



# CENELEC GUIDE 3

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**Interrelation between regulations  
and standards Part 1: Reference to  
standards – The main ways of  
application  
Part 2: Harmonisation of regulations  
and reference to standards**

**Edition 1, 2001-01**

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The present document had been adopted on May 7<sup>th</sup> 1974 by the Council of the de facto association CENELEC and published as CENELEC Memorandum 1.

The 40<sup>th</sup> General Assembly of CENELEC (Prague 6/7 June 2000) decided to replace CENELEC Memoranda and Standing Documents by CENELEC Guides. As a result, CENELEC Memorandum 1 was converted into CENELEC Guide n° 3. No change was made to the text of the original document. CENELEC, however, has added footnotes whenever clarification or updating was needed.



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## **Foreword**

This CENELEC Guide is intended to clarify the relations between authority regulations and standards, a subject which gains increasing importance not only at the national level but also at regional level. At both levels governmental and standards organizations work together closely on harmonization matters.

This CENELEC Guide is based on the long experience in the electrotechnical field in the Western European countries and takes into account existing solutions which have proved to be adequate to the need of practice and to be flexible in their relation.

This CENELEC Guide is recommended for use in all discussions between authorities and standards organizations when they try to find appropriate solutions for interrelation between the regulations and the standards on various levels.

## **Interrelation between regulations and standards**

### **1. Introduction**

- 1.1 The governments and their representatives, i.e. the authorities, are responsible for the issuing of regulations with the aim to protect the citizens of their countries against certain dangers and inconveniences. These regulations most often concern safety, health and environment of the citizens. They may also concern consumer protection or prevention from fraudulent transactions, in the latter case for example by legislation on weights and measures.
- 1.2 At the same time the governments have an interest - or have even accepted as part of international agreements - to avoid such national regulations which are not internationally harmonized and thus may give rise to technical trade barriers.
- 1.3 Documents issued by governmental administrations, but not having the character of regulations, are not dealt with in this connection, e.g. specifications for direct use of these administrations in connection with their purchasing.

### **2. Regulation**

- 2.1 A regulation may be more or less detailed, for example from formulating the objectives in general terms to stipulating all the appropriate technical details. It may cover one or more aspects of the object and may also be restricted to one or a few ways of use of the object. The purpose of regulations may also be different as they sometimes aim at the benefit of the users (e.g. the safe use of electrical appliances), sometimes the benefit of a third party (e.g. the possibility for radiocommunication without disturbance from motor vehicles).
- 2.2 The text of regulations may be of different character, the most usual being:
  - a) The text has indicative character, which means that it indicates one of several possible solutions, e.g. a technical description not being the only one to satisfy the requirements.
  - b) The text may be of explicative character, which means that it is explaining a description. This is in general the case for definitions of terms, classification, and such test methods which form the basis for stipulating admissible limits and alike.
  - c) The text may be of repetitive character. Even if the text in itself is very specific, it may partly consist of facts taken from adjacent fields, e.g. a conventional limit for heat resistance.

### **3. Reference to acknowledged technical rules**

- 3.1 When an authority finds it not appropriate to give a fully detailed text in its regulation it can make a reference in a general form, e.g. to the "present state of technology" or alike. Most advantageous may be a reference to "generally acknowledged technical rules", together with an indication how the said rules are to be located and interpreted, but preferably not excluding "other acknowledged rules".
- 3.2 This type of reference is an extremely flexible method as it does not impair technical progress and gives the necessary margin for technical development.
- 3.3 A reference to acknowledged technical rules may be classified as a first step which can, in some cases, lead to a second step by an additional reference to a standard.

### **4. Incorporation in a regulation of the content of a standard**

- 4.1 When an authority has at its disposal a text in an existing standard which it finds necessary to quote, that text can be incorporated in a regulation. By this means the technical details can be transferred from a standard to a regulation. The authority transforms the incorporated technical text to be part of the regulation and assumes the same responsibility for the incorporated text as for all other parts of the statutory document.
- 4.2 Such incorporation offers the users the advantage of recognizing directly from the regulation the liabilities incumbent on them. This also applies to those persons supervising the observance of the regulations.
- 4.3 In case of incorporation, the relevant standards organization must safeguard that the incorporation does not interfere with its responsibility in the future preparation of standards. A standard may be applied to sectors other than those covered by the regulation and the standards organization must therefore be reasonably free, if and when so required, to revise or withdraw the standard in question.
- 4.4 The static legal nature of an incorporated text does only in rare cases correspond to a dynamic technical development in a field. The incorporation may sometimes bind for a long period the technical solution chosen. There are therefore risks that progress - technically and economically - is considerably humpered due to the difficulties arising when regulations have to be amended and completed.

## **5. The significance of reference to standards**

- 5.1 One of the legislative means at the disposal of an authority is to base a regulation on a standard, or to refer to a standard in a regulation, thus making a regulation more complete. The fundamental principles for using reference to standards in legislation or regulations are given in the ISO/IEC Code of Principles on "reference to standards" (1977). In this Code a summary is given of the advantages of using reference to standards as well as the fundamental measures to be taken for proper interrelations between on one side regulations and on the other side standards referred to. Some fundamental definitions are given in chapter 9.
- 5.2 By the reference to standards a regulation is kept free from more or less detailed technical provisions for which the usual standardization work is the more appropriate means for an optimum solution for all the parties concerned. The technique of standardization comprise a procedure for commonly agreed revision when justified with regard to the technical development and changes in conditions.
- 5.3 Reference does not mean delegation. The authority is entitled to cancel a reference at any time and replace it either by another reference, or by insertion of the necessary provisions into the regulation.
- 5.4 Different ways of reference to standards in regulations of administrative and technical character are possible and are presented in Part 1 of this document. Some additional aspects coming into the picture in case of harmonization between some countries, e.g. within a region, are given in Part 2.

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## Part 1

# The concept of reference to standards and the main ways of application

### 6. Intensity of commitment of a reference

6.1 The intensity of commitment of a reference may differ in various cases.

A reference can imply

unconditional application

conditional application

or

exclusive reference

indicative reference

6.2 Explanation of the terms

6.2.1 Exclusive reference

An exclusive reference means that the standard referred to must be followed in order to fulfil the aim of the regulation.

6.2.2 Indicative reference

An indicative reference means that one way of fulfilling the aim of a regulation is to follow a certain standard. It is admitted that there may be other ways of doing so, from the outset or in the future. Other solutions are possible, even if the solution according to the standard in practice will be the recommended one, more or less strongly.

If another solution is chosen by a person or a company they have to be prepared to prove that the solution fulfils the aim of the regulation to an extent equivalent to the solution described in the standard.

### 7. Identification of a reference

7.1 A reference to a standard may in the regulation be identified more or less rigidly

by number and edition (or date)

by 1) number only, or  
2) title only, or  
3) title and number

dated reference

non-dated reference

## 7.2 Explanation of the terms

### 7.2.1 Dated reference

7.2.1.1 In the case of dated reference the authority assumes full responsibility that a certain edition of the standard referred to is fulfilling the aim of the regulation. At the stage of publishing the regulation it is important that:

- a) the standard referred to is indicated precisely,
- b) the issuing of the standard referred to has been announced officially in a proper way.

7.2.1.2 By dated reference the progress of engineering may be impaired because of the difficulties to amend or complete simultaneously a regulation and the standard referred to. The use of dated reference also presupposes that the authority avails of sufficient expert knowledge in the relevant field.

### 7.2.2 Non-dated reference

7.2.2.1 In case of non-dated reference future amendments or completions of a given standard are made valid automatically. The standard is allowed to evolve according to the usual processes, and the validity of the reference is automatically transferred to the new edition.

7.2.2.2 The non-dated reference has the advantage over other types of reference that the regulation can be held to comply with the latest degree of development and that it does not itself need to be adapted to new findings. It will thus be possible to adjust only the standard to the latest findings taking account economical and practical views and with the least administrative formalities.

7.2.2.3 Non-dated reference should primarily be applied in cases where an authority wishes to cover a relatively large technical field by a regulation and where it can be sure that the responsible standards organizations are adequately active. Moreover, it is necessary that the balance of parties involved in the preparation (and in the revision) is maintained and that the public is kept sufficiently informed.

7.2.2.4 The use of non-dated reference cannot give rise to objections from the juridical point of view with the motivation that it makes the content of a regulation dependent on a standard not subject to sufficient influence of the authority. It must be reminded that an authority has the right to intervene at any time by means of new or revised regulations, if it finds that the use of the method is not working satisfactorily. This means that the authority always has the possibility of full control of items for which the non-dated reference is used or planned to be used.

7.2.2.5 The non-dated reference should preferably be of the indicative type, especially when a regulation together with its reference cannot pretend to give all appropriate solutions. If so used, the reference gives a reasonable freedom of choice between appropriate alternative solutions fulfilling the aim of the regulation.

## **8. Reference to acknowledged rules**

8.1 An authority may combine a reference in legal terms ("generally-acknowledged rules", "latest state of technology") with an additional reference to a certain series of standards ("reference to acknowledged rules and to unspecified standards"). The identification of the series of standards may be made by mentioning the series designation or the organization responsible for preparing and issuing the series.

8.2 Such additional references may be exclusive or indicative (see 6), in most cases and preferably indicative.

8.3 The series of standards referred to is deemed to give such technical rules which are interpreted as empirical indications for the application of the regulation, and in case of accident a court may consider them as being appropriate and complying with the latest technical development.

If a part of the series of standards is found applicable, but has not been followed, the supplier of the equipment has to prove that an infraction of the "generally-acknowledged rules" has not been committed.

8.4 An unspecified indicative reference means that a person or a company choosing another solution than those given in the series of standards has to prove that the solution falls within the margins of "generally-acknowledged rules" to an extent equivalent to the solution described in the standard.

## 9. Definition of terms

- 9.1 Regulation (legal or administrative regulation): A regulation fixed by law, or emanating from a body legally empowered, which is obligatory, whether generally or for a particular field.
- 9.2 Technical specification: A document fixing the technical characteristics of products. The technical specification includes among other things, terminology, safety, performance, dimensions, processes of manufacture, designation and marking, packaging, application.
- 9.3 Technical regulation: A legislative document which contains technical specifications.
- 9.4 Standard (technical standard): A technical specification drawn up by general agreement, approved by an organization which is generally acknowledged and available to the public. It is based on scientific findings, technology and experience with the aim of achieving the best general advantage.
- 9.5 Reference to standard: A reference, made by an authority in a regulation, to a standard issued by a standard organization.
- 9.6 Exclusive reference (to standard): A reference in a regulation stating that a certain standard must be followed in order to fulfil the aim of a regulation.
- 9.7 Indicative reference (to standard): A reference in a regulation stating that one way of fulfilling the aim of a regulation is to follow a certain standard.
- Remark: This statement may in reality mean a recommendation, the strength of which is depending on the case.
- 9.8 Dated reference (to standard): A reference in a regulation identifying by number and edition (or a date) a standard referred to.
- 9.9 Non dated reference (to standard): A reference in a regulation identifying only by number and/or title a standard referred to, and not the edition or date (which implies that further revisions of the standard will be automatically referred to from the date of issue).
- 9.10 Reference to acknowledged rules: A reference in general terms in a regulation, e.g. to "present state of technology" or "generally-acknowledged technical rules".
- 9.11 Reference to acknowledged rules and to unspecified standards: A reference to acknowledged rules materialized by an additional reference to a series of standards.
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## 10. Schematic presentation

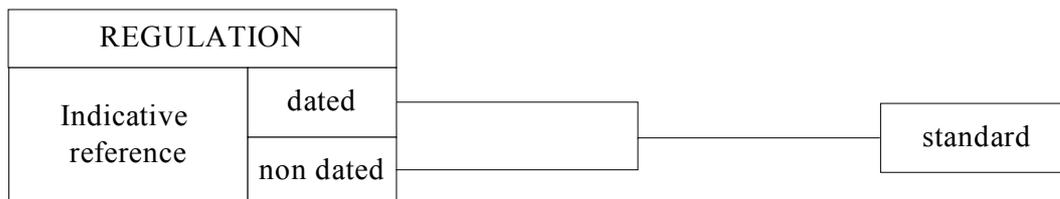
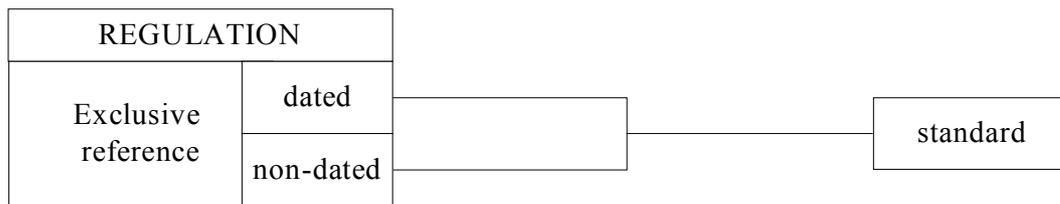
### 10.1 Self-contained regulations

REGULATION In general terms or technical details
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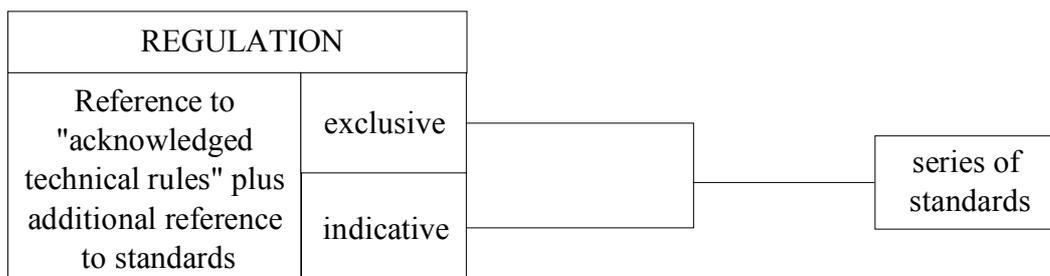
REGULATION Reference to “acknowledged technical rules”
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REGULATION Standards text incorporated, literally or in content
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### 10.2 Regulations containing reference to specified standards



### 10.3 Regulations containing reference to acknowledged rules and to unspecified standards



## Part 2

### Harmonization and reference to standards

#### 11. Introduction

11.1 As a mean to eliminate existing trade barriers between the member countries, insofar as they emanate from discrepancies in national regulations and standards, communities of states can refer to standards in their common directives, preferably to such standards which are harmonized between the member states.

Note: In case of the European Community, EC, the laying down of an aim by directives is assured according to Article 189, Paragraph 3 of the Treaty of Rome <sup>1</sup>.

11.2 The various possibilities of harmonization (total and optional), together with the relevant applications of reference to standards on the national level, are presented below.

11.3 Hindrances to the export of products to countries outside the community of states are not dealt with in this context.

#### 12. Total harmonization

12.1 Total harmonization means that an existing national regulation has the same content as a directive agreed upon within a community of states.

12.2 If and when total harmonization is reached, earlier existing technical trade barriers are removed, and the conditions of competition are the same for all member states. In individual cases, disadvantages at an initial stage may occur to those manufacturing, service etc, in the form of expenses for changes of production or service facilities.

12.3 At the initial stage of total harmonization there will normally be a transitional period during which both the regional and national regulations are valid, but this transitional period will be of short duration.

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<sup>1</sup> According to the Amsterdam Treaty (entered into force on 1 May 1999), Article 189 of the Treaty establishing the European Communities is renumbered Article 249.

### **13. Optional harmonization**

- 13.1 Optional harmonization means that in the countries there may exist - in parallel to a national regulation in concordance with a directive within a community of states - a national regulation having a technical content less rigorous than the directive.

In case of optional harmonization two different systems of technical specifications for a product may coexist in one or more member states.

One system is represented by the harmonized technical regulations and standards referred to. For products which are manufactured according to this system a free circulation within the community of states is assured.

A second system is represented by the still existing national technical regulations and standards referred to, the revision of which is left to the discretion of each member state. For products which are manufactured in accordance with this system, a free circulation is assured within the country of origin, but not necessarily in each of the other member states.

- 13.2 Optional harmonization gives a certain freedom of choice, but does not lead to one single market. In a country having national technical specifications differing from those harmonized there may exist two categories of products, the harmonized and the national. For the users this may be confusing, and sometimes a higher technical knowledge is required at the stage of choice.

A manufacturer can choose between making products in compliance with the requirements of either both systems or one of the systems. Manufacturing according to the more rigorous harmonized system is most often more expensive, but gives:

- the advantage of free export to the other member countries;
- the disadvantage of competition from such manufacturers in the own country, which manufacture according to the less rigorous national regulation.

### **14. Choice between total and optional harmonization**

For selecting the possibilities for harmonization, i.e. the total and the optional harmonization, the following should be considered:

- 14.1 The total harmonization should be aimed at in as many cases as possible in order to reach the same conditions in all member countries, so that practically one common market is achieved.

- 14.2 The optional harmonization is recommended in cases where a quick amelioration of the exchange of goods between the member countries has to be achieved and total harmonization would require a very long transitional period. At least in those cases where the exchange of goods between some of the member countries is essential a later total harmonization should be aimed at.

## **15. Harmonization and reference to standards**

There are different possibilities for combination between on one side the total and optional harmonization and on the other side the application of reference to standards.

- 15.1 Total harmonization combined with indicative reference to standards preferably a series of standards in the national regulations means that the common aim of the directive is fulfilled provided that national standards are harmonized.
- 15.2 When a directive gives safety requirements in general terms it could be implemented on the national level by a regulation in which a reference to acknowledged rules is combined with a reference to a series of standards. Harmonization is not reached unless these standards are harmonized.

