

# CURRENT STATE OF STANDARDIZATION



IN BELGIUM

BUREAU DE NORMALISATION - BUREAU VOOR NORMALISATIE - NBN



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## CURRENT STATE OF STANDARDIZATION IN BELGIUM

Information booklet destined for the Members of a Standardization  
Committee





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# 1. Standardization and standards

## 1.1 Introduction

Standardization is the process whereby agreements are made between different interested parties on specific characteristics of a product, service or company process.

Its objective is to establish rules of good practice. The interested parties can be companies as well as administrations, research centres, universities, colleges of higher education, trade unions or consumers' associations. The document or another medium in which the agreements are defined is called "standard".

It is important that each interested party gets the opportunity to take part in standardization activities. Anyone who participates in standardization shares his knowledge with others in order to profit from the advantages it may bring. Standardization strives for efficient, safe, healthy and sustainable products, services and processes.

The NBN (Bureau de Normalisation) is the Belgian standards organization, and represents the Belgian interests amongst the European and international standardization bodies.

The NBN, as the knowledge centre on Belgian standardization is at the crossroads for the exchange of technical information and for raising the awareness of interested parties - at Belgian level - concerning the importance of standards.

## 1.2 The importance of standardization and standards

Standardization and the resulting standards, make economic exchanges easier and more efficient, enhance the quality of goods and services, safety in general and improve the health of people and animals.

European and international standards play a key role in the elimination of technical trade barriers.

Following a number of developments, both at technical and social level, standards and standardization are becoming increasingly important.

Standardization is essential for:

- new technical developments whereby companies, products and services are in technical terms, more and more linked to their environment;
- the growing internationalization;



- the ever shortening life-cycle of products;
- quality assurance;
- changes in business organization, which means that companies collaborate more intensively with other companies, such as under co-makership and for the management of the supply chain.

Standards have long been an important source of technical knowledge and are becoming increasingly important for the following reasons:

- The national and European laws refer more often to standards (e.g. environmental law, construction and product directives, as well as specifications of public procurements contracts;
- standards form the basis for quality systems;
- since certification is increasingly important, it may be essential to demonstrate that works are carried out according to the standards (for instance in the context of “Product Liability”).

### 1.3 Consensus

Technical arrangements can be made at three levels: at global, regional (e.g. European) and national level.

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Standards are consensus based. Consensus does not mean “discuss until you have an agreement”, and does not necessarily imply reaching unanimity. “Consensus” indicates the absence of sustained opposition to the proposal. Everyone must be convinced of the fairness of the arguments put forward and willing to apply the standard.


ISO defines consensus as a “General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all concerned and to reconcile any conflicting arguments(NBN EN 45020:2009 Standardization and related activities - General vocabulary (ISO/IEC Guide 2:2004), § 1.7).

Sufficient support is required for a standard to be approved. In the development of a standard, all interested parties must be involved. As the search for a consensus may lead to immobility and lack of clarity of the global standardization policy, NBN may in exceptional cases allow deviation from the fundamental consensus principle.



## 2. Belgian standardization

### 2.1 A short history



By decree law of September 20, 1945, standardization in Belgium gets for the first time an official status. By way of a private initiative, there previously existed under the protection of the “Comité central industriel” (now called the Federation of Enterprises in Belgium - FEB) the Belgian Standards Association (Association belge de Standardization (ABS)), which was founded in 1919. The ABS took a pioneering role through the publication of over one hundred standards, particularly in the building industry and the metal construction sector, to which documents of the Governments and industry could make reference.

In 1945, the legislator created the Belgian Standards Institute (Belgisch Instituut voor Normalisatie/Institut belge de normalisation (“BIN-IBN”)) as a non-profit organization, a parastatal organization that was responsible to the Minister of economy.

The IBN was given the task of mapping out the Belgian standardization policy. It published several thousands of standards in the context of the rebuilding of the infrastructure of Belgium during the postwar period and following the first economic development of what was later to become the European Union.

As from the 1980's and even more during the 1990's European standardization, aimed at the development of a single market, achieved an explosive growth. In parallel, standardization became more and more important for a growing number of economic and social activities. The expertise and standardization activities shifted therefore from the IBN to the experts in the field.

An audit that was performed in 1999-2000 at the request of the Minister of Economy, to which IBN was responsible, demonstrated that if no fundamental reforms were undertaken, IBN would no longer be able to perform its mission.

Taking into account the results of the audit, the government proposed a bill to Parliament that resulted in the Standardization Act of April 3, 2003. As a result of this Act, IBN was dissolved and replaced by NBN

### 2.2 Mission and values of the NBN

#### Mission

- As Belgium's national standardization body, to address the standardization needs of the Belgian stakeholders.
- Develop as the centre of knowledge on standardization

The NBN's core tasks:



- The identification of the needs for new standards and technical documents as well as the available resources to realize them;
- The coordination of standardization work and the aim for harmonization;
- Promotion of standards and coordination of measures intended to facilitate their use;
- The representation of the Belgian interests in European and international standardization bodies;
- The management of Belgian conformity assessment and certification systems relating to standards, in particular the conformity mark BENOR;
- Support pre-normative research and awareness actions, undertaken by collective research centers under the agreement framework concluded with the Bureau de Normalisation and aimed at small and medium enterprises.

### Values

The NBN stands for:

- Neutral, active, transparent;
- Efficiency, professionalism, customer oriented;
- An organization where employees have the opportunity to develop their own skills, personally as well as professionally.

Strategic objectives

- Promote innovation amongst the Belgian stakeholders;
- Take positions at international level concerning standardization matters;
- Distribution of documents and optimization of the flow of information;
- Research any opportunities concerning certification;
- Develop alternative financing arrangements;
- Achieve the operational recurring objectives;
- Be active in the field of marketing and branding.

## 2.3 Legal status and financing

According to the Act of March 16, 1954 on the control of some institutions of public utility, the NBN is a parastatal type C. As a semi-governmental institution, NBN receives an annual grant from the Federal Public Service Economy (FPS Economy), to which it is responsible.

Other major sources of financing include the sale of standards.

## 2.4 Organizational structure of NBN

According to the April 3, 2003 Act on standardization, NBN is managed by two bodies, a Management Committee and a Board of Directors. In addition, the Federal Public Service Economy, SMEs, and Energy (FPS Economy), set up a Supreme Council for Standardization. The Council, either on its own initiative or at the request of the Minister for Economy, has the task to provide advice on all matters relating to standardization policy and standards development on national and international level.





### 2.4.1 The Board of Directors

The NBN's Board of Directors is composed of representatives of companies, unions, federal and regional authorities as well as consumer organizations. It has 30 effective and 30 alternate members.

The Board of Directors has the following tasks:

- 1° the approval of the general standardization programs;
- 2° the creation and dissolution of the standardization committees;
- 3° recognition of the standardization sectoral operators and withdrawal of their recognition;
- 4° the approval of draft standards;
- 5° where appropriate, present the standards to the King for ratification;
- 6° assess the performance of the management committee and standardization committees and formulate opinions and recommendations to the Minister and the Management Committee on these matters.

### 2.4.2 The Management Committee

The Management Committee consists of the President of the Management Committee and a technical director. It is responsible for the daily management of the NBN and undertakes all necessary actions to ensure that all tasks are carried out.

## 2.5 Standardization policy

The Standardization Act of April 3, 2003 focuses on a philosophy of decentralization and public/private partnership. This is reflected in the composition of the Board of Directors, in the yearly inventory of priorities in the field of standardization policy as well as in the concrete organization of activities. The Standardization Act of April 3, 2003, also created a Supreme Council for Standardization.

### 2.5.1 Sectoral operators

The sectoral operators take charge of the administrative and technical follow-up of one or more standardization committees or subcommittees, as well as of working groups wherein standards are developed, or positions are adopted concerning the documents which are developed at Belgian, European (CEN, CENELEC, ETSI) or international level (ISO, IEC).

A sectoral operator must be recognized by the Executive Board, and can be a physical person. However, considering the conditions that have to be fulfilled by a sectoral operator to be recognized by the Executive Board, it is more often an organization.

To be recognized as a sectoral operator, the following conditions must be fulfilled:



- 1° be resident in Belgium;
- 2° prove his administrative, technical and financial capabilities, be impartial and lead from his residence in Belgium the works of the standardization committees in determined fields, in conformity with standardization programs and according to guidelines determined by the NBN.
- 3° by its specific character, expertise and relations in the country, be representative in Belgium of the aforementioned areas.

In June 2008, the Board of Directors of NBN recognized 24 sectoral operators.

### **2.5.2 General guidelines of the standardization programs**

Every calendar year NBN organizes amongst interested stakeholders a survey on standardization in Belgium. Based on the list of standardization committees at international, European and Belgian levels, stakeholders can indicate in which committees they wish to participate, either as a committee member or as sectoral operator.

After approval by the Board of Directors, the standardization committees for which a sectoral operator has filed an application, will determine the work program for the next calendar year. This work program, called the general schedule of standardization programs, determines the priorities of the standardization policy and is consistent with the expectations of the stakeholders,

The Board of Directors may instruct the NBN itself to act as sectoral operator. This would for example be for horizontal committees covering general subjects, for example quality management or corporate social responsibility, but for which there is presently no sectoral operator.

### **2.5.3 The Supreme Council for Standardization**

The Supreme Council for Standardization is an independent advisory body. The advisory body has the task to furnish recommendations to the responsible minister concerning all matters relating to national and international standardization policy and development. These opinions are publicly available. In addition, an annual report is also published by the Supreme Council for Standardization concerning its activities.

The Supreme Council for Standardization is composed of representatives:

- from the scientific world;
- from social interest groups;
- from economic factors.

The secretariat is held by the FPS Economy.

Published recommendations during 2006-2008:

- diagnosis in relation to the translation of standards into Dutch (2006-12-12);
- the selling price of standards (2007-06-12);
- resources for the consultation of standards (2007-06-12);
- standards antennas (2007-10-11);
- proposals / recommendations for the Belgian standardization policy (2008-11-27);



#### Annual reports

- Annual report 2006
- Annual report 2007
- Annual report 2008

## 2.6 Standardization committees' working method

### 2.6.1 Membership

Membership of a standardization committee is open to any natural or legal persons having their registered office or residence in Belgium. Furthermore, as a member you must have a clear, direct and current interest in the activities of the standards committee (s) which you wish to be member of. Finally, as a member a contribution to the technical work must also be made.

The sectoral operator may request from each committee member an annual contribution for their participation in the standardization work (of a committee). This contribution must not exceed € 2000 per year and is indexable; it is based on the actual costs incurred by the sectoral operator for the management of the standards committee.

The sectoral operator applies transparent and non-discriminatory membership fees that generate the same rights for all committee members belonging to the same category as defined by the sectoral operator.

The rates are lower for passive participation which is limited to receiving the working documents of the committee, than for active participation, which includes attending meetings and/or taking positions.

### 2.6.2 Working method of a standardization committee

A high degree of freedom is given by NBN to the sectoral operators for the setting up of standardization activities by the committees that the Board of Directors has entrusted them. Nevertheless, some basic ground rules were agreed upon in the Internal Rules for Standards Committees.

The consultation of committee members' in relation to working documents is by preference performed electronically. The chairman of the standardization committee can however call a meeting of all its members upon motivated requests by a committee member.

The standardization committee takes its decisions in principle by consensus, as defined by ISO (see 1.3).

If a consensus within a standards committee cannot be reached, decisions are taken by two-thirds of votes cast. In order to participate in the decision, a committee member must at least be active six months within this committee prior voting taking place. This period may be shortened by a simple majority vote.

The working language adopted by the Standards Committee members for



meetings and reporting is Dutch and / or French. Each Committee decides independently whether to use French and/or Dutch in its reports and announcements. At international and European level, the working language for the Belgian contribution is English.

## 2.7 Categories of standards: ratification and registration

### 2.7.1 Categories of standards

Today, the vast majority (about 90%) of standards in Belgium are prepared at European level (CEN, CENELEC); the remainder of the standards are specifically aimed at the Belgian market.

It is therefore essential that the Belgian stakeholders are kept informed of the preparation of European standards, and if necessary are able to participate in their development.

As the diffusion and ratification of standards throughout the European Union remains of the competence of each Member State, Belgian regulations have determined specific procedures for each type of standards:

- ratification of Belgian standards by Royal Decree;
- registration of foreign, European and international standards.

### 2.7.2 Ratification of Belgian standards (NBN)

The ratification applies to specific Belgian standards in areas where Belgium has built up an experience that is not currently covered by European standards (e.g. fire safety, special glass, etc.) or for example "national annexes" that are necessary for the implementation of European standards, whilst covering safety, climate and other aspects that are of national competence.

The ratification takes place following a public inquiry that is announced in the Belgian Official Gazette (Moniteur belge) and after approval by the Executive Board of NBN, through publication of a Royal Decree.

The ratification of specific Belgian standards, is becoming increasingly rare, due to the advent of European standards (EN) within the framework of the European policy to achieve a single market.

Furthermore, the leeway for Member States that wish to establish national standards has been significantly reduced.



The Directive 98/34/EC sets out the different situations that can occur when a member country wishes to publish a standard (apart from registration, which is described further down). If a European standard covers the same subject as a proposed national standard, the latter is ruled out.

Whenever a national standard is prepared, Member States should accordingly be notified:

- The notifications for voluntary standards, are done by NBN through the CEN (European committee for standardization)
- The notifications for mandatory standards (e.g. directives, decisions, regulations or administrative provisions) are done by the FPS Economy, through the European Commission.

If, following the notification, member states show interest in those standards, the Commission can encourage the development of a European standard.

### **2.7.3 Registration of foreign, European and international standards and documents**

The CEN / CENELEC rules state that each European standard must be implemented by the national standardization bodies, and that the conflicting national standards must be withdrawn.

A European standard (EN) must therefore automatically be transposed into a Belgian (NBN EN) standard.

The implementation requirement can be met in two ways:

- by conversion into a Belgian standard (e.g. NBN) and publication in the Belgian Official Gazette (Moniteur belge) after approval by the Executive Board of NBN.
- a statement that accepts the EN and declares it a valid standard for Belgium (a so-called "endorsement").

Through the compulsory implementation, all European standards within the European Union acquire the status of national standards in all countries of the European Union. In Belgium the option of publishing an NBN EN standard is generally chosen.

Yet, not all European and international standardization documents are automatically registered.

At European level, apart from European standards (EN), there also exist European Technical Specifications (TS).

Their implementation is voluntary. Conflicting national standards do not need therefore to be repealed.

Internationally, there is no compulsory implementation of ISO, IEC standards. However these can in principle be adopted as Belgian standards.

If EN, ISO and IEC standards are taken over as a Belgian standard, a Belgian cover page has to be made.

The following is indicated on this cover:



- the title;
- the number of the Belgian standard;
- a national foreword in Dutch and French, in which it is stated that for the said subject the European and /or international standard has been taken over as a Belgian standard.

The standard is then added to the cover page, taking into account the available languages and the requested version: French, English and German for a European standard (CEN/CENELEC), English and French for international standards.

For a certain number of European and / or International standards, a Dutch standard is also made available. Dutch versions are sometimes established, under cooperation agreements with the Belgian administrations, the NEN (Dutch Standards Institute) or users.

The Belgian standards commission sees the adoption of untranslated ISO or IEC standards as an added value, as it enables them to declare ISO and IEC standards as true and acceptable.

The adopted ISO and IEC standards are also included in the NBN catalogue, thus reaching a broader Belgian public.



## 3. European standardization

### 3.1 Introduction

There are three European standards organizations:

- European Committee for Standardization (CEN): concerning all areas in the field of European standardization, with the exception of electrotechnical and telecommunications standards.
- European Committee for Electrotechnical Standardization (CENELEC): concerning European electrotechnical Standardization;
- European Telecommunications Standards Institute (ETSI): concerning European standardization in the field of telecommunication.

CEN and CENELEC are composed of national members (one member per country), that include the national standards bodies of all EU Member States and EFTA; the Belgian members of CEN and CENELEC are NBN and CEB respectively.

The members of ETSI are however individual companies; these include producers and users in the field of telecommunications.

### 3.2 CEN, CENELEC and ETSI objectives

European standardization activities pursue the following objectives:

- promote the application of global ISO and / or IEC standards within the EU and EFTA countries.
- harmonize national standards and standardization documents;
- establish new European standards (EN), Technical specifications (TS) and Harmonization documents on subjects for which no national standards exist;
- develop and apply procedures for the mutual recognition of test results and certificates;
- cooperation between the EU, EFTA and European and global economic scientific and technical organizations;
- contribute to the elimination of technical trade barriers.

### 3.3 CEN, CENELEC and ETSI organizational structure

The general policy of CEN and CENELEC is determined by the General Assembly (GA); however at CEN, it is largely delegated to the Board of Directors (CA). These bodies are represented by delegates from all CEN and CENELEC members respectively. Their decisions are binding for all members.

The coordination of the CEN en CENELEC technical work is in the hands of the Technical Board (TB). This Technical Board:



- acts as an advisory committee for the Board of Directors;
- coordinates the harmonization of standards (based on the outcome of the approval process);
- is responsible for the monitoring of standards programs;
- ensures their implementation.

As for CEN, CEN/BT receives input from so-called “sector rapporteurs” , that may each create an organization around them for counseling purposes. Sector rapporteurs report during CEN/BT meetings.

For quick administrative decisions and policy preparation on behalf of the CEN/ BT, the TB/TC Management Group (TCMG) has been set up.

The CEN / BT imposes itself a 36 months period for the development of new standards.

The general policy of ETSI is determined by the General Assembly (GA), in which all members of ETSI are represented. The coordination and supervision of the technical work is largely delegated to the ETSI Board, which consists of 25 elected members. Guidance is given to the Board by a number of advisory groups. For strategically important subjects, special committees are set up.

Further information on CEN, CENELEC and ETSI can be found on their respective websites:

<http://www.cen.eu>, <http://www.cenelec.eu> and <http://www.etsi.org>.



### 3.4 Procedure of work for CEN and CENELEC

#### 3.4.1 Technical Committees

Technical Committees at CEN and CENELEC are set up by the Technical Board (BT). By principle, the Technical Committee deals with subjects on the basis of a work program approved by the Technical Board. This work program is integrated by the CEN/TC into its Business Plan.

If no CEN/CENELEC platform is required or desired for a particular subject, the CEN Management Centre (CMC) or in the case of CENELEC the Central Secretariat handle the matter themselves.

However, if for this subject an ISO / IEC platform exists, CEN and CENELEC can have recourse to the "Reporting Secretariat" (SR) of the ISO or IEC Technical (Sub) Committee.

The members of a CEN or CENELEC Technical Committee, are the national members of EU and EFTA. For Belgium, NBN and BEC are respectively member of CEN and CENELEC.

Because of the mandatory implementation of CEN and CENELEC standards as national ones (see 2.7.3), the work of the Technical Committees also has



consequences at national level. All member states must therefore respond to voting documents. In this respect, NBN brings out the Belgian vote for all documents that are being circulated, and abstains in the absence of any stakeholders or expertise at Belgian level.

### 3.4.2 Subcommittees

CEN and CENELEC provide for the possibility of setting up Subcommittees (SC).

This is however discouraged in favor of a structure that only includes Technical Committees and Working Groups. Furthermore CEN and CENELEC can create BT Task Forces. These are special units working on one particular subject, according to the rules for Technical Committees. Finally CEN and CENELEC also have BT working groups (BT/WG) that are often precursors of a Technical Committee, as well as Joint Working Groups (JWG).

Once a Subcommittee has been setup by a Technical Committee (with the approval of CEN/BT), it can execute the approved work program independently.

### 3.4.3 Working Groups, Task Groups and Ad Hoc Groups

For the preparation of standards, a Working Group (WG) and possibly a Task Group (TG) or Ad Hoc Group (AHG) is set up by the Technical (Sub) Committee. All these groups are given a clear mandate and are temporary in character.

Members of a Working Group, Task Group or Ad Hoc Group are experts in their field, and are personally appointed by the national standardization bodies, the Technical Committees as well as liaison organizations. In one such group two experts from the same country may therefore defend different points of view.

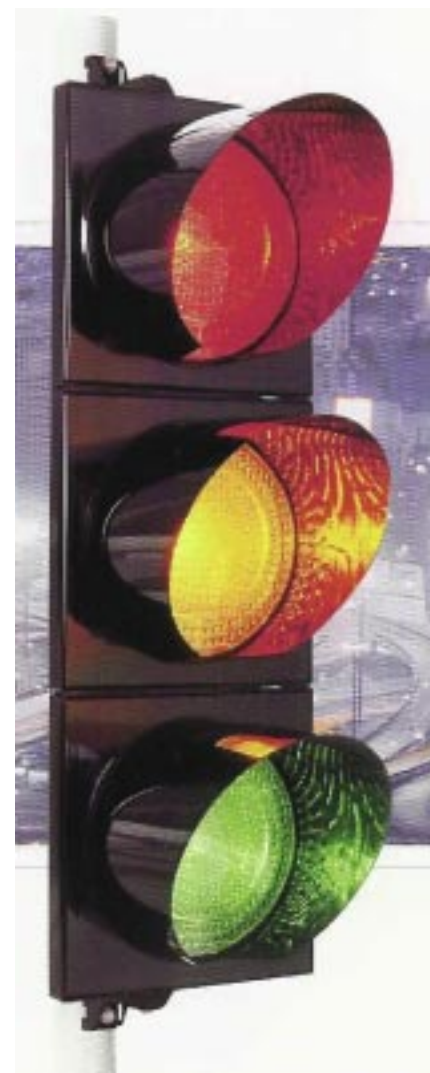
The group nevertheless anticipates that at some point one national vote will have to be expressed. NBN consequently asks the members of a Working Group, Task Group or Ad Hoc Group to consult with each other, and respect their mandate. It is exactly for this reason that members of the Working Groups, Task Groups or Ad Hoc Groups must simultaneously be a member of the relevant Belgian mirror commission.

## 3.5 European documents

The main task of the Technical (Sub) Committees is to elaborate and maintain European standards.

In particular instances it may be decided to publish other documents. The following types of documents can be distinguished:

- European standard (see 3.5.1);
- Harmonized document (see 3.5.2);
- Technical Specification (see 3.5.3);
- Technical Report (see 3.5.4);



- Various ETSI publications (see 3.5.5);
- New European documents, such as CWA and ES (see 3.5.6).

### **3.5.1 European standard (EN)**

The national standardization bodies must in principle, as members of CEN/ CENELEC, adopt it as national standard without any changes. Translation in the national language is however allowed. Draft European standards are available from NBN as draft 'NBN EN' standards (prEN, Draft European Standard). Conflicting national standards must be withdrawn before a determined date.

After a period of five years, each standard has to be assessed and consequently be either confirmed without changes, revised or withdrawn.

Technical errors in standards can be corrected by the publication of a corrigendum. Deemed necessary adjustments to a standard are in the form of an amendment. The various stages in the drafting of an amendment are the same as for a standard.

### **3.5.2 Harmonized documents (HD) (CENELEC)**

Harmonized documents have the same status as European standards, but are supplemented by national choices.

Members of CENELEC shall publish a corresponding national standard or at least announce the publication of a Harmonized Document (HD). After a predetermined date, a conflicting national standard must be withdrawn. By the lack of a national standard there is no obstacle for the publication of a Harmonization Document.

Unlike for a European standard, a nationally motivated and approved derogation on the basis of 'exceptional circumstances' is possible for a Harmonization Document. When a Harmonization Document is replaced by a European standard, it is withdrawn on the predetermined date.

The project of a Harmonization Document is available as a prHD (Draft Harmonization Document).

### **3.5.3 Technical Specification (TS)**

A Technical Specification is a normative document adopted by CEN, that can thereafter become the subject of a European standard.

If in relation to a technical subject a consensus cannot be reached or if the state of the art on the subject is insufficient for the drafting of a standard, a Technical Specification (TS) is temporarily established for a period of three years (renewable once for three years). A Technical Specification may also be used for rapid publication of mid-term results during the standard development program.

National standards of EU Member States that are in conflict with Technical



Specifications may be maintained until the said document is converted into a European Standard (EN). Publication of a Technical Specification is not compulsory. A national standardization institute may choose to exclusively make the Technical Specification available to the public.

### 3.5.4 Technical Report (TR)

A Technical Report (TR) will be issued if it appears desirable that certain data be published for information. This may include technical data, as well as an inventory of regulations and standards by country.

### 3.5.5 ETSI publications

European Standards (EN), previously named European Telecommunication Standards (ETS), are also produced by ETSI. Moreover ETSI publishes 'fast-track' ETSI standards (ES), drawn up by its members. Furthermore, ETSI Guides (EC), Technical Specifications (TS) and Technical Reports (TR) are prepared by the ETSI members or by the Technical Body. In contrast to CEN/CENELEC, there are no Harmonization documents at ETSI.



### 3.5.6 New European documents (CEN/ CENELEC Workshop Agreement (CWA))

A number of new European documents are available from the European standardization organizations CEN and CENELEC, which may or may not be developed outside the traditional development process followed by standards, namely the CEN / CENELEC Workshop Agreement (CWA). Through the CWA, European standardization aims to take into account the European industry's need for 'fast-track' European specifications.

### 3.6 Development process of European documents

There are six stages of European document development. These are:

- Proposal and registration stage (see 3.6.1);
- Preparation stage (see 3.6.2);
- Committee stage (see 3.6.3);
- Enquiry stage (see 3.6.4);
- Approval stage (see 3.6.5);
- Publication stage (see 3.6.6).

In special cases, in order to accelerate the development, a number of stages can be skipped.



### 3.6.1 Proposal and registration stage

Proposals for new European standardization activities can be submitted by:

- the CEN, CENELEC and ETSI members;
- global and European trade, professional, technical and scientific organizations;
- EFTA Secretariat and the European Commission.

Following a positive poll result of the proposals presented by the CEN-CENELEC to its members, these will be integrated into their work program.

If a subject is taken up into the European work program, the “Standstill Agreement” is applicable.

The Standstill agreement imposes a ban on activities by CEN and CENELEC members during the development of a European standard or harmonization document to avoid thwarting the intended harmonization.

Nor should any new or revised national standards be published that are not in accordance with the European standard or harmonization document under development.

The decision to impose or cancel a Standstill Agreement is made by the Technical Board (BT). At CEN level, a request for dispensation from the Standstill agreement can be dealt with by the Technical Committee.

At CEN and CENELEC there are in principle two procedures to elaborate a standard: the “Questionnaire procedure” and the “Technical Committee procedure”.

#### 3.6.1.1 Questionnaire procedure

CEN and CENELEC take reference as much as possible from existing ISO or IEC documents. If such documents are inexistent or their content proves unacceptable at European level, they may decide to take another document as basis for a standard. This other document would typically be prepared by another national standards body.

During the “Questionnaire procedure” (QP), this reference document is presented to the CEN and CENELEC members to verify the following:

- whether there is enough interest for harmonization concerning that subject;
- the degree of similarity between the various national standards treated in the document for review;
- whether the document to be reviewed as European standard (EN), Harmonization document (HD) or Technical Specification (TS) is acceptable.

The document is sent to the CEN or CENELEC members, who then must indicate within a set time whether they find this document acceptable as European standard. In the case of a new document, the “Primary Questionnaire” (PQ) is used. Whenever a reference document is being reviewed, of which a previous version has already been accepted as a Harmonization document,



the “Updating Questionnaire” (UQ) is used, providing it does not fall under the “parallel voting procedure (see 5.2).

Reactions to the Primary or Updating Questionnaires are, together with an opinion of the relevant Technical Committee or Reporting Secretariat submitted to the Technical Board.

Based on this data, the Technical Board shall decide on the continuation of the questionnaire.

### 3.6.1.2 Technical Committee procedure

The “Technical Committee procedure” is applied when no usable documents are at hand, and ISO and IEC cannot or do not want to take up the work on the basis of a cooperation agreement. Projects of standards are elaborated within the Task Forces or Working Groups of the Technical Committees.



### 3.6.2 Preparatory stage

Once a new work proposal has been accepted, the concerned Technical Committee or Subcommittee takes charge of the “working document” (WD), and if necessary, a working group is created for this purpose.

### 3.6.3 Committee stage

The preparatory stage ends as soon as a definitive document is available for discussion and consensus building (see 1.3) in the Technical Committee or Subcommittee. During the Committee stage, the document can circulate as a draft standard within the standardization institutes.

### 3.6.4 Enquiry stage

During the public enquiry stage, the document circulates amongst the national standards institutes for a period of five months for the “parallel voting

procedure”, see 5.2) as a draft standard (prEN) . This is the most important stage for assessing the document.

The submitted comments on the prEN ( in Belgium, draft NBN EN), are gathered together by the national standardization institutes and discussed within the relevant Committee in order to determine the national points of view. The national standardization institutes submit the comments on the draft standard, and these are discussed in the relevant CEN, CENELEC or ETSI Committee.

The national circumstances of some member states may cause problems when a European standard or harmonization document is implemented unchanged. The Member State can then submit a request for an exception to the European standard or the harmonization document, provided the problem cannot be solved



at national level.

In the parallel voting procedure with ISO / IEC (see 5.2), these documents fall under the "Draft International Standard / Committee Document for Vote" procedure.

### 3.6.5 Approval stage

During the approval phase, the document circulates for two months as a final draft amongst the national institutes for a final vote ("Formal Vote"). This final vote is a weighted vote, where different factors are applied to the various countries according to their importance (see table 1).

In 2007, CEN/CENELEC comprised the following members:

**Table 1 - Weighing factors as per 1 January 2007**

Country weighing factor		Country weighing factor	
France	29	Bulgaria	10
Great Britain	29	Sweden	10
Italy	29	Denmark	7
Germany	29	Finland	7
Spain	27	Ireland	7
Poland	27	Lithuania	7
Romania	14	Norway	7
The Netherlands	13	Slovak Republic	7
Belgium	12	Cyprus	4
Greece	12	Estonia	4
Hungary	12	Latvia	4
Portugal	12	Luxembourg	4
Czech Republic	12	Slovenia	4
Switzerland	10	Malta	3
Austria	10	Iceland	3

### 3.6.6 Publication stage

If the result of the Formal Vote is positive, CEN, CENELEC and ETSI announce that the European standard is adopted. They also notify by which date the publication of the European standard must be announced, conflicting national documents withdrawn and the European standard implemented. Normally a national standard that is to be replaced must be withdrawn six months after the publication of the European standard.

The respective national standards institutes have the task of providing a national cover for this draft standard. It is the responsibility of all stakeholders to study the draft standard and if necessary react to it.

### 3.6.7 Study projects

Study projects (“items for future work”) can be secured within a Technical (Sub) Committee. These are projects that cannot as yet be planned because their importance, priority or exact scope still needs to be defined, or because some (technical) research remains necessary. Whenever such a project is ready to enter standardization, it goes through the normal stages beginning with the proposal stage.

## 3.7 Mutual information and the ‘Vilamoura’ procedure of CENELEC

In accordance with the European directive 98/34/EEC, EU countries must communicate to a central point their intention to begin new work or to review existing standards. “New work”, is defined as any proposed regular standardization activity, with the exception of the review of existing national standards or the adjustment of national standards to European and global (‘International’) standards. In this respect, countries can keep track of the subjects notified by other countries, and when they themselves express interest in these can ascertain if it is useful to cooperate or discuss the subject at European level.

Within CENELEC the additional “Vilamoura” procedure has been agreed upon. The aim of this procedure is to quickly develop harmonized standards in a decentralized way, through cooperation between the members. As a result of this procedure, each CENELEC member commits itself by means of a “notification” or “revision” to inform the other members of planned new work. This must take place before the drafting of a national work document. When a member reacts positively, he must indicate which expert shall participate.

When at least four members react positively, the work is assigned to an existing Technical Committee; if this is the case, the IEC is also informed and asked if they can take on the work. In the absence of a Technical Committee or if it is unwilling to do the work, a Task Force under the responsibility of the Technical Board is set up.

If there are less than four positive responses, a Working Group is set up, with the initiating member as project leader.

“Revision of existing standards”, is understood as the revision of a national standard that does not fall



under the Standstill Agreement (see 3.6.1). These revisions must also be submitted for comments to the other member states. If at least four members react positively, the work is executed at European level. If there are less than five interested members, the initiating member can start the revision procedure, however he must give the other members access to meetings as well as send them the relevant documents. This can be done in the national language of the initiating member.

As soon as the standard is ready, the “Questionnaire Procedure” (see 3.6.1.1) for this particular document is started (for the English language document). In case none of the members react positively to a “revision”, the initiating member may carry on the work without further obligations towards CENELEC.



## 4. International (worldwide) standardization

### 4.1 Introduction

There are two global standardization bodies:

- International Organization for Standardization (ISO) in all fields of global standardization, except for electrotechnical and telecommunications standards;
- International Electrotechnical Commission (IEC) for global standardization in the field of electrotechnology.

In the telecommunications field, technical reference documents are prepared by the International Telecommunication Union (ITU). As the ITU is no standardization body, it is not further discussed in the framework of this brochure.

National standardization bodies are the respective ISO and IEC members. Belgium is represented by NBN as member of ISO and by BEC as member of IEC.

A close working relationship between ISO and IEC, has led to nearly identical procedures. The standardization activities in the field of information technology are handled in the joint Technical Committee JTC1.



### 4.2 ISO and IEC objectives

The ISO and IEC's main objective is to develop global standards through voluntary participation by many countries. There is no obligation to apply ISO and IEC standards and countries are free to implement them or not. Most of these worldwide standards are however directly or indirectly used for European standardization; in this case the European standard or Harmonization document becomes compulsory within the EU. Active monitoring of the development of global standards can therefore have positive effects on EU countries.



### 4.3 ISO and IEC organizational structure

The general policy of ISO and IEC is defined by the ISO Council and the IEC Council Board.

The technical work in ISO is coordinated by the Technical Management Board that also acts as Advisory Committee for the Council. The IEC technical coordination is done by the Standardization Management Board. Finally, the technical coordination between IEC and ISO is entrusted to the Joint Technical Advisory Board (JTAB).

Meetings of the ISO Council and Technical Board respectively take place two and three times a year, one of which being in the context of the ISO General Assembly. As for meetings of the IEC Council Board and Standardization



Management Board, these take place three times a year, one of which is in the context of the annual General Meeting. During this General Meeting, a certain number of technical (sub) committees get together. These Working Groups arrange their own meetings.

Further information can be found on the respective websites of ISO and IEC, <http://www.iso.org> and <http://www.iec.ch>

#### 4.4 Working method of ISO and IEC

Worldwide standards are developed by the committees established by ISO and IEC, that can delegate their tasks to one or more Subcommittees. Every Technical (Sub) Committee has a defined task within the global standardization field. For the elaboration of defined projects, a Technical (Sub) Committee can create one or several project teams. Upon recommendation by the Joint Technical Advisory Board (JTAB), ISO and IEC Joint Technical Committees can be set up.

The members of an ISO or IEC Technical (Sub) Committee are the national members. The secretariat of a Technical Committee (TC) or Sub Committee (SC) is managed by the respective national member.

The national member shall appoint one or more secretaries for the Technical (Sub) Committee. The “convenorship” of a Working Group is held by one of its members.

A project team is led by a project manager that is nominated by the initiator of the project.

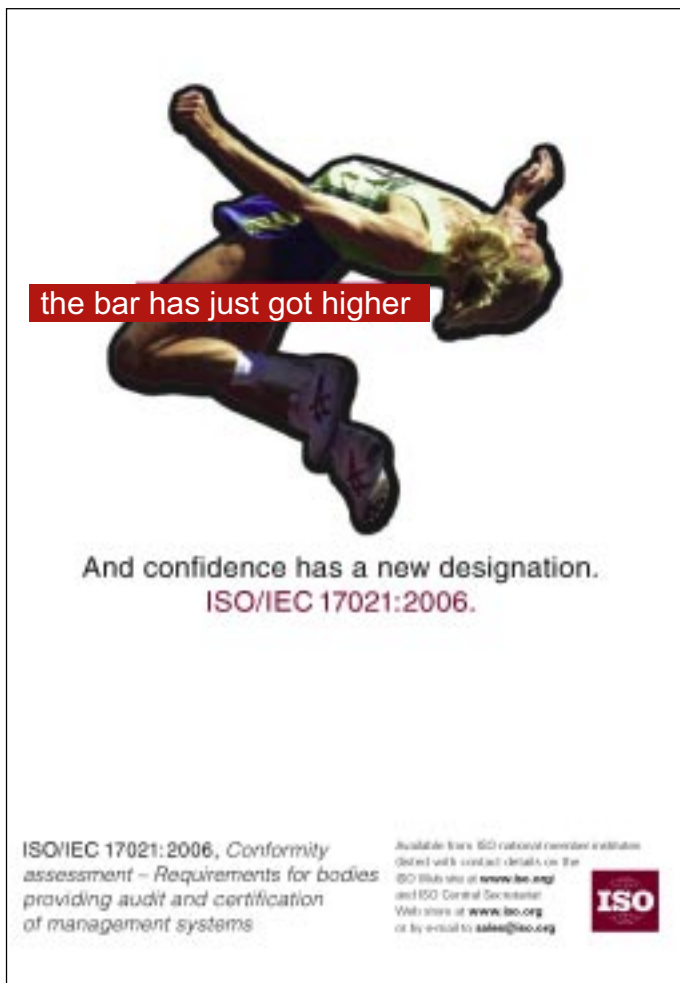
For each Technical (Sub) Committee, an ISO or IEC member can indicate whether he wishes to become a “participating member” (P-member), an “observing member” (O-member) or no member at all:

- O-members receive the documents from the Technical Committee and have the right to react to them as well as to attend meetings of this committee;
- P-members participate actively in the work of the Technical Committee. They are obliged to vote and - if possible - to attend meetings. If the participation of a P-member is insufficient, his membership can temporarily be revoked;
- a country that is not a member of a particular Technical Committee still receives the projects as well as the definitive standards from that committee for information and is able to vote on any draft standard as part of the voting procedure;
- if a country wishes to become a P or O-member of a Subcommittee, that country must be P or O-member of the respective Technical Committee;
- to participate actively in a Technical- or Sub Committee, a member has to be P-member of this Technical Committee of Subcommittee.

The national standardization member of a country, can send a delegation to each Technical (Sub) Committee meeting. The national positions are brought forward at the meeting by this delegation. In ISO and IEC working groups, the



delegation is represented by individual persons; they are nominated by their respective standardization institutes as expert in their field. By principle, documents presented by the respective work groups, are only made available to their members, and not to the national standardization institutes.



#### 4.5 Global documents

ISO and IEC publish various documents, such as :

- International Standards (ISO or IEC);
- Technical Specifications (TS);
- Technical Reports (TR);
- ISO or ISO/IEC Guides;
- Publicly available Specifications (PAS);
- International Workshop Agreements (IWA);
- Technology Trend Assessments (TTA);
- International Standardized Profiles (ISP).

#### 4.6 Elaboration of worldwide documents

The main task of the technical (sub) committees is to develop " International Standards " and keep them up to date.

In special cases it may be decided to publish other types of documents, such as a "Technical Specification" or a "Technical Report".

Every standard must, after a period of five years, be assessed by the P-members in order to be confirmed, revised or withdrawn. By issuing a "corrigendum" technical inaccuracies in a standard can be corrected. Adjustments to a standard that are deemed necessary are published in the form of an "amendment" which, in its development, goes through the same stages as a standard.

There are six stages in the development of a standard; these are:

- proposal stage (see 4.6.1);
- preparatory stage (4.6.2);
- committee stage (see 4.6.3);
- enquiry stage (see 4.6.4);
- approval stage (see 4.6.5);
- publication stage (see 4.6.6).

In certain cases, some stages can be skipped in order to speed up the



development. Skipping the preparatory stage (and sometimes the committee stage) occurs most often in practice.

#### 4.6.1 Proposal stage

A proposal for a new standardization activity is submitted to the relevant Technical (Sub) Committee as a "Proposal for New Work Item (NP)". The proposal circulates amongst P-members for a vote, as well as O-members for information. The voting period is three months. In general, the proposal is adopted provided a majority of P-members vote in favour of it and if there is an active participation by a minimum number of P-members (in the case of ISO five P-members and for IEC 25%, with a minimum of 4). The project is then registered under a number and a project leader is nominated.



If the proposal contains a detailed standard, the P-members can decide whether to pass the document through the accelerated procedure, which means it enters directly the Committee or Enquiry stage.

#### 4.6.2 Preparatory stage

The responsible Technical (Sub) Committee ensures the elaboration of the proposal as a Working Document (WD). This can be done through the setting up of a separate Working group or project team. This stage ends when a document is made available to the national standardization organizations.

#### 4.6.3 Committee stage

The document circulates amongst the national standardization institutes as a "Committee Draft" (CD). This is the most important stage for determining the contents of the document. P- as well as O-members can submit their comments. A "Committee Draft" may circulate several times in modified form, until it obtains sufficient support or it is decided to cancel it.

#### 4.6.4 Enquiry stage

The document circulates amongst national standards organizations as a "Committee Draft for Vote" (CDV) within IEC and "Draft International Standard" (DIS) within ISO and ISO / IEC JTC 1. The voting period is five months.

This gives members a final opportunity to communicate their technical comments on the concerned draft standard. The suitability of the draft standard to pass to the following stage is decided by a majority of the P-members' votes; (in the counting of the votes the O-members' negative votes are also taken into



account).

In the “parallel voting” procedure (see 5.2) with CEN/CENELEC, these documents fall under the “Enquiry”. If in the enquiry stage no negative votes are registered, it can be decided under certain conditions to bypass the approval stage and to move on to the publication stage.

#### **4.6.5 Approval stage**

The document circulates amongst national standards organizations as a Final Draft International Standard (FDIS).

During this stage, the formal acceptance of the document is decided by the members. The voting term is two months. An FDIS is accepted as an International Standard if at least two thirds of the P-members vote in favour of it and no more than a fourth of the votes are against.

Abstentions and negative votes without technical comments are not counted.

These documents come under the “Formal Vote” procedure in the “parallel voting” procedure with CEN/CENELEC (see 5.2).

#### **4.6.6 Publication stage**

During this stage, the document is prepared for publication. It ends with the publication of the standard.

#### **4.6.7 Study projects**

Within a Technical (Sub) Committee study projects can be determined, mostly on the occasion of the “Strategic Policy Statement” (IEC) or the “Business Plan from the Technical Committee” (ISO). These are projects in a premature stage that can as yet not be planned, but where some research is required. As soon as such a standardization project is ready to be implemented, it runs its normal course starting from the proposal stage.



## 5. Cooperation between European and worldwide standardization

### 5.1 Vienna Agreement for CEN/ISO and Dresden Agreement for CENELEC/IEC

The Vienna and Dresden Agreements provide the basis of an extensive cooperation between respectively CEN and ISO and CENELEC and IEC concerning the development of European and worldwide standards. They do this as follows:

- keep each other informed about their respective work program and the types of standards in development;
- if they wish, they are able to participate in each other's policy and Technical (Sub) Committee at Working Group meetings either physically or in writing;
- organize joint coordination meetings at Technical Committee or Technical Board level;
- collaborate in the elaboration of standards and come to an agreement on whether the work will take place at world or European level.

Generally, if standards are jointly developed, work is carried out at world level. Whenever CENELEC finds it necessary to draft a standard or revise an existing European one, it is examined whether it can be done directly at ISO/IEC level. If indeed this is possible, CEN/CENELEC imposes a deadline for the circulation of the Final Draft International Standard (FDIS), and nominates a project leader. If during the development process of a standard CEN/CENELEC realizes that for technical or procedural reasons or because of the delays it cannot accept the results, ISO/IEC is informed of this; CEN/CENELEC then continues the work within their organization. Thereafter, ISO/IEC is also free to develop and complete their own standard on this same topic.

Existing ISO/IEC standards are taken over as European standard through the Questionnaire procedure (see also 3.6.1.1). ISO/IEC has to be informed if the CEN/CENELEC members wish to take over the amended ISO/IEC standard, and if necessary the relevant worldwide standard will be adapted.

If on the other hand work is jointly carried out, the relevant CEN/CENELEC documents are also sent to ISO/IEC which, according to the circumstances, may decide either :



- to await publication of a definitive European standard and by way of the 'fast-track procedure' adopt it as a worldwide standard.
- or proceed to parallel voting.

## 5.2 Parallel voting on ISO and CEN documents

Projects of standards are, following the Vienna and Dresden Agreements, reviewed by ISO/IEC and CEN on the basis of a same document. The CEN/CENELEC Enquiry runs in parallel to the "Draft International Standard" (DIS) for ISO, and for IEC to the "Committee Draft for Vote" (CDV). During this round, and in the light of European directives and specific European situations, the CEN/CENELEC members are notably asked to review and analyze draft standards, and if necessary submit European deviations (Common modifications). These enquiries last for five months, at European as well as world level. The Formal Vote of CEN/CENELEC runs in parallel to the ISO/IEC FDIS, and is the last stage prior the approval of a standard. Member countries have to issue a European as well as a worldwide vote. Dissenting votes must be notified to both bodies.

- If, at world as well as European level, the results of the votes are positive, ISO/IEC publishes the definitive standard which is then accepted unchanged by CEN/CENELEC as a European standard.
- If the worldwide voting result is positive, but at European level negative, the CEN/CENELEC can continue to work separately on a modified standard. Proposed changes are in that case communicated to ISO/IEC.
- In case voting results differ from those indicated above, it will be decided who will eventually continue the development of the standard.



## 6. Standards and CE-marking

### 6.1 Standards and national regulations

Standards are voluntary documents; however, if the legislator makes reference to them, they can be used as a means to comply with legislation.

If standards are used within the framework of legislation, the legislator can indicate that conformity with a standard confers a presumption of conformity to legal requirements. The legislator can also indicate which parts of a standard are most relevant in respect of legislation.

The reference structure applied by the legislator is important. If reference is made to specific parts of a standard (not a complete one), a "closed" (dated) reference has to be used.

An "open" (undated) reference means that the legislator has enough trust in the entire standard to continuously apply to it a presumption of conformity with applicable legal requirements.

### 6.2 Relationship between Directive, standard and CE-marking

#### 6.2.1 Introduction

The post-1992 European internal market, with a population of about 300 million, forms a large market. To enable the free movement of goods within this market, it is essential that trade barriers are lifted. Evidently this also applies to trade barriers in the technical field.

Technical trade barriers arise when there are disparities in the following:

- regulations (for instance relating to collective interests, such as security and health);
- national standards (NBN in Belgium, DIN in Germany, etc);
- inspection and certification procedures; these must guarantee the conformity of a product in relation to legislation and national standards. If a country requires additional certification, in addition to certification in the country where the product was fabricated, this is regarded as a technical trade barrier.

#### 6.2.2 European Directives

European directives can be considered as "laws at European level". The member states of the European Economic Area (EEA) are required to transpose these Directives into national law within a certain period (usually two years). Directives thus acquire force of law at national level.



In 1985 the European Council decided on a New Approach in the drafting of European directives. Under this New Approach directives are classified not by product, but by product category.

By this New Approach, the directives are formulated according to the ultimate purpose of the product. Products that are brought on the market may not endanger the safety or cause damage to health.

### **6.2.3 European standards**

In the "New Approach" directives, only general requirements are formulated for the fields of safety and health, referred to as "Essential Requirements". The technical development of these essential requirements is as much as possible laid down in European standards.

The European Commission, by mandate, orders the European standardization institutes CENELEC (for electrotechnical products), ETSI (for telecommunication and information technology) and CEN (for other products) to develop standards. These European standards contain technical specifications for a product or group of products within the scope of a directive.

Standards are not legal documents, but publications in the private law sphere. Implementation of standards is voluntary. However, it is true that if the manufacturer follows the specified standards, the procedure for obtaining the CE marking, indicating that the product meets the relevant requirements, will be accelerated. From the moment the text of a European standard officially becomes available from the national standards institutes, they are obliged to publish it and withdraw or amend all conflicting standards. CEN imposes that this takes place within six months after the availability date.

### **6.2.4 CE-marking**

Products that fall under the "New Approach" directive can only be marketed or commercialized if they meet the essential requirements of the directive put into place for the concerned group of products.

The requirements of a European directive are the same for all concerned products. However for certain dangerous ones the European Commission found it necessary to strengthen and improve the monitoring of compliance with requirements of the relevant directives.

This is why the European Commission, in 1990, laid down eight assessment procedures, from module A to module H inclusive (updated in 2008 - Decision 768/2008/EC). By applying these procedures, one ensures that a product complies with the essential requirements of the relevant directive(s). In the case of module A, these assessment procedures can exclusively be followed by the manufacturer, or depending on the type of product in mandatory collaboration with an external institution (modules B to H). Such institutions



are also referred to as "Notified Bodies", because they are designated by the national authorities and notified to the European Commission and the Member states. The directives' appendices indicate which modules must be applied to which products. For a majority of the products, for which a slight risk of injury exists, the manufacturer can in general follow module A.

As for the Construction Products directive (CPD), it follows a different procedure. The Decision relating to the modules does not apply to this directive. The Construction Products Directive has its own systematics, and specific procedures with modules that differ in certain respects. In principle they relate the choice of module to the risks involving the use of products that do not meet the required standard or other harmonized technical specifications. In this directive, the CE marking is not applied on the basis of compliance with the directive, but on the basis of compliance with the European harmonized standard. In the case of products that require an inspection, the possibility is given not to have to make use of an external inspection body.

As a standard procedure each manufacturer must evaluate the risks of his products, reduce the identified risks through technical design and warn against the residual risks. If a product is found to comply with relevant directives, the manufacturer establishes a declaration of conformity, applies the CE marking ("Conformité Européenne") and joins instructions for safe usage.

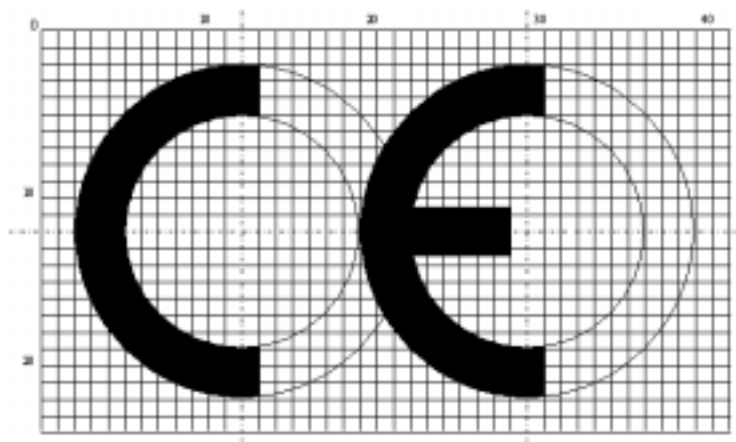
Applying the CE-marking to a product means it can be freely marketed within the European Economic Area (EEA). The manufacturer, in order to prove that it fulfills the directives' requirements, must include a technical file.

This file is strictly destined for the competent authorities (Labor Inspection, Testing Service, etc.), and should not be presented to third parties.

Standards, although not always legally binding, play strategically an important role in the marketing of a product. It is therefore in the interest of the manufacturer to ascertain which directives and standards relate to his product. Depending on his economic engagements, the manufacturer must consider if it is appropriate for him to participate or not in standardization committees. It will be for him more important to participate, if he wants to exert influence on the acceptance of his products or ideas through standardization.

**6.2.5 CEN/CENELEC European Mark of Conformity to European Standards (Keymark)**

CEN and CENELEC have set up a system for the benefit of European industry by which the conformity of products to European standards is established.



The Keymark is a certification mark delivered by an independent party which demonstrates that the product meets the requirements of the relevant European standards applied at the time the products were marketed and which were identified in the relevant Keymark system. The Keymark is registered and legally protected by CEN/CENELEC.

The Keymark is internationally registered, but also in each country where such registration is necessary to ensure its protection.



The specific Keymark system specifies the necessary requirements for executing the process by which a Keymark license can be given to the manufacturer for use with its product. The rules for each particular Keymark system, describe these requirements specifying the necessary rules for the implementation of that system.

The use of Keymark does not preclude the use of other certification marks on the product.

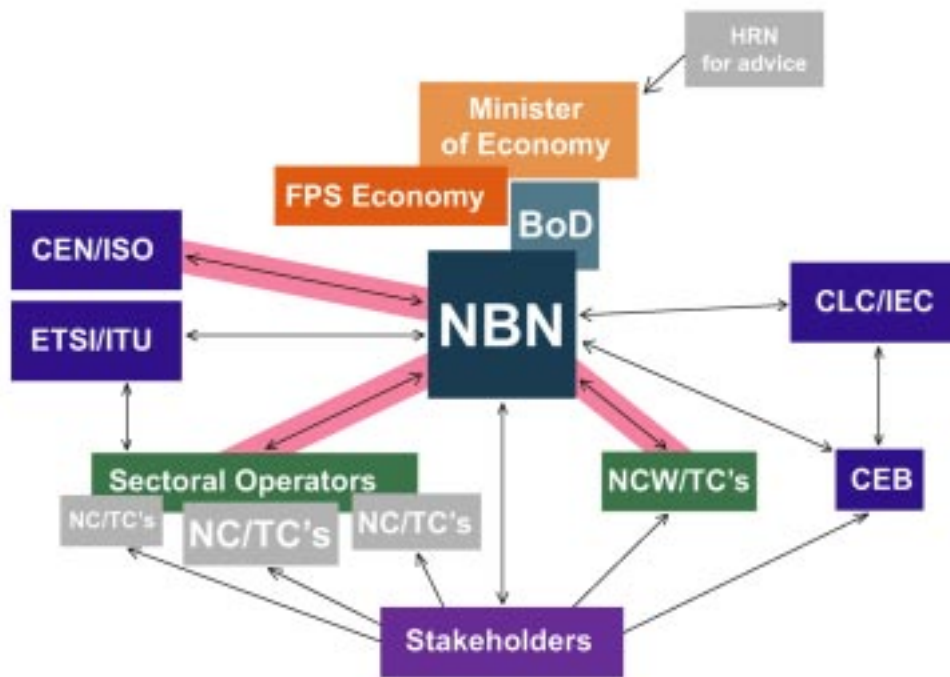
The rules of the specific Keymark system must include at least the following requirements:

- The requirement that the authorized certification bodies be located in a country covered by the members or affiliates of CEN / CENELEC.
  - The proof of the product's conformity to the requirements of the European standard(s) must be based on type tests in a third party laboratory.
  - The manufacturer must implement a quality system on the production line of his product for which the Keymark license is issued and which is based on quality standards of a level at least equal to the ISO 9000 series.
- By granting the license, the empowered certification body must take into account the existence of any certificate concerning the quality system issued by a certification body accredited by a member of the European cooperation for Accreditation (EA).
- Periodic monitoring by the empowered certification body including tests on samples from the production line or from commercial products, as well as monitoring of the manufacturer's quality system.

A description of this European certification system is given in the "CEN/ CENELEC Internal Regulations - part 4 - Certification".



# 7. The workings of standardization



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## Legend

HRN: Supreme Council for Standardization  
 BoD: Board of Directors  
 CLC: CENELEC  
 NC: National Committee under SO  
 NCW: National Committee without SO  
 TC: Technical Committee

 NBN - 2010





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