Enterprise and Industry Directorate-General

Directive on cableway installations designed to carry persons

Application guide

to Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons

European Commission

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1. Foreword

The EU Directive on cableways (also known as ropeways) is a product of the 'New Approach' legislative procedure, which provides for the introduction of comprehensive legal machinery based on 'essential requirements' guaranteeing a high level of protection. The responsibility of the public authorities is now limited to essentials, allowing enterprises wide scope in fulfilling their obligations.

The machinery is completed with the definition of standard procedures for establishing compliance with essential requirements. These procedures, referred to as modules, mainly involve those responsible for placing products on the market and the independent entities referred to as 'notified bodies'. This method is known as the Global Approach, since the procedures cover all types of products.

The cableways Directive fully reflects these principles. As a result, users conversant with this type of directive are on familiar ground, while a general Commission guide published in 2000 provides a valuable reference source for others ([1]).

At the same time, the present guide highlights a number of specific features arising from the fact that, with the exception of the smallest category, cableways are not a conventional product. Combining configuration elements which facilitate on-site integration, they are, in an inseparably linked manner, both infrastructure and means of transport. In classic forms of transport, the infrastructure (road, rail, ports or airports) can be easily distinguished from the carrier 'vehicle', which can travel between infrastructure sections with little or no difficulty. Lacking an on-board power source, cableway vehicles (also known as carriers) cannot function outside their installation.

This on-site integration, which is the distinguishing overall feature of these installations, means that the Member States are free to adopt their site-development rules and building and operating approval procedures, while the Directive regulates industrial production aspects and the corresponding market with reference

([1]) *Guide to the application of the directives based on the New Approach and the Global Approach*: http://europa.eu.int/comm/enterprise/newapproach/newapproach.htm

to the twin elements of safety components and subsystems. These two basic concepts are defined in the Directive. The most original aspect, that of the subsystem, is fleshed out in Annex I.

The Directive is designed to ensure the safety and free movement of cableway components by harmonising passenger safety and protection requirements. Its two fundamental objectives are passenger safety and the creation of a single market.

The Guide is intended to provide a reference source for both economic operators seeking entry to the single market and the competent regulatory authorities, but does not replace or amend the Directive, which remains the sole binding legal instrument.

The information addressed to the 25 EU Member States in this Guide also applies to Iceland, Liechtenstein and Norway as signatories to the agreement on the European Economic Area (EEA). The extension of the single market to the entire EEA ensures that its member countries and their economic operators have the same rights and obligations as their EU counterparts.

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2. Objectives and recitals of the Directive

The recitals preceding the body of the Directive, which are discussed below, have no intrinsic legal value. At the same time, they provide a coherent picture of the entire text and give effect to Article 253 of the Treaty which reads '… directives … shall state the reasons on which they are based …'. They define the ultimate objective of the text and clarify its precise meaning.

The accompanying observations make it possible to highlight:

- the general principles underlying the New and Global Approaches;
- the specific features of the sector and installations concerned, which may be important for a clear understanding and correct application of the Directive;
- the ultimate objective of the Directive, namely to ensure the free movement of safety components and subsystems which comply with its provisions and, consequently, guarantee a high level of safety.

The relationship between a recital and the corresponding Directive Article will be noted whenever a direct link exists. To facilitate understanding each recital has been assigned a keyword title.

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty establishing the European Community, and in particular Articles 47(2), 55 and 95 thereof,
Having regard to the proposal from the Commission (1),
Having regard to the opinion of the Economic and Social Committee (2),
In accordance with the procedure provided for in Article 251 of the Treaty (3),
Whereas:

Purpose

(1) Cableway installations designed to carry persons (hereinafter referred to as 'cableway installations') are designed, manufactured, put into service and operated with the object of carrying persons. Principally, cableway installations are mountain lift systems used in high-altitude tourist resorts and consisting of funicular railways, cable cars, gondolas, chairlifts and drag lifts, but may also consist of cableway installations used in urban transport facilities. Some types of cableway installation may use other, completely different basic principles which cannot be excluded a priori. Therefore, provision should be made for introducing specific requirements designed to achieve the same safety objectives as those laid down in this Directive.

Another Directive deals with lifts ([2]), a related technology developed in parallel, and the two instruments are mutually exclusive in scope, as Article 1(6) of the present Directive points out.

Tourism and industry

(2) Cableway installations are principally operated in connection with tourism, particularly in mountain areas, which plays an important role in the economy of the regions concerned and is becoming an increasingly important factor in the trade balances of the Member States. From a technical point of view, the cableway installations sector also ranks among the industrial activities linked to the production of capital equipment and to activities in the building and civil engineering sector.

The Directive focuses on the main concern of the market, namely industrial equipment. The infrastructure and civil engineering elements are distinguished from the rest of the installation comprising capital equipment. The difference in treatment is important and justified, since the respective markets have very little in common. For example, infrastructure is built and monitored on site, whereas capital equipment is always accompanied by a variety of documents - particularly certificates of conformity with the relevant requirements. Nevertheless, certain common safety principles remain.

Non-harmonised national regulations

(3) Member States are responsible for ensuring the safety of cableway installations at the time of manufacture, putting into service and during operation. Moreover, they

([2]) European Parliament and Council Directive 95/16/EC on the approximation of laws of the Member States relating to lifts, OJ L 213, 7.9.1995.

are responsible, together with the competent authorities, for such matters as land-use, regional planning and environmental protection. National regulations differ widely as a result of techniques peculiar to the national industry as well as local customs and knowhow. They stipulate specific dimensions and devices and particular characteristics. In the light of these circumstances, manufacturers are obliged to redefine their equipment for each market. This makes it difficult to provide standard solutions and adversely affects competitiveness.

Essential safety

(4) The essential health and safety requirements must be observed in order to ensure that cableway installations are safe. Those requirements are to be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.

Cross-frontier installations

(5) Further, cableway installations may straddle frontiers and the construction thereof may run up against conflicting national rules.

Creating a single market

(6) Steps should be taken to define, on a Community-wide basis, essential human safety and health requirements, environmental protection and consumer protection requirements applicable to cableway installations, subsystems and their safety components. Without this, mutual recognition of national regulatory provisions would create insoluble political and technical difficulties as regards interpretation and liability. By the same token, standardisation without prior definition of harmonised regulatory requirements is not sufficient to solve the problems.

The stakes (personal safety, the environment, consumer services, etc.) are such that voluntary standardisation in the absence of a stringent legal framework would not suffice. The Directive therefore seeks to create conditions leading to the establishment of a single market in safety components and subsystems for cableways. This will enable small and medium-sized enterprises in particular to have access to the EU market.

Essential market transparency and confidence

(7) Responsibility for approving cableway installations is generally vested in a service of the competent national authorities; in certain cases, approval of the components cannot be obtained beforehand but only when the customer applies for such approval. By the same token, the requisite inspection of the cableway installation prior to its entry into service may result in the rejection of certain components or in diverse technological solutions. Such a state of affairs leads to increased costs and longer delivery periods and is particularly penalising for foreign manufacturers. Moreover, cableway installations are also carefully monitored by the public services

when they are operational. The causes of serious accidents may be linked to the choice of site, to the system of transport itself, to the structures, or to the way in which the system is operated and maintained.

Common high level of safety

(8) *In these circumstances, the safety of cableway installations depends equally on the surrounding conditions, on the quality of the industrial goods supplied and on the way in which they are assembled, installed on site and monitored during operation. This underlines the importance of having a general overview of cableway installations in order to assess the level of safety and of adopting a common approach at Community level to quality assurance. In these circumstances, in order to enable manufacturers to overcome their present difficulties and in order to enable users to derive the full benefit from cableway installations and to enjoy an equal level of development in all Member States, a set of requirements should be defined, together with control and inspection procedures to be applied uniformly in all Member States*

(9) *Persons using cableways, from all Member States and beyond, must be ensured a satisfactory level of safety. In order to meet this requirement, it is necessary to define procedures and examination, control and inspection methods. This necessitates the use of standardised technical devices which must be incorporated in cableway installations.*

The environment and sustainable tourism

(10) *Where Council Directive 85/337/EEC so requires, the effects of cableway installations on the environment must be assessed; above and beyond the effects mentioned in that Directive, both environmental protection and requirements in connection with the sustainable development of tourism should be taken into account.*

Point 10(c) of Annex II to the above-mentioned Directive refers to mechanical ski-lifts in general and cable cars specifically ([3]). It is for Member States to define the criteria establishing the need for such assessment.

The Directive with which this guide is concerned governs the design, construction and operation of cableway transport installations, including maintainability and operability. It does not cover the corresponding choice of location, which is likewise not considered by harmonised European standards. It is for the competent authorities of the Member States to authorise the siting of installations, which is the reason for having the prior authorisation procedure, the details of which remain the responsibility of the individual Member States (see Article 11(1)).

([3]) Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment. OJ L 175, 5.7.1985.

Public contracts

(11) Cableway installations may come within the scope of Council Directive 93/38/EEC of 14 June 1993 coordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors.

Directive 93/38/EEC was replaced by Directive 2004/17/EC of 31 March 2004([4]). Cableway transport may fall within the scope of the new Directive if the operational conditions (route, capacity, frequency) are fixed by a competent authority and are not exclusively dependent on free enterprise and competition. However, this is not the case in all Member States; in some, operating companies are quite free in their choice of route, capacity and timetable.

Technical specifications and contracts

(12) Technical specifications should be included in the general documentation or specifications accompanying any contract. Those technical specifications must be defined by reference to European specifications where such specifications exist.

Contracts for cableways are transactions in which demand is created by professional purchasers ('main contractors' - frequently the future operators) who often select constructors by competition. In such cases, demand takes the form of public or private invitations to tender (usually the latter). Use of these European specifications, of which harmonised standards provide a good example (see Article 2), promotes contract transparency and the recognition of required safety levels.

Harmonised EU standards

(13) In order to make it easier to prove that the essential requirements have been complied with, it is useful to have harmonised European standards, compliance with which enables it to be presumed that the product is in conformity with the said essential requirements. Harmonised European standards are drawn up by private bodies and must retain their non-mandatory status. For this purpose, the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are recognised as the bodies competent to adopt harmonised standards that follow the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984.

The established machinery for the application of New Approach directives should be used. The EU legislator defines specific political objectives by laying down the detailed essential requirements that a manufacturer must observe to comply with the legislation. At the same time, the Commission can ask the European standardisation organisations to draw up harmonised EU standards as the basis for compliance with the essential requirements. Such standards, whose use remains voluntary, supplement the legislation, by fleshing out the essential requirements laid down by the EU legislator with technical specifications.

The application of harmonised standards under a New Approach directive is a way of demonstrating, without other special justification, compliance with the essential requirements (see Recital 15). However, other specific evidence (safety studies, other

([4]) OJ L 134, 30.04.2004, p.1.

standards, testing, etc.) can also be advanced to establish the conformity of the installation. Harmonised standards are not mandatory. While compliance with harmonised standards implies the presumption of conformity with the essential requirements, failure to comply with a standard does not imply non-observance of a requirement.

(14) *For the purposes of this Directive, a harmonised standard is a technical specification (European standard or harmonisation document) adopted by one or other of those bodies or both at the request of the Commission pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services and in accordance with the general guidelines referred to above. In relation to standardisation, the Commission should be assisted by the committee referred to in that Directive, which will, if necessary, consult technical experts.*

The Commission asked the Technical Committee 242 (TC 242) to provide a set of standards (see Appendix III), compliance with which would entail a presumption of conformity with the essential requirements, thereby creating a statute of harmonised standards.

Presumption of conformity

(15) *Only safety components or subsystems of an installation which conform to a national standard transposing a harmonised standard, the reference of which has been published in the Official Journal of the European Communities, are deemed to conform to the relevant essential requirements of this Directive, regardless of the need for any special justification.*

This represents a general principle under the New Approach and this recital merely restates the legal advantage of conformity with harmonised standards (see Article 3(2)).

Nor should it be concluded from this wording that harmonised standards which have not yet been transposed are not valid or that a component cannot be evaluated in the absence of harmonised standards or by direct reference to the essential requirements even when a harmonised standard exists.

Primacy of the essential requirements

(16) *In the absence of European specifications, the technical specifications should, as far as possible, be defined by reference to other standards in use in the Community. Main contractors may define the additional specifications needed to supplement European specifications or other standards. These provisions must ensure that the harmonised Community-level requirements with which cableway installations must comply are satisfied.*

There are two aspects to this recital, namely the absence of European specifications and the definition of specifications by main contractors.

The additional specifications are the responsibility of the main contractor (and of him only), who must take due account of the essential requirements. It would be

contrary to both the spirit and letter of the Directive for the authorities to draw up additional specifications, since this would impede free movement.

On the other hand, after considering what is required, the main contractor may be led to propose specifications which depart from the existing standards with regard to such aspects as technical performance, technology or maintenance. Such additional specifications are acceptable insofar as they do not create market barriers.

International dimension of standardisation

(17) *It is, moreover, in the interest of the Member States to have an international standardisation system capable of producing standards which are actually used by international trading partners and satisfy the requirements of Community policy.*

Uniform assessment procedures

(18) *In certain Member States at the moment in the general documentation or specifications peculiar to each contract, main contractors may indicate the control and inspection procedures. Those procedures must in future, notably in the case of safety components, fall within the framework of the Council Resolution of 21 December 1989 ([5]) concerning a global approach to conformity assessment. The concept of safety component applies not only to physical objects but also to intangible objects such as software. The procedures for assessing the conformity of safety components must be based on use of the modules provided for in Council Decision 93/465/EEC ([6]). In the case of critical safety components, the principles and conditions for the application of design quality assurance should be defined; such an approach is necessary in order to promote the general adoption of the quality assurance system in undertakings.*

The Directive is subject not only to the New Approach but also to the Global Approach. The latter entails the use of pre-established methods to assess the conformity of products, in this case safety components of cableways. These methods are now widely employed and involve notified bodies, i.e. competent and independent bodies notified by Member States (see Article 16).

Three aspects of this recital should be stressed:

- The conformity of safety components is assessed by traditional methods using modules under the Global Approach (see Article 7 and Annex V).

- Special provisions apply to full quality control (see Annex V, Module H). The importance of quality control is taken into account more generally, thereby facilitating or simplifying the notified bodies' assessment procedures.

- The general introduction of quality-control systems within enterprises called for during the drafting of the Directive has now largely been completed for all activities (design and execution). This inevitably influences the choice of modules.

([5]) OJ C 10 of 16.1.1990.
([6]) OJ L 220 of 30.8.1993.

Safety analysis

(19) When conducting methodical safety analysis of cableway installations, it is necessary to identify the components on which the safety of the cableway installation depends.

This Directive provides for the compulsory safety analysis of cableways, which has so far only been practised in certain Member States and has often been limited to special installations.

Fields of use

(20) In their contractual documents, main contractors lay down, by reference to European specifications, the characteristics which manufacturers are under a contractual obligation to observe, particularly for safety components. In these circumstances, the conformity of the components is linked principally to their field of use and not solely to free movement on the Community market.

The field of use of all components is not limited to their characteristics (speed, capacity, etc.), but also covers their functions and essential or possible interfaces with other components. If this field were not defined and complied with, the overall safety of the installation, which is the goal of the essential requirements, might not be guaranteed.

CE marking of safety components

(21) Safety components should bear the CE marking to be affixed either by the manufacturer or by his authorised representative established within the Community. The CE marking means that the safety component complies with the provisions of this Directive and those of other applicable Community Directives on CE marking.

CE marking is covered by Article 18 of the Directive together with Annex IX. It must be accompanied by the EC declaration of conformity provided for by Article 7. CE marking confirms that the product, in this case the safety component, complies with all relevant EU provisions and has undergone appropriate conformity assessment As a result, the Member States may not restrict the marketing and use of safety components bearing the CE marking unless this is justified by evidence of non-conformity of a component already on the market pursuant to Article 14 of the Directive.

Absence of subsystem marking

(22) It is not necessary to affix the CE marking to subsystems subject to the provisions of this Directive, but, on the basis of the assessment of conformity following the procedures laid down for this purpose in this Directive, the declaration of conformity will suffice. This is without prejudice to the obligation incumbent on manufacturers to affix the CE marking to certain subsystems in order to certify that they conform with other Community provisions applicable to them.

Most subsystems are put into circulation as separate parts originating from a variety of suppliers prior to their assembly when the installation is erected. This makes it impossible to mark subsystems as such.

The exemption applies to the CE marking alone; subsystems remain subject to the other obligations and the assessment and declaration of conformity.

The reservation concerning the possible application of other directives clearly reveals the cumulative nature of the requirements laid down in such instruments.

Safeguard clause for the Member States

(23) Member States' responsibility for safety, health and other aspects covered by the essential requirements on their territory must be recognised in a safeguard clause providing for appropriate Community procedures.

This is an important requirement: the European Union defines essential safety requirements as a basis for the creation of a single market. The Member States must monitor the components and subsystems market and retain responsibility for the safety of the installations constructed on their territory. Appropriate safeguard clauses therefore have to be introduced to enable the Member States to perform their duties and allow the Commission to examine the validity of measures taken by the national monitoring authorities (see Article 14).

Verification of subsystems

(24) A procedure is necessary for the inspection of subsystems of cableway installations before they are put into service. Such inspection must enable the authorities to satisfy themselves that at each stage of the design, manufacturing and entry into service the result obtained conforms with the applicable provisions of this Directive. This must enable manufacturers to count on equal treatment, irrespective of the Member State in question. The principles and conditions governing EC verification of subsystems of installations should therefore be defined.

This recital represents a response to a particular feature of the the sector in question. The national authorities remain responsible for the safety of the installations on their territory (see Article 11) and retain the necessary powers to this end (procedures and authorisations for new installations, inspection and possible shutdown of existing installations). In particular, it should be stressed that the integration of subsystems which satisfy the relevant essential requirements, does not necessarily mean that the installation itself complies with those essential requirements.

Subsystems are assessed by notified bodies (see Article 10) in accordance with the procedure described in Annex VII. Pursuant to this, the manufacturer, who may in fact have a major role to play in assembly, must issue an 'EC' declaration of conformity. There is a clear parallel here with the assessment procedure for safety components, even though it is true that the subsystem is sometimes assessed not before but after it has been assembled in the installation: this is why the manufacturer's conformity assessment declaration is sometimes made after assembly in the installation (see Chapter III).

Operational safety

(25) The constraints linked to the operation of cableway installations must be taken into account in the safety analysis, albeit not in such a way as to jeopardise the principle of free movement of goods or the safety of cableway installations. Consequently, although this Directive does not cover the actual operation of cableway installations, the Commission should propose to the Member States a series of recommendations designed to ensure that such installations situated on their territory are operated in such a way as to offer users, operating personnel and third parties a high degree of protection.

The Directive covers neither the operation nor the maintenance of installations, but account should be taken at the design and construction stages (both covered by the Directive) of the maintainability and operability of the installations (see Article 1(5)). Since this aspect essentially depends on installation configuration, these constraints need to be examined in each individual case.

Innovation

(26) In the case of cableway installations, full-scale tests can be carried out on technological innovations only on the construction of a new installation. In these circumstances, a procedure should be provided for which, while ensuring that the essential requirements are complied with, also enables special conditions to be established.

The Directive seeks to avoid any rigidity in application which could impede innovation (see Article 11(3)). The national authorities have always refused to approve innovations in passenger transport until numerous precautions have been taken and guarantees provided. These include provisional operation, at a reduced performance level, to allow the execution of lengthy on-site tests. Clearly, the essential requirements must be satisfied and the special measures must not create market obstacles; hence, the arrangements made in the context of the building authorisation and installation commissioning procedures (see Chapter IV).

Transitional position and modification of existing situation

(27) Cableway installations for which authorisation has been given but in connection with which building work has not yet started or which are already under construction must comply with the provisions of this Directive, unless Member States decide otherwise, giving their reasons, and an equally high level of protection is achieved. The provisions of this Directive must be complied with where existing cableway installations are modified if national legislation requires such modifications to be authorised.

The first part of this recital refers to the transitional situation which could have arisen when the Directive finally entered into force, that is essentially after 3 May 2004. Article 20 of the Directive defines the arrangements applicable to the installations concerned which are all known since they have received a building approval.

Afterwards, the rule laid down in Article 1(4), last indent, of the Directive fully reflects the second part of this provision and is discussed below.

Equivalent operational safety for all installations

(28) It is not necessary to require all existing cableway installations to be brought into conformity with the provisions applicable to new installations. However, this may prove necessary if the essential safety objectives are not complied with. In that event, the Commission should propose to the Member States a series of recommendations designed to ensure that existing cableway installations on their territory afford users a high degree of protection in the light of the provisions applicable in this field to new installations.

This recital reflects the obvious concern of passengers, who are the final consumers, and the general goal of a high level of safety pursued by the European Union and its institutions. In this context, the Commission can make 'recommendations' to the Member States in order to guarantee a high level of safety of existing facilities with the aim of meeting essential objectives.

Coordination of notified bodies

(29) Particularly in the absence of a European specification, the notified bodies responsible for procedures for assessing the conformity both of safety components and of subsystems of cable installations must coordinate their decisions as closely as possible. The Commission must ensure that they do so.

Many installations will incorporate components and subsystems that have been evaluated by different notified bodies. It is obviously very important for assessments to be sufficiently uniform to reveal compatibilities and incompatibilities and for the necessary confidence in the work done to avoid interruptions and duplication of activity resulting in delays, additional costs and confusion.

In conjunction with the Member States, the Commission endeavours to establish close cooperation between the notified bodies with a view to ensuring the consistent technical application of conformity assessment procedures. To this end, the notified bodies covered by this Directive meet to coordinate their activities and devise coherent methods so that all their investigations can be based on the same techniques and produce comparable results (see Article 16).

Advisory committee

(30) Implementation of the essential requirements, particularly with regard to the safety of the installation, and the coordination of all procedures, call for the establishment of a committee.

This recital refers to the standing advisory committee set up to promote cooperation between national administrations in applying the essential safety requirements and other Directive provisions (see Article 17).

Implementing measures

(31) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 ([7])laying down the procedures for the exercise of implementing powers conferred on the Commission

The Treaty establishing the European Community assigns the Commission executive and legislative responsibility at EU level. For this Directive, the Commission is assisted by the advisory committee referred to in the preceding recital, which operates in accordance with rules already laid down in the above-mentioned 'committee procedure' Decision (see Article 17).

([7]) OJ L 184 of 17.7.1999.

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3. Provisions of the Directive

The provisions of the Directive are set out in nine titled chapters and 23 articles. Some articles are divided into numbered paragraphs and unnumbered sub-paragraphs. To facilitate the reading of, and reference to, the provisions of this text, the principal subdivisions are preceded by notes or brief explanations.

CHAPTER I General provisions

Comprising Articles 1 to 4, this chapter covers definitions, lays down the scope of the Directive and stipulates the obligations to meet the essential requirements and conduct a safety analysis.

Article 1

Scope

Article 1 contains six paragraphs, which together define and clarify its scope.

1. This Directive shall apply to cableway installations designed to carry persons.

2. For the purposes of this Directive 'cableway installations designed to carry persons' shall mean installations made up of several components that are designed, manufactured, assembled and put into service with the object of carrying persons.

These on-site installations are used for the carriage of persons in vehicles or by towing devices, for which the suspension and/or traction is provided by cables positioned along the line of travel.

The cable and the passenger transport objective are the essential determinants of scope. In addition to being carried, passengers may be towed, as in the case of drag lifts.

3. *The installations concerned are:*

a) funicular railways and other installations with vehicles mounted on wheels or other suspension devices for which traction is provided by one or more cables;

Although funicular railways mainly operate on wheels supported by rails, air-cushioned installations also exist.

'Inclined lifts' designed in accordance with the provisions of Directive 95/16/EC, need not also comply with the present Directive, being expressly excluded by paragraph 6 of this article.

b) cable cars where the cabins are lifted and/or displaced by one or more carrier cables; this category also includes gondolas and chairlifts;

These are all installations in which vehicles and their passengers are suspended by one or more cables; they are sometimes referred to as 'aerial tramways'.

c) drag lifts, where users with appropriate equipment are dragged by means of a cable.

Passengers are generally towed over snow, although plastic carpeting or even grass surfaces are possible. Instead of skis or skates, passengers may use wheeled equipment (bicycles, scooters, rollers) or sledges. This category also includes small ski tows for which the cable is within arm's reach, which are known as 'rope tows' in some Member States.

4. *This Directive shall apply to:*

Cableways are inseparably linked infrastructures and industrial products. This fact leads the Directive to present a hierarchical product breakdown covering the concepts of installations, subsystems and safety components, in which the whole does not possess the same characteristics as its parts and each part is subject to separate rules (see Chapter II – Safety components, Chapter III – Subsystems and Chapter IV - Installations).

installations built and put into service, as from its entry into force,

The initial operation of the installation by the final user on EU territory is generally considered to constitute entry into service. As it involves the carriage of passengers, an activity very often regulated at national level as will be seen in Article 11 below, it thus depends on an operating authorisation.

subsystems and safety components placed on the market, as from its entry into force.

Placing on the market is the initial action of making available a component or subsystem on completion of the manufacturing process with a view to its distribution

or use on EU territory. Products may be made available against payment or free of charge. The concept applies to individual products and not to a product type, whether singly manufactured or mass-produced.

'Placing on the market' should be carefully distinguished from the concept of 'sale'. A product is considered as placed on the market, either when it is physically transferred or after ownership has been transferred, irrespective of the legal instrument governing the transfer of ownership (loan, gift, sale or hire). Stocks of safety components and subsystems which were still held by manufacturers on 3 May 2004 and which have not yet been released for distribution or use, have not yet been placed on the market. In this case, if these stocked products come under the scope of the Directive (see below for the exceptional case of spare parts), they must comply with the essential requirements of the Directive when they are placed on the market.

There is no 'placing on the EU market' in the following cases:

– safety components or subsystems that are exhibited (here, a visible indication must make clear that the item in question cannot be placed on the market until conformity has been established);

– components or subsystems released by a third-country manufacturer to an authorised representative established in the EU who is responsible for establishing conformity;

– components or subsystems manufactured in a Member State but intended for export to a third country;

– components or subsystems simply held in store by the manufacturer;

– components or subsystems released to another manufacturer responsible for further operations (assembly, processing, etc.).

The latter case will obviously arise frequently in view of the complexity of the installations and the time required for assembly. Conformity assessment can therefore take place during assembly, although certain operations, such as the testing of new subsystems, can only be carried out when this is completed.

It concerns such harmonisation provisions as are necessary and sufficient in order to ensure and guarantee compliance with the essential requirements referred to in Article 3(1).

This defines the scope of the Directive which, as always under the New Approach, restricts legislative harmonisation to the essential requirements to be satisfied by safety components, subsystems and installations.

In the event that important characteristics, subsystems or safety components of existing installations undergo modifications for which a new authorisation for entry into service is required by the Member State in question, such modifications and their repercussions on the installation as a whole must satisfy the essential requirements referred to in Article 3(1).

In other words, a significant modification will necessitate a 'bringing into conformity' limited to the modified part and its consequences for the remainder of the in-

stallation. The safety components and subsystems in question must then be subjected to the same procedures as for new installations in order to establish their compliance with the essential requirements. However, the safety components and subsystems of existing installations which have not been significantly altered do not have to be brought into compliance with the Directive (see Appendix I, point 5).

The concept of 'significant' or 'important' is not defined other than by the procedure for the return to service. This normally implies that the configuration of the installation has been modified; for example, such developments as an increased level of installation safety, increased speed, the replacement of vehicles by a new model or the replacement of a counterweight by a hydraulic system could represent significant modifications.

On the other hand, spare parts for existing installations are not automatically subject to a conformity assessment and need not necessarily be accompanied by corresponding certificates prior to being placed on the EU market. This applies to components or subsystems that are identical, or at least similar, to the original item provided exclusively as a replacement part in the context of normal maintenance, thereby obviating the need for a new authorisation covering entry into service. These components and subsystems may continue to be governed by national rules (see also Appendix I, point 8)

As will be seen below, it is for the Member States to take the necessary measures to ensure the safety of all operating installations and, consequently, to monitor the application of this clause as regards both modifications necessitating a new operating authorisation and verification of the replacement of components or subsystems under satisfactory conditions in the context of maintenance.

5. *For the purposes of this Directive:*

– *'installation' shall mean the entire on-site system, consisting of infrastructure and the subsystems listed in Annex I where infrastructure specially designed for each installation and constructed on site shall mean the layout, systems data, structures along the line and station structures required for the construction and operation of the installation, including the foundations,*

The Directive is based on a distinction between safety components, as defined in the following indent, infrastructure and the subsystems listed in Annex I and, finally, installations.

Subsystems and infrastructure are distinguished because subsystems can be regarded as commercial items, subject to rules governing the free movement of goods. The distinction must be made with great care, since subsystem conformity will be assessed by a notified body pursuant to Annex VII of the Directive, whereas infrastructure and installations remain the responsibility of the Member States.

Infrastucture covers all concrete elements cast on site and fixed structures not forming part of a subsystem. Annex I clearly explains the possible demarcation between certain types of mechanical equipment and infrastructure. While the latter excludes safety components within the meaning of the Directive, it may well be entirely or partially important for installation safety.

– *'safety component' shall mean any basic component, set of components, subassembly or complete assembly of equipment and any device incorporated in*

the installation for the purpose of ensuring a safety function and identified by the safety analysis, the failure of which would endanger the safety or health of persons, be they users, operatives or third parties,

The correct understanding of the Directive hinges on this definition.

Two aspects should be considered:

- on the one hand, a safety component is not necessarily a basic element but can be a group of components or even a complete set of equipment;

- on the other, a component is said to be a 'safety' component if it is installed for the purpose of ensuring a safety function, namely helping to maintain installation safety.

The 'safety' component (whether basic or a set of parts) must be classified as such and the classification recorded in the safety analysis (see Article 4).

– *'main contractor' shall mean any natural or legal person who commissions the construction of an installation*

The main contractor defines the objectives of the construction operation, frequently acting through a representative. Some national legislation requires the appointment of an approved representative.

The main contractor has a role to play from the design stage onwards and the Directive defines certain aspects of this.

– *operability' shall mean all the technical provisions and measures which have an impact on design and realisation and are necessary in order for the installation to operate safely,*

The distinction between operability and operation is important, since the Directive does not apply to operation which the Member States are responsible for monitoring.

Technical provisions and measures relating to the operability of an installation are directly dependent on its configuration and should be defined at the start of the project (e.g. displaced controls, emergency shutdown switches).

– *'maintainability' shall mean all the technical provisions and measures which have an impact on design and realisation and are necessary for maintenance designed to ensure that the installation operates safely.*

The distinction between maintainability and maintenance is similary important since, by analogy with operations, the Directive does not apply to maintenance which the Member States are responsible for monitoring. Technical provisions and measures relating to the maintainability of an installation are directly dependent on its configuration and should be defined at the start of the project. (e.g. suitable access to equipment requiring maintenance in the light of probable servicing frequency; installation of subsidiary systems).

6. This Directive shall not apply to:

– *lifts within the meaning of Directive 95/16/EC,*

The exclusion is categorical, although the features of certain installations may give rise to some uncertainty, as inclined lifts could also be considered as small funiculars. The application of the relevant legislation will rely on a joint case-by-case examination between the main contractor, the authorities and the manufacturer. The constructor will then know which requirements have to be satisfied, regardless of the technical solutions adopted. This single decision covers the whole installation.

– *cable-operated tramways of traditional construction,*

– *installations used for agricultural purposes,*

– *on-site or mobile equipment for use in fairgrounds and/or amusement parks which is designed for leisure purposes and not as a means for transporting persons,*

The distinction was made not only on technological grounds but also with reference to installation goals, i.e. transport or leisure activities.

Because of the large area covered, leisure or exhibition parks are frequently equipped with cableways in a strict sense and these are subject to the Directive.

– *mining installations or on-site installations used for industrial purposes,*

Mining installations are subject to specific regulations in the Member States.

With regard to installations constructed and used for industrial purposes, exclusion depends on the dual conditions of location and use.

– *cable-operated ferries,*

Boat lifts, whether or not carrying passengers, are also excluded.

– *rack railways,*

The need for exclusion may seem obvious given that rack railways do not make use of cables. Nevertheless, since the two technologies, i.e. cable (funicular) and non-cable (rack railway), have often been applied in the same context under the supervision of the same authorities, they have frequently been equated from the legal standpoint.

– *chain-driven installations.*

Article 2

European specifications and harmonised standards

This article, which appears in all New Approach directives, refers to several concepts and principles peculiar to the approach including, in particular, the simultaneous application of several directives, essential requirements, technical specifications and harmonised European standards. The last paragraph sets out the procedure to be followed in the event of objections to European specifications, and especially to harmonised standards. Some of these concepts will be considered in greater detail in the comments on the following articles.

1. *This Directive shall apply without prejudice to other Community Directives, although compliance with the essential requirements laid down in this Directive may call for the application of special European specifications established for that purpose.*

The New Approach directives are designed to protect the public interest by covering risks linked to a product. The first clause of this paragraph recalls that safety components, subsystems or installations may be subject to several directives, covering different types of risk. The manufacturer is responsible for ensuring conformity with all relevant directives for the purpose of placing a product on the EU market.

A particular feature of New Approach directives is that the essential requirements specify only target results relating to the public interest or risk management without proposing technical solutions for their attainment. At the same time, the second clause highlights a possible need to supplement essential requirements, which do not contain any detailed manufacturing provisions, with European technical specifications.

2. *'European specification' shall mean a common technical specification, European technical approval or a national standard transposing a European standard.*

This paragraph lists the different types of specification which exist in practice, including harmonised European standards. Common technical specifications and European technical approvals are unknown in cableways. On the other hand, European standardisation in this field, begun well before the appearance of the Directive and adopted within its framework, correlates closely with its scope (see Appendix III).

European or harmonised standards are technical specifications adopted by the European standardisation bodies on the basis of a Commission mandate. Thus, CEN was asked to draw up harmonised standards following the Directive's adoption. The CEN/TC 242 technical committee, set up in 1990, was instructed to implement the standardisation programme (see Appendix III) in the light of the requirements arising from the Directive.

While the Directive favours European standards as an means of ensuring compliance with the essential requirements, their use is not mandatory (see Appendix I, point 1).

3. *The references of European specifications, which may be common technical specifications, European technical approvals within the meaning of Directive 93/38/*

EEC or national standards used to transpose harmonised European standards, shall be published in the Official Journal of the European Communities.

To ensure legal validity, the references of these standards must be published in the OJEU ([8]), since such identification is the first condition enabling harmonised standards to confer a presumption of conformity with the essential requirements of the Directive (see Article 3). Publication of the reference in the OJEU is designed to fix the date from which the presumption of conformity will apply.

4. *Member States shall publish the references of national standards used to transpose harmonised standards.*

The second condition enabling a harmonised standard to confer a presumption of conformity with the essential requirements is its unaltered transposition at national level. It does not, however, have to be transposed in all the Member States for this condition to be satisfied. Since national standardisation bodies must make harmonised standards available to all interested parties, the manufacturer can choose any of the corresponding national standards and still benefit from the presumption of conformity.

5. *In the absence of harmonised European standards, Member States shall take the necessary measures to inform the parties concerned of those existing national standards and technical specifications which are regarded as important or useful for ensuring proper transposition of the essential requirements referred to in Article 3(1).*

Pursuant to the rules of procedure of the standardisation bodies, the transposition of a harmonised European standard necessitates the withdrawal of any conflicting national standards.

Nevertheless, pending the availability of harmonised standards, the Member States must inform the parties concerned of existing national rules that are valid in the context of the implementation of the Directive and may take the form of current standards or technical regulations designed to ensure compliance with the essential requirements. The description 'important or useful' does not in any way render them mandatory or authorise their national imposition, since the manufacturer is free to choose the most appropriate means of meeting the essential requirements.

6. *Those technical specifications which are also required to supplement European specifications or other standards must not jeopardise compliance with the essential requirements referred to in Article 3(1).*

Reference to existing texts or specific obligations must be without prejudice to the obligation to comply with the essential requirements.

7. *Where a Member State or the Commission considers that a European specification as referred to in paragraph 2 does not entirely satisfy the essential requirements*

([8]) Standards references are published in the series C of the OJEU. As soon as references are published, updates are available on the DG Enterprise and Industry website at: http://europa.eu.int/comm/enterprise/standards_policy/index.htm

referred to in Article 3(1), the Commission or Member State concerned shall bring the matter before the committee referred to in Article 17, giving the reasons therefore. The committee shall deliver an opinion without delay.

The Directive provides for a formal appeal procedure against European specifications that do not fully conform to the essential requirements; this procedure necessitates consultation of the standing committee set up pursuant to Article 17.

The EU is dependent on the reliability of the European standardisation system, which must operate on the basis of consistency, transparency, openness and consensus. At the same time, a posteriori verification is also possible. The EU retains control of the final results in view of the need to publish the references of the standards in question in the OJEU to ensure their legal validity. Furthermore, by allowing formal objections to harmonised European standards, the New Approach has also created a system to monitor the conformity of such standards with the mandatory legal requirements.

In the light of the committee's opinion and following consultations with the committee set up pursuant to Directive 98/34/EC in the case of harmonised European standards, the Commission shall inform the Member States whether or not it is necessary to withdraw the European specifications in question from the published information referred to in paragraph 3.

While not in any way affecting its overall status of harmonised European standard, the procedure is designed to revoke the presumption of conformity with the Directive. Consequently, if, in the opinion of the committee, a harmonised standard does not fully conform to the essential requirements, the Commission and the Member States must delete the corresponding references from their respective publications, thereby ensuring that one of the two conditions necessary for the presumption of conformity is not satisfied.

Article 3

Essential requirements, harmonised standards and presumption of conformity

Harmonisation relies on essential requirements, conformity with which is mandatory. Compliance with harmonised standards, while not being mandatory, confers a presumption of such conformity.

Presumption of conformity is important since it removes the need to positively demonstrate the compliance – often difficult to establish – of an examined installation or part thereof with the essential requirements.

1. *The installations and their infrastructure, subsystems and safety components of an installation must comply with the essential requirements which are laid down in Annex II and are applicable to them.*

It is necessary to respect the essential requirements, which basically define the objectives to be achieved. Efforts are made to formulate those requirements sufficiently precisely to create demonstrable legal obligations. At the same time, the wording remains broad enough to allow the assessment of conformity with the

requirements even in the absence of harmonised standards or where the manufacturer decides not to use the latter.

Thus, the means of achieving the objectives fixed by the essential requirements continues to be optional. In particular, the application of harmonised standards remains voluntary and the conformity assessment is always made with reference to the essential requirements. If a manufacturer decides not to observe a harmonised standard, he must prove that the safety component, subsystem or installation in question complies with the essential requirements.

2. *Where a national standard transposing a harmonised European standard the reference for which has been published in the Official Journal of the European Communities covers the essential safety requirements laid down in Annex II, the installations and their infrastructure, subsystems and safety components of any installation constructed in accordance with the standard shall be presumed to comply with the relevant essential requirements.*

As has been pointed out, product conformity, i.e. compliance with the essential requirements listed in Annex II, can be established by reference to the provisions of harmonised European standards, in particular because conformity with the harmonised standards confers a presumption of conformity with essential requirements if the references of the standards concerned have been published in the OJEU and they have been transposed at national level (see comments on Article 2).

Article 4

Safety analysis and report

This article contains important and relatively innovative provisions by requiring a safety analysis and report in all cases. The aim is both to ensure the ultimate safety of the installation and identify the safety components and subsystems subject to the EU common market to which the main provisions of this Directive relate.

1. *At the request of the main contractor or his authorised representative, all planned installations shall be subject to a safety analysis as defined in Annex III which covers all safety aspects of the system and its surroundings in the context of the design, realisation and putting into service and makes it possible to identify from past experience risks liable to occur during operation.*

There are three elements to this paragraph, namely:

- a compulsory safety analysis in respect of all installations, representing a basic and innovative contribution of the Directive;
- execution of the analysis at the request of the main contractor or his representative, with only the client and not the analysing body being identified;
- extension of the analysis beyond the system itself to take account of location and anticipate the operation of the installation.

This safety analysis is conducted at project level. Its results can help in defining the installation configuration and identifying the role of components in ensuring safe-

ty in the light of that configuration. It makes it possible to identify the risks associated with the installation's operation and environment, which must be taken into account during design, construction and entry into service.

The safety analysis essentially covers:

– specific project features affecting the environment and surrounding area;

– infrastructure;

– subsystem interfaces;

– subsystem/infrastructure interfaces.

Given his knowledge of the site, the main contractor must ensure that the risks associated with the installation site and safety aspects relating to the environment are taken into consideration. He must take into account the restrictions put in place to ensure the safety of the system at the level of its operating modes (operation and maintenance).

See, also, the comments in Annex III.

2. *The safety analysis shall be the subject of a safety report recommending the measures envisaged to deal with any such risks and including a list of the safety components and subsystems which must be covered by the provisions of Chapter II or III, as the case may be.*

The safety report is intended to ensure that all involved in the construction of the installation recognise and accept the measures proposed for dealing with potential operating risks in the spirit of Point 2.2 of Annex II (Essential requirements). It also enables all the parties concerned to identify safety components and subsystems which could benefit from free movement on the EU market provided they comply with the essential requirements.

CHAPTER II Safety components

Safety components are the first product category covered by the Directive to benefit from free movement on the EU market in accordance with New Approach principles. They are defined in Article 1(5) and are to be identified in the safety analysis conducted in respect of each installation (see Article 4).

Article 5 of this Chapter recalls the obligation on the Member States to organise and effectively conduct comprehensive market surveillance to ensure that safety components cannot be placed on the market or put into service if they endanger the safety of persons or property. Article 6 states that the surveillance authorities of the Member States must authorise the free movement of safety components which satisfy the essential requirements. Article 7 lays down the rules enabling safety components to be freely placed on the market and put into service in the EU.

Article 5

Market surveillance - national authorities

1. Member States shall take all necessary measures to ensure that safety components:

- *are placed on the market only if they permit the construction of installations complying with the essential requirements referred to in Article 3(1),*
- *are brought into service only if they permit the construction of installations which are not liable to endanger the health or safety of persons or, where applicable, the safety of property when properly installed and maintained and used for its intended purpose.*

This provision highlights an instrument crucial to the application of New Approach directives, namely market surveillance, which is the responsibility of Member States.

Market surveillance involves two main obligations:

(1) the surveillance authorities must ensure that safety components placed on the market or brought into service comply with the national provisions transposing the Directive and, therefore, allow the construction of installations which comply with the essential requirements without jeopardising safety, and (2) if necessary, the authorities must take corrective measures proportionate to the level of risk or non-conformity to enforce conformity. Corrective action should be undertaken on a case by case basis. This consists firstly in requiring the manufacturer to bring the product into conformity with the applicable provisions and to redress the infringemen. Ultimately, if there is no other way of maintaining the safety level laid down by the Directive, the authority may temporarily restrict the placing on the market or bringing into service of the component in question or withdraw it, thereby generally initiating the safeguard procedure (see Article 14).

Market surveillance takes place after the manufacturer has placed the component on the market (see Article 7). Such surveillance cannot be conducted at the design and production stages, that is before the manufacturer has officially accepted responsibility for the conformity of the component, generally by affixing the CE marking.

The Directive does not lay down specific provisions regarding the organisation of market surveillance. Each Member State may apply its own system without func-

tional or geographical constraints regarding the division of responsibilities between the authorities, provided that surveillance is effective and covers the entire territory.

The important factor is for the authority to observe the proportionality principle in surveillance so as to correlate its activities with the degree of danger or non-conformity involved and limit itself to the attainment of safety objectives without overburdening manufacturers with unnecessary tasks and, in particular, without unduly influencing the free movement of components.

2. *This Directive shall not affect Member States' entitlement to lay down, in compliance with the Treaty, such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected when using the installations in question, provided that this does not mean that the installations are modified in a way not specified in the Directive.*

Member States are not totally free to define additional requirements relating to installation use. Such requirements may only be taken into account if they relate to personal safety, particularly for workers, and do not impede the free movement of safety components, which would be the case if such components had to be modified.

In practice, this means that the Member States may define general or particular rules governing the use of installations so long as they do not entail any modification of components.

Article 6

Free movement of complying components

Member States may not, on the basis of this Directive, prohibit, restrict or impede the placing on their national markets of safety components intended to be used in an installation where such components comply with the provisions of this Directive.

The Member States are obliged to allow the free movement of all safety components complying with the Directive.

Similarly, the Member States may not, under guise of the procedures for authorising entry into service (see. Chapter IV), prohibit, restrict or impede the free movement of components or subsystems that comply with the Directive (Article 11(5)).

Article 7

Establishment of conformity – the manufacturer

1. *Member States shall regard the safety components referred to in Article 4(2) bearing the CE conformity marking shown in Annex IX and accompanied by the EC declaration of conformity provided for in Annex IV as conforming with all the relevant provisions of this Directive.*

The first paragraph of this provision lays down two basic principles introduced by the Directive with a view to the correct operation of the single market: (1) the two visible signs that a safety component complies with the Directive are the CE marking and the EC declaration of conformity; (2) Member States may not repeat anal-

ysis or examination of any safety components accompanied by these two items. All checks have already been conducted on behalf of the manufacturer who, as a result, accepts ultimate responsibility for the conformity of his component with the Directive.

The following paragraphs explain how the manufacturer does this in greater detail.

2. *Before a safety component is placed on the market, the manufacturer or his authorised representative established in the Community must:*

a) submit the safety component to a conformity assessment procedure in accordance with Annex V, and

The manufacturer or his representative must demonstrate the conformity of his component with the Directive by subjecting it to one of the conformity assessment procedures defined in the different modules referred to in Annex V. The modules or combinations thereof indicated are equivalent and provide the same assurance of compliance with the essential requirements. It is for the manufacturer to select the most appropriate module. On the basis of his chosen procedure, the notified body (see Articles 7(3) and 16) can issue the following certificates:

Module B+D	EC type-examination certificate and approval of production quality-assurance system
Module B+F	EC type-examination certificate and certificate of conformity
Module G	Certificate of conformity
Module H	EC design-examination certificate and approval of complete quality-assurance system

(See also comments in Annex V)

b) affix the EC conformity marking on the safety component and, on the basis of the modules laid down in Decision 93/465/EEC, draw up an EC declaration of conformity in accordance with Annex IV.

The manufacturer or his representative affixes the marking and draws up the EC declaration of conformity (see Annex IV) following an examination by a notified body; it is not for that body to make the declaration or affix the CE marking.

3. *The procedure for assessing safety component conformity shall be carried out at the request of the manufacturer or his authorised representative established in the Community by the notified body referred to in Article 16 and appointed by him for this purpose.*

The conformity assessment must always be conducted by a third-party notified body (see Article 16). The choice of notified body lies with the manufacturer, who need not take account of the nationality of the main contractor (rarely known at this stage). As a result, the national authorities cannot influence this choice in any way. Because of the large number of safety components and subsystems present

in an installation, the documents presented will generally have been drawn up by different notified bodies.

4. *Where the safety components are subject to other Directives concerning other aspects and also providing for the affixing of the CE conformity marking, the marking shall indicate that the safety component is also presumed to conform to the provisions of those other Directives.*

This is the general principle of single CE marking: the CE marking constitutes a statement by the manufacturer that the product in question complies with all the relevant EU provisions and not merely with those of the present Directive.

Directives which may be applicable to cableway installations include those relating to machinery (98/37/EEC), electromagnetic compatibility (89/336/EEC), low-voltage equipment (73/23/EEC) and personal protective equipment (89/686/EEC). It is for the manufacturer to determine the relevant legislation in each individual case.

5. *Where neither the manufacturer nor his authorised representative established in the Community has complied with the obligations of paragraphs 1 to 4, those obligations shall devolve on whomsoever places the safety component on the Community market. The same obligations shall apply to whomsoever manufactures safety components for his own use.*

The Directive must be observed and applied by all concerned and safety components must comply therewith. If the manufacturer or his representative have not subjected a safety component to a conformity assessment procedure and/or have not affixed the CE marking and/or have not drawn up the EC declaration of conformity, this must be done by the person placing the safety component on the market. In other words, the buyer, importer, etc. who places the safety component on the market cannot escape his responsibilities on the ground that the manufacturer has failed to fulfil his obligations. There is an obligation and a responsibility to purchase and import products that are in conformity with the Directive.

While the concept of manufacture for own use may appear a little surprising in this context given the absence of a market, passenger transport is involved and a high level of safety must be guaranteed regardless of the origin and method of manufacture of the safety component.

CHAPTER III Subsystems

Like Articles 5, 6 and 7 in respect of safety components, the three articles making up this Chapter define rules for placing subsystems on the market, which constitute the second product category subject to the Directive that can be freely traded on the EU market. This Chapter also incorporates provisions on market surveillance (Article 8), freedom of movement (Article 9) and, finally, the manufacturer's establishment of conformity, in this case adapted to subsystems.

Article 8

Market surveillance – national authorities

Member States shall take all necessary measures to ensure that subsystems within the meaning of Annex I are placed on the market only if they permit the construction of installations complying with the essential requirements referred to in Article 3(1).

As with safety components, the Member States monitor subsystem markets to ensure that manufacturers' products are suitable for use in the construction of installations complying with the Directive. The explanation of market surveillance in respect of safety components applies equally to the subsystems market (see comments on Article 5).

Subsystems are listed in Annex I, in respect of which relevant comments are provided.

Article 9

Free movement of complying subsystems

Member States may not, on the basis of this Directive, prohibit, restrict or impede the national marketing for use in an installation of subsystems which comply with the provisions of this Directive.

The same basic pronciple applies to subsystems as to safety components: the Member States must do nothing to prevent the marketing, that is the free movement, of subsystems complying with the provisions of the Directive (see Article 6).

Article 10

Establishment of conformity – the manufacturer

1. *Member States shall regard subsystems within the meaning of Annex I which are accompanied by the EC declaration of conformity provided for in Annex VI and by the technical documentation provided for in paragraph 3 of this Article, as being in conformity with the relevant essential requirements referred to in Article 3(1).*

By analogy with Article 7(1) in respect of safety components, this article states that subsystems complying with the essential requirements must be accompanied by the EC declaration of conformity (see Annex VI) and the relevant technical documentation. The presence of the declaration and technical documentation bears witness to the conformity of the subsystem with the Directive. As a result, Member States cannot repeat the examination or inspection of the subsystems.

2. *The EC procedure for examining subsystems shall be carried out at the request of the manufacturer or his authorised representative established in the Community or, in their absence, any natural or legal person who places the subsystem in question on the market, by the notified body referred to in Article 16 which the manufacturer or his authorised representative or the abovementioned person appointed for that purpose. The EC declaration of conformity shall be drawn up by the manufacturer or his authorised representative or the abovementioned person on the basis of the EC examination in accordance with Annex VII.*

Although the principle governing the conformity assessment of a subsystem prior to marketing is the same as that applicable to safety components, the procedure differs owing to the greater complexity of the subsystem concept.

It is for the manufacturer or his representative established in the EU to submit the subsystem for evaluation by a notified body of his choice. Sometimes, however, subsystems are not placed on the market by manufacturers, but for example, by contractors, engineering companies and contracting authorities. Consequently, with a view to avoiding a legal vacuum in this field, the Directive also provides that, in the absence of a manufacturer or his representative (preference being given to the former where one exists), 'the natural or legal person placing the subsystem on the market' (for example, an assembler) should apply for EC examination.

Furthermore, the assessment is to be conducted on the basis of the EC examination referred to in Annex VII and not with reference to modules. This EC examination of subsystems, reponsibility for which is assigned to notified bodies (see Article 16), involves analysis of the interfaces between all the components, whether or not they are safety components, used in a subsystem. The examination procedure covers investigation of the maintenance procedures defined for the subsystem in question (operating and maintenance instructions).

The manufacturer is required to draw up an EC declaration of confirmity in accordance with Annex VI, confirming the compliance of the subsystem with the essential requirements of the Directive. It is not, however, necessary to affix the CE marking to subsystems. Since the final assembly of subsystems as complete units generally takes place only on the installation site, an EC declaration of conformity in respect of a new system cannot be drawn up until immediately before entry into service.

3. *The notified body shall draw up the EC examination certificate in accordance with Annex VII and the technical documentation which accompanies it. The technical documentation must include all the necessary documents concerning the characteristics of the subsystem and, where appropriate, all the documents certifying the conformity of the safety components. It must also contain all the relevant details of the conditions of, and restrictions on, use and of the instructions for servicing.*

It is usual practice for the technical documentation in respect of each subsystem to contain:

– the certificates and declarations of conformity issued in respect of the different subsystem components. Certificates may have been issued by different notified bodies, since responsibility for the entire series of examinations need not be assigned to a single entity (see Annex V);

– the (standard or specific) overall subsystem plan showing the possible configuration(s) of the safety components;

– the list of features determining the field of use of the subsystem;

– operating and maintenance instructions or at least a list of features to be specified in the operating and maintenance instructions;

– the list of tests to be performed on the subsystem inside the installation.

The safety components of a subsystem presented for evaluation are not subject to additional inspection. If their fields of application and interfaces are defined appropriately, the components can certainly be used in the subsystem pursuant to the Directive, so that the notified body merely has to establish compliance with these framework conditions and the efficient interaction of the different subsystem elements.

CHAPTER IV Installations

The next three articles specify the rules applicable to installations, following the same structure as the previous two chapters. They set out certain obligations imposed by the Directive on the national authorities in the area remaining within the jurisdiction of the Member States.

Article 11

Procedures and controls by Member States

1. Each Member State shall lay down procedures for authorising the construction and the putting into service of installations which are located within its territory.

The Directive does not deal with the authorisation procedures in force in Member States. This is not, moreover, necessary in the context of the free movement of goods provided the national authorisation procedures do not hinder free movement (see paragraph 5).

2. Member States shall take all appropriate measures and determine the procedures to ensure that safety components and subsystems referred to in Annex I incorporated in installations constructed in their territory are installed and put into service only if they permit the construction of installations which are not liable to endanger the safety and health of persons or, where applicable, the safety of property, when properly installed and maintained and used in accordance with their intended purpose.

The absence of a final inspection of the installation as a whole could compromise the safety of persons even if the various elements of the installation comply with this Directive. It is not enough to have certified safety components and subsystems to configure a safe installation. A risk could arise from an inappropriate interaction between the various subsystems or safety components. This paragraph states that it is for Member States to guarantee the smooth interaction of all the elements assembled in an installation.

The Member States may neither check the conformity of the safety components nor that of the subsystems. However, they must implement a procedure designed to check, in addition to the overall state of the installation, the smooth interaction of the subsystems in order to ensure the operating safety of the installation as a whole. For example, they should be able to ensure:

- that the procedures provided for in the Directive have been applied to the safety components or subsystems incorporated in an installation;
- that they have been incorporated bearing in mind their areas of use, so that they do not entail risks for persons or property;
- that the documentation regarding the use and maintenance of each of them has been given to the main contractor.

3. Where a Member State considers a safety component or subsystem referred to in Annex I to have been designed or constructed using an innovative approach, it shall take all appropriate measures and may make the construction and/or putting into

service of an installation in which such innovative components or subsystems are to be used subject to special conditions. It shall immediately inform the Commission thereof, stating its reasons. The Commission shall immediately refer the matter to the committee provided for in Article 17.

The purpose of this Article is to avoid restriction of innovation (see Recital 26). To be innovative, a product does not simply have to be new; it should also be outside the sector's field of experience. Consequently, a product which complies with existing technical standards is a priori not innovative.

The assessment of the innovative nature of a safety component or subsystem may take account of the experiences of non-EU countries, provided that the safety requirements of those countries correspond to the Directive's essential requirements. If a number of components or subsystems with innovative aspects are placed on the market simultaneously, their use within the EU must be subject to identical conditions.

In addition, the safety components and subsystems with innovative aspects must also be subject to a conformity assessment procedure in accordance with Annexes V or VII.

It should be stressed that it is the installation as a whole system that the Member State may subject to special conditions as part of the authorisation procedure. It is not the 'innovative' subsystem or safety component, which a notified body will have already examined and the manufacturer will have placed on the market, since, notwithstanding its innovative nature, they have considered it to be in compliance with the essential safety requirements.

4. *Member States shall take all appropriate measures to ensure that the installations are constructed and put into service only if they have been designed and constructed in such a way as to guarantee compliance with the essential requirements referred to in Article 3(1).*

The purpose of the provision is to ensure that the installation itself also fulfils the Directive's essential requirements, thus ensuring a high level of safety. However, unlike safety components and subsystems, the Directive does not specify how the Member States should guarantee this high level of safety for installations.

Member States' inspections are to comprise the following aspects:

- infrastructure,
- the interfaces between the subsystems,
- the interfaces between the subsystems and the infrastructure,
- the specific influences of the project on the site of the installation,
- taking into account the environment,
- completeness of the certificates and declarations of conformity for all the safety components and subsystems and the safety analysis.

The safety components and subsystems are no longer covered by these inspections, since, as already stated, the manufacturer has submitted them to conformity assessment by a notified body (see Articles 7 and 10).

5. *On the basis of the provisions referred to in paragraph 1, Member States may not prohibit, restrict or hinder the free movement of safety components and subsystems referred to in Annex I which are accompanied by an EC declaration of conformity within the meaning of Article 7 or Article 10.*

The provision refers to, and confirms, the principle of free movement of goods (see Articles 6 and 9) and reminds Member States that the procedures for authorising the construction and putting into service of an installation cannot be used to hinder free movement.

6. *The safety analysis, the EC declarations of conformity and the accompanying technical documentation relating to the safety components and subsystems referred to in Annex I must be submitted by the main contractor or his authorised representative to the authority responsible for approving the installation, and a copy of them shall be kept at the installation.*

This accompanying technical documentation is limited to the documentation which accompanies the conformity declarations of the safety components and subsystems. In no circumstances is provision made to return to the Member States all the documentation used by the notified bodies to carry out their examinations.

The examination of the detailed documents regarding the various safety components and subsystems is the responsibility of the notified bodies and the final certificate documents this. The authority responsible for approving the installation does not, therefore, have to check the detailed documents and consequently has not to require them.

For guidance, the following documents are to be submitted:

– Safety analysis

– EC Declaration of conformity for safety components:

  Technical documents to be provided:

  - Certificate of conformity
  - Identification (e.g. overall plan)
  - Field of use
  - List of basic components
  - Compatible interfaces, instructions for adjustment, assembly and maintenance.

– EC Declaration of conformity for subsystems

  Technical documents to be provided:

- Certificate of conformity
- Identification (e.g. overall plan)
- Field of use
- Compatible interfaces, instructions for adjustment, assembly and maintenance.

7. Member States must ensure that the safety analysis, the safety report and the technical documentation are provided and include all the documentation concerning the characteristics of the installation and, where appropriate, all the documents certifying the conformity of the safety components and subsystems referred to in Annex I. In addition, documents must exist setting out the necessary conditions, including the restrictions on operation, and full details of servicing supervision, adjustment and maintenance.

Article 12

Observance of the Directive in the construction and putting into service of installations

Without prejudice to other legislative provisions, Member States may not prohibit, restrict or impede the construction and putting into service within their territories of installations which comply with this Directive.

This provision stresses the fact that Member States' responsibilities regarding safety and their continued authority regarding the installation as a whole does not allow them to create obstacles which undermine the provisions of the Directive.

Article 13

Consideration of the safety report

Member States shall ensure that an installation remains in operation only if it conforms to the conditions set out in the safety report.

Monitoring of the operating safety of the installation as a whole must be regulated by the Member States throughout the service life of the installation (i.e. the technical life of the installation, which is laid down in specific laws in some Member States). If, to eliminate any risks, the safety report provides for a programme of measures to be observed and applied throughout the service life of the installation, procedures must be established to ensure that the programme is observed.

CHAPTER V Safeguards

As part of market surveillance Member States are obliged to take restrictive measures regarding products covered by the Directive which could compromise the health and safety of persons or property. Article 14 provides for a very specific procedure which is applied widely in other 'New Approach' directives and is designed to allow the Commission to examine whether national measures limiting the free movement of components and subsystems are justified. Article 15 is much shorter and reminds Member States of their obligation to also take appropriate restrictive measures regarding dangerous installations.

Article 14

Restrictions on free movement - Safeguard procedure

1. Where a Member State ascertains that a safety component bearing the CE conformity marking placed on the market and used in accordance with its intended purpose or a subsystem with an EC declaration of conformity as referred to in Article 10(1), used in accordance with its intended, purpose, is liable to endanger the safety and health of persons, and, where applicable, the safety of property, it shall take all appropriate measures to restrict the conditions of use of the component or subsystem or prohibit its use.

The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision and whether non-conformity is due, in particular, to:

a) failure to satisfy the essential requirements referred to in Article 3(1),

b) incorrect application of the European specifications referred to in Article 2(2) in so far as application of those specifications is invoked,

c) shortcomings in the European specifications referred to in Article 2(2).

2. The Commission shall enter into consultations with the parties concerned as quickly as possible. Where, after such consultation, the Commission finds that:

– the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is based on shortcomings in the European specifications, the Commission shall, after consulting the parties concerned, initiate the procedure referred to in Article 2(7) if the Member State which has taken the decision intends to maintain it,

– the measures relating to a safety component are unjustified, it shall immediately so inform the manufacturer or his authorised representative established in the Community and the Member State which took the measures,

– the measures relating to a subsystem are unjustified, it shall immediately so inform the manufacturer or his authorised representative established in the Community or, in their absence, any natural or legal person having placed the subsystem in question on the market, and the Member State which took the measures.

3. Where a safety component bearing the CE conformity marking is found not to comply, the competent Member State shall take appropriate action against whomsoever affixed that marking and drew up the EC declaration of conformity and shall so inform the Commission and the other Member States.

4. Where a subsystem with an EC declaration of conformity is found not to comply, the competent Member State shall take appropriate action against whomsoever drew up the EC declaration of conformity and shall so inform the Commission and the other Member States.

5. The Commission shall ensure that the Member States are kept informed of the outcome of the procedure.

Article 15

Operating restrictions or shutting-down an installation

If a Member State finds that an approved installation which is used in accordance with its intended purpose is liable to endanger the safety and the health of persons and, where appropriate, the safety of property, it shall take all appropriate measures to restrict the conditions of operation of the installation or to prohibit the operation thereof.

This Article reflects the fact that the Directive concerns not only goods in circulation but also on-site installations. It allows the Member State responsible for the safety of an installation that could compromise the health and safety of persons or property to react immediately. This is done outside the scope of the Directive, but may sometimes justify application of Article 14, for example if safety components and subsystems are involved.

CHAPTER VI Notified bodies

This Chapter, which contains a single article, lays down the notification rules regarding the bodies authorised to assess safety components and subsystems.

Member States are responsible for designating the bodies they notify, subject to the criteria set out in Annex VIII to the Directive. The body's compliance with these criteria must be subject to regular surveillance on the part of the Member State that appointed it, which is also responsible towards other Member States and the EU institutions.

Once notified by a Member State, a body may immediately carry out its activities throughout the internal market. Similarly, manufacturers may choose any notified body from those appointed to perform a conformity assessment procedure (see Articles 7 and 10).

Article 16

Notification procedure

1. Member States shall notify the Commission and the other Member States of the bodies responsible for carrying out the conformity assessment procedure referred to in Articles 7 and in Article 10, specifying the field of competence of each body. The Commission shall assign identification numbers to them. The Commission shall publish in the Official Journal of the European Communities the list of notified bodies, together with their identification number and their fields of competence, and shall ensure that the list is kept up to date.

Notification plays a decisive role in the functioning of the system. The Member State authorities are obliged to accept certificates issued by the bodies notified to them.

The list published in the OJEU ([9]) is for information only and has no legal value. The number is allocated purely for administrative purposes to ensure consistent management of the list. A notified body is assigned the same number if it is notified under several directives. The Commission must ensure that each notified body receives a single identification number, however many directives it is notified under.

It is the official notification that marks the moment from which the bodies are authorised to issue certificates. This happens when all the information required (in particular the name of the body, the range of products covered, the duration of the notification and the conformity assessment procedures for which the body is notified) and the identification number allocated beforehand by the Commission are sent to the Commission and the other Member States.

The Member States are not obliged to notify a body for all the modules or procedures described in the Directive or for all the products which fall within its scope. Furthermore, the body cannot be notified for part of a module, but must carry out the conformity assessment on the basis of an entire module. For example, for module H, a body cannot be notified for assessing only point 7 (design control).

([9]) The list is constantly updated and may be consulted on the Internet via the Europa server at the following addresses: http://europa.eu.int/comm/enterprise/rail_guided_transport/index.htm (list updated each month) http://europa.eu.int/comm/enterprise/nando-is/home/index.cfm (list updated more frequently).

2. *Member States shall apply the criteria laid down in Annex VIII in assessing the bodies to be notified. Bodies meeting the assessment criteria laid down in the relevant harmonised European standards shall be presumed to fulfil those criteria.*

The criteria set out in Annex VIII are minimum criteria to be taken into consideration by the states to determine whether a body is competent on a technical level, whether it can carry out the conformity assessment procedures and whether it can prove that it operates in a non-discriminatory, transparent, neutral, independent and impartial fashion. Application of the same criteria for assessing bodies is important for creating trust between Member States. Accreditation in accordance with the assessment criteria provided for in the EN 45000 series of standards is not compulsory, but helps offset differences between the notification criteria from one state to another and create an atmosphere of trust. The importance of such accreditation is recognised in the second part of the paragraph, since bodies which obtain accreditation with reference to EN 45000 standards are assumed to meet the criteria of Annex VIII.

3. *A Member State which has approved a body must withdraw its notification if it finds that the body no longer meets the criteria referred to in Annex VIII. It shall immediately inform the Commission and the other Member States thereof.*

The Commission and the Member States are obliged to act where there is a doubt about the competence of a notified body. Further to the Member State's obligation to withdraw notification if a body no longer meets the requirements or its obligations, the Commission may initiate infringement proceedings against a Member State if it fails to do so, in accordance with Article 226 of the EC Treaty. The other Member States may also apply the procedure provided for in Article 227 of the EC Treaty if they contest the fact that a body notified by another Member State adequately meets the requirements or its obligations.

Withdrawal of notification has no effect on the certificates issued by the notified body before it is established that the notification must be withdrawn.

4. *Should the need arise, coordination of the notified bodies shall be implemented in accordance with Article 17.*

Coordination of notified bodies, which is particularly necessary for complex installations involving many safety components and several subsystems, is organised under the aegis of the Commission by a working group consisting of representatives of the notified bodies. The working group has a chairperson, elected from among its members, and a technical secretariat which organises the meetings. It proposes solutions to problems and makes recommendations regarding conformity assessment. Notified bodies are obliged to participate in coordination activities and may have their notification withdrawn if they refuse to cooperate. Cooperation and technical discussions are confined to issues relating to conformity assessment and do not broach legal matters or the interpretation of the Directive. In general, notified bodies must exchange information on certificates refused or withdrawn in order to ensure uniform application of EU legislation and to prevent defective components from being submitted several times for testing or certification, possibly with notified bodies in other Member States coming to a different conclusion. This information must, of course, only concern the type of product and the reasons for refusing or withdrawing it, without divulging confidential information or the technical specifications covered by the secrecy clause in the contract between the applicant for certification and the notified body.

CHAPTER VII Committee

The Commission's implementing powers as regards EU legislation lead it frequently to consult committees and expert groups in order to enter into dialogue with national authorities and interested parties and thus improve implementation of EU legislation.

Article 17

Committee on harmonisation of national regulations on cableway installations designed to carry persons

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. The committee shall draw up its rules of procedure.

CHAPTER VIII CE conformity marking

CE marking is the most visible external evidence of the application of European Directives. It is the manufacturer's responsibility and indicates conformity with all the directives applying to the marked product (see Article 7).

CE marking is compulsory for the safety components covered by the Directive and intended for the EU market and must be attached before the components are placed on the market.

Article 18

CE marking of safety components

1. The CE conformity marking shall consist of the letters 'CE'. Annex IX sets out the model to be used.

CE conformity marking consists exclusively of the letters CE followed by the last two figures of the year in which it was affixed and by the identification number of the notified body.

The obligation to affix CE marking extends to all the safety components intended for the EU market which fall within the scope of the Directive and which must, therefore, comply with the Directive's essential requirements.

CE marking is the only written indication showing that the manufacturer of the safety component has met all his obligations under all the applicable directives. Sometimes, products which are not safety components within the meaning of this Directive nevertheless bear the CE marking since, for example, they fall within the scope of the 'machinery' or 'pressure equipment' Directive.

2. The CE conformity marking shall be affixed to each safety component distinctly and visibly or, where that is not possible, on a label inseparably attached to the component.

As a general rule, CE marking must be affixed on the component. The manufacturer decides where the marking is to be affixed, provided it is visible and legible. It is not necessary to mark all the components in an assembly. The visibility requirement means that CE marking must be easily accessible to all the parties. It must neither be omitted nor transferred from the product to the packaging or to the accompanying documents for purely aesthetic considerations.

3. The affixing on safety components of markings which are likely to mislead third parties as to the meaning and form of the CE conformity marking shall be prohibited. Any other marking may be affixed to the safety component, provided that the visibility and legibility of the CE conformity marking are not thereby reduced.

CE marking is not an origin mark, since the component may have been manufactured outside the EU. It should not be confused with marks such as trademarks, identification marks and quality labels, which fulfil a different function and must not affect the legibility of the CE marking. Member States must not introduce any reference in national legislation to another mark which would indicate conformity with the objectives of the CE marking.

4. *Without prejudice to Article 14:*

a) where a Member State establishes that the CE conformity marking has been wrongly affixed, the manufacturer of the safety component or the authorised representative of the latter established in the Community shall be obliged to make the product conform as regards the provisions concerning the CE conformity marking and to end the infringement under the conditions imposed by the Member State;

b) should non-conformity persist, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the safety component in question, or to ensure that it is withdrawn from the market in accordance with the procedures provided for in Article 14.

The market surveillance authorities must check whether the affixing and use of CE marking comply with EU directives. Member States must provide for appropriate measures in their national legislation to prevent abuse or improper use of CE marking.

If necessary, the surveillance authority must take appropriate remedial action to protect CE marking, which also includes the possibility of limiting free movement of the component because of incorrect CE marking according to the procedures described in Article 14 of the Directive.

CHAPTER IX Final provisions

The following five articles are the usual, general implementing measures.

Article 19

Grounds for decisions and information on remedies

Any decision taken pursuant to this Directive which restricts the use of safety components or of a subsystem in an installation or the placing on the market thereof shall state the grounds on which it is based. Such a decision shall be notified at the earliest opportunity to the party concerned, who shall at the same time be informed of the legal remedies available to him under the law in force in the Member States concerned and of the time limits to which such remedies are subject.

This is a normal legal provision governing relations between the Member State which took the measure in application of the Directive and the person(s) or businesses which can claim an interest in contesting the decision taken.

Article 20

Transitional provisions for work in progress

Installations for which authorisation has been given before the entry into force of this Directive and for which construction has not yet started must comply with the provisions of this Directive, unless Member States decide otherwise, stating their reasons, and an equally high level of protection is achieved.

The Directive came into force on 3 May 2000, the date of its publication in the OJEU (see Article 22). However, like most New Approach directives, this Directive provided for a transitional period until 3 May 2004, during which the Member States could continue to apply existing rules (see Article 21).

Article 20 refers to the situation of the installations on the deadline for application of the Directive, i.e. 3 May 2004. This provision means that any installation which had been authorised but for which construction had not begun by 3 May 2004 should be reviewed by the Member State in question. If the installation in question complies with the essential requirements of the Directive, the Directive applies in full. If, however, it does not comply, the Member State may maintain the authorisation, but it must guarantee an equally high level of protection. This must depend on a position taken by the authorities of the Member State in question.

A Member State fails in its obligations either if it does not intervene, and allows construction to begin, or if it emerges that the level of guaranteed protection is not high enough.

Installations in this position are all known since they have been the subject of a construction authorisation. A Member State should be able to show, on request, that it has taken a decision on this, giving its reasons. If it is not able to do so, the Directive should apply.

Article 21

Transposition, transitional period and report on the implementation of the Directive

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 3 May 2002. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

3. Member States shall, for a period of four years following entry into force of this Directive, allow:

– the construction and putting into service of installations,

– the placing on the market of subsystems and safety components

which conform to the provisions in force in their territories on the date of entry into force of this Directive.

The transitional period allowed manufacturers, notified bodies and surveillance authorities to gradually adapt to the new rules. It also permitted the drawing up of harmonised standards, which are very important in this sector, although implementation of the Directive does not depend on their existence.

At the end of the transitional period, on 3 May 2004, each Member State had to bring to an end its national system and repeal any national legislation contrary to the Directive. Consequently, since 3 May 2004, Member States have been required to accept components and subsystems which are declared to be in conformity with the Directive and – in the case of components – bear CE marking.

4. The Commission shall report to the European Parliament and the Council on the implementation of this Directive, and in particular Article 1(6) and 17 thereof, not later than 3 May 2004 and, if necessary, submit any proposal for appropriate amendments.

Article 22

Entry into force

This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 23

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 20 March 2000.


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4. Annexes

ANNEX I Subsystems of an installation

General points on the concept of the subsystem

The concept of a subsystem obliges notified bodies to examine a large part of the 'interfaces' (between the components of a subsystem and between subsystems) and to leave only the assessment of the overall configuration of the installation up to the Member State authorities. The breakdown of subsystems as set out by this Annex should make it possible to reconstruct the installation easily from that breakdown.

Various interpretations can be placed on the concept of 'subsystem'. It may designate a main group or one of its subdivisions. The declaration and assessment of conformity can therefore be adapted to suit the level chosen. Various options are thus possible:

- An overall assessment covering an entire subsystem and rendering separate assessments for each of the parts unnecessary;
- Separate assessments and declarations for each of the parts, whose joint use has been taken into account; an overall assessment does not produce any added value and is therefore unnecessary;
- With a subsystem which as a whole is the product of a new combination, the interactions justify a further assessment in addition to the assessment of its parts.

This is the case, in particular, for vehicles considered either as a single sub-system (e.g. for the serial production of a general manufacturer) or as the assembly of several subsystems (e.g. when a specific carrier made by a coach-builder is combined with suspension gear usually used for other carriers)

Finally, and in all cases, it is up to the manufacturer to decide on the level of detail of the subdivision (without going beyond the list provided in this annex), which will vary depending on the type of installation. The breakdown appears in the safety report.

For the purposes of this Directive, an installation is divided up into infrastructure and the subsystems listed below,

Infrastructure is clearly distinguished from subsystems. This arises from its nature: it is not, as such, a product which must be allowed free movement.

Thus, the separation between infrastructure and mechanical equipment, winding gear and so on has a certain importance. A functional criterion is proposed in order to establish the distinction. Where the support and stability function is preponderant, one is dealing with infrastructure. Mechanical equipment, on the other hand, can be easily changed and is likely to be adjusted many times

Consequently, on the line, the tower foundations obviously count as infrastructure. Any other fixed structure may also be considered infrastructure if it is not examined by a notified body as part of the conformity assessment of a safety component or subsystem.

For example, a manufacturer can either have the towers and brackets assessed as safety components belonging to the mechanical equipment of the line engineering (which would be particularly justified for standard components) or include them in infrastructure (in particular for specific parts created for an installation).

On the other hand, the main axles of sheaves, with their clamping and adjusting devices and of course the sheaves, rollers, pulleys and so on are not part of the infrastructure. Likewise the brake-blocks, guides, rope positioning devices and so on count as mechanical equipment. Access ladders and walkways, in particular walkways alongside brackets, will in general be associated with the component they accompany. They can therefore be considered as part of the infrastructure or the mechanical parts of structures along the line.

In any event, infrastructure comprises the design documents concerning the system data and the calculation of the line and cables.

with exploitability and maintainability having to be taken into account in each case:

The reason for mentioning exploitability and maintainability is to point out that the pieces of auxiliary equipment which allow, facilitate or make safe operation and maintenance are part of the subsystems or infrastructure to which they belong.

1. Cables and cable connections

Cables are often called ‘ropes’ or ‘wire ropes’. Electrical cables are obviously excluded. Guy cables are included, but not those used for prestressing concrete or anchoring the foundations.

A cable alone is a safety component, as are the connections, but a cable with its connections is a subsystem. This is the case, for instance, of a spliced looped cable.

2. *Drives and brakes*

The electromechanical devices related to these two functions form part of the subsystem, but those associated with control are part of the electrotechnical devices subsystem mentioned later.

3. *Mechanical equipment*

Mechanical equipment forms the main interface with infrastructure. The word 'mechanical' should be understood in the broad sense and may include parts which do not move while the installation is in operation, such as guides, rope-catchers, etc.

3.1. *Cable winding gear*

Winding gear design may vary widely and there may be very little interdependence between various pieces of winding equipment. These may therefore each be considered as a separate subsystem.

The concrete blocks which act as counterweights form part of the winding gear and not the infrastructure.

3.2. *Station machinery*

This covers, on the one hand, the positioning and circulating of the cables (with the exception of the driving parts, which are covered by drives) and, on the other, the machinery located in the stations. For installations where vehicles are equipped with detachable fittings, all the devices allowing and monitoring the attaching and detaching of fittings and the slowing down and speeding up of vehicles are included under this heading. The ancillary equipment necessary for their maintenance is also covered insofar as it comprises safety components.

3.3. *Line engineering*

These are devices for positioning, moving and catching cables on the structures along the line. The equipment necessary for maintenance is either included in this subsystem or considered as infrastructure.

4. *Vehicles*

4.1. *Cabins, seats or drag devices*

This means the passenger compartment including the framework, in the case of cabins. For chair lifts, not only the seat, the seat back and the safety bar are included, but also the beam linking the seat to the suspension mechanism. Drag (or towing) devices cover drag lifts and include the whole mechanism linking the cable to the user, with the exception of the grip for drag lifts with spring boxes and fixed-grip drag lifts and the socket for drag lifts with detachable rods.

4.2. Suspension gear

For drag lifts the part providing suspension may be included in the towing device.

4.3. Driving gear

This exists only for vehicles intended for bi-cable installations, or for funiculars. For mono-cables with two fittings per vehicle, the bar may be considered as driving gear or included with fittings or suspension gear.

4.4. Connections to the cable

This subsystem comprises the grips and harnesses (for looped cables) or the end fixings (for open cables).

5. Electrotechnical devices

The following subdivisions refer to parts which are relatively independent from each other, which does not mean they cannot be considered as a single subsystem.

5.1. Monitoring, control and safety devices

5.2. Communication and information equipment

5.3. Lightning protection equipment

6. Rescue equipment

The subsystem may exclusively comprise fixed or mobile devices or a combination of the two. This only includes equipment which forms part of the installation and does not include approved accessories such as personal protective equipment (PPE).

Since many of the devices used are personal protective equipment (PPE) and there is no reason to impose procedures which have no added value, one of the following situations will apply:

– the equipment constitutes PPE with CE marking and is used in its field of application as PPE, and a new assessment is not necessary;

– the equipment is specially designed for cableways and is to be assessed under this Directive;

– the equipment constitutes PPE but is used outside its field of application and an additional assessment is necessary under this Directive.

6.1. Fixed rescue equipment

Fixed devices or those permanently installed may in themselves be reduced installations (rescue cableway) located in a station or on towers. The special vehicles belonging to these installations are part of the following subsystem.

6.2. Mobile rescue equipment

This covers, for instance, special vehicles used for rescue purposes.

NB: below are a few examples of the breakdown of an installation into subsystems, leaving aside infrastructure:

- Example 1: Cables and cable connections, - drives and brakes, - mechanical equipment, - cabins, seats or drag devices, - suspension equipment, - connections to the cable, - monitoring, control and safety devices, - communication and information equipment, - lightning protection equipment, - rescue equipment.

- Example 2: Cables and cable connections, - drives and brakes, - mechanical equipment, - vehicles, - electro-technical devices, - rescue equipment.

- Example 3: Cables and cable connections, - winding station (group consisting of drives, breaks, cable winding gear, station machinery and electro-technical devices), - line engineering including the line-end station, - vehicles, - rescue equipment.

ANNEX II Essential requirements

1. Purpose

This Annex sets out the essential requirements, including maintainability and operability, applicable to the design, construction and entry into service of installations referred to in Article 1(5) of this Directive.

2. General requirements

2.1. Safety of persons

The safety of users, workers and third parties is a fundamental requirement for the design, construction and operation of installations.

'Workers' is understood to mean operating personnel. Indeed, the safety of operating personnel is a requirement from the point of view of operability and maintainability. However, the safety of workers on a construction site and the safety of workers in a factory are not covered

2.2. Principles of safety

All installations must be designed, operated and serviced in accordance with the following principles, which are to be applied in the order given:

– *eliminate or, if that is not possible, reduce risks by means of design and construction features,*

– *define and implement all necessary measures to protect against risks which cannot be eliminated by the design and construction features,*

– *define and state the precautions which should be taken to avoid the risks which it has not been possible to eliminate completely by means of the provisions and measures referred to in the first and second indents.*

2.3. Consideration of external factors

Installations must be so designed and constructed as to make it possible to operate them safely, taking into account the type of installation, the nature and physical features of the terrain on which it is installed, its surroundings and atmospheric and meteorological factors, as well as possible structures and obstacles located in the vicinity either on the ground or in the air.

The safety analysis required for all installations (see Article 4) must take account of all external data. It is made at the request of the main contractor or his authorised representative.

To be able to take account, at the design stage, of the external constraints specific to a given installation, particularly as regards the natural environment and surroundings of the installation, the manufacturer requires precise information re-

garding local constraints. The list of these constraints will be drawn up by the main contractor or his authorised representative.

The following aspects may be considered:

- Wind
- Reduced visibility (night, fog, smog, etc.)
- Lightning
- Snow load
- Snow pressure
- Ice formation
- Ice fall
- Avalanches
- Rock falls
- Earthquakes
- Torrents, floods
- Groundwater
- Landslides and other geological occurrences
- Falling trees, trees blown down
- Temperature range on site
- Fire, explosion
- Damage caused by a vehicle (private car, lorry, piste groomer, etc.)
- Obstacles due to aviation
- Electricity and communication lines
- Compensation of potential in relation to equipment external to the installation (snowmaking, etc.)
- Chemical/physical constraints
- Crossings (roads, paths, overhead lines, other man-made features, tracks, surface water, etc.)
- Buildings close to the installation.

2.4. Dimensions

The installation, the subsystems and all the safety components must be dimensioned, designed and constructed to withstand, with a sufficient degree of safety, all stresses encountered under all foreseeable conditions, including those which occur when not in operation, and taking account in particular of outside

influences, dynamic effects and fatigue phenomena, while complying with the acknowledged rules of the art, in particular with regard to the choice of materials.

The operating conditions which the main contractor must establish for each installation (field of use) are the basis for deciding what stresses must be taken into account.

Account is taken of the rules of the art when the European specifications in existence on the date of construction of the installation are observed or when proof of an equivalent level of safety is provided.

2.5. Assembly

2.5.1. The installation, the subsystems and all the safety components must be designed and constructed in such a way as to ensure that they can be safely assembled and put into place.

Devices such as supports, cable grippers or clips, guides, collective and personal protective equipment for assembly personnel, adjusting gauges, etc. must be checked to ensure they are suited to the way they are expected to be handled and put into place.

Safety at work in the factory and on the worksite is covered by other regulations.

2.5.2. The safety components must be so designed as to make assembly mistakes impossible, either as a result of construction or by means of appropriate markings on the components themselves.

The purpose will be to prevent assembly mistakes either at the design stage (e.g. by the inclusion of foolproof devices) or by appropriate warnings (marking, instructions, etc.).

2.6. Integrity of the installation

2.6.1. The safety components must be designed and constructed and be usable in such a way as to ensure that, in every case, their own operational integrity and/or the safety of the installation is ensured, as defined in the safety analysis in Annex III, so that their failure is highly improbable and with an adequate safety margin.

Checks must be carried out to ensure that any possible failure of a safety component is covered by measures to ensure that the safety component will continue to function and that it is not likely to directly affect the safety of the rest of the installation or any persons. It is the responsibility of the notified bodies to examine this aspect.

2.6.2. The installation must be designed and constructed in such a way as to ensure that, during its operation, any failure of a component which might affect safety, even indirectly, is met by an appropriate measure being taken in good time.

The appropriate measures are, in particular, the inspections, monitoring, servicing and operational measures mentioned in the instruction and maintenance manual.

2.6.3. The safeguards referred to in points 2.6.1 and 2.6.2 must apply throughout the period between two scheduled inspections of the component concerned. The time period for the scheduled inspection of the safety components must be clearly indicated in the instruction manual.

2.6.4. Safety components which are incorporated into installations as spare parts must satisfy the essential requirements of this Directive and the conditions relating to the smooth interaction with the other parts of the installations.

Safety components, like subsystems, used as spare parts do not have to be identical or similar to the replaced component or subsystem, but in this case their safety and that of their incorporation in the installation must be verified: their conformity with the essential requirements falls under the procedure provided for in the Directive (see Article 7). This rule, of course, applies to the safety components covered by this Directive (see Article 1(4)).

In practice, the spare part must be at least equivalent to the original part and account must be taken of any known weaknesses concerning it.

If a safety component consists of a set of parts, the requirements determined in the conformity assessment procedure for a given part also apply to the spare part used as a replacement. This must be confirmed by a declaration by the manufacturer referring to the conformity assessment of the safety component.

2.6.5. Measures must be taken to ensure that the effects of a fire in the installation do not endanger the safety of persons being transported and workers.

For overhead installations in operation, priority should be given to persons on the line and the sensitivity of the cables to the effects of heat. This will often mean attempting to maintain the movement of the haulage rope to bring the passengers to a station without delay. In any event, account must be taken of the possibility of cables breaking and falling, including those in the station opposite to that in which the fire has occurred.

2.6.6. Special measures must be taken to protect installations and persons from the effects of lightning.

2.7. Safety devices

2.7.1. Any defect in the installation which could result in a failure endangering safety must, where practicable, be detected, reported and processed by a safety device. The same applies to any normally foreseeable external event which may endanger safety.

2.7.2. It must be possible at all times to shut down the installation manually.

2.7.3. After the installation has been shut down by a safety device, it must not be possible to restart it unless appropriate action has been taken.

The appropriate action is usually set out in writing in the instruction manual.

Logically, the shut-down must continue as long as the reason for it persists and the restarting of the installation must be the result of a conscious act.

2.8. Maintainability

The installation must be designed and constructed so as to enable routine or special maintenance and repair operations and procedures to be carried out safely.

This requirement applies to the components that usually have to be maintained and repaired in an installation. The criteria to be observed and the safety provisions to be applied in this field are generally covered in the instruction manual.

The on-site or external provision of repair and maintenance equipment must be in keeping with the frequency of the operations.

2.9. Nuisance

The installation must be designed and constructed in such a way as to ensure that any internal or external nuisance resulting from noxious gases, noise emissions or vibrations falls within the prescribed limits.

The emission limits are laid down in specific regulations. In certain cases (operating the installation with standby drive) appropriate measures can be taken. Particular account must be taken of the requirements concerning worker protection.

3. Infrastructure requirements

As stated in Annex I, infrastructure is not a subsystem. It does not involve notified bodies but is part of the installation (see Article 1(5)). Nevertheless, its role regarding safety is fundamental.

3.1. Layout, speed, distance between vehicles

3.1.1. The installation must be designed to operate safely taking into account the characteristics of the terrain and its surroundings, atmospheric and meteorological conditions, any possible structures and obstacles located in the vicinity either on the ground or in the air in such a way as to cause no nuisance or pose no danger under any operational or servicing conditions or in the event of an operation to rescue persons.

See 2.3 above

3.1.2. Sufficient distance must be maintained laterally and vertically between vehicles, towing devices, tracks, cables, etc., and possible structures and obstacles located in the vicinity either on the ground or in the air, taking account of the vertical, longitudinal and lateral movement of the cables and vehicles or of the towing devices under the most adverse foreseeable operating conditions.

3.1.3. The maximum distance between vehicles and ground must take account of the nature of the installation, the type of vehicles and the rescue procedures. In the case of open cars it must also take account of the risk of fall as well as the psychological aspects associated with the distance between vehicles and ground.

3.1.4. The maximum speed of the vehicles or towing devices, the minimum distance between them and their acceleration and braking performance must be chosen to ensure the safety of persons and the safe operation of the installation.

3.2. Stations and structures along the line

3.2.1. Stations and structures along the line must be designed, installed and equipped so as to ensure stability. They shall permit safe guidance of the cables, vehicles and the towing devices, and enable maintenance to be safely carried out, under all operating conditions.

3.2.2. The entry and exit areas of the installation must be designed so as to guarantee the safety of the traffic of vehicles, towing devices and persons. The movement of vehicles and towing devices in the stations must be capable of taking place without risk to persons, taking into account their possible active collaboration to their movement.

4. Requirements relating to cables, drives and brakes and to mechanical and electrical installations

4.1. Cables and their supports

4.1.1. All measures must be taken in line with the acknowledged rules of the art:

- *to avoid cables or their attachments breaking,*
- *to cover their minimum and maximum stress values,*
- *to ensure that they are safely mounted on their supports and prevent derailment,*
- *to enable them to be monitored.*

For all installations, the fundamental principle of safety is based on maintaining the integrity of the cables (see paragraph 2.6 above).

4.1.2. As it is not possible to prevent all risk of cable derailment, measures must be taken to ensure that cables can be retrieved and the installation shut down without risk to persons in the event of derailment.

As a general rule, this requirement does not apply specifically to cables but rather to subsystems which are in direct contact with cables, such as the mechanical equipment of structures along the line (sheave trains) or cable connections (fixings, grips).

4.2. Mechanical installations

NB: the following requirements relate to subsystem 2 in Annex I (not subsystem 3).

4.2.1. Drives

The drive system of an installation must be of suitable performance and capability, adapted to the various operating systems and modes.

In order to meet this requirement, the main contractor or his authorised representative must communicate the various operating systems and modes planned.

4.2.2. Standby drive

The installation must have a standby drive with an energy supply which is independent of that of the main drive system. A standby drive is not, however, necessary if the safety analysis shows that people can leave the vehicles and, in particular, towing devices easily, quickly and safely even if a standby drive is not available.

The standby drive system must make it possible to get the vehicles and their passengers to a station so as to limit the number of cases where an evacuation has to be carried out on the line itself, as such operations are long and delicate. It should not be confused with the operating drive systems.

4.2.3. Braking devices

4.2.3.1. In an emergency, it must be possible to shut down the installation and/or the vehicles at any moment, under the most unfavourable conditions in terms of authorised load and pulley adhesion during operation. The stopping distance must be as short as the security of the installation dictates.

With regard to the dimensioning of the braking system, the 'most unfavourable conditions in terms of … pulley adhesion' (friction values between cable and pulley) and 'the most unfavourable conditions in terms of … load' must be taken into account. It should be borne in mind that these are conditions 'authorised… during operation' i.e. specific conditions which have to be defined. The operating conditions are specified by the main contractor.

4.2.3.2. Deceleration values must be within adequate limits fixed in such a way as to ensure both the safety of persons and satisfactory behaviour of vehicles, cables and other parts of the installation.

It is necessary not only to ensure the sound dynamic behaviour of the installation (swing, oscillations, variations in slack and tension, etc.) but also to verify that the parameters resulting from braking are compatible with the component parts of the installation. The position of the passengers must be taken into account to ensure that their stability is ensured.

4.2.3.3. *In all installations there must be two or more braking systems, each capable of bringing the installation to a halt, and coordinated in such a way that they automatically replace the active system when its efficiency becomes inadequate. The traction cable's last braking system must act directly on the driving pulley. These provisions do not apply to drag lifts.*

The requirement is that there be two brakes, of which at least one acts at a point as close as possible to the cable. The requirement will be deemed to have been met if the last brake is placed on the driving pulley.

4.2.3.4. *The installation must be fitted with an effective clamp and locking mechanism to guard against premature restarts.*

Locking means maintaining a stationary position.

4.3. Control devices

The control devices must be designed and constructed so as to be safe and reliable, to withstand normal operating stresses and external factors such as humidity, extreme temperatures or electromagnetic interference and so as not to cause dangerous situations, even in the event of operational error.

Operations undertaken by staff which result in an admissible operational state but which are liable under specific circumstances to entail dangers cannot be prevented by the control devices. The operating manual must deal with these various cases.

4.4. Communication devices

Suitable facilities must be provided to enable operational staff to communicate with one another at all times and to inform users in case of emergency.

On an installation, the distances between stations may be considerable. Effective communication is thus essential for coordinating the actions of operational staff.

Suitable acoustic and visual means for informing users in cases of emergency include, for example, one-way information devices located in the cabins, loud-speakers attached to towers and portable loud-speakers. There is no requirement for information to be two-way.

5. Vehicles and towing devices

5.1. Vehicles and/or towing devices must be designed and fitted out in such a way that under foreseeable operating conditions no person can fall out or encounter any other risks.

Some installation systems depend on active cooperation on the part of users to ensure safe carriage (e.g. during boarding and disembarkation in the case of continuously moving installations, closure of guardrails on chair-lifts, use of drag lifts, etc.). In order to achieve the goal of protecting persons in these cases, users must be informed about how they should behave. This information may be provided, in

particular, with the aid of pictograms and boards/signs or through instructions given by operating personnel.

Concerning the risk of falling, compliance with this requirement depends on users behaving normally.

5.2. *The fittings of vehicles and towing devices must be dimensioned and constructed so as not to:*

– *damage the cable, or*

– *slip, except where slippage does not significantly affect the safety of the vehicle, the towing device or the installation under the most unfavourable conditions.*

This requirement relates to the fact that control of vehicle movement is generally achieved through control of cable movement and that, as a result, non-slippage between cable and vehicle fittings must be ensured.

However, this article indicates that non-slippage has its limits. In certain exceptional circumstances, slippage may be a safety factor.

5.3. *Vehicle doors (on cars, cabins) must be designed and constructed in such a way as to make it possible to close and lock them. The vehicle floor and walls must be designed and constructed so as to withstand pressure and loads exerted by users under any circumstances.*

The purpose of locking is to prevent the doors being opened by passengers along the line by direct action on the doors or on their normal closing system.

The loads exerted by users, referred to in the article, are defined as the load values applicable in the case of the fully loaded vehicle (containing the maximum permitted number of persons). Loads due to acts of vandalism or violent attacks carried out with the aim of damaging the vehicle are not to be taken into consideration here.

5.4. *If for reasons of operational safety an operator is required on board the vehicle, the vehicle must be fitted with the equipment required for him to carry out his tasks.*

This point must be resolved at the beginning of the design stage.

5.5. *Vehicles and/or towing devices and, in particular, their suspension mechanisms must be designed and fitted so as to ensure the safety of workers servicing them in accordance with appropriate rules and instructions.*

5.6. *In the case of vehicles equipped with disconnectable fittings, all measures must be taken to bring to a halt, without risk to users, at the moment of departure, any vehicle whose fitting has been incorrectly connected to the cable and, at the moment of arrival, any vehicle whose fitting has not been disconnected, and to prevent the vehicle from falling.*

This requirement may involve, firstly, putting in place arrangements to ensure the sound execution of the attaching and detaching process. It then entails safely immobilising a vehicle which has not been successfully attached or detached, without necessarily awaiting the end of the attaching or detaching process to establish that fact.

5.7. Funicular vehicles and, in so far as the configuration of the installation so permits, bi-cable cable cars must be equipped with an automatic braking device on the track, when the possibility of carrier cable breaking cannot reasonably be excluded.

Conversely, it can be concluded that driving gear brakes/track brakes may be dispensed with after an analysis of the safety of the hauling rope, taking into account all the provisions regarding the installation itself, has shown that the possibility of the rope breaking can be reasonably excluded.

Driving gear brakes are necessary in cases where specific risks to the installation's hauling rope are not covered by other measures.

5.8. Where all risk of derailment of the vehicle cannot be eliminated by other measures, the vehicle must be fitted with an anti-derailment device which enables the vehicle to be brought to a halt without risk to persons.

The article applies to vehicles on a track (rail or carrying rope).

6. Equipment for users

The access to embarkation areas and exit from disembarkation areas and the embarkation and disembarkation of users must be organised with regard to the movement and stopping of vehicles in such a way as to ensure the safety of persons, in particular in areas where there is a risk of falling. It must be possible for children and persons with reduced mobility to use the installation safely if the installation is designed for the transport of such persons.

It is not imperative to cover all risks by technical measures. It is admissible to provide for operational measures for certain risks, with due account being taken in the installation's design. These measures must be set out in the service instructions.

In order to ensure the safe carriage of children and persons with reduced mobility, it may be necessary on some installations to issue specific rules (e.g. children must be accompanied by adults).

7. Operability

7.1. Safety

7.1.1. All technical provisions and measures must be taken to ensure that the installation is used for its intended purpose according to its technical specification and to the specified operating conditions and that the instructions on safe operation and maintenance can be complied with. The instruction manual and the corresponding notes shall be drawn up in an official language or languages of the Community

which may be determined in accordance with the Treaty by the Member State in the territory of which the installation is constructed.

7.1.2. The persons responsible for operating the installation must be provided with the appropriate material resources and must be qualified to carry out the task in hand.

The control and stop buttons, as well as the monitoring tools required by operators, must be decided on during the installation's design stage.

Manufacturers have every right to expect that their equipment will be placed in the hands of competent personnel, and the main contractor must take care to ensure that this is the case.

Member States may draw up requirements relating to the qualifications of persons entrusted with the management and operation of installations.

7.2. Safety in the event of immobilisation of the installation

All technical provisions and measures must be adopted to ensure that users can be brought to safety within a set time appropriate to the type of installation and its surroundings when the installation is immobilised and cannot be restarted quickly.

The choice of installation type and arrangements for getting vehicles to a station or evacuating passengers must take into account the surroundings in general and the nature of the surfaces passed over in particular (water, glaciers, rocky cliffs, etc.).

7.3. Other special provisions concerning safety

7.3.1. Operators' stands and workplaces

Movable parts which are normally accessible in the stations must be designed, constructed and installed in such a way as to preclude any risks or, where such risks exist, be fitted with protective devices so as to prevent any contact with parts of the installation which may cause accidents. These devices must be of a type that cannot easily be removed or rendered inoperative.

7.3.2. Risk of falling

Workplaces and working areas, including those used only occasionally, and the access to them, must be designed and constructed in such a way as to prevent persons required to work or move in them from falling. Should the construction not be adequate, they must also be provided with anchorage points for personal protective equipment to prevent falls.

ANNEX III Safety analysis

The safety analysis required for every cableway installation referred to in Article 1(5) of this Directive must take into account every mode of operation envisaged. The analysis must follow a recognised or established method and take into account the current state of the art and the complexity of the installation in question. The aim is also to ensure that the design and configuration of the installation should take account of the local surroundings and the most adverse situations in order to ensure satisfactory safety conditions.

The Directive guarantees freedom of choice of method, provided it is a recognised one which takes into account the state of the art, the complexity of the installation and the operating modes envisaged.

If the local surroundings are to be integrated into the operational setup, there has to be a dialogue between all the parties involved. This ties in the technical aspects, particularly equipment configuration, with operational and site data.

The main contractor must satisfy himself that the risks linked to the site have been properly taken into account. He must also make sure that the measures relating to the operability and maintainability of the installation are acceptable.

This safety analysis, drawn up in concertation, makes it possible to ensure that all parties agree on the nature of the measures to be taken in order to cope with dangerous situations.

Risk-reducing measures fall into three categories:

- measures at the level of checking the configuration (drawing up and checking of the line calculations, for example);
- measures at the design level, at the components and subsystems construction stage or at the infrastructure level;
- measures at the operation and maintenance level (including measures possibly intended for users).

The analysis must also cover the safety devices and their effect on the installation and related subsystems that they bring into action so that either:

– *they are capable of reacting to an initial breakdown or failure detected so as to remain either in a state that guarantees safety, in a lower operating mode or in a fail-safe state, or*

– *they are redundant and are monitored, or*

– *they are such that the probability of their failure can be evaluated and they are of a standard equivalent to that achieved by safety devices that meet the criteria in the first and second indents.*

The safety analysis must be used to draw up an inventory of risks and dangerous situations as referred to in Article 4(1) of this Directive and to determine the list of safety components referred to in Article 4(2) thereof. The result of the safety analysis must be summarised in a safety report.

The safety report drawn up on the basis of the analysis (see Article 4(2)) is crucial for the main contractor, who will have to accept it since the entire operation, analysis and report, is undertaken 'at his request' (see Art 4(1)), and the choices made at the configuration stage will commit him particularly with regard to the measures decided upon, which he will have to take at the operation and maintenance level.

ANNEX IV Safety components: EC declaration of conformity

This Annex applies to the safety components referred to in Article 1(5) of this Directive with a view to establishing their compliance with the essential requirements which concern them referred to in Article 3(1) of the Directive and defined in Annex II.

The EC declaration of conformity and the accompanying documentation must be dated and signed. It must be drawn up in the same language or languages as the instruction manual referred to in point 7.1.1 of Annex II.

The declaration must state the following particulars:

– *the references of this Directive,*

– *name, business name and full address of the manufacturer or his authorised representative established in the Community. An authorised representative must also give the name, business name and full address of the manufacturer,*

The authorised representative, if there is one (it is not compulsory) must be established in the EU, which will not necessarily be the case for the manufacturer, who may be established elsewhere. The manufacturer's commercial representatives (and approved distributors) should not be confused with the authorised representative, who is formally designated by the manufacturer to act on his behalf in all matters relating to this Directive.

– *description of the component (make, type, etc.),*

This description must refer not only to the manufacturer's own criteria but also, where necessary, to the categories, classes or other specifications contained in the standards.

Where a component comprises several parts, the listing of those parts must be complete, such that the assembly complies well with the criteria making its assessment possible.

The correspondence between the physical product on site and the CE declaration of conformity must be verifiable without ambiguity.

– *details of the conformity declaration procedure used (Article 7 of this Directive),*

This is the assessment procedure carried out by a notified body in accordance with one of the modules contained in Annex V to the Directive.

– *all relevant provisions with which the component must comply and, in particular, the conditions of use,*

The most immediate means to meet this requirement is the definition of the interfaces and of the limits to use which have been verified by the notified body during the conformity assessment procedure and which will have to be taken into account during assessment of the subsystem in which the component will be incorporated.

– *the name and address of any body notified, involved in the conformity procedure and the date of the EC examination certificate with details, where appropriate, of the duration and conditions of validity of the certificate,*

The conditions of validity will essentially correspond to the conditions of use referred to above.

The duration is referred to in the conditional as only module B provides for this possibility (see Annex V).

– *where appropriate, the reference of the harmonised standards applicable,*

– *identification of the person empowered to sign on behalf of the manufacturer or his authorised representative established in the Community.*

The existing literature can be referred to for additional aspects regarding the EC declaration of conformity described in this Annex IV. This is particularly so as regards the declaration commiting its signatory: i.e. either the manufacturer or his authorised representative.

ANNEX V Safety components: Assessment of conformity

1. *Scope*

This Annex applies to safety components with a view to checking compliance with the essential requirements referred to in Article 3(1) of this Directive and defined in Annex II. It concerns the assessment by one or more notified bodies of the intrinsic conformity of a component, considered in isolation, with the prescribed technical specifications.

2. *Procedures*

The assessment procedures implemented by the notified bodies both at the design and production stage are based on the modules defined in Council Decision 93/465/EEC along the lines indicated in the following table. The solutions in this table are considered to be equivalent and can be used at the manufacturer's discretion.

Conformity assessment comprises modules for the design phase of the safety components (module B), their production phase (modules D and F) or both (modules H and G). The component must go through the two phases before being placed on the market. The manufacturer can choose, from among four complete procedures (B+D; B+F; H, or G), the one which seems most appropriate and economic as a means of assessing the component.

Theoretically, there is no time limit on the validity of certificates issued by notified bodies (see. Annex I, point 6). A manufacturer may therefore market a component of a certain model on the basis of a certificate issued several years previously. In practice, however, it is highly probable that commercial pressure and the evolution of the state of art will compel him to modify the model.

The notified bodies cannot limit their liability, for instance by making the validity of their certificates subject to a time limit.

Modules must be applied taking into account the specific supplementary conditions in each module.

None of the modules can be subdivided without compromising the consistency of the system or calling into question the liability which rests with the manufacturer and the notified bodies. This also means that the notified body should be able to assume liability for, and have authority to perform, conformity assessments in accordance with a complete module, without prejudice, of course, to the possibility of subcontracting some of the technical tasks (such as tests and examinations) (see also Module B, point 4.2).

MODULE B: EC TYPE-EXAMINATION CERTIFICATE

This module covers only the design phase and must be supplemented by module D or F, which concerns assessment during the production phase. At the end of the

procedure, the notified body issues the EC type-examination certificate. However, the identification number of the notified body involved in the conformity assessment in accordance with module B is not stated on the component. The identification number of the notified body is only placed after the CE marking if that body is involved in the production phase (see Annex XI).

1. *This module describes that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of this Directive.*

2. *The application for EC type-examination must be lodged by the manufacturer or by his authorised representative established within the Community with a notified body of his choice.*

The application must include:

– *the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,*

– *a written declaration that the same application has not been lodged with any other notified body,*

– *the technical documentation, as described in point 3.*

The applicant must place at the disposal of the notified body a specimen, representative of the production envisaged and hereafter called 'type'. The notified body may request further specimens if needed for carrying out the test programme.

3. *The technical documentation must enable the conformity of the component with the requirements of this Directive to be assessed. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the component.*

The documentation must contain as far as is relevant to assessment:

– *a general type-description,*

– *conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc,*

– *descriptions and explanations necessary for the understanding of the said drawings and schemes and the operation of the product,*

– *the list of the European specifications referred to in Article 2(2) of this Directive, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the European specifications referred to in Article 2(2) of this Directive do not exist,*

– *the results of design calculations made, examinations carried out, etc,*

– *test reports.*

It must also indicate the field of use of the component.

In order to avoid placing an excessive burden on manufacturers, the technical documentation made available to the notified bodies must be limited to those items which are necessary for the conformity assessment. Without prejudice to the obligations of notified bodies with respect to the national authorities which notified them, the legal protection of confidential information must be guaranteed.

4. *The notified body:*

4.1. *must examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the components which have been designed in accordance with the relevant provisions of the European specifications referred to in Article 2(2) of this Directive as well as those which have been designed without applying the relevant provisions of those European specifications;*

4.2. *must perform or have performed the appropriate examinations and necessary tests to check whether, where the European specifications referred to in Article 2(2) of this Directive have not been applied, the solutions adopted by the manufacturer meet the essential requirements of this Directive;*

A notified body may entrust some of its technical tasks (e.g. tests and examinations) to another body, provided that the competence of that body has been duly established and is regularly checked. The notified body may under no circumstances subcontract all of its activities. The notified body may, for example, subcontract the tests, while continuing to evaluate the results and ensuring the validation of the test report with respect to the essential requirements. A notified body which uses the services of subcontractors remains in all cases responsible for the results of the assessment. The EC type-examination certificate is always issued in the name and under the responsibility of the notified body.

4.3. *must perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant European specifications, these have actually been applied;*

4.4. *must agree with the applicant the location where the examinations and necessary tests are to be carried out.*

5. *Where the type meets the provisions of this Directive, the notified body must issue an EC type-examination certificate to the applicant. The certificate must state the name and address of the manufacturer, the conclusions of the examination, the conditions for its validity, the duration thereof and give the necessary data for identification of the approved type.*

As has already been pointed out, it is not necessary to state the period of validity of the examination certificate for any of the other modules in Annex V. The only exception is module B, which includes a type examination. In any case, it should only be possible to limit the period of validity if specific reasons are cited (see Appendix I, point 6).

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body. If the notified body refuses to issue an EC type-examination certificate to the manufacturer, the former must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. *The applicant must inform the notified body which holds the technical documentation concerning the EC type-examination certificate of all modifications of the approved component which must receive additional approval where such changes may affect the conformity of the component with the essential requirements or the prescribed conditions of use. This additional approval is given in the form of an addition to the original EC type-examination certificate.*

7. *Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.*

This is part of the notified bodies' general responsibility to inform the other notified bodies of all certificates which have been suspended, withdrawn, issued or refused. The intention is to prevent an application for a certificate for a component which is not in conformity with the requirements from being submitted repeatedly. Each notified body is free to choose the manner of communicating this information to the other bodies, in particular within the Coordination Group of Notified bodies (CSG), which brings together all the notified bodies under this Directive.

8. *The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.*

9. *The manufacturer or his authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for at least 30 years after the last component has been manufactured.*

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the component on the Community market.

MODULE D: PRODUCTION QUALITY ASSURANCE

The manufacturer has the possibility of using a quality system in order to establish conformity with the regulatory requirements. The modules based on quality assurance techniques are, in this case, modules D (production quality assurance) and H (full quality assurance).

Module D is designed for use in combination with module B (EC type-examination certificate) but the assessment may be performed by a different notified body to

the one which applied module B. Module D is used to assess a quality system approved for the production, inspection and testing of finished products.

1. *This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the components concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive. The manufacturer or his authorised representative established within the Community must affix the CE marking to each component and must draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for monitoring as specified in point 4.*

2. *The manufacturer must operate an approved quality system for production, final component inspection and testing as specified in point 3, and is subject to monitoring as specified in point 4.*

3. *Quality system*

3.1. *The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice, for the components concerned.*

This application must include:

– *all relevant information for the component category envisaged,*

– *the documentation concerning the quality system,*

– *if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.*

If the manufacturer has an EN 1SO 9001: 2000 certification issued by an accredited body, it provides a copy of its certification to the notified body when it applies for an assessment. On this basis, the quality manufacturing system benefits from a presumption of conformity with the corresponding quality assurance modules in so far as the quality system also enables it to demonstrate the component's conformity with the essential requirements. Consequently, the notified body will be able to limit its own evaluation to the organisation of the specific manufacture of the category of component in question.

3.2. *The quality system must ensure compliance with the type as described in the EC type-examination certificate and with the requirements of this Directive.*

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must, in particular, contain an adequate description of:

– *the quality objectives and the organisational structure, responsibilities and powers of the management with regard to component quality,*

– *the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,*

– *the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,*

– *the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc,*

– *the means to monitor the achievement of the required component quality and the effective operation of the quality system.*

3.3. *The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonised standards.*

It is not compulsory for the quality system to be based on the 'relevant harmonised standards', i.e. standards EN ISO 9001:2000. However, a quality system implementing those standards confers a presumption of conformity on the corresponding quality assurance modules in so far as the quality system enables the manufacturer to demonstrate that the product is in conformity with the essential requirements of the Directive.

In order not to place an excessive burden on the manufacturer, the technical documentation made available to the notified body should be limited to those elements which are necessary for the conformity assessment. It therefore seems logical for a quality system approved by a notified body or accredited certification body to be taken into account where the conformity assessment is performed in accordance with module D or H, irrespective of whether it is performed on the same or a different category of product. In these cases, however, the notified body must ensure that the certificate covers the relevant provisions of the Directive. Similarly, it must ascertain whether additional checks are required relating specifically to the (new) category of product, although it will often not need to repeat the approval procedure for the entire system.

The auditing team must have at least one member with experience of evaluating in the component technology concerned. The evaluation procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. *The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner at a proper and efficient level.*

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in point 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

4.1. *The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.*

4.2. *The manufacturer must allow notified body entrance for inspection purposes to the places of manufacture, inspection and testing, and storage, and must provide it with all necessary information, in particular:*

– *the quality system documentation,*

– *the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.*

It follows from the previous comments that, in the case of EN ISO 9001:2000 certification, it will be sufficient to examine only those specifications and test certificates which refer directly to the safety component concerned.

4.3. *The notified body must periodically carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and must provides an audit report to the manufacturer.*

4.4. *Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out or cause to be carried out, tests to verify that the quality system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has taken place, a test report.*

5. *The manufacturer must, for a period ending at least 30 years after the last component has been manufactured, keep at the disposal of the national authorities:*

– *the documentation referred to in the second indent of the second paragraph of point 3.1,*

– *the updating referred to in the second paragraph of point 3.4,*

– *the decisions and reports from the notified body which are referred to in points 3.4, 4.3 and 4.4.*

6. Each notified body must give the other notified bodies the relevant information concerning all quality system approvals issued and withdrawn.

See Module B, point 7

MODULE F: PRODUCT VERIFICATION

Module F is also designed for use in combination with module B (EC type-examination certificate) and the assessment may also be performed by a different notified body to the one which applied module B. Module F is designed to guarantee conformity of the components with the type described in the EC type-examination certificate.

1. This module describes the procedure whereby a manufacturer or his authorised representative established within the Community checks and attests that the components subject to the provisions of point 3 are in conformity with the type described in the EC type-examination certificate and satisfy the requirements of this Directive.

2. The manufacturer must take all measures necessary in order that the manufacturing process ensures conformity of the components with the type as described in the EC type-examination certificate and with the requirements of this Directive. He shall affix the CE marking to each component and shall draw up a declaration of conformity.

3. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the components to the requirements of this Directive either by examination and testing of every component as specified in point 4 or by examination and testing of components on a statistical basis, as specified in point 5, at the choice of the manufacturer.

The manufacturer or his authorised representative resident within the Community must keep a copy of the declaration of conformity for a period ending at least 30 years after the last component has been manufactured.

4. Verification by examination and testing of every component

4.1. All components must be individually examined and appropriate tests as set out in the relevant European specification(s) referred to in Article 2 or equivalent tests shall be carried out in order to verify their conformity with the type described in the EC type-examination certificate and to (sic) the requirements of this Directive.

4.2. The notified body must affix or cause to be affixed, its identification symbol to each approved component and draw up a written certificate of conformity relating to the tests carried out.

4.3. The manufacturer or his authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.

5. Statistical verification

5.1. The manufacturer must present his components in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.

5.2. All components must be available for verification in the form of homogeneous lots. A random sample must be drawn from each lot. Components in a sample must be individually examined and appropriate tests as set out in the European specification(s) referred to in Article 2(2) of this Directive, or equivalent tests, shall be carried out to ensure their conformity with the requirements of this Directive and to determine whether the lot is accepted or rejected.

5.3. The statistical procedure must use the following elements:

- *a statistical method,*
- *a sampling plan with its operational characteristics.*

5.4. In the case of accepted lots, the notified body must affix, or cause to be affixed, its identification number to each component, and shall draw up a written certificate of conformity relating to the tests carried out. All components in the lot may be put on the market, except those components from the sample which were found not to be in conformity.

If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent the putting on the market of that lot. In the event of the frequent rejection of lots the notified body may suspend statistical verification.

The manufacturer may, under the responsibility of the notified body, affix the latter's identification number during the manufacturing process.

5.5. The manufacturer or his authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.

MODULE G: UNIT VERIFICATION

This module covers the design, manufacture and operation of the assessed safety component. The conformity assessment of a 'unit' in terms of its design is performed in accordance with the principles applied to module B, except with regard to the EC type-examination certificate, which is not issued in this case. In module G the notified body also supervises the construction of the 'unit' with respect to the relevant requirements.

1. *This module describes the procedure whereby the manufacturer ensures and declares that the component concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of this Directive that apply to it. The manufacturer or his authorised representative established within the Community must affix the CE marking to the component and must draw up a declaration of conformity.*

2. *The notified body must examine the component and must carry out the appropriate tests as set out in the relevant European specifications referred to in Article 2(2) of this Directive, or equivalent tests, to ensure its conformity with the relevant requirements of this Directive.*

The notified body must affix, or cause to be affixed, its identification number on the approved component and shall draw up a certificate of conformity concerning the tests carried out.

3. *The aim of the technical documentation is to enable conformity with the requirements of this Directive to be assessed and the design, manufacture and operation of the component to be understood.*

For the purposes of assessment, the documentation must include the following:

- *a general description of the type,*
- *conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc,*
- *descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the component,*
- *a list of the relevant European specifications applied in total or partially referred to in Article 2(2) of this Directive, as well as a description of the solutions adopted by the manufacturer to meet the essential requirements of the Directive, where the European specifications referred to in Article 2(2) have not been applied,*
- *the results of the design calculations made, examinations carried out, etc,*
- *test reports,*
- *fields of use of components.*

MODULE H: FULL QUALITY ASSURANCE

The manufacturer has the possibility of using a total quality assurance system in order to establish conformity with the regulatory requirements.

1. *This module describes the procedure whereby a manufacturer who satisfies the obligations of paragraph 2 must ensure and declare that the components concerned*

satisfy the relevant requirements of this Directive. The manufacturer or his authorised representative established within the Community must affix the CE marking to the component and must draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for the surveillance as specified in point 4.

2. *The manufacturer must operate an approved quality system for design, manufacture and final component inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.*

3. *Quality system*

3.1. *The manufacturer must lodge an application for assessment of his quality system with a notified body.*

The application must include:

– *all relevant information for the category of component envisaged,*

– *the documentation relating to the quality system.*

See Module D, point 3.1

3.2. *The quality system must ensure compliance of the components with the relevant requirements of this Directive.*

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must in particular include an adequate description of:

– *the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and component quality,*

– *the technical design specifications, including the European specifications referred to in Article 2(2) of this Directive, that will be applied and, where the European specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the products will be met,*

– *the design control and design verification techniques, processes and systematic actions that will be used when designing the components pertaining to the category of components covered,*

– *the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,*

– *the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,*

– *the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc,*

– *the means to monitor the achievement of the required design and component quality and the effective operation of the quality assurance system.*

3.3. *The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonised standard.*

See Module D, point 3.3

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. *The manufacturer must undertake to fulfil the obligations arising from the quality system as approved and to uphold it so that it remains adequate and efficient.*

The manufacturer or his authorised representative must keep the notified body that has approved the quality system of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It must notify it decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

4.1. *The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.*

4.2. *The manufacturer must allow the notified body entrance for inspection purposes to the places of design, manufacture, inspection and testing, and storage, and shall provide it with all necessary information, in particular:*

– *the quality system documentation,*

– *the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc,*

– *the quality reports as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.*

See Module D, point 4.2

4.3. *The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.*

4.4. *Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.*

5. *The manufacturer must, for a period ending at least 30 years after the last component has been manufactured, keep at the disposal of the national authorities:*

– *the documentation referred to in the second indent of the second subparagraph of point 3.1,*

– *the updating referred to in the second subparagraph of point 3.4,*

– *the decisions and reports from the notified body which are referred to in points 3.4, 4.3 and 4.4.*

6. *Each Notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.*

7. *Supplementary requirements: design examination*

The Directive lays down supplementary provisions for conformity assessment according to module H. This means that conformity with standards EN ISO 9001: 2000 must be supplemented by additional elements in order to take into account the specific features of the safety components used in cableways.

The notified body which carries out the assessment in accordance with module H should be able to assume liability and to have the authority to perform the assessment in accordance with the complete module, including the additional provisions referring to design surveillance.

'Surveillance of the component design' consists in either checking the design of each safety component individually, or checking the design of each 'family' of safety components.

7.1. The manufacturer must lodge an application for examination of the design with a single Notified body.

7.2. The application must enable the design, manufacture and operation of the component to be understood, and shall enable conformity with the requirements of this Directive to be assessed.

It must include:

- *the technical design specifications, including the European specifications referred to in Article 2(2) of this Directive that have been applied,*
- *the necessary supporting evidence for their adequacy, in particular when the European specifications referred to in Article 2(2) of this Directive have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf.*

7.3. The notified body must examine the application and where the design meets the provisions of this Directive, must issue an EC design examination certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions for its validity, the data necessary for identification of the approved design and, if relevant, a description of the component's functioning.

7.4. The applicant must keep the notified body that issued the EC design examination certificate of any modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect conformity to the essential requirements referred to in Article 3(1) of this Directive or the prescribed conditions for use of the component. This additional approval is given in the form of an addition to the original EC design examination certificate.

7.5. Each Notified bodies must forward to the other notified bodies the relevant information concerning:

- *the EC design examination certificates and additions issued,*
- *the EC design approvals and additional approvals withdrawn,*
- *the EC design examination certificates and additions refused.*

See Module B, point 7

ANNEX VI Subsystems: EC declaration of conformity

The EC declaration of conformity described in this Annex is broadly similar to the one for safety components (see Annex IV). There are, however, some differences which take account, in particular, of the fact that the information provider, who will often be the applicant for the EC examination referred to below, can be the assembler (see Articles 10(2) and Appendix II) of the components which make up the subsystem without being the manufacturer of any of the subsystem components.

This Annex applies to the subsystems referred to in Article 9 of this Directive in order to ensure they fulfil the essential requirements concerning them referred to in Article 3(1) of this Directive.

The EC declaration of conformity must be drawn up by the manufacturer, or his authorised representative established in the Community, or, where such a persons is not available, any natural or legal person, who places the subsystem on the market; the EC declaration and the accompanying technical documentation must be dated and signed.

Since subsystems do not bear CE markings, it is the EC declaration of conformity and the technical documentation which indicate the subsystem's conformity with the Directive (see Article 10).

This EC declaration of conformity and the technical documentation must be drawn up in the same languages or languages as the instruction manual referred to in point 7.1.1 of Annex II and must contain the following information:

– *the reference of this Directive,*

– *the name and address of the person who ordered EC examination,*

– *a description of the subsystem,*

This description must make it possible to identify precisely the safety components incorporated in the subsystem, and to identify the subsystem in the infrastructure together with the associated interfaces.

– *the name and address of the notified body which carried out the EC examination, referred to in Article 11 of this Directive,*

– *all relevant provisions with which the subsystem must comply, in particular any operating restrictions or operating conditions,*

These are provisions relating to the subsystem and not a compilation of provisions specific to safety components incorporated in the subsystem.

– *the outcome of the EC examination referred to in Annex VII (EC conformity certificate),*

– *particulars of the person who is authorised to sign a legally binding declaration for the manufacturer, or his authorised representative or, where such a person is not available, the natural or legal person, who places the subsystem on the market.*

ANNEX VII Subsystems: Assessment of conformity

In the case of subsystems, the Directive lays down a specific procedure for assessing their conformity, rather than relying on the modules used for safety components (see Annex V).

1. *EC examination is the procedure whereby, at the request of the manufacturer or his authorised representative established in the Community or, where such a person is not available, any natural or legal person who assumes responsibility for placing the subsystem on the market, a notified body checks and attests …*

The application may be submitted only by the manufacturer, his authorised agent established in the EU or, if such a person is not available, the person placing the subsystem on the market (see comments on Article 10(2)). This cannot be done either directly by the owner or on an ex officio basis by the notified body. Each has their own role and therefore their own liability. The fact that the manufacturer has obtained an EC certificate removes none of his obligations. He remains responsible for the subsystem's conformity with the Directive. The notified body applies the procedure described in Annex VII, draws up the EC examination certificate and compiles the technical documentation which accompanies it. The manufacturer (or his authorised representative, or, if such a person is not available, the person placing the system on the market) submits the application and draws up the EC declaration of conformity.

… that a subsystem is:

– *in conformity with the provisions of the Directive and other relevant provisions in compliance with the Treaty,*

– *in conformity with the technical documentation, and completed.*

The EC examination of a subsystem may be done by assessing the procedure for validating the assembly of safety components which make up the subsystem and the conformity of the subsystem in its completed state. It is not necessary for the EC examination to be performed on the complete system.

The period of validity of certificates issued by notified bodies is not limited (see Appendix I, point 6). A manufacturer may therefore market a subsystem on the basis of a certificate issued several years previously. In practice, however, it is highly probable that commercial pressure, the evolution of the state of art and the characteristics particular to each installation will compel him to modify the model.

Notified bodies cannot limit their liability, e.g. by imposing a time limit on the validity of their certificates.

2. *The examination of the subsystem is carried out at each of the following stages:*

– *design,*

– *construction and acceptance trials once the subsystem has been completed.*

Where a procedure was evaluated by a notified body, the checks provided for in the aforementioned procedure should be carried out, without the notified body having to take part in these operations itself.

3. *The technical documentation accompanying the examination certificate must comprise the following:*

– *construction plans and calculations, electrical and hydraulic diagrams, control circuit diagrams, description of computer and automatic systems, operating and servicing instructions, etc,*

– *a list of the safety components referred to in Article 4(2) of this Directive which are used in the subsystem,*

– *copies of the EC declaration of conformity as provided for in Annex IV for these safety components together with the corresponding construction plans and a copy of the reports on any other tests and trials carried out.*

These documents, provided by the applicant, concern at this stage only the notified body which evaluates the subsystem and draws up the EC examination certificate. It is not necessary to submit entire files which the notified bodies were sent for the purpose of assessing the safety components which constitute the subsystem.

4. *Documentation and correspondence in connection with the EC examination procedures must be drawn up in the same language or languages as the instruction manual referred to in point 7.1.1 of Annex II.*

5. *Surveillance*

5.1. *It shall be ensured by means of surveillance that during construction of the subsystem the obligations arising from the technical documentation are fulfilled.*

5.2. *The notified body responsible for EC examination must have permanent access to the production shops, storage areas and, where necessary, to prefabrication areas, testing plants and more generally to any locations it feels it needs to visit in order to perform its task. The manufacturer or his authorised representative or, where such a person is not available, the natural or legal person who places the subsystem on the market must provide it with, or arrange for it to be provided with, any documents required to that end, notably the plans and technical documentation relating to the subsystem.*

5.3. The notified body responsible for EC examination must periodically carry out audits to ensure compliance with the provision of this Directive. On each visit it must provide the site supervisor responsible with an audit report. It may ask to be brought in to inspect various stages of the work.

5.4. In addition, the notified body may pay unexpected visits to the production shops. During such visits it may carry out full or partial audits. The notified body must draw up a report on the visit and, where necessary, submit an audit report to the site supervisor responsible.

6. Each Notified body must publish periodically the relevant information concerning:

- *all applications for EC examination received,*
- *all EC examination certificates issued,*
- *all EC examination certificates refused.*

See Annex V, Module B, point 7.

ANNEX VIII Minimum criteria to be taken into account by Member States for the notification of bodies

All the conformity assessment procedures provided for in this Directive require the intervention of an external assessment body: the notified body. It is therefore essential for the credibility of the system that the notified bodies act with proven competence, integrity and professionalism (see Article 16). This Annex lists the minimum criteria which these bodies must satisfy in order to be designated by a Member State.

1. *The notified body, its director and staff responsible for carrying out the verification operations may not be either the designer, manufacturer, supplier or installer of the safety components or subsystems which they inspect or the authorised representative of any of those parties or the natural or legal person, who places these safety components or subsystems on the market. They may not become involved, either directly or as authorised representatives, in the design, manufacture, construction, marketing, servicing or operation of these safety or subsystems. This does not preclude the possibility of exchanges of technical information between the manufacturer and the notified body.*

2. *The notified body and its inspection staff must carry out the verification operations with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of the verifications.*

3. *The notified body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with the verification operations; it must also have access to the equipment required for special verification.*

4. *The staff responsible for inspection must have:*

- *sound technical and professional training,*
- *satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,*
- *the ability required to draw up the certificates, records and reports required to authenticate the performance of the tests.*

5. *The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.*

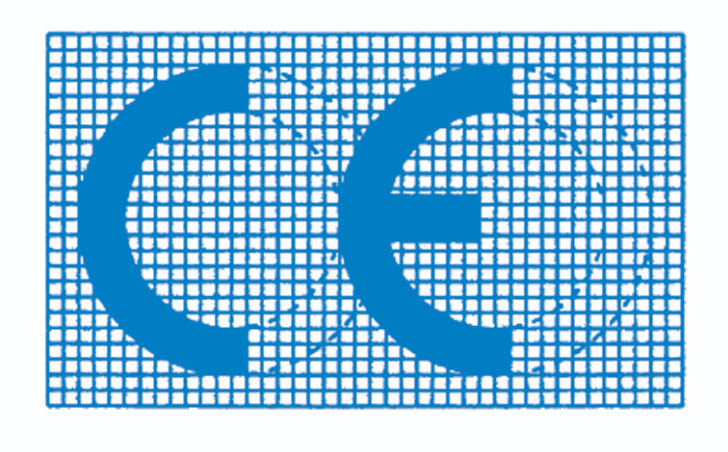
6. The notified body must take out civil liability insurance unless its liability is assumed by the State in accordance with national law or the Member State itself is directly responsible for the inspections.

7. The staff of the body must be bound by professional secrecy (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) with regard to all information it acquires in carrying out its tasks under this Directive or any provision of national law giving effect to it.

ANNEX IX CE conformity marking

The CE marking is a conformity marking (see Article 18) which must not undergo graphic change. The manufacturer must not, for example, merge the graphic design of the CE marking with that of his own brand, nor elongate or deform the CE marking.

The 'CE' conformity marking shall consist of the letters 'CE' taking the following form:



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

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale safety components.

The CE marking shall be followed by the last two figures of the year in which it was affixed and by the identification number of the notified body that deals with the procedures referred to in Article 7(3) of this Directive.

The CE marking shall only be followed by the identification number of the notified body if it is involved in the production stage (modules D, F, H and G). Thus, the CE marking is never followed by the identification number of a notified body involved in conformity assessment according to module B. Sometimes several notified bodies could be involved in the production stage, which is possible where several Directives are applicable. In such cases, the CE marking is followed by several identification numbers.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5. Appendices

APPENDIX I Principal questions raised

1. What is a harmonised standard, and what purpose does it serve?

A – A harmonised standard within the meaning of the New Approach is a European technical standard which has followed a particular procedure and has been drawn up having regard to essential requirements contained in a New Approach Directive.

The particular procedure comprises:

– The mandate, i.e. the formal invitation of the European Commission assigning to the usual standardisation bodies (CEN, CENELEC, ETSI) the task of drawing up appropriate technical standards to facilitate the application of a given Directive. This mandate enables deadlines to be fixed and specific resources to be allocated.

– Verification that the standard satisfies the essential requirements contained in a Directive and the drawing up of a table of correspondence between certain articles in the standard and certain essential requirements. This table, provided for information, constitutes an 'Annex ZA'.

– Approval by the Commission of the document thus drawn up and publication of the standards' references in the OJEU.

– Transposition at national level. National standardisation bodies are obliged to incorporate the standards in question, in identical form, in their own collection. It is they who are responsible for the commercial dissemination of the standards.

B – Conformity with a harmonised standard (not legally binding) confers the presumption of conformity with the corresponding essential requirements (legally binding), which are referred to in the information annex 'ZA'. This applies, of

course, only to the subject matter dealt with in the standard. A single essential requirement may well require several standards to be met.

This presumption is very useful:

– for manufacturers, who in conforming with the standard have a guarantee that their product will be presumed to be in conformity with the essential requirements and can definitely bear the CE marking,

– for the notified body responsible for assessment, as this task will be made much easier,

– and also for the authorities of the Member States as far as configuration of the installation is concerned.

Very often, standards lay down characteristics and means, based on experience and know-how, whereas essential requirements contain objectives and require results. The demonstrations required for conformity are different in each of the two cases.

2. *Is application of a harmonised standard compulsory?*

No, the mere fact of the standard being harmonised does not mean it is compulsory

In the mechanism of the New Approach, compliance with the essential requirements contained in a legally binding Directive is compulsory. To achieve this, manufacturers are always free to choose the most appropriate means, whether that be the harmonised standard or another method.

As stated under the previous question, the only obligation linked to the status of harmonised standard (an obligation deriving from the internal rules of CEN) is that it be included in the collection of national standards in each Member State, which means that any and all national standards which contradict it must be withdrawn within a given period, as explained below.

By contrast, it may be that in certain markets or for certain orders, placed by public bodies for example, compliance with certain standards, harmonised or not, will be contractually imposed. This has nothing to do with the status of the standard itself.

3. *Why is it that, in the overall work of the CEN/TC 242 concerning safety requirements for cableway installations designed to carry persons, some standards are not harmonised standards?*

These are the standards EN 1907, Terminology, and EN 12408, Quality assurance.

These two standards do not correspond directly to essential requirements, and that is why they are not 'harmonised': the simple fact of operating a certain form of quality assurance or of using a particular term correctly cannot constitute an essential requirement, which most often is a requirement to achieve a certain result in terms of safety.

By contrast, the TC 242 felt that it was useful, for a good understanding of the standards and to avoid tedious repetitions, to have a terminology standard, and

that, moreover, appropriate quality assurance could help to obtain the results required in other standards.

That is why these two standards, designated as 'support standards', are not harmonised and do not include an annex ZA as the others do.

4. *Is it lawful to retain a national rule, whether contained in a law or regulation, which is in contradiction with a harmonised standard applicable to safety components and subsystems, citing as the reason the fact that the rule concerned is in conformity with essential requirements and that an 'A-deviation' has been recorded in due and proper form in a harmonised standard?*

Basically, the answer is no.

Nevertheless, it is not national regulations, but the safety components and subsystems which have to be assessed in terms of essential requirements. The majority of national regulations can be regarded as complying with essential requirements, and it is this fact moreover, that made rapid agreement on this subject possible. However, if each Member State were to retain its own rules as a result, no progress would be made at all towards the common market.

The Directive is a legislative instrument of total harmonisation. This means that the Directive replaces all corresponding national provisions in the field. As far as the free circulation of goods is concerned, the Directive relates to safety components and subsystems. Transposition of the Directive into national legislations and regulations must have the effect of ensuring that components and subsystems duly declared, certified and marked with regard to compliance with essential requirements cannot be prohibited or their placing on the market impeded or restricted (Articles 6 and 9 of the Directive). This will take precedence over any other national rule which is retained with regard to safety components and subsystems.

Any 'A-deviations' referred to in information annexes to harmonised standards stem from the fact that standardisers, whether European or national, do not have the power themselves to amend legislative or regulatory texts and that, in addition, certain exceptions relating to components and subsystems may have been maintained while the reference Directive was not yet fully applied. However, once the total harmonisation Directive is fully applied, 'A-deviations' which risk creating a barrier with regard to safety components and subsystems covered by the Directive are no longer justified.

5. *What rules apply to the relocation of an installation, within a Member State or from one Member State to another?*

In the new location, the installation is deemed to be a new installation and must therefore comply with the associated rules, in particular those relating to safety analysis and to the procedures for construction and putting into service (see Articles 4 and 11).

In the case of safety components and subsystems taken from the original installation without undergoing any modification requiring a new authorisation for entry into service, there is no reason to require certificates and markings as there is no placing on the market, in the sense that this is not the first time they have been made available for use. The situation is different for safety components or subsystems which have undergone modifications. In respect of these, the Directive stipu-

lates that essential requirements must be met (see Article 1(4), last subparagraph).

The fact that the Directive does not lay down any requirements in respect of cases not involving a first placement on the market does not prevent Member States from prescribing particular rules governing the re-utilisation of certain components or subsystems on their territory. This freedom is to be exercised having regard to the safety objectives for which Member States remain responsible (see Article 11(2)). The safety analysis must take account of the experience gained with the initial installation and of whether the components and subsystems come from the same or different sources.

In this context it should be noted that, as far as application of the Directive is concerned, it does not matter whether the new location is in the transferred installation's Member State of origin or in another Member State.

6. Must or can the EC examination certificates provided by notified bodies include durations of validity? Is a duration of five years justified a priori?

Nothing in the New Approach Directives justifies a systematic limit, either of five years or of any other duration.

Often, the origin of this practice lies in the confusion between conformity assessment (which takes place before the product is placed on the market) and market surveillance (which takes place after the product has been placed on the market). The notified body intervenes only prior to placing on the market, in order to assess the conformity of a safety component or a subsystem with the essential requirements. If the component (or the subsystem) is not in conformity, it cannot be placed on the market by the manufacturer. If it is in conformity, however, it will receive its certificate of conformity and can be placed on the market for an unlimited period. The issuing of the EC examination certificate marks the end of the notified body's involvement. Once the product is on the market, the surveillance authority takes over and is responsible for checking that the component or the subsystem is in conformity with the provisions of the Directive. The clear distinction between the role of the notified body and that of the surveillance authority explains, from the point of view of the New Approach, the absence of durations of validity in the EC examination certificates.

It is true that the text of the Directive refers to a limited duration. However, the reference to a limited duration is merely conditional ('where appropriate') and concerns only safety components in Annexes IV and V to the Directive. Closer examination reveals that this notion of duration of validity is referred to solely in the description of module B and not in the others. This is explained by the fact that, in this module, the notified body has to carry out checks concerning the representativity of the 'type' of product examined, whereas in the other modules, which range from unit verification to full quality control, this representativity does not feature in the same way, so that there is no justification for a time limit.

Finally, there are other time criteria which may come into play and which could also produce a degree of confusion. However, these are criteria which no longer relate to a product, and hence to a certificate, but to quality systems, for example. Should one, for example, limit a certificate to a few months because the current certificate will soon expire and the manufacturer's quality system must soon be audited? The answer is no, for a twofold reason, both ethical and practical. Ethics dictate that a negative assumption should not be placed on the outcome of a future audit (especially where, by definition, it is a renewal audit), while practical

considerations suggest that one should avoid the inescapable multiplicity of certificates which would systematically be generated by this kind of time limit, which is, moreover, not necessary for compliance with the Directive.

7. *Who judges the safety analysis drawn up for each installation?*

It is up to the authorities of the Member States to specify this in the authorisation procedures for construction and entry into service (see Article 11(6)). Each State may lay down its own procedure.

Verification of the safety analysis and other verifications may be entrusted to third parties, generally chosen for their competence and independence.

8. *Do safety components intended for the maintenance of installations existing prior to the full entry into force of the Directive have to be assessed, declared to be in conformity and given the CE marking?*

This question has been the subject of a long and wide-ranging debate, often under the heading of 'parts' (see standing committee, group of experts, CIRCA forum, etc.). The conclusion can be formulated as follows:

'Safety components and subsystems which have ceased to be manufactured for new installations but continue to be produced, in the context of normal maintenance, as identical or virtually identical replacements for parts of existing installations, i.e. constructed before 3 May 2004, do not have to be given the CE marking and can remain subject to national rules.'

There are two corollaries to this rule:

- Safety components and subsystems which are routinely manufactured and used for both new and existing installations must be assessed, declared to be in conformity and given the CE marking.

- All the Member States should act in this way. If some were to require across the board marking, manufacturers would have no choice but to have all their products assessed and marked.

In this way the Directive is complied with, and the negative effects which would be caused by an across the board obligation to mark (and therefore to assess) parts are avoided.

Indeed, Article 1(4) of the Directive states that, for existing installations, modifications are subject to the new rules only if a new authorisation for entry into service is necessary. From this it logically follows that minor modifications and, a fortiori, maintenance not involving modification, will not bring an installation under the scope of the Directive.

9. *I manufacture parts which will subsequently be incorporated into a new installation. How can I know whether my parts are safety components and thus whether I have to involve a notified body to assess them?*

It is indeed possible for a manufacturer not to know whether his component will be a safety component, particularly in the early stages of the implementation of

the Directive. He may also be unaware that his component is to be incorporated into a cableway installation designed to carry persons, and by the same token may not be aware of the Directive's existence.

A component only actually becomes a safety component when it is incorporated into an installation, as stated in the definition given in Article 1(5) of the Directive. While the procedures refer to placing on the market, the intended purpose is always the construction of an installation (Articles 5 and 8). Where this intended purpose has not yet been established, therefore, no prohibitions or restrictions can be applied.

A manufacturer of a component should ask himself what use the user could make of his product. If application on a cableway installation appears to be a lucrative outlet, it is in his interest, both for commercial reasons and for reasons of his own and legal security, to anticipate a request for assessment and to offer from the outset a component bearing the CE marking. The assessment can be carried out at any time but no later than when the manufacturer receives a request for it from the contractor who incorporates the component into a subsystem very probably having a safety function.

For the purchaser of a component, the CE marking gives a guarantee that there will be no subsequent problem in the event of its being classified as a safety component.

10. *Can a manufacturer who has received ISO 9001 certification from an accredited body issue, without further formality, a declaration of conformity relating to module D (production quality assurance) or H (total quality assurance)?*

No. Certificates relating to safety components for cableway installations designed to carry persons can be issued only by bodies notified under Directive 2000/9/EC.

However, notified bodies will clearly take account of the manufacturer's quality system and limit their investigations to the components concerned (see Annex V).

11. *What is the state of the art?*

The state of the art corresponds to what is known and considered to be compliant at a given point in time. This notion of time is very important as the state of the art in itself evolves continuously, or almost continually, and if the reference is not specified it is easy for misunderstandings or misinterpretations to occur. Acknowledged rules of the art, a very closely related concept, are technical solutions recognised by a majority of experts as reflecting the state of the art. They evolve in an intermittent manner and in fact incorporate a notion of place, particularly when a set of regulations has to be taken into account.

Concerning this subject, reference can be made to the standard EN 45020. This distinction is not always taken into account, and in current parlance the terms are used interchangeably. Thus, depending on the language version, essential requirement 2.4 is formulated with reference to the acknowledged rules of the art or the state of the Art.

APPENDIX II Definitions

1. *Accreditation*

It is provided by an accreditation body and is an instrument that makes it possible to assess the competence, impartiality and integrity of a body to be notified. Although it is not compulsory, accreditation is regarded as a key technical criterion for evaluation, enabling the technical aspects of notification to be reinforced and differences between notification criteria to be reduced.

2. *Accreditation body or system*

A body, system or network of sectoral bodies which perform accreditation. The authority of an accreditation body must be derived from a public authority.

3. *Certificate*

A document furnished by a notified body on completion of the examination which it carries out on a safety component (see Annex V) or subsystem (see Annex VII). It certifies conformity with the essential requirements relating to the product examined.

4. *Surveillance authority*

From the point of view of the Directive, the surveillance authority (see Appendix VI) is the authority designated by each Member State to be responsible for market surveillance operations in relation to safety components and subsystems for cableways (see Articles 5 and 8).

From the point of view of the cableway sector, the surveillance authority is also the body which, on behalf of the public authority concerned, is responsible for monitoring the carriage of persons by cableways.

Depending on the political and administrative structures in each Member State, these two types of control may be performed at national, regional or local level. The level at which surveillance takes place may depend on the legal nature, location and degree of technical complexity of each installation.

Market surveillance of safety components and subsystems may be carried out by the bodies which monitor transport, or by other bodies.

5. *Safety component*

This term is defined in Article 1(5), 2nd indent, of the Directive.

6. *EC declaration of conformity*

A document drawn up by the manufacturer, his authorised representative or any other person responsible for placing a safety component or subsystem on the mar-

ket, declaring that the product concerned is in conformity with the essential requirements relating to it.

7. Assembler

The role of assembler is performed by a constructor who is not the direct manufacturer of the elements which make up the assembly but who ensures overall consistency and assumes responsibility for the assembly thus put together and placed on the market. This assembly generally constitutes a subsystem.

8. Conformity assessment

This demonstrates that certain essential requirements relating to a product, a process or a system have been met. The assessment of conformity with essential requirements under this Directive can only be carried out by a third party. An accreditation body is not a conformity assessment body.

9. Operability

This term is defined in Article 1(5), 4th indent, of the Directive.

10. Operation

This is the fact of using an installation to transport persons. As with any mechanical system, operation requires energy, a degree of surveillance (in situ or remote) and maintenance. Operation takes place under the responsibility of an operator. The Directive does not concern operation.

11. Installation

This is defined in Article 1(5), 1st indent, of the Directive.

12. Maintainability

This term is defined in Article 1(5), 5th indent, of the Directive.

13. Maintenance

All technical, administrative and management actions during the life cycle of a product (here, of an installation) intended to maintain it or restore it to a state in which it can perform the function required (here, the safe carriage of persons). The Directive does not concern maintenance.

14. Main contractor

This term is defined in Article 1(5), 3rd indent, of the Directive.

This term and its definition should be adhered to, since equating it with the owner or operator could well fail to reflect reality. The main contractor is the one who actually takes responsibility and makes the decisions concerning the purchase of the installation.

15. Putting into service

The first use, for its intended purpose, by the end user, within the territory of the EU, of a product covered by the Directive.

16. Placing on the market

First instance of an individual product being placed on the EU market for distribution or use within the territory of the EU.

17. Notified body

Notified bodies are charged with the task of implementing the conformity assessment procedures provided for in the Directive for safety components and subsystems (see Appendix IV).

18. Subsystem

It is necessary to refer to the list in Annex I in order to gain a better idea of what constitutes an intermediate level between components, whether or not they are safety components, and the installation taken as a whole. They are functional assemblies of variable importance. The content of the notion of 'assembly' may vary from one installation to another. Subsystems are assessed by notified bodies, which check the relevance of the assembly with regard to the functions performed.

APPENDIX III Standardisation programme

A special technical committee, the TC 242, was created by CEN in 1989 to draw up safety specifications concerning the principal parts of cableway installations designed to carry persons. Moreover, the competencies of the TC 168, dedicated to the safety of steel wire ropes and responsible in particular for two parts of standards on ropes used specifically on installations for the carriage of persons, have not been amended.

Starting from the approval of the Directive in 2000, this work was carried out under a mandate from the European Commission with a view to aiding application of Directive 2000/9/EC. Upon completion of the procedure, these standards are published in the OJEU and must be incorporated into the series of national standards of the Member States. The Member States of the European Economic Area (EEA) have to do the same. Other states such as Switzerland and Andorra will follow suit as they have opted for voluntary application of the Directive.

The initial standardisation programme of TC42 was composed of 13 standards. This programme has been completed by the subdivision of certain standards into several parts, as well as by two technical reports on preventing and combating fires. There are also two non-harmonised standards that concern terminology and quality assurance. No essential requirement may be linked with them, but they are useful as a 'support' for the overall setup. Finally, the technical report in two parts on preventing and combating fires provides a reference text which contains recommendations only and which does not necessarily reflect a 'recognised state of the art'. It constitutes the beginning of a supplementary response to essential requirement 2.6.5.

The table of correspondence between essential requirements and the various standards, which is given following the standardisation programme, shows the complexity of cableways and the degree of interlinkage between the different standards. The foreword to each of them underlines the unity of the programme to which it belongs.

STANDARDISATION PROGRAMME ([10])

Standardisation organisation	Reference	Title	Status
CEN/TC 168	EN 12385-8:2002	Steel wire ropes – Safety – Part 8: Stranded hauling and carrying-hauling ropes for cableway installations designed to carry persons	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12385-9:2002	Steel wire ropes – Safety – Part 9: Locked coil carrying ropes for cableway installations designed to carry persons	Harmonised standard Publication OJEU C230, 20.9.2005

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([10]) Standards references are published in the series C of the OJEU. As soon as references are published, updates are available on the DG Enterprise and Industry website at: http://europa.eu.int/comm/enterprise/standards_policy/index.htm
The list is constantly updated and may be consulted on the Internet via the Europa server at the following http://europa.eu.int/comm/enterprise/nando-is/home/index.cfm (list updated more frequently) http://europa.eu.int/comm/enterprise/rail_guided_transport/index.htm (list updated each month).

Standardisation organisation	Reference	Title	Status
CEN/TC 242 (All the documents prepared by the TC 242 bear the general title: Safety requirements for passenger transportation by rope)	EN 1907	Terminology	Non-harmonised standard
	EN 12929-1:2004	General provisions – Part 1: Requirements for all installations	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12929-2:2004	General provisions – Part 2: Additional requirements for reversible bicable aerial ropeways without carrier truck brakes	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12930:2004	Calculations	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12927-1:2004	Ropes. Part 1: Selection criteria for ropes and their end fittings	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12927-2:2004	Ropes. Part 2: Safety factors	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12927-3:2004	Ropes. Part 3: Long splicing of 6 strand hauling, carrying hauling and towing ropes	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12927-4:2004	Ropes. Part 4: End fittings	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12927-5:2004	Ropes. Part 5: Storage, transportation, installation and tensioning	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12927-6:2004	Ropes. Part 6: Discard criteria	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12927-7:2004	Ropes. Part 7: Inspection, repair and maintenance	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12927-8:2004	Ropes. Part 8: Non-destructive testing	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 1908: 2004	Tensioning devices	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 13223:2004	Drive systems and other mechanical equipment	Harmonised standard Publication OJEU C230, 20.9.2005

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Standardisation organisation	Reference	Title	Status
CEN/TC 242 (All the documents prepared by the TC 242 bear the general title: Safety requirements for passenger transportation by rope)	EN 13796-1:2005	Carriers. Part 1: Grips, carrier trucks, on-board brakes, cabins, chairs, carriages, maintenance carriers, tow-hangers	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 13796-2:2005	Carriers. Part 2: Slipping resistance tests for grips	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 13796-3:2005	Carriers Part 3: Fatigue testing	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 13243:2004 EN 13243:2004/ AC:2005	Electrical installations other than drive systems	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 13107:2004	Civil engineering works	Harmonised standard Publication OJEU C230,20.9.2005
	EN 1709:2004	Precommissioning inspection, maintenance and operational tests	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 1909:2004	Recovery and evacuation	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12397:2004	Operation	Harmonised standard Publication OJEU C230, 20.9.2005
	EN 12408	Quality Assurance	Non-harmonised standard
	TR 14819-1	Prevention and fight against fire. Part 1: Funicular railways in tunnels	Technical report
	TR 14819-2	Prevention and fight against fire. Part 2: Other funicular railways and other installations	Technical report

CORRESPONDENCE TABLE BETWEEN THE ESSENTIAL REQUIREMENTS AND THE PROGRAMME OF HARMONISED STANDARDS

For information, and to make it easier to locate the most useful texts, the following table indicates the standards in which the essential requirements are dealt with, generally partially. It should be remembered that the presumption of conformity applies in reverse: from the standard to the essential requirement, and that each harmonised standard presents the correlations in question in Annex ZA.

In most cases, the essential requirements are expressed in terms of objectives which are achieved by various measures which may involve numerous components and several subsystems. As the most general requirements concern all the harmonised standards, they are not included in this table, which is in no way exhaustive.

Essential Requirement		Harmonised Standards
No	Subject	
2.3	Consideration of external constraints	EN 12929-1:2004 EN 12929-2:2004 EN 13223:2004
2.4	Dimensioning	EN 12929-1:2004 EN 12929-2:2004 EN 1908:2004 EN 13223:2004 EN 13107:2004 EN 13796-1:2005
2.5	Assembly	EN 12929-1:2004 EN 13223:2004 EN 13107:2004 EN 13796-1:2005
2.6.1	Integrity. Improbable failure	EN 12929-1:2004 EN 12929-2:2004 EN 12385-8:2002 EN 12385-9:2002 EN 12927-1:2004 EN 12927-2:2004 EN 12927-3:2004 EN 12927-4:2004 EN 12927-5:2004 EN 12927-6:2004 EN 12927-7:2004 EN 12927-8:2004 EN 1908:2004 EN 13223:2004 EN 13243:2004/AC:2005 EN 13107:2004
2.6.2	Integrity. Failure and appropriate measure	EN 12929-1:2004 EN 13223:2004 EN 13243:2004 /AC:2005
2.6.3	Integrity. Verification intervals	EN 12929-1:2004 EN 13223:2004
2.6.4	Integrity. Replacement parts	EN 12929-1:2004 EN 13223:2004 EN 1909:2004
2.6.5	Integrity. Fire	EN 12929-1:2004 EN 13223:2004
2.6.6	Integrity. Lightning	EN 13223:2004 EN 13243:2004/AC:2005
2.7.1	Safety equipment. Dealing with defects	EN 12929-1:2004 EN 13223:2004 EN 13243:2004/AC:2005 EN 1909:2004 EN 12397:2004
2.7.2	Safety devices. Manual shut-down	EN 13223:2004 EN 13243:2004/AC:2005 EN 13796-1

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Essential Requirement		Harmonised Standards
No	Subject	
2.7.3	Safety devices. Restarting	EN 12929-2:2004 EN 13796-2:2005 EN 13796-1:2005
2.8	Maintainability	EN 13223:2004 EN 13796-1:2005
2.9	Nuisance	EN 12929-2:2004 EN 13243:2004/AC:2005 EN 1709: 2004 EN 13796-1:2005
3.1.1	Infrastructure Layout… Taking into account of the terrain and the surroundings	EN 13796-1:2005
3.1.2	Infrastructure. Layout…Structure gauges (clearances)	EN 12929-1:2004 EN 13223:2004 EN 13796-1:2005
3.1.3	Infrastructure. Layout…Height above ground	EN 12929-1:2004 EN 13796-1:2005
3.1.4	Infrastructure. Layout…Speed, headway, acceleration	EN 12929-2:2004 EN 13796-1:2005
3.2.1	Infrastructure. Stations and line	EN 12929-1:2004 EN 12929-2:2004 EN 1709: 2004 EN 12397: 2004 EN 13796-1:2005
3.2.2	Infrastructure. Boarding and alighting areas	EN 12929-1:2004 EN 12929-2:2004 EN 12929-3:2004 EN 12929-5:2004 EN 12929-6:2004 EN 12929-7:2004 EN 12929-8:2004 EN 1908:2004/AC:2005 EN 13223:2004 EN 13243:2004 EN 13107:2004 EN 12397:2004 EN 13796-1:2005
4.1.1	Ropes and their supports. Safety	EN 12929-1:2004 EN 12929-2:2004 EN 12929-8:2004 EN 13223:2004 EN 13243:2004 EN 13107:2004/AC:2005 EN 1909:2004 EN 12397:2004 EN 13796-1
4.1.2	Ropes and their supports. Derailment	EN 12929-1:2004 EN 12929-2:2004 EN 13223:2004 EN 13243:2004/AC:2005 EN 1909:2004 EN 12397:2004
4.2.1	Machinery. Drives	EN 12929-1:2004 EN 12929-2:2004 EN 13223:2004

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Essential Requirement		Harmonised Standards
No	Subject	
4.2.2	Machinery. Emergency drives	EN 12929-1:2004 EN 12929-2:2004 EN 1908:2004 EN 13223:2004 EN 13107:2004 EN 13796-1:2005
4.2.3	Machinery. Braking devices	EN 12929-1:2004 EN 13223:2004 EN 13107:2004 EN 13796-1:2005
4.3	Control devices	EN 12929-1:2004 EN 12929-2:2004 EN 12385-8:2002 EN 12385-9:2002 EN 12927-1:2004 EN 12927-2:2004 EN 12927-3:2004 EN 12927-4:2004 EN 12927-5:2004 EN 12927-6:2004 EN 12927-7:2004 EN 12927-8:2004 EN 1908:2004 EN 13223:2004 EN 13243:2004/AC:2005 EN 13107:2004
4.4	Communication devices	EN 12929-1:2004 EN 13223:2004 EN 13243:2004/AC:2005
5.1	Carriers/hauling. Falls	EN 12929-1:2004 EN 13223:2004
5.2	Carriers/hauling. Fittings	EN 12929-1:2004 EN 13223:2004 EN 1909:2004
5.3	Carriers/hauling. Doors, floor, walls	EN 12929-1:2004 EN 13223:2004
5.4	Carriers/hauling. Equipment for the attendant	EN 13223:2004 EN 13243:2004/AC:2005
5.5	Carriers/hauling. Safety of workers	EN 12929-1:2004 EN 13223:2004 EN 13243:2004/AC:2005 EN 1909:2004 EN 12397:2004
5.6	Carriers/hauling. Connections, disconnections	EN 13223:2004 EN 13243:2004/AC:2005 EN 13796-1:2005
5.7	Carriers/hauling. On-board brakes	EN 12929-2:2004 EN 13796-2:2005 EN 13796-1:2005
5.8	Carriers/hauling. Anti-derailment devices – shut-down	EN 13223:2004 EN 13796-1:2005

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Essential Requirement		Harmonised Standards
No	Subject	
6	Equipment for users	EN 12929-2:2004 EN 13243:2004/AC:2005 EN 1709: 2004 EN 13796-1:2005
7.1.1	Operability. Instructions and directions	EN 13796-1:2005
7.1.2	Operability. Material resources and qualifications	EN 12929-1:2004 EN 13223:2004 EN 13796-1:2005
7.2	Operability. Shut-down and repatriation of passengers	EN 12929-1:2004 EN 13796-1:2005
7.3.1	Operability. Operators' stands and workplaces	EN 12929-2:2004 EN 13796-1:2005
7.3.2	Operability. Risk of falls	EN 12929-1:2004 EN 12929-2:2004 EN 1709: 2004 EN 12397: 2004 EN 13796-1:2005

APPENDIX IV List of notified bodies

This list contains the bodies notified by the Member States, as well as the conformity assessment procedures which these bodies are authorised to use as at 1 May 2005. Member States may at any time notify a new body or withdraw notification from one of these bodies. The Commission publishes a regularly updated consolidated list (all sectors) in the Official Journal of the European Union (series C). The specific list for this Directive can also be consulted at the following websites:

http://europa.eu.int/comm/enterprise/nando-is/home/index.cfm

http://europa.eu.int/comm/enterprise/rail_guided_transport/cableways.htm

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 2000/9/EC
Cableway installations designed to carry persons

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures/modules	Annexes/articles of the Directives
STROJIRENSKY ZKUSEBNI USTAV S.P. Hudcova 56B 621 00 BRNO Czech Republic	1015	Cableway installations designed to carry persons: drag lifts	EC type-examination EC examination for assessment of conformity of subsystems Production quality assurance Product verification Unit verification Full quality assurance	Annex V Module B Annex VII Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
TUV CZ S.R.O. Novodvorska 994 142 21 PRAHA 4 Czech Republic	1017	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
SERVICE TECHNIQUE DES REMONTÉES MÉCANIQUES ET DES TRANSPORTS GUIDES Rue de la Piscine 1461 38400 Saint Martin d'Hères France	1267	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
DIPL.-ING. HUBERT SCHUPFER ZIVILINGENIEUR FÜR WIRTSCHAFTSINGENIEURWESEN IM MASCHINENBAU SACHVERSTÄNDIGER FOR SEILBAHNTECHNIK Obermieming 148 A A-6414 MIEMING Austria	1339	Cableway installations designed to carry persons: safety Components	EC Type-examination Product verification Unit verification	Annex V - Module B Annex V - Module F Annex V - Module G
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII

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Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures/modules	Annexes/articles of the Directives
ÖQS - ZERTIFIZIERUNGS - UND BEGUTACHTUNGS GMBH Gonzagagasse 1/24 1010 WIEN Austria	1346	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module H
TÜV INDUSTRIE SERVICE GMBH - TÜV SOD GRUPPE Westendstraße, 199 80686 MÜNCHEN Germany	0036	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
TÜV THÜRINGEN E.V. Melchendorfer Straße. 64 99096 ERFURT Germany	0090	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
ASOCIACION ESPANOLA DE NORMALIZACION Y CERTIFICACION (AENOR) C/ Génova, 6 E-28004 MADRID Spain	0099	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
TÜV- ÖSTERREICH Krugerstrasse 16 1010 WIEN Austria	0408	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
ELECTRICAL INSPECTION FIMTEKNO OY P.O. Box 38 00211 HELSINKI Finland	0599	Cableway installations designed to carry persons: safety Components	EC Type-examination Product verification Unit verification	Annex V - Module B Annex V - Module F Annex V - Module G
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII

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Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures/modules	Annexes/articles of the Directives
TÜV STC S.R.O. Jasikova, 6 821 03 BRATISLAVA Slovakia	1353	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
TECHNICKA INSPEKCIA (TI) Vazovova, 7/A 81107 BRATISLAVA Slovakia	1354	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
SKUSOBNA OCEL' OVYCH LAN Park Komenského 14 04384 KOSICE Slovakia	1357	Cableway installations designed to carry persons: safety Components	EC Type-examination	Annex V - Module B
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
VYSKUMNY USTAV DOPRAVNY, AS. Vel'kÿ Diel 3323 01008 ZILINA Slovakia	1358	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
WPK - WERKSTOFFPRUFUNG-PLANUNG-KONTROLL-GES.M.E.H. Griesbachwinkel 45 5761 MARIA ALM Austria	1424	Cableway installations designed to carry persons: safety Components	EC Type-examination Product verification Unit verification	Annex V - Module B Annex V - Module F Annex V - Module G
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII
TRANSPORTOWY DOZOR TECHNICZNY (TDT) ul. Chalubinskiego 4 00 928 WARSZAWA Poland	1468	Cableway installations designed to carry persons: safety Components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII

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Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures/modules	Annexes/articles of the Directives
2XM ZERTIFIZIERUNGS GMBH Farbergasse 15 6850 DORNBIRN Austria	1491	Cableway installations designed to carry persons: safety components	EC Type-examination EC examination for assessment of conformity of subsystems Product verification Unit verification	Annex V - Module B Annex VII Annex V - Module F Annex V - Module G
CERTRA S.R.L. Via Negreli, 13 39100 BOLZANO Italy	1620	Cableway installations designed to carry persons: safety components	EC Type-examination Production quality assurance Product verification Unit verification Full quality assurance	Annex V - Module B Annex V - Module D Annex V - Module F Annex V - Module G Annex V - Module H
		Cableway installations designed to carry persons: subsystems	EC examination for assessment of conformity of Subsystems	Annex VII

APPENDIX V List of national transposition measures communicated to the Commission

BE *Arrêté royal du 23/01/2003 relatif aux installations à câbles transportant des personnes.*
Ref.: Moniteur Belge 27/02/2003 p. 9560.

CZ *Nařízení vlády o technických požadavcích na zařízení pro dopravu osob (70/2002 Sb).*

DK *Bekendtgørelse nr. 177 af 14/03/2002 om tovbaneanlæg til personbefordring.*

DE ***Baden-Württemberg***
Gesetz zur Änderung des Landesseilbahngesetzes vom 29 Oktober 2003.
Ref.: Gesetzblatt Nr. 14 ausgegeben am 7. November 2003.

Bayern
Gesetz für Änderung des Bayerischen Eisenbahn– und Bergbahngesetzes sowie zur Änderung anderer Rechtsvorschriften vom 25. Mai 2003.
Ref.: Bayerisches Gesetz- und Verordnungsblatt Nr. 12/2003.

Berlin
Gesetzes über Seilbahnen (Landesseilbahngesetz) vom 9 März 2004.
Ref.: GVBl. für Berlin Nr.12, S.110, ausgegeben am 16 März 2004.

Brandenburg
Brandenburgischen Bauordnung vom 16 Juli 2003.
Ref.: GVBl. I Nr. 12, ausgegeben am 21. Juli 2003.

Bremen
Gesetz über Seilbahnen für den Personenverkehr im Lande Bremen (Bremisches Seilbahngesetz – BremSeilbG) vom 12. Oktober 2004.
Ref.: Gesetzblatt der Freien Hansestadt Bremen Nr. 54, S. 523, ausgegeben am 15. Oktober 2004.

Hamburg
Hamburgischen Seilbahngesetzes vom 18. Februar 2004.
Ref.: Hamburgisches GVBl. Nr. 12, S.101, ausgegeben am 3. März 2004.

Hessen
Verordnung zur Änderung der Verordnung über den Bau und Betrieb von Seilbahnen vom 12. Mai 2004.
Ref.: GVBl. für das Land Hessen (Teil 1) Nr. 10, S.200, ausgegeben am 26. Mai 2004.

Mecklenburg-Vorpommern
Gesetz über Seilbahnen im Land Mecklenburg-Vorpommern (Landesseilbahngesetz – LseilbG M-V) vom 20. Juli 2004.
Ref.: GVBl für das Mecklenburg-Vorpommern Nr. 14, V 318 ff., ausgegeben am 28. Juli 2004.

Niedersachsen
Niedersächsischen Gesetz über Eisenbahnen und Seilbahnen (NESG) vom 16.12.2004.
Ref.: Niedersächsischen Gesetz- und Verordnungsblatt auf Seite 658 (Nds.GVBl. 2004, S. 658) am 30. Dezember 2004.

Nordrhein-Westfalen
Gesetz über die Seilbahnen in Nordrhein-Westfalen (SeilbG NRW) vom 16. Dezember 2003.
Ref.: GVBl. NRW Nr. 57, S.774, ausgegeben am 23. Dezember 2003.

Rheinland-Pfalz
Landesseilbahngesetz des Landes Rheinland-Pfalz vom 15. Oktober 2004.
Ref.: Gesetz- und Verordnungsblatt für das Land Rheinland-Pfalz Nr. 19, S. 447 vom 26. Oktober 2004.

Saarland
Gesetz Nr. 1534 zur Änderung des Gesetzes über Eisenbahnen, Bergbahnen und Seilschwebebahnen sowie weiterer Vorschriften vom 8. Oktober 2003.
Ref.: Amtsblatt des Saarlandes vom 11. Dezember 2003.

Sachsen
Gesetz über Seilbahnen und Schleppaufzüge im Freistaat Sachsen (Landesseilbahngesetz – LseilbG) vom 30. September 2003.

Sachsen-Anhalt
Gesetz über die Umweltverträglichkeitsprüfung im Land Sachsen-Anhalt und die Anpassung des Landesrechts vom 27. August 2002.
Ref.: GVBl. LSA Nr. 47/2002, ausgegeben am 30. August 2002.

Schleswig-Holstein
Gesetzes über Seilbahnen für den Personenverkehr (Landesseilbahngesetz – LseilbG -) vom 27. Mai 2004.
Ref.: GVBl. Für das Schleswig-Holstein Nr. 7, S. 144, ausgegeben am 24. Juni 2004.

Thüringen
Thüringer Bergbahngesetz vom 12. Juni 2003, veröffentlicht am 19. Juni 2003 im Gesetz – und Verordnungsblatt für den Freistaat Thüringen.
Ref.: GVBl. Nr. 9 ausgegeben am 19. Juni 2003

EE *Lifti ja köistee ohutuse seadus.*
Majandusministri 1. juuli 2002. a määrus nr 38 'Nõuded liftile, köisteele, alamsüsteemile ja ohutusseadisele, nende teabega varustamisele ja vastavusmärgi paigaldamisele'
Majandusministri 1. juuli 2002. a määrus nr 39 'Lifti, alamsüsteemi ja ohutusseadise nõuetele vastavuse hindamise ja tõendamise kord ning nõuetele vastavuse hindamiseks vajalikud vastavushindamise protseduurid'.

EL *Προεδρικό Διάταγμα 12/2004: 'Εγκαταστάσεις με συρματόσχοινα για την μεταφορά προσώπων - Εναρμόνιση της Οδηγίας 2000/9/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 2ης Μαρτίου 2000 (L 106/3.5.2000 της Επίσημης Εφημερίδας των Ευρωπαϊκών Κοινοτήτων)'.*
Ref.: Φύλλο Εφημερίδας της Κυβερνήσεως 7 τεύχος Α, της 16ης Ιανουαρίου 2004.

ES *Real Decreto 596/2002 de 28/06/2002 por el que se regulan los requisitos que deben cumplirse para la proyección, construcción, puesta en servicio y explotación de las instalaciones de transporte de personas por cable.*
Ref. Boletín Oficial del Estado nº 163 del 09/07/2002 p. 24767

FR *Décret nº 2003-426 du 9/05/ 2003 relatif à la mise sur le marché des constituants et sous-systèmes assurant la sécurité des remontés mécaniques.*
Réf.: Journal Officiel de la République Française du 11 mai 2003 p. 8169.

Ordonnance n° 2004-1198 du 12 novembre 2004 portant diverses dispositions d'adaption au droit communautarie dans le domaine des installations à câbles transportant des personnes et relatives aux remontées mécaniques en montagne.
Réf.: Journal Officiel de la République Française du 14 novembre 2004.

IE *Statutory Instrument No. 470 of 2003 - European Communities (Cableway Installations Designed to Carry Persons) Regulations 2003, of 3rd October 2003.*
Ref.: Iris Oifigiúil No. 85, page 1035, published 24th October 2003.

IT *Decreto Legislativo 12 giugno 2003, n 210. Attuazione della direttive 200/9/CE in materia di impianti a fune adibiti al trasporto di persone e relativo sistema sanzionatorio.*
Ref.: Gazetta Ufficiale della Republica Italiana n. 184 del 9 agosto 2003 - Serie Generale.

CY *Basic Requirements Cableway Installations for the transportation of Persons Regulations of 2004. 13.02.2004, issue number 3810, in Annex III Part I of that issue. P.I.74/2004.*

LV *Ministru kabineta 2003.gada 21.oktobra noteikumi Nr.578 'Noteikumi par cilvēku pārvadāšanai paredzētām trošu ceļu iekārtām'.*
Grozījumi Ministru kabineta 2003. gada 21.oktobra noteikumi Nr.578 'Noteikumi par cilvēku pārvadāšanai paredzētām trošu ceļu iekārtām' **.**

LT *Lietuvos Respublikos Socialinės apsaugos ir darbo ministro ir Lietuvos Respublikos aplinkos ministro įsakymas Nr. 137/559 'Dėl techninio reglamento 'Keleiviniai lynų keliai' patvirtinimo'.*

LU *Réglement Grand Ducal du 04/04/2003 relatif aux installations à câbles transportant de personnes.*
Réf.: Mémorial Grand Ducal nº A-54 du 29/04/2003 p. 916.

HU *A gazdasági és közlekedési minister 26/2003. (IV. 28.) GKM rendelete a kötélvontatású személyszállító vasutakról és az Országos Vasúti Szabályzat III. kötetének kiadásáról 104/2003. (XII.29.) GKM r. Egyes miniszteri rendeleteknek a csatlakozással összefüggésben szükséges módosításáról.*
26/2003. (IV. 28.) GKM rendelet a kötélvontatású személyszállító vasutakról és az Országos Vasúti Szabályzat III. kötetének kiadásáról.

MT *Cableway Installations Designed to Carry People Regulations, 2002 under the Product Safety Act (Cap 427).*

NL *Wet van 5 februari 2004, houdende regels met betrekking tot de productie, de keuring en de exploitatie van kabelinstallaties voor personenvervoer (Wet kabelbaaninstallaties)*
Ref.: Staatsblad 2004, 73.

AT *Bundesgesetz, mit dem ein Bundesgesetz über Seilbahnen erlassen wird (Seilbahngesetz 2003 – Seilbahn G 2003) und mit dem das Eisenbahngesetz 1957 geändert wird.*
Réf.: Bundesgesetzblatt für die Republik Österreich vom 21. November 2003 (BGBL I No; 103/2003).

PL *Rozporządzenie Ministra Infrastruktury z dnia 11 grudnia 2003 r. w sprawie zasadniczychwymagań dla kolei linowych przeznaczonych do przewozu osób. Dz. U. 2004/15/130.*

PT *Decreto-Lei n.º 313/2002 de 23/12/2002.*
Ref.: Diário da Republica I Serie A n.º 296 23 de Dezembro 2002 p.7996.

SI *Zakon o žičniških napravah za prevoz oseb – ZUPO.*

SK *Nariadenie vlády Slovenskej republiky č. 183/2002 Coll., ktorým sa ustanovujú podrobnosti o technických požiadavkách a postupoch posudzovania zhody na zariadenia určené na osobnú lanovú dopravu. Amended by 78/2004.*

FI *Valtioneuvoston asetus henkilökuljetukseen tarkoitetuista Köysiratalaitteistoista 253/2002 annettu 4/04/2002.*
Ref.: Suomen Säädöskokoelma N:o 247-256 10/4/2002.

SE *BFS 2002: 9 Föreskrifter om ändring av Boverkets föreskrifter och allmänna rad om hissar och vissa andra motordrivna anordningar (Kapitel 2. 15, Bilaga 1) beslutade den 12/04/2002.*
Ref.: Boverkets författningssamling.
SFS 2002: 186 Förordning om ändring I förordningen (1994:1215) om tekniska egenkapskrav pa byggnadsverk, m.m (paragraf 19, 35 f) utfärdad den 18/04/2002.
Ref.: Svensk författsningssamling 30/04/2002.

UK *The Cableway installations Regulations 2004, made on 28th January 2004.*
Ref: Statutory Instruments 2004 No. 129.

APPENDIX VI Useful addresses

European Commission
Enterprise and Industry Directorate-General
Aerospace, security, defence and equipment
H/1 Aerospace, defence and maritime industries
Rue de la Loi, 200
B-1049 BRUSSELS
Belgium
Tel. +32 2 299 11 11
Fax +32 2 296 70 14
E-mail: Entr-aerosp-def-mar@cec.eu.int
URL: http://europa.eu.int

European Standardisation Committee CEN
Rue de Stassart, 36
B-1050 BRUSSELS
Belgium
Tel. +32 2 550 08 11
Fax +32 2 550 18 19
E-mail: infodesk@cenorm.be
URL: http://www.cenorm.be

International trade associations

OITAF
Organizzazione Internazionale Trasporti a Fune
(International Organisation for Transport by Rope)
Secrétariat: Ufficio Trasporti Funiviari, Palazzo Provinciale 3B, via Crispi,10
IT-39100 BOLZANO
Italy
Tel. +39 0471 414 600
Fax +39 0471 414 616
URL: http://www.oitaf.org

FIANET
Fédération Internationale des Associations Nationales
des Exploitants de Téléphériques
(International Federation of National Ropeway Operators Associations)
21, chemin des Sources
FR-38240 MEYLAN
France
Tel. +33 476 90 51 27
Fax +33 476 90 49 58
URL: http://www.sntf.org

IARM
International Association of Ropeway Manufacturers
109, rue Aristide Bergés
BP47-(entr'Alp)
FR-3840 Voreppe

Member State Surveillance Authorities

Belgium
Ministère des Affaires Economiques
Direction Générale Qualité et Sécurité
North Gate III
Bd du Roi Albert II 16
BE-1000 Brussels
Tel. +32 2 206 49 10
Fax +32 2 206 57 52
URL: http://www.mineco.fgov.be

Cyprus
Ministry of Communications and Works
Department of Electrical and Mechanical Services
P.O. Box 29669
CY-1722 Nicosia
Tel. +357 22 800 571
Fax +357 22 800 401
URL: http://www.mcw.gov.cy

Estonia
Ministry of Economic Affairs and Communications
Harju 11
EE-15072 Tallin
Tel. +37 26 25 63 88
Fax +37 26 31 36 60
URL: http://www.mkm.ee

Greece
Ministry of Development
General Secretariat for Industry
80 Michalakopoulou St.
EL-10190 Athens
Tel. +30 01 720 45 54
Fax +30 01 725 13 00
URL: http://www.ypan.gr

Ireland
Railway Safety and Investment Division
Department of Transport
44 Kildare Street
IR-Dublin 2
Tel. +353 1 604 12 41
Fax +353 1 604 11 59
URL: http://www.transport.ie

Denmark
Arbejdstilsynet (Danish Working Environment Authority)
Landskronagade 33
DK-2100 Copenhagen
Tel. +45 39 15 21 11
Fax +45 39 27 14 88
URL: http://www.at.dk

Spain
Ministerio de Fomento
Dirección General de Ferrocarriles
Paseo de la Castellana, 67-Planta 4ª- A-496
ES-28071 MADRID
Tel. +34 91 59 77 100
Fax +34 91 59 78 581
URL: http://www.fomento.es

Ministerio de Ciencia y Tecnología
Paseo de la Castellana 160
ES-28071 Madrid
Tel. +34 91 349 40 65
Fax +34 91 349 43 00
URL: http://www.micit.go.es

Italy
Ministero delle Infrastrutture e dei Trasporti
Via G. Caraci, 36
IT-00157 Rome
Tel. +39 06 415 86 431
Fax +39 06 415 86 418
URL: http://www.infrastrutturetrasporti.it

Germany
Bayerisches Staatsministerium für Wirtschaft,
Infrastruktur, Verkehr und Technologie
Referat VII/8
Prinzregentstrasse 28
DE-80538 Munich
Tel. +49 89 21 62 23 11
Fax +49 89 21 62 33 1
URL: http://www.stmwvt.bayern.de

France
Ministère des Transports, de l'Equipement, du Tourisme et de la Mer
Direction des affaires économique et internationales
Direction générale de la mer et des transports
Arche Sud
FR-92055 La Défense Cedex
Tel. +33 1 40 81 17 16
Fax +33 1 40 81 16 30
URL: http://www.transports.equipement.gouv.fr

Lithuania
Ministry of Social Security and Labour
Technical Safety Division
A. Vivulskio 11
LT-2693 Vilnius
Tel. +37 05 26 64 272
Fax +37 05 26 44 209
URL: http://www.socmin.lt

Austria
Bundesministerium für Verkehr, Innovation und Technologie
Abt II / C13
Radetzkystrasse 2
AT-1030 Vienna
Tel. +43 1 711 62 27 07
Fax +43 1 711 62 27 99
URL: http://www.bmvit.gv.at

Slovenia
Ministry of Transport
Transport Inspectorate
Langusova ulica 4
SI-1000 Ljubljana
Tel. +386 1 478 81 10
Fax +386 1 478 81 49
URL: http://www.gov.si

Latvia
Ministry of Economics
Entrepreneurship and Industry Department
Brivibas Str. 55
LV-1519 Riga
Tel. +37 17 01 30 51
Fax +37 17 28 08 89
URL: http://www.em.gov.lv

Poland
Ministry of Infrastructure
Rail Department
Chalubinskiego Street 4/6
PO-00-928 Warsaw
Tel. +48 22 630 14 10
Fax +48 22 630 14 31
URL: http://www.mi.gov.pl

Finland
Ministry of Social Affairs and Health
Department for Occupational Safety and Health
P.O.Box 536
FI-33101 Tampere
Tel. +358 3 260 85 39
Fax +358 3 260 85 31
URL: http://www.stm.fi

Luxembourg
Inspection du Travail et des Mines
Boîte postale 27
L-2010 Luxembourg
Tel. +35 24 78 61 85
Fax +35 24 06 04 7
URL: http://www.itm.etat.lu

Hungary
Ministry of Economy and Transport
Railway Department
Harvéd utca 13-15
HU-1055 Budapest
Tel. +361 336 79 90
Fax +361 336 79 89
URL: http://www.gkm.gov.hu

Portugal
Instituto Nacional do Transporte Ferroviario
Rua Padre Luís Aparício 7
PO-1150-248 Lisbon
Tel. +351 21 31 789 53
Fax +351 21 31 789 40
URL: http://www.intf.pt

Malta
Ministry for Competitiveness and Communications
Market Surveillance Directorate
3A Old Mint Street
Valletta CMR 02
Tel. +356 21 221 020
Fax +356 22 125 222
URL: http://www.mcmp.gov.mt

Czech Republic
Ministry of Transport and Communications
Tracks and Railway Transport Department
Nábřeží Ludvika Svobody 12
CZ-11015 Prague 1
Tel. +420 972 231 003
Fax +420 972 231 355
URL: http://www.mdcr.cz

The Netherlands
Ministry of Transport
Railways Safety
PO Box 20901
NL- 2500 The Hague
Tel. +31 70 35 17 22 7
Fax +31 70 35 16 59 1
URL: http://www.minvenw.nl

Slovakia
Ministry of Transport, Post and Telecommunications
Námestie Slobody 6
P.O.Box 100
SK-810 05 Bratislava
Tel. +42 125 949 42 19
Fax +42 125 244 22 74
URL: http://www.telecom.gov.sk

Sweden
National Board of Housing, Building and Planning
Box 534
SE-37123 Karlskrona
Tel. +46 455 35 32 93
Fax +46 455 35 32 21
URL: http://www.boverket.se

United Kingdom
The Health and Safety Executive in Great Britain
The Health and Safety Executive for Northern Ireland
Lyme Vale Court
Parklands Business Park,
Newcastle Road,
Stoke-on-Trent
ST4 6NW
Tel. +44 1782 602391
URL: http://www.hse.gov.uk

Surveillance authorities EEA

Norway
Det Norske Veritas
N-7495 Trondheim
Tel. +47 73 90 35 02
Fax +47 73 90 35 44
URL: http://www.dnv.no

APPENDIX VII Text of the Directive

3.5.2000 EN Official Journal of the European Communities L 106/21

DIRECTIVE 2000/9/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 March 2000

relating to cableway installations designed to carry persons

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 47(2) and Articles 55 and 95 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Cableway installations designed to carry persons (hereinafter referred to as 'cableway installations') are designed, manufactured, put into service and operated with the object of carrying persons. Principally, cableway installations are mountain lift systems used in high-altitude tourist resorts and consisting of funicular railways, cable cars, gondolas, chairlifts and drag lifts, but may also consist of cableway installations used in urban transport facilities. Some types of cableway installation may use other, completely different basic principles which cannot be excluded *a priori*. Therefore, provision should be made for introducing specific requirements designed to achieve the same safety objectives as those laid down in this Directive.

(2) Cableway installations are principally operated in connection with tourism, particularly in mountain areas, which plays an important role in the economy of the regions concerned and is becoming an increasingly important factor in the trade balances of the Member States. From a technical point of view, the cableway installations sector also ranks among the industrial activities linked to the production of capital equipment and to activities in the building and civil engineering sector.

(3) Member States are responsible for ensuring the safety of cableway installations at the time of manufacture, putting into service and during operation. Moreover, they are responsible together with the competent authorities for such matters as land-use, regional planning and environmental protection. National regulations differ widely as a result of techniques peculiar to the national industry as well as local customs and knowhow. They stipulate specific dimensions and devices and particular characteristics. In the light of these circumstances, manufacturers are obliged to redefine their equipment for each market. This makes it difficult to provide standard solutions and adversely affects competitiveness.

(4) The essential health and safety requirements must be observed in order to ensure that cableway installations are safe. Those requirements are to be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.

(5) Further, cableway installations may straddle frontiers and the construction thereof may run up against conflicting national rules.

(6) Steps should be taken to define, on a Community-wide basis, essential human safety and health requirements, environmental protection and consumer protection requirements applicable to cableway installations, subsystems and their safety components. Without this, mutual recognition of national regulatory provisions would create insoluble political and technical difficulties as regards interpretation and liability. By the same token, standardisation without prior definition of harmonised regulatory requirements is not sufficient to solve the problems.

(7) Responsibility for approving cableway installations is generally vested in a service of the competent national authorities; in certain cases, approval of the components cannot be obtained beforehand but only when the customer applies for such approval. By the same token, the requisite inspection of the cableway installation prior to its entry into service may result in the rejection of certain components or in diverse technological solutions. Such a state of affairs leads to increased costs and longer delivery periods and is particularly penalising for foreign manufacturers. Moreover, cableway installations are also carefully monitored by the public services when they are operational. The causes of serious accidents may be linked to the choice of site, to the system of transport itself, to the structures, or to the way in which the system is operated and maintained.

(8) In these circumstances, the safety of cableway installations depends equally on the surrounding

[1] OJ C 70, 8.3.1994, p. 8 and OJ C 22, 26.1.1996, p. 12.
[2] OJ C 388, 31.12.1994, p. 26.
[3] Opinion of the European Parliament of 6 April 1995 (OJ C 109, 1.5.1995, p. 122), confirmed on 27 October 1999 (not yet published in the Official Journal), Council common position of 28 June 1999 (OJ C 243, 27.8.1999, p. 1) and Decision of the European Parliament of 27 October 1999 (not yet published in the Official Journal). Council Decision of 16 December 1999.

conditions, on the quality of the industrial goods supplied and on the way in which they are assembled, installed on site and monitored during operation. This underlines the importance of having a general overview of cableway installations in order to assess the level of safety and of adopting a common approach at Community level to quality assurance. In these circumstances, in order to enable manufacturers to overcome their present difficulties and in order to enable users to derive the full benefit from cableway installations and to enjoy an equal level of development in all Member States, a set of requirements should be defined, together with control and inspection procedures to be applied uniformly in all Member States.

(9) Persons using cableways, from all Member States and beyond, must be ensured a satisfactory level of safety. In order to meet this requirement, it is necessary to define procedures and examination, control and inspection methods. This necessitates the use of standardised technical devices which must be incorporated in cableway installations.

(10) Where Council Directive 85/337/EEC [1] so requires, the effects of cableway installations on the environment must be assessed; above and beyond the effects mentioned in that Directive, both environmental protection and requirements in connection with the sustainable development of tourism should be taken into account.

(11) Cableway installation may come within the scope of Council Directive 93/38/EEC of 14 June 1993 coordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors [2].

(12) Technical specifications should be included in the general documentation or in the technical specifications peculiar to each contract. Those technical specifications must be defined by reference to European specifications where such specifications exist.

(13) In order to make it easier to prove that the essential requirements have been complied with, it is useful to have harmonised European standards, compliance with which enables it to be presumed that the product is in conformity with the said essential requirements. Harmonised European standards are drawn up by private bodies and must retain their non-mandatory status. For this purpose, the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are recognised as the bodies competent to adopt harmonised standards that follow the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984.

(14) For the purposes of this Directive, a harmonised standard is a technical specification (European standard or harmonisation document) adopted by one or other of those bodies, or by both, at the request of the Commission pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services [3] and in accordance with the general guidelines referred to above. In relation to standardisation, the Commission should be assisted by the committee referred to in that Directive, which will, if necessary, consult technical experts.

(15) Only safety components or subsystems of an installation which conform to a national standard transposing a harmonised standard the reference of which has been published in the *Official Journal of the European Communities*, are deemed to conform to the relevant essential requirements of this Directive, regardless of the need for any special justification.

(16) In the absence of European specifications, the technical specifications should as far as possible be defined by reference to other standards in use in the Community. Main contractors may define the additional specifications needed to supplement the European specifications or other standards. These provisions must ensure that the harmonised Community-level requirements with which cableway installations must comply are satisfied.

(17) It is, moreover, in the interest of the Member States to have an international standardisation system capable of producing standards which are actually used by international trading partners and satisfy the requirements of Community policy.

(18) In certain Member States at the moment in the general documentation or specifications peculiar to each contract, main contractors may indicate the control and inspection procedures. Those procedures must in future, notably in the case of safety components, fall within the framework of the Council resolution of 21 December 1989 concerning a global approach to conformity assessment [4]. The concept of safety component applies not only to physical objects but also to intangible objects such as software. The procedures for assessing the conformity of safety components must be based on use of the modules provided for in Council Decision 93/465/EEC [5]. In the case of critical safety components, the principles and conditions for the application of design quality assurance should be defined; such an approach is necessary in order to

[1] Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ L 175, 5.7.1985, p. 40). Directive as last amended by Directive 97/11/EC (OJ L 73, 14.3.1997, p. 5).

[2] OJ L 199, 9.8.1993, p. 84. Directive as last amended by Directive 98/4/EC (OJ L 101, 1.4.1998, p. 1).

[3] OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

[4] OJ C 10, 16.1.1990, p. 1.

[5] Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation Directives (OJ L 220, 30.8.1993, p. 23).

promote the general adoption of the quality assurance system in undertakings.

(19) When conducting methodical safety analysis of cableway installations, it is necessary to identify the components on which the safety of the cableway installation depends.

(20) In their contractual documents, main contractors lay down, by reference to European specifications, the characteristics which manufacturers are under a contractual obligation to observe, particularly for safety components. In these circumstances, the conformity of the components is linked principally to their field of use and not solely to free movement on the Community market.

(21) Safety components should bear the CE marking to be affixed either by the manufacturer or by his authorised representative established within the Community. The CE marking means that the safety component complies with the provisions of this Directive and those of other applicable Community Directives on CE marking.

(22) It is not necessary to affix the CE marking to subsystems subject to the provisions of this Directive but, on the basis of the assessment of conformity following the procedures laid down for this purpose in this Directive, the declaration of conformity will suffice. This is without prejudice to the obligation incumbent on manufacturers to affix the CE marking to certain subsystems in order to certify that they conform with other Community provisions applicable to them.

(23) Member States' responsibility for safety, health and other aspects covered by the essential requirements on their territory must be recognised in a safeguard clause providing for the appropriate Community procedures.

(24) A procedure is necessary for the inspection of subsystems of cableway installations before they are put into service. Such inspection must enable the authorities to satisfy themselves that at each stage of the design, manufacturing and entry into service, the result obtained conforms with the applicable provisions of this Directive. This must enable manufacturers to count on equal treatment, irrespective of the Member State in question. The principles and conditions governing EC verification of subsystems of installations should therefore be defined.

(25) The constraints linked to the operation of cableway installations must be taken into account in the safety analysis, albeit not in such a way as to jeopardise the principle of free movement of goods or the safety of cableway installations. Consequently, although this Directive does not cover the actual operation of cableway installations, the Commission should propose to the Member States a series of recommendations designed to ensure that such installations situated on their territory are operated in such a way as to offer users, operating personnel and third parties a high degree of protection.

(26) In the case of cableway installations, full-scale tests can be carried out on technological innovations only on the construction of a new installation. In these circumstances, a procedure should be provided for which, while ensuring that the essential requirements are complied with, also enables special conditions to be established.

(27) Cableway installations for which authorisation has been given but in connection with which building work has not yet started or which are already under construction must comply with the provisions of this Directive, unless Member States decide otherwise, giving their reasons, and an equally high level of protection is achieved. The provisions of this Directive must be complied with where existing cableway installations are modified if national legislation requires such modifications to be authorised.

(28) It is not necessary to require all existing cableway installations to be brought into conformity with the provisions applicable to new installations. However, this may prove necessary if the essential safety objectives are not complied with. In that event, the Commission should propose to the Member States a series of recommendations designed to ensure that existing cableway installations on their territory afford users a high degree of protection in the light of the provisions applicable in this field to new installations.

(29) Particularly in the absence of a European specification, the notified bodies responsible for procedures for assessing the conformity both of safety components and of subsystems of cable installations must coordinate their decisions as closely as possible. The Commission must ensure that they do so.

(30) Implementation of the essential requirements, particularly with regard to the safety of the installation, and coordination of all procedures call for the establishment of a committee.

(31) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1],

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

1. This Directive shall apply to cableway installations designed to carry persons.

2. For the purposes of this Directive 'cableway installations designed to carry persons' shall mean installations made up of several components, designed, manufactured, assembled and put into service with the object of carrying persons.

[1] OJ L 184, 17.7.1999, p. 23.

These on-site installations are used for the carriage of persons in vehicles or by towing devices, whereby the suspension and/or traction is provided by cables positioned along the line of travel.

3. The installations concerned are:

(a) funicular railways and other installations with vehicles mounted on wheels or on other suspension devices where traction is provided by one or more cables;

(b) cable cars where the cabins are lifted and/or displaced by one or more carrier cables; this category also includes gondolas and chair lifts;

(c) drag lifts, where users with appropriate equipment are dragged by means of a cable.

4. This Directive shall apply to:

— installations built and put into service, as from its entry into force,

— subsystems and safety components placed on the market, as from its entry into force.

It concerns such harmonisation provisions as are necessary and sufficient in order to ensure and guarantee compliance with the essential requirements referred to in Article 3(1).

In the event that important characteristics, subsystems or safety components of existing installations undergo modifications for which a new authorisation for entry into service is required by the Member State in question, such modifications and their repercussions on the installation as a whole must satisfy the essential requirements referred to in Article 3(1).

5. For the purposes of this Directive:

— 'installation' shall mean the whole on-site system, consisting of infrastructure and the subsystems listed in Annex I where infrastructure specially designed for each installation and constructed on site shall mean the layout, system data, station structures and structures along the line, which are needed for the construction and the operation of the installation, including the foundations,

— 'safety component' shall mean any basic component, set of components, subassembly or complete assembly of equipment and any device incorporated in the installation for the purpose of ensuring a safety function and identified by the safety analysis, the failure of which endangers the safety or health of persons, be they users, operating personnel or third parties,

— 'main contractor' shall mean any natural or legal person who commissions the construction of an installation,

— 'operability' shall mean all the technical provisions and measures which have an impact on design and realisation and are necessary in order for the installation to operate safely,

— 'maintainability' shall mean all the technical provisions and measures which have an impact on design and realisation and are necessary for maintenance designed to ensure that the installation operates safely.

6. This Directive shall not apply to:

— lifts within the meaning of Directive 95/16/EC [1],

— cable-operated tramways of traditional construction,

— installations used for agricultural purposes,

— on-site or mobile equipment for use in fairgrounds and/or amusement parks which are designed for leisure purposes and not as a means for transporting persons,

— mining installations or on-site installations used for industrial purposes,

— cable-operated ferries,

— rack railways,

— chain-driven installations.

Article 2

1. This Directive shall apply without prejudice to other Community Directives, although compliance with the essential requirements laid down in this Directive may call for the application of special European specifications established for that purpose.

2. 'European specification' shall mean a common technical specification, a European technical approval or a national standard transposing a European standard.

3. The references of European specifications, which may be common technical specifications, European technical approvals within the meaning of Directive 93/38/EEC or national standards used to transpose harmonised European standards, shall be published in the *Official Journal of the European Communities*.

4. Member States shall publish the references of national standards used to transpose harmonised European standards.

5. In the absence of harmonised European standards, Member States shall take the necessary measures to inform parties concerned of those existing national standards and technical specifications which are regarded as important or useful for ensuring proper transposition of the essential requirements referred to in Article 3(1).

[1] Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ L 213, 7.9.1995, p. 1).

6. Those technical specifications which are also required to supplement European specifications or other standards must not jeopardise compliance with the essential requirements referred to in Article 3(1).

7. Where a Member State or the Commission considers that a European specification as referred to in paragraph 2 does not entirely satisfy the essential requirements referred to in Article 3(1), the Commission or the Member State concerned shall bring the matter before the committee referred to in Article 17 giving the reasons therefor. The committee shall deliver an opinion without delay.

In the light of the committee's opinion and following consultations with the committee set up pursuant to Directive 98/34/EC in the case of harmonised European standards, the Commission shall inform the Member States whether or not it is necessary to withdraw the European specifications in question from the published information referred to in paragraph 3.

Article 3

1. The installations and their infrastructure, subsystems and safety components of an installation must comply with the essential requirements which are laid down in Annex II and are applicable to them.

2. Where a national standard transposing a harmonised European standard the reference for which has been published in the *Official Journal of the European Communities* covers the essential safety requirements laid down in Annex II, the installations and their infrastructure, subsystems and safety components of any installation constructed in accordance with the standard shall be presumed to comply with the relevant essential requirements.

Article 4

1. At the request of the main contractor or his authorised representative, all planned installations shall be subject to a safety analysis as defined in Annex III which covers all safety aspects of the system and its surroundings in the context of the design, realisation and putting into service and makes it possible to identify from past experience risks liable to occur during operation.

2. The safety analysis shall be the subject of a safety report recommending the measures envisaged to deal with any such risks and including a list of the safety components and subsystems which must be covered by the provisions of Chapter II or III, as the case may be.

CHAPTER II

SAFETY COMPONENTS

Article 5

1. Member States shall take all necessary measures to ensure that safety components:

— are placed on the market only if they permit the construction of installations complying with the essential requirements referred to in Article 3(1),

— are put into service only if they permit the construction of installations which are not liable to endanger the health or safety of persons or, where applicable, the safety of property when properly installed and maintained and used for their intended purpose.

2. This Directive shall not affect Member States' entitlement to lay down, in compliance with the Treaty, such requirements as they may deem necessary to ensure that persons and in particular workers are protected when using the installations in question, provided that this does not mean that the installations are modified in a way not specified in the Directive.

Article 6

Member States may not, on the basis of this Directive, prohibit, restrict or impede the placing on their national markets of safety components intended to be used in an installation where such components comply with the provisions of this Directive.

Article 7

1. Member States shall regard safety components referred to in Article 4(2) bearing the CE conformity marking shown in Annex IX and accompanied by the EC declaration of conformity provided for in Annex IV as conforming with all the relevant provisions of this Directive.

2. Before a safety component is placed on the market, the manufacturer or his authorised representative established in the Community must:

(a) submit the safety component to a conformity assessment procedure in accordance with Annex V, and

(b) affix the CE conformity marking on the safety component and, on the basis of the modules laid down in Decision 93/465/EEC, draw up an EC declaration of conformity in accordance with Annex IV.

3. The procedure for assessing safety component conformity shall be carried out at the request of the manufacturer or his authorised representative established in the Community by the notified body referred to in Article 16 and appointed by him for this purpose.

4. Where the safety components are subject to other Directives concerning other aspects and which also provide for the affixing of the CE conformity marking, the marking shall indicate that the safety component is also presumed to conform to the provisions of those other Directives.

5. Where neither the manufacturer nor his authorised representative established in the Community has complied with the obligations of paragraphs 1 to 4, those obligations shall devolve on whomsoever places the safety component on the market in the Community. The same obligations shall apply to whomsoever manufactures safety components for his own use.

CHAPTER III

SUBSYSTEMS

Article 8

Member States shall take all necessary measures to ensure that subsystems within the meaning of Annex I are placed on the market only if they permit the construction of installations complying with the essential requirements referred to in Article 3(1).

Article 9

Member States may not, on the basis of this Directive, prohibit, restrict or impede the placing on their national markets for use in an installation, of subsystems which comply with the provisions of this Directive.

Article 10

1. Member States shall regard subsystems within the meaning of Annex I which are accompanied by the EC declaration of conformity based on the model provided for in Annex VI and by the technical documentation provided for in paragraph 3 of this Article, as conforming with the relevant essential requirements referred to in Article 3(1).

2. The EC procedure for examining subsystems shall be carried out at the request of the manufacturer or his authorised representative established in the Community or, in their absence, any natural or legal person who places the subsystem in question on the market, by the notified body referred to in Article 16 which the manufacturer or his authorised representative or the abovementioned person appointed for that purpose. The EC declaration of conformity shall be drawn up by the manufacturer or his authorised representative or the abovementioned person on the basis of the EC examination in accordance with Annex VII.

3. The notified body shall draw up the EC examination certificate in accordance with Annex VII and the technical documentation which accompanies it. The technical documentation must include all the necessary documents concerning the characteristics of the subsystem and, where appropriate, all the documents certifying the conformity of the safety components. It must also contain all the relevant details of the conditions of, and restrictions on, use and of the instructions for servicing.

CHAPTER IV

INSTALLATIONS

Article 11

1. Each Member State shall lay down procedures for authorising the construction and the putting into service of installations which are located within its territory.

2. Member States shall take all appropriate measures and determine the procedures to ensure that safety components and subsystems referred to in Annex I incorporated in installations constructed in their territory are installed and put into service only if they permit the construction of installations which are not liable to endanger the safety and health of persons or, where applicable, the safety of property, when properly installed and maintained and used in accordance with their intended purpose.

3. Where a Member State considers a safety component or subsystem referred to in Annex I to have been designed or constructed using an innovative approach, it shall take all appropriate measures and may make the construction and/or putting into service of an installation in which such innovative components or subsystems are to be used subject to special conditions. It shall immediately inform the Commission thereof, stating its reasons. The Commission shall immediately refer the matter to the committee provided for in Article 17.

4. Member States shall take all appropriate measures to ensure that the installations are constructed and put into service only if they have been designed and constructed in such a way as to guarantee compliance with the essential requirements referred to in Article 3(1).

5. On the basis of the provisions referred to in paragraph 1, Member States may not prohibit, restrict or hinder the free movement of safety components and subsystems referred to in Annex I which are accompanied by an EC declaration of conformity within the meaning of Article 7 or Article 10.

6. The safety analysis, the EC declarations of conformity and the accompanying technical documentation relating to the safety components and subsystems referred to in Annex I must be submitted by the main contractor or his authorised representative to the authority responsible for approving the installation, and a copy of them shall be kept at the installation.

7. Member States must ensure that the safety analysis, the safety report and the technical documentation are provided and include all the documentation concerning the characteristics of the installation and, where appropriate, all the documents certifying the conformity of the safety components and subsystems referred to in Annex I. In addition, documents must exist setting out the necessary conditions, including the restrictions on operation, and full details of servicing supervision, adjustment and maintenance.

Article 12

Without prejudice to other legislative provisions, Member States may not prohibit, restrict or impede the construction and putting into service within their territories of installations which comply with this Directive.

Article 13

Member States shall ensure that an installation remains in operation only if it conforms to the conditions set out in the safety report.

CHAPTER V

SAFEGUARDS

Article 14

1. Where a Member State ascertains that a safety component bearing the CE conformity marking placed on the market and used in accordance with its intended purpose or a subsystem with an EC declaration of conformity as referred to in Article 10(1), used in accordance with its intended, purpose, is liable to endanger the safety and health of persons, and, where applicable, the safety of property, it shall take all appropriate measures to restrict the conditions of use of the component or subsystem or prohibit its use.

The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision and whether non-conformity is due, in particular, to:

(a) failure to satisfy the essential requirements referred to in Article 3(1),

(b) incorrect application of the European specifications referred to in Article 2(2) in so far as application of those specifications is invoked,

(c) shortcomings in the European specifications referred to in Article 2(2).

2. The Commission shall enter into consultation with the parties concerned at the earliest opportunity. Where, after such consultation, the Commission finds that:

— the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is based on shortcomings in the European specifications, the Commission shall, after consulting the parties concerned, initiate the procedure referred to in Article 2(7) if the Member State which has taken the decision intends to maintain it,

— the measures relating to a safety component are unjustified, it shall immediately so inform the manufacturer or his authorised representative established in the Community and the Member State which took the measures,

— the measures relating to a subsystem are unjustified, it shall immediately so inform the manufacturer or his authorised representative established in the Community or, in their absence, any natural or legal person having placed the subsystem in question on the market, and the Member State which took the measures.

3. Where a safety component bearing the CE conformity marking is found not to comply, the competent Member State shall take appropriate action against whomsoever affixed that marking and drew up the EC declaration of conformity and shall so inform the Commission and the other Member States.

4. Where a subsystem with an EC declaration of conformity is found not to comply, the competent Member State shall take appropriate action against whomsoever drew up the EC declaration of conformity and shall so inform the Commission and the other Member States.

5. The Commission shall ensure that the Member States are kept informed of the outcome of the procedure.

Article 15

If a Member State finds that an approved installation which is used in accordance with its intended purpose is liable to endanger the safety and the health of persons and, where appropriate, the safety of property, it shall take all appropriate measures to restrict the conditions of operation of the installation or to prohibit the operation thereof.

CHAPTER VI

NOTIFIED BODIES

Article 16

1. Member States shall notify the Commission and the other Member States of the bodies responsible for carrying out the conformity assessment procedure referred to in Articles 7 and in Article 10, specifying the field of competence of each body. The Commission shall assign identification numbers to them. The Commission shall publish in the *Official Journal of the European Communities* the list of notified bodies, together with their identification number and their fields of competence, and shall ensure that the list is kept up to date.

2. Member States must apply the criteria laid down in Annex VIII in assessing the bodies to be notified. Bodies meeting the assessment criteria laid down in the relevant harmonised European standards shall be presumed to fulfil those criteria.

3. A Member State which has notified a body must withdraw its notification if it finds that the body no longer meets the criteria laid down in Annex VIII. It shall immediately inform the Commission and the other Member States thereof.

4. Should the need arise, coordination of the notified bodies shall be implemented in accordance with Article 17.

CHAPTER VII

COMMITTEE

Article 17

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. The committee shall draw up its rules of procedure.

CHAPTER VIII

CE CONFORMITY MARKING

Article 18

1. The CE conformity marking shall consist of the letters 'CE'. Annex IX sets out the model to be used.

2. The CE conformity marking shall be affixed to each safety component distinctly and visibly or, where that is not possible, on a label inseparably attached to the component.

3. The affixing on safety components of markings which are likely to mislead third parties as to the meaning and form of the CE conformity marking shall be prohibited. Any other marking may be affixed to the safety component, provided that the visibility and legibility of the CE conformity marking are not thereby reduced.

4. Without prejudice to Article 14:

(a) where a Member State establishes that the CE conformity marking has been wrongly affixed, the manufacturer of the safety component or the authorised representative of the latter established in the Community shall be obliged to make the product conform as regards the provisions concerning the CE conformity marking and to end the infringement under the conditions imposed by the Member State;

(b) should non-conformity persist, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the safety component in question, or to ensure that it is withdrawn from the market in accordance with the procedures provided for in Article 14.

CHAPTER IX

FINAL PROVISIONS

Article 19

Any decision taken pursuant to this Directive which restricts the use of safety components or of a subsystem in an installation or the placing on the market thereof shall state the grounds on which it is based. Such a decision shall be notified at the earliest opportunity to the party concerned, who shall at the same time be informed of the legal remedies available to him under the law in force in the Member States concerned and of the time limits to which such remedies are subject.

Article 20

Installations for which authorisation has been given before the entry into force of this Directive and for which construction has not yet started must comply with the provisions of this Directive, unless Member States decide otherwise, stating their reasons, and an equally high level of protection is achieved.

Article 21

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 3 May 2002. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

3. Member States shall, for a period of four years following entry into force of this Directive, allow:

— the construction and putting into service of installations,

— the placing on the market of subsystems and safety components

which conform with the provisions in force in their territories on the date of entry into force of this Directive.

4. The Commission shall report to the European Parliament and the Council on the implementation of this Directive, and in particular Article 1(6) and 17 thereof, not later than 3 May 2004 and, if necessary, submit any proposal for appropriate amendments.

Article 22

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 23

This Directive is addressed to the Member States.

Done at Brussels, 20 March 2000.

For the European Parliament	*For the Council*
The President	*The President*
N. FONTAINE	J. GAMA

3.5.2000 EN Official Journal of the European Communities L 106/29

ANNEX I

SUBSYSTEMS OF AN INSTALLATION

For the purposes of this Directive, an installation is divided up into infrastructure and the subsystems listed below, with exploitability and maintainability having to be taken into account in each case:

1. Cables and cable connections

2. Drives and brakes

3. Mechanical equipment

3.1. Cable winding gear

3.2. Station machinery

3.3. Line engineering

4. Vehicles

4.1. Cabins, seats or drag devices

4.2. Suspension gear

4.3. Driving gear

4.4. Connections to the cable

5. Electrotechnical devices

5.1. Monitoring, control and safety devices

5.2. Communication and information equipment

5.3. Lightning protection equipment

6. Rescue equipment

6.1. Fixed rescue equipment

6.2. Mobile rescue equipment

ANNEX II

ESSENTIAL REQUIREMENTS

1. **Purpose**

This Annex sets out the essential requirements, including maintainability and operability, applicable to the design, construction and entry into service of installations referred to in Article 1(5) of this Directive.

2. **General requirements**

2.1. *Safety of persons*

The safety of users, workers and third parties is a fundamental requirement for the design, construction and operation of installations.

2.2. *Principles of safety*

All installations must be designed, operated and serviced in accordance with the following principles, which are to be applied in the order given:

— eliminate or, if that is not possible, reduce risks by means of design and construction features,

— define and implement all necessary measures to protect against risks which cannot be eliminated by the design and construction features,

— define and state the precautions which should be taken to avoid the risks which it has not been possible to eliminate completely by means of the provisions and measures referred to in the first and second indents.

2.3. *Consideration of external factors*

Installations must be so designed and constructed as to make it possible to operate them safely, taking into account the type of installation, the nature and physical features of the terrain on which it is installed, its surroundings and atmospheric and meteorological factors, as well as possible structures and obstacles located in the vicinity either on the ground or in the air.

2.4. *Dimensions*

The installation, the subsystems and all its safety components must be dimensioned, designed and constructed to withstand, with a sufficient degree of safety, all stresses encountered under all foreseeable conditions, including those which occur when not in operation, and taking account in particular of outside influences, dynamic effects and fatigue phenomena, while complying with the acknowledged rules of the art, in particular with regard to the choice of materials.

2.5. *Assembly*

2.5.1. The installation, the subsystems and all the safety components must be designed and constructed in such a way as to ensure that they can be safely assembled and put into place.

2.5.2. The safety components must be so designed as to make assembly mistakes impossible, either as a result of construction or by means of appropriate markings on the components themselves.

2.6. *Integrity of the installation*

2.6.1. The safety components must be designed and constructed and be usable in such a way as to ensure that, in every case, their own operational integrity and/or the safety of the installation is ensured, as defined in the safety analysis in Annex III, so that their failure is highly improbable and with an adequate safety margin.

2.6.2. The installation must be designed and constructed in such a way as to ensure that, during its operation, any failure of a component which might affect safety, even indirectly, is met by an appropriate measure being taken in good time.

2.6.3. The safeguards referred to in points 2.6.1 and 2.6.2 must apply throughout the period between two scheduled inspections of the component concerned. The time period for the scheduled inspection of the safety components must be clearly indicated in the instruction manual.

2.6.4. Safety components which are incorporated into installations as spare parts must satisfy the essential requirements of this Directive and the conditions relating to the smooth interaction with the other parts of the installations.

2.6.5. Measures must be taken to to ensure that the effects of a fire in the installation do not endanger the safety of persons being transported and workers.

2.6.6. Special measures must be taken to protect installations and persons from the effects of lightning.

2.7. *Safety devices*

2.7.1. Any defect in the installation which could result in a failure endangering safety must, where practicable, be detected, reported and processed by a safety device. The same applies to any normally foreseeable external event which may endanger safety.

2.7.2. It must be possible at all times to shut down the installation manually.

2.7.3. After the installation has been shut down by a safety device, it must not be possible to restart it unless appropriate action has been taken.

2.8. *Maintainability*

The installation must be designed and constructed so as to enable routine or special maintenance and repair operations and procedures to be carried out safely.

2.9. *Nuisance*

The installation must be designed and constructed in such a way as to ensure that any internal or external nuisance resulting from noxious gases, noise emissions or vibrations falls within the prescribed limits.

3. Infrastructure requirements

3.1. *Layout, speed, distance between vehicles*

3.1.1. The installation must be designed to operate safely taking into account the characteristics of the terrain and its surroundings, atmospheric and meteorological conditions, any possible structures and obstacles located in the vicinity either on the ground or in the air in such a way as to cause no nuisance or pose no danger under any operational or servicing conditions or in the event of an operation to rescue persons.

3.1.2. Sufficient distance must be maintained laterally and vertically between vehicles, towing devices, tracks, cables, etc., and possible structures and obstacles located in the vicinity either on the ground or in the air, taking account of the vertical, longitudinal and lateral movement of the cables and vehicles or of the towing devices under the most adverse foreseeable operating conditions.

3.1.3. The maximum distance between vehicles and ground must take account of the nature of the installation, the type of vehicles and the rescue procedures. In the case of open cars it must also take account of the risk of fall as well as the psychological aspects associated with the distance between vehicles and ground.

3.1.4. The maximum speed of the vehicles or towing devices, the minimum distance between them and their acceleration and braking performance must be chosen to ensure the safety of persons and the safe operation of the installation.

3.2. *Stations and structures along the line*

3.2.1. Stations and structures along the line must be designed, installed and equipped so as to ensure stability. They shall permit safe guidance of the cables, vehicles and the towing devices, and enable maintenance to be safely carried out, under all operating conditions.

3.2.2. The entry and exit areas of the installation must be designed so as to guarantee the safety of the traffic of vehicles, towing devices and persons. The movement of vehicles and towing devices in the stations must be capable of taking place without risk to persons, taking into account their possible active collaboration to their movement.

4. **Requirements relating to cables, drives and brakes and to mechanical and electrical installations**

4.1. *Cables and their supports*

4.1.1. All measures must be taken in line with the latest technological developments:

— to avoid cables or their attachments breaking,

— to cover their minimum and maximum stress values,

— to ensure that they are safely mounted on their supports and prevent derailment,

— to enable them to be monitored.

4.1.2. It is not possible to prevent all risk of cable derailment, measures must be taken to ensure that cables can be retrieved and the installations shut down without risk to persons in the event of derailment.

4.2. *Mechanical installations*

4.2.1. Drives

The drive system of an installation must be of a suitable performance and capability, adapted to the various operating systems and modes.

4.2.2. Standby drive

The installation must have a standby drive with an energy supply which is independent of that of the main drive system. A standby drive is not, however, necessary if the safety analysis shows that people can leave the vehicles and, in particular, towing devices easily, quickly and safely even if a standby drive is not available.

4.2.3. Braking

4.2.3.1. In an emergency, it must be possible to shut down the installation and/or the vehicles at any moment, under the most unfavourable conditions in terms of authorised load and pulley adhesion during operation. The stopping distance must be as short as the security of the installation dictates.

4.2.3.2. Deceleration values must be within adequate limits fixed in such a way to ensure both the safety of the persons and the satisfactory behaviour of the vehicles, cables and other parts of the installation.

4.2.3.3. In all installations there must be two or more braking systems, each capable of bringing the installation to a halt, and coordinated in such a way that they automatically replace the active system when its efficiency becomes inadequate. The traction cable's last braking system must act directly on the driving pulley. These provisions do not apply to drag lifts.

4.2.3.4. The installation must be fitted with an effective clamp and locking mechanism to guard against premature restarts.

4.3. *Control devices*

The control devices must be designed and constructed so as to be safe and reliable, to withstand normal operating stresses and external factors such as humidity, extreme temperatures or electromagnetic interference and so as not to cause dangerous situations, even in the event of operational error.

4.4. *Communication devices*

Suitable facilities must be provided to enable operational staff to communicate with one another at all times and to inform users in case of emergency.

5. **Vehicles and towing devices**

5.1. Vehicles and/or towing devices must be designed and fitted out in such a way that under foreseeable operating conditions no person can fall out or encounter any other risks.

5.2. The fittings of vehicles and towing devices must be dimensioned and constructed so as not to:

— damage the cable, or

— slip, except where slippage does not significantly affect the safety of the vehicle, the towing device or the installation

under the most unfavourable conditions.

5.3. Vehicle doors (on cars, cabins) must be designed and constructed in such a way as to make it possible to close and lock them. The vehicle floor and walls must be designed and constructed so as to withstand pressure and loads exerted by users under any circumstances.

5.4. If for reasons of operational safety an operator is required on board the vehicle, the vehicle must be fitted with the equipment required for him to carry out his tasks.

5.5. Vehicles and/or towing devices and, in particular, their suspension mechanisms must be designed and fitted so as to ensure the safety of workers servicing them in accordance with appropriate rules and instructions.

5.6. In the case of vehicles equipped with disconnectable fittings, all measures must be taken to bring to a halt, without risk to users, at the moment of departure, any vehicle whose fitting has been incorrectly connected to the cable and, at the moment of arrival, any vehicle whose fitting has not been disconnected, and to prevent the vehicle from falling.

5.7. Funicular vehicles and, in so far as the configuration of the installation so permits, bi-cable cable cars must be equipped with an automatic braking device on the track, when the possibility of carrier cable breaking cannot reasonably be excluded.

5.8. Where all risk of derailment of the vehicle cannot be eliminated by other measures, the vehicle must be fitted with an anti-derailment device which enables the vehicle to be brought to a halt without risk to persons.

6. **Equipment for users**

The access to embarkation areas and exit from disembarkation areas and the embarkation and disembarkation of users must be organised with regard to the movement and stopping of vehicles in such a way as to ensure the safety of persons, in particular in areas where there is a risk of falling.

It must be possible for children and persons with reduced mobility to use the installation safely if the installation is designed for the transport of such persons.

7. **Operability**

7.1. *Safety*

7.1.1. All technical provisions and measures must be taken to ensure that the installation is used for its intended purpose according to its technical specification and to the specified operating conditions and that the instructions on safe operation and maintenance can be complied with. The instruction manual and the corresponding notes shall be drawn up in an official language or languages of the Community which may be determined in accordance with the Treaty by the Member State in the territory of which the installation is constructed.

7.1.2. The persons responsible for operating the installation must be provided with the appropriate material resources and must be qualified to carry out the task in hand.

7.2. *Safety in the event of immobilisation of the installation*

All technical provisions and measures must be adopted to ensure that users can be brought to safety within a set time appropriate to the type of installation and its surroundings when the installation is immobilised and cannot be restarted quickly.

7.3. *Other special provisions concerning safety*

7.3.1. Operators' stands and workplaces

Movable parts which are normally accessible in the stations must be designed, constructed and installed in such a way as to preclude any risks or, where such risks exist, be fitted with protective devices so as to prevent any contact with parts of the installation which may cause accidents. These devices must be of a type that cannot easily be removed or rendered inoperative.

7.3.2. Risk of falling

Workplaces and working areas, including those used only occasionally, and the access to them, must be designed and constructed in such a way as to prevent persons required to work or move in them from falling. Should the construction not be adequate, they must also be provided with anchorage points for personal protective equipment to prevent falls.

ANNEX III

SAFETY ANALYSIS

The safety analysis required for every cableway installation referred to in Article 1(5) of this Directive must take into account every mode of operation envisaged. The analysis must follow a recognised or established method and take into account the current state of the art and the complexity of the installation in question. The aim is also to ensure that the design and configuration of the installation should take account of the local surroundings and the most adverse situations in order to ensure satisfactory safety conditions.

The analysis must also cover the safety devices and their effect on the installation and related subsystems that they bring into action so that either:

— they are capable of reacting to an initial breakdown or failure detected so as to remain either in a state that guarantees safety, in a lower operating mode or in a fail-safe state,

— they are redundant and are monitored, or

— they are such that the probability of their failure can be evaluated and they are of a standard equivalent to that achieved by safety devices that meet the criteria in the first and second indents.

Safety analysis must be used to draw up the inventory of risks and dangerous situations in accordance with Article 4(1) of this Directive and to determine the list of safety components referred to in Article 4(2) thereof. The result of the safety analysis must be summarised in a safety report.

ANNEX IV

SAFETY COMPONENTS: EC DECLARATION OF CONFORMITY

This Annex applies to the safety components referred to in Article 1(5) of this Directive with a view to establishing their compliance with the essential requirements which concern them referred to in Article 3(1) of the Directive and defined in Annex II.

The EC declaration of conformity and the accompanying documentation must be dated and signed. It must be drawn up in the same language or languages as the instruction manual referred to in point 7.1.1 of Annex II.

The declaration must state the following particulars:

— the references of this Directive,

— name, business name and full address of the manufacturer or his authorised representative established in the Community. An authorised representative must also give the name, business name and full address of the manufacturer,

— description of the component (make, type, etc.),

— details of the conformity declaration procedure used (Article 7 of this Directive),

— all relevant provisions with which the component must comply and, in particular, the conditions of use,

— the name and address of any body notified, involved in the conformity procedure and the date of the EC examination certificate with details, where appropriate, of the duration and conditions of validity of the certificate,

— where appropriate, the reference of the harmonised standards applicable,

— identification of the person empowered to sign on behalf of the manufacturer or his authorised representative established in the Community.

ANNEX V

SAFETY COMPONENTS: ASSESSMENT OF CONFORMITY

1. **Scope**

This Annex applies to safety components with a view to checking compliance with the essential requirements referred to in Article 3(1) of this Directive and defined in Annex II. It concerns the assessment by one or more notified bodies of the intrinsic conformity of a component, considered in isolation, with the prescribed technical specifications.

2. **Procedures**

The assessment procedures implemented by the notified bodies both at the design and production stage are based on the modules defined in Council Decision 93/465/EEC along the lines indicated in the following table. The solutions in this table are considered to be equivalent and can be used at the manufacturer's discretion.

ASSESSMENT OF THE CONFORMITY OF SAFETY COMPONENTS

Design	Production
1. EC type-examination Module 'B'	1(a) Production quality assurance Module 'D'
	1(b) Product verification Module 'F'
2. Full quality assurance Module 'H'	2. Full quality assurance Module 'H'
3. Unit verification Module 'G'	3. Unit verification Module 'G'

Modules must be applied taking into account the specific supplementary conditions in each module.

MODULE B: EC TYPE-EXAMINATION

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of this Directive.

2. The application for EC type-examination must be lodged by the manufacturer or by his authorised representative established within the Community with a notified body of his choice.

The application must include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— the technical documentation, as described in point 3.

The applicant must place at the disposal of the nofitied body a specimen, representative of the production envisaged and hereinafter called 'type'. The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation must enable the conformity of the component with the requirements of this Directive to be assessed. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the component.

The documentation must contain as far as is relevant to assessment:

— a general type-description,

— conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of the said drawings and schemes and the operation of the product,

— the list of the European specifications referred to in Article 2(2) of this Directive, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the European specifications referred to in Article 2(2) of this Directive do not exist,

— the results of design calculations made, examinations carried out, etc.,

— test reports.

It must also indicate the field of use of the component.

4. The notified body:

4.1. must examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the components which have been designed in accordance with the relevant provisions of the European specifications referred to in Article 2(2) of this Directive as well as those which have been designed without applying the relevant provisions of those European specifications;

4.2. must perform or have performed the appropriate examinations and necessary tests to check whether, where the European specifications referred to in Article 2(2) of this Directive have not been applied, the solutions adopted by the manufacturer meet the essential requirements of this Directive;

4.3. must perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant European specifications, these have actually been applied;

4.4. must agree with the applicant the location where the examinations and necessary tests are to be carried out.

5. Where the type meets the provisions of this Directive, the notified body must issue an EC type-examination certificate to the applicant. The certificate must state the name and address of the manufacturer, the conclusions of the examination, the conditions for its validity, the duration thereof and give the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body. If the notified body refuses to issue an EC-type certificate to the manufacturer, the former must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications of the approved component which must receive additional approval where such changes may affect the conformity of the component with the essential requirements for the prescribed conditions for its use. This additional approval is given in the form of an addition to the original EC type-examination certificate.

7. Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.

8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for at least 30 years after the last component has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the component on the Community market.

MODULE D: PRODUCTION QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the components concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive. The manufacturer or his authorised representative established within the Community must affix the CE marking to each component and must draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for monitoring as specified in point 4.

2. The manufacturer must operate an approved quality system for production, final component inspection and testing as specified in point 3, and is subject to monitoring as specified in section 4.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body or his choice, for the components concerned.

The application must include:

— all relevant information for the component category envisaged,

— the documentation concerning the quality system,

— if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2. The quality system must ensure compliance with the type as described in the EC type-examination certificate and with the requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must in particular contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to competent quality,

— the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

— the means to monitor the achievement of the required component quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonised standards.

The auditing team must have a least one member with experience of evaluating in the component technology concerned. The evaluation procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner at a proper and efficient level.

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body entrance for inspection purposes to the places of manufacture, inspection and testing, and storage, and must provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out or cause to be carried out, tests to verify that the quality system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has taken place, a test report.

5. The manufacturer must, for period ending at least 30 years after the last component has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second subparagraph of point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decisions and reports from the notified body which are referred to in points 3.4, 4.3 and 4.4.

6. Each notified body must give the other notified bodies the relevant information concerning all quality system approvals issued and withdrawn.

MODULE F: PRODUCT VERIFICATION

1. This module describes the procedure whereby a manufacturer or his authorised representative established within the Community checks and attests that the components subject to the provisions of point 3 are in conformity with the type described in the EC type-examination certificate and satisfy the requirements of this Directive.

2. The manufacturer must take all measures necessary in order that the manufacturing process ensures conformity of the components with the type as described in the EC type-examination certificate and with the requirements of this Directive. He shall affix the CE marking to each component and shall draw up a declaration of conformity.

3. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the components to the requirements of this Directive either by examination and testing of every component as specified in point 4 or by examination and testing of components on a statistical basis, as specified in point 5, at the choice of the manufacturer.

The manufacturer or his authorised representative resident within the Community must keep a copy of the declaration of conformity for a period ending at least 30 years after the last component has been manufactured.

4. Verification by examination and testing of every component

4.1. All components must be individually examined and appropriate tests as set out in the relevant European specification(s) referred to in Article 2 or equivalent tests shall be carried out in order to verify their conformity with the type described in the EC type-examination certificate and to the requirements of this Directive.

4.2. The notified body must affix or cause to be affixed, its identification symbol to each approved component and draw up a written certificate of conformity relating to the tests carried out.

4.3. The manufacturer or his authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.

5. Statistical verification

5.1. The manufacturer must present his components in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.

5.2. All components must be available for verification in the form of homogeneous lots. A random sample must be drawn from each lot. Components in a sample must be individually examined and appropriate tests as set out in the European specification(s) referred to in Article 2(2) of this Directive, or equivalent tests, shall be carried out to ensure their conformity with the requirements of this Directive and to determine whether the lot is accepted or rejected.

5.3. The statistical procedure must use the following elements:

— a statistical method,

— a sampling plan with its operational characteristics.

5.4. In the case of accepted lots, the notified body must affix, or cause to be affixed, its identification number to each component, and shall draw up a written certificate of conformity relating to the tests carried out. All components in the lot may be put on the market, except those components from the sample which were found not to be in conformity.

If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent the putting on the market of that lot. In the event of the frequent rejection of lots the notified body may suspend statistical verification.

The manufacturer may, under the responsibility of the notified body, affix the latter's identification number during the manufacturing process.

5.5. The manufacturer or his authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.

MODULE G: UNIT VERIFICATION

1. This module describes the procedure whereby the manufacturer ensures and declares that the component concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of this Directive that apply to it. The manufacturer or his authorised representative established within the Community must affix the CE marking to the component and must draw up a declaration of conformity.

2. The notified body must examine the component and must carry out the appropriate tests as set out in the relevant European specifications referred to in Article 2(2) of this Directive, or equivalent tests, to ensure its conformity with the relevant requirements of this Directive.

The notified body must affix, or cause to be affixed, its identification number on the approved component and shall draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documentation is to enable conformity with the requirements of this Directive to be assessed and the design, manufacture and operation of the component to be understood.

For the purposes of assessment, the documentation must include the following:

— a general description of the type,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the component,

— a list of the relevant European specifications applied in total or partially referred to in Article 2(2) of this Directive, as well as a description of the solutions adopted by the manufacturer to meet the essential requirements of the Directive, where the European specifications referred to in Article 2(2) have not been applied,

— the results of the design calculations made, examinations carried out, etc.,

— test reports,

— fields of use of components.

MODULE H: FULL QUALITY ASSURANCE

1. This module describes the procedure whereby a manufacturer who satisfies the obligations of paragraph 2 must ensure and declare that the components concerned satisfy the relevant requirements of this Directive. The manufacturer or his authorised representative established within the Community must affix the CE marking to the component and must draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for the surveillance as specified in point 4.

2. The manufacturer must operate an approved quality system for design, manufacture and final component inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

— all relevant information for the category of component envisaged,

— the documentation relating to the quality system.

3.2. The quality system must ensure compliance of the components with the relevant requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must in particular include an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and component quality,

— the technical design specifications, including the European specifications referred to in Article 2(2) of this Directive, that will be applied and, where the European specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the products will be met,

— the design control and design verification techniques, processes and systematic actions that will be used when designing the components pertaining to the category of components covered,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

— the means to monitor the achievement of the required design and component quality and the effective operation of the quality assurance system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard.

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising from the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body entrance for inspection purposes to the places of design, manufacture, inspection and testing, and storage, and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 30 years after the last component has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second subparagraph of point 3.1,

— the updating referred to in the second subparagraph of point 3.4,

— the decisions and reports form the notified body which are referred to in points 3.4, 4.3 and 4.4.

6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

7. Supplementary requirements; design examination

7.1. The manufacturer must lodge an application for examination of the design with a single notified body.

7.2. The application must enable the design, manufacture and operation of the component to be understood, and shall enable conformity with the requirements of this Directive to be assessed.

It must include:

— the technical design specifications, including the European specifications referred to in Article 2(2) of this Directive that have been applied,

— the necessary supporting evidence for their adequacy, in particular where the European specifications referred to in Article 2(2) of this Directive have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf.

7.3. The notified body must examine the application and where the design meets the provisions of this Directive, must issue an EC design examination certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the component's functioning.

7.4. The applicant must keep the notified body that issued the EC design examination certificate informed of any modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect conformity to the essential requirements referred to in Article 3(1) of this Directive or the prescribed conditions for use of the component. This additional approval is given in the form of an addition to the original EC design examination certificate.

7.5. The notified bodies must forward to the other notified bodies the relevant information concerning:

— the EC design examination certificates and additions issued,

— the EC design approvals and additional approvals withdrawn,

— the EC design examination certificates and additions refused.

ANNEX VI

SUBSYSTEMS: EC DECLARATION OF CONFORMITY

This Annex applies to the subsystems referred to in Article 9 of this Directive in order to ensure that they fulfil the essential requirements concerning them referred to in Article 3(1) of this Directive.

The EC declaration of conformity must be drawn up by the manufacturer, or his authorised representative established in the Community, or, where such a person is not available, any natural or legal person, who places the subsystem on the market; the declaration and the accompanying technical documentation must be dated and signed.

This EC declaration of conformity and the technical documentation must be drawn up in the same language or languages as the instruction manual, referred to in point 7.1.1 of Annex II and must contain the following information:

— the reference of this Directive,

— the name and address of the person who ordered EC examination,

— a description of the subsystem,

— the name and address of the notified body which carried out the EC examination, referred to in Article 11 of this Directive,

— all relevant provisions with which the subsystem must comply, in particular any operating restrictions or operating conditions,

— the outcome of EC examination referred to in Annex VII (EC conformity certificate),

— particulars of the person who is authorised to sign a legally binding declaration for the manufacturer, or his authorised representative or, where such a person is not available, the natural or legal person, who places the subsystem on the market.

ANNEX VII

SUBSYSTEMS: ASSESSMENT OF CONFORMITY

1. EC examination is the procedure whereby, at the request of the manufacturer or his authorised representative established in the Community or, where such a person is not available, any natural or legal person who assumes responsibility for placing the subsystem on the market, a notified body checks and attests that a subsystem is:

   — in conformity with the provisions of the Directive and other relevant provisions in compliance with the Treaty,

   — in conformity with the technical documentation, and

   — completed

2. The examination of the subsystem is carried out at each of the following stages:

   — design,

   — construction and acceptance trials once the subsystem has been completed.

3. The technical documentation accompanying the examination certificate must comprise the following:

   — construction plans and calculations, electrical and hydraulic diagrams, control circuit diagrams, description of computer and automatic systems, operating and servicing instructions, etc.,

   — a list of the safety components referred to in Article 4(2) of this Directive which are used in the subsystem,

   — copies of the EC declaration of conformity as provided for in Annex IV for these safety components together with the corresponding construction plans and a copy of the reports on any other tests and trials carried out.

4. Documentation and correspondence in connection with EC examination procedures must be drawn up in the same language or languages as the instruction manual referred to in point 7.1.1 of Annex II.

5. Surveillance

5.1. It shall be ensured by means of surveillance that during construction of the subsystem the obligations arising from the technical documentation are fulfilled.

5.2. The notified body responsible for EC examination must have permanent access to the production shops, storage areas and, where necessary, to prefabrication areas, testing plants and more generally to any locations it feels it needs to visit in order to perform its task. The manufacturer or his authorised representative or, where such a person is not available, the natural or legal person who places the subsystem on the market must provide it with, or arrange for it to be provided with, any documents required to that end, notably the plans and technical documentation relating to the subsystem.

5.3. The notified body responsible for EC examination must periodically carry out audits to ensure compliance with the provisions of this Directive. On each visit it must provide the site supervisor responsible with an audit report. It may ask to be brought in to inspect various stages of the work.

5.4. In addition, the notified body may pay unexpected visits to the production shops. During such visits it may carry out full or partial audits. The notified body must draw up a report on the visit and, where necessary, submit an audit report to the site supervisor responsible.

6. Each notified body must publish periodically the relevant information concerning:

   — all applications for EC examination received,

   — all EC examination certificates issued,

   — all EC examination certificates refused.

ANNEX VIII

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

1. The notified body, its director and the staff responsible for carrying out the verification operations may not be either the designer, manufacturer, supplier or installer of the safety components or subsystems which they inspect or the authorised representative of any of those parties or the natural or legal person, who places these safety components or subsystems on the market. They may not become involved, either directly or as authorised representatives, in the design, manufacture, construction, marketing, servicing or operation of these safety components or subsystems. This does not preclude the possibility of exchanges of technical information between the manufacturer and the notified body.

2. The notified body and its inspection staff must carry out the verification operations with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of the verifications.

3. The notified body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with the verification operations; it must also have access to the equipment required for special verification.

4. The staff responsible for inspection must have:

   — sound technical and professional training,

   — satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,

   — the ability required to draw up the certificates, records and reports required to authenticate the performance of the tests.

5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.

6. The notified body must take out civil liability insurance unless its liability is assumed by the State in accordance with national law or the Member State itself is directly responsible for the inspections.

7. The staff of the body must be bound by professional secrecy (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) with regard to all information it acquires in carrying out its tasks under this Directive or any provision of national law giving effect to it.

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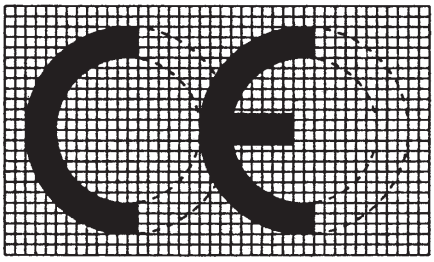
ANNEX IX

CE CONFORMITY MARKING

The CE conformity marking shall consist of the letters 'CE' taking the following form:



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

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale safety components.

The CE marking shall be followed by the last two figures of the year in which it was affixed and by the identification number of the notified body that deals with the procedures referred to in Article 7(3) of this Directive.

European Commission

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