COMMISSION OF THE EUROPEAN COMMUNITIES

COM(90) 263 final - SYN 204

Brussels, 19 June 1990

Amended proposal for a

COUNCIL DIRECTIVE

on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity

(presented by the Commission pursuant to Article 149(3) of the EEC-Treaty)

THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100A thereof,

Having regard to the proposal from the Commission [1],

In cooperation with the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

1. Whereas Council Directive 86/361/EEC [4] introduced the initial stage of the mutual recognition of type approval for telecommunications terminal equipment and in particular in its Art. 9 envisaged a further stage for full mutual recognition of type approval for terminal equipment;

2. Whereas Council Decision 87/95/EEC [5]sets out the measures to be implemented for the promotion of standardization in Europe and the preparation and implementation of standards in the field of information technology and Telecommunications;

3. Whereas the Commission has issued a Green Paper on the development of the common market for telecommunications services and equipment [6] proposing to accelerate the introduction of the full mutual recognition of type approval as the measure vital for the development of a competitive Community-wide terminal market;

4. Whereas the Council in its Resolution of 30 June 1988 on the development of the common market for telecommunications services and equipment up to 1992 [7] considers as a major goal in the telecommunications policy the full mutual recognition

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(1)

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(4) OJ N° L 217, 05.08.1986, p. 21

(5) OJ N° L36, 07.02.1987, p 31

(6) COM(87)290

(7) OJ N° C 257, 04.10.1988, p. 1

of type approval for terminal equipment on the basis of the rapid development of common European conformity specifications;

5. Whereas the terminal equipment sector is a vital part of the telecommunications industry which is one of the industrial mainstays of the Community economy;

6. Whereas the Council Resolution of 7 May 1985[8] provides for a new approach to technical harmonization and standards;

7. Whereas the field of application of the Directive must be based on a general definition of the term "terminal equipment" so as to allow the technical development of products;

8. Whereas Community law, in its present form, provides - notwithstanding one of the fundamental rules of the Community, namely the free movement of goods - that obstacles to movement within the Community, resulting from disparities in national legislation relating to the marketing of products, must be accepted in so far as such requirements can be recognized as being necessary to satisfy imperative requirements; whereas, therefore, the harmonization of laws in this case must be limited only to those requirements necessary to satisfy the essential requirements relating to terminal equipment; whereas these requirements must replace the relevant national requirements because they are essential;

9. Whereas the essential requirements must be satisfied in order to safeguard the general interest; whereas these requirements must be applied with discernment to take account of the state of the art at the time of manufacture and economic requirements;

10. Whereas Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Members States relating to electrical equipment designed for use within certain voltage limits[9] and Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations[10], as amended by Directive 88/182/EEC[11], are applicable, inter alia, to the fields of telecommunications and information technology;

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(8) OJ N° C136, 04.06.1985, p. 1

(9) OJ N° L 77, 26.03.1973, p. 29

(10) OJ N° L 109, 26.04.1983, p. 8

11. Whereas Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of Member States relating to electromagnetic compatibility[12] is applicable, inter alia, to the fields of telecommunications and information technology;

12. Whereas in respect of the essential safety requirements and in order to help manufacturers to prove conformity to these essential requirements it is desirable to have standards harmonized at European level for the prevention of hazards arising out of the design and manufacture of terminal equipment and in order to allow checks of conformity to the essential requirements; whereas these standards harmonized at European level are drawn up by private-law bodies and must retain their non-binding status; whereas for this purpose the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are the bodies recognized as competent to adopt harmonized standards in accordance with the general guidelines for cooperation between the Commission and these two bodies signed in 13 November 1984; whereas within the meaning of this Directive a harmonized standard is a technical specification (European standard or harmonization document) adopted by either or both of these bodies, on the basis of a remit from the Commission in accordance with the provisions of Directive 83/189/EEC, and on the basis of the general guidelines referred to above;

13. Whereas the formal adoption of the statutes of the European Telecommunications Standards Institute (ETSI) on 12 February 1988 creates a new opportunity to produce harmonised standards in the telecommunications field, whereas after implementation by the Member States of the ETSI rules of procedures which depend on their authority it will be possible to introduce ETSI into the framework of European standardisation as stipulated in Directive 83/189/EEC;

14. Whereas in respect of the essential requirements related to interworking with public telecommunications networks, it is in general not possible to comply with such requirements other than by the application of unique solutions; whereas such solutions shall therefore be mandatory;

15. *Whereas it is essential to ensure that notified bodies are of a high standard throughout the Community and meet minimum criteria of competence, impartiality and financial and other independence from clients;*

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(11) OJ N° L 81, 26.03.1988, p. 75

(12) OJ N° L 139, 23.05.1989, p. 19

16. Whereas it is appropriate to set up a committee bringing together parties directly concerned with the implementation of this Directive, in particular the national bodies designated for certifying conformity, to assist the Commission in executing the tasks entrusted to it by this Directive; *Whereas representatives of the telecommunications organisations, users, consumers, manufacturers, service providers and the trade unions should have the right to be consulted;*

17. Whereas the Member States' responsibility for safety, health and the other aspects covered by the essential requirements on their territory must be recognized in a safeguard clause providing for adequate Community protection procedures;

18. Whereas the addressees of any decision taken under this Directive must be informed of the reasons for such a decision and the means of appeal open to them;

19. Whereas the measures aimed at the gradual establishment of the internal market must be adopted by 31 December 1992; whereas the internal market consists of an area without internal frontiers within which the free movement of goods, persons, services and capital is guaranteed,

HAS ADOPTED THIS DIRECTIVE :

CHAPTER I

SCOPE, PLACING ON THE MARKET AND FREE MOVEMENT

Article 1

1. This Directive shall apply to terminal equipment.

2. For the purposes of this Directive terminal equipment means equipment intended

   a) to be connected to the termination of a public telecommunications network by an electrically conductive system,

   and/or

   b) to interwork with a public telecommunications network,

   and/or

   c) to interwork via a public telecommunications network.

   For cases b) and c) the system of connection to support the interworking may be wire, radio, optical, or other electromagnetic systems.

3. *The intended purpose shall be declared by the manufacturer or supplier of the equipment.*

Article 2

Member States shall take all necessary steps to ensure that terminal equipment may be placed on the market and put into service only if it complies with the requirements laid down in this Directive when it is properly installed and maintained and used for its intended purpose.

Article 3

Terminal equipment shall satisfy the following essential requirements, when they are relevant :

a) user safety in so far as this requirement is not covered by Directive 73/23/EEC;

b) safety of employees of public *telecommunications* network operators in so far as this requirement is not covered by Directive 73/23/EEC;

c) protection of the *public* telecommunications network from harm;

d) interworking of terminal equipment with network equipment for the purpose of establishing, modifying, charging for, and clearing real or virtual connections;

e) interworking of terminal equipment, in justified cases, *as determined in accordance with the procedure laid down in Article 13.*

Article 4

Member States shall not impede the placing on the market and the free circulation and use on their territory of terminal equipment which complies with the provisions of this Directive.

Article 5

1. Member States shall presume compliance with the essential requirements referred to in Article 3 a) and b) in respect of terminal equipment which is in conformity with the national standards implementing the relevant harmonised standards the references of which have been published in the Official Journal of the European Communities. Member States shall publish the references of such national standards.

2. The Commission, in accordance with the procedure laid down in Article 13, shall decide which harmonised standards, implementing the essential requirements referred to in Article 3 c), d) and e) will be transformed *in whole or in part* into technical regulations compliance with which shall be mandatory and the references of which shall be published in the Official Journal of the European Communities.

Article 6

Where a Member State or the Commission considers that the harmonised standards referred to in Article 5 do not entirely meet *or exceed* the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Committee referred to in Article 12, hereinafter referred to as "the Committee", giving the reasons therefore. The Committee shall deliver an opinion without delay.

In the light of the Committee's opinion and after consultation of the standing Committee set up by Directive 83/189/EEC, the Commission shall inform the Member States whether or not it is necessary to withdraw references to those standards and any related technical regulations from the Official Journal of the European Communities.

Article 7

1. Where a Member State finds that terminal equipment bearing the CE mark under the provisions laid down in chapter III, does not comply with the relevant essential requirements when properly used in accordance with *the purpose intended by the manufacturer,* it shall take all appropriate measures to withdraw such products from the market or to prohibit or restrict their being placed on the market.

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

a) incorrect application of the harmonised standards referred to in Article 5;

b) shortcomings in the harmonised standards referred to in Article 5 themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that any measure as referred to in paragraph 1 is justified it shall immediately so inform the Member State that took the action and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the harmonised standards, the Commission, after consulting the parties concerned, shall bring the matter before the Committee within two months if the Member State which has taken the measures intends to maintain them, and shall initiate the procedures referred to in Article 6.

3. Where terminal equipment which does not comply with the relevant essential requirements bears the CE mark the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall keep the Member States informed of the progress and outcome of this procedure.

CHAPTER II

CONFORMITY ASSESSMENT

Article 8

1. According to the choice of the manufacturer or his authorized representative established within the Community, terminal equipment shall be subject to either EC type examination, as described in Annex 1, or to EC declaration of conformity, as described in Annex 4.

2. An EC type examination as described in Annex 1 shall be accompanied by a declaration issued according to the EC declaration of conformity to type procedure as described in Annex 2 or Annex 3.

3. The records and correspondence relating to the procedures referred to in this Article shall be in an official language of the Member State where the said procedure will be carried out, or in a language acceptable to the notified body involved.

Article 9

1. Member States shall notify to the other Member States and the Commission the bodies which they have designated for carrying out tasks pertaining to the procedures referred to in Article 8, the specific tasks for which each body has been designated, and the identification codes of the designated bodies.

   The Commission shall publish the list of these notified bodies together with the tasks for which they have been designated, in the Official Journal of the European Communities and shall keep the list up to date.

2. Member States shall apply the minimum criteria, set out in Annex 5, for the designation of bodies. Bodies that satisfy the criteria fixed by the relevant harmonised standards shall be presumed to satisfy the criteria set out in Annex 5.

3. A Member State that has designated a body shall annul the designation if the body no longer meets the criteria for designation referred to in paragraph 2. It shall immediately inform the other Member States and the Commission accordingly and withdraw the notification.

4. In order to facilitate the determination of conformity of terminal equipment with technical regulations and standards, the notified bodies shall recognise documentation issued by third country relevant bodies, when agreements between the Community and the third country concerned have been concluded on the basis of a mutually-satisfactory understanding.

CHAPTER III

CE MARK OF CONFORMITY AND INSCRIPTIONS

Article 10

1. The CE mark of conformity, which shall consist of the symbol "CE" in conformity with the specimen in Annex 6, shall be affixed to terminal equipment in a clearly visible, easily legible and indelible form. It shall be followed by the last two digits of the year in which it was affixed.

2. The affixing of marks which are likely to be confused with the CE mark of conformity shall be prohibited.

3. Terminal equipment shall be identified by the manufacturer by means of type, batch, or serial numbers *and the manufacturer's name.*

Article 11

Where it is established that the CE mark has been affixed to terminal equipment which:

- does not conform to an approved type;

- conforms to an approved type which does not meet the essential requirements applicable to it;

or, where the manufacturer has failed to fulfil his obligations under the relevant EC declaration of conformity,

the notified body shall withdraw the EC type examination certificate, as referred to in Annex 1, the EC quality system approval certificate, as referred to in Annex 3 or the EC design examination certificate as referred to in Annex 4, as relevant, notwithstanding any decisions taken under Article 7.

CHAPTER IV

COMMITTEE

Article 12

1. A standing Committee for terminal equipment is hereby set up. The Committee shall be called the Approvals Committee for Telecommunications Equipment (ACTE). The Committee shall be composed of representatives appointed by the Member States. It shall be chaired by a representative of the Commission. Each Member State shall appoint two representatives. The representatives may be accompanied by experts.

   The Committee shall draw up its own rules of procedure.

2. *The Commission will periodically consult the representatives of the telecommunications organsations, the consumers, the manufacturers, the service providers and the trade unions and will inform the Committee on the outcome of such consultations, with a view to taking due account of this outcome*.

Article 13

1. The representative of the Commission shall submit to the Committee established in Article 12, a draft of the measures to be taken as referred to in Article 5.2. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

2. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

3. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by qualified majority. If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

CHAPTER V

FINAL AND TRANSITIONAL PROVISIONS

Article 14

1. Where, for a given terminal equipment, harmonised standards as referred to in Article 5 do not exist, national conformity specifications shall be applicable. These national conformity specifications shall not impose requirements beyond those strictly necessary to respect the essential requirements set out in Article 3.

   The right to place on the market terminal equipment, which has received national type approval on the basis of national conformity specifications, may be limited to the territory of the Member State where the national conformity specification applies except if it complies with a national specification of another Member State and is intended for re-sale or for use in this Member State.

2. A national authority shall recognize, for the purpose of national type approval, a certificate of conformity to its own national conformity specification, accompanied by the appropriate test reports, which has been issued by a notified body of another Member State and shall not impose a requirement for any repetition of tests.

   A national authority shall recognize, for the purpose of national type approval, a certificate of conformity based on the national conformity specifications of another Member State provided that these conformity specifications are equivalent to those used in the Member State of the authority.

Article 14.a

The Commission shall draw up a report every two years on the implementation of this Directive, including progress on drawing up the relevant harmonised standards and on transforming them into mandatory technical regulations, as well as any problems that have arisen in the course of implementation. The report will also outline the activities of the Committee established in Article 12, and assess progress in achieving an open competitive market for terminal equipment at Community level consistent with the essential requirements in Article 3

Article 15

Directive 86/361/EEC is hereby repealed with effect from *[1 January 1992]*[1].

Article 16

1. Member States shall introduce the measures necessary to comply with this Directive not later than *[1 January 1992]*[1]. They shall forthwith inform the Commission thereof.

   The provisions adopted pursuant to the first subparagraph shall make express reference to this Directive.

2. Member States shall inform the Commission of the provisions of national law which they adopt in the field governed by this Directive.

Article 17

This Directive is addressed to the Member States.

Done at Brussels, 1990

For the Council,
The President

(1) To be adapted at the date of adoption of the Directive.

ANNEX 1

EC type examination

1. The EC type examination is that part of the procedure by which a notified body ascertains and attests that terminal equipment, representative of the production envisaged and hereinafter called the "type", conforms to the essential requirements that apply to it.

2. The application for EC type examination shall be lodged by the manufacturer or his authorized representative established within the Community with one of the notified bodies designated to carry out EC type examination.

   The application shall include :

   - the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition;

   - a written declaration that the application has not been lodged with any other notified body;

   - the technical documentation, as described in paragraph 3.

   The applicant shall place the type, in the required quantity, at the disposal of the notified body.

3. The technical documentation shall enable understanding of the design, manufacture and operation of the product, *so far as is relevant for* assessment of conformity of the product with the essential requirements that apply to it.

The documentation shall contain so far as relevant for assessment :

- 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 product.
- a list of the standards referred to in Article 5, applied in full or in part, declarations of conformity to the standards referred to in Article 5.1 where such standards have been applied, and descriptions of the solutions adopted to meet the essential requirements where the standards referred to in Article 5.1 have not been applied;
- results of design calculations made, examinations carried out, etc;
- test reports.

4. The notified body shall,

4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5.1, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 5.1 have not been applied, the solutions adopted by the manufacturer meet the essential requirements of the directive referred to in Article 3 a) and b);

4.3. perform or have performed the appropriate examinations and necessary tests to check that the type complies with the relevant harmonised standards referred to in Article 5.2;

5. Where the type conforms to the applicable essential requirements the notified body shall issue an EC type examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type.

Relevant parts of the technical documentation shall be annexed to the certificate and kept by the notified body.

6. The applicant shall keep the notified body that has issued the EC type examination certificate informed of any modification to the approved type.

   Modifications to the approved type must receive additional approval from the notified body that issued the EC type examination certificate where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC type examination certificate.

7. Each notified body shall publish periodically the relevant information concerning :

   - the applications for EC type examination received;
   - the EC type examination certificates and additions issued;
   - the EC type examination certificates and additions refused;
   - the EC type examination certificates and additions withdrawn.

8. The other notified bodies may receive copies of the EC type examination certificates and/or their additions and any annexes.

ANNEX 2

EC declaration of conformity to type

1. This declaration of conformity is that part of the procedure whereby the manufacturer ensures and declares that the products concerned are in conformity with the type as described in the EC type examination certificate and satisfy the requirements of the Directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity.

2. The manufacturer shall take all measures necessary in order that the manufacturing process shall ensure compliance of the manufactured products with the type as described in the EC type examination certificate and with the requirements of the Directive that apply to them.

3. A notified body chosen by the manufacturer shall carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, shall be carried out to check the conformity of the production output with the relevant requirements of the directive. In those cases where one or more of the products checked do not conform the notified body shall take appropriate measures.

ANNEX 3

EC declaration of conformity to type (production Quality Assurance)

1. This declaration of conformity is that part of the procedure whereby a manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned are in conformity with the type as described in the EC type examination certificate and satisfy the requirements of the Directive that apply to them. The manufacturer shall affix the CE mark to each product and shall draw up a written declaration of conformity.

2. The manufacturer shall operate an approved quality system for production, final product inspection and testing as specified in paragraph 3 and shall be subject to EC surveillance as specified in paragraph 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with one of the notified bodies designated to carry out quality system approval.

The application shall include :

- all relevant information for the product category envisaged;

- the quality system's documentation;

- an undertaking to carry out the obligations arising from the quality system as approved;

- an undertaking to maintain the quality system as approved to ensure its continuing suitability and effectiveness;

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

3.2. The quality system shall ensure compliance of the products with the type as described in the EC type examination certificate and with the requirements of the Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall 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 programmes, plans, manuals and records.

It shall contain in particular an adequate description of :

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality;

- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

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

- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

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

The assessment team shall 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 shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision. Where the notified body decides to approve the quality system, it shall issue an EC quality system approval certificate.

3.4. The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended modification to the quality system.

The notified body shall 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 re-assessment is required.

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

4. EC surveillance

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

4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection, testing and storage and shall 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 shall 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. During such visits full or reduced audits may be carried out by the notified body. The notified body shall provide a visit report and, if applicable, an audit report to the manufacturer.

5. Each notified body shall publish periodically the relevant information concerning the EC quality system approval certificates issued and withdrawn.

ANNEX 4

EC DECLARATION OF CONFORMITY (Full Quality Assurance)

1. This declaration of conformity is the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned satisfy the requirements of the Directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity.

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing as specified in paragraph 3 and shall be subject to EC surveillance as specified in paragraph 4.

3. Quality system

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

The application shall include :

- all relevant information for the product category envisaged
- the quality system's documentation
- an undertaking to carry out the obligations arising from the quality system as approved
- an undertaking to maintain the quality system as approved to ensure its continuing suitability and effectiveness.

3.2. The quality system shall ensure compliance of the products with the requirements of the Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall 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 shall contain in particular an adequate description of :

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to design and product quality
- the technical design specifications including harmonised standards and technical regulations laid down in Article 5
- the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used
- the examination and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out
- the means by which it is ensured that the test and examination facilities respect the requirements for notified bodies designated for testing
- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard. (i.e. EN 29001)

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

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

The notified body shall 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 re-assessment is required.

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

4. EC surveillance

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

4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations 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 foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc
- the quality records as foreseen 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 shall 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. During such visits full or reduced audits may be carried out by the notified body. The notified body shall provide a visit report and, if applicable, an audit report to the manufacturer.

5. Each notified body shall publish periodically the relevant information concerning the quality system approvals issued and withdrawn.

6. Design examination

6.1. The manufacturer shall lodge an application for examination of the design with a notified body.

6.2. The application shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the relevant requirements of the Directive.

It shall include :

- the technical design specifications, including harmonised standards and technical regulations laid down in article 5 that have been applied

- the necessary supporting evidence for their adequacy. This supporting evidence shall include the results of tests carried out by an inhouse notified body designated for testing or on behalf of the manufacturer by a notified body designated for testing.

6.3. The notified body shall examine the application and where the design meets the provisions of the Directive that apply to it shall 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 product's functioning.

6.4. The applicant shall keep the notified body that has 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 examination certificate where such changes may affect the conformity with the essential requirements of the Directive or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC design examination certificate.

6.5. The notified bodies shall publish periodically the relevant information concerning :

- the applications for EC design examination received
- the EC design examination certificates and additions issued;
- the EC design examination certificates and additions reissued
- the EC design examination certificates and additions refused
- the EC design approvals and additional approvals withdrawn.

ANNEX 5

Minimum criteria to be taken into account by Member States when appointing notified bodies.

1. The notified body, its director and the staff responsible for carrying out the tasks for which the notified body has been designated shall not be a designer, manufacturer, supplier or installer of terminal equipment, nor the authorized representative of any of such parties. They shall not become directly involved in the design, construction, marketing or maintenance of terminal equipment, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the notified body.

2. The notified body and its staff must carry out the tasks for which the notified body has been designated 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 any tests or inspection, especially from persons or groups of persons with an interest in such results.

3. The notified body must have at its disposal the necessary staff and facilities to enable it to perform properly the administrative and technical work associated with the tasks for which it has been designated.

4. The staff responsible for tests or inspections must have :

   - sound technical and professional training;

   - satisfactory knowledge of the requirements of the tests or inspections they carry out and adequate experience of such tests or inspections;

   - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests or inspections.

5. The impartiality of test and inspection staff must be guaranteed. Their remuneration must not depend on the number of tests or inspections carried out nor on the results of such tests or inspections.

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

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

ANNEX 6

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