



CENELEC



Primer on Standards

Uncovering the mysteries
of standardization in Europe

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Introduction

This primer is intended as a basic introduction to the influential, challenging and yet relatively unknown world of *electrotechnical standardization*. Whether you study or teach, work in a small family business, a law firm, or a multinational, whether you manufacture, market or simply use electrotechnical products, this guide will provide answers to your most common questions. It will also give you a closer look at CENELEC, the *European Committee for Electrotechnical Standardization*, the main topic of this booklet.

Although at first the term standardization may summon images of a faceless Brave New World where everything is the same shape and size, nothing is further from the truth! Standardization is actually a highly efficient way to achieve mobility through compatibility, and quality through market-driven needs. *Standards*, in fact, are so much a part of our lives that we no longer even notice they are around - until something happens to show how vital they really are.

Even though standardization's most pressing goal is undoubtedly to ensure safety, it also facilitates commerce and eases communication. European standardization, as we will see throughout this booklet, fosters economic exchanges when a product conforming to the standards of one European country is granted access to all of CENELEC 22 member countries because *CENELEC standards* are identical from Portugal to Finland, from Malta to Iceland.

In our increasingly global world, acquaintance with *standards* has grown on the manufacturer's side in their need to refer to them when they place their goods on the European market. However among consumers and others not directly involved in manufacturing, the general rule is still lack of awareness, misconceptions and confusion. This is quite understandable, though, as *standards* are highly complex animals with numbered references, multiple amendments, and regular updates to keep pace with technology. This is why we have included a chapter in this guide that explains basically just what a *standard* is, the different kinds of *standards*, why they should be applied by industries and the advantages for consumers.

Throughout the world, standardization in each country or region is flavoured by its specific historical, economic and cultural context. Many of Europe's best recipes are the product of co-operation between European legislation and standardizers. The process has a terminology of its own, and it is not easy to grasp concepts such as *harmonized standards*, *New Approach Directives*, and *presumption of conformity*, learn how standards are developed and to which products they apply, or comprehend their relationship with European Legislation. This guide will try to clarify these and other questions as simply as possible.

We will also try to describe what is special about electrotechnical standardization, particularly in the European context. Product and services using electrical energy always need a system to run properly. Working and interchanging within the parts of this system requires standardization of characteristics, tolerances, interfaces, dimensions and last but not least, a high level of user protection. All this explains why electrotechnology was an early runner in international and regional standardization. The International Electrotechnical Commission (IEC) was founded in 1906, 20 years before its sister organization ISO (International Standardization Organization), which was created in 1926 (at that time called ISA).

CENELEC began its European standardization work in 1958 under the name of CENELCOM. CENELEC today, like its CENELCOM ancestor, acts as a federation of European Electrotechnical Committees. CENELEC in fact is the sum of its National Committees and it stands today as a world player in standardization thanks to their know-how, help and continuous support.

Many CENELEC National Committees are even older than the IEC. As early as 1883, the first electrotechnical standardization institution in Europe began its work in Austria, issuing the first Austrian national *standard* in 1889. Germany followed in 1893 and the UK in 1902.

And moving farther into the past, standardization is surely ONE of the world's oldest activities.... A story widely reported states that the width of the Space Shuttle's booster rockets, transported by rail through mountain tunnels, is determined by the standard railway gauge in the US and UK, which in turn is inherited from a long string of measurements that began with the space needed by a pair of Imperial Roman horses to travel along the roads of ancient Britain! Although this story has been debunked as an "urban legend", it is nonetheless a whimsical illustration of the way *standards* have always been with us.

We hope you enjoy this primer. If we have not been able to answer all your questions feel free to contact us at the CENELEC Central Secretariat <http://www.cenelec.org>, at the CENELEC *Online Info Service* at info@cenelec.org, or at any of our members.

Pieter Parlevliet
CENELEC Secretary General



chapter

1

Introducing CENELEC

CENELEC, the European Committee for Electrotechnical Standardization, was created in 1973 as a result of the merger of two previous European organizations: CENELCOM and CENEL. Nowadays, CENELEC is a non-profit technical organization set up under Belgian law and composed of the National Electrotechnical Committees of 22 European countries. In addition, 13 National Committees from Central and Eastern Europe are participating in CENELEC work with an Affiliate status. Their ultimate goal as affiliates is gaining full membership to CENELEC Standardization activities.

CENELEC's mission is to prepare voluntary electrotechnical standards that help develop the Single European Market/European Economic Area for electrical and electronic goods and services removing barriers to trade, creating new markets and cutting compliance costs.

For doing this, CENELEC is strongly committed to

- Lead the improvement of product quality, product safety, service quality and service safety in the fields of electricity, electronics and associated technologies, including protection of the environment and as result, make a major contribution to the welfare of society
- Serve and promote the interests of CENELEC's members and stakeholders, the electrotechnical industry, the cooperating organizations, and the social and economical partners in the areas of standardization and conformity assessment in the fields of electricity, electronics and associated technologies
- Support IEC, the *International Electrotechnical Commission*, in achieving its mission: to be globally recognized as the provider of standards and conformity assessment and related services needed to facilitate international trade in the fields of electricity, electronics and associated technologies

But in addition to the regular standardization work achieved by CENELEC since its foundation, a European Council Resolution of 7th May 1985 gave CENELEC a new dimension to its mission by recognizing it as the Standardization Body able to provide *harmonized standards* for the electrotechnical field under the *New Approach* (see Chapter 5).

CENELEC Historical Background

In 1959, five European IEC National Electrotechnical Committees (Belgium, France, Germany, Italy and the Netherlands -all six EEC member countries but Luxembourg), met and formed a body which became known from 1963 as CENELCOM, *the European Committee for the Coordination of Electrical Standards in the Common Market Countries*. The aim was to harmonize national standards in areas where trade barriers existed. By the end of 1959, some principles that are still valid today, had already been drawn up:

- Priority to IEC standardization work whenever possible
- Mutual information on new national work
- Technical cooperation in technical groups
- Cooperation in testing and certification

CENEL, the *European Committee for the Coordination of Electrical Standards*, the second direct ancestor of CENELEC, was formed in October 1960. CENELCOM members met with the IEC National Electrotechnical Committees of seven EFTA countries (Austria, Denmark, Norway, Portugal, Sweden, Switzerland and United Kingdom) and Finland. CENEL studied IEC standards and their implementation within the countries involved. CENELCOM and CENEL worked side by side until the end of 1972, when Denmark, Ireland and the United Kingdom decided to join the EEC.

From January 1st 1973, CENELCOM and CENEL were disbanded and a new organization was established: CENELEC (the acronym was mentioned for the first time in the Steering Committee meeting of Paris on 3-4 May 1972). The new body took over all the work of its two predecessors, including responsibility for the CENEL Components Committee (founded in 1970) which later became the CENELEC Electronic Components Committee (CECC).

CENELEC Today

Nowadays, CENELEC is composed of the National Electrotechnical Committees of 22 European countries. Membership is evolving almost every year for there are still 13 Affiliate members whose main priority is to become members of the organization.

Membership

The members of CENELEC are the National Electrotechnical Committees of 22 European countries:

- The 15 countries of the European Union: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom
- 3 EFTA members: Iceland, Norway, and Switzerland
- Plus the Czech Republic, Hungary, Slovakia and Malta

CENELEC is also proud to have 13 affiliate countries that will one day join CENELEC as full members. These affiliates come from the following countries: Albania, Bosnia-Herzegovina, Bulgaria, Cyprus, Estonia, Latvia, Poland, Romania, Slovenia, Turkey and the Ukraine. Once an Affiliate complies with the conditions for full membership it may become a CENELEC member with all its rights as well as responsibilities.

In addition to this, CENELEC also counts 32 *Cooperating Partners*. Cooperation Agreements signed with these industrial partners (European Associations of manufacturers for a given sector) allow for direct cooperation and mutual contribution to each other's work. Specifically, and as stated in CENELEC Guide 14, these agreements guarantee direct input from *Cooperating Partners* into the standardization work undertaken by CENELEC. They may thus advise on and state standardization priorities, may propose drafts as a contribution to the European standardization process and may deliver expert advice on legislative consequences of new standards.

Structure

The **General Assembly (AG)** is the governing body of CENELEC. It is chaired by the President, currently Mr. Yves Saulnier, and has the full power of decision within the organization. It determines its policy and is composed of the delegations from the National Electrotechnical Committees of each of the 22 member countries of CENELEC. It is also worth noting that these National Committees are also the IEC members in each respective country.

The **Administrative Board (CA)** controls and monitors the daily management of CENELEC and defines the orientation of the policies. It is led by the President.

The **Technical Board (BT)** coordinates all technical activities, which include the selection of international standards for consideration as *Reference Documents*, and sets up and monitors operations of the CENELEC Technical Committees and Working Groups. It consists of one permanent delegate from each of the 22 CENELEC members along with a number of observers, and is chaired by the President.

Finally, we find the **Technical Committees (TC)**. These bodies are responsible for the preparation of standards within their scope. They are composed of national delegations designated by the CENELEC members. At the end of 2001, there were 371 active CENELEC Committees, Sub-Committees, Task Forces and Working Groups.

The **CENELEC Central Secretariat (CS)**, located in Brussels, is in charge of the daily operations, coordination and promotion of all CENELEC activities. With a staff of around 30 people, CENELEC CS acts as a permanent office responsible for the execution and management of the daily matters in support of the AG and CA. It is managed by the Secretary General, Mr. P.C. Parlevliet.

The Central Secretariat handles all the tasks assigned to it by the General Assembly, the Administrative Board and the Technical Board and is responsible for the liaison and all correspondence with the Services of the European Commission and the EFTA Secretariat.

CENELEC's priority areas of standardization

The priority areas for CENELEC standardization work are those which determine the safety and the free movement of goods and services and/or that are directly or indirectly related to EU Directives. These are mainly:

- The development and implementation in Europe of a portfolio of European Electrotechnical Standards as far as possible in full conformity with the relevant international standards for electrotechnology prepared by the IEC, the *International Electrotechnical Commission*
- Proposals and drafts introduced by CENELEC's Cooperating Partners, consumers' associations and social partners
- The scope of all New Approach Directives concerning the electrotechnical field
- Specific proposals by CENELEC members for the preparation of relevant European Standards. This includes the aim to feed in the resulting drafts into the international work at IEC level
- Requests of the relevant user industry and authorities to start the creation of standards needed for the free movement and/or certification of electronic components

The latest technological changes as well as the evolution of the energy market in the European Union have led to two new additional areas of standardization for CENELEC:

- Merging technologies, like the ICT field, lead to obscure borderlines, responsibilities and scopes for the standardization organizations. The consequence is confusion for standardizers and delay of standardization work, while experts care for timeliness of standards. At the same time, a solid standards contribution for the European infrastructure in the ICT field is in demand
- CENELEC observes that the energy market moves from national monopolies to international ownership in a free market. The new market forces and an increasing political attention towards energy conservation as well as emerging technologies like small-scale cogeneration, or fuel cells will require support from standardization work to achieve optimal results

The European Standards Organizations and their counterparts at world level

CENELEC has two sister organizations at European level: CEN and ETSI. At international level, each of the European Standards Organizations has a counterpart: CENELEC is the IEC's, that of CEN is ISO, and ETSI's counterpart is ITU.

CEN

CENELEC's sister organization handles the preparation of European Standards in all domains but electrotechnical and telecommunications. CEN is the biggest of the European Standardization bodies and shares with CENELEC the same *Internal Regulations*. Membership to both CEN and CENELEC is normally granted at the same time. Its international counterpart is the *International Organization for Standards* (ISO).

ETSI

This other sister European organization is open for membership to all relevant organizations and industry with an interest in telecommunication standardization and that belong to a country within the geographical area of the European Confederation of Posts and Telecommunications Administrations. Its international counterpart is the ITU, *International Telecommunications Union*.

IEC

The International Electrotechnical Commission (IEC) is the oldest of the International Standardization Organizations. It was founded back in 1906 with the support of 7 countries.

The IEC counts today 48 full members (all nation states with National Electrotechnical Committees) 8 associate members and 6 Pre-Associates. It is globally recognized as the provider of standards and related services needed to facilitate international trade in the electrotechnical field. But unlike CENELEC's membership, IEC members are not required to adopt the standards issued by this body at national level.

CENELEC members also represent their countries directly in the IEC. They ensure close cooperation and parallel adoption procedures between the technical work going on in the relevant bodies of CENELEC and IEC. The direct source of *Reference*

Documents used as a basis for CENELEC Standards is found in the publications and draft documents of this institution.

In order to guarantee a smooth process with predefined premises, an arrangement was set. The *Dresden Agreement*, approved by the IEC and CENELEC in September 1996, is the result of the revision of the old *Lugano Agreement* ratified back in 1991 by both organizations. The *Dresden Agreement* offers the possibility to begin standardization at international level of an item that was primarily meant to be dealt with at European level. Please refer to Chapter 3 for more information regarding this agreement.


ISO

Established in 1947, it is a non-governmental, worldwide federation of National Standardization Bodies. The approximately 140 members of the *International Organization for Standardization* each represent a single country and are “most representative of standardization in that country”. The mission of ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services. ISO is most closely related to CEN to which it is linked by an equivalent document to the above-mentioned Dresden Agreement relating CENELEC to the IEC. In this case, the Vienna Agreement was signed by both organizations in 1991.

ITU

The *International Telecommunications Union* was established in 1932 although it dates back to 1865 when 20 European countries already met in the first *International Telegraphic Convention*. Membership includes 189 countries and over 600 sector players. Its role is to adopt recommendations with the purpose to standardize telecommunications on a worldwide basis. ITU is most closely related to ETSI.





chapter 2

The European Standard

What is a standard?

There are standards everywhere. Most of the time we don't even notice them. We may hear talking about a "standard bed" a "standard size photograph" or "standard time", but that's about all.

Standards may be also expressed in terms of language: something becomes recognizable and real when both the sender and the receiver know what they are talking about, that is, when they are using the same parameters or *standards*. "Cold" may be "colder" or "warmer" depending on the origin of the person referring to the temperature. In the same manner, "big" is "bigger" or "smaller" depending who's looking at an object... So then, what is the metric system if not a worldwide standard?

Taking advantage of the recent conversion of 12 European currencies into the euro, we can graphically use its introduction as a way to illustrate the fact that more than 300 million Europeans have had to change their monetary standards. All Germans knew, and still know what exactly they could purchase with 10, 50, or 100 DM. The same goes for the French, the Dutch, etc. Inversely, Italians, Spaniards or anyone else knew exactly, and certainly still know how much a dinner in a restaurant or a specific car should cost in Lira or Pesetas. And this is not to mention salaries! The arrival of the euro has disrupted all these concepts and we are all currently trying to create new ones.

For our specific purposes however, Part 3 of the CEN/CENELEC *Internal Regulations* defines a Standard as a *Document, established by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. Standards should be based on consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.*

Standards in everyday life

This definition given above may be rather technical and confusing. To put it in other words, we will use two very simple examples that explain the concept of *standard* in everyday life: *A credit card and a sheet of paper.*

We certainly agree with the fact that any given bank can issue its credit card following its very own specifications. A bank could issue a credit card that is round, thinner and with two additional chips. But would consumers, the very clients of this bank, like to exchange their old-fashioned, rusty credit cards for these new, trendy ones? Probably not... unless a real compatibility with the "standard card" is guaranteed. This is because behind the old credit cards there are a lot more facts than just the card itself, and consumers count on everything that goes with it (worldwide acceptance that means mobility and independence, money machines adapted only for "standard" cards, even wallets are made too in this pattern). This "standard size" has gone even further and now is widely accepted and recognized as a reference size for other documents like visiting cards. Thus, it is easy to understand that if a new trendy card is not compatible with the worldwide *standard* card, its success would automatically be very limited, or rather, it would be a complete failure.

This example describes quite well the more unknown and difficult world of electrotechnical standards. Standardizing these products, processes and services is a quite time-consuming task that can nevertheless offer great benefits to

European trade and consumers. Having one common *standard* that guarantees access to 22 different European countries means a product can reach a much wider market at a cheaper development and testing cost. Standard products gain automatic acceptance by their target as they can identify and consequently accept these products: *standards mean recognition*.

However, and just like the credit card, no one is obliged to follow the standards, provided that the products are safe and serve their purpose*. Manufacturers who do not apply them may risk a difficult and slow acceptance by consumers. But if we look at it otherwise, this non-obligation opens the door to research and development in the given field. If all manufacturers were forced to always follow the same process in order to comply, this may hamper the development of more advanced equipment. If a new type of credit card proves to be better and more secure, then consumers would certainly accept it, and it could gradually become the next “standard card” to which all other services would quickly adapt. This can only happen if the market is flexible and standards are not compulsory (provided that the product is safe).

Another example would be the *A4 paper size*. Not many people know the real dimensions of an A4 sheet of paper. But it is also true that A4 has become the reference for printers, folders, envelopes, publications, software, etc. No one is forced to follow it but A4 has certainly become the *rule*, the *reference*, the *recognized non-written law*.

These two very simple examples clearly show that standards make life easier to both consumers and manufacturers while - also very important - they do not constrain market development. A manufacturer with a great new idea may go further with it. If the market and consumers accept it, others will certainly follow the idea, thus giving the opportunity for standards to be developed in that specific field.

EN, the European Standard

European Standards (EN) are documents that have been ratified by one of the 3 European Standards Organizations, CEN, CENELEC or ETSI. They are designed and created by all interested parties through a transparent, consensual process.

European Standards are a key component of the Single European Market. Though rather technical and unknown to the general public and media, they represent one of the most important issues for business. Although often perceived as boring and not particularly relevant to some organizations, managers or users, they are

* Except when application is mandatory by legislation.

actually crucial in facilitating trade and hence have high visibility among manufacturers inside and outside the European territory. A *standard* represents a model specification, a technical solution against which a market can trade. It codifies best practice and is usually state of the art.

In essence, standards relate to products, services or systems. Now, however, standards are no longer created solely for technical reasons but have also become platforms to enable greater social inclusiveness and engagement with technology, as well as convergence and interoperability within a growing market across industries.

But the **European Standard** is something much more relevant than this. The *Internal Regulations, Part 3*, states that the EN (*European Standard*) "*carries with it the obligation, in accordance with IR Part 2, to be implemented at national level, by being given the status of a national standard and by withdrawal of any conflicting national standards*".

The fact that CENELEC *Standards* must be transposed into a national *standard* in all member countries guarantees that a manufacturer has easier access to the market of all these European countries when applying *European Standards*. This applies whether the manufacturer is based in the CENELEC territory or not. Member countries must also withdraw any conflicting national standard: the *EN* prevails over any national standard.

All National Committees and all standardization partners such as consumers, trade unions, European industry and the European Commission and EFTA Secretariat participate in the four *CENELEC Technical Board* meetings each year. CENELEC thus provides a highly effective instrument to respond in a timely and competent manner to legislative and economic requirements.

Benefits of European Electrotechnical Standardization

CENELEC has changed the electrotechnical field in Europe by removing practically all barriers to trade for electrotechnical products, systems and services. National standards have been replaced by European standards implemented identically Europe-wide. At the same time, conflicting national standards have been withdrawn. These achievements create a unified and open market throughout Europe. If reciprocity existed with other regional standardization bodies, practically no technical barriers to trade would exist in the world for electrotechnical products.

CENELEC intends in many cases to develop standards for the electrotechnical market even before the market expresses its needs. Elaborated by consensus,

CENELEC *Standards* are of the highest quality because all interested parties are invited to contribute to their development: manufacturers, consumers, environmentalists and anyone who has anything to say or is concerned by standards.

CENELEC Standards define the characteristics of electrotechnical products or services. These characteristics usually determine the performance and safety requirements that are voluntarily agreed upon by the interested parties. But in the electrotechnical field, things are more complicated and safety of consumers is the number one priority. The European Commission often encourages and supports this safety policy, which leads us to the so-called *harmonized standards*.

The participation of National Committees and the two-step approach (national consensus building followed by consensus building among National Committees) contribute to the strength of CENELEC, reflecting the subsidiarity principle, and the different cultures and views of Europeans in standardization as well. National Committees play a very important role for they provide a platform for small companies who, for financial and language reasons, can only participate at national level.

Output of CENELEC European Standards

CENELEC publishes every year a large amount of European Standards, EN's, for the electrotechnical field. But not all standards published are reflected in our output statistics. In fact, CENELEC only counts as *valid* standards those that are currently active and stops counting those that have been withdrawn after the *date of withdrawal or DOW*. Such a status provokes situations in which the publication of a new standard (for which an old one is withdrawn) results in a real output of zero.

In this sense, CENELEC ended up the year 2000 with a total of 3633 standards in its portfolio. The overall figure one year later, at the end of 2001 was *only* 4004, meaning that the net output of standards in 2001 was 371 when reality shows that the real output was 467. There is a gap of 96 standards *missing*, meaning that they have been withdrawn.

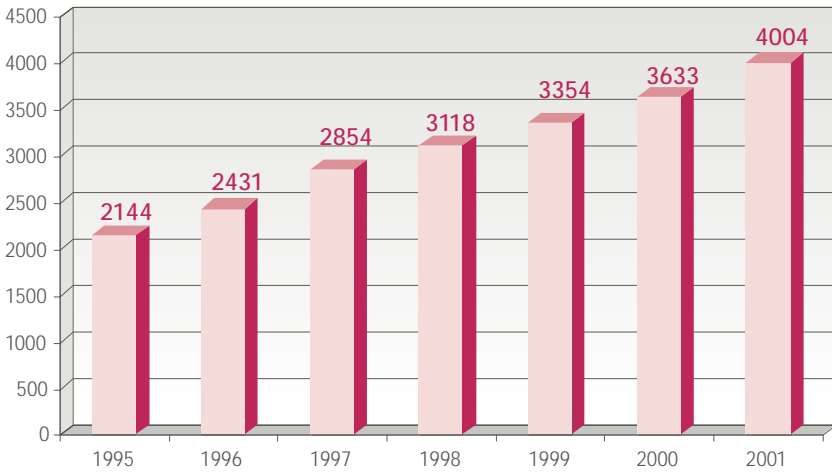


Figure 1: Total active CENELEC Standards at the end of every year

But ironically, CENELEC does not sell nor publish *European Standards*. We may better explain the situation if we say that CENELEC brings about standardization in Europe because it just prepares, drafts, and compiles the document and circulates its definitive version while the National Committees are ultimately responsible for publishing and selling the official version in their respective languages (in some cases, only the English version is endorsed). In other words, it is not possible to buy EN 50000, but BS EN 50000 (published and sold by the British Committee in English) or DIN EN 50000 (published and sold by the German Committee in German), and so on.



chapter

3

Understanding the Cenelec Standard

The EN and the HD

CENELEC publishes two kinds of *standards*, the *European Standard (EN)* and the *Harmonized Document or HD*. Although normally speaking we refer to both of them as *standards*, in detail the HD and the *EN* differ slightly. In fact, while the *EN* must be literally transposed as it is, word by word, in all CENELEC member countries, in the HD it is only the technical content that must be transposed into national *standards*. Furthermore, the HD can be dispersed among different/several national *standards*, unlike the *EN* that must exactly follow the same structure and to which nothing may be added nor removed.

Dates related to standards

- The date of ratification (DOR): Date the CENELEC Technical Board notes the approval of an EN or HD, from which time the standard may be said to be adopted. For administrative reasons, the formal *DOR* date is taken as the first day of the month following the *Technical Board* decision
- Date of availability (DAV): Date when the definitive text in the official language versions of an approved *EN* or *HD* is distributed by the CENELEC Central Secretariat
- Date of announcement (DOA): Latest date by which the existence of an EN or HD has to be announced at national level by the CENELEC members
- Date of publication (DOP): Latest date by which an EN has to be implemented at national level by publication of an identical national *standard* or by endorsement
- Date of withdrawal (DOW): Latest date by which national *standards* conflicting with an *EN* or *HD* have to be withdrawn

Special National Conditions and A-deviations

A *special national condition* is a national characteristic or practice that cannot be changed even over a long period of time. These special conditions normally refer to weather and ground conditions that for obvious reasons cannot be altered. For the countries in which the special condition applies, these provisions are normative. For the others, they are simply informative. The strength of the *CENELEC Standard* is that all these *special national conditions* are listed in an annex to the *standard*. This way, they are available to all manufacturers and no one has an advantage over the others in terms of nationality, in an efficient way to building up a truly unified market.

An *A-deviation* is a national divergence arising from an incompatible legislation, the alteration of which is beyond the scope of the CENELEC member. In this case, things become a bit more complicated and two scenarios may be possible:

- In the case of a *harmonized standard* (fulfilling the requirements of a European Directive), and for EU countries, *A-deviations* are simply not allowed. In the case of a non-EU country, the *A-deviation* is valid until the conflicting legislation has been removed (this applies to Iceland, Norway, Switzerland, the Czech Republic, Malta, Hungary and Slovakia)

- In the case of a *European standard* (not related to the requirements of any *Directive*), the *A-deviations* remain valid until the moment this legislation has been removed.

Just like in the case of *special national conditions*, *A-deviations* are also an integral part of the *European Standard* (annexed to it) letting everyone know about the possible changes to be applied should a product be introduced in a listed country.

In any case, *special national conditions* and *A-deviations* are not necessarily negative for they are both treated as an integral component to the text. CENELEC is in no case the cause of the problem. It merely highlights the existence of an inconvenience that must be taken into account by manufacturers, and one that, if necessary, should be solved by either European or national Authorities (the latter in case of non-harmonized standards).

CENELEC and the IEC

CENELEC also works in close cooperation with the IEC, the *International Electrotechnical Committee*, as one of our main policies is to develop *standards* with a global application. In this sense, many IEC Standards become *CENELEC Standards* (about 66% of CENELEC Standards are identical to those of the IEC).

This strong relation is first of all illustrated by the fact that the 22 CENELEC Members are also IEC Members. Since the start of its existence, CENELEC has used the publications and draft documents issued by IEC as the most important source of reference documents for the preparation of its European Standards.

The process by which European standardization items are offered to the IEC for possible international standardization is established in the *Dresden Agreement*. It comprises a chapter on the common planning of work, whereby each new work item identified at European level can be offered to IEC provided the work can be completed in a defined time period, and a chapter on parallel procedures, providing for simultaneous publication of identical Standards. This agreement also guarantees that any *standard* already ratified by CENELEC will be automatically offered to the IEC for possible acceptance at international level.

But here we now find the main difference between IEC *Standards* and CENELEC's. IEC does not require its members to implement the *standards* published while those very same IEC *Standards*, under an *EN* reference this time but same numbering as the IEC, must be implemented by all CENELEC countries. This method, at European level, also guarantees *that any conflicting national standard*

must also be withdrawn. The advantage for the manufacturer in applying *CENELEC Standards* emanating from the IEC is that, besides granting access to all 22 CENELEC countries, these same *standards* are recognized worldwide thanks to the work of the IEC.

Sometimes CENELEC adopts IEC Standards but slightly modifies them with some *common modifications*, which are a few alterations added for the European marketplace. Normally, these *common modifications* include tougher guarantees of health and safety to be applied for the European market. These *standards* count for about 10% of all *CENELEC Standards*.

It is very easy to differentiate purely *European homegrown standards* from *European Standards* that have been adopted from the IEC. Just look at the numbering; if you find an EN of the 50000 series, it is a *homegrown European Standard*, while an EN of the 60000 series is always an *IEC Standard*. It is also possible that you find an *IEC/EN Standard* (60000 series) that provides *presumption of conformity* because it is a *harmonized* one.

The CENELEC – IEC Agreement: The Dresden Agreement

History

The Dresden Agreement, initially known as the Lugano Agreement, covers the planning of new work and parallel voting. It was concluded in 1996.

Objectives

- To expedite the publication and common adoption of international *standards*
- To ensure the rational use of available resources. Full technical consideration of the content of the *standard* should therefore preferably take place at international level
- To accelerate the *standards'* preparation process in response to market demands
- To facilitate the adoption of European Standards internationally

Common planning of new work

Since all CENELEC members are also members of the IEC, the procedure noted below covers the need for new work arising at the European level.

New work arises at European level via either the CENELEC AG or the CENELEC BT. As a matter of policy, CENELEC would endeavour to ascertain whether the IEC could undertake this work.

Categories of New Work

- New work of European origin
- Required modifications to *IEC Standards* to tailor them to European needs, or
- The need to revise *IEC Standards*

Ownership

The Agreement requires the IEC to advise CENELEC whether it can undertake the work. This should be done as soon as possible and, at the latest, within six months. If accepted, and acceptable to CENELEC, the work becomes an IEC project. If the IEC rejects the work proposal or if the IEC's timescale is too protracted for CENELEC, then CENELEC will continue the work.

Progression of New Work

- Progress details on these projects, whether undertaken by CENELEC or the IEC, are exchanged between the two organizations on a monthly basis
- Draft *standards* prepared by CENELEC must be of a quality consistent with ISO/IEC Directives. They are subject to a five-month inquiry period. CENELEC is obliged to take note of comments received via the IEC network
- A parallel voting period of two months is stipulated in the Agreement. If IEC and CENELEC votes are positive, the *standard* is published both as an *IEC Standard* and an *EN Standard* in Europe. If the IEC vote is positive, but the CENELEC one is not, it is published as an *IEC Standard*. CENELEC may decide to publish it with common agreed *European modifications*

The Agreement also covers the adoption of previously published *European Standards* as *IEC Standards*.

Results of the cooperation with the IEC

In overall terms, 75% of CENELEC standards are identical to or based upon IEC's. Next charts clearly show this relationship and its evolution in the past years.

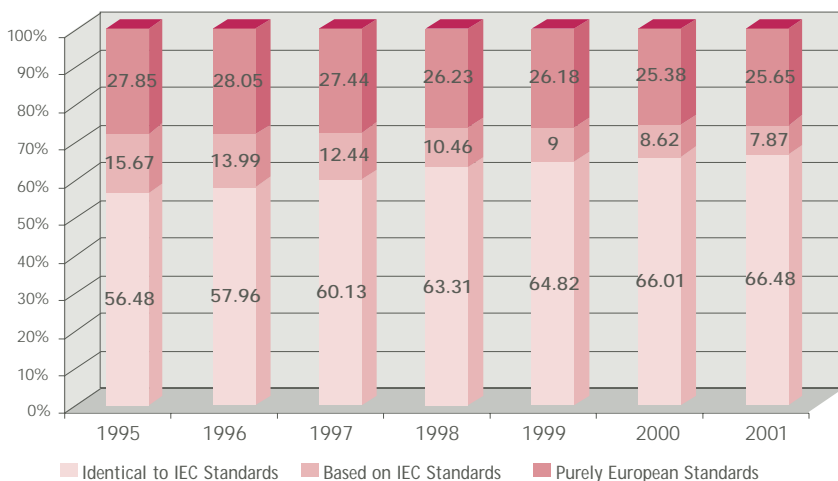


Figure 2: Evolution of the equivalence between active CENELEC standards and IEC standards since 1995

Overall level of equivalence between CENELEC Standards and IEC's at the end of the year 2001

Identical to IEC's	2662	66.5%
Based on IEC's	315	8%
Purely European	1027	25.5%
Total	4004	100%

The Vilamoura Procedure

In addition to the benefits of the Dresden Agreement, and in order to ensure that progress made at international level is not being overridden at national level, CENELEC has set a notification procedure all members have to follow: the Vilamoura Procedure.

In essence, this agreement obliges all CENELEC members to notify any national standardization project to all other members should there be an interest for a common standard at European level. If there is no reaction in a maximum period of 3 months, then the country in question may continue developing this internal project.



chapter

4

The Cenelec Conformity Assessment Forum

The CENELEC Conformity Assessment Forum: A Voluntary Approach to Conformity Assessment based on CENELEC Standards

From its creation in 1973, CENELEC has included within its terms of reference the promotion of mutual recognition agreements for testing and/or certification of electrical products, as a natural complement to its activities for the *harmonization of European Standards* in the electrotechnical area.

As a result, in most cases the National Electrotechnical Committees, members of CENELEC, all these years have been involved in, or have actively promoted, the creation of mutual recognition agreements for the testing and certification of products on a voluntary basis.

CCAF Goals

The *CENELEC Conformity Assessment Forum*, CCAF, is meant to be a focal point for *Conformity Assessment* in the electrotechnical field at European level, based on the following policies:

- To establish a formal link between the *standards* work of CENELEC and voluntary *Conformity Assessment* schemes operating in the electrotechnical field, with due regard to other interested parties
- The testing and certification bodies should have freedom to manage and operate their individual schemes in line with their market demands
- The principal aim of CCAF is the promotion of *European Standards* as the basis for *Conformity Assessment*

CCAF provides a platform within the CENELEC area for consideration of *Conformity Assessment* policy matters to be used by all interested parties on a voluntary basis.

In this sense, CCAF will

- Advise the CENELEC AG on *Conformity Assessment* policies in the electrotechnical *standards* field
- Coordinate the resolution of identified *Conformity Assessment* activity problems linked to the application of *CENELEC standards*
- Liaise with the appropriate regional and international bodies active in *Conformity Assessment* matters
- Facilitate the exchange of information on related policy issues

Mutual Recognition Agreements signed by CCAF

Free circulation of goods throughout Europe presupposes market acceptance in one country of the national *conformity* marks delivered to the product in another country, preferably without any retesting of the product and its corresponding costs and delays. CENELEC has thus nurtured a series of mutual recognition agreements between *Conformity Assessment Bodies* in different fields, as follows:

- *CENELEC Certification Agreement (CCA)* for the whole range of products covered by the *Low Voltage Directive*, including IT equipment
- *HAR Agreement* for electrical cables and cords
- *CECC System* for electronic components
- *Low Voltage Agreement Group (LOVAG)* for low voltage switchgear and controlgear
- *Short-circuit Testing Liaison Agreement (STLA)* for high voltage switchgear and controlgear
- *ENEC Agreement* for luminaires (and other equipment such as the safety of IT equipment on the basis of EN 60950)
- *Keymark Agreement* for household appliances.

Mutual recognition of test results, inspection reports, certificates or marks of *conformity* is a process by which an organization participating in a mutual recognition arrangement gives confidence to its customers that testing, inspection and/or certification performed by another participating organization is equally acceptable as its own.

The prerequisites for such mutual recognition are the following:

- The requirements for the products are specified in *European Standards*
- The procedures for assessment of new participating bodies and the criteria for acceptance of these bodies are harmonized
- The parties involved in the *Conformity Assessment* have earned mutual trust and apply the relevant *standards* in a uniform way





chapter

5

The European Standardization System & its relationship with EU Legislation

The New Approach to EU Legislation

The creation of the Single Market in Europe was laid down in four basic principles commonly identified as the “4 freedoms”. These *freedoms* refer to the free movement of *goods, services, capital and workers*. Previously, differences between national laws, *standards*, and *conformity assessment* procedures made trade between the member states difficult, expensive and time-consuming. A quick action was required.

The principal goal of the Single Market was to eliminate all barriers to trade existing between the Member States. In order to faster remove these barriers, a new legislative technique and strategy was established: The New Approach.

This new legal framework, the *New Approach to Technical Harmonization and Standardization*, was passed as a Council Resolution on May 7th 1985,

(OJ 85/C136/1). It was created in order to "harmonize" the health, safety, and environmental requirements of Member States into one single European legislative package. The outcome was called New Approach Directives, which are broad regulatory requirements to which confronted products must conform. In every case, one piece of legislation replaced 12 (15 after the last enlargement to Austria, Finland and Sweden). Member States are obliged to adopt the *New Approach Directives* because European legislation always prevails over national one, which must be replaced.

The New Approach represents a major change in policy for it makes reference to voluntary European Standards as the most appropriate method for technical implementation of legally-imposed requirements for products under European law.

In fact, it is probably the "*Old Approach*" that caused slow development of the Internal Market until 1985. Before this date, civil servants at the Commission used to draft detailed technical specifications that were annexed to the *Directives*. This process was long and required the continuous updating of documents. With the *New Approach*, the European Commission proposed the necessary mandatory performance requirements to ensure health, safety, etc. and asked the 3 recognized *European Standards Organizations*, who created *standards* with the help of technical experts, the application of the principles that guarantee compliance with the corresponding requirements.

The New Approach provides for three European Standards Bodies to plan, draft, create and adopt standards Europe-wide. These are:

- CEN, the *European Committee for Standardization*, in Brussels, responsible for standards in all fields except electrotechnology and telecommunications
- CENELEC, the *European Committee for Electrotechnical Standardization*, also in Brussels, prepares standards for electrotechnology
- ETSI, the *European Telecommunications Standards Institute*, in Sophia-Antipolis, prepares standards for Telecommunications

The *Global Approach to Testing, Certification and Conformity Assessment*, adopted in 1989, supplements the *New Approach*. It provided for the establishment of harmonized procedures to assess the conformity of products with the requirements of the *New Approach Directives* and the placing of the *CE Marking* to such products. *Notified Bodies*, that are officially recognized organizations within Member States, can certify conformity on the basis of the *New Approach*, if required by the Directive in question.

Legal framework of the New Approach

New Approach Directives are based on *Article 95* of the EC Treaty, and adopted according to the co-decision procedure provided for in *Article 251* of the EC Treaty.

Adopted *New Approach Directives* are notified to Member States and published in the *L series* of the *Official Journal of the European Communities*. Commission proposals for *New Approach Directives* are published in the *C series* of the *Official Journal*.

The principles of the New Approach

New Approach Directives are based on the following principles:

- Legislation is restricted to regulatory specifications that must be met before products can be placed on the European market place. These specifications are outlined in the *New Approach Directives* and mainly refer to essential requirements that are of public interest (health and safety)
- The necessary *standards* ensuring that products meet these regulatory requirements are created by the competent recognized *European Standardization Organization*, CEN, CENELEC or ETSI, depending on the field of work, under a contractual relationship with the European Commission (and the EFTA Secretariat), known as a mandate. They will be called *harmonized standards*
- *The references to harmonized standards* will be published in the OJEC. It is only from this moment that the harmonized standards will grant presumption of conformity
- Application of *harmonized standards* or other technical specifications remains voluntary. Manufacturers are always free to choose any technical solution that provides compliance with the essential requirements set by the *Directive*. This is a very important clause for it guarantees the ground for technical development, crucial when manufacturers of new or innovative products for which *standards* do not yet exist want to certify their products according to the legal European framework
- Only products fulfilling the essential requirements may be placed on the European market and put into service
- National authorities must acknowledge that products manufactured in conformity to *harmonized standards* are presumed to conform to all the necessary legal requirements established by the *Directives*

- Manufacturers may choose between different conformity assessment procedures provided for in the applicable *Directive*

Essential Health and Safety Requirements

A fundamental principle of the *New Approach* is to limit legislative harmonization to the essential requirements that are of public interest. These requirements deal in particular with the protection of health and safety of users (usually consumers and workers) although sometimes cover other fundamental requisites, like protection of the environment. Complying with the essential requirements is mandatory because they lay down the necessary elements for the protection of the public interest. All manufacturers are obliged to meet these legally-binding requirements specific to each product. Only products complying with these essential requirements may be placed on the European market and the law does not distinguish between European manufacturers and manufacturers from other countries.

The above paragraph leads us to the explanation of a new concept, *Conformity Assessment*, that is, *the process by which compliance with the essential requirements set by the Directives is determined*. This process may be carried out with or without the use of *standards*. This principle is important to manufacturers of avant-garde products for which *standards* do not yet exist for it ensures that *harmonized standards* do not become the only technical solution, consequently impeding technological development. If a manufacturer decides not to apply *harmonized standards*, he may do so and market the product directly on the basis of the essential requirements, although he will have to demonstrate compliance. In other words: *products placed on the market must comply with legislation but not necessarily with standards*.

Old Approach / New Approach

The *harmonization of standards*, like law 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*. Different sets of *standards* were not only costly, but also created major difficulties to trade between European countries. It became necessary to create a new, integrated, European system of standardization.

The Role of European Standards in New Approach Directives

Harmonized Standards are European Standards (EN), adopted by one of the *European Standards Organizations*, that are prepared in accordance with the General Guidelines agreed between the European Commission and the European Standards Organizations following a mandate issued by the Commission after consultation with the EU Member States.

Harmonized standards exist when the European Standards Bodies formally present to the Commission the *European Standards* they have elaborated in conformity with the mandate they have received. Standards become *harmonized* when they fulfill the corresponding requirements set in the EU Directives. The Commission publishes the references of these *harmonized standards* in its Official Journal, the OJEC*.

Basically, the application of *harmonized standards* deems to fulfill the essential requirements set by the *New Approach Directives*. *Harmonized standards* are the only ones to provide *presumption of conformity* with the European legal framework but their application remains voluntary. So, where is the trick then?

Standards, whether *harmonized* or not, are voluntary. However, products must comply with legislation. In other words, *the manufacturer may not follow the given standards but must in all cases comply with the law* (in terms of essential requirements). He may do so following other means. If the product is safe, he may place it on the market, although he has to carry the burden of proof.

We may rephrase the above concept into this: *harmonized standards*, either issued by CENELEC, CEN or ETSI are *the only ones in the world helping manufacturers comply with the law*. This happens once the reference of the *harmonized standard* has been published in the OJEC. One exception only: for the *Low Voltage Directive*, (LVD), publication in the OJEC may not even be necessary before presumption of conformity is granted. The *LVD Directive* is the only one providing presumption of conformity according to the text of the *standard* itself, and there is no need to wait for publication in the OJEC.

The application of *harmonized standards* provides *presumption of conformity* towards the authorities, a guarantee of recognition towards consumers, and compliance becomes automatically demonstrated.

* For reasons of easy reading, by the notion *harmonized standards* is understood all European standards offered by one of the ESOs prepared in accordance with the General Guidelines agreed between the Commission and the ESOs, following a mandate issued by the Commission after consultation of the member states through the Committee 98/34 and for which references have been published in the OJEC.

The CENELEC Harmonized Standard

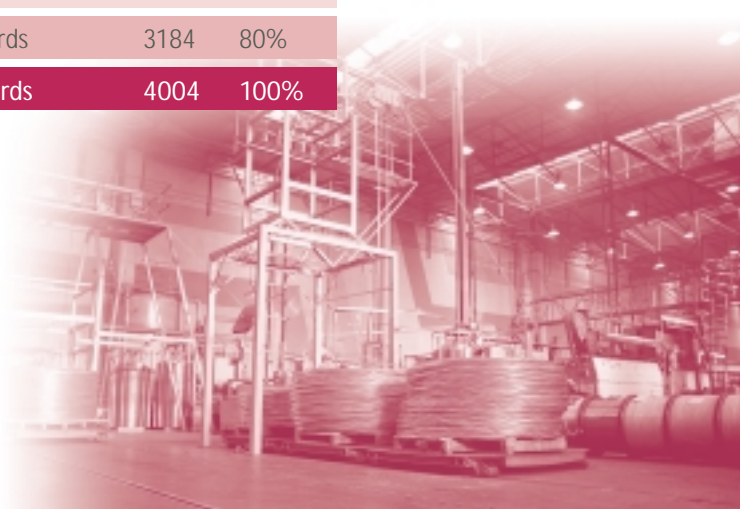
CENELEC has been developing *harmonized standards* since the beginning of the *New Approach*. Now we can present the following portfolio:

At the end of 2001, 820 out of 4004 CENELEC Standards had been *harmonized*, representing about 20% of all CENELEC Standards. The Commission is now considering the notification of 20 additional standards. Other 323 projects are currently under development. When you visit our website, www.cenelec.org you will be able to recognize all *harmonized standards* because they carry the European flag next to the EN number.

Total CENELEC Harmonized Standards, end 2001



CENELEC Harmonized Standards	820	20%
Other CENELEC Standards	3184	80%
Total CENELEC Standards	4004	100%



New Approach Directives for which CENELEC has been mandated EN's so far:

Directive Area	Directive Reference
• Construction Products	89/106/EEC
• Electromagnetic Compatibility	89/336/EEC
• Electrical Equipment for Potentially Explosive Atmospheres	94/9/EC
• Interoperability of European high-speed railway	96/48/EC
• Low Voltage Equipment	73/23/EEC
• Medical Devices	93/42/EEC
• Medical Devices: Active Implantable	90/385/EEC
• Medical Devices: In Vitro Diagnostic	98/79/EC
• Non-automatic weighing instruments	90/384/EEC
• Personal Protective Equipment	89/686/EEC
• Pressure Equipment	97/23/EC
• Radio & Telecom Terminal Equipment	99/5/EC
• Recreational Craft	94/25/EC
• Safety of Machinery	98/37/EC
• Safety of Toys	88/378/EEC

To assist manufacturers and other interested parties, the *Official Journal of the European Communities* provides a list of *harmonized standards* for each *Directive*. This possibility is also offered by *Information on the Links between Products, Directives and Standards in the Electrotechnical Field*, published once a year by CENELEC.

More information about the New Approach Directives and the harmonization process can be found at the following EU websites:

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/index.html>

www.NewApproach.org

www.europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm*

Added-value of both Harmonized and European Standards

Even though *harmonized standards* provide an important source for international recognition and are our most visible accomplishment, the core of our work has always been, and still is, *European standards*, which count for about 80% of our total number of Standards (3184 out of 4004 at the end of 2001).

Although it is true that *harmonized standards* provide *presumption of conformity* with the essential requirements covered by the standards and their references are published in the *Official Journal of the European Communities*, we should not underestimate the key role that CENELEC's *European standards* play in CENELEC's 22 member states. The advancements CENELEC has made since 1973 in favor for a unified European market for the electrotechnical sector in which manufacturers can introduce a product in several countries applying one single set of standards and removing an equal number of national ones in every case is certainly remarkable.

Applying *European standards*, whether harmonized or not, carry many important advantages to the manufacturer. A key one is *recognition*. Products manufactured according to *standards* not emanating from one of the *European Standards Bodies* are not always recognized by insurers, lending institutions, retailers, conformity assessment bodies or consumers, and may consequently limit its acceptance in the marketplace, particularly when a *European Standard* already exists for that specific product.

In addition to this, European standards that are not mandated may not necessarily be directed towards fulfilling essential requirements like health or safety aspects of products. They may well define other characteristics such as durability, performance, appearance or even cultural preferences. They could even specify test methods or implement measurement guides.

* This link refers to the *Commissions Blue Guide to the Implementation of Directives Based on the New Approach and the Global Approach*. This guide complements the information contained in this Primer and may be downloaded for free at the indicated URL



chapter

6

CE Marking, Conformity Assessment & Market Surveillance under the New Approach

Identifying the CE Marking

The EU's *New Approach to Technical Harmonization and Standards* aims to ensure that only products meeting the requirements set by the EU legislation can circulate within the EU. The CE Marking was therefore chosen as an easily identifiable label to indicate compliance with these requirements. The CE Marking is a declaration of conformity with European legislation designed to show all parties concerned that a product meets all the appropriate requirements specified by *New Approach Directives*. It may be compared to a passport for entrance into the EU market.

CE in the term *CE Marking* stands for *Conformité Européenne (European Conformity)*

and as stated above, it only applies to products that are governed by at least one of the New Approach Directives. Nevertheless, it must be stressed that *it is compulsory to affix it on all products for which one of these Directives applies*. If a product is covered by more than one *New Approach Directive*, the CE Marking symbolizes that the product conforms to *all New Approach Directives* applying to it.

Harmonized Standards and the Presumption of Conformity

The main feature of *harmonized standards* is the fact that they grant *presumption of conformity* with European legislation and consequently the product can enter the whole European market without the legal obligation to show any other equivalent marks or guarantees.

Presumption of conformity is the legal principle relating to *harmonized standards* that explains the relationship between the legislative and the standardization processes. Thanks to this interaction, the European Commission and the European Standards Bodies, CEN, CENELEC and ETSI, cooperate in order to produce *harmonized standards*. A contractual relationship, broadly known as a *mandate*, is then developed stipulating that the *Standards Body* will produce standards (electrotechnical standards in the case of CENELEC) that will provide a technical solution or a technical interpretation complying with the essential requirements defined in a given *New Approach Directive*.

When the standard is completed and the conditions of the Commission's mandate are met, the Commission publishes the reference of the standard in the *Official Journal of the European Communities, OJEC*. Once this notice is published, the *European Standard*, now called *European Harmonized Standard*, will provide *presumption of conformity*. A manufacturer using a *harmonized standard* in the design and/or production process of a product is presumed to be in conformity with the corresponding essential requirements set by the European *Directives*.

The application of *harmonized standards*, which grant presumption of conformity, remains voluntary in the field of *New Approach Directives*. Consequently, a product may be manufactured directly on the basis of the essential requirements. The key is always this: *Applying a standard is voluntary; complying with the law is mandatory*.

Introduction to the Basic Principles of the CE Marking

The *CE Marking* may certainly be called *the passport to Europe for products*. *CE-Marking* a product that falls under one of the *New Approach Directives* is not an option for the manufacturer, it is simply *required by law*. All manufacturers,

regardless of the product's origin or the plant's location, are required to affix this *CE Marking* to products that are governed by *New Approach Directives*.

The *CE Marking* should not be confused with quality marks or labels for consumers to identify the excellence of a product. It is a visible sign affixed by the supplier of the product to show EU member states' authorities and other parties concerned that the product is in compliance with all the *New Approach Directives* applying to it.

Determining Which Directives Apply to my Product

The first step to compliance is the responsibility of the manufacturer to determine which *Directives* apply to the product. This is sometimes a difficult task since a product may be regulated by more than one *Directive*. In this respect, CENELEC publishes every year in June the CD-ROM *Links between Products, Directives and Standards* in the Electrotechnical Field. Visiting web sites such as CENELEC's or the European Commission's one may also help.

Once the *Directives* and the requirements have been identified, the manufacturer must then apply the appropriate *standards* and/or elaborate his product on the basis of the essential requirements if he intends to sell the product within the European market. Finally, and depending on the individual *Directive*, he may have to undertake a method of *Conformity Assessment*.

The *CE Marking* does not provide any information about the *Directives or Standards* that apply to the product nor about the method of *Conformity Assessment* used to bring the product into compliance. This information is provided by other accompanying documents such as the *Declaration of Conformity*.

Who Affixes the CE Marking

It is the manufacturer or his *Authorized Representative*, established in the European Union, who affixes the *CE Marking* to the product. It is certainly not affixed by a *Notified Body* (officially recognized bodies that conduct *Conformity Assessment* tests for products that fall under those *New Approach Directives* that require this compliance procedure).

The *CE Marking* must be affixed visibly, legibly and indelibly to the product, to its data plate or, where this is not possible, to its packaging.

Where a *Notified Body* is involved in the production control phase according to the applicable *Directives*, its identification number must follow the *CE Marking*. More complete instructions for the design and placing of the *CE Marking* are available in the *Directive 93/68/EEC*, also referred to as the *CE Marking Directive*.

CE Marking vs. other marks

The *CE Marking* is the *only marking symbolizing conformity to all the legal obligations relating to manufacturers* for a given product as required by the applicable *European New Approach Directives* providing for its affixing.

However, it should be noted that products may bear additional marks, most of them granted by independent third party certification bodies. Depending on its relevance in the market where the product is sold, any given mark is a *guarantee of confidence mostly addressed to consumers*. Why consumers? Because large manufacturers always know what they are buying. They are specialists and/or technicians and can consequently verify the quality of the components themselves. Basically, any *mark of guarantee* is superfluous to manufacturers and is mainly addressed to consumers.

A product may bear any additional markings or marks only if:

- They fulfill a different function from that of the *CE Marking*
- They do not cause any confusion with it
- They do not reduce its legibility and visibility

The Supplier's Declaration of Conformity

Products covered by *New Approach Directives* such as the *Low Voltage Directive*, the *Toys Directive* or the *EMC Directive* may be certified by the manufacturer himself and do not require the intervention of a *Notified Body*. In that case only, the manufacturer verifies himself the conformity of his products to the applicable *Directives*.

The manufacturer may fill out the *Declaration of Conformity*, sign it and affix the *CE Marking* to products or equipment only if he can prove conformity to the applicable requirements set in the *Directives* or to *harmonized standards*. Proof of this is provided in the *Technical File* that the manufacturer must also compile. See the *Manufacturer's Role* for more information relating to this.

Some other products, mostly those involving higher risks for both consumers and workers, cannot be certified by the manufacturer only. They must undergo one or more of the modules for *Conformity Assessment* foreseen in the *Global Approach to Conformity Assessment* involving the intervention of an independent third party: a *Notified Body*.

Notified Bodies

Notified Bodies are independent test houses or *certification bodies* that carry out the *Conformity Assessment* procedures referred to in the applicable *New Approach Directive*. *Notified bodies* are designated and notified by each Member State and must have the necessary qualifications, not only technical but also independence, impartiality, and integrity to meet the testing and/or certification requirements set by the *Directives*. Certificates issued by a *Notified Body* in one Member State must be accepted throughout the European Union.

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

Otherwise, you may access online information from the Europa website at:

http://www.europa.eu.int/comm/enterprise/ticqa/db_index.htm

or from the EOTC website, the *European Organization for Conformity Assessment* at:

<http://www.ticqa.eotc.be>

TICQA is a very complete database that allows searches of *Notified Bodies* combining different criteria such as "product to be tested" "country" "sector of activity" or "test type".

Conformity Assessment in the New Approach

Conformity Assessment is any activity concerned with determining directly or indirectly that the relevant requirements set by the *New Approach Directives* are fulfilled. This process can be carried out with or without the use of *standards*.

Conformity Assessment may vary in levels of complexity depending on the level of risk associated with the product being assessed. If the risk factor of the product is low and/or if *harmonized standards* have been used to meet the essential requirements of the *New Approach Directives* applying to it, then, no third party

Conformity Assessment procedure may be required, regardless of the origin or location of the manufacturer. In this case, he may directly declare, once the necessary product evaluations have been performed through the *Declaration of Conformity*, that the product meets the essential requirements of the Directive(s) that govern it.

As the risk for consumers and workers increases, the level of complexity of the *Conformity Assessment* process increases. Some New Approach Directives describe the range and content of possible *Conformity Assessment* procedures, which are considered to give the necessary level of protection and among which the manufacturer can make a choice.

The Global Approach to Conformity Assessment

In Europe, the goal of the *New Approach Directives* was to eliminate differences between national laws, thereby eliminating barriers to trade between the EU Member States. But barriers were still visible, particularly between testing and certification procedures. This is the reason behind the creation of an integrated policy for technical harmonization that had to be implemented. This scheme was called *Global Approach to Conformity Assessment*. Its main feature is the fact that it incorporated *harmonized Conformity Assessment* procedures within the *New Approach Directives*.

The *Global Approach* was completed by *Council Decision 90/683/EEC*, replaced and updated by *Decision 93/465/EEC*. This *Decision* lays down the guidelines for the use of *Conformity Assessment* procedures in *technical harmonization Directives* as well as harmonizes the rules for the affixing and use of the *CE Marking*.

These guidelines range from *self-declaration* by the sole manufacturer to a declaration by the manufacturer combined with *third party certification by a Notified Body*, depending on the nature and risk factor of the product. The *Global Approach* provides evaluation that a product has been tested and verification of the compliance of the product for sale in Europe.

The Manufacturer's role

The manufacturer is the person ultimately responsible for designing, manufacturing and the compliance of a given product. Even if certain facets of the production or components of his product are outsourced, he is the one who must ensure its compliance with the European legislation relating to it.

More often than we may think, the products to be introduced in the European

Market are governed by one (or sometimes more) *New Approach Directive*.

The manufacturer thus bears sole responsibility for introducing a product that complies with all the requirements of the relevant *Directives*. He must also make sure that he follows any *Conformity Assessment* procedures when required, including the *Technical File*, the *CE Marking* and the *Declaration of Conformity*.

A manufacturer may be established inside or outside the European Union; but in all cases the product must comply with the applicable European legislation if it is to be or has been introduced in the European Union. Whether inside or outside the European territory, to make things easier the manufacturer may appoint an *Authorized Representative* (in this case it must be located within the European Union) to act on his behalf.

It is also useful for manufacturers to know that European legislation is quite strict on “upgraded products” and treats most modifications or new functions added as if they were new products, and as such they are held to the same certification requirements as any other new product.

Just as a reminder, it should not be forgotten that *complying with the law is always mandatory* and that *only products complying with those essential requirements may be placed on the European market*.

The Technical File

The advantage of *New Approach Directives* is that they include, for many products, the opportunity for manufacturers to directly declare conformity to the essential requirements. But this right to declare compliance with the European legislation means that the manufacturer is the only one responsible for completing and updating all the procedures required by the legislation.

For all products covered by the *New Approach Directives* the manufacturer has to declare compliance with the *essential health and safety* requirements. For some products the *New Approach Directives* also require the intervention of a *Notified Body* (depending on the level of risk of the product). Whether or not the intervention of an independent third party is required (*Notified Body*), the manufacturer must always prepare a *Technical File*.

The *Technical File* is the written justification that all parts and functions of the product are safe (thus complying with the essential health and safety requirements set by the *New Approach Directive*) and can therefore be placed on the European Market. *The Technical File* includes the information that proves the technical basis

for conformity of the product to the requirements stated by the *Directive(s)*.

The manufacturer is obliged to keep this *Technical File* for ten years after the last unit of the product has been placed on the market. This is the rule unless otherwise stated in the applicable *Directive*.

User's Manual or Instructions

It may appear superfluous, but the user's manual is an essential element towards ensuring safety. It must include all the required information for the correct and safe use of a product, like:

- Information on possible remaining risks
- Identification and warning of dangerous applications
- Instructions on how to safely use the product
- Identification of safety precautions to be taken
- Consideration of reasonably foreseeable misuse

Declaration of Conformity

Once the product has been made according to the requirements set by the applicable Directives, the manufacturer may fill out the *Technical File*, prepare the *Declaration of Conformity* and affix the *CE Marking*.

The *Declaration of Conformity* is a document informing national authorities and other parties concerned that the product meets the essential requirements of the applicable *Directives*, or that the product complies with an EC type-examination certificate issued on the basis of compliance with the essential requirements of the applicable *Directives*.

National Marks

New Approach Directives requiring *CE Marking* are to replace the requirements set by national law and other national markings related to safety, health, consumer protection, etc. Therefore, the *CE Marking* is the only marking which implies conformity of a product with *New Approach Directives*.

However, market forces and habits still make it appealing for manufacturers to use additional national markings in addition to the *CE Marking*. Moreover,

manufacturers are often approached by private testing houses that promote their own "national marks" for products introduced in a specific country. In any case, it is only the *CE Marking* that implies conformity with European legislation.

Consequently, Member States may not maintain or introduce new markings that will symbolize compliance with requirements of the *New Approach Directives for the CE Marking* is the only marking implying conformity of a product to *New Approach Directives*.

The only way a product may bear other markings (always together with the *CE Marking*) is by not reducing the visibility and legibility of the CE Marking, and by not creating any confusion whatsoever.

Principles of Market Surveillance in the European Union

Market Surveillance is an essential tool for the enforcement of *New Approach Directives*.

The purpose of market surveillance is to ensure that the provisions of applicable *Directives* are complied with across the European Union. Citizens are entitled to an equivalent level of protection throughout the whole single market, regardless of the origin of the product. Moreover, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.

Member States must nominate or establish authorities to be responsible for market surveillance. These public authorities may be any kind of governmental body established for this purpose in a given Member State.

Market surveillance activities

National *surveillance authorities* shall monitor that products on the market comply with the provisions of the applicable national legislation transposing the *European New Approach Directives*.

Efficient enforcement usually requires that *surveillance authorities* act in cooperation with manufacturers and suppliers in order to prevent non-compliant products from being placed on the market.

In case of an incident or random check, the surveillance authority may require access to the manufacturer's *Declaration of Conformity and Technical File*. The manufacturer, his Authorized Representative or the person responsible to market

products must be able to provide this information in a brief period of time set by the surveillance authority. If the product is found to be non-compliant, action will depend on the degree of non-compliance.

Products imported from third countries

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*. The importing company is also responsible, according to the Directives, for carrying out the required *Conformity Assessment* procedures, if *applicable*.

If the manufacturer is not established in any of the countries of the European Union, he may appoint an *Authorized Representative*, established within the Community, to act on his behalf. If he does not have one, then the person responsible for placing the product on the European market may become responsible to some extent.

Customs authorities shall, in the case of products imported from third countries, suspend the release of goods if:

- They find products that display certain characteristics which would give rise to a serious risk to health and safety
- They find products that are not accompanied by a document or not marked in accordance with applicable rules on product safety.

For the well-functioning of these procedures, it is essential that *customs authorities* and market *surveillance authorities* keep each other informed and take appropriate action based on the information received.

Surveillance authorities will hold the person responsible for affixing the *CE Marking* to a non-compliant product accountable. National laws are very strict on this matter and penalties may include imprisonment.

COOPERATING PARTNERS

AIE	European Association of Electrical Contractors
CAPIEL	Coordinating Committee for the Associations of Manufacturers of Industrial Electrical Switchgear and Controlgear in the European Union
CEA	Comité Européen des Assurances
CECAPI	European Committee of Electrical Installation Equipment Manufacturers
CECED	European Committee of Manufacturers of Electrical Domestic Equipment
CECIMO	European Committee for Co-operation of the Machine Tool Industries
CELMA	Federation of National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires in the European Union
COCIR	European Coordination Committee of the Radiological and Electromedical Industries
COGEN Europe	The European Association for the Promotion of Cogeneration
COTREL	Committee of Associations of European Transformers Manufacturers
EACEM	European Association of Consumer Electronics Manufacturers
ECCA	European Cable Communications Association
ECI	European Copper Institute
ECMA	European Computer Manufacturers Association
ECSS Secretariat	European Cooperation for Space Standardization
EDMA	European Diagnostic Manufacturers Association
EECA	European Electronic Component Manufacturers Association
EEPCA	European Electrical Product Certification Association
EPIA	European Photovoltaic Industry Association
EPSMA	European Power Supply Manufacturers Association
ESONE	Committee for European Studies on Norms for Electronics
EURALARM	European Manufacturers and Installers of Fire and Security Systems
EURELECTRIC	Union of the Electricity Industry
EUROBAT	Association of European Accumulator Manufacturers
EUROCAE	European Organization for Civil Aviation Equipment
EUROPACABLE	European Confederation of Associations of Manufacturers of Insulated Wires and Cables
EVA	European Vending Association
KONNEX	Konnex Association
NORMAPME	European Office of Craft, Trades and Small & Medium Enterprises for Standardization
OIML	International Organization of Legal Metrology
TIE	Toy Industries Europe
UIC	International Union of Railways

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