of conformity when the product is placed on the market. Depending on the procedure, the EC declaration of conformity must either ensure that the product satisfies the essential requirements of the applicable directives, or that the product is in conformity with the type for which a type-examination certificate has been issued and satisfies the essential requirements of the applicable directives.

The EC declaration of conformity must be kept for at least ten years from the last date of manufacture of the product.

This is the responsibility of the manufacturer or the authorised representative established within the Community. In some cases the importer or the person responsible for placing on the market must take on this responsibility.

The contents of the EC declaration of conformity are laid down, directive by directive, in accordance with the products concerned. The standard EN 45014 has been drawn up with the objective of providing the general criteria for the declaration of conformity, and it can also be used as a guidance document in view of New Approach directives.

As a minimum the following information should be provided:

- the name and address of the manufacturer or the authorised representative issuing the declaration
- the identification of the product (name, type or model number, and any relevant supplementary information, such as lot, batch or serial number, sources and numbers of items)
- all relevant provisions complied with the referenced standards or other normative documents (such as national technical standards and specifications) in a precise, complete and clearly defined way
- all supplementary information that may be required (for example grade, category), if applicable;
- the date of issue of the declaration; signature and title or an equivalent marking of authorised person
- the statement that the declaration is issued under the sole responsibility of the manufacturer and, if applicable, the authorised representative.

Other useful information to be included in the EC declaration of conformity is the name, address and identification number of the notified body when it has been involved in the conformity assessment procedure, as well as the name and address of the person who keeps the technical documentation.

Where several New Approach directives apply to a product, the manufacturer or the authorised representative can, basically, merge all the declarations into a single document. Consequently, the EC declaration should also provide information on whether or not it covers only one directive. In such a case the declaration should include a reference to other directives.

The EC declaration of conformity must be made available to the surveillance authority immediately upon request. Moreover, Directives relating to machinery, gas appliances, potentially explosive atmospheres, recreational craft, lifts and high-speed rail systems require that products are accompanied by the EC declaration of conformity.

The EC declaration of conformity must be drawn up in one of the official languages of the Community. For products, which are required to be accompanied by the declaration of conformity, it has to be in the official language of the country of use.

12. Notified bodies

Notified bodies carry out the tasks pertaining to the conformity assessment procedures referred to in the applicable New Approach directives when a third party is required.

Member States take the final responsibility for the competence of the notified bodies. Therefore, they must verify the competence of the bodies seeking notification. This shall be based on the following criteria:

- availability of personnel and equipment
- independence and impartiality in relation to those directly or indirectly concerned with the product (such as the designer, the manufacturer, the manufacturer's authorised representative, the supplier, the assembler, the installer, the user)
- technical competence of personnel that is relevant to the products and conformity assessment procedure in question
- maintenance of professional secrecy and integrity
- subscription to civil liability insurance, unless that liability is covered by the state under national law.

The assessment of the body seeking notification will determine if the body fulfils the requirements. Accreditation according to the EN 45000 series of standards is a support to the technical part of notification. The EN 45000 series cover different types of conformity assessment bodies (certification bodies, testing laboratories, inspection bodies and accreditation bodies). The EN 45000 standards consist, in general terms, of a part dealing with the organisation and management of the body, and a part dealing with the technical requirements relating to the operation of the body.

The determination of the technological knowledge and experience of the body seeking notification, and its capability to carry out assessment and verification with regard to specific technical specifications or general objectives or performance requirements in accordance with the directive in question is essential.

Elements such as knowledge of the products and conformity assessment procedures in question, technology involved, and voluntary nature of standards must be considered. The request for product related knowledge is, in particular, important for conformity assessment procedures that involve a quality system (modules D, E, H and their variants), because the quality system must ensure that the product in question meets the requirements of the applicable directive.

Where a notified body operates conformity assessment according to different modules, it may lead to the need to apply several of the EN 45000 standards. This is evident since the modules, like the standards, relate to different technical activities.

For the technical competence (such as equipment, training and qualification of personnel) assessment on the basis of each relevant standard should be carried out.

Most of the national accreditation bodies of the Member States fulfill and operate according to the requirements of these standards, and have put into place peer evaluation schemes in order to attain mutual recognition of the accreditation results.

Member States are responsible for ensuring that notified bodies maintain their competence at all times and are capable of carrying out the work for which they are notified. It is up to the Member States to choose the means and methods for this. However, the practice concerning surveillance and re-assessment developed by the accreditation bodies should be followed. Member States may also decide to notify a body for a limited period of time, and to renew the notification subsequently (this is a normal practice).

List of Notified bodies designated by the Member states and EFTA countries (EEA members) under the New Approach Directives. Including their identification numbers as well as the tasks for which they have been notified, this list is established per Directive and covers the bodies notified up to 30 Sept. 2003.

Notified Bodies per Directive

Directive	**Number bodies**
87/404/EEC Simple pressure vessels	75
88/378/EEC Toys	54
89/100/EEC Construction products	151
2004/108/EC Electromagnetic Compatibility	35
89/686/EC Personal protective equipment	96
90/384/EEC Non-automatic weighting instruments	321
90/385/EEC Active implantable medical devices	18
90/396/EEC Gas appliances	35
92/42/EEC Hot water boilers	37
93/15/EEC Civil explosives	6
93/42/EEC Medical devices	60
94/25/EC Recreational crafts	21
94/9/EC Potentially explosive atmospheres	27
95/16/EC Lifts	124
96/48/EC High-speed rail systems	11
96/98/EC Marine equipment	27
97/23/EC Pressure equipment	58
98/37/EC Machinery	135
98/79/EC In vitro medical devices	14
99/36/EC Transportable pressure equipment	43
99/5/EC R&TTE	40
2000/14/EC Noise from equipment for outdoor use	7

Notification procedure and withdrawal of notification

Notification is an act to inform the Commission and the other Member States that a body, which fulfills the requirements, has been designated to carry out conformity assessment according to a directive.

The Commission publishes a list of notified bodies in the *Official Journal of the European Communities* for information purposes. The list is constantly updated and can be obtained directly from the Commission services.

Notification procedure

Member States are free to notify a body at any time after the directive has been adopted. Each body receives a single number irrespective of the number of directives for which it is notified. The notification takes effect after it has been sent to the Commission and the other Member States.

The Commission ensures that a consolidated list of notified bodies is regularly kept up to date. The Commission has this list published for information purposes in the *Official Journal of the European Communities.* The Member States should also publish at the national level the information concerning all notified bodies.

Withdrawal of notification

The Commission and the Member States have the responsibility to act when doubt arises about the competence of a notified body, either at the moment of notification or thereafter. The body in question should have the possibility to appeal against such a decision. Whether this appeal postpones the de-notification or not depends on the national legislation.

The withdrawal of a notification does not affect certificates issued by the notified body.

General responsibilities of notified bodies

Notified bodies shall operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner.

Notified bodies shall employ the necessary personnel, which has sufficient and relevant knowledge and experience to carry out conformity assessment in accordance with the directive in question.

They shall also ensure that they know the situation of relevant standards.

Notified bodies must keep their national notifying authorities informed of their activities. They must also be prepared to provide to their notifying authorities all information concerning the proper implementation of the conditions under which they were notified, either at the request of their notifying authorities or of the Commission.

Notified bodies have generally an obligation to inform the other notified bodies and the national surveillance authority about all certificates suspended or withdrawn and, on request, about certificates issued or refused. They shall also provide the surveillance authority. However, notified bodies are not responsible for providing the EC declaration of conformity or the technical documentation.

Notified bodies are and must remain third parties independent of their clients and other interested parties. In order to guarantee impartiality, the notified body and its staff has to be free from any commercial, financial and other pressure that might influence their judgment The body also has to implement procedures to ensure that its work cannot be influenced from outside. The structure of the body shall safeguard impartiality, especially if the body has other activities than those as a notified body. Further, the body shall have policies and procedures that distinguish between the tasks carried out as a notified body and any other activity in which the body is engaged.

They should also ensure that their activities outside the scope of the New Approach directives do not compromise or diminish confidence in their competence, objectivity, as notified bodies. The body and its staff (whether directly employed or subcontracted) responsible for the activities carried out as a notified body may, for instance, neither be the manufacturer, the authorised representative, a supplier or their commercial competitor, nor offer or provide (or have offered or provided) consultancy or advice to any of these parties as regards the design, construction, marketing or maintenance of the products in question. However, this does not preclude the possibility of exchanging technical information and guidance between the manufacturer, the authorised representative, suppliers and the notified body.

As a general rule – as inappropriate for notified bodies to be responsible for market surveillance.

The notified body should also require all staff acting on its behalf to declare any potential conflict of interest.

Notified bodies shall have under their control the necessary personnel, who have sufficient knowledge and experience relating to the products and conformity assessment procedure in question, and who are subject to appropriate training. In particular, knowledge and experience should relate to relevant regulatory requirements and enforcement policies, European and international standardisation activities, relevant technologies, production methods and verification procedures, and normal conditions of use of the product in question.

Notified bodies shall make adequate arrangements to ensure confidentiality of the information obtained in the course of conformity assessment.

The manufacturer in particular retains, however, the overall responsibility for the conformity of the product with all the requirements of the applicable directives, even if some stages of the conformity assessment are carried out under the responsibility of a notified body.

Notified bodies and conformity assessment

The primary task of a notified body is to provide services for conformity assessment on the conditions set out in the directives. This is a service to the manufacturers in an area of public interest.

Manufacturers are free to choose any notified body that has been designated to carry out the conformity assessment procedure in question according to the applicable directive.

This means that a notified body must be capable of taking the responsibility and have the competence to carry out the conformity assessment according to a complete module or for several complete modules. Consequently, the body cannot be notified for part of a module.

A body notified for modules D, E, H or their variants must be capable of taking the responsibility not only for the aspects of the quality systems involved but also for product-related requirements. In either case the notified body may subcontract some of the operations. A notified body wishing to offer services according to several conformity assessment procedures must fulfill the relevant requirements for the respective tasks, and this has to be assessed according to the requirements for each different procedure in question. However, since the scope of most New Approach directives can be relatively wide and heterogeneous, a notified body need not be qualified to cover all products falling within its scope, just a defined range of products within its scope.

Notified bodies shall have appropriate structures and procedures to ensure that the conduct of conformity assessment and the issuing of certificates are subject to a review process. Relevant procedures must, in particular, cover obligations and responsibilities in relation to suspension and withdrawal of certificates, requests addressed to the manufacturer to take corrective measures, and reporting to the competent authority.

They should provide relevant information to the manufacturer and the authorised representative regarding the directive in question.

The technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the directives.

The notified body must be established on the territory of the notifying Member States, it may have activities or personnel outside the Member State, or even outside the Community. Certificates are, however, always issued by and in the name of the notified body. Since the notified body always has to carry out its assessment functions within the jurisdiction of the designating Member State, it shall inform the notifying authority, which must be capable of ensuring the monitoring.

Notified bodies and subcontracting

A notified body can subcontract strictly limited technical tasks (such as tests and examinations), as long as these can be defined as substantial and coherent parts of the technical operation. The notified body cannot under any circumstances subcontract all of its activities, as that would make the notification meaningless. Notified bodies may for example subcontract tests while continuing to assess their results and, in particular, to validate the test report in order to evaluate whether the requirements of the directive are met. Similarly, subcontracting is possible in the field of certification of quality systems by using external persons as auditors, provided that the notified body carries out the evaluation of the audit results.

The notified body remains entirely responsible for the work carried out for it by the subcontractor. It can have its notification withdrawn for any reason connected with its subcontractor.

Coordination and cooperation

A coherent application of the conformity assessment procedures requires close cooperation between the notified bodies, the Member States and the European Commission.

The Commission, in coordination with Member States, also ensures that cooperation is organised between the notified bodies.

Notified bodies should, basically, be excluded from the responsibility of market surveillance activities. This is to avoid conflicts of interest.

13. CE marking

Principles of CE marking

- The CE marking symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer.
- The CE marking affixed to products is a declaration by the person responsible that:

- the product conforms to all applicable Community provisions, and
- the appropriate conformity assessment procedures have been completed.

Member States are not allowed to restrict the placing on the market and putting into service of CE marked products, unless such measures can be justified on the basis of evidence of the noncompliance of the product.

The directives providing for the affixing of the CE marking mostly follow the principles of the New Approach and the Global Approach.

CE marking can be introduced as legal conformity marking if:

- the method of total harmonisation is used
- the directive contains conformity assessment procedures according to Decision 93/465/EEC.

As a general rule, all New Approach directives provide for the affixing of the CE marking. It does not indicate that the product was manufactured in the Community.

Products to be CE marked

- The CE marking is mandatory and must be affixed before any product subject to it is placed on the market and put into service, save where specific directives require otherwise.
- Where products are subject to several directives, which all provide for the affixing of the CE marking, the marking indicates that the products are presumed to conform to the provisions of all these directives.
- A product may not be CE marked, unless it is covered by a directive providing for its affixing.

The CE marking must be affixed:

- to all new products, whether manufactured in the Member States or in third countries
- to used and second-hand products imported from third countries
- to substantially modified products that are subject to directives as new products.

Directives may exclude the application of the CE marking on certain products, even if the directive otherwise applies to the product. As a general rule, such products are subject to free circulation, if:

- they are accompanied by a declaration of compliance (as is the case for products playing a minor part with respect to the health and safety)
- they are accompanied by a statement (as is the case for custom-made medical devices)
- they are accompanied by a statement (as is the case for custom-made medical devices)
- they are accompanied by a certificate of conformity (as is the case for components referred to in the Directive relating to potentially explosives atmospheres)
- the product bears the manufacturer’s name and an indication of maximum capacity (as is the case for instruments not subject to conformity assessment according to the Directive relating to non-automatic weighing instruments)
- the product is manufactured in accordance with sound engineering practice (as is the case for certain vessels)
- During the transitional period of a directive the manufacturer usually has the choice to either meet the requirements of the directive or the relevant national regulations.

Affixing of the CE marking

The CE marking must be affixed by the manufacturer, or by the authorised representative established within the Community.

The provisions regarding the affixing of the CE marking vary between directives.

The manufacturer, whether established inside or outside the Community, is the person ultimately responsible for the conformity of the product with the provisions of the directive and for the affixing of the CE marking.

The manufacturer may appoint an authorised representative established in the Community to act on his behalf.

The CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant directives. This will usually be at the end of the production phase.

The CE marking symbolises conformity to essential public interests covered by the directives in question.

The requirement for visibility means that the CE marking must be easily accessible for all parties.

The CE marking shall only be followed by the identification number of the notified body if it is involved in the production phase. Thus, the identification number of a notified body involved in conformity assessment according to module B *does not follow the CE marking.* Sometimes several notified bodies are involved in the production phase, which is possible where more than one directive is applicable. In these situations several identification numbers follow the CE marking.

Thus, the CE marking may appear on products either:

- *Without* an identification number, which means that a notified body did not intervene in the production phase (module A where the notified body only intervened during the design phase, and the combination of modules B and C) or
- *With* an identification number, which means that the notified body assumes the responsibility:

- for the tests on specific aspects of the product (where the notified body intervened during the production phase),
- or product checks,
- for the examinations and tests carried out to assess the conformity of the product during the production control phase (modules F and G) or
- for the assessment of production, product quality assurance or
- full quality assurance (modules D, E, H and their variants).

The CE marking and the identification number of the notified body do *not necessarily have to be affixed within the Community*. They may be affixed in a third country, for example if the product is manufactured there and the notified body carried out conformity assessment in accordance with the directive in that country. The CE marking and the identification number can also be affixed separately, as long as they remain combined.

The CE marking consists exclusively of the letters **'CE'** followed by the identification numbers of any notified body involved in the production phase. Pictograms or other marks indicating, for instance, the category of use are, according to some New Approach directives, complementary to the CE marking but do not form part of it**.** For instance, the symbol to indicate that telecommunications terminal equipment is suitable for connection to the public telecommunications network, or the equipment class identifier required for radio equipment. Some directives also require that the last digits of the year in which the CE marking was affixed is indicated.

CE marking and other marks

CE marking is the only marking which symbolises conformity to all the obligations incumbent on manufacturers for the product as required by the applicable directives providing for its affixing.

National conformity markings are incompatible with CE marking.

When transposing the directives, Member States shall incorporate the CE marking in their national regulations and administrative procedures.

In view of the objectives of technical harmonisation, markings and marks additional to the CE marking need to fulfill a different function from that of the CE marking. Thus, they should provide an added value in signifying conformity with objectives that are different from those to which the CE marking relates (for example environmental aspects not covered by applicable directives).

The affixing of legal marking (such as a protected trademark of a manufacturer), or of acceptable certification and other marks additional to the CE marking, is allowed to the extent that such markings or marks do not create confusion with the CE marking, and that they do not reduce the legibility and visibility of the CE marking.

14. Market surveillance

14.1. Principles of market surveillance

Market surveillance is an essential tool for enforcing New Approach directives, in particular by taking measures to check that products meet requirements of the applicable directives, that action is taken to bring non-compliant products into compliance, and that sanctions are applied when necessary.

A high level of protection is envisaged in the New Approach directives. This requires Member States to take all necessary measures to ensure that products may be placed on the market and put into service only if they do not endanger the safety and health of persons, or other interests covered by the applicable New Approach directives, when correctly constructed, installed and maintained, and used in accordance with their purpose. This implies an obligation for Member States to organise and carry out market surveillance, in a way that is effective and sufficiently extensive to discover non-compliant products. This is to protect not only the interests of consumers, workers and other users, but also the interests of economic operators from unfair competition.

The obligation for market surveillance is complementary to the provisions of the New Approach directives that require Member States to allow free movement of products that are in compliance with the requirements.

The Directive relating to toys 88/378/EEC [23] lays down provisions for the market surveillance authority, and obliges the Member States to send to a report the Commission every three years. The surveillance authority must be entitled to obtain access to places of manufacture or storage, to receive information, and to select a sample and take it away for examination and testing.

Other New Approach directives do not contain special provisions on how market surveillance should be organised and carried out in Member States. The Directive on general product safety has a more detailed description of the obligation of Member States to organise market surveillance and to adopt appropriate surveillance tools.

Market surveillance is the responsibility of public authorities. The legal and administrative market surveillance infrastructures differ from one Member State to another, however an equivalent level of protection can be ensured throughout the Community.

To guarantee the quality of the test data, the testing facility used by the authority should comply with the relevant criteria of the EN 45001 standard.

The authority should also be independent.

The surveillance authority may subcontract technical tasks (such as testing or inspection) to another body. The responsibility for any decision to be taken on the basis of such advice shall reside in the surveillance authority.

As a general rule, it is inappropriate for notified bodies to be responsible for market surveillance. In order to avoid a conflict of interest it is necessary to make a clear distinction between conformity assessment (which takes place before the product is placed on the market) and market surveillance (which takes place after the product has been placed on the market).

New Approach directives include certain provisions that require Member States to inform the Commission or the other Member States.

Directives relating to active implantable medical devices, potentially explosive atmospheres, medical devices and in vitro diagnostic medical devices have provisions on confidentiality.

Information on activities underway that concern individual economic operators should generally be considered as confidential. An exception to this may be justified where the health and safety of consumers is subject to serious and immediate danger.

Market surveillance involves two main stages:
I. National surveillance authorities shall monitor that products placed on the market comply with the provisions of the applicable national legislation transposing the New Approach directives;
II. Subsequently, when necessary, they shall take action to establish conformity.

Market surveillance authorities must monitor products placed on the market. The aim is to find out whether or not a product complies with the applicable provisions at the moment when placed on the market and, if relevant, when put into service. Basically, market surveillance cannot take place during the design and production stages, that is before the manufacturer has taken formal responsibility for the conformity of the products, usually by affixing the CE marking. However, this does not exclude collaboration between the surveillance authority and the manufacturers and suppliers.

For market surveillance to be efficient, resources should be concentrated where risks are likely to be higher or non-compliance more frequent, or where a particular interest can be identified. Statistics and risk assessment procedures can be used for this purpose. To be able to monitor products placed on the market, surveillance authorities shall have the power, competence and resources:

- to regularly visit commercial, industrial and storage premises
- to regularly visit, if appropriate, work places and other premises where products are put into service. This is usually not necessary for consumer products that are made available in shops or otherwise on the market. It is *more important for products (for example machinery and pressure equipment) that are directly, after being manufactured, installed and put into service at the premises of the client*
- to organise random and spot checks
- to take samples of products, and to subject them to examination and testing; and
- to require all necessary information.

Although market surveillance cannot, basically, take place during the design and production stages, the surveillance authority may make a check on the production premises after a non-compliance has been discovered to verify whether or not a constant error can be established. However, such a provision is difficult to apply where the manufacturing process takes place outside the Community.

Other exceptions to the principle that market surveillance can only take place after the manufacturer has taken formal responsibility for the products are trade fairs, exhibitions and demonstrations. Most New Approach directives allow the showing of non-compliant products under such circumstances.

Market surveillance should cover all applicable provisions of the directives in question. *To a certain extent formal checks are sufficient*, for example regarding the CE marking and its affixing, the availability of the EC declaration of conformity, the information accompanying the product and the correct choice of conformity assessment procedures. More profound checks are necessary to verify the material conformity of the product, for example regarding the correct application of the conformity assessment procedure, the compliance with the essential requirements, and the contents of the EC declaration of conformity. In practice, individual market surveillance operations can focus on certain aspects of the requirements.

Besides market surveillance operations other public mechanisms exist :

- *Labor inspectorates* that check safety at the workplace, for example, can discover that the design or construction of a machine, or personal protective equipment bearing the CE marking, is not in conformity with the applicable requirement. Consequently, they may take measures that affect the placing on the market of a product and, thus, carry out market surveillance, or they may contact the market surveillance authority that may take the necessary measures.
- Information on the compliance of a product at the moment when it was placed on the market can also be obtained during *in-use inspections*, or by analysing the factors that caused an accident.
- *Complaints from consumers* or other users about the product, or from manufacturers or distributors about unfair competition can also provide information for market surveillance purposes.

Monitoring of products placed on the market may be divided between several authorities on the national level, for example functionally or geographically. Where the same products are subject to control by more than one authority, *coordination* between services within a Member State is necessary.

Member States are obliged, according to *the Directive on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC)*, to ensure adequate controls.

Market surveillance authorities must be impartial regarding all voluntary marks, labels and arrangements, and they may only be taken into consideration, in a transparent and non-discriminatory way, for the risk assessment. Accordingly, products may not be excluded from market surveillance operations even if they have been subject to voluntary certification or other voluntary initiatives.

New Approach directives provide for two different tools that enable surveillance authorities to receive information on the product: the EC declaration of conformity and the technical documentation. These must be made available by the manufacturer, the authorised representative established within the Community, or under certain circumstances by the importer or person responsible for placing on the market.

Other natural or legal persons, such as *notified bodies*, distributors, retailers, suppliers or subcontractors, *cannot be obliged* to make these available. However, they can assist the surveillance authority in obtaining them. Further, the surveillance authority may request the notified body to provide information on the conduct of conformity assessment
for the product in question.

The EC declaration of conformity must be made available for the market surveillance authority immediately upon request. Therefore, it should be kept inside the Community. A failure to present the declaration when requested by a national surveillance authority may constitute sufficient grounds for doubting the presumption of conformity with the requirements of the directive.

The technical documentation must be made available. Authority cannot request it systematically. *In general*, it can be requested only during random checks made for market surveillance purposes, or when there are grounds for a concern that a product does not offer the

level of protection required in all respects. Initially the surveillance authority may be provided with only a summary of the technical documentation.

More detailed information (for example certificates and decisions from the notified body) can, nevertheless, be requested in cases of serious doubt about the conformity of the product to the Community regulations. The full technical documentation should be requested only where clearly necessary, and not, for example, when only a detail has to be checked.

Further, failure to present the documentation in response to a duly substantiated request by a national surveillance authority, within an acceptable delay, may constitute sufficient grounds for doubting the presumption of conformity with the requirements of the directive.

A national authority may request a translation of the technical documentation and the EC declaration of conformity into its official language. However, it should avoid doing so if they, especially the detailed technical information of the documentation, are available in a language that can be understood by the national authority in question. If the authority considers a translation necessary, it must clearly define the part of the documentation to be translated and allow reasonable time for this to take place. No further conditions may be imposed on the translation.

It must be possible to make the technical documentation available in the Community. The technical documentation can be kept in any format (for example as a hard copy or CD-ROM).

Member States must ensure that everyone receiving information about the contents of the technical documentation during market surveillance is bound to secrecy according to principles laid down in the national legislation.

14.2. Corrective actions

Competent national authorities must take action to enforce conformity, when they discover that a product is not in compliance with the provisions of the applicable directives.

The corrective action depends on the degree of noncompliance. However, the difference between *non-substantial and substantial non-compliance* is not always clear, and must be decided on a case by case basis.

The incorrect affixing of the CE marking can usually be considered as a non-substantial non-compliance.

Examples of typically *non-substantial non-compliance* could also be the situations where

- other conformity markings provided for in the directive are incorrectly affixed, or
- where the EC declaration of conformity cannot be provided for immediately or it does not accompany the product when this is mandatory,
- or the requirement to accompany other information provided for in the directive(s) is complied with insufficiently, or,
- where applicable, the identification number of the notified body has not been affixed to the CE marking.

Non-conformity to essential requirements must usually be considered as a substantial non-compliance, because this may, for instance, present a potential or actual risk to the health and safety of citizens.

However, non-conformity to a harmonised standard is not, as such, sufficient evidence of non-conformity to essential requirements, but indicates that further investigations may be necessary.

If a product covered by a New Approach directive is not CE marked, it is an indication that the product does not comply with the essential requirements or the conformity assessment procedure has not been applied and, consequently, the product may, for instance, endanger the health and safety of persons. Such non-compliance should be considered as substantial.

Enforcement of conformity can be achieved by obliging the manufacturer, the authorised representative, or other responsible persons, to take required measures. Corrective action can also take place if the necessary measures are taken (for example the product is modified or withdrawn from the market), either as a result of consultations carried out by the surveillance authority or as a result of formal or informal warnings. In all cases the surveillance authority must establish accompanying measures to ensure that conformity is enforced.

Action taken against non-substantial non-compliance can be on two levels.

* *First*, the surveillance authority should oblige the manufacturer,
or the authorised representative, to make the product already on the market, comply with the provisions.

* *Secondly*, the authority shall, ultimately, restrict or prohibit the placing on the market and the putting into service of the product and ensure that it is withdrawn from the market.

Action to prohibit or restrict the placing on the market may first be temporary.

Any decision taken by national authorities to restrict or prohibit the placing on the market, or the putting into service, or to withdraw products from the market must state the exact grounds on which it is based. The party concerned – in particular, the manufacturer, or the authorised representative established in the Community – shall be notified.

Unless the matter is urgent (for example the product presents a serious and immediate danger to the health and safety of persons), the manufacturer, or the authorised representative established in the Community, should have an opportunity to be consulted in advance, before the competent authority takes action to restrict the free circulation of products. In practice, it should be considered as sufficient when the manufacturer or the authorised representative has been provided with an opportunity to react. However, it should not delay the proceeding, if the manufacturer or the authorised representative remains passive.

14.3. Complementary activities

Surveillance authorities should not limit their activities to monitoring products placed on the market, and to taking the necessary corrective actions. Informal contacts and other collaboration between the authority and the manufacturers and suppliers may help in preventing the placing on the market of non-compliant products. For instance, the authority can provide general advice and guidance to the economic operators on the application of the directives. Further, the authority should also consider the possibilities of raising the awareness of consumers and other users, for example on issues relevant to their health and safety.

New Approach directives require that action is taken against persons who affix the CE marking to non-compliant products.

The Directives relating to low voltage equipment, hot-water boilers, and refrigeration appliances do not explicitly require this. However, it should be considered that this obligation applies to all New Approach Directives.

Action should, as well, be taken against the manufacturer (or other person) responsible for placing a non-compliant product on the market. These actions can, for instance, consist of warnings or legal proceedings. Actions must also be considered against the notified body, if it was involved in the conformity assessment procedure that had, as a result, non-compliant products. In such cases, the competence of the notified body may need to be assessed as well.

Since New Approach directives do not specify any penalty, Member States remain free to choose the sanctions to be used when infringements take place.

Usually some products from the same product series will have already been sold or even put into use after the non-compliance has been discovered. In these cases, it is important to ensure that persons who might be exposed to a risk from a product are informed. This should basically be considered as a responsibility of the manufacturer or the distributor. The warning can take the form of a general publication or, if the number of persons at risk is limited, it can be directed to individuals.

When a competent authority decides to restrict or prohibit the placing on the market and the putting into service of a product, or to withdraw it from the market, it should also consider — in accordance with the principle of proportionality — whether or not it would be necessary to destroy the product, or ban its export to other Member States, and to require the withdrawal of certificates. Sometimes it is also important to verify whether or not decisions need to be taken for other products which have the same technical features as those subject to market surveillance actions, in order to ensure a high level of protection.

New Approach directives may require the competent authority to take special action regarding non-compliant products. For instance, the directive relating to telecommunications terminal equipment requires Member States to disconnect equipment from the public telecommunication network if it is not used for the intended purpose.

14.4. Safeguard clause procedure

Conditions for invoking the safeguard procedure

The decision to restrict the free movement of a CE marked product in case of substantial non-compliance usually invokes the safeguard clause procedure. This procedure is aimed to enable the Commission to keep an overview of such measures and to consider whether or not they are justified. In addition, the exchange of information between national surveillance authorities on corrective actions taken, whether or not based on substantial noncompliance, should take place, where this is considered appropriate and necessary, and where the need for confidentiality as well as transparency can be respected. A manufacturer, the authorised representative, or other person may consider himself to have suffered a loss as a result of an inappropriate national measure that restricted the free movement of a product.

The safeguard clause is designed to allow the Commission to analyse the justification of national measures restricting the free movement of CE marked products (products presumed to comply with requirements). Secondly, it provides a means to inform all national surveillance authorities about dangerous products, and, accordingly, to have the necessary restrictions extended to all Member States so as to ensure an equivalent level of protection throughout the Community.

The safeguard clause shall be applied to products that fall within the scope of a New Approach directive and bear the CE marking provided by such a directive. Consequently, the safeguard clause cannot be applied to products that are not CE marked. However, according to the Directive relating to machinery safety components and according to the Directive relating to medical devices, custom-made medical devices may be subject to the safeguard clause procedure, although they may not be CE marked. As regards the Directive on marine equipment the safeguard clause is applicable to products that bear the mark of conformity provided for in the Directive. The Directives relating to low voltage equipment, construction products, active implantable medical devices, and radio and telecommunications terminal equipment *do not lay down as a precondition for invoking the safeguard clause that the CE marking is affixed to the product.* However, it should generally be considered that also under these Directives the safeguard clause is only applied to products which are considered to comply with all applicable provisions (including the provisions regarding CE marking). The reason for this is that the safeguard clause allows a Member State to challenge a product, which is, basically, subject to free movement. For corrective action in cases where a noncompliance has been established regarding products that either are or are not CE marked.

For the safeguard clause to be applicable, the non-conformity has to be established regarding a systematic failure in the design of a whole series of products manufactured, however limited the series. For an isolated error, limited to the territory of the Member State that has discovered the non-compliance, there is no need to invoke the safeguard clause, since there is no need to take action on Community level.

The application of the safeguard clause requires that the competent national authority decides to restrict or forbid the placing on the market and, possibly, the putting into service of the product, or has it withdrawn from the market.

Conformity can be enforced if the national authority requests the manufacturer or the authorised representative to take the necessary measures, or if the product is modified or *voluntarily withdrawn* from the market. Unless a formal decision is taken in these cases, to prohibit or restrict the placing on the market of the product or to have it withdrawn from the market, the safeguard clause procedure is not invoked. Thus, a direct exchange of information between market surveillance authorities may be necessary.

The findings that justify the national measure are established either by the market surveillance authority on its own initiative, or based on information received from a third party (such as consumers, competitors, consumer organisations, labour inspectorates). Further, the national measure must be based on evidence (for example tests or examinations) that constitutes sufficient proof of errors in the product design or the manufacture to indicate a foreseeable potential or actual danger or other substantial non-compliance, even when the products are correctly constructed, installed, maintained and used in accordance with their intended purpose or in a reasonably foreseeable way. There is a gray zone between correct and incorrect maintenance and use.

In evaluating this, the data supplied by the manufacturer on the labeling, in the instructions, in the user's manual or in promotion materials are to be taken into consideration.

Where non-compliance with harmonised standards that give a resumption of conformity is established, the manufacturer, or the authorised representative in the Community, must be requested to provide evidence about compliance with essential requirements. *The decision of the competent authority to take corrective action must always be based on an established non-compliance with the essential requirements invoking the application of the safeguard clause.*

Notification to the Commission

As soon as a competent national authority restricts or forbids the free movement of a product in such way that the safeguard clause is invoked, the Member State must immediately notify the Commission indicating the reasons and justification for the decision. The official notification usually takes place via the Permanent Representation with a copy sent to the

Commission department responsible for managing the directive in question.

Member States have to inform the other Member States as well as the Commission when invoking the safeguard clause according to the Directive relating to low voltage equipment (LVD). In several sectors Member States tend to send a copy of their notification to other Member States. The copy is usually sent via the Permanent Representation.

Member States that have received such a notification from another Member State should decide if action is necessary, and take into account
that such action must be justified.

The notification should include:

- a reference to the directive(s), and in particular to the essential requirements, against which the non-compliance has been established
- name and address of the manufacturer, the authorised representative, and in addition – if necessary – the name and address of the importer or other person responsible for placing the product on the Community market
- a copy of the declaration of conformity
- the name and number of the notified body
- information on the procedure which was used by the authority to verify the compliance of the product; and
- a comprehensive assessment and evidence to justify the measure (for example harmonised standards or other technical specifications used by the authority, the test reports and identification of the testing laboratory).

Four hypotheses must be distinguished as from the moment of the notification.

(1) *The products in question present a serious and immediate risk to health or safety.*

- In this case the market surveillance authorities must take measures to prohibit the placing on the market in accordance with the applicable Community or national rules, and request the customs authorities to mark the commercial invoice accompanying the product, and any other relevant accompanying document, with the words 'Dangerous product release for free circulation not authorised .

(2) *The products in question do not comply with Community or national rules on product safety.*

- In this case the market surveillance authorities must take appropriate measures, if necessary prohibiting the placing on the market under the rules in question. In cases where placing on the market is prohibited, they must ask the customs authorities to mark the commercial invoice accompanying the products, and any other relevant accompanying document, with 'Product not in conformity — release for free circulation not authorised.

(3) *The products in question do not present a serious and immediate risk and cannot be considered as not conforming to the rules applicable to product safety.*

- In this case the products must be released for free circulation, provided that all the other conditions and formalities regarding release for free circulation are met.

(4) *The customs authorities have not been notified of any action taken by the market surveillance authorities.*

- In this case the products in question must be released for free circulation, at the latest within three working days from the suspension of release, provided that all the other conditions and formalities regarding release for free circulation have been met.

Where the manufacturer, the authorised representative, in such a way that it complies with the applicable provisions, the Member State should withdraw the safeguard clause notification or other responsible person, agrees to modify the product.

Administering the safeguard clause

The Commission is responsible for administering the safeguard clause at Community level, and for ensuring that it applies to the whole of the Community. To this end, the Commission consults the interested parties to verify whether or not the action that invoked the safeguard clause can be justified.

After the Commission departments responsible for managing the directive have been informed, they will, as a general rule, first contact the Member State and the national surveillance authority which invoked the procedure, and the manufacturers concerned or their authorised representative. The Commission may also contact the other Member States most directly concerned by the case in question (usually the Member States where the manufacturer or notified body is established), and the notified bodies (or other third parties) involved in the conformity assessment procedure.

If the Commission considers it necessary, it may — in collaboration with the Member State(s) concerned — seek the opinion of other adequately qualified, impartial bodies or experts capable of providing further information directly relevant to the subject (such as other surveillance authorities, other notified bodies, scientific committees of the Commission, standards organisations, conformity assessment bodies, organisations representing industry, distributors or consumers, trade unions, research institutes or scientific experts). Although these consultations can be relatively wide, the urgency of the problem is taken into account and the procedure is kept as short as possible. At the end of the consultation procedure, the Commission takes an opinion on the justification of the national measure that restricted or prohibited the free movement of products.

Where the Commission considers in its opinion that the action is justified, it informs the Member State concerned and the other Member States immediately. The Commission may also decide to publish this opinion.

Consequently, Member States have an obligation to take appropriate action, with a view to the opinion of the Commission, to ensure a similar level of protection throughout the Community.

Where the Commission considers in its opinion that the action is justified, it informs the Member State concerned and the other Member States immediately.

The Commission may also decide to pub action, with a view to the opinion of the Commission, to ensure a similar level of protection throughout the Community.

Protection of CE marking

The affixing of the CE marking to a product is considered to be deceiving because consumers or users, for instance, are likely to get the impression that the product in question satisfies certain Community safety provisions. Competent authorities must, therefore, have at their disposal legal instruments that enable them to act where the deceptive use of the CE marking is evident. Action must be taken to enforce conformity, and against those responsible for a non-compliant product bearing the CE marking.

The affixing of marking and marks in addition to the CE marking is subject to certain restrictions . The surveillance authority shall take the necessary measures to ensure that the principles of CE marking are respected and, where necessary, take appropriate action.

The action to be taken by market surveillance authorities shall be decided on a case by case basis.

15. Information exchange system

15.1. Rapid exchange of information

The Directive on general product safety GPS (2001/95/EC) [8]provides a legal basis for an information exchange system for emergency situations. This *system for the rapid exchange* of information on dangers arising from the use of consumer products (RAPEX) is a general and horizontal early warning and monitoring system. It is designed for handling urgent situations caused by new, used or repaired products that present a serious and immediate risk to the health and safety of consumers. Its essential aim is to provide information in order to allow authorities of all Member States to take immediate and appropriate action when a serious risk arising from a product has been detected.

RAPEX applies to all products intended or consumers, or likely to be used by consumers, which, used under normal or reasonably foreseeable conditions, present, for any reason, an immediate and serious risk to the health and safety of consumers. *It covers both foodstuffs and industrial (non-food) products*. It is also applicable to consumer products covered by the New Approach directives and it is, in particular, *important for toys and low voltage products*. This is because the New Approach directives do not provide for such a procedure.

As soon as a serious and immediate risk is detected, the national authority must consult, insofar as possible and appropriate, the producer or distributor of the product concerned. The authority should try to obtain the maximum of information on the products and the nature of the danger, without compromising the need for rapidity.

A Member State shall inform the Commission when it adopts, or decides to adopt, emergency measures to prevent, restrict or impose specific conditions on the possible marketing or use of consumer products presenting a serious and immediate risk.

A further condition for invoking RAPEX is that the effects of the risk can go beyond the territory of the Member State concerned. Member States are not required, as is the case under the safeguard clause procedure according to the New Approach directives, to provide evidence to justify the national measure. The Commission verifies that the information complies with the provisions of the Directive on general product safety, and will pass it to the other Member States.

Where RAPEX has been applied, the Commission, after consulting the Member States and at the request of at least one of them, may adopt a decision requiring Member States to take temporary measures. This is to ensure the protection of health and safety of consumers and the proper functioning of the single market.

The safeguard clause procedures under the New Approach directives apply independently from RAPEX. Accordingly, RAPEX does not necessarily have to come into play before the safeguard clause procedure is applied. However, the safeguard clause procedure has to be applied, in

addition to RAPEX, when the Member State takes a decision *to permanently prohibit or restrict* the free movement of CE marked products on the basis of a danger or other serious risk presented by the product.

Medical devices: vigilance system

The medical devices vigilance system applies to all incidents which might lead to, or might have led to, the death of a patient or a user.

A databank containing, among other information, data obtained in accordance with the vigilance system will be set up and made accessible to the competent authorities.

The vigilance system is different from the safeguard clause procedure, since it requires notification even if the manufacturer takes the necessary measures on a voluntary basis. However, the vigilance system does not necessarily have to come into play before the safeguard clause procedure is applied.

Community injury data-collection and information exchange system

The Community action program on injury prevention within the framework for action in the field of public health aims to contribute to public health activities which seek to reduce the incidence of injuries, particularly injuries caused by home and leisure accidents.

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The data is collected from hospitals and other appropriate establishments and services within the Member States, and by means of surveys. The collection and transmission of data to the information system is carried out under the responsibility of the Member States, which have an obligation to ensure the reliability of sources.

15.2. Other information exchange systems at Community level

The safeguard clause procedure, under the New Approach directives, provides a means to exchange information, although its primary objective is to verify whether or not the national measure can be justified and, if this is the case, to resolve the problem at Community level.

Administrative cooperation. Outline of administrative cooperation.

Administrative cooperation mechanisms between national surveillance authorities, therefore, need to be developed to increase the efficiency of surveillance, to minimize the effect of different surveillance practices and to reduce the overlapping of national surveillance operations.

In addition, cooperation can be useful for exchanging views and solving practical problems.

Administrative cooperation calls for mutual trust and transparency between national surveillance authorities. Member States and the Commission need to be informed about the way enforcement of New Approach directives, in particular market surveillance of products covered by the New Approach, is organised throughout the single market. This includes information about national authorities in charge of market surveillance for the different product sectors, and about national market surveillance mechanisms to clarify how monitoring of products placed on the market takes place and what corrective actions and other activities the surveillance authority is entitled to use. Transparency is also necessary regarding the national rules on confidentiality.

For the achievement of effective market surveillance in the Community, it is important that national surveillance authorities assist each other. On request, a national authority should make information available and provide other assistance. Without prior request, a national authority may consider sending to the other national authorities all relevant information concerning operations that constitute, or are likely to constitute, breaches of New Approach directives, which may have an impact on the territory of other Member States.

The safeguard clause requires consultation and an opinion taken by the Commission that justifies the national measure before the information is forwarded to other Member States.

Cooperation and mutual assistance are, in particular, necessary to ensure that action can be taken against all those who are responsible for a non-compliant product being placed on the market. In such cases the authority of the Member State, where the manufacturer, the authorised representative, or other responsible person is established, needs to be contacted. . When a national authority acts due to information it has received from another national body, it should report back to this authority on the outcome of the action.

Moreover, market surveillance would be more efficient, on the Community level, if the national surveillance authorities could agree on how to allocate their resources in such a way that a maximum number of different product types could be covered in each sector. To avoid duplication of product tests, or other investigations for market surveillance purposes, national authorities should build up a mechanism to exchange a summary report of these tests. National surveillance authorities should also consider whether or not there is special need to carry out technical analyses or laboratory tests when another surveillance authority has already done so, and the results are available to those authorities or may at their request be placed at their disposal.

Information exchanged between national surveillance authorities has to be covered by professional secrecy.

Cooperation between national administrations takes place in working groups set up under the New Approach directives.

Administrative cooperation between national authorities carrying out market surveillance is taking place in the following sectors:

- low voltage equipment,
- electromagnetic compatibility ,
- machinery (Machex) ,
- medical devices (in particular regarding the vigilance system),
- telecommunications terminal equipment,
- recreational craft, and
- consumer products .

15.3. Products imported from third countries

Regulation (EEC) No 339/93 [36] applies to products imported from third countries, whether or not covered by New Approach directives.

A manufacturer established in a third country is responsible, in the same way as a manufacturer established in a Member State, for designing and manufacturing a product in accordance with all applicable New Approach directives and for carrying out the required conformity assessment procedure, where the product is intended to be placed or put into service on the Community market .

The manufacturer may appoint an authorised representative established in the Community to act on his behalf .

Where the manufacturer is not established in the Community and has no authorised representative in the Community, the importer or person responsible for placing the product on the Community market may become responsible to some extent.

As regards products covered by New Approach directives, the attention of customs authorities must be drawn, in particular, to the CE marking of toys.

According to the Regulation (EEC) No 339/93 and the Directive on general product safety — the surveillance authorities have an obligation to notify the customs authorities of their findings, which concern products imported from third countries.

The following three situations may be possible:

(1) *Products imported from third countries intended for consumers or likely to be used by them present a serious and immediate risk to health and safety according to the Directive on general product safety.*

In this case the system for the rapid exchange of information on dangers arising from the use of consumer products according to the Directive on general product safety applies to consumer products covered by New Approach directives or other Community legislation. As a consequence, market surveillance authorities in all Member States are informed, and they may in turn inform the national customs authorities about products imported from third countries, which display characteristics giving rise to a serious doubt as to the existence of a serious and immediate risk to health and safety. This information is of particular importance for customs authorities where it involves measures banning or withdrawing from the market products imported from third countries, based on a Commission decision.

(2) *Products imported from third countries are not accompanied by documents, or bear no conformity marking or labeling as provided for by Community or national rules on product safety.*

- In this case the market surveillance authorities must inform the customs authorities in order to draw their attention to the existence of such products falling under the scope of Regulation (EEC) No 339/93.

(3) *Products imported from third countries, which present a risk to health or safety that is not serious and immediate, and are subject to measures prohibiting or restricting their placing on the market, or imposing their withdrawal from the market.*

- In this case the Member State taking these measures must notify them to the Commission according to the safeguard clause procedure under the New Approach directives.

15.4. Agreement on the European Economic Area (EEA)

The Agreement on the European Economic Area is established between the European Community and Iceland, Liechtenstein and Norway. The Agreement extends the single market to these three EFTA States.

The objective of the EEA Agreement is to establish a dynamic and homogeneous European Economic Area, based on common rules and equal conditions of competition.

Mutual recognition agreements (MRA)

- Mutual recognition agreements are established between the Community and the government of third countries, which are on a comparable level of technical development and have a compatible approach concerning conformity assessment.
- These agreements are based on the mutual acceptance of certificates, marks of conformity and test reports issued by the conformity assessment bodies of either party in conformity with the legislation of the other party.

In principle MRAs should cover all the industrial products for which the regulations of at least one of the parties require third party conformity assessment.

MRAs are not based on the necessity to mutually accept other party's standards or technical regulations, or to consider the legislation of the two parties as equivalent. Nevertheless, the two legislations are, as a rule, deemed to ensure a comparable level regarding the protection of health, safety, environment or other public interests.

As a result of the different conditions established and the interest of third countries and the Community, the Commission was authorised to negotiate with the following countries: United States, Japan, Canada, Australia, New Zealand, Hong Kong, Israel, Singapore, Philippines, South Korea and Switzerland, Australia, New Zealand.

Technical assistance

Technical assistance is a transfer of knowledge and legislation policies, such as the New Approach and the GlobalApproach, but also a transfer of European best practice. It enables European experience to be shared with partners from non-member countries in all areas.

The main aims of technical assistance, therefore, are to increase trade relationships and investment opportunities, improve the quality of goods on the domestic market, help the recipient countries develop their own infrastructure and to reinforce the human capacity of the countries in the technical areas.

Technical assistance programmes take place in the fields of institutional cooperation, standardisation, metrology, certification, accreditation, quality management and quality assurance. These programmes are intended for countries that are not on a comparable level with the Member States in these fields.

Technical assistance programmes can be regionally or nationally oriented.

There is no single model for technical assistance as every country is at a different stage of development and seeks the fulfilment of different objectives.

The PRAQ programmes (the Regional Programmes on Quality Assurance and other related fields) are examples of regional assistance.

16. Council Resolutions and Directives

16.1. Council Resolution 85/C136/01 of 7 May 1985 on a New Approach to technical harmonisation and standards

In 1985 a European Council Resolution on a new approach to technical harmonization and standards proposed a radical change in regulating the technical aspects of industrial products approved by the Council on 16 July 1984 [1].

The Council believes that standardization goes a long way towards ensuring that industrial products can be marketed freely and also towards creating a standard technical environment for undertakings in all countries, which improves competitiveness not only on the Community market but also on external markets, especially in new technology.

Accordingly, the Council adopts the following principles for a European standardization policy:

- Agreement by the Member States to keep a constant check on the technical regulations which are applied - whether de jure or de facto - on their territory so as to withdraw those which are obsolete or unnecessary.
- Agreement by the Member States to ensure the mutual recognition of the results of tests and the establishment, where necessary, of harmonized rules as regards the operation of certification bodies.
- Extension of the Community practice in matters of technical harmonization of entrusting the task of defining the technical characteristics of products to standards, preferably European but if necessary national, where the conditions necessary for this purpose, particularly as regards health protection and safety, are fulfilled.
- A very rapid strengthening of the capacity to standardize, preferably at European level, with a view to facilitating on the one hand harmonization of legislation by the Community and on the other industrial development, particularly in the field of new technologies, since this could in specific circumstances involve the Community in introducing new procedures to improve the drawing up of standards (e.g. standardization bureaus, ad hoc committees). The adoption of European standards would be submitted to the European standardization bodies for approval.

CEN and CENELEC (one or the other, or both according to the products covered by the Directive) are the competent bodies to adopt European harmonized standards within the scope of the Directive.

Under the New Approach, the European Commission gives mandates to the standards organizations to develop technical standards that meet the essential health and safety requirements of CE Mark directives.

New Approach Directives foresee that the European Standards organizations (e.g. CEN), following a mandate given by the Commission, will elaborate European Standards (EN), or identify existing ENs, *which will offer technical solutions to meet the essential requirements.*

The 88\295 EEC Directive refers to three types of documents:

- · Harmonization Document or Harmonized Standard (HD)
- · European Standard (EN)
- · European on-draft Standard (ENV)

The Harmonized Standard definition is expressed in the Directive motivation, where it is said that: "...whereas, *in order to facilitate proof of conformity with these essential requirements and to permit monitoring of that conformity, it is desirable to have Europe-wide harmonized standards*...", which *"...must retain their status as non-mandatory texts*...", then, : "*...the European Committee for standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are recognized as being the competent bodies to adopt harmonized standards*..." and, finally, it is said that: " a *Harmonized Standard is a technical specification* (European Standard or Harmonization Document) adopted by either or both of these bodies...".

The Harmonized Standards:

- · have a voluntary character
- · are adopted by the Standardization European Committees
- · are published in the Official Journal of the European Communities
- · the compliance with them, attributes the "conformity presumption"
- · are based on international standards (ISO or IEC) and concern general aspects.

They imply the participation to their elaboration of all the involved parts (Manufacturers, Users, Notified Bodies, Government Authorities, etc.)

The Importance of Harmonized Standards

A harmonized standard is an European standard (EN), prepared under the mandate of the European Commission or the EFTA Secretariat with the purpose of supporting the essential requirements of a directive. The mandate does not necessarily cover the complete standard, and it is possible to include other, additional provisions in the text of the standard, the application of which is not mandatory. When this is the case, distinction should be made between the regulated area of the standard, which "supports" the requirements of the directive, and the voluntary area of the standard.

The procedure of preparing a harmonized standards

In principle, the procedure of preparing and adopting a harmonized standard is the same as the procedure of adopting European Standards, the difference being in that the role of "CEN Consultant" is included during public inquiry, who reviews the draft standard from the point of view of meeting the provisions given in the wording of the mandate, and from the point of view of meeting the essential requirements of the corresponding European directives.

It often occurs that a mandated *standard supports more than one European directive* (e.g. the draft standard on garage doors, which creates a presumption of conformity with the requirements of the directive on machines and the directive on construction products as well as the directive on EMC). If this is the case, several CEN Consultants will review the standard, each giving their report for the relevant field.

Prior to formal casting of votes on the mandated standard, the CEN Consultant will be engaged again to confirm, within four weeks, the final text of the standard for voting. If the

Consultant refuses to confirm the text, further coordination will be necessary between the Consultant, the chairman and the technical secretary of the CEN TC who has prepared the draft.

When, in terms of the CEN/CENELEC rules, the result of formal voting is positive, the CEN Administrative Center will send to its members the text of the standard to be transposed into their national standards systems. At the same time, the European Commission and the EFTA Secretariat will be notified.

At this point, the mandated standard is still a "candidate" for a harmonized standard.

It is only after all Member States have communicated, through the intermediary of the CEN Administrative Center, to the European Commission and the EFTA Secretariat the title of the mandated standard translated into their national languages (e.g. the Spanish AENOR communicates the Spanish translation of the title, the Greek ELOT the Greek translation, etc.), that an announcement of the mandated standard is published in the Official Journal of the European Communities together with the indication of the directive in whose support the standard has been prepared. Through this act, a mandated European standard becomes a "Harmonized Standard".

From now on, this standard may – and with some directives must – be applied in order to prove conformity with the requirements of the Directive. Out of more than 3900 mandated standardization projects in support of 21 New Approach Directives, as many as 2,350 had been ratified by the end of 2001, which is 60 % of all planned standards.

Once reference to these standards have been published by the Commission in the Official Journal of the European Communities (OJEC), and once they have been transposed into identical national standards by the National Standardization Bodies (NSB) in the Member States, they will give a presumption of conformity with respect to the essential requirements that they deal with.

Note: It should be noted that the process of transposition by all the NSBs does not need to have taken place for such presumption of conformity, though of course the national bodies are obliged to transpose all new ENs.

Such standards are qualified in New Approach Directives as "harmonized standards".

Standards remain voluntary.

Therefore, *under New Approach, there is no obligation to use ENs.*

Where other technology is used to meet the essential requirements, or in the absence of standards, the burden of proof that the product meets the essential requirements will rest on the person affixing the CE marking (producer, his authorized representative in the Community or by the importer of the product).

The Commission publishes references of harmonized standards as they are presented to the Commission by the European Standards Organizations.

There is a vast body of European standards not mandated by the European Commission. These standards are not directed toward either the Old Approach or New Approach Directives. While the use of these standards is in theory voluntary, they can support claims of a product's quality either for marketing or legal purposes.

The standards define characteristics such as durability, appearance, quality, and even cultural preferences. These standards are not directed toward either the Old Approach or New Approach Directives. While the use of these standards is in theory voluntary, they can support claims of a product's quality either for marketing or legal purposes. *These standards cover such products as* furniture, household appliances (non-electrical), sports equipment, carpeting, footwear, and small hand-held tools. The standards define characteristics such as durability, appearance, quality, and even cultural preferences.

Technical Harmonization: Standardization

The harmonization of standards, like laws and conformity assessment procedures, has greatly simplified technical regulation in Europe. Prior to harmonization, *each country developed its own standards through a national standards body*. And, like differing and conflicting laws and conformity assessment procedures, fifteen sets of standards were not only costly, but also created technical barriers to trade between European countries. *It became necessary to create a new, integrated, European system of standardization.*

The new system provides for three standards bodies to create standards on a Europe-wide level:
- The European Committee for Standardization (CEN) in Brussels, Belgium.
- The European Committee for Electrical Engineering Standardization (CENELEC) in Brussels, Belgium; and
- The European Telecommunications Standards Institute (ETSI), in Sophia Antipolis, France.

CENELEC activities are in the electrical engineering sector, while ETSI specializes in telecommunications. All other sectors are covered by CEN.

The European Standards (ENs) that play a role in New Approach Directives are known as Harmonized Standards. Harmonized Standards are standards that support European legislation. They
(1) have been mandated by the European Commission,
(2) have been developed by the European Standards Bodies above,
(3) address essential requirements of New Approach Directives and
(4) notification of their development has been published in the Official Journal of the European Communities.

For example, the following harmonized standards have met all the conditions above and relate to certain Essential Health and Safety Requirements of the Safety of Machines Directive 98/37/EC [11]:

CEN EN 894-1 Safety of machinery – Ergonomics requirements for the design of displays and control actuators – Part 1: General principles for human interactions with displays and control actuators

CEN EN 894-2 Safety of machinery – Ergonomics requirements for the design of displays and control actuators – Part 2: Displays.

Technically speaking, the use of a Harmonized Standard is voluntary. That is, a manufacturer can elect to use a Harmonized Standard (like the ones above), or elect to use a non-Harmonized Standard (an American Standard, for example) to meet essential requirements. When using a Harmonized Standard, however, the manufacturer is presumed in conformity with the law. On the contrary, using a standard that is not a Harmonized Standard will impose additional responsibilities. The use of anything but a Harmonized Standard places a burden of proof upon the manufacturer that the product meets essential requirements. This proof may be provided by the manufacturer's Technical File, by the employment of a third party (consultant, testing house, etc.), or by a combination of the two. (The directive will prescribe conformity assessment procedures that are commensurate with the risk of injury associated with the product.)

HOW DO EUROPEAN STANDARDS RELATE TO THE CE MARK?

Prior to the harmonization of standards under the New Approach, each European country developed its own standards through a national standards body. The new system provides for three standards bodies to create standards on a Europe-wide scale:
- the European Committee for Standardization (CEN) in Brussels, Belgium
- the European Committee for Electrotechnical Standardization (CENELEC) in Brussels
- the European Telecommunications Standards Institute (ETSI) in Sophia Antipolis, France.

CENELEC activities are in the electrotechnical sector, while ETSI specializes in telecommunications. CEN covers all other sectors.

CEN and CENELEC's principal members are national standards bodies, while ETSI's membership incorporates a wider range of interested parties. These three are the only bodies that can develop a European standard (EN). When work on a European standard begins in one of these standards bodies, work on a corresponding national standard must stop. European standards, like European laws and European conformity assessment procedures, preempt and replace national (member state) standards.

The European standards (ENs) that play a role in New Approach Directives are known as "harmonized standards." These standards supporting European legislation:

- are mandated by the European Commission
- have been developed by the European standards bodies listed above, and
- address essential requirements of the New Approach Directives. These standards become officially recognized as harmonized standards when they are cited in the Official Journal of the European Communities.

There is a vast body of European standards that is not mandated by the European Commission. These standards are not directed towards either the Old Approach or the New Approach Directives. While the use of these standards is in theory voluntary, they can support claims of a product's quality either for marketing or legal purposes. These standards cover such products as furniture, household appliances (non-electrical), sports equipment, carpeting, footwear and small hand-held tools (which are not covered by the Machinery Directive). They define characteristics such as durability, appearance, quality and even cultural preferences.

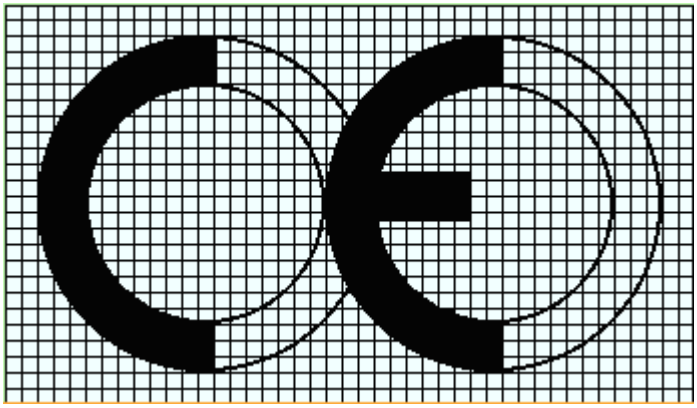
Products that meet the applicable technical standards developed by the three standards organizations are presumed to conform to the requirements of EU directives and are allowed to circulate freely within the European Union. Use of European standards is seen as a "fast track" for gaining CE mark compliance for a product. For many products, though, a manufacturer can choose not to comply with the CEN, CENELEC, or ETSI standards, if the firm can demonstrate that its product satisfies the essential safety and performance requirements of the directives.

16.2. Directive 93/68/EEC on CE marking

WHAT IS THE CE MARK, AND WHAT IS ITS PURPOSE?

The European Commission describes the CE mark (an acronym for the French phrase "Conformite Europeenne") as a "passport" that allows manufacturers to circulate industrial products freely within the internal market of the EU. The CE mark [5] certifies that the products have met EU health, safety and environmental requirements that ensure consumer and workplace safety. All manufacturers in the EU and abroad must affix the CE mark to those products covered by the "New Approach" directives in order to market their products in Europe. Once a product receives the CE mark, it can be marketed throughout the EU without having to undergo further product modification.

The CE conformity marking shall consist of the initials "CE " in the form shown below



If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm;

The affixing of markings on the products which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the products or the data plate provided that the visibility and legibility of the CE marking is not thereby reduced.

The most important items of the CE – Mark Directive

Member States shall presume that products bearing the CE marking comply with all the provisions of this Directive, including the conformity assessment procedures;

- Where the products are subject to other Directives covering other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the products in question are also presumed to conform to the provisions of those other Directives.
- The CE marking shall indicate conformity only to the Directives applied by the manufacturer;
- EC verification is the procedure whereby a manufacturer or his authorized representative established within the Community ensures and declares that the products are in conformity to the type described in the EC type-examination certificate.
- The manufacturer shall take all the necessary measures for the manufacturing process to ensure that the products conform to the type described in the EC type-examination certificate;
- The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and draw up a *declaration of conformity*.
- The approved body shall carry out the appropriate examinations and tests in order to check the conformity of the products with the requirements of this Directive by examination and testing of products.
- The manufacturer or his authorized representative must be able to supply on request the approved body's certificates of conformity.
- Where non-conformity, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market.

EC declaration of conformity
The EC declaration of conformity must contain certain elements:

- The manufacturer must establish the technical documentation and he or his authorized representative established within the Community must keep it on Community territory at the disposal of the relevant national authorities for inspection purposes for a certain period after the last product has been manufactured.
- Where neither the manufacturer nor his authorized representative is established within the Community, this obligation is the responsibility of the person who places the products on the Community market, e.g. the importer.

Technical documentation must enable the conformity of the product to the requirements of this Directive to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the product. It must include certain information.

16.3. Low Voltage Directive (LVD) 73/23/EEC

Directive 73/23/EEC [7]was adopted by the Council with the aim of harmonizing the laws of the Member States relating to electrical equipment designed for use within certain voltage limits.

From 1st January 1997, the requirements of the Low-voltage Directive in respect of CE-marking must be applied to electrical equipment and materials to be placed on the market in all other EU and EEA countries.

The term "*electrical equipment*" is not defined in the Directive. Therefore it is to be interpreted according to the internationally recognised meaning of this term. The definition in the "International Electrotechnical Dictionary" of IEC (International Electrotechnical Commission) is :

"any item used for such purposes as generation, conversion, transmission, distribution or utilization of electrical energy, such as machines, transformers, apparatus, measuring instruments, protective devices, wiring material, appliances."

Which products are covered ?

The Directive applies to all electrical equipment designed for use with a voltage rating of between 50 and 1000 V for a.c. and between
75 and 1500 V for d.c. Voltage ratings refer to the voltage of the electrical input or output, *not to voltages which may appear inside the equipment.*

The accompanying battery-charger as well as equipment with integrated power supply unit within the voltage ranges of the Directive, are in the scope of the LVD. This applies also, in the case of battery-operated equipment with supply voltage rating under 50 V AC and 75 V DC, for their accompanying power supply unit (e.g. Laptops).

However, the following are *excluded from the scope* of the "Low Voltage" Directive:

- Electrical equipment for use in a potentially explosive atmosphere
- Electrical equipment for radiology and medical purposes
- Electrical parts for lifts
- Electricity meters

which are covered by other Community directives, and

- Plugs and socket outlets for domestic use
- Electric fence controllers
- Specialized electrical equipment, for use on ships, aircraft or railways,

which complies with the safety provisions drawn up by international bodies in which the Member States participate, which so far are not covered by any Community directive and therefore must not be CE marked.

The Directive covers consumer and capital goods designed to operate within those voltage limits, including in particular :

- electrical appliances,
- lighting equipment including ballasts, switch gear and control gear,
- electric wiring, appliance couplers and cord sets,
- electrical installation equipment etc.

Are "components" included in the scope ?

In general, the scope of the Directive includes both electrical equipment intended for incorporation into other equipment and equipment intended to be used directly without being incorporated.

However, some types of electrical devices, designed and manufactured for being used as basic components to be incorporated into other electrical equipment, are such that *their safety* to a very large extent *depends on how they are integrated into the final product* and the overall characteristics of the final product. These basic components include electronic and certain other components.

Taking into account the objectives of the "Low Voltage" Directive, such basic components, the safety of which can only, to a very large extent, be assessed taking into account *how* they are incorporated, *are not covered as such by the Directive*. In particular, *they must not be CE marked*.

However, other electrical components which are intended for being incorporated into other electrical equipment, but for which a safety assessment is feasible, like - for example - some types *of transformers and electrical motors, are covered as such by the Directive and must be CE marked.*

Moreover, the scope of the exclusion of basic components must not be misunderstood and extended to items like lamps, starters, fuses, switches for household use, elements of electrical installations, etc., which, even if they are often used in conjunction with other electrical equipment and have to be properly installed in order to deliver their useful function, are themselves to be considered electrical equipment in the sense of the Directive.

Equipment and phenomena outside the scope of the Directive :

- Electrical equipment for use in an explosive atmosphere
- Electrical equipment for radiology and medical purposes
- Electrical parts for goods and passenger lifts
- Electricity meters
- Plugs and socket outlets for domestic use
- Electric fence controllers
- Radio-electrical interference

Specialized electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate.

Which safety aspects are covered by the Directive?

The Directive covers all risks arising from the use of electrical equipment, including not just electrical ones but also mechanical, chemical (such as, in particular, emission of aggressive substances) and all other risks. The Directive also covers health aspects of noise and vibrations, and ergonomic aspects as far as ergonomic requirements are necessary to protect against hazards in the sense of the Directive.

It should be noted that electromagnetic compatibility (emission and immunity) aspects are excluded from the scope of this Directive and are separately regulated under the EMC Directive 2004/108/EC.

Radiation aspects are limited to those directly relevant for health and safety of persons and domestic animals and do not cover electromagnetic disturbances in the sense of the EMC Directive. The Commission interpret that all electromagnetic aspects relating to safety including

functional safety are covered by the LVD. This covers also the effect of electromagnetic fields, emitted by electrical apparatus.

Tools for live working (like screwdrivers etc.) **are not included**. However, such tools are covered by standard EN 60900, not published under the LV Directive. Hand-held and transportable electrically driven tools such as power tool and lawnmowers are not covered by the LVD but by the Machinery Directive. Insulating tapes, for which safety depends critically not only on their intrinsic characteristics but also on how they are used under very variable conditions, are not considered electrical equipment and are not covered by the Directive. A European standard, EN 60454, exists for such tapes, which is not published under the Low Voltage Directive.

According to the Article 12, the Directive shall not apply to electrical equipment intended for export to third countries.

The LVD includes active components such as integrated circuits, transistors, diodes, rectifiers, triacs, opto-semi-conductors; passive components such as capacitors, inductance, resistors, filters; electromechanical components such as connectors, devices for mechanical protection which are part of equipment, relays with terminals for printed circuit boards, micro switches. A further assessment of the safety aspects related to the way in which such components are incorporated is in general also necessary.

Mandatory safety requirements applicable in the EU

Article 2 of the Directive states:

"The Member States shall take all appropriate measures to ensure that electrical equipment may be placed on the market only if, having been constructed in accordance with good engineering practice in safety matters in force in the Community, it does not endanger the safety of persons, domestic animals or property when properly installed and maintained and used in applications for which it was made."

Any national standards or national specifications related to the safety of electrical equipment do not have a mandatory status and may not be a condition for its placing on the market.

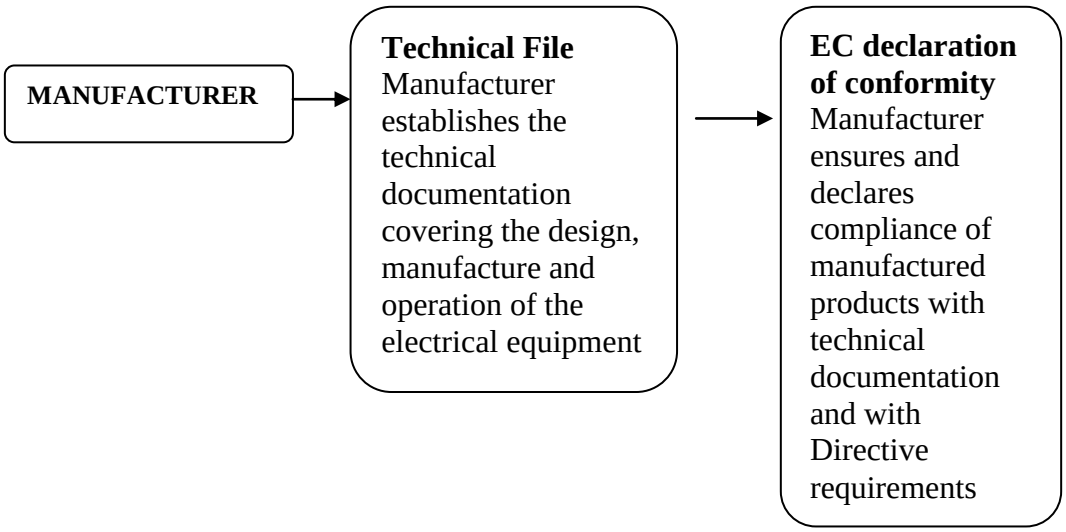
Conformity assessment procedures under the "Low Voltage" Directive

The manufacturer or his authorized representative established in the Community ensures and declares conformity of the electrical equipment with the provisions of the Directive. This includes three main elements:

Technical documentation

Before a product is placed on the market *the manufacturer* puts together the technical documentation which makes it possible to assess whether the electrical equipment complies with the requirements of the Directive.

Flow chart for the conformity assessment procedures for in LVD



Declaration of conformity

The manufacturer or his authorized representative established in the Community are also required, and are the only ones authorized to do so, to draw up in writing a declaration of conformity before placing the product on the market.

CE marking

Before it is placed on the market the electrical equipment must have the "CE" marking affixed. Only the manufacturer or his authorized representative established in the Community are authorized to affix the "CE" marking.

The responsibilities of the importer

Unless the importer is also the manufacturer's authorized representative, he will not in general, have detailed knowledge of which directives have been considered by the manufacturer or which standards have been applied. As a consequence, the importer cannot:

- affix CE marking
- draw up the EC declaration of conformity
- compile the Technical File.

Where neither the manufacturer nor his authorized representative are established within the Community, the importer is the person first placing the product on the EC market and is therefore responsible for ensuring that the requirements are complied with.

Where no standards within the meaning of the Directive have been applied, the manufacturer has to provide within the technical documentation a description of the solutions adopted to satisfy the safety requirements of the Directive.

The manufacturer or his authorized representative established in the Community may wish in certain cases to ask in advance for a report to be drawn up by a notified body in accordance with the procedure provided for and to keep it together with the technical documentation. The availability of such a report would make matters easier and speedier in the event of a challenge by the authorities.

What must be included in the technical documentation?

It must include details of the design, manufacture and operation of the electrical equipment in so far as these details are needed to assess the conformity of the electrical equipment with the requirements of the Directive.

Accordingly, it contains:

- a general description of the electrical equipment,
- design and manufacture drawings plus diagrams of components, sub- assemblies, circuits, etc.,
- descriptions and explanations needed to understand the above mentioned drawings and diagrams plus the operation of the electrical equipment,
- a list of the standards used, in full or in part, and a description of the solutions employed to meet the safety aspects of this directive when standards have not been applied,
- the results of design calculations and of checks carried out, etc.,
- test reports (in fact, the test reports which may be available, either established by the manufacturer or a third party).

The manufacturer or his authorized representative established in the Community must keep this documentation at the disposal of the national authorities for inspection purposes for at least ten years from the last date of manufacture of the product. The technical documentation may be kept on electronic support, provided that it is easily accessible for inspection. Where the manufacturer is not established in the Community and he has no authorized representative in the Community, this obligation is incumbent upon the importer or the person responsible for placing the product on the Community market.

What must be included in the declaration of conformity?
The content of the declaration of conformity as follows:
- name and address of the manufacturer or his authorised representative established within the Community,
- a description of the electrical equipment,
- reference to the harmonized standards,
- where appropriate, reference to the specifications on which conformity is declared,
- identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorized representative established within the Community,
- the last two digits of the year in which the CE marking was affixed (for the first time).

The declaration of conformity must be drawn up at least in one of the official languages of the Community.

Today, many European standards have been harmonized with the Low-voltage Directive. As each type of product can be regarded as having its own special associated safety risks, each standard is aimed at a particular group of products. The standards then include all the safety requirements that are relevant for the particular type of product: in other words, it is not only purely electrical risks (electric shock, arcing, fire) that are covered by the Directive and the associated standards, but also mechanical risks such as dangerous temperature, radiation, poisoning, environmental aspects, mechanical strength etc. It is important for the manufacturer actively to choose appropriate standards for his products. All safety standards prescribe inspection and testing to ensure that the detailed requirements have been fulfilled. In many cases, this can involve several hundred detailed requirements that must be verified before the product can be regarded as fulfilling the requirements of the standard.

LVD's standards

Cenelec EN 41003: 1998
Particular safety requirements for equipment to be connected to telecommunication networks, Date expired (1.1.2002)

Cenelec EN 50083-1: 1993
Cable networks for television signals, sound signals and interactive services Part 1: Safety requirements

Cenelec EN 50090-2-2: 1996
Home and Building Electronic Systems (HBES) — Part 2-2: System overview - General technical requirements Date expired (1.8.2004)

Cenelec EN 50091-1-1: 1996
Uninterruptible power systems (UPS) — Part 1-1: General and safety requirements for UPS used in operator access areas Date expired (1.6.2002)

Cenelec EN 50178: 1997
Electronic equipment for use in power installations

Cenelec EN 60335-1: 1988
Safety of household and similar electrical appliances — Part 1: General requirements

Cenelec EN 50366: 2003
Rotating electrical machines — Part 11: Thermal protection Household and similar electrical appliances - Electromagnetic fields - Methods for evaluation and measurement.

Cenelec EN 60065: 2002
Audio, video and similar electronic apparatus - Safety requirements.

Cenelec EN 60598-1: 2004
Luminaires — Part 1: General requirements and tests

16.4. Directive 2004/22/EC on Measuring Instruments

Correct and traceable measuring instruments can be used for a variety of measurement tasks. Those responding to reasons of public interest, public health, safety and order, protection of the environment and the consumer authorised representative means a natural or legal person who is established within the Community and authorised by a manufacturer, in writing, to act on his behalf for specified tasks within the meaning of this Directive [10].

*The performance of measuring instruments is particularly sensitive to the environment***,** particular the electromagnetic environment. Immunity of measuring instruments to electromagnetic interference forms an integral part of this Directive and the immunity requirements of EMC Directive 2004/108/EC should therefore *not apply.*

Legal metrological control should not lead to barriers to the free movement of measuring instruments. Where legal metrological control is prescribed, only measuring instruments complying with common performance requirements should be used.

The state of the art in measurement technology is subject to constant evolution which may lead to changes in the needs for conformity assessments. Therefore, for each category of measurement and, where appropriate, sub-assemblies, there must be an appropriate procedure or a choice between different procedures of equivalent stringency.

Scope

This Directive establishes the requirements that the devices and systems have to satisfy with a view to their being placed on the market

This Directive applies to the devices and systems with a measuring function defined in the instrument-specific annexes concerning

1) water meters,
2) gas meters and volume conversion devices,
3) active electrical energy meters,
4) heat meters,
5) measuring systems for continuous and dynamic measurement of quantities of liquids other then water,
6) automatic weighing instruments,
7) taximeters, material measures,
8) dimensional measuring instruments
9) exhaust gas analysers .

Definitions

For the purposes of this Directive:

- measuring instrument means any device or system with a measurement function;
- legal metrological control means the control of the measurement tasks intended for the field of application of a measuring instrument, for reasons of public interest, public health, public safety, public order, protection of the environment, protection of the consumers
- authorised representative means a natural or legal person who is established within the Community and authorised by a manufacturer, in writing, to act on his behalf for specified tasks within the meaning of this Directive

- harmonised standard means a technical specification adopted by CEN, CENELEC or ETSI or jointly by two or all of these organisations and prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations
- Measurand is the particular quantity subject to measurement
- Influence quantity is a quantity that is not the measurand but that affects the result of measurement
- Rated Operating Conditions are the values for the measurand and influence quantities making up the normal working conditions of an instrument
- Disturbance is influence quantity having a value within the limits specified in the appropriate requirement but outside the specified rated operating conditions of the measuring instrument An influence quantity is a disturbance if for that influence quantity the rated operating conditions are not specified
- Critical change value is the value at which the change in the measurement result is considered undesirable.

Climatic environments are the conditions in which measuring instruments may be used. The manufacturer shall specify the upper temperature limit and the lower temperature limit and indicate whether the instrument is designed for condensing or non-condensing humidity as well as the intended location for the instrument, i.e. open or closed.

Temperature Limits				
Upper temperature limit	30°C	40°C	55°C	55°C
Lower temperature limit	5°C	- 10°C	- 25°C	- 40°C

According to the climatic operating environment in which the instrument is intended to be used either the damp heat-steady state (non-condensing) or damp heat cyclic (condensing) test may appropriate.

Mechanical environments are classified into classes M1 to M3

M1 This class applies to instruments used in locations with vibration and shocks of low significance, e.g. for instruments fastened to light supporting structures subject to negligible vibrations and shocks transmitted from local blasting or pile-driving activities, slamming doors, etc.

M2 This class applies to instruments used in locations with significant or high levels of vibration and shock, e.g. transmitted from machines and passing vehicles in the vicinity or adjacent to heavy machines, conveyor belts, etc.

M3 This class applies to instruments used in locations where the level of vibration and shock is high and very high, e.g. for instruments mounted directly on machines, conveyor belts, etc.

The following influence quantities shall be considered in relation with mechanical environments:

— Vibration

— *Mechanical shock.*

Electromagnetic environments are classified into classes E1, E2 or E3.

E1 This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in residential, commercial and light industrial buildings.

E2 This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in other industrial buildings.

E3 This class applies to instruments supplied by the battery of a vehicle. Such instruments shall comply with the requirements of E2 and the following additional requirements:

— voltage reductions caused by energising the starter-motor circuits of internal combustion engines,

— load dump transients occurring in the event of a discharged battery being disconnected while the engine is running.

The following influence quantities shall be considered in relation with electromagnetic environments:
— Voltage interruptions,
— Short voltage reductions,
— Voltage transients on supply lines and/or signal lines,
— Electrostatic discharges,
— Radio frequency electromagnetic fields,
— Conducted radio frequency electromagnetic fields on supply lines and/or signal lines,
— Surges on supply lines and/or signal lines.
Other influence quantities to be considered, where appropriate, are:
— Voltage variation,
— Mains frequency variation,
— Power frequency magnetic fields,
— Any other quantity likely to influence in a significant way the accuracy of the instrument.

Metrological tests shall be carried out during or after the application of the influence quantity, whichever condition corresponds to the normal operational status of the instrument when that influence quantity is likely to occur.

Other required parameters and performances

Reproducibility

The application of the same measurand in a different location or by a different user, all other conditions being the same, shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE (maximum permissible error).

Repeatability

The application of the same measurand under the same conditions of measurement shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE.

Sensitivity

A measuring instrument shall be sufficiently sensitive for the intended measurement task.

Durability

A measuring instrument shall be designed to maintain an adequate stability of its metrological characteristics over a period of time estimated by the manufacturer, provided that it is properly installed, maintained and used according to the manufacturer's instruction when in the environmental conditions for which it is intended.

Reliability

A measuring instrument shall be designed to reduce as far as possible the effect of a defect that would lead to an inaccurate measurement result, unless the presence of such a defect is obvious.

Where a measuring instrument is designed for the measurement of values of the measurand that are constant over time, the measuring instrument shall be insensitive to small fluctuations of the value of the measurand.

A measuring instrument shall be designed so as to allow the control of the measuring tasks after the instrument has been placed on the market and put into use. If necessary, special equipment or software for this control shall be part of the instrument. The test procedure shall be described in the operation manual. When a measuring instrument has associated software which provides other functions besides the measuring function, the software that is critical for the metrological characteristics shall be identifiable.

A hardware component that is critical for metrological characteristics shall be designed so that it can be secured.

Software that is critical for metrological characteristics shall be identified as such and shall be secured. Software identification shall be easily provided by the measuring instrument.

A measuring instrument shall bear the following inscriptions:
— manufacturer's mark or name
— information in respect of its accuracy
plus, when applicable:
— information in respect of the conditions of use
— measuring capacity
— measuring range
— identity marking
— number of the EC-type examination certificate or the EC design examination certificate
— information whether or not additional devices providing metrological results comply with the provisions of this Directive on legal metrological control.

An instrument of dimensions too small or of too sensitive a composition to allow it to bear the relevant information shall have its packaging, if any, and the accompanying documents required by the provisions of this Directive.

The instrument shall be accompanied by *information on its operation*, unless the simplicity of the measuring instrument makes this unnecessary. Information shall be easily understandable and shall include where relevant:
— rated operating conditions
— mechanical and electromagnetic environment classes
— the upper and lower temperature limit, whether condensation is possible or not, open or closed location
— instructions for installation, maintenance, repairs, permissible adjustments
— instructions for correct operation and any special conditions of use
— conditions for compatibility with interfaces, sub-assemblies or measuring instruments.

The scale interval for a measured value shall be in the form 1.10^n, 2.10^n, or 5.10^n, where n is any integer or zero. The unit of measurement or its symbol shall be shown close to the numerical value. The units of measurement used and their symbols shall be in accordance with the provisions of Community legislation on units of measurement and their symbols.

Conformity evaluation

A measuring instrument shall be designed so as to allow ready evaluation of its conformity with the appropriate requirements of this Directive.

Active electrical energy meters

An active electrical energy meter is a device which measures the active electrical energy consumed in a circuit.

Note: Electrical energy meters may be used in combination with external instrument transformers, depending upon the measurement technique applied. However, this Annex covers only electrical energy meters but not instrument transformers.

Specific requirements

1. Accuracy

The manufacturer shall specify the class index of the meter. The class indices are defined as: Class A, B and C.

These ranges shall recognize the typical characteristics of electricity supplied by public distribution systems.

The voltage and frequency ranges shall be at least:
$0{,}9 \cdot U_n$ The voltage and frequency ranges shall be at least:
$0{,}9 \cdot U_n \leq U \leq 1{,}1 \cdot U_n$
$0{,}98 \cdot f_n \leq f \leq 1{,}02 \cdot f_n$
U_n is the specified reference voltage,
f_n is the specified reference frequence.
Power factor range (PF) at least from $\cos\varphi = 0{,}5$ inductive to $\cos\varphi = 0{,}8$ capacitive.

The effects of the various measurands and influence quantities are evaluated separately.

The error of , that shall not exceed the MPE stated in Table , is calculated as:

$$\text{error} = \sqrt{a^2 + b^2 + c^2 + ...}$$

When the meter is operating under varying-load current, the percentage errors shall not exceed the limits given in the table.

	Operating temperature		
	+ 5°C ÷ + 30°C		
Meter class	A	B	C
Single phase meter, polyphase meter if operating with balanced load			
$I_{min} \le I \le I_{tr}$	3,5	2	1
$I_{tr} \le I \le I_{max}$	3,5	2	0,7
Polyphase meter is operating with single phase load			
$I_{tr} \le I \le I_{max}$	4	2,5	1

Where

I_{tr} is the value of I above which the error lies within the smallest MPE corresponding to the class index of the meter.

I_{min} is the value of I above which the error lies within maximum permissible errors.

I_{max} is the value of I for which the error lies within MPEs.

Electromagnetic disturbances

As electrical energy meters are directly connected to the mains supply and as mains current is also one of the measurands, a special electromagnetic environment is used for electricity meters. The meter shall comply with the electromagnetic environment E2.

The electromagnetic environment and permissible effects reflect the situation that there are disturbances of long duration which shall not affect the accuracy beyond the critical change values and transient disturbances, which may cause a temporary degradation or loss of function or performance but from which the meter shall recover and shall not affect the accuracy beyond the critical change values. When there is a foreseeable high risk due to lightning or where overhead supply networks are predominant, the metrological characteristics of the meter shall be protected.

Critical change values for disturbances of long duration

Disturbance	Critical change values in % for meters of class		
	A	**B**	**C**
Reversed phase sequence	1,5	1,5	0,3
Voltage unbalance (only applicable to polyphase meters)	4	2	1
Harmonic contents in the current circuits	1	0,8	0,5
DC and harmonics in the current circuit	6	3	1,5
Fast transient bursts	6	4	2
Magnetic fields; HF (radiated RF) electromagnetic field; Conducted disturbances introduced by radio-frequency fields; and Oscillatory waves immunity	3	2	1

In the case of electromechanical electricity meters, no critical change values are defined for harmonic contents in the current circuits and for DC and harmonics in the current circuit.

Permissible effect of transient electromagnetic phenomena

The effect of an electromagnetic disturbance on an electrical energy meter shall be such that during and immediately after a disturbance

— any output intended for testing the accuracy of the meter does not produce pulses or signals corresponding to an energy of more than the critical change value and in reasonable time after the disturbance the meter shall:

— recover to operate within the MPE limits, and

— have all measurement functions safeguarded, and

— allow recovery of all measurement data present prior to the disturbance, and

— not indicate a change in the registered energy of more than the critical change value.

The critical change value in kWh is $m \cdot U_n \cdot I_{max} \cdot 10^{-6}$

(m being the number of measuring elements of the meter, U_n in Volts and I_{max} in Amps).

For overcurrent the critical change value is 1,5 %.

The display of the total energy shall have a sufficient number of digits to ensure that when the meter is operated for 4 000 hours at full load ($I = I_{max}$,PF = 1) the indication does not return to its initial value and shall not be able to be reset during use.

When the voltage is applied with no current flowing in the current circuit (current circuit shall be open circuit), the meter shall not register energy at any voltage between $0,8.U_n$ and $1,1.U_n$.

Conformity assessment

The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:

B + F or B + D or H1.

16.5. Machinery Directive 98/37/EC

For the purposes of this Directive, "*Machinery*", means an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material.

The term Machinery covers any equipment, whether for domestic, commercial or industrial applications, that has parts actuated by a power source other than manual effort. These are defined as components which are placed on the market "to fulfill a safety function when in use and the failure or malfunctioning of which endangers the safety or health of exposed persons". However, there are some exceptions; excluded from the Directive are certain machines where the risks are wholly covered by other Directives. For example, machinery where the risks are mainly of an electrical origin are covered by the Low Voltage Directive (73/23/EEC).

Member States shall take all appropriate measures to ensure that machinery or safety components covered by this Directive may be placed on the market and put into service only if they do not endanger the health or safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for their intended purpose.

The manufacturer must carry out necessary research or tests on components, fittings or the completed machine to determine whether by its design or construction, the machine is capable of being erected and put into service safely.

Compliance is demonstrated by CE marking affixed to the equipment when complete and supported by a Declaration of Conformity signed by the manufacturer or his representative within the Community.

Implementation of the Machinery Directive [11] and the necessity for affixing the CE marking From 1 January 1995, machines supplied within the EEA must:

1. Satisfy wide-ranging health and safety requirements for example on construction, moving parts and stability
2. In some cases be subjected to type examination by an approved body and
3. Carry CE marking.

What do the Regulations require?

Broadly the Regulations split machinery into two categories:

1. Machinery of a particularly hazardous nature which is listed in the Directive:

A. Machinery:

1. Circular saws (single or multi-blade) for working with wood and analogous materials or for working with meat and analogous materials.

1.1. Sawing machines with fixed tool during operation, having a fixed bed with manual feed of the workpiece or with a demountable power feed.

1.2. Sawing machines with fixed tool during operation, having a manually operated reciprocating saw-bench or carriage.

1.3. Sawing machines with fixed tool during operation, having a built-in mechanical feed device for the work-pieces, with manual loading and/or unloading.

1.4. Sawing machines with movable tool during operation, with a mechanical feed device and manual loading and/or unloading.

2. Hand-fed surface planing machines for woodworking.
3. Thicknessers for one-side dressing with manual loading and/or unloading for woodworking.
4. Band-saws with a fixed or mobile bed and band-saws with a mobile carriage, with manual loading and/or unloading, for working with wood and analogous materials or for working with meat and analogous materials.
5. Combined machines of the types referred to in 1 to 4 and 7 for working with wood and analogous materials.
6. Hand-fed tenoning machines with several tool holders for woodworking.
7. Hand-fed vertical spindle moulding machines for working with wood and analogous materials.
8. Portable chainsaws for woodworking.
9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
10. Injection or compression plastics-moulding machines with manual loading or unloading.
11. Injection or compression rubber-moulding machines with manual loading or unloading.
12. Machinery for underground working of the following types:

- machinery on rails: locomotives and brake-vans,
- hydraulic-powered roof supports,
- internal combustion engines to be fitted to machinery for underground working.

13. Manually-loaded trucks for the collection of household refuse incorporating a compression mechanism.
14. Guards and detachable transmission shafts with universal joints as described in section.
15. Vehicles servicing lifts.
16. Devices for the lifting of persons involving a risk of falling from a vertical height of more than three meters
17. Machines for the manufacture of pyrotechnics.

B. Safety components

1. Electro-sensitive devices designed specifically to detect persons in order to ensure their safety (non-material barriers, sensor mats, electromagnetic detectors, etc.).
2. Logic units which ensure the safety functions of bimanual controls.
3. Automatic movable screens to protect the presses referred to in 9,10 and 11.
4. Roll-over protection structures (ROPS).
5. Falling-object protective structures (FOPS).

These products must be submitted to an approved body which will undertake full testing, or, where transposed harmonised European Standards exist, verify from the technical file that they have been correctly applied. Then the manufacturer or importer must make a Declaration of Conformity and affix CE marking. A copy of the technical file must be held by the approved body.

The following are excluded from the scope of this Directive:

- machinery whose only power source is directly applied manual effort, unless it is a machine used for lifting or lowering loads,
- machinery for medical use used in direct contact with patients,
- special equipment for use in fairgrounds and/or amusement parks,
- steam boilers, tanks and pressure vessels,
- machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity,
- radioactive sources forming part of a machine,
- firearms,
- storage tanks and pipelines for petrol, diesel fuel, inflammable liquids and dangerous substances,
- means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or on road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, on public road or rail networks or on water. Vehicles used in the mineral extraction industry shall not be excluded,
- seagoing vessels and mobile offshore units together with equipment on board such vessels or units,
- cableways, including funicular railways, for the public or private transportation of persons,
- agricultural and forestry tractors, as defined in Article 1(1) of Directive 74/150/EEC
- machines specially designed and constructed for military or police purposes,
- lifts which permanently serve specific levels of buildings and constructions, having a car moving between guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal

What is the status of the Machinery Safety Standards?

Compliance with European harmonised standards is one way of meeting the essential health and safety requirements of the Machinery Directive. The European Committee for Standardisation (CEN) is working to produce a complex of European standards at three levels in support of the Machinery Directive.

The first (A) level comprises general principles for the design of all types of machinery (e.g. EN 292 Mechanical Design and EN 60204 Electrical Design).

The second (B) level covers specific safety devices and ergonomic aspects of ranges of machinery types (e.g. EN 418 Emergency Stop Equipment).

The third (C) level covers specific classes of machinery by calling up the appropriate standards from the first two levels and addressing requirements specific to class (e.g. EN 60204-31Sewing Machines).

Most of the Level A and B standards have been published but some 600 technical committees and working groups are working to produce the Level C standards. It will be several years before all these Level C standards are published.

The EC declaration of conformity is the procedure by which the manufacturer, or his authorised representative established in the Community declares that the machinery being placed on the market complies with all the essential health and safety requirements applying to it.

Before drawing up the EC declaration of conformity, the manufacturer, or his authorised representative in the Community, shall have ensured and be able to guarantee that the documentation listed below is and will remain available on his premises for any inspection purposes:

(a) a technical construction file comprising:
- an overall drawing of the machinery together with drawings of the control circuits,
- full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the conformity of the machinery with the essential health and safety requirements,
- a list of: the essential requirements of this Directive, standards, and other technical specifications, which were used when the machinery was designed,
- a description of methods adopted to eliminate hazards presented by the machinery,
- if he so desires, any technical report or certificate obtained from a competent body or laboratory,
- if he declares conformity with a harmonised standard which provides therefor, any technical report giving the results of tests carried out at his choice either by himself or by a competent body or laboratory,
- a copy of the instructions for the machinery;

(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.

The manufacturer must carry out necessary research or tests on components, fittings or the completed machine to determine whether by its design or construction, the machine is capable of being erected and put into service safely.

In selecting the most appropriate methods, the manufacturer must apply the following principles, in the order given:
- eliminate or reduce risks as far as possible (inherently safe machinery design and construction),
- eliminate or reduce risks as far as possible (inherently safe machinery design and construction),
- take the necessary protection measures in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted, indicate whether any particular training is required and specify any need to provide personal protection equipment.

- The machinery must be designed to prevent abnormal use if such use would engender a risk. In other cases the instructions must draw the user's attention to ways - which experience has shown might occur - in which the machinery should not be used.
- The machinery must be designed to prevent abnormal use if such use would engender a risk. In other cases the instructions must draw the user's attention to ways - which experience has shown might occur - in which the machinery should not be used**.**
- When designing and constructing machinery, the manufacturer must take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protection equipment (such as footwear, gloves, etc.).
- Machinery must be supplied with all the essential special equipment and accessories to enable it to be adjusted, maintained and used without risk.

- The manufacturer must supply integral lighting suitable for the operations concerned where its lack is likely to cause a risk despite ambient lighting of normal intensity.
- Control systems must be designed and constructed so that they are safe and reliable, in a way that will prevent a dangerous situation arising.

Machinery must be fitted with indicators (dials, signals, etc.) as required for safe operation. The operator must be able to read them from the control position.

EC type-examination is the procedure by which a notified body ascertains and certifies that an example of machinery satisfies the provisions of this Directive which apply to it.

The *notified body* shall carry out the EC type-examination in the manner described below:

- it shall examine the technical construction file to verify its appropriateness and the machine supplied or made available to it,
- during the examination of the machine, the body shall:

(a) ensure that it has been manufactured in conformity with the technical construction file and may safely be used under its intended working conditions;

(b) check that standards, if used, have been properly applied;

(c) perform appropriate examinations and tests to check that the machine complies with the essential health and safety requirements applicable to it.

- If the example complies with the provisions applicable to it the body shall draw up an *EC type-examination certificate* which shall be forwarded to the applicant. That certificate shall state the conclusions of the examination, indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved example.
- The manufacturer or his authorised representative established in the Community shall inform the notified body of any modifications, even of a minor nature, which he has made or plans to make to the machine to which the example relates. The notified body shall examine those modifications and inform the manufacturer or his authorised representative established in the Community whether the EC type-examination certificate remains valid.
- A body which refuses to issue an EC type-examination certificate shall so inform the other notified bodies. A body which withdraws an EC type-examination certificate shall so inform the Member State which notified it. The latter shall inform the other Member States and the Commission thereof, giving the reasons for the decision.
- The files and correspondence referring to the EC type-examination procedures shall be drawn up in an official language of the Member State where the notified body is established or in a language acceptable to it.

16.6. Directive on Medical Devices 93/42/EEC

This Directive [20] shall apply to medical devices and their accessories.

Medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

Accessory means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

This Directive does not apply to:
(a) in vitro diagnostic devices;
(b) active implantable devices covered by Directive 90/385/EEC;
(c) medicinal products covered by Directive 65/65/EEC;
(d) cosmetic products covered by Directive 76/768/EEC ;
(e) human blood, human blood products, human plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;
(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin;
(g) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

In order to demonstrate conformity with the essential requirements and to enable conformity to be verified, it is desirable to have harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices.

Essential requirements

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:
- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

It is necessary, essentially for the purpose of the conformity assessment procedures, to group the devices into four product classes; hereas the classification rules are *based on the vulnerability of the human body* taking account of the potential risks associated with the technical design and manufacture of the devices.

The conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products.

For Class II-a devices, the intervention of a notified body should be compulsory at the production stage; whereas, for devices falling within Classes II-b and III which constitute a high risk potential, inspection by a notified body is required with regard to the design and manufacture of the devices.

Class III is set aside for the most critical devices for which explicit prior authorization with regard to conformity is required for them to be placed on the market.

Medical devices should, as a general rule, bear the CE mark to indicate their conformity with the provisions of this Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose.

Clinical investigations

Objectives

The objectives of clinical investigation are:

- to verify that, under normal conditions of use, the performance of the devices conform to those referred and
- to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

Active medical device

Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

Devices with a measuring function

Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

Essential requirements. General Requirements.

The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),

- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfills the relevant provisions of this Directive.

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and to the requirements of the Directive which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EC type-examination certificate and with the requirements of this Directive which apply to them.

16.7. General Product Safety Directive (GPSD) 2001/95/EC

The purpose of this Directive [8] is to ensure that products placed on the market are safe.

In order to ensure a high level of consumer protection, the Community must contribute to protecting the health and safety of consumers. Horizontal Community legislation introducing a general product safety requirement, and containing provisions on the general obligations of producers and distributors, on the enforcement of Community product safety requirements and on rapid exchange of information and action at Community level in certain cases, should contribute to that aim.

It is very difficult to adopt Community legislation for every product which exists or which may be developed; there is a need for a broad-based, legislative framework of a horizontal nature to deal with such products

It is therefore necessary to establish at Community level a general safety requirement for any product placed on the market, or otherwise supplied or made available to consumers, intended for consumers, or likely to be used by consumers under reasonably foreseeable conditions even if not intended for them. In all these cases the products under consideration can pose risks for the health and safety of consumers which must be prevented.

Apply to new and second-hand consumer products, except new products that are covered by specific European safety legislation. Products covered include (but are not restricted to) clothing, medicines, primary agricultural and horticultural products, food and drink, household goods, nursery goods and motor vehicles.

Where products are subject to specific safety requirements imposed by Community legislation, this Directive shall apply only to the aspects and risks or categories of risks not covered by those requirements.

The Directive does not apply to products for use in the workplace by employees or for those which are to be exported outside the EU.

Safe product shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.

Dangerous product shall mean any product which does not meet the definition of "safe product".

Taking into account the following points in particular:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance

- the effect on other products, where it is reasonably foreseeable that it will be used with other products
- the presentation of the product, the labeling, any warnings and instructions for its use and disposal and any other indication or information regarding the product
- the categories of consumers at risk when using the product, in particular children and the elderly.

This Directive *does not cover services.* The safety of the equipment used by service providers themselves to supply a service to consumers does not come within the scope of this Directive since it has to be dealt with in conjunction with the safety of the service provided.

Products which are designed exclusively for professional use but have subsequently migrated to the consumer market should be subject to the requirements of this Directive.

Appropriate independent certification recognised by the competent authorities may facilitate proof of compliance with the applicable product safety criteria.

Manufacturer and distributor obligations

The manufacturers must put on the market products which comply with the general safety requirement. In addition, they must provide consumers with the necessary information in order to assess a product's inherent threat, particularly when this is not directly obvious, and take the necessary measures to avoid such threats (e.g. withdraw products from the market, inform consumers, recall products which have already been supplied to consumers, etc.).

Distributors are also obliged to supply products that comply with the general safety requirement, to monitor the safety of products on the market and to provide the necessary documents ensuring that the products can be traced.

If the manufacturers or the distributors discover that a product is dangerous, they *must notify* the competent authorities and, if necessary, cooperate with them.

Both producers and distributors should cooperate with the competent authorities in action aimed at preventing risks and inform them when they conclude that certain products supplied are dangerous.

RAPEX system.

Rapid intervention where products pose a serious risk

Collaboration between the enforcement authorities of the Member States is necessary in particular the Community Rapid Information System (*RAPEX*), improved collaboration at operational level on market surveillance and other enforcement activities, in particular risk assessment, testing of products, exchange of expertise and scientific knowledge, execution of joint surveillance projects and tracing, withdrawing or recalling dangerous products. Access to RAPEX shall be open to third countries or international organisations, within the framework of agreements between the Community and those countries or international organisations, according to arrangements defined in these agreements. RAPEX is essentially aimed at a rapid exchange of information in the event of a serious risk.

PROCEDURES FOR THE APPLICATION OF RAPEX AND GUIDELINES FOR NOTIFICATIONS

RAPEX covers products that pose a serious risk to the health and safety of consumers.

Pharmaceuticals, which come under *Directives 75/319/EEC and 81/851/EEC*, are excluded from the scope of RAPEX.

Member States notifying the Commission shall provide all available details. In particular, the notification shall contain the information at least:

(a) information enabling the product to be identified

(b) a description of the risk involved, including a summary of the results of any tests/analyses and of their conclusions which are relevant to assessing the level of risk

(c) the nature and the duration of the measures or action taken or decided on, if applicable
(d) information on supply chains and distribution of the product, in particular on destination countries.

Such information must be transmitted using the special standard notification form.

The Commission shall, in the shortest time possible, verify the conformity with the provisions of the Directive of the information received under RAPEX and, may, when it considers it to be necessary and in order to assess product safety, carry out an investigation on its own initiative. In the case of such an investigation, Member States shall supply the Commission with the requested information to the best of their ability.

It is necessary, for the purpose of ensuring a consistent, high level of consumer health and safety protection and preserving the unity of the internal market, that the Commission be informed of any measure restricting the placing on the market of a product or requiring its withdrawal or recall from the market. Effective supervision of product safety requires the setting-up at national and Community levels of a system of rapid exchange of information in situations of serious risk requiring rapid intervention in respect of the safety of a product. It may be necessary to deal with serious product-safety problems requiring rapid intervention which affect or could affect, in the immediate future, all or a significant part of the Community.

The Commission should periodically examine the manner in which this Directive is applied and the results obtained, in particular in relation to the functioning of market surveillance systems, the rapid exchange of information and measures adopted at Community level, together with other issues relevant for consumer product safety in the Community, and submit regular reports to the European Parliament and the Council on the subject.

If the Commission becomes aware of a serious risk from certain products to the health and safety of consumers in various Member States, it may, after consulting the Member States, and, if scientific questions arise which fall within the competence of a Community Scientific Committee, the Scientific Committee competent to deal with the risk concerned, adopt a decision in the light of the result of those consultations.

Information available to the authorities of the Member States or the Commission relating to risks to consumer health and safety posed by products shall in general be available to the public, in accordance with the requirements of transparency and without prejudice to the restrictions required for monitoring and investigation activities. In particular the public shall have access to information on product identification, the nature of the risk and the measures taken.

A product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards, the references of which have been published by the Commission in the Official Journal of the European Communities.

The conformity of a product to the general safety requirement shall be assessed by taking into account the following elements in particular, where they exist:
(a) voluntary national standards transposing relevant European standards,
(b) the standards drawn up in the Member State in which the product is marketed,
(c) Commission recommendations setting guidelines on product safety assessment,
(d) product safety codes of good practice in force in the sector concerned,
(e) the state of the art and technology,
(f) reasonable consumer expectations concerning safety.

Producers and distributors shall, within the limits of their respective activities, cooperate with the competent authorities, at the request of the latter, on action taken to avoid the risks posed by products which they supply or have supplied.

The presence of *warnings* does not exempt any person from compliance with the other requirements laid down in this Directive.

Member State obligations

In order to ensure the effective enforcement of the obligations incumbent on producers and distributors, the Member States should establish or designate authorities which are responsible for monitoring product safety and have powers to take appropriate measures. It is necessary in particular for the appropriate measures to include the power for Member States to order or organise, immediately and efficiently, the withdrawal of dangerous products already placed on the market. Where necessary, the appropriate powers and procedures should be available to the authorities to decide and apply any necessary measures rapidly. The safety of consumers depends to a great extent on the active enforcement of Community product safety requirements. The Member States should, therefore, establish systematic approaches to ensure the effectiveness of market surveillance and other enforcement activities and should ensure their openness to the public and interested parties.

Member States shall ensure that producers and distributors comply with their obligations under this Directive in such a way that products placed on the market are safe. Member States shall establish or nominate authorities competent to monitor the compliance of products with the general safety requirements and arrange for such authorities to have and use the necessary powers to take the appropriate measures incumbent upon them under this Directive.

Member States shall ensure that consumers and other interested parties are given an opportunity to submit complaints to the competent authorities on product safety and on surveillance and control activities and that these complaints are followed up as appropriate. Member States shall actively inform consumers and other interested parties of the procedures established to that end.

Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

The authorities receiving information covered by professional secrecy shall ensure its protection.

Any measure adopted under this Directive and involving restrictions on the placing of a product on the market or requiring its withdrawal or recall must state the appropriate *reasons on which it is based*.

The penalties in UK - supplying an unsafe product can result in a fine of up to £5,000 for each offense, and/or a term of imprisonment of up to three months.

The parties concerned shall, whenever feasible, be given an *opportunity to submit their views* before the adoption of the measure. If this has not been done in advance because of the urgency of the measures to be taken, they shall be given such opportunity in due course after the measure has been implemented. Measures requiring the withdrawal of a product or its recall shall take into consideration the need to encourage distributors, users and consumers to contribute to the implementation of such measures.

Every three years, following 15 January 2004, *the Commission shall submit a report on the implementation of this Directive to the European Parliament and the Council***.** The report shall in particular include information on the safety of consumer products, in particular on improved traceability of products, the functioning of market surveillance, standardisation work, the functioning of RAPEX and Community measures have been taken. The Member States shall provide the Commission with all the necessary assistance and information for carrying out the assessments and preparing the reports.

What are your rights as consumers?

For the first time, moral issues come into the Directive. Goods recognised as dangerous in the EU can no longer be dumped onto third world countries where laws are less forceful than in Europe.

The following are some of the new benefits to consumers of GSPD:

- Clearer and more understandable information and warnings on dangerous products are given. This means that you can work out the particular risks you run.
- Special attention concentrates on people who are most at risk such as children and old people.
- A clearer definition is given of what a product actually is. The Directive now covers products like laser pens, chain saws, paints and pesticides which were originally intended for the professional market but are now widely used in the home.
- The responsibilities of producers and retailers for withdrawing dangerous products from shops are greater. These are described more clearly.
- They must also recall dangerous products that have already been bought and used.
- Products bought in the EU by mail order or through the Internet are included.
- Better enforcement of the law will be possible because manufacturers and suppliers will now have to tell their national authorities (like trading standards departments in the UK) what they are doing to prevent unacceptable risks to consumers.
- A more effective rapid information exchange (RAPEX) in emergency situations in the EU will take place. National authorities will work together to warn of dangerous products that can move from one country to another.
- There will be a strengthening of European standards to make sure that products conform to safety requirements and to provide better guidelines for manufacturers.

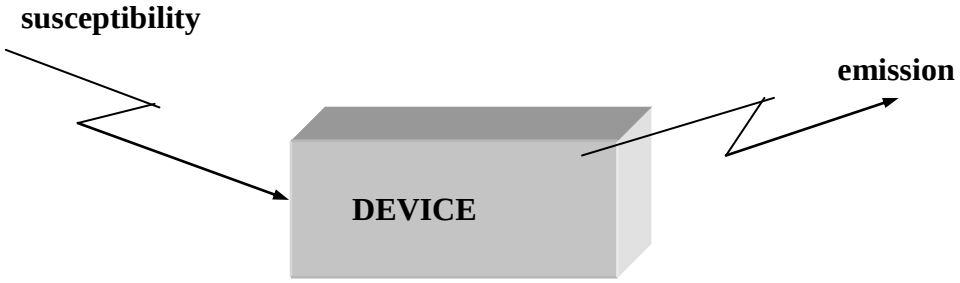
What can you do as responsible consumers?

- Realize there is no such thing as absolute safety. You are the one who has to judge what risks are acceptable and how to assess and manage them.
- Be aware of ‘new’ products that might have all sorts of risks not necessarily foreseen at the design stage.
- Read labels and instructions. Look for cautions and warnings. Search for standards and safety marks.
- Take back items if there is a product recall for a refund or replacement.
- Report at any suspect products to your ‘competent authority’.
- Your duty is to use products in the normal way and for the purpose they were made.

16.8. *Electromagnetic Compatibility* (EMC) Directive 2004/108/EC

Electromagnetic compatibility (EMC) means the ability of an electrical and electronic appliance, equipment and installation containing electrical and/or electronic components to *function satisfactorily* in its electromagnetic environment without introducing intolerable electromagnetic disturbances to anything in that environment.

"Function satisfactorily" means here without degradation of quality of performance below an acceptable performance criteria level.



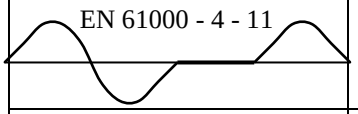
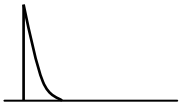
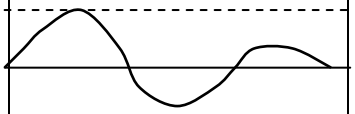
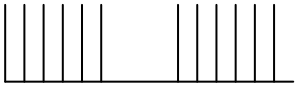
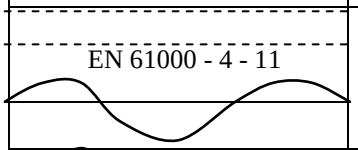
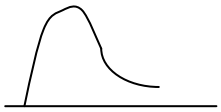
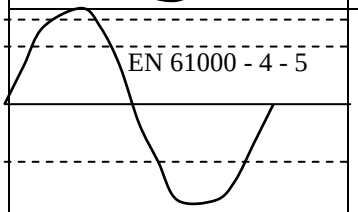
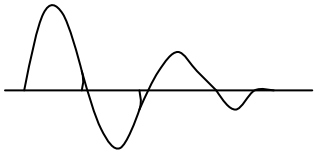
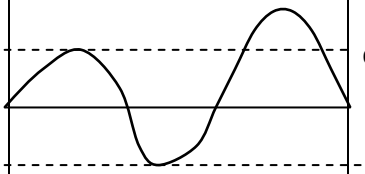
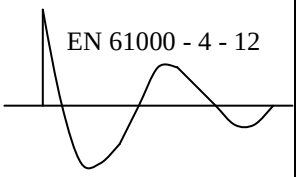
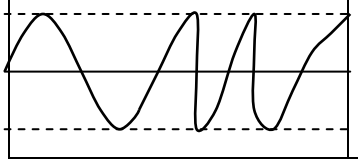
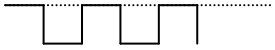
Electromagnetic disturbance means any electromagnetic phenomenon which may degrade the performance of equipment. An electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself.

Electromagnetic environment means all electromagnetic phenomena observable in a given location.

This Directive should not deal with the safety of equipment.

The new Electromagnetic Compatibility Directive 2004/108/EC [13] was published in the Official Journal on 31 December 2004. National legislation implementing this new version will apply from 20 July 2007 and Directive 89/336/EEC will be repealed from that date.

The Directive applies to a vast range of apparatus encompassing as broadly as possible all electrical appliances, systems and installations whether or not they are connected to the mains.

Disturbances in the mains supply			
Long disturbances (> 2,5 S)		**Pulse disturbances**	
	drop-out, outage		spike t_r/t_p , µS/µS
	undervoltage, brownout, swell		burst
	sag (15% to 100%)		Double exponetial Pulse (DEP) t_r/t_p , µS/µS
	surge		Damped Oscillatory Wave (DOW)
	overvoltage, swell		ring wave t_r/f , µS/kHz
	frequency variation	d.c. 	dip

The equipment covered by this Directive should include both apparatus and fixed installations. However, separate provision should be made for each. This is so because, whereas apparatus as such may move freely within the Community, fixed installations on the other hand are installed for permanent use at a predefined location, as assemblies of various types of apparatus and, where appropriate, other devices. The composition and function of such installations correspond in most cases to the particular needs of their operators.

The Directive applies to apparatus liable to cause electromagnetic disturbances or whose normal operation may be affected by such disturbances.

The Directive directly covers several sectors of electrical and electronic engineering, in particular household appliances, consumer electronics, industrial manufacturing, information technology, radio communication and telecommunications apparatus.

Apparatus explicitly listed *within the scope* of the EMC Directive (emission and immunity); non restrictive list:

- Electrical household appliances, portable tools and similar equipment.
- Fluorescent lighting luminaries fitted with starters.
- Fluorescent lamps.
- Industrial manufacturing equipment.
- Information technology equipment (ITE).
- Domestic radio and television receivers.
- Radio and television broadcast transmitters.
- Aeronautical and marine radio apparatus.
- Marine equipment is covered by the Directive 96/98/EC . Equipment intended for use in aircraft in flight is covered by the Council Regulation № 39922/91.
- Educational electronic equipment.

Apparatus in training, research and educational establishments intended for studying electromagnetic phenomena, may exceed the limits of emitted disturbance contained in the relevant standards. The training, research or educational establishment shall take all necessary measures to ensure that apparatus installed outside the electromagnetic environment can function properly.

- Radio equipment intended for use in amateur radio bands if commercially available.
- Telecommunication terminal equipment (covered by Directive 91/263/EEC) and earth stations for communications by satellite equipment (covered by Directive 93/97/EEC).

The electromagnetic compatibility essential requirements to be observed for apparatus covered by Directive 91/263/EEC or 93/97/EEC [17], insofar as they are not specific to such apparatus, are those laid down in the Directive 2004/108/EC.

- Radio communication transmitters not covered by Directive 91/263/EEC or by Directive 93/97/EEC.
- Radio communication receivers.
- Non-automatic weighing instruments: the EMC Directive *covers the emission requirements*. The immunity requirements are laid down in Directive 90/384/EEC.
- Agricultural and forestry tractors: the EMC Directive *covers the immunity requirements*. The emission requirements are covered by Directive 75/322/EEC.

Apparatus *totally excluded* (emission and immunity) from the EMC Directive (non restrictive list):

- Radio equipment used by radio amateurs unless the apparatus is available commercially.
- Radio equipment and telecommunications terminal equipment should not be covered by this Directive since they are already regulated by Directive 1999/5/EC.The electromagnetic compatibility requirements in both Directives achieve the same level of protection.
- Motor vehicles, covered by Directive 72/245/EEC.
- Active implantable medical devices, covered by specific Directive 90/385/EEC [22].

- Medical devices, covered by specific Directive 93/42/EEC [20].
- In vitro Diagnostic Medical Devices, covered by Directive 98/79/EC [21].
- Equipment intended for use in aircraft in flight covered by the Council Regulation (EEC) № 3922/91 of 16 December 1991.
- Marine equipment, if covered by the specific Directive 96/98/EC.

Aircraft or equipment intended to be fitted into aircraft should not be covered by this Directive, since they are already subject to special Community or international rules governing electromagnetic compatibility.

Entertainment products (e.g. radios, cassette and compact disc players), intended for fitment in vehicles, fall within the scope of Directive 95/54/EC [14] the so-called "Automotive EMC Directive" and are governed by the substantive provisions therein. The EMC protection and safety requirements applicable to motor vehicles are laid down by the Automotive EMC Directive.

Electromagnetically passive (passive-EM) equipment is excluded from the scope of the EMC Directive. Equipment is considered a passive-EM equipment if, when used as intended (without internal protection measures such as filtering or shielding) and without any user intervention, it does not create or produce any switching or oscillation of current or voltage and is not affected by electromagnetic disturbances.

Exclusion, for example of the following equipment from the application of the EMC Directive, on the clear understanding that they include no active electronic part:

- cables and cabling systems, cables accessories,
- equipment containing only resistive loads without any automatic switching device; e.g. simple domestic heaters with no controls, thermostat, or fan, batteries and accumulators.

Although components always fulfill a function within the apparatus in which they are incorporated, they do not always in themselves perform a direct function. For example, a transistor, mounted on a printed circuit board with the function of amplification fulfills a function but it is only the complete card which fulfills the expectations of the end-user, as specified by the manufacturer, e. g. the amplification of a given signal.

Another example is a cathode-ray tube which performs a function within the visual display unit in which it is installed, but only the complete monitor supplies the user with
the direct function sought, i.e. that of the visual display screen. The transistor and the cathode-ray tube perform no direct function and cannot, therefore, be regarded as "apparatus" but are components, whereas the printed circuit board, and the monitor are apparatus.

Similar examples of components *without* a direct function are:

- electrical or electronic components forming part of electrical or electronic circuits:resistors, capacitors, coils, diodes, transistors, thyristors, triacs, etc., integrated circuits
- Cables and cabling accessories
- All or nothing relays
- Plugs, sockets, terminal blocks, etc.
- LEDs, liquid-crystal displays, etc.
- Simple mechanical thermostats

These types of components *with no direct function* are not considered as apparatus within the meaning of the EMC Directive. The EMC Directive does not apply to them. They need incorporation into an apparatus that will deliver the expected intended direct function.

Some components that can be placed on the market in retail outlets for distribution and/or putting into service delivering a direct function. Plug-in cards, such as smart cards or input/output modules, designed for incorporation into computers are apparatus commonly found in retail outlets, and available to the general public. Once cards of this type are inserted in a PC they perform a direct function for the user. They must therefore be considered as apparatus and are, consequently, subject to the provisions of the EMC Directive.

They must be designed in such a way that they become fully EMC compliant (emissions and immunity) when they are installed as intended in the apparatus, in any of its possible variants and

configurations, without exceptions, and used in the electromagnetic environment determined by the manufacturer.

Similar examples of components *with a direct function* are:

- plug-in cards for computer systems, micro-processor cards, central processing unit cards/mother boards, electronic mail cards, telecommunication cards, etc.,
- programmable logic controllers,
- lift controls,
- electric motors (except induction motors),
- computer disk drives,
- power supply units (PSU), where they take the form of autonomous equipment,
- electronic temperature controls.

Application of the Directive to systems

A computer "system" consisting of a CPU, keyboard, printer, monitor, etc. is a good example. Each one of those parts is an apparatus placed on the market independently from the others and complying in full with the EMC Directive.

The manufacturer of each constituent piece of apparatus in the system has already fully applied the Directive, and particularly taken into account the expected electromagnetic environment and the intended use. This kind of "system" neither needs an additional CE marking no an additional EC declaration of conformity for the "system" as a whole.

"Systems" within the EMC Directive

For the purposes of the EMC Directive, a *system is defined* as a combination of several equipment, finished products, and/or components (hereinafter called ”parts”) combined, designed and/or put together by the same person (system manufacturer) intended to be placed on the market for distribution as a single functional unit for an end user and intended to be installed and operated together to perform a specific task.

The system as a whole is a final apparatus; within the meaning of the EMC Directive it is an apparatus; it can enjoy free movement within the EEA. It must therefore be designed and put together so as to comply with the essential requirements of the EMC Directive. This compliance should include any reasonably foreseeable situation, in any intended electromagnetic environment and in any of its configurations.

An apparatus, that could also be called a system, composed of other apparatus and/or components (whether or not they are CE marked) and which is a single commercial unit, must comply fully with the EMC Directive. An illustrative example is a computer CPU, composed of a power supply, CD ROM, mother board and disk drive supplied in
an enclosure. This “system” is regarded as an apparatus and therefore subject to the EMC Directive.

Systems assembled from only CE marked apparatus

As a good example we can take again the computer system consisting of a CPU, keyboard, printer, monitor, etc. Here these parts are put together by the same person (the system manufacturer) and placed on the market as a single functional unit, and that this person assumes responsibility for the compliance of the system as a whole with the Directive. Since the manufacturer(s) of each part of the system has/have already fully applied the Directive, and particularly taken into account the expected electromagnetic environment and the intended use, there are additional requirements for the system manufacturer to apply to comply with the EMC Directive.

The EC declaration of conformity, as well as the instructions for use must refer to the system as a whole.

The system as a whole does not need to bear the CE marking. Manufacturers of systems described above should be aware that combining two or more CE marked subassemblies may not

automatically produce a system which meets the requirements of the relevant standard. E.g.: a combination of CE marked PLC's (Programmable Logic Controllers) and motor drives within a machine tool put together to be placed on the market as a system may fail the requirements.

If the electromagnetic environment in which the system is used is different from that intended by the system manufacturer, the system may be subject to EMC problems.

Most often systems or apparatus are offered in different configurations, to perform different tasks. These configurations are variants of a complete or complex configuration.

The responsible person should attempt to define, from an EMC perspective, the configuration most likely to cause the maximum disturbance, or to be the most susceptible to possible disturbances. This configuration, often called the "worst case" should be defined, so that the other possible configurations are included in it in EMC terms. The "worst case" may often be the most complex variant. Such a configuration is then brought into full compliance with the Directive, possibly by an advice of an EMC expert. The manufacturer then declares conformity and affixes the CE marking.

Once the worst case configuration defined above is in conformity, the manufacturer (assembler or integrator) can place on the market any of the possible variants or configurations without further verification, since they are included in it in EMC terms. He then draws up and signs the EC declaration of conformity and affixes the CE marking to each variant.

Application of the Directive to installations

In normal usage the word "installation" is sometimes used to refer to an optional combination of several apparatus, to perform a specific task where the end-user is the person who decides which apparatus are used to construct this so-called "installation" and where the apparatus were not intended to be placed on the market as a single functional unit.

A good example of such an "installation" is a HI-FI installation composed of an amplifier, tuner, CD player and cassette deck, each of them separately CE marked and separately placed on the market.

Fixed installations, including large machines and networks, may generate electromagnetic disturbance, or be affected by it. There may be an interface between
fixed installations and apparatus, and the electromagnetic disturbances produced by fixed installations may affect apparatus, and vice versa. In terms of electromagnetic
compatibility, it is irrelevant whether the electromagnetic disturbance is produced by apparatus or by a fixed installation. Accordingly, fixed installations and apparatus should be subject to a coherent and comprehensive regime of essential requirements. It should be possible to use harmonised standards for fixed installations in order to demonstrate conformity with the essential requirements covered by such standards.

Due to their specific characteristics, fixed installations need not be subject to the affixation of the 'CE' marking or to the declaration of conformity.

It is not pertinent to carry out the conformity assessment of apparatus placed on the market for incorporation into a given fixed installation, and otherwise not commercially available.

Manufacturers of equipment intended to be connected to networks should construct such equipment in a way that prevents networks from suffering unacceptable degradation of service when used under normal operating conditions.

The EMC assembly instructions given by the manufacturer(s) of parts, and the whole method of installation has to be in accordance with good engineering practice within the context of installations, as well as installation rules that will ensure the compliance of the whole installation with the essential requirements of the EMC Directive.

Installations which are intended to be moved (*movable installations*) to and operated in a range of locations (e.g. the outside broadcast vehicle of a TV or radio station) may experience or cause changes in the electromagnetic environment.
Such a movable installations have to comply with the Directive.

Technical justification

Only three types of emitted disturbances have to be considered at present:

- conducted (continuous and intermittent) radio-frequency disturbance;
- radiated radio frequency disturbance;
- harmonics, flicker and voltage fluctuations on the mains power supply.

Regarding immunity, the list of phenomena to be considered is given in the relevant standards.

The Directive does not impose any lower or upper limits on the apparatus as regards power output or selection of transmission frequencies.

The Directive, therefore directly covers several sectors of electrical and electronic engineering, in particular household appliances, consumer electronics, industrial manufacturing, information technology, radio communication and telecommunications apparatus.

The major changes between 2004/108/EC and 89/336/EEC are listed below:

• Electromagnetic compatibility of equipment divided into two subsets – apparatus and fixed installations, to allow different regulatory provisions for each of these.
• Apparatus is defined as any finished appliance made commercially available as a single functioning unit intended for the user, which is liable to generate electromagnetic disturbance
• Fixed Installations, defined even if definition is ambiguous, as a particular combination of several types of apparatus and other devices, which are assembled, installed and intended to be used permanently at a pre defined location.
• CE marking required for all apparatus including components for use in
apparatus, but optional for fixed Installations. The concept of 'direct function' that appeared in the 1997 Commission Guidelines is no longer relevant.
• Conformity: Assessed by manufacturer - Demonstrated through technical documentation - optional involvement of Notified Body - attested through a declaration of conformity prior to fixing of CE marking.
• Use Harmonised Standards and conformity assessment is not required.
• Declaration of conformity must now include identification of the apparatus in terms of type, batch or serial numbers.
• Internal Production Control plus technical documentation is required
• Clear definition of manufacturer responsibilities
• Clearer Conformity procedures
• EC Type Examination Certificate disappears
• Competent Bodies become Notified Bodies
• Simpler documentation requirements
• R&TTE compliance options not changed
Better information requirements for user instructions including non-residential use.

The EMC Directive is a new-approach directive laying down apparatus protection requirements and leaving it to standards, primarily European harmonised standards, to define technical requirements to achieve the level of protection required.

The EMC Directive is a total harmonisation Directive, i.e. its provisions replaced the national ones concerned when they came into force.

The main objective of the EMC directive is to *guarantee the free movement* of apparatus and to create an acceptable electromagnetic environment in the EEA territory. In order to achieve it, a *harmonised and acceptable level of protection* is requested in the Directive.

The main goals are:

- To ensure that the electromagnetic disturbances produced by electrical and electronic apparatus does not affect the correct functioning of other apparatus (emission).
- To ensure that apparatus have an adequate level of intrinsic immunity to electromagnetic disturbances to enable them to operate as intend (immunity).

Immunity means the ability of apparatus to perform satisfactorily against the performance criteria specified for the apparatus in the presence of an electromagnetic disturbance.

The protection objective of the EMC Directive is to ensure that the functioning of appliances, installations or systems is not degraded by an electromagnetic phenomenon. If an apparatus, when used as intended, does not degrade the performance of others in its electromagnetic environment, both present and foreseeable, it should be considered compliant with the emission essential requirement of the Directive.

With regard to *immunity* apparatus should be constructed in such a way that it has an adequate level of electromagnetic immunity in the usual electromagnetic environment where the apparatus is intended to work so as to allow its operation, taking into account the levels of disturbance generated by apparatus complying with the standards.

"To operate as intended" means using the apparatus in accordance with the manufacturer's instructions and using it in the electromagnetic environment determined by standards chosen by the manufacturer.

To achieve these objectives, the EMC Directive lays down protection requirements and procedures under which the manufacturer may himself assess his apparatus against these requirements or may have it assessed by third parties. Obviously, the goal of the protection requirement is not to guarantee absolute protection of the above apparatus (e.g. zero emission level or total immunity of the apparatus). These requirements accommodate both physical facts and practical reasons. To ensure that this process remains open to future technical developments, the EMC Directive only describes protection requirements along general lines.

The electrical engineering industry has a large number of SME's (small and medium size enterprises), capable of assessing their products. where the manufacturer applies the relevant provisions of the harmonised standards, he may ask a test house to carry out some tests for him. Of course he is and remains fully responsible for his apparatus. The manufacturer is fully responsible for defining what parts of the conformity assessment he is able to undertake "in-house" and which ones require outside help.

When compliant with the provisions of the EMC Directive, electrical and electronic apparatus may be placed on the market in the EU territory, freely moved and operated as designed and intended in the expected electromagnetic environment.

EMC harmonised standards

The design and manufacture of equipment is subject to essential requirements in relation to electromagnetic compatibility. Those requirements are given technical expression by harmonised European standards, to be adopted by the various European standardisation bodies, European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (CENELEC) and European Telecommunications Standards Institute (ETSI). CEN, CENELEC and ETSI are recognised as the competent institutions in the field of this Directive for the adoption of harmonised standards, which they draw up in accordance with the general guidelines for cooperation between themselves and the Commission.

Compliance with a harmonised standard means conformity with its provisions.

16.9. Biological aspects of EMC (GSM and Human Health)

Mobile radiotelephony was first demonstrated in USA in 1946. The first generation was an analogue system. A new digital system, the second generation, called GSM (Global System for Mobile communication) at 900 MHz and later 1800 MHz was launched in 1992. The third generation system UMTS (Universal Mobile Telecommunications System) is being introduced since 2000.

Biological Effects of Electromagnetic Fields.

Living organisms are subject to many different forms of man-made electromagnetic fields. Due to the widespread use of GSM even a very small risk could have consequences for public health, especially when in such a risk the children are involved. Statistically children and young people are more sensitive to VHF electromagnetic fields. The changes produced depend on many physical and biological factors.

The absorption of electromagnetic energy is governed by the electromagnetic properties of tissue media, specifically, permiability and permitivity. In addition, the depth of penetration into tissue is a function of frequency. I general, when considering the interaction of electromagnetic fields with biological systems, it is necessary to account for frequency or wave length and its relationship to the physical dimensions of the body. The first consequence is that at sufficiently high power levels, exposure to microwave frequency fields could produce heating of tissues in the body.

It is a classic fact, that 80% of the human body is a water. On the other hand, the resonant frequency of H_2O is 2,4 GHz (microwave range). This fact is very indicative indeed. In October 1999 after WTR (Wireless Technology research) program, in some interviews has been emphasised that “those who use wireless phones have a higher chance of brain cancer”.

In the last couple of years national and international expert groups have reported extensive risk assessment for electromagnetic fields.

As a conclusion, a list of recommendations is given in order to minimize the risk. In the meanwhile everybody ought to decide for himself whether to take some precautions. However the responsibility concerning the children is much more higher.

Background

There are currently about 50 million mobile phones in use in the UK compared with around 25 million in 2000 and 4,5 million in 1995. These are supported by about 40 000 base stations in the UK network. The majority of these base stations operate under the Global System for Mobile Communications (GSM).

In less than ten years since the first GSM network was commercially launched as the second generation of mobile phones, it has become the world's leading and fastest growing telecommunications system. It is in use by more than one-sixth of the world's population and it has been estimated that at the end of January 2004 there were 1 billion GSM subscribers across more than 200 countries. The growth of GSM continues unabated with more than 160 million new customers in the last 12 months.

Statistically around 80% of the European population use mobile phones.

The revolution in communications continues world-wide. The third generation of mobile phones, 3G, is now being marketed in the UK and in many other countries and it is to be expected that further developments will become available in due course. In addition, there are many other telecommunications and related systems in use, all of which result in exposure of the population to radio frequency (RF) fields.

The extensive use of mobile phones suggests that users do not in general judge them to present a significant health hazard. Rather they have welcomed the technology and brought it into use in their everyday lives. Nevertheless, since their introduction, there have been persisting concerns about the possible impact of mobile phone technologies on health.

Since then, the widespread development in the use of mobile phones world-wide has not been accompanied by associated, clearly established increases in adverse health effects. Within the UK, there is a lack of hard information showing that the mobile phone systems in use are damaging to health. It is important to emphasize this crucial point.

Scientific research and statistics

When a human body is exposed to an electromagnetic field, a circulatory eddy current will be induced in the body. This induced current can be analyzed using Faraday's law and modeling the body as an impedance network.

In last couple of years national and international expert groups have reported extensive risk assessment for electromagnetic fields. In 2000 the Swedish so called RALF report was presented (Electrical hypersensitivity and health risk from electric and magnetic fields). In 2003 a Norwegian expert group reported on "Mobile telephones and health". The International Independent Expert Group on Electromagnetic Fields reported on "Recent Research on Mobile Telephony and Cancer and Other Selected Biological Effects". In short these expert groups have reached the same conclusion as phrased by the Steward Commission in UK.

A number of national expert groups in other countries have made similar risk assessments, among others in Canada (1999), Germany (2001), the Netherlands (2000-2002), France (2003).

The US Food and Drug Administration writes on its web-site: "The available scientific evidence does not show that any health problems are associated with using wireless phones".

In 1999 took the early initiative of setting up the Independent Expert Group on Mobile Phones (IEGMP) to review the situation. Its report, "Mobile Phones and Health" [29] (**the Steward Report**), was published in May 2000. It stated:

" The balance of evidence to date suggests that exposures to RF radiation below NRPB (National Radiological Protection Board) and ICNIRP (International Commission on Non-Ionizing Radiation Protection) guidelines do not cause adverse health effects to the general population.

" There is now scientific evidence, however, which suggests that there **may be biological effects** occurring at exposures below these guidelines.

" We conclude therefore that **it is not possible at present to say** that exposure to RF radiation, even at levels below national guidelines, is totally without potential adverse health effects, and that the gaps in knowledge are sufficient to justify a precautionary approach.

" We recommend that **a precautionary approach** to the use of mobile phone technologies be adopted until much more detailed and scientifically robust information on any health effects becomes available."

The Board of NRPB notes that a central recommendation in the Steward Report was that a precautionary approach to the use of mobile phone technologies be adopted until much more detailed and scientifically robust information on any health effects becomes available.

Various subsequent reports from across the world have supported the main thrust of its general conclusions.

Since then, the widespread development in the use of mobile phones world-wide has not been accompanied by associated, clearly established increases in adverse health effects. Within the UK, there is a lack of hard information showing that the mobile phone systems in use are damaging to health. *It is important to emphasize this crucial point.*

Nevertheless, the following issues have to be taken into consideration:

First, the widespread use of mobile phone technologies is still fairly recent and technologies are continuing to develop at a pace which is outstripping analyses of any potential impact on health

Second, there are data which suggest that RF fields can interfere with biological systems.

Third, because the use of mobile phone technologies is a fairly recent phenomenon, it has not yet been possible to carry out necessary long-term epidemiological studies and evaluate the findings. However, an increase in the risk of acoustic neuromas has recently been reported in

people in Sweden with more than ten years' use of mobile phones. This study has been able to obtain long-term follow-up data and highlights the need for extended follow-up studies on phone users, as has been noted in a number of reviews . Epidemiological studies, because of a lack of sensitivity, may miss any effects in small subsets of the general populations studied. This is a reason why the Board welcomes the large international cohort study proposed for support by the Mobile Telecommunications and Health Research (MTHR) program. A recent German study has also suggested concerns.

Fourth, a recent paper has suggested possible effects on brain function resulting from the use of 3G phones, although the study has some limitations and needs replication. The Stewart Report had previously identified the need for research on brain function.

Fifth, populations are not homogeneous and people can vary in their susceptibility to environmental and other challenges. There are well-established examples in the literature of the genetic predisposition of some groups that could influence sensitivity to disease. This remains an outstanding issue in relation to RF exposure and one on which more
information is needed. A number of people also report symptoms they ascribe to electromagnetic hypersensitivity arising from exposure to a range of electromagnetic fields (EMFs) encountered in everyday life. There is concern by an increasing number of individuals, although relatively small in relation to the total UK population, that they are adversely affected by exposure to RF fields from mobile phones.

Sixth, IEGMP considered that children might be more vulnerable to any effects arising from the use of mobile phones because of their developing nervous system, the greater absorption of energy in the tissues of the head and a longer lifetime of exposure. Data on the impact on children have not yet been forthcoming. The potential for undertaking studies to examine any possible effects on children, however, are limited for ethical reasons.

Seventh, there remain particular concerns in the UK about the impact of base stations on health, including well-being. Despite current evidence which shows that exposures of individuals are likely to be only a small fraction of those from phones, they may impact adversely on well-being. The large numbers of additional base stations which will be necessary to effectively roll out the 3G and other new networks are likely to exacerbate the potential impact. People can also be concerned about effects on property values when base stations are built near their homes.

The Board believes that the main conclusions reached in the Stewart Report in 2000 still apply today and that *a precautionary approach to the use of mobile phone technologies should continue to be adopted.*

Addressing public health concerns

The Steward Report made a number of other recommendations that were designed to provide more information about the operation of mobile phones and base stations and to address public concerns about this technology. This sought to allow individuals, local communities and local authorities to make informed choices about how the technology should be developed.

Exposure guidelines

A recommendation in the Steward Report was that, as a precautionary approach, the ICNIRP (1998) guidelines for public exposure be adopted for use.

Base stations

Mobile phone base stations are low-power multi-channel two-way radios. A mobile phone (cell phone) is a low-power, single-channel, two-way radio. When you talk on such a mobile phone, you (and perhaps dozens of other people around you) are talking to a nearby base station. From that base station your phone call goes into the regular land-line phone system.

Because mobile phones and their base stations are two-way radios, they produce
radio-frequency (RF) energy (that's how they communicate), and they expose people near them

to RF energy. However, because both the phones and the base stations are low power (short range), the RF energy exposure levels from them are generally very low.

The consensus of the scientific community, both in the US and internationally, is that the power from these mobile phone base station antennas is far too low to produce health hazards as long as people are kept away from direct access to the antennas.

It is critical to be aware of the difference between *antennas*, the objects that produce RF energy. It is the **antennas** that people need to keep their distance from.

It is also important to be aware that there are many different designs of mobile phone base stations that vary widely in their power, their characteristics, and their potential for exposing people to RF energy.

There are wide variety of types of base stations.

Macrocells provide the main framework of the system. Where there are areas of high demand, as in busy streets and shopping areas, *microcells* are used to infill the network and help to prevent 'lost' calls. *Picocells* may be installed in buildings or other enclosed areas to improve signal strength and to infill the network in areas of high demand for calls.

The Steward Report recommended that there should be an independent, random, ongoing audit of base stations.

It is important that as the networks develop there is a need for clarity in terms of legal responsibilities and regulations in relation to the installation of microcells and picocells and the availability of information about their deployment.

There are some reasons to be concerned about human health effects from the hand-held mobile (cellular) phones themselves (although it is not certain that any risks to human health actually exist). These concerns exist because the antennas of these phones deliver much of their RF energy to very small volumes of the user's body. Base station antennas do not create such "hot spots" (unless you are standing directly in front of one), so the potential safety issues concerning the phones have no real applicability to the base station antennas.

Mobile phones and SAR values

SAR (Specific energy absorption rate) – Rate at which energy is absorbed by unit mass of tissue in electromagnetic field (in W/kg).

In September 2001 the European Committee for Electrical Standardisation (CENELEC) published a standard testing procedure for the measurement of specific energy absorption rate (SAR) from mobile phones. However, it is still difficult for people to readily and easily acquire the necessary information so that comparisons of different phones can be made.

The Board welcomes the provision of information on the SAR from phones by all manufacturers using a standard testing procedure. This is an important contribution to providing information to the public about the potential for exposure and informs consumer choice. It recommends that comparative information on the SAR from phones is readily available to the consumer. The inclusion of comparative data on the SAR from phones in its promotional literature by at least one retailer is a welcome development. The public also need to be able to understand the merits and limitations of published SAR values.

According to ICNRP [28], the highest level of SAR for the mass GSM products is 2W/kg and when the device is near ear – then 0,88 W/kg. In fact, because of the automatic control of the output power of the device, the tested value of SAR should be even less (who knows). Nevertheless, the world health organisation recommends to minimize the calling time and also to use a distance interface (free hands).

A number of recommendations were made in the Stewart Report to improve the transparency of the local planning process and to improve the planning procedure.

In Scotland and Northern Ireland the recommendation to require full planning approval for all base station sites has been essentially implemented.

Developing technologies

A variety of additional technologies are now being progressively developed and implemented in the field of telecommunications. New technologies include third-generation (3G) mobile telephony, wireless local area networks (WLANs), Bluetooth and ultra-wideband (UWB) technology, and radio-frequency identification (RFID) devices.

It is important to understand the signal characteristics and field strengths arising from new telecommunications systems and related technologies, to assess the RF exposure of people, and to understand the potential biological effects on the human body.

Sensitive groups

Populations as a whole are not genetically homogeneous and people can vary in their susceptibility to environmental hazards. There could also be a dependency on age. The issue of individual sensitivity remains an outstanding one in relation to RF exposure and one on which more information is needed.

IEGMP considered that children might be more vulnerable to any effects arising from the use of mobile phones. The potential for undertaking studies to examine any possible effects on children are, however, limited for ethical reasons. It was recommended in the Stewart Report that the *use of mobile phones by children should be minimized* and this was supported by the Departments of Health. Text messaging has considerable advantages as the phone is in use for only a short time, when the phone transmits the message, compared with voice communication.

The Board concludes that, in the absence of new scientific evidence, the recommendation in the Stewart Report on limiting the use of mobile phones by children remains appropriate as a precautionary measure. The Board also welcomes an initiative by the World Health Organization in its EMF programme to focus attention on research relevant to the potential sensitivity of children.

Additionally, there is concern by an increasing number of individuals, although relatively small in relation to the total population, that they are adversely affected by exposure either to EMFs in general or specifically to RF fields from mobile phones. A European Commission group of experts termed the syndrome *'electromagnetic hypersensitivity'*.

Members of the public who have written to the Department of Health in England in relation to RF exposure have reported a variety of distressing symptoms including dizziness, fatigue, chronic headache, irregular heart beat, nausea and vertigo, and loss of memory and concentration. These and other symptoms are reported to result from exposure to a range of EMFs, including RF fields, encountered in everyday life. Similar symptoms were reported to IEGMP at open meetings. Many people also consider that there are serious long-term risks associated with such exposures. In Sweden electromagnetic hypersensitivity has been addressed nationally, accepted as a physical impairment, and a scheme is in place to improve home and working conditions for people who consider themselves to be sufferers.

Mobile phones and driving

The Steward Report demonstrated that there is good experimental evidence that the use of mobile phones whilst driving has a detrimental effect on drivers' responsiveness. This translates into a substantial increased risk of an accident. The evidence suggested that the negative effects of phone use while driving were similar whether the phone was hand-held or hands-free.

Hands-free kits

There has been considerable interest in the extent to which hands-free kits could reduce the exposure of phone users. The Steward Report contained a recommendation that independent testing should be available which would allow the effectiveness of such devices to be

demonstrated and information provided at the point of sale. The Department of Trade and Industry has commissioned independent testing of various devices and this has shown
their use results in a reduction in the exposure of the head by about 50%. However, a standard testing procedure is not yet available.

The provision of information needs to use all the media with emphasis on ensuring that information on such issues as SAR and exposure guidelines are presented in a straightforward way.

Health-related research

Outstanding health-related concerns can be addressed by epidemiological (human health) studies, experimental investigations with animals, and the use of cell-based techniques. Dosimetric studies are important for understanding the exposure of people from various sources and human volunteer studies can investigate short-term interactions of RF fields, for example, with brain function. In the area of telecommunications, however, technological change is rapid and it is a challenge to carry out comprehensive research and to determine the possibility of any health effects.

Research into any health effects of exposure to RF fields is still in a developmental phase. There are analogies with work on the consequences of exposure to EMF's from power lines.

According to the experts, if there will not be taken appropriate measures, the electromagnetic radiation of the human body from the cell – phones could provoke a global crises of the human health. Today the number of people all over the word is more than 1,9 billions . Dr. George Karlo, a supervisor of the US research project (US$ 28) considers that around 2010 there will be 500 thousand new incidents of brain and eye cancers because of using the cell -phones. According to BBC now such a cases are around 30 - 50 thousand per year. According the scientists the electromagnetic radiation of cell – phones is could be a reason of headache, high blood pressure, brain tumors, Alchimer disease etc. Unfortunately in more cases there is too long latent period and it is to late for prevention measures.

The VHF radiation decreases the quantity of antioxidants , which is very important for the human health. Take measures in order to increase your immunity.

The MTHR program was launched in February 2001 with an initial budget of £7.36 million funded by government and industry on a 50 : 50 basis. To date around 30 projects have been funded through MTHR with additional support from the Home Office, the Department of Trade and Industry, and industry. It presently has a budget of £8.8 million, all of which has now been allocated to the ongoing research program. The RF-related research in the UK is complementary to further research being carried out world-wide, much of it coordinated through the WHO EMF program.

The Board further recommends that government and industry should provide support for a continuation of the program.

The Board particularly supports the need for further research, in the following areas:

(a) an international cohort study of mobile phone users aimed at pooling and sharing experimental design, findings and expertise internationally,

(b) an expanded program of research on TETRA signals and biological effects,

(c) effects of RF exposure on children,

(d) investigation of public concerns about mobile phone technology,

(e) electromagnetic hypersensitivity and its possible impact on health, including well-being, associated with mobile phone technology,

(f) studies of RF effects on direct and established measures of human brain function and investigations of possible mechanisms involved,

(g) complementary dosimetry studies focused on ascertaining the exposure of people to RF fields.

A review of the evidence on mobile phones and brain cancer concludes that "a weight-of-evidence evaluation shows that the current evidence for a causal association between cancer and exposure to RF energy is weak and unconvincing." [25].

The Health Council of the Netherlands "sees no reason to recommend limiting the use of mobile phones by children." [26].

A French expert group previously concluded that there was "an absence of health effects due to waves emitted from base stations." Their 2004 update concludes that "More recent scientific data do not cause this conclusion to be called into question... " and that "the increased density of base stations in conglomerations does not increase the level of electromagnetic fields, rather the contrary." A review of the literature on "electromagnetic hypersensitivity" concludes that the symptoms "can be severe", but that the syndrome appears to be "unrelated to the presence of electromagnetic fields" [27].

Some practical advises in order to minimize the negative consequences:

1. Limit the time of calling as short as possible. Use it only for very important (emergency) cases. Even 2 minutes conversation is changing the normal brain's electrical activity.
2. The children must use GSM only when emergency. There skull is still forming, so it is too thick and more vulnerable – the radiation penetrates deeper.
3. Don't use the device when charging, because then the radiation is stronger.
4. Don't put the device on your ear before connection because when dialing the electromagnetic power is higher.
5. Use an external earpiece that keeps the phone away from the head.
6. Don't hang your GSM near to the heart , on your waist or into your pocket.
7. Don't use GSM in closed metallic area like a lift, car etc. because the radiation back to the body because of the electromagnetic reflection.
8. Avoid using GSM in areas where the signal is poor. A week signal from the base station causes modern handset to increase their broadcast power.
9. Use devices with a low level of SAR.

The balance of evidence to data suggests that exposures to RF radiation below ICNIRP guidelines do not cause adverse health effects to the general population.However the existing knowledge gaps and the prevailing scientific uncertainty justify a certain precautionary attitude regarding the use of handsets for mobile telephony. Due to the widespread use of mobile phones even a very small risk could have consequences for public health. This information should be addressed both to adults, young people and children.

16.10. Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)

In its resolution of 5 May 1994 [18] on combating the harmful effects of non-ionizing radiation , the European Parliament called on the Commission to propose legislative measures seeking to limit the exposure of workers and the public to non-ionizing electromagnetic radiation;

Community minimum requirements for the protection of health and safety of workers in relation to electromagnetic fields exist for work with display screen equipment.

Community measures were introduced to encourage improvements in the safety and health at work of pregnant workers and workers who have
recently given birth or are breastfeeding.

This oblige employers to assess activities which involve a specific risk of exposure to non-ionising radiation, to protect against established adverse health effects that may result as a consequence of exposure to electromagnetic fields.

Actions on limiting the exposure of the general public to electromagnetic fields should be balanced with the other health, safety and security benefits that devices emitting electromagnetic fields bring to the quality of life, in such areas as telecommunications, energy and public security.

The framework should be regularly reviewed and reassessed in the light of new knowledge and developments in technology and applications of sources and practices giving rise to exposure to electromagnetic fields.

Such basic restrictions and reference levels should apply to all radiations emitted by electromagnetic fields with the exception of optical radiation and ionising radiation. For optical radiation the relevant scientific data and advice still require further consideration, and for ionising radiation Community provisions already exist.

In order to assess compliance with the basic restrictions provided in this recommendation, the national and European bodies for standardisation (e.g. CENELEC, CEN) should be encouraged to develop standards within the framework of Community legislation for the purposes of the design and testing of equipment.

Interference problems with pacemakers may occur at levels below the recommended reference levels and should therefore be the object of appropriate precautions which, however, are not within the scope of this recommendation and are dealt with in the context of legislation on electromagnetic compatibility and medical devices.

In accordance with the principle of proportionality, this recommendation provides general principles and methods for the protection of members of the public while leaving it to the Member States to provide for detailed rules.

Member States may, in accordance with the Treaty, provide for a higher level of protection than that set out in this recommendation. In order to increase awareness of the risks of, and measures of protection against, electromagnetic fields, Member States should promote the dissemination of information and rules of practice in this field, in particular with regard to the design, installation and use of equipment, so as to aim at obtaining levels of exposure that do not exceed the recommended restrictions. The Member States should take note of progress made in scientific knowledge and technology with respect to non-ionizing radiation protection.

Definitions

For the purposes of this recommendation, the term electromagnetic fields (EMF) includes static fields, extremely low frequency (ELF) fields and radiofrequency (RF) fields, including microwaves, encompassing the frequency range of 0 Hz to 300 GHz.

A. Physical quantities

In the context of EMF exposure, eight physical quantities are commonly used:

Contact current (IC) between a person and an object is expressed in amperes (A). A conductive object in an electric field can be charged by the field.

Current density (J) is defined as the current flowing through a unit cross section perpendicular to its direction in a volume conductor such as the human body or part of it, expressed in amperes per square meter (A/m^2).

Electric field strength is a vector quantity (E) that corresponds to the force exerted on a charged particle regardless of its motion in space. It is expressed in volts per metre (V/m).

Magnetic field strength is a vector quantity (H), which, together with the magnetic flux density, specifies a magnetic field at any point in space. It is expressed in amperes per metre (A/m).

Magnetic flux density is a vector quantity (B), resulting in a force that acts on moving charges, it is expressed in teslas (T). In free space and in biological materials, magnetic flux density and magnetic field strength can be interchanged using the equivalence $1\ A/m = 4\pi.10^{-7}$ T.

Power density (S) is the appropriate quantity used for very high frequencies, where the depth of penetration in the body is low. It is the radiant power incident perpendicular to a surface, divided by the area of the surface and is expressed in watts per square meter (W/m^2).

Specific energy absorption (SA) is defined as the energy absorbed per unit mass of biological tissue, expressed in joules per kilogram (J/kg). In this recommendation it is used for limiting non-thermal effects from pulsed microwave radiation.
Specific energy absorption rate (SAR) averaged over the whole body or over parts of the body, is defined as the rate at which energy is absorbed per unit mass of body tissue and is expressed in watts per kilogram (W/kg). Whole body SAR is a widely accepted measure for relating adverse thermal effects to RF exposure. Besides the whole body average SAR, local SAR values are necessary to evaluate and limit excessive energy deposition in small parts of the body resulting from special exposure conditions. Examples of such conditions are: a grounded individual exposed to RF in the low MHz range and individuals exposed in the near field of an antenna.

Of these quantities, magnetic flux density, contact current, electric and magnetic field strengths and power density can be measured directly.

B. Basic restrictions and reference levels

These basic restrictions and reference levels for limiting exposure have been developed following a thorough review of all published scientific literature.

For the application of restrictions based on the assessment of possible health effects of electromagnetic fields, differentiation should be made between basic restrictions and reference levels.

Basic restrictions. Restrictions on exposure to time-varying electric, magnetic, and electromagnetic fields which are based directly on established health effects and biological considerations are termed 'basic restrictions'. Depending upon the frequency of the field, the physical quantities used to specify these restrictions are magnetic flux density (B), current density (J), specific energy absorption rate (SAR), and power density (S). Magnetic flux density and power density can be readily measured in exposed individuals.

Reference levels. These levels are provided for practical exposure-assessment purposes to determine whether the basic restrictions are likely to be exceeded. Some reference levels are derived from relevant basic restrictions using measurements and/or computational techniques and some reference levels address perception and adverse indirect effects of exposure to EMF's. The derived quantities are electric field strength (E), magnetic field strength (H), magnetic flux density (B), power density (S), and limb current (I_L). Quantities that address perception and other indirect effects are (contact) current (I_C) and, for pulsed fields, specific energy absorption (SA). In any particular exposure situation, measured or calculated values of any of these quantities can be compared with the appropriate reference level. Respect of the reference level will ensure respect of the relevant basic restriction.

If the measured value exceeds the reference level, it does not necessarily follow that the basic restriction will be exceeded. Under such circumstances, however, there is a need to establish whether there is respect of the basic restriction.

Quantitative restrictions on static electric fields are not given in this recommendation. However, it is recommended that annoying perception of surface electric charges and spark discharges causing stress or annoyance should be avoided.

Some quantities such as magnetic flux density (B) and power density (S) serve both as basic restrictions and reference levels, at certain frequencies.

Basic restrictions

Depending on frequency, the following physical quantities (dosimetric/exposimetric quantities) are used to specify the basic restrictions on electromagnetic fields:

— between 0 and 1 Hz basic restrictions are provided for magnetic flux density for static magnetic fields (0 Hz) and current density for time-varying fields up to 1 Hz, in order to prevent effects on the cardiovascular and central nervous system,

— between 1 Hz and 10 MHz basic restrictions are provided for current density to prevent effects on nervous system functions,

— between 100 kHz and 10 GHz basic restrictions on SAR are provided to prevent whole-body heat stress and excessive localized heating of tissues. In the range 100 kHz to 10 MHz, restrictions on both current density and SAR
are provided,
— between 10 GHz and 300 GHz basic restrictions on power density are provided to prevent heating in tissue at or near the body surface.

The basic restrictions, given in Table 1, are set so as to account for uncertainties related to individual sensitivities, environmental conditions, and for the fact that the age and health status of members of the public vary.

Table 1
Basic restrictions for electric, magnetic and electromagnetic fields
(0 Hz to 300 GHz)

Frequency range	Magnetic flux density (mT)	Current density (mA/m^2). rms	Whole body average SAR (W/kg)	Localised SAR (head and trunk) (W/kg)	Localised SAR (limbs) (W/kg)	Power density (W/m^2)
0 Hz	40	-	-	-	-	-
0–1 Hz	-	8	-	-	-	-
1–4 Hz	-	8/f	-	-	-	-
4–1000 Hz	-	2	-	-	-	-
1-100kHz	-	f/500	-	-	-	-
100kHz-10MHz	-	f/500	0,08	2	4	-
10MHz-10GHz	-	-	0,08	2	4	-
10-300GHz	-	-	-	-	-	10

Notes:
1. f is the frequency in Hz.
2. The basic restriction on the current density is intended to protect against acute exposure effects on central nervous system tissues in the head and trunk of the body and includes a safety factor. The basic restrictions for ELF fields are based on established adverse effects on the central nervous system. Such acute effects are essentially instantaneous and there is no scientific justification to modify the basic restrictions for exposure of short duration. However, since the basic restriction refers to adverse effects on the central nervous system, this basic restriction may permit higher current densities in body tissues other than the central nervous system under the same exposure conditions.
3. Because of electrical inhomogeneity of the body, current densities should be averaged over a cross section of 1 cm^2 perpendicular to the current direction.
4. For frequencies up to 100 kHz, peak current density values can be obtained by multiplying the rms value by $\sqrt{2}$ (=1,414). For pulses of duration t_p the equivalent frequency to apply in the basic restrictions should be calculated as $f = 1/(2t_p)$.
5. For frequencies up to 100 kHz and for pulsed magnetic fields, the maximum current density associated with the pulses can be calculated from the rise/fall times and the maximum rate of

change of magnetic flux density. The induced current density can then be compared with the appropriate basic restriction.
6. All SAR values are to be averaged over any six-minute period.
7. Localized SAR averaging mass is any 10g of contiguous tissue; the maximum SAR so obtained should be the value used for the estimation of exposure. These 10g of tissue are intended to be a mass of contiguous tissue with nearly homogeneous electrical properties. In specifying a contiguous mass of tissue, it is recognized that this concept can be used in computational dosimetry but may present difficulties for direct physical measurements. A simple geometry such as cubic tissue mass can be used provided that the calculated dosimetric quantities have conservative values relative to the exposure guidelines.
8. For pulses of duration tp the equivalent frequency to apply in the basic restrictions should be calculated as $f = 1/(2t_p)$.

Additionally, for pulsed exposures, in the frequency range 0,3 GHz to 10 GHz and for localized exposure of the head, in order to limit and avoid auditory effects caused by thermoelastic expansion, an additional basic restriction is recommended. This is that the SA should not exceed 2mJ/kg averaged over 10 g of tissue.

Reference levels

Reference levels of exposure are provided for the purpose of comparison with values of measured quantities. Respect of all recommended reference levels will ensure respect of basic restrictions.

If the quantities of measured values are greater than the reference levels, it does not necessarily follow that the basic restrictions have been exceeded. In this case, an assessment should be made as to whether exposure levels are below the basic restrictions.

The reference levels for limiting exposure are obtained from the basic restrictions for the condition of maximum coupling of the field to the exposed individual, thereby providing maximum protection. A summary of the reference levels is given in Tables . The reference levels are generally intended to be spatially averaged values over the dimension of the body of the exposed individual, but with the important proviso that the localized basic restrictions on exposure are not exceeded.

In certain situations where the exposure is highly localized, such as with hand-held telephones and the human head, the use of reference levels is not appropriate. In such cases respect of the localized basic restriction should be assessed directly.

Field levels
Table 2
Reference levels for electric, magnetic and electromagnetic fields
(0 Hz to 300 GHz, unperturbed rms values)

Frequency range	E –field strength (V/m)	H – field strength (A/m)	B – field (μT)	Equivalent wave power density S_{eq} (W/m^2)
0-1Hz	-	$3{,}2.10^4$	4.10^4	-
1-8Hz	10000	$3{,}2.10^4/f^2$	$4.10^4/f^2$	-
8-25Hz	10000	4000/f	5000/f	-
0,025-0,8kHz	250/f	4/f	5/f	-
0,8-3kHz	250/f	5	6,25	-
3-150kHz	87	5	6,25	-
0,15-1MHz	87	0,73/f	0,92/f	-
1-10MHz	$87/f^{1/2}$	0,73.f	0,92.f	-
10-400MHz	27	0,073	0,092	2
0,4-2GHz	$1{,}375.f^{1/2}$	$0{,}073.f^{1/2}$	$0{,}0046.f^{1/2}$	f/200
2-300GHz	61	0,16	0,20	10

Notes:
1. f as indicated in the frequency range column.
2. For frequencies between 100 kHz and 10 GHz, S_{eq}, E2, H2, and B2 are to be averaged over any six-minute period.
3. For frequencies exceeding 10 GHz, S_{eq}, E_2, H_2, and B_2 are to be averaged over any $68/f^{1,05}$ - minute period (f in GHz).
4. No E-field value is provided for frequencies < 1 Hz, which are effectively static electric fields. For most people the annoying perception of surface electric charges will not occur at field strengths less than 25 kV/m. Spark discharges causing stress or annoyance should be avoided.

Note:

No higher reference levels on exposure to ELF fields are provided when exposures are of short duration. In many cases, where the measured values exceed the reference level, it does not necessarily follow that the basic restriction will be exceeded. Provided that adverse health impacts of indirect effects of exposure (such as microshocks) can be avoided, it is recognized that the general-public reference levels can be exceeded provided that the basic restriction on the current density is not surpassed. In many practical exposure situations external ELF fields at the reference levels will induce current densities in central nervous-system tissues that are below the basic restrictions. Also it is recognized that a number of common devices emit localized fields in excess of the reference levels. However, this generally occurs under conditions of exposure where the basic restrictions are not exceeded because of weak coupling between the field and the body.

For peak values, the following reference levels apply to the E-field strength (V/m), H-field strength (A/m) and the B-field (μT):

— for frequencies up to 100 kHz, peak reference values are obtained by multiplying the corresponding rms values by $\sqrt{2}$ (=1,414). For pulses of duration t_p the equivalent frequency to apply should be calculated as $f = 1/(2t_p)$,

— for frequencies between 100 kHz and 10 MHz peak reference values are obtained by multiplying the corresponding rms values by 10^{α},

where

$\alpha = (0{,}665 \log(f/105) + 0{,}176)$, f in Hz,

— for frequencies between 10 MHz and 300 GHz peak reference values are obtained by multiplying the corresponding rms values by 32.

Note:

Generally, with regard to pulsed and/or transient fields at low requencies, there are frequency-dependent basic restrictions and reference levels from which a hazard assessment and exposure guidelines on pulsed and/or transient sources can be derived. A conservative approach involves representing a pulsed or transient EMF signal as a Fourier spectrum of its components in each frequency range, which can then be compared with the reference levels for those frequencies. The summation formulae for simultaneous exposure to multiple frequency fields can also be applied for the purposes of determining compliance with the basic restrictions.

Although little information is available on the relation between biological effects and peak values of pulsed fields, it is suggested that, for frequencies exceeding 10 MHz, S_{eq} as averaged over the pulse width should not exceed 1000 times the reference levels or that field strengths should not exceed
32 times the fields strength reference levels. For frequencies between about 0,3 GHz and several GHz and for localized exposure of the head, in order to limit or avoid auditory effects caused by thermoelastic expansion, the specific absorption from pulses must be limited. In this frequency range, the threshold SA of 4-16 mJ kg^{-1} for producing this effect corresponds, for 30–µ.s pulses, to peak SAR values of 130-520 W kg^{-1} in the brain. Between 100 kHz and 10 MHz, peak values for the fields strengths are obtained by interpolation from the 1,5-fold peak at 100 kHz to the 32-fold peak at 10 MHz.

Contact currents and limb currents

For frequencies up to 110 MHz additional reference levels are recommended in order to avoid hazards due to contact currents. The contact current reference levels are presented in Table 3. The reference levels on contact current were set to account for the fact that the threshold contact currents that elicit biological responses in adult women and children are
approximately two-thirds and one-half, respectively, of those for adult men.

Table 3
Reference levels for contact currents from conductive objects (f in kHz)

Frequency range	Max contact current (mA)
0Hz – 2,5kHz	0,5
2,5kHz – 100kHz	0,2.f
100kHz – 110MHz	20

For the frequency range 10 MHz to 110 MHz, a reference level of 45 mA in terms of current through any limb is recommended. This is intended to limit the localised SAR over any six-minute period.

Exposure from sources with multiple frequencies

In situations where simultaneous exposure to fields of different frequencies occurs, the possibility that these exposures will be additive in their effects must be considered.

Calculations based on such additivity should be performed separately for each effect; thus separate evaluations should be made for thermal and electrical stimulation effects on the body.

Basic restrictions

In the case of simultaneous exposure to fields of different frequencies, the following criteria should be satisfied in terms of the basic restrictions.

For electric stimulation, relevant for frequencies from 1 Hz up to 10 MHz, the induced current densities should be added according to:

$$\sum_{i=1Hz}^{10MHz} \frac{J_i}{J_{L,i}} \leq 1$$

For thermal effects, relevant from 100 kHz, specific energy absorption rates and power densities should be added according to:

$$\sum_{i=100kHz}^{10GHz} \frac{SAR_i}{SAR_L} + \sum_{i>10GHz}^{300GHz} \frac{S_i}{S_L} \leq 1$$

where

J_i is the current density at frequency i,

$J_{L,i}$ is the current density basic restriction at frequency i as given in Table 1,

SAR_i is the SAR caused by exposure at frequency i,

SAR_L is the SAR basic restriction given in Table 1,

S_i is the power density at frequency i,

S_L is the power density basic restriction given in Table 1.

Reference levels

For application of the basic restrictions, the following criteria regarding reference levels of field strengths should be applied.

For induced current densities and electrical stimulation effects, relevant up to 10 MHz, the following two requirements should be applied to the field levels:

$$\sum_{i=1Hz}^{1MHz} \frac{SAR_i}{SAR_{L,i}} + \sum_{i>1MHz}^{10MHz} \frac{E_i}{a} \leq 1$$

and

$$\sum_{j=1Hz}^{150kHz} \frac{H_i}{H_{L,i}} + \sum_{j>150kHz}^{10MHz} \frac{H_j}{b} \leq 1$$

where

E_i is the electric field strength at frequency i;

E_L, i is the electric field strength reference level from Table 2;

H_j is the magnetic field strength at frequency j;

H_L, j is the magnetic field strength reference level from Table 2;

a is 87 V/m and **b** is 5 A/m (6,25 μT).

Compared to the ICNIRP (International Commission on Non-Jonising Radiation Protection) guidelines [28] which deal with both occupational and general public exposure, cut off points in the summations correspond to exposure conditions for members of the public.

The use of the constant values (a and b) above 1 MHz for the electric field and above 150 kHz for the magnetic field is due to the fact that the summation is based on induced current densities,

and should not be mixed with thermal effect circumstances. The latter forms the basic for $E_{L,i}$ and H_L, j above 1 MHz and 150 kHz respectively, found in Table 2.

For thermal effect circumstances, relevant from 100 kHz, the following two requirements should be applied to the field levels:

$$\sum_{i-100kHz}^{1MHz}\left(\frac{H_i}{c}\right)^2+\sum_{i>150kHz}^{300GHz}\left(\frac{E_i}{E_{L,i}}\right)^2\le 1$$

$$\sum_{j=100kHz}^{150kHz}\left(\frac{H_i}{d}\right)^2+\sum_{j>150kHz}^{300GHz}\left(\frac{H_j}{H_{L,j}}\right)^2\le 1$$

and where
E_i is the electric field strengthen at frequency i;
E_L, i is the electric field reference level from Table 2;
H_j is the magnetic field strength at frequency j;
H_L, j is the magnetic field reference level derived from Table 2;
c is $87/f^{1/2}$ V/m and d 0,73/f A/m.

Again, compared to the ICNIRP guidelines [28] some cut-off points have been adjusted for public exposure only.

For limb current and contact current, respectively, the following requirements should be applied:

$$\sum_{k=10MHz}^{110MHz}\left(\frac{I_k}{I_{L,k}}\right)^2\le 1$$

$$\sum_{n>1}^{110MHz}\left(\frac{I_n}{I_{C,n}}\right)^2\le 1$$

where
l_k is the limb current component at frequency k,
$I_{L,k}$ is the reference level for limb current, 45 mA,
l_n is the contact current component at frequency n,
$I_{C,n}$ is the reference level for contact current at frequency (see Table 3).

The above summation formulae assume worst-case phase conditions among the fields from the multiple sources. As a result, typical exposure situations may in practice result in less restrictive exposure levels than indicated by the above formulae for the reference levels.

16.11. Automotive EMC Directive 95/54/EC

A vehicle and its electrical/electronic systems shall be so designed, constructed and fitted as to enable the vehicle, in normal conditions of use, to comply with the requirements of this Directive [14].

The Directive covers:

— requirements regarding the immunity to radiated and conducted disturbances for functions related to direct control of the vehicle, related to driver, passenger and other road users' protection and related to disturbances, which would cause confusion to the driver or other road users,

— requirements regarding the control of unwanted radiated and conducted emissions to protect the intended use of electrical or electronic equipment at own or adjacent vehicles or nearby, and the control of disturbances from accessories that may be retrofitted to the vehicle.

Immunity-related functions are:

(a) functions related to the direct control of the vehicle:

— by degradation or change in engine, gear, brake, suspension, active steering, speed limitation devices, for example,

— by affecting driver's position, e.g. seat or steering wheel positioning,

— by affecting driver's visibility: e.g. dipped beam, windscreen wiper,

(b) functions related to driver, passenger and other road-user protection:

— e.g. airbag and safety restraint systems,

(c) functions which, when disturbed, cause confusion to the driver or other road users:

— optical disturbances: incorrect operation of e.g. direction indicators, stop lamps, end outline marker lamps, rear position lamp, light bars for emergency system, wrong information from warning indicators,

— acoustical disturbances: incorrect operation of anti-theft alarm, horn, for example,

(d) functions related to vehicle data bus functionality:

— by blocking data transmission on vehicle data bus-systems, which are used to transmit data, required to ensure the correct functioning of other immunity-related functions,

(e) functions which, when disturbed, affect vehicle statutory data: e.g. tachograph, odometer.

A vehicle and its electrical/electronic systems shall be so designed, constructed and fitted as to enable the vehicle, in normal conditions of use, to comply with the requirements of this Directive.

A representative vehicle shall be selected from this schedule for the purpose of being tested, in mutual agreement between the manufacturer and the competent authority. This vehicle shall represent the vehicle type. The choice of vehicle shall be based on the electrical/electronic systems offered by the manufacturer.

The vehicle manufacturer must provide a statement of frequency bands, power levels, antenna positions and installation provisions for the installation of RF-transmitters, even if the vehicle is not equipped with RF transmitter at time of type-approval. This should cover all mobile radio services normally used in vehicles.

A vehicle shall be tested for radiated emissions and for immunity to radiated disturbances. No tests for conducted emissions or immunity to conducted disturbances are required for vehicle type-approval.

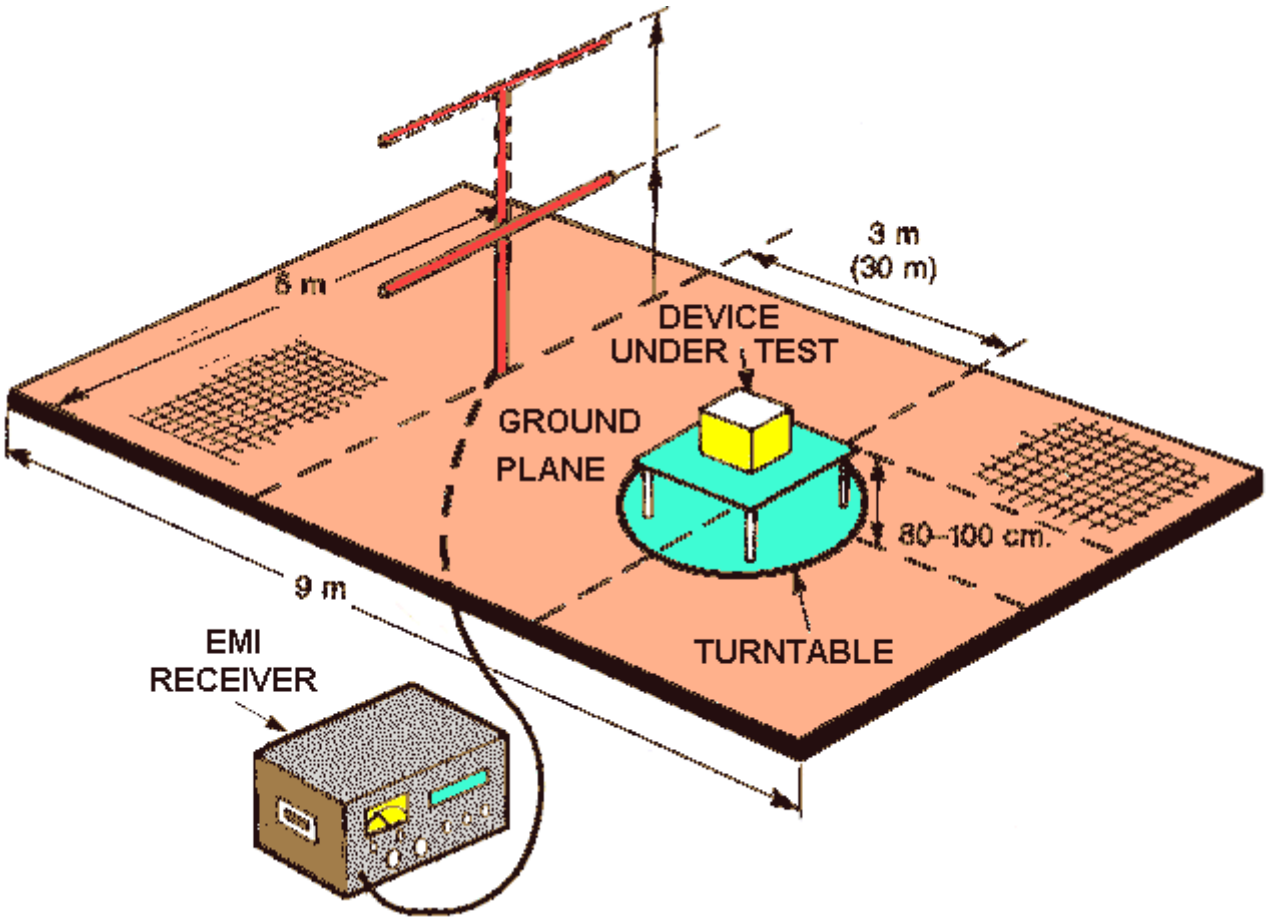
Before testing, the technical service has to prepare a test plan in conjunction with the manufacturer, which contains at least mode of operation, stimulated functions, monitored functions, pass/fail criterias and intended emissions.

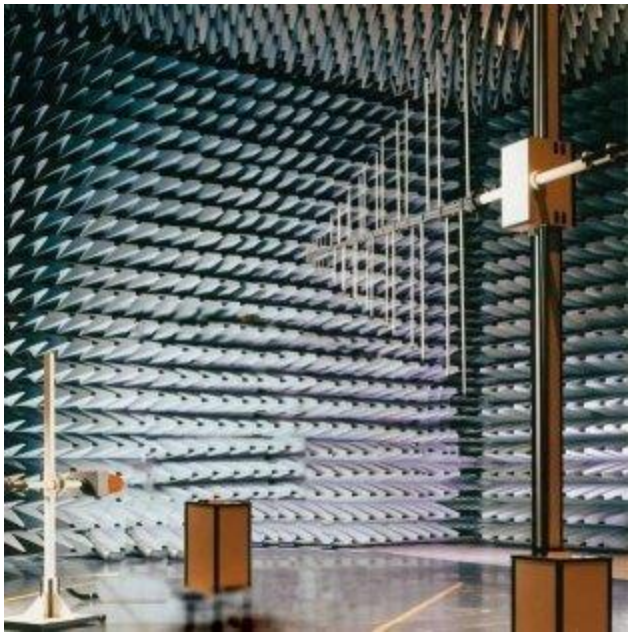
The method of measurement shall be defined by the vehicle manufacturer in accordance with the technical service.

Method of measurement of radiated broadband electromagnetic emissions from vehicles

This test is intended to measure the broadband emissions generated by electrical or electronic systems fitted to the vehicle (e.g. ignition system or electric motors).

The limits apply throughout the frequency range 30 MHz to 1 000 MHz for measurements performed in a **semi anechoic chamber** or an outdoor test site.


3 m
(30 m)
DEVICE
UNDER TEST
GROUND
PLANE
80–100 cm.
9 m
EMI
RECEIVER
TURNTABLE



The technical service shall perform the test at the intervals specified in the CISPR 12 standard throughout the frequency range 30 to 1 000 MHz.

Alternatively, if the manufacturer provides measurement data for the whole frequency band from a test laboratory accredited to the applicable parts of ISO 17025 and recognized by the Approval Authority, the technical service may divide the frequency range in 14 frequency bands 30-34, 34-45, 45-60, 60-80, 80-100, 100-130, 130-170, 170-225, 225-300, 300-400, 400-525, 525-700, 700-850, 850-1 000 MHz and perform tests at the 14 frequencies giving the highest emission levels within each band to confirm that the vehicle meets the requirements.

ISO – International Organization for Standardization

CISPR – International Special Committee on Radio Interference

The maximum of the readings relative to the limit (horizontal and vertical polarisation and antenna location on the left and right-hand sides of the vehicle) in each of the 14 frequency bands shall be taken as the characteristic reading at the frequency at which the measurements were made.

Method of testing for Immunity of Vehicles to Electromagnetic Radiation

This test is intended to demonstrate the immunity of the vehicle electronic systems. The test may be alternatively performed in an outdoor test site for all vehicles. The engine shall normally turn the driving wheels at a steady speed of 50 km/h if there is no technical reason due to the vehicle to define a different condition. The vehicle shall be on an appropriately loaded dynamometer.

The vehicle shall be exposed to electromagnetic radiation in the 20 to 2 000 MHz frequency ranges in vertical polarization.

16.12. EMC in Medical Devices

Electromagnetic compatibility (EMC) and electrical safety assessments are mandatory for all sorts of equipment in almost every country around the globe. This, of course, does not exclude medical equipment. On the contrary, meeting the even stricter requirements spelled out in the applicable standards is crucial to survive today's tough market environment. Increased processor speeds, faster data access, and accelerated examination processes all contribute to more sensitive devices which might fail under electromagnetic stress.

Quite a few cases of faulty devices have been made public, including implantable cardiac pacemakers that fail because of interference produced by the equipment surrounding the patient. These devices malfunction as a result of exposure to intentional transmitters like cell phones and other wireless devices. And these are not the only delicate systems that have shown susceptibility. Every medical device, whether used in a home, doctor's office or hospital, could potentially disturb equipment in its proximity or could be subject to dangerously omnipresent disturbances.

Applicable Standards

With few exceptions, most countries follow the guidelines given in the IEC standard EN 60601-1-1 (Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems). This standard refers to the EN 60601-1-2 (Medical electrical equipment — Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests) as the regulatory document for EMC matters.

Although it appears to be a European standard, its international acceptance goes beyond the borders of the European Union (partly using the IEC version, IEC 60601-1-2, of the standard). The FDA states the following: "This standard should serve as a baseline for all of the appropriate device areas. However, where there are existing CDRH guidance documents with additional EMC specifications then these will supersede the basic IEC requirements."

Radiated and Conducted Emissions Requirements

Most medical devices are required to be in compliance with CISPR 11 (emissions limits for industrial, scientific, and medical equipment). Simpler medical equipment that includes no clock frequencies at or greater than 9 kHz may also be tested under CISPR 14 (emissions limits for household appliances and tools). Information technology (IT) equipment that is either intended to be connected to the medical device or is part of a system may be classified and tested to CISPR 22.

With CISPR 11 and 22, it needs to be determined which class the equipment falls under: Class A for industrial environments (such as industrial buildings) with higher limits; or Class B for domestic use with more stringent requirements. Keep in mind that hospitals are often considered residential environments. Several other standards may apply to the product depending on its intended use. The correct usage of them should be evaluated by an accredited test lab or certification body.

Generally, emission testing will be conducted in semi-anechoic chambers or at open area test sites (OATS). The amount of time needed for emission testing greatly varies depending on how close the signals come to the limit line and at how many frequencies the equipment actually fails the specification. Test times from 4-6 hours are a good average. At OATS facilities, the test time is additionally increased by the influence of ambient noises that can be found everywhere in our environment. The operator needs to identify those and include them in his consideration and evaluation of the results. Average test times range from 4-10 hours.

In addition to the radiated emission verification, manufacturers must undergo conducted emission testing. This testing is applied to the main power leads of the systems using a LISN (line impedance stabilization network). This coupling device filters all ambient noise from the power supply network and enables the tester to obtain exact readings from the equipment undergoing testing.

Two other documents are categorised ‘emission’ standards. The EN 61000-3-2 (Part 3-2: Limits - Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)) and EN 61000-3-3 (Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current $\leq$ 16 A per phase and not subject to conditional connection). Switching power supplies can produce harmonic distortion on the mains.

Designers should make sure that power factor correction is used and that the power supply which will be used in the system fulfills the requirements.

The table is a reference guide for the applicable emission standards.

Guidance and manufacturer's declaration – electromagnetic emission (IEC 60601-1-2)		
The equipment or system is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such a environment		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The equipment or system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Group 2	The equipment or system must emit EM energy in order to perform its intended function. Nearby electronic equipment may be affected
RF emissions CISPR 11	Class A and B	The equipment or system is suitable in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A, B, C, D or not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies or not applicable	
RF emissions CISPR 14-1	Complies	The equipment is not suitable for interconnection with other equipment
RF emissions CISPR 15	Complies	The equipment is not suitable for interconnection with other equipment

Immunity Requirements

Electrostatic Discharge (ESD)

IEC 61000-4-2 is the generic standard which is called out for ESD testing in IEC 60601-1-2:2001. The testing concerns the sensitivity of the device being tested against several different kinds of discharges, namely air and contact discharge. It is therefore important to clearly identify and document the test points in case the need arises to reproduce the testing. Usually, all user accessible areas of the device are subject to test. IEC 61000-4- 2 defines the test levels in relation to different applications and provides test procedures. These requirements are rather new as the IEC 60601- 1-2:2001 just recently came into effect. Compared with older products that were tested some time ago, the new designs will likely need greater insulation thickness, creep age and clearance distances as well as further measures to comply with the requirement.

Radiated RF Immunity

For this aspect, the medical standard calls for IEC 61000-4-3. The equipment under test (EUT) is exposed to radiated emission in several frequency ranges. Under this influence, the device is still expected to work properly and failures are only allowed to very strict tolerances. For the limits and the applicable tests, the standard distinguishes between life-supporting and non-life supporting medical electrical equipment (guidelines can be found in the tables below).

Generally, the EUT will be exposed to the radiation from different sides in order to make sure that the orientation does not have an influence to the susceptibility.

Electrical Fast Transients (EFT)

IEC 61000-4-4 describes the testing and the applicable levels for EFT for medical devices. An EFT happens anytime a discharge occurs. For instance, this could happen when a load is being switched off. As the switch opens, arcing occurs between the contacts jumping up from low voltage and high frequency to higher voltage and lower frequency in the final phase of the opening. Those transients couple into power cables and other unprotected circuits in their close proximity.

Surge Immunity

IEC 61000-4-5 concerns the surge immunity. Surges can occur on the AC power mains again as a result of switching operations in the power grid (as opposed to the EFT) and from nearby lightning strikes. Naturally, these pulses can be coupled into the signal lines as well. However, this mostly happens when we find long cables attached to the I/O ports of the systems.

Conducted RF Immunity

This test is again categorized in life supporting equipment, non life supporting equipment, shielded-location-use equipment, intentional transmitters and battery-powered equipment. The manufacturer needs to choose the appropriate classification and can, of course, seek advice at test houses or certification bodies. Radio frequency fields are coupled into all ports of the equipment under test. The systems must show, as in all the prior mentioned tests, a well defined immunity against the disturbance. IEC 61000-4-6 is the standard to follow as mandated by IEC 60601-1-2.

Magnetic Field Immunity

IEC 61000-4-8 is to determine whether or not magnetic fields affect the device under test. Equipment rated for both 50 and 60 Hz is subjected to field strengths of 3 A/m at 50 Hz and again at 60 Hz. In some cases, this test step can be waived if the system does not contain any parts which are susceptible to magnetic fields. Sensitive components could be hall-effect sensors or bimetal switches. Keep in mind that today's medical technology often uses high power magnetic fields. Hence, it is recommended to increase the levels which are dictated by the standard.

Voltage Dips, Interruptions and Variations

Standard IEC 61000-4-11 requires immunity against voltage dips, short interruptions and voltage variations in low-voltage power supply networks. The requirement applies to equipment and systems that have an input power rating of up to 1000 VA or an input current of maximal 16 A. As before, the devices need to function within given performance criteria at different levels of testing.

Guidance and manufacturer's declaration – electromagnetic immunity		
The equipment or system is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such a environment		
Immunity test	**IEC 60601**	**Electromagnetic environment**
Electrostatic Discharge (ESD) IEC 610000-4-2	± 6 kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity (RH) should be at least 30 %
Electrical transient/burst IEC 610000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 610000-4-5	± 1 kV difference mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines	< 5% U_T (> 95% dip inU_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of typical commercial or hospital environment. If the user of the equipment or system required continued operation during power mains interruption, if is recommended that the equipment or system be powered from an uninterruptible power supply (UPS) or a battery.
Power frequency magnetic field IEC 61000-4-8	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage to application of the test level		

Guidance for manufacturer's declaration – electromagnetic immunity – for supporting equipment or system (IEC 60601 – 1 – 2)			
The equipment or system is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such a environment			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 10 V_{rms} 150 kHz to 80 MHz 10 V/m 80 MHz to 2,5 GHz	V_1, V V_2, V E_2, V/m	Portable and mobile RF communications equipment should be used no closer to any part of the equipment or system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. *Recommended separation distance* $d = \frac{3,5}{V_1}\sqrt{P}$ $d = \frac{12}{V_2}\sqrt{P}$ $d = \frac{12}{E_1}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{23}{E_1}\sqrt{P}$ 800 MHz to 2,5 GHz Where **P** is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and **d** is recommended separation distance in meters. Field strength from fixed RF transmitters, as should be less than the compliance level in each frequency range
Note 1: At 80 MHz and 800 MHz the high frequency range applies. Note 2: These guidelines may not apply all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

- The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are
  6,765 MHz to 6,795 MHz;
  13,553 MHz to 13,567 MHz;
  26,957 MHz to 27,283 MHz and
  40,66 MHz to 40,70 MHz.
- The compliance levels in the ISM frequency band between 150kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patients areas. For this reason , an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency range.
- Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment or system should be occurred to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting .
- Over the frequency range 150 kHz to 80 MHz, field strength should be less than V_1.

Achieving Compliance

Choosing the right test plan is important and can represent a challenge for all involved parties. A number of factors have to be taken into account before one can even start thinking about testing for compliance. For example:

- Is the system patient connected or not?
- Is the system stationary or portable?
- Will it be used in shielded rooms?
- What are the numbers and type of interfaces and cables?
- What are the processor speeds and clock frequencies?
- In what environment will the system be used?
- What countries will the system be sold in?

From the beginning of every project, the designer should seek to use already tested components as there are power supplies, filters and other assemblies that must automatically used. These can make things much easier when the final evaluation comes to the table. However, keep in mind that the assumption "compliant + compliant = compliant" is not necessarily true. Every system needs to be evaluated in its final setup, and unforeseen problems might occur due to cabling, enclosure modifications and the interaction of all components.

16.13. R&TTE Directive 99/5/EC

On April 7, 1999, the European Commission published a Directive [15] in the *Official Journal of the European Communities* that will have a significant impact on the marketing of telecommunications equipment in Europe.

In principle, the directive covers all radio equipment (RE) and TTE, but exceptions are provided for equipment used exclusively for activities concerning public security, defense, state security, and the activities of the state in the area of criminal law. Also excluded are the following:

- Radio equipment and subparts used by radio amateurs, unless the equipment is available commercially.
- Equipment falling within the scope of Marine Equipment Directive 96/98/EC [33].
- Cabling and wiring.
- Receive-only radio equipment.
- Products, appliances, and components used in the field of civil aviation.
- Air traffic management equipment and systems.

The directive defines *radio equipment* as a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilizing the spectrum allocated to terrestrial and/or space radio communication.

Telecommunications terminal equipment is defined as a product enabling communication, or a relevant component thereof, which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks.

The Essential Requirements

The R&TTE Directive [15] is a so-called New Approach directive, which means, among other things, that it defines essential requirements that are applicable to all apparatus falling within its scope and that establish the legal basis for compliance. The three general essential requirements that are applicable to all apparatus under the R&TTE Directive are :

1. The protection of the health and safety of the user and any other person, including the objectives with respect to safety requirements contained in Low Voltage Directive 73/23/EEC, but without that directive's voltage limit of 50–1500 V.
2. The protection requirements with respect to electromagnetic compatibility (EMC) contained in EMC Directive 2004/108/EC.

3. The requirement that radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial and/or space radio communication and orbital resources so as to avoid harmful interference.

Thus, the Low Voltage Directive and the EMC Directive, which are horizontal directives, are *no longer applicable* for equipment falling under the R&TTE Directive.

Harmonised standards

It would be highly impractical and may even be impossible to design and verify products directly against these highly abstract requirements. To overcome this problem, specific standards are developed by ETSI, the European Committee for Standardization (CEN), and the European Committee for Electrotechnical Standardization (CENELEC). Once adopted and published in the *Official Journal of the European Communities*, these technical standards gain the status of harmonized standards. Then, if the relevant harmonized standards are met, products are considered in compliance with the essential requirements of the directive.

Conformity Assessment Procedures

In order to prove a product is in compliance with the provisions of the R&TTE Directive, the manufacturer must follow a conformity assessment procedure.

Module A (Internal Production Control)

This procedure is only applicable to telecommunications terminal equipment. Under this module the manufacturer must verify the product's compliance with the provisions of the directive. The way in which such verification is carried out is not prescribed; however, the manufacturer is directed to take all necessary measures to ensure the equipment is in compliance. The manufacturer must draw up a written declaration of conformity and must affix the appropriate CE mark to each product.

Module Aa (Internal Production Control Plus Specific Tests)

Applicable to radio equipment that meets the requirements of harmonized standards, Module Aa consists of Module A supplemented by the following requirements:

- For each radio type a certain set of essential radio tests must be carried out by, or on behalf of, the manufacturer.
- The manufacturer must declare that all selected tests have been carried out and that compliance is established.
- The manufacturer must affix the notified body's number together with the CE mark on the product.

Module H (Full Quality Assurance)

Module H is applicable to both RE and TTE and is based on international standard ISO 9001 requirements. Under this module, the manufacturer must have a quality system that covers design and verification, manufacture, and final inspection and testing. The quality system must be approved by a notified body. The manufacturer must draw up a written declaration of conformity and must affix the appropriate CE mark to each product unit.

The procedure known as a *technical construction file* can be used for RE or TTE. The manufacturer presents a technical construction file to a Notified Body. This file should consist of the technical documentation. In addition, for radio equipment the file must contain the results of the essential radio test suite agreed previously with the Notified Body.

Are antennas covered by the Directive?

Antennas may be subdivided into *active* and *passive* types. In this categorisation, an "active" antenna is one that, as supplied, includes one or more electronic components interacting with the signal. All other antennas are in principle considered "passive", irrespective of gain or directional properties.

Active antennas are relevant components of the RTTE Directive, and thus are subject to the full requirements of the Directive if placed on the market as a single commercial unit for distribution or final use.

Passive antennas are not considered as relevant components of the RTTE Directive, and thus fall outside the scope of the RTTE Directive if placed on the market as a single commercial unit for distribution or final use. Passive antennas, if they are marketed in conjunction with a radio product, will be subject to all the requirements of the Directive as part of the overall radio product.

Manufacturers who place on the market radio products without an antenna or with an antenna which is intended to allow replacement have a responsibility to provide information on the general types and characteristics of antennas that may be used with their equipment in order that the overall radio equipment will remain compliant.

6.14. Directive 96/98/EC on marine equipment

Shipping accidents are a matter of serious concern to the Community, in particular those that cause loss of human life and pollution of the Member States' seas and coastlines. The risk of shipping accidents can be effectively reduced by means of common standards that ensure high safety levels in the performance of the equipment carried on board ships. The framework of the common transport policy further measures must be adopted to ensure safety in maritime transport.

The purpose of this Directive shall be to enhance safety at sea and the prevention of marine pollution through the uniform application of the relevant international instruments relating to the equipment to be placed on board ships for which safety certificates are issued by or on behalf of Member States pursuant to international conventions and to ensure the free movement of such equipment within the Community.

Council Directive is the appropriate legal instrument as it provides a framework for uniform and compulsory application of the international testing standards by Member States.

International conventions require flag States to ensure that the equipment carried on board ships complies with certain safety requirements and to issue the relevant certificates.

Common rules must be laid down to eliminate differences in the implementation of international standards.

'Testing standards` shall mean the standards set by
- the International Maritime Organization (IMO),
- the International Organization for Standardization (ISO),
- the International Electrotechnical Commission (IEC),
- the European Committee for Standardization (CEN),
- the European Committee for Electrotechnical Standardization (Cenelec)

and
- the European Telecommunication Standards Institute (ETSI).

In the case of radiocommunication equipment, the flag State administration shall require that such equipment does not unduly affect the requirements of the radio-frequency spectrum.

In the case of a new ship which, irrespective of its flag, is not registered in a Member State but is to be transferred to the register of a Member State, such a ship shall, on transfer, be subject to inspection by the receiving Member State to verify that the actual condition of its equipment corresponds to its safety certificates and either complies with this Directive and bears the mark or is equivalent, to the satisfaction of that Member State's administration, to equipment type-approval in accordance with this Directive.

In the case of a new ship which, irrespective of its flag, is not registered in a Member State but is to be transferred to the register of a Member State, such a ship shall, on transfer, be subject to inspection by the receiving Member State to verify that the actual condition of its equipment corresponds to its safety certificates and either complies with this Directive and bears the mark or is equivalent, to the satisfaction of that Member State's administration, to equipment type-approval in accordance with this Directive.

In the case of radiocommunication equipment, the flag State administration shall require that such equipment does not unduly affect the requirements of the radio-frequency spectrum.

The conformity-assessment procedure shall be:

(i) EC type-examination (module B) and, before equipment is placed on the market and according to the choice made by the manufacturer or his authorized representative established within the, all equipment shall be subject to:

(a) the EC declaration of conformity to type (module C),

(b) the EC declaration of conformity to type (production-quality assurance) (module D),

(c) the EC declaration of conformity to type (product-quality assurance) (module E),

(d) the EC declaration of conformity to type (product verification) (module F); or

(ii) EC full-quality assurance (module H).

Where sets of equipment are produced individually or in small quantities and not in series or in mass, the conformity-assessment procedure may be the EC unit verification (module G).

Modules for conformity assessment

EC TYPE-EXAMINATION (MODULE B)

A notified body must ascertain and attest that a specimen, representative of the production envisaged, complies with the provisions of the international instruments that apply to it.

The application for the EC type-examination must be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well,
- a written declaration that the same application has not been lodged simultaneously with any other notified body,
- the technical documentation.

The applicant must place at the disposal of the notified body a specimen, representative of the production. The notified body may request further specimens if needed for the test program.

The technical documentation must make it possible to assess the product's compliance with the requirements of the relevant international instruments. It must, as far as is relevant for such assessment, cover the design, the building standard, manufacture, installation and functioning of the product.

The notified body must:

- examine the technical documentation and verify that the type has been manufactured in accordance with the technical documentation,
- perform the appropriate examinations and necessary tests or have them performed to check whether the requirements of the relevant international instruments have actually been met,
- agree with the applicant the location where the examinations and necessary tests will be carried out.

Where the type meets the provisions of the relevant international instruments, the notified body must issue an EC type-examination certificate to the applicant. The certificate must give the name and address of the manufacturer, details of the equipment, the conclusions of the examination, the conditions of its validity and the necessary data for identification of the approved type.

If a manufacturer is refused a type-certification, the notified body must give detailed reasons for that refusal.

The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved product, which must receive additional approval where such changes may affect compliance with the requirements or the prescribed conditions for use of the product. Such additional approval must be given in the form of an addition to the original EC type-examination certificate.

The manufacturer or his authorized representative established within the Community must keep with the technical documentation copies of EC type-examination certificates and their additions for at least 10 years after the last product has been manufactured.

CONFORMITY TO TYPE (MODULE C)

A manufacturer or his authorized representative established within the Community must ensure and declare that the products concerned conform to type as described in the EC type-examination certificate and satisfy the requirements of the international instruments that apply to them. The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity.

PRODUCTION-QUALITY ASSURANCE (MODULE D)

The manufacturer must operate an approved quality system for production, final-product inspection and testing.

Quality system

The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice for the products concerned.

The application must include:

- all relevant information for the product category envisaged,
- the documentation concerning the quality system,
- the technical documentation of the approved type and a copy of the EC type-examination certificate.

The quality system must ensure that the products conform to type as described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality-system documentation must permit a consistent interpretation of the quality programs, plan, manuals and records.

It must, in particular, include an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the manufacturing, quality-control and quality-assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

The notified body must assess the quality system to determine whether it satisfies the requirements.

The manufacturer must be notified of the decision. The notification must include the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the notified body.

The purpose of surveillance is to make sure that the manufacturer duly fulfills the obligations arising out of the approved quality system.

The manufacturer must allow the notified body access for inspection purposes to the locations of manufacture, inspection and testing and storage and must provide it with all necessary information, in particular:

- the quality-system documentation,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

PRODUCT-QUALITY ASSURANCE (MODULE E)

Under the quality system, each product must be examined and appropriate tests must be carried out in order to ensure its compliance with the relevant requirements of the international instruments.

The notified body must assess the quality system to determine whether it satisfies the requirements.

Surveillance under the responsibility of the notified body.

The manufacturer must allow the notified body access for inspection purposes to the locations of inspection, testing and storage and must provide it with all necessary information, in particular:

- the quality-system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

In addition, the notified body may pay unannounced visits to the manufacturer.

PRODUCT VERIFICATION (MODULE F)

A manufacturer or his authorized representative established within the Community must check and attest that the products conform to the type as described in the EC type-examination certificate.

The notified body must carry out the appropriate examinations and tests in order to check that the product complies with the requirements of the international instruments either by examination and testing of every product.

Verification by examination and testing of every product.

All products must be individually examined and appropriate tests must be carried out in order to verify their conformity to type as described in the EC type-examination certificate.

Statistical verification

The manufacturer must present his products in the form of homogeneous lots and must take all measures necessary to ensure that the manufacturing process ensures the homogeneity of each lot produced.

A random sample must be drawn from each lot. Products in a sample must be individually examined and appropriate tests must be carried out to ensure that they comply with the requirements of the international instruments which apply to them and to determine whether the lot is to be accepted or rejected.

If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent that lot's being put on the market.

UNIT VERIFICATION (MODULE G)

The notified body must examine the individual product and carry out appropriate tests to ensure that it complies with the relevant requirements of the international instruments.

The aim of the technical documentation is to enable compliance with the requirements of the international instruments to be assessed and the design, manufacture and operation of the product to be understood.

FULL-QUALITY ASSURANCE (MODULE H)

It must, in particular, include an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the technical design specifications, including standards, that will be applied and the assurance that the essential requirements of the international instruments that apply to the products will be met,
- the design-control and design-verification techniques, processes and systematic actions that will be used in the design of the products pertaining to the product category covered,
- the corresponding manufacturing, quality-control and quality-assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

The notified body must assess the quality system to determine whether it satisfies the requirements.

EC surveillance under the responsibility of the notified body

The manufacturer must allow the notified body access for inspection purposes to the locations of design, manufacture, inspection and testing and storage and must provide it with all necessary information, in particular:

- the quality-system documentation,
- the quality records as provided for in the design part of the quality system, such as the results of analyses, calculations, tests, etc.,
- the quality records as provided for in the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

Design examination

The documentation must, so far as they are relevant to assessment, include:

- a general description of the type,
- conceptual-design, build standard and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes, including the operation of the product,
- the results of design calculations made, impartial examinations carried out, etc.,
- impartial test reports,
- manuals for installation, use and maintenance.

Notified body

Minimum criteria to be taken into account by Member States for the designation of bodies:

1. Notified bodies must fulfill the requirements of the relevant EN 45000 series.
2. A notified body must be independent and must not be controlled by manufacturers or by suppliers.
3. A notified body must be established within the territory of the Community.
4. Where type-approvals are issued by a notified body on behalf of a Member State, the Member State must ensure that the qualifications, technical experience and staffing of the notified body are such as will enable it to issue type-approvals which comply with the requirements of this Directive and to guarantee a high level of safety.
5. A notified body must be in a position to provide maritime expertise.

A notified body is entitled to perform conformity-assessment procedures for any economic operator established within or out of the Community.

On-board equipment for testing (extract)

Item designation	**Testing standards**	**Modules for conformity assessment**					
		B + C	B + D	B + E	B + F	G	H
1	2	3					
Life-saving appliances							
Life-buoys	IMO Resolution MSC.81		x	x	x		
Lifejackets	IMO Resolution MSC.81		x	x	x		
Thermal protective aids	IMO Resolution MSC.81		x	x	x		
Lifeboats	IMO resolution MSC.81		x			x	
Fast rescue boats	IMO resolution MSC.81		x			x	
Marine evacuation system	IMO resolution MSC.81		x			x	
Radar reflector for lifeboats and rescue boats	IMO Resolution A.384 ISO 8729 (1998)		x	x	x	x	
Navigation equipment							
Magnetic compass	EN ISO 449 (1999) EN ISO 694 (2001) ISO 2269 (1992)		x	x	x	x	
Gyro compass	EN ISO 8728 (1998) EN 60945 (1997)		x	x	x	x	
Echo-sounding equipment	EN ISO 9875 (1997) EN 60945 (1997) EN 61162		x	x	x	x	
Speed and distance measuring equipment (SDME)	EN 61023 (1999) EN 60945, EN 61162		x	x	x	x	
Radiocommunication equipment							
HF marine safety information equipment	ETS 3000 067 EN 60945 EN 61162		x	x	x	x	
Aeronautical two way VHF radio telephone apparatus	ETS 300 067 EN 60945 EN 61162		x	x	x	x	
NAVTEX receiver	EN 300 065 EN 301 011 IEC 61097-6 (1995) IEC 60945 (1996)						

Equipment covered by this Directive should, as a general rule, bear a mark to indicate its compliance with the requirement of this Directive. The use of equipment not bearing the mark of conformity may be allowed in exceptional circumstances.

Equipment which complies with the relevant international instruments and is manufactured in accordance with the conformity-assessment procedures shall have the mark affixed to it by the

manufacturer or his authorized representative established within the Community. The mark shall be followed by the identification number of the notified body which has performed the conformity-assessment procedure, if that body is involved in the production-control phase, and by the last two digits of the number of the year in which the mark is affixed. The identification number of the notified body shall be affixed under its responsibility either by the body itself or by the manufacturer or his authorized representative established within the Community. The mark shall be affixed to the equipment or to its data plate so as to be visible, legible and indelible throughout the anticipated useful life of the equipment.

Reference and title of the standard	Publication OJ
EN 50065-1:1991 Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz Part 1: General requirements, frequency bands and electromagnetic disturbances	C 101 of 1998-04-03
Amendment A1:1992 to EN 50065-1:1991 Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz Part 1: General requirements, frequency bands and electromagnetic disturbances	C 101 of 1998-04-03
Amendment A2:1995 to EN 50065-1:1991 Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz Part 1: General requirements, frequency bands and electromagnetic disturbances	C 101 of 1998-04-03
Amendment A3:1996 to EN 50065-1:1991 Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz Part 1: General requirements, frequency bands and electromagnetic disturbances	C 101 of 1998-04-03
EN 50081-1:1992 Electromagnetic compatibility - Generic emission standard -- Part 1: Residential, commercial and light industry	C 101 of 1998-04-03
EN 50081-2:1993 Electromagnetic compatibility - Generic emission standard -- Part 2: Industrial environment	C 101 of 1998-04-03
EN 50082-1:1992 Electromagnetic compatibility - Generic immunity standard -- Part 1: Residential, commercial and light industry	C 101 of 1998-04-03
EN 50082-1:1997 Electromagnetic compatibility - Generic immunity standard -- Part 1: Residential, commercial and light industry	C 101 of 1998-04-03
EN 50082-2:1995 Electromagnetic compatibility - Generic immunity standard Part 2: Industrial environment	C 101 of 1998-04-03
EN 50083-2:1995 Cabled distribution systems for television, sound and interactive multimedia signals -- Part 2: Electromagnetic compatibility for equipment	C 101 of 1998-04-03
Amendment A1:1997 to EN 50083-2:1995 Cabled distribution systems for television, sound and interactive multimedia signals -- Part 2: Electromagnetic compatibility for equipment	C 101 of 1998-04-03
EN 50090-2-2:1996 Home and building electronic systems (HBES) -- Part 2-2: System overview - General technical requirements	C 101 of 1998-04-03
EN 50091-2:1995 Uninterruptible power systems (UPS) -- Part 2: EMC requirements	C 101 of 1998-04-03
EN 50130-4:1995 Alarm systems Part 4: Electromagnetic compatibility - Product family standard: Immunity requirements for components of fire, intruder and social alarm systems	C 101 of 1998-04-03
EN 50148:1995 Electronic taximeters	C 101 of 1998-04-03
EN 50199:1995 Electromagnetic compatibility (EMC) - Product standard for arc welding equipment	C 101 of 1998-04-03
EN 50227:1997 Control circuit devices and switching elements proximity sensors, d.c. interface for proximity sensors and switching amplifiers (NAMUR)	C 101 of 1998-04-03
EN 55011:1991 Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	C 101 of 1998-04-03

Amendment A1:1997 to EN 55011:1991 Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	C 101 of 1998-04-03
Amendment A2:1996 to EN 55011:1991 Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	C 101 of 1998-04-03
EN 55013:1990 Limits and methods of measurement of radio disturbance characteristics of broadcast receivers and associated equipment	C 101 of 1998-04-03
Amendment A12:1994 to EN 55013:1990 Limits and methods of measurement of radio disturbance characteristics of broadcast receivers and associated equipment	C 101 of 1998-04-03
Amendment A13:1996 to EN 55013:1990 Limits and methods of measurement of radio disturbance characteristics of broadcast receivers and associated equipment	C 101 of 1998-04-03
EN 55014-1:1993 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus , Part 1: Emission - Product family standard	C 101 of 1998-04-03
Amendment A1:1997 to EN 55014-1:1993 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus , Part 1: Emission - Product family standard	C 101 of 1998-04-03
EN 55014-2:1997 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus Part 2: Immunity - Product family standard	C 101 of 1998-04-03
EN 55015:1993 Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment	C 101 of 1998-04-03
EN 55015:1996 Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment	C 101 of 1998-04-03
Amendment A1:1997 to EN 55015:1996 Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment	C 101 of 1998-04-03
EN 55020:1988 Immunity from radio interference of broadcast receivers and associated equipment	C 101 of 1998-04-03
EN 55020:1994 Electromagnetic immunity of broadcast receivers and associated equipment	C 101 of 1998-04-03
Amendment A11:1996 to EN 55020:1994 Electromagnetic immunity of broadcast receivers and associated equipment	C 101 of 1998-04-03
EN 55022:1987 Limits and methods of measurement of radio interference characteristics of information technology equipment	C 101 of 1998-04-03
EN 55022:1994 Limits and methods of measurement of radio disturbance characteristics of information technology equipment	C 101 of 1998-04-03
Amendment A1:1995 to EN 55022:1994 Limits and methods of measurement of radio disturbance characteristics of information technology equipment	C 101 of 1998-04-03
Amendment A2:1997 to EN 55022:1994 Limits and methods of measurement of radio disturbance characteristics of information technology equipment	C 101 of 1998-04-03
EN 55103-1:1996 Electromagnetic compatibility - Product family standard for audio, video, audio-visual and entertainment lighting control apparatus for professional use -- Part 1: Emission	C 101 of 1998-04-03

EN 55103-2:1996 Electromagnetic compatibility - Product family standard for audio, video, audio-visual and entertainment lighting control apparatus for professional use -- Part 2: Immunity	C 101 of 1998-04-03
EN 60118-13:1997 Hearing aids , Part 13: Electromagnetic compatibility (EMC)	C 101 of 1998-04-03
EN 60439-1:1994 Low-voltage switchgear and controlgear assemblies Part 1: Type-tested and partially type-tested assemblies	C 101 of 1998-04-03
Amendment A11:1996 to EN 60439-1:1994 Low-voltage switchgear and controlgear assemblies -- Part 1: Type-tested and partially type-tested assemblies	C 101 of 1998-04-03
EN 60521:1995 Class 0,5, 1 and 2 alternating-current watt-hour meters	C 101 of 1998-04-03
EN 60555-2:1987 Disturbances in supply systems caused by household appliances and similar electrical equipment , Part 2: Harmonics	C 101 of 1998-04-03
EN 60555-3:1987 Disturbances in supply systems caused by household appliances and similar electrical equipment, Part 3: Voltage fluctuations	C 101 of 1998-04-03
Amendment A1:1991 to EN 60555-3:1987 Disturbances in supply systems caused by household appliances and similar electrical equipment, Part 3: Voltage fluctuations	C 101 of 1998-04-03
EN 60601-1-2:1993 Medical electrical equipment -- Part 1: General requirements for safety -- Collateral standard: Electromagnetic compatibility - Requirements and tests	C 101 of 1998-04-03
EN 60669-2-1:1996 Switches for household and similar fixed-electrical installations -- Part 2: Particular requirements -- Section 1: Electronic switches	C 101 of 1998-04-03
Amendment A11:1997 to EN 60669-2-1:1996 Switches for household and similar fixed-electrical installations -- Part 2: Particular requirements -- Section 1: Electronic switches	C 101 of 1998-04-03
EN 60669-2-2:1997 Switches for household and similar fixed electrical installations -- Part 2: Particular requirements -- Section 2: Electromagnetic remote-control switches (RCS)	C 101 of 1998-04-03
EN 60669-2-3:1996 Switches for household and similar fixed electrical installations -- Part 2: Particular requirements -- Section 3: Time-delay switches (T.D.S.)	C 101 of 1998-04-03
EN 60687:1992 Alternating-current static watt-hour meters for active energy (Classes 0,2 S and 0,5 S)	C 101 of 1998-04-03
EN 60730-1:1995 Automatic electrical controls for household and similar use -- Part 1: General requirements	C 101 of 1998-04-03
Amendment A1:1997 to EN 60730-1:1995 Automatic electrical controls for household and similar use -- Part 1: General requirements	C 101 of 1998-04-03
Amendment A11:1996 to EN 60730-1:1995 Automatic electrical controls for household and similar use -- Part 1: General requirements	C 101 of 1998-04-03
EN 60730-2-5:1995 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for automatic electrical burner control systems	C 101 of 1998-04-03

EN 60730-2-6:1995 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for automatic electrical pressure sensing controls including mechanical requirements	C 101 of 1998-04-03
Amendment A1:1997 to EN 60730-2-6:1995 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for automatic electrical pressure sensing controls including mechanical requirements	C 101 of 1998-04-03
EN 60730-2-7:1991 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for timers and time switches	C 101 of 1998-04-03
Amendment A1:1997 to EN 60730-2-7:1991 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for timers and time switches	C 101 of 1998-04-03
EN 60730-2-8:1995 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for electrically operated water valves, including mechanical requirements	C 101 of 1998-04-03
Amendment A1:1997 to EN 60730-2-8:1995 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for electrically operated water valves, including mechanical requirements	C 101 of 1998-04-03
Amendment A2:1997 to EN 60730-2-8:1995 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for electrically operated water valves, including mechanical requirements	C 101 of 1998-04-03
EN 60730-2-9:1995 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for temperature sensing controls	C 101 of 1998-04-03
Amendment A1:1996 to EN 60730-2-9:1995 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for temperature sensing controls	C 101 of 1998-04-03
Amendment A2:1997 to EN 60730-2-9:1995 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for temperature sensing controls	C 101 of 1998-04-03
EN 60730-2-11:1993 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for energy regulators	C 101 of 1998-04-03
Amendment A1:1997 to EN 60730-2-11:1993 Automatic electrical controls for household and similar use -- Part 2: Particular requirements for energy regulators	C 101 of 1998-04-03
EN 60870-2-1:1996 Telecontrol equipment and systems -- Part 2: Operating conditions -- Section 1: Power supply and electromagnetic compatibility	C 101 of 1998-04-03
EN 60945:1997 Maritime navigation and radiocommunication equipment and systems - General requirements - Methods of testing and required test results	C 101 of 1998-04-03
EN 60947-1:1991 Low-voltage switchgear and controlgear -- Part 1: General rules	C 101 of 1998-04-03
Amendment A11:1994 to EN 60947-1:1991 Low-voltage switchgear and controlgear -- Part 1: General rules	C 101 of 1998-04-03
EN 60947-2:1996 Low-voltage switchgear and controlgear -- Part 2: Circuit-breakers	C 101 of 1998-04-03

Amendment A11:1997 to EN 60947-2:1996 Low-voltage switchgear and controlgear -- Part 2: Circuit-breakers	C 101 of 1998-04-03
EN 60947-3:1992 Low-voltage switchgear and controlgear -- Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	C 101 of 1998-04-03
Amendment A1:1995 to EN 60947-3:1992 Low-voltage switchgear and controlgear -- Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	C 101 of 1998-04-03
EN 60947-4-1:1992 Low-voltage switchgear and controlgear -- Part 4: Contactors and motor-starters -- Section 1: Electromechanical contactors and motor-starters	C 101 of 1998-04-03
Amendment A2:1997 to EN 60947-4-1:1992 Low-voltage switchgear and controlgear -- Part 4: Contactors and motor-starters -- Section 1: Electromechanical contactors and motor-starters	C 101 of 1998-04-03
EN 60947-4-2:1996 Low-voltage switchgear and controlgear -- Part 4: Contactors and motor-starters -- Section 2: A.C. semiconductor motor controllers and starters	C 101 of 1998-04-03
EN 60947-5-1:1991 Low-voltage switchgear and controlgear -- Part 5: Control circuit devices and switching elements -- Section 1: Electromechanical control circuit devices	C 101 of 1998-04-03
Amendment A12:1997 to EN 60947-5-1:1991 Low-voltage switchgear and controlgear -- Part 5: Control circuit devices and switching elements -- Section 1: Electromechanical control circuit devices	C 101 of 1998-04-03
EN 60947-5-2:1997 Low-voltage switchgear and controlgear -- Part 5: Control circuit devices and switching elements -- Section 2: Proximity switches	C 101 of 1998-04-03
EN 60947-6-1:1991 Low-voltage switchgear and controlgear -- Part 6: Multiple function equipment -- Section 1: Automatic transfer switching equipment	C 101 of 1998-04-03
Amendment A11:1997 to EN 60947-6-1:1991 Low-voltage switchgear and controlgear -- Part 6: Multiple function equipment -- Section 1: Automatic transfer switching equipment	C 101 of 1998-04-03
EN 60947-6-2:1993 Low-voltage switchgear and controlgear -- Part 6: Multiple function equipment -- Section 2: Control and protective switching devices (or equipment) (CPS)	C 101 of 1998-04-03
Amendment A11:1997 to EN 60947-6-2:1993 Low-voltage switchgear and controlgear -- Part 6: Multiple function equipment -- Section 2: Control and protective switching devices (or equipment) (CPS)	C 101 of 1998-04-03
EN 61000-3-2:1995 Electromagnetic compatibility (EMC) -- Part 3: Limits -- Section 2: Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)	C 101 of 1998-04-03
Amendment A13:1997 to EN 61000-3-2:1995 Electromagnetic compatibility (EMC) -- Part 3: Limits -- Section 2: Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)	C 101 of 1998-04-03
EN 61000-3-3:1995 Electromagnetic compatibility (EMC) -- Part 3: Limits -- Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current up to and including 16 A	C 101 of 1998-04-03
EN 61008-1:1994 Electrical accessories - Residual current operated circuit-breakers without integral overcurrent protection for household and similar uses (RCCB's) -- Part 1: General rules	C 101 of 1998-04-03

Amendment A2:1995 to EN 61008-1:1994 Electrical accessories - Residual current operated circuit-breakers without integral overcurrent protection for household and similar uses (RCCB's) -- Part 1: General rules	C 101 of 1998-04-03
EN 61009-1:1994 Electrical accessories - Residual current operated circuit-breakers with integral overcurrent protection for household and similar uses (RCBO's) -- Part 1: General rules	C 101 of 1998-04-03
Amendment A1:1995 to EN 61009-1:1994 Electrical accessories - Residual current operated circuit-breakers with integral overcurrent protection for household and similar uses (RCBO's) -- Part 1: General rules	C 101 of 1998-04-03
EN 61036:1996 Alternating current static watt-hour meters for active energy (classes 1 and 2)	C 101 of 1998-04-03
EN 61037:1992 Electronic ripple control receivers for tariff and load control	C 101 of 1998-04-03
Amendment A1:1996 to EN 61037:1992 Electronic ripple control receivers for tariff and load control	C 101 of 1998-04-03
EN 61038:1992 Time switches for tariff and load control	C 101 of 1998-04-03
Amendment A1:1996 to EN 61038:1992 Time switches for tariff and load control	C 101 of 1998-04-03
EN 61131-2:1994 Programmable controllers -- Part 2: Equipment requirements and tests	C 101 of 1998-04-03
Amendment A11:1996 to EN 61131-2:1994 Programmable controllers -- Part 2: Equipment requirements and tests	C 101 of 1998-04-03
EN 61543:1995 Residual current-operated protective devices (RCDs) for household and similar use - Electromagnetic compatibility	C 101 of 1998-04-03
EN 61547:1995 Equipment for general lighting purposes - EMC immunity requirements	C 101 of 1998-04-03
EN 61800-3:1996 Adjustable speed electrical power drive systems -- Part 3: EMC product standard including specific test methods	C 101 of 1998-04-03
ETS 300 684:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for commercially available amateur radio equipment	C 101 of 1998-04-03
ETS 300 279 ETS 300 279/A1:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for Private land Mobile Radio (PMR) and ancillary equipment (speech and/or non-speech)	C 101 of 1998-04-03
ETS 300 340 ETS 300 340/A1:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) for European Radio Message System (ERMES) paging receivers	C 101 of 1998-04-03
ETS 300 445 ETS 300 445/A1:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for wireless microphones and similar Radio Frequency (RF) audio link equipment	C 101 of 1998-04-03
ETS 300 447:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for VHF FM broadcasting transmitters	C 101 of 1998-04-03

ETS 300 673:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for 4/6 GHz and 11/12/14 GHz Very Small Aperture Terminal (VSAT) equipment and 11/12 Satellite News Gathering (SNG) Transportable Earth Station (TES) equipment	C 101 of 1998-04-03
ETS 300 385 ETS 300 385/A1:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for digital fixed radio links and ancillary equipment with data rates at around 2 Mbit/s and above	C 101 of 1998-04-03
ETS 300 446:1997 Radio Equipment and Systems (RES); ElectroMagnetic Compatibility (EMC) standard for second generation Cordless Telephone (CT2) apparatus operating in the frequency band 864,1 MHz to 868,1 MHz, including public access services	C 101 of 1998-04-03
ETS 300 680-1:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for Citizens Band (CB) Radio and ancillary equipment (speech and/or non speech) Part 1: Angle-modulated	C 101 of 1998-04-03
ETS 300 680-2:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for Citizens Band (CB) Radio and ancillary equipment (speech and/or non speech) Part 2: Double Side Band (DSB) and/or Single Side Band (SSB)	C 101 of 1998-04-03
ETS 300 682:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for On-Site Paging equipment	C 101 of 1998-04-03
ETS 300 683:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for Short Range Devices (SRD) operating frequencies between 9 kHz and 25 GHz	C 101 of 1998-04-03
ETS 300 329:1997 Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) for Digital Enhanced Cordless Telecommunication (DECT) equipment	C 101 of 1998-04-03
EN 300 386-2:1997 Electromagnetic compatibility and Radio spectrum Matters (ERM); Telecommunications network equipment Electromagnetic Compatibility (EMC) requirements	C 101 of 1998-04-03

ISO 7637-0:1990. Road vehicles. Electrical disturbance by conduction and coupling.
Part 0: Definitions and general.
ISO 7637-1:1990. Road vehicles. Electrical disturbance by conduction and coupling.
Part 1: Passenger cars and light commercial vehicles with nominal 12-V supply voltage.
Electrical transient conduction along supply lines only.
ISO 11451-3:1994. Road vehicles. Electrical disturbances by narrow-band radiated electromagnetic energy.Vehicle test methods. Part 3: On-board transmitter simulation.
ISO 11451-4:1995. Road vehicles. Electrical disturbances by narrow-band radiated electromagnetic energy. Vehicle test methods. Part 4: Bulk current injector (BCI).
ISO 11452-1:1995. Road vehicles. Electrical disturbances by narrow-band radiated electromagnetic energy. Component test methods. Part 1: General and definitions.
ISO 11452-2:1995. Road vehicles. Electrical disturbances by narrow-band radiated electromagnetic energy. Component test methods. Part 2: Absorber-lined chamber.
ISO 11452-3:1995. Road vehicles. Electrical disturbances by narrow-band radiated electromagnetic energy. Component test methods. Part 3: Transverse electromagnetic mode (TEM) cell.
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