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A Guide to the EU Directive on Radio Equipment and Telecommunications Terminal Equipment

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ABSTRACT

This guide (prepared under contract by Helen Delaney and Rene van de Zande, DVZ Joint Ventures) is an easy-to-use introductory reference for industry and government officials on the requirements of the European Union's (EU) *Directive on Radio Equipment and Telecommunications Terminal Equipment (1999/5/EC)*. It is designed to help business and government officials understand the purpose of the directive, its relationship to other directives, the essential requirements contained in the directive, and the basic steps necessary for compliance. The guide offers explanations of such requirements as: the products covered by the directive; products excluded from the directive; essential requirements; interface specifications requirements; harmonized standards; placing equipment on the market and into service; safeguards; conformity assessment routes; CE marking and inscriptions; and equipment class identifiers. The guide contains the text of the directive and a list of applicable standards. In addition, the guide references appropriate sections of *NIST Special Publication 951: A Guide to EU Standards and Conformity Assessment* for further information on some of the generic conformity assessment concepts and requirements of the EU's New Approach.

Key Words: base stations; CEN; CENELEC; conformity assessment; directives; European Union; interface; land mobile base stations; New Approach directives; marine radio equipment; microwave links; mobile radios; radio equipment; radio frequency; satellite; technical construction files; telecommunications equipment; telephone; telex; user manuals; VSATs

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The Directive on Radio Equipment and Telecommunications Terminal Equipment 1
(1999/5/EC)

Applicable since April 8, 2000

To Be Considered:

1999/5/EC, or the R&TTE Directive, replaces the "Terminals" Directive (98/13/EC), as well as Common Technical Regulations adopted under that Directive, and a large number of existing national approval regulations.

The new directive replaces the more stringent requirements of the former directive. There is no longer a requirement for a manufacturer to obtain type approval (See SP 951 A Guide to EU Standards and Conformity Assessment, Page 22) before placing telecommunications terminal equipment on the market. He or she can simply declare conformity (See SP 951, Page 26) and affix the CE Mark (See SP 951, Page 17).

The main changes this Directive brings about are:

- Introduction of the Manufacturers Declaration of Conformity (See *SP 951, Page 26*.)

  Assessment of the conformity of a product with the requirements of the Directive now becomes the responsibility of the manufacturer instead of a third party.

- *Lower requirement*s

  Terminal access requirements have been removed. Fixed network terminal equipment now needs to comply only with electrical safety and electromagnetic compatibility (EMC) requirements. Radio equipment needs to use the spectrum effectively and not cause harmful interference. In exceptional cases, the EU can introduce additional public interest requirements. Examples of public interest requirements might be for safety of critical radio equipment on sea and inland waterway vessels.

- *New approach to standards*

  Common Technical Regulations (CTRs) under the previous directive were Harmonized Standards (See SP 951, Page 11) that were mandatory. In the R&TTE Directive, CTRs will be replaced by voluntary standards. Standards will continue to play a prominent role in determining whether a product complies with the legal requirements. But when standards are not available or not appropriate, a manufacturer still has a route to market. In these cases, however, the manufacturer must demonstrate how the requirements of the Directive are met in his Technical Construction File (See SP 951,

1 Readers of this report may wish to refer to NIST SP 951: A Guide to EU Standards and Conformity Assessment, which is available at NIST's website at: http://ts.nist.gov/ca.

Page 24).

- *Scope: Complete coverage of the sector*

  The Directive replaces national regimes. Any problems caused by the fact that the radio frequency spectrum in the Community is not fully harmonized are handled through specific provisions in the Directive.

- *Obligation for network operators to publish their interfaces*

  Operators of public telecommunications services now have to publish the characteristics of their interfaces, thereby allowing any manufacturer to construct terminal equipment to be attached to that network.

- *Obligation for Member States (See SP 951, Page 1) to publish the rules to access the radio frequency spectrum*

  The radio frequency spectrum is not fully harmonized in the Community. The Directive doesn't harmonize the spectrum. Manufacturers should, therefore, be aware of national differences in allocation and usage. Member States are committed to publish such details allowing manufacturers to build products capable of operating in as large a market as possible.

- *Obligation for Manufacturers to inform the end user of intended use and limitations of use*

  Manufacturers must inform users of the intended use and the limitations of use both on the packaging and in the User's Manual (See SP 951, Page 26). This means that the manufacturer must inform the user on the networks for which a terminal has been designed and communicate clearly for which of the radio spectra of the Member States it has been designed.

- *The R&TTE Directive regulates radio equipment for the first time on the European level. It effectively removes the necessity of going to each Member State national administration for type approval. Manufacturers may now simply declare compliance with the Directive.*

- *The Essential Requirements of the Low Voltage and EMC Directive2s have been*

[2] In 1998, the EMC Directive was included in the Simpler Legislation for the Internal Market (SLIM) program, designed to streamline and simplify EU law. As a result, several drafts of a new EMC Directive have been prepared and are located at the following URL: http://europa.eu.int/comm/enterprise/electr_equipment/emc/slim/review.htm.

As of September 2001, suggested changes in the draft include improving and simplifying some important definitions in the directive, such as *apparatus*, *component*, and *fixed installation*. New terms have been added, such as *readymade connecting device*, and others have been removed. The role of a Competent Body, unique to the EMC directive, will no longer exist under the revised directive. Under the new EMC Directive, these organizations will become Notified Bodies and will have a smaller role, which will align the EMC directive more closely with the R&TTE Directive. Depending upon the compliance route chosen by a manufacturer, there may or may not be a need for a report from a Notified Body. The revised EMC Directive may be in effect as early as 2003, with a two-year transition period. Manufacturers should also be aware that CEN, CENELEC and ETSI completed a review all EMC

incorporated into the R&TTE Directive, although those two Directives remain in force because they have wider applications than radio and telecommunications equipment.

- *Standards published under the Low Voltage Directive (73/23/EEC) and the EMC Directive (89/336/EEC), will give presumption of conformity to the electrical safety and EMC requirements of the R&TTE Directive.*

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Purpose of the Directive on Radio Equipment and Telecommunications Terminal Equipment

The purpose of the Directive on Radio Equipment and Telecommunications Terminal Equipment is to:

> *provide safety to users, prevent disturbance to the functioning of other equipment, and manage the radio spectrum.*

I. Definitions

The following are definitions of key terms used throughout the Directive.

- **Apparatus**: Any equipment that is either radio equipment or telecommunications terminal equipment or both.
- **Telecommunications Terminal Equipment**: A product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services).
- **Radio Equipment:** A product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilizing the spectrum allocated to terrestrial/space radiocommunication.
- **Radio Waves**: Electromagnetic waves of frequencies from 9 kHz to 3000 GHz, propagated in space without artificial guide.
- **Interface:**
  - A network termination point, which is a physical connection point at which a user is provided with access to public telecommunications network; and/or
  - An air interface specifying the radio path between radio equipment

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standards, their relevance and their applicability in December 2000. A Report of the Strategic Review Panel of EMC Harmonised Standards may be viewed at the following URL: http://europa.eu.int/comm/enterprise/electr_equipment/emc/slim/report.pdf.

and their technical specifications.

- **Equipment Class**: A class identifying particular types of apparatus, which under this Directive are considered similar, and those interfaces for which the apparatus is designed. Apparatus may belong to more than one equipment class.
- **Technical Construction File:** A file describing the apparatus and providing information and explanations as to how the applicable essential requirements have been implemented.

  Note: The technical construction file must be kept for a period ending at least 10 years after the last product has been manufactured; and it must be available to National Authorities of Member States for inspection purposes.

- **Harmonized Standard:** A technical specification adopted by a recognized standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement, compliance with which is not compulsory. (A list of harmonized standards is contained on page 43 of this report.)
- **Harmful Interference**: Interference which endangers the functioning of a radionavigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with the applicable Community or national regulations.

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Basic Steps to Compliance

II. Determining Whether the Product Has to Comply with the Radio Equipment and Telecommunications Terminal Equipment Directive

A. Products Totally Covered by the Directive

- *Terminal equipment attached to public telecommunication networks and equipment which uses the radio frequency spectrum.*

- *An apparatus that incorporates a medical device or, specifically, an active implantable medical device as an integral part, or as an accessory.*

- *An apparatus that is a component or a separate technical unit of a vehicle as it was defined in either the Directive on the radio interference (electromagnetic compatibility) of vehicles, or in the Directive on the type-approval of two or three-wheel motor vehicles.*

B. Products Excluded from the Directive

Annex I of the Directive lists the equipment outside the scope of the Directive as follows:

- *equipment used by radio amateurs, unless the equipment is available commercially (Note that kits of components to be assembled by radio amateurs and commercial equipment modified by, and for the use of, radio amateurs are not regarded as commercially available equipment.);*

- *marine equipment;*

- *cabling and wiring;*

- *receive-only radio equipment that is solely used to receive sound and TV broadcasting services;*

- *specified products, appliances, and components in the field of civil aviation; and*

- *air-traffic management equipment and systems meeting appropriate technical specifications.*

Also excluded from the Directive are all apparatus used exclusively for activities of public security, defense, state security, and the activities of the state in the area of criminal law.

III. Essential Requirements

Note: The essential requirements in this Directive depend on the nature of the equipment. However, all equipment must meet essential requirements of health and safety (including the safety aspects of the Low Voltage Directive), and the protection requirements of the EMC Directive. In addition, for radio equipment the Directive addresses harmful interference of the spectrum and orbit (for satellite systems).

All apparatus must comply with the following essential requirements:

- the protection of the health and the safety of the user and any other person; and
- the protection necessary with regard to EMC.

And, to avoid harmful interference, radio equipment must be constructed so that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources.

Apparatus within certain equipment classes or apparatus of particular types may also be required to do some or all of the following:

- interwork via networks with other apparatus and be able to connect to interfaces of the appropriate type;

- avoid harming the network or misusing network resources, which might cause an unacceptable degradation of service;

- incorporate safeguards to ensure that the personal data and privacy of the user and the subscriber are protected;

- support certain features to protect against fraud;

- support certain features to ensure access to emergency services; and

- support features that will facilitate use by disabled users.

Note: The manufacturer is well advised to consult the R&TTE Harmonized Standards. They provide guidance not only to the products covered by the Directive, but to the hazards associated with them as well.

IV. Notification and Publication of Interface Specifications

Member State operators (*See SP 951, Page 1)* of public telecommunications will publish technical specifications of all the types of interfaces that are used in their area before services provided through those interfaces are made publicly available, and they will regularly publish any updates in the specifications. The specifications will be detailed enough to allow for the design of telecommunications terminal equipment capable of using all of the services provided through the corresponding interface.

Among other things, the specifications will include all the information that manufacturers would need to carry out the relevant tests for the essential requirements applicable to the telecommunications terminal equipment. The operators will make those specifications readily available.

> *Note: Terminal equipment manufacturers and suppliers should note that the purpose of the publication is to permit the design of terminals capable of functioning correctly. Assuming that the information published is adequate and accurate, the task of ensuring the interworking with and via the network rests with terminal equipment manufacturers, as does the compliance to Essential Requirements. Statements relating to IPR or copyright in Interface publications may not be complete.*
>
> *Terminal equipment manufacturers and suppliers should also note that in a multi-operator environment, it will be prudent to consider the interface publications of several operators (including indirect access operators) before deciding what terminals might be suitable for a given market.*

V. Harmonized Standards *(See SP 951, Page 11.)*

Any apparatus that meets the conditions laid down in Harmonized Standards is presumed to be in compliance with the Essential Requirements of the Directive.

The Commission may withdraw Harmonized Standards that have shortcomings.

Note: In 1988, the European Telecommunications Standards Institute (ETSI) was established and given mandates by the European Commission to develop standards that formed the basis for the Common Technical Regulations of the telecommunications directive this Directive replaces. (See Page 1, New approach to standards.)

Standards continue to be developed by ETSI in the field of telecommunications terminal equipment as voluntary Harmonized Standards and are published in the Official Journal of the European Communities. (See List of R&TTE Harmonized Standards contained in this Guide on Page 43.)

VI. Placing Equipment on the Market *(See SP 951, Page 19.)*

An apparatus should be placed on the market only if, when it is properly installed, maintained, and used for its intended purpose, it complies with the appropriate essential requirements identified above and the other relevant provisions of this Directive.

If it is determined that an equipment class (*See Equipment Class Identifier, Page 12 of this Document)* needs to comply with particular essential requirements, any apparatus of that equipment class already on the market can continue to be placed there for a reasonable period, provided that it was first placed on the market before the determination.

The manufacturer must provide information for the user on the intended use of the apparatus, together with a Declaration of Conformity *(See SP 951, Page 26)* to the essential requirements. For radio equipment, the manufacturer may put such information on the packaging along with instructions on how the apparatus is to be used in the area in which it is located *(See Annex VII, Para. 5)*. Where it concerns telecommunications terminal equipment, the information should be sufficient to identify interfaces of the public telecommunications networks to which the equipment will be connected.

Note: Terminal equipment manufacturers should, in addition to the possible use of familiar or branded names, refer to the Public Network Operators' published technical specifications of interfaces. (See IV, Page 6 of this Document: Notification and Publication of Interface Specifications.) A declaration of intended purpose is not itself a guarantee of interworking.

Note: This provision also applies to receive-only equipment.

In addition, the manufacturer must alert the user to potential restrictions or requirements for using the radio equipment if it makes use of radio frequency bands whose use is not harmonized throughout the European Community. Such information should be prominently displayed on the packaging.

If certain radio equipment uses frequency bands whose use is not harmonized throughout the European Community, the manufacturer must notify the appropriate national authority for

spectrum management that he or she intends to place such equipment on its national market. This should be done no less than four weeks before placing the equipment on the market and included must be information about the radio characteristics of the equipment (in particular, frequency bands, channel spacing, type of modulation, and RF-power) as well as the identification number of the Notified Body *(See SP 951, Page 20)* referred to in *Annex IV* or *Annex V* of this Directive.

VII. Putting Equipment into Service and the Right to Connect Equipment

Note: Putting into service takes place at the moment of first use within the Community by the end user.

Manufacturers may put apparatus into service for its intended purpose as long as it complies with the appropriate essential requirements identified above and the other relevant provisions of this Directive.

But radio equipment that violates guidelines of effective and appropriate use of the radio spectrum, produces harmful interference, or raises public health concerns may incur some usage restrictions. Additionally, if apparatus declared to be compliant with the provisions of this Directive causes serious damage to a network, harmful radio interference, or harm to the network or its functioning, the operator may be authorized to refuse its connection, disconnect it, withdraw it from service, or take other appropriate measures.

VIII. Free Movement of Equipment

As long as an apparatus bears the CE Marking referred to in *Annex VII* of this Directive, it will not be subject to restrictions or be prohibited from being placed on the market by any Member State.

If the apparatus is subject to other directives that also provide for the affixing of the CE Marking, it should be indicated that the apparatus fulfils the provisions of those other directives, too. However, should one or more of those directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the apparatus fulfils the provisions only of those directives applied by the manufacturer. In this case, references to these directives must be given in accompanying documents, such as the Declaration of Conformity (*See SP 951, Pages 17 and 26).*

Note: Equipment on display at trade fairs, exhibitions, or demonstrations, does not have to comply with the directive or bear the CE Marking. There must be a visible sign, however, that the equipment cannot be marketed or put into service until it complies with the Directive.

IX. Safeguards

If any apparatus within the scope of this Directive does not comply with the requirements of this

Directive, the apparatus will be withdrawn from the market or from service. Reasons for non-compliance include:

- incorrect application of the Harmonized Standards *(See SP 951, Page 11)*;
- shortcomings in the Harmonized Standards; and
- failure to satisfy the requirements necessary when the apparatus does not meet the Harmonized Standards.

If there are problems with the equipment, its use on the market may be restricted or prohibited altogether. For example, radio equipment may be withdrawn from the market if it has caused or seems likely to cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands.

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Conformity Assessment

Note: To comply with the essential requirements dealing with electrical health and safety and EMC, the manufacturer may use the conformity assessment procedures specified in Directive 73/23/EEC, The Low Voltage Directive, and Directive 89/336/EEC, the Directive on Electromagnetic Compatibility, as an alternative to the procedures laid out below.

Standards published under the Low Voltage Directive and the EMC Directive will give presumption of conformity to the electrical safety and EMC requirements of this Directive.

Conformity assessment is the procedure(s) used to demonstrate the compliance of the apparatus with all the relevant essential requirements. There are three different routes to demonstrate compliance, depending on the type of equipment.

Route 1: Non-Radio Terminal Equipment and Radio Receive-Only Equipment: If telecommunications terminal equipment does not make use of the spectrum allocated to terrestrial/space radio communication (*if it is non-radio terminal equipment)* and receiving parts of radio equipment (*if it is radio receive-only equipment)*, the manufacturer may choose to apply the procedures described in one of the following:

- ***Annex II**: Internal Production Control (See SP 951, Pages 8 & 9, Module A)*

For non-radio terminal equipment and radio receive-only equipment the situation is straightforward: "internal production control". This means the manufacturer simply creates a file that defines how the equipment meets the requirements of the Directive, declares conformity with the essential requirements, and affixes the CE Marking. The file may indicate that the equipment complies with the relevant Harmonized Standard(s), or that the essential requirements are met by other technical solutions. Annex II is the simplest way.

- ***Annex IV***: *Internal Production Control (Module A) plus specific apparatus tests and Technical Construction File submitted to a Notified Body (See SP 951, Page 24).*

- ***Annex V***: *Full Quality Assurance*
  Finally, the production of the equipment may be integrated into the manufacturer's existing Quality Assurance system and have that audited by a Notified Body.

Route 2: Radio Transmitting Equipment, Harmonized Standards:
Note: Conformity Assessment for radio transmitting equipment is more complicated. If a Harmonized Standard exists, the simplest choice is internal production control plus certain apparatus-specific tests, which may be conducted by the manufacturer.

Alternatively, a Technical Construction File may be transmitted to a Notified Body for an opinion, or the production of the equipment integrated into a QA system audited by a Notified Body. (These last two options are the only ones that can be used if no Harmonized Standard exists. See Route 3.)

Note: The manufacturer does not have to accept the opinion of a Notified Body. This could, however, weaken the manufacturer's defense in the event of a court case.

If a manufacturer has applied Harmonized Standards (*See SP 951, Page11)* and the radio equipment is transmitting equipment, the manufacturer may choose between the procedures described in one of the following:

- *Annex III: Internal production control (Module A) plus specific apparatus tests.*

  Note: All essential radio test suites for each type of apparatus must be carried out by the manufacturer or on his behalf by a Notified Body. The identification of essential test suites is the responsibility of the Notified Body except where the test suites are defined in the Harmonized Standards. In other words, if the essential radio test suites are chosen from a Harmonized Standard, a Notified Body does not have to intervene in the conformity assessment process.

- ***Annex IV***: *Internal Production Control (Module A) plus specific apparatus tests and Technical Construction File submitted to a Notified Body, or*

- ***Annex** V: Full Quality Assurance.*

Route 3: Radio Transmitting Equipment, No Harmonized Standards:
If a manufacturer has not applied, or has only applied in part, the Harmonized Standards, and radio equipment is transmitting equipment, the manufacturer should apply the procedures described in either:

- ***Annex IV*** : *Internal Production Control (Module A) plus specific apparatus tests (radio test*

suites carried out by a Notified Body) and Technical Construction File, or

- ***Annex** V: Full Quality Assurance.*

Note: Records and correspondence relating to conformity assessment procedures should be in an official language of the country in which the procedure will be carried out, or in a language accepted by the Notified Body involved.

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CE CONFORMITY MARKING AND INSCRIPTIONS

The Manufacturer (*See SP 951, Page 22)* or his Authorized Representative (*See SP 951, Page 23)* must place the CE Marking (*See SP 951, Page* 17) on apparatus that complies with all the relevant essential requirements. *(See Annex VII)*

Where the procedures identified in *Annex III*, *IV* or *V* are used, the marking shall be accompanied by the identification number of the Notified Body. Radio equipment shall, in addition, be accompanied by the equipment class identifier if it has been assigned. Any other marking may be affixed to the equipment provided that the visibility and legibility of the CE Marking is not reduced. No apparatus, whether or not it complies with the relevant essential requirements, may bear any other marking that is likely to deceive third parties as to the meaning and form of the CE Marking specified in *Annex VII*.

Equipment Class Identifier

Note: The European Commission is the authority that establishes equivalence between Member State interfaces and assigns an equipment class identifier. The following list is intended as a guide for manufacturers. Manufacturers should consult a Notified Body for products for which such guidance is not yet available.

Radio Equipment and Telecommunications Equipment that can be placed on the market and be put into service without restrictions are known as "Class 1" equipment. There is no Equipment Class Identified for this class of equipment and no marking of such is required.

Class 1:
Terminal equipment attached to fixed networks and non-transmitting radio equipment:

1. ISDN (ISDN Basic Rate, ISDN Primary Rate, ISDN U, Broadband ISDN ATM).

2. PSTN (Analogue single line, Analogue multi-line (with/without DDI), equipment attached to Centrex interfaces or Virtual Private Networks).

3. Leased lines (2w and 4w analogue (baseband), 2w and 4w analogue (voiceband), Digital, SDH, optical).

4. Wired data equipment (X.21, X.25, ethernet, token ring, token bus, TCP/IP, frame relay).

5. Wired interactive broadcast equipment (unswitched vision/sound, switched vision/sound).

6. Telex (single line equipment, multiple line equipment).

7. Receive-only radio equipment.

8. Other terminal equipment attached to fixed networks.

Radio equipment, which transmits only under the control of a network:

9. GSM handsets, including GSM 900, GSM 1800, GSM 1900 (and when it appears GSM 450).

10. TFTS terminal equipment.

11. Land Mobile earth stations in the 1,5/1,6 GHz bands.

12. Land Mobile earth stations operating in the Ku-band.

13. TETRA end-user equipment (non-DMO).

14. Satellite Personal Communication earth stations operating in the 1,6/2,4 GHz bands.

15. Satellite Personal Communication earth stations operating in the 1,9/2,1 GHz bands.

16. Low data rate Land Mobile earth stations in the 1,5/1,6 GHz bands

17. Other Radio equipment, which transmits only under the control of a network.

Radio transmitters technically harmonized in the Community and which Member States do not constrain putting into service:

18. DECT equipment.

Radio Equipment for which Member States apply restrictions on the putting into service or placing on the market is known as "Class 2" equipment. An Equipment Class Identifier is assigned to equipment of this class. ***Equipment in this class must be marked by an alert sign (a circle with an exclamation point inside - See Commission Decision of 6 April 2000). This indicates that the transmitting radio equipment operates in non-harmonized frequency bands***

and can cause interference.

Class 2:

Other Radio Equipment:

1. *Other.*
2. *VSATs in the C-band.*
3. *VSATs in the Ku-band.*
4. *Satellite News Gathering Earth Stations in the Ku-band.*
5. *TETRA Direct Mode of Operation.*
6. *TETRAPOL*
7. *Private Mobile Radio.*
8. *Short Range Devices.*
9. *Microwave links.*
10. *Fixed radio links.*
11. *Broadcast transmitters.*
12. *Maritime radio equipment.*
13. *Infrastructure equipment (e.g., base stations).*
14. *Radio equipment, operating in amateur radio bands.*

Note: Spectrum-management remains a national matter. Authorities in the Member States are allowed to regulate radio interfaces, but are required to publish their regulations.

Affixing a marking not in conformity with the above regulations may result in action against the responsible person or, if the person who affixed the marking is not identifiable, action may be taken against the holder of the apparatus at the time the non-compliance is discovered.

The manufacturer should mark on apparatus its type, batch, and/or serial numbers, as well as the name of the manufacturer or the person responsible for placing the apparatus on the market.

ANNEX I of the Directive

Equipment Excluded from this Directive

This Directive does not cover the following equipment:

- Equipment used by radio amateurs, unless the equipment is available commercially (Note that kits of components to be assembled by radio amateurs and commercial equipment modified by, and for the use of, radio amateurs are not regarded as commercially available equipment.);
- Marine equipment;
- Cabling and wiring;
- Receive-only radio equipment that is solely used to receive sound and TV broadcasting services;
- Specified products, appliances, and components that fall under Council Regulation 3922/91 in the field of civil aviation; and
- Air-traffic management equipment and systems that come under Council Directive 93/65 EEC.

ANNEX II of the Directive

Conformity Assessment Procedure: *Internal Production Control*

This module describes the procedure whereby the Manufacturer or his Authorized Representative who carries out the specified obligations ensures and declares that the products concerned satisfy the requirements of this Directive that apply to them. The Manufacturer (or his Authorized Representative) must affix the CE marking to each product and draw up a written Declaration of Conformity *(See SP 951, Page 26)*.

The manufacturer must establish the technical documentation (Technical Construction File), which must enable the conformity of the product with the essential requirements to be assessed. It must cover the design, manufacture and operation of the product, and, in particular, include the following:

- a general description of the product;
- a conceptual design as well as manufacturing drawings and schemes of components, sub-assemblies, circuits, and so on;
- descriptions and explanations necessary for the understanding of those drawings and

schemes and the operation of the product;
- a list of the Harmonized Standards *(See SP 951, Page 11)*, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where Harmonized Standards have not been applied or do not exist;
- results of design calculations made, examinations carried out, and so on; and
- test reports.

The manufacturer must keep the above technical documentation for a period of at least ten years after the last product has been manufactured, so that the relevant national authorities may inspect it at any time.

If neither the manufacturer nor his authorized representative is established within the European Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the European Community market.

The manufacturer must keep a copy of the Declaration of Conformity (*See SP 951, Page 26)* with the technical documentation.

The manufacturer must take all measures necessary to see that the manufacturing process ensures compliance of the manufactured products with the technical documentation referred to in this Annex and with the appropriate requirements of this Directive.

ANNEX III of the Directive

Conformity Assessment Procedure: *Internal Production Control plus Specific Apparatus Tests*

This Annex consists of *Annex II*, plus the following supplementary requirements, which are appropriate to the sector:

- For each type of apparatus, all essential radio test suites must be carried out by the manufacturer or on his behalf. The identification of the test suites that are considered to be essential is the responsibility of a notified body chosen by the manufacturer except where the test suites are defined in the Harmonized Standards *(See SP 951, Page 11)*.
- The manufacturer must declare that these tests have been carried out and that the apparatus complies with the essential requirements and must affix the notified body's identification number during the manufacturing process.

ANNEX IV of the Directive

Conformity Assessment Procedure: *Technical Construction File*

This *Annex* consists of *Annex III* plus the following supplementary requirements:

- The technical documentation described in *Annex II* and the declaration of conformity to specific radio test suites described in *Annex III* must form a technical construction file.

- The manufacturer must present the file to one or more notified bodies, and each of the notified bodies must be informed of others who have received the file. The notified body must review the file and if it is considered that it has not been properly demonstrated that the requirements of the Directive have been met, the notified body may issue an opinion to the manufacturer and must inform the other notified bodies who have received the file accordingly. Such an opinion must be given within four weeks of receipt of the file by the notified body. On receipt of this opinion, or after the end of the four-week period, the apparatus may be placed on the market.

- The manufacturer must keep the file for a period of at least ten years after the last apparatus has been manufactured, so that the relevant national authorities may inspect it.

ANNEX V of the Directive (See Annex V of the Directive for an unabridged description.)

Conformity Assessment Procedure: *Full Quality Assurance*

Full quality assurance is the procedure whereby the manufacturer who satisfies the obligations described below ensures that the products concerned meet the relevant requirements of the Directive. The manufacturer must affix to each product the CE Marking and draw up a written declaration of conformity.

The obligations mentioned above are the following:

- The manufacturer must operate an approved quality system for design, manufacture, and final product inspection and testing as specified below:

    - The manufacturer must lodge an application for assessment of his quality system with a notified body. The application must include all relevant information on the planned products as well as the quality system's documentation.

    - The quality system must 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 must be documented in a systematic and orderly manner in the form of written policies, procedures, and instructions. This quality system documentation must ensure a common understanding of the quality policies and procedures such as quality programs, plans, manuals and records.

- ♦ It must contain in particular an adequate description of:
    1. The quality objectives and the organizational structure, responsibilities, and powers of the management with regard to design and product quality;
    2. The technical specifications, including the Harmonized Standards *(See SP 951, Page 11)* and technical regulations as well as relevant test specifications that will be applied and, where the harmonized standards will not be applied in full, the means that will be used to ensure that the essential requirements of the Directive that apply to the products will be met;
    3. 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;
    4. The corresponding manufacturing, quality control, and quality assurance techniques, processes, and systematic actions that will be used;
    5. The examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out, as well as the results of the tests carried out before manufacture where appropriate;
    6. The means by which it is ensured that the test facilities meet the appropriate requirements for the performance of the necessary tests;
    7. The quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, and so on; and
    8. The means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

- ♦ The notified body must assess the quality system to determine whether it satisfies the necessary requirements explained above. The evaluation procedure must include an assessment visit to the manufacturer's premises. The manufacturer will be notified of the decision, and the notification will include the conclusions of the examination and the reasoned assessment decision.
- ♦ The manufacturer must undertake to fulfill the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient. In addition, the manufacturer must inform the notified body that has approved the quality system whenever the manufacturer intends to update the quality system. The notified body will then evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements or whether a reassessment is required. The manufacturer will be informed of that decision.

- The manufacturer must also be subject to surveillance by the notified body as described below:

    - ♦ The purpose of surveillance is to make sure that the manufacturer fulfils the obligations of the approved quality system;
    - ♦ The manufacturer must allow the notified body access, for inspection purposes, to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, including: (1) the quality system documentation; (2) the quality records as foreseen by the design part of the quality system, such as results of

analyses, calculations, tests, and so on; (3) 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, and so on.
    - The notified body will make audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and will provide an audit report to the manufacturer.
    - 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 to check the proper functioning of the quality system where necessary; it will provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

- The manufacturer must, for a period of at least ten years after the last product has been manufactured, keep at the disposal of the national authorities:
    - the quality system's documentation,
    - the information on updates to the quality system, and
    - the decisions and reports from the notified body referred to above.

ANNEX VI of the Directive

Note: Annex VI establishes the minimum criteria to be considered by Member States when designating notified bodies.

ANNEX VII of the Directive

Marking of Equipment to Indicate CE Conformity *(See Annex VII of the Directive)*

FOR FURTHER INFORMATION, PLEASE REFER TO THE FOLLOWING TEXT OF THE DIRECTIVE.

Text of the Directive on Radio Equipment and Telecommunications Terminal Equipment (1999/5/EC)

The following text of the Directive on Radio Equipment and Telecommunications Terminal Equipment (1999/5/EC) has been taken from EUR-Lex, the digital version of the legislation issued in the Official Journal of the European Communities. Web site:http://europa.eu.int/eur-lex/en/lif/dat/1999/en_399L0005.html

Only European Community's legislation printed in the Official Journal of the European Communities is deemed to be authentic.

DIRECTIVE 1999/5/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty establishing the European Community, and in particular Article 100a,
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 189b of the Treaty(3), in the light of the joint text approved by the Conciliation Committee on 8 December 1998,
(1) Whereas the radio equipment and telecommunications terminal equipment sector is an essential part of the telecommunications market, which is a key element of the economy in the Community; whereas the directives applicable to the telecommunications terminal equipment sector are no longer capable of accommodating the expected changes in the sector caused by new technology, market developments and network legislation;
(2) Whereas in accordance with the principles of subsidiarity and proportionality referred to in Article 3b of the Treaty, the objective of creating an open competitive single market for telecommunications equipment cannot be sufficiently achieved by the Member States and can therefore be better achieved by the Community; whereas this Directive does not go beyond what is necessary to achieve this aim;
(3) Whereas Member States may rely upon Article 36 of the Treaty to exclude certain classes of equipment from this Directive;
(4) Whereas Directive 98/13/EC(4) consolidated the provisions relating to telecommunications terminal equipment and satellite earth station equipment, including measures for the mutual recognition of their conformity;
(5) Whereas that Directive does not cover a substantial proportion of the radio equipment market;
(6) Whereas dual-use goods are subject to the Community regime of export controls introduced by Council Regulation (EC) No 3381/94(5);
(7) Whereas the broad scope of this Directive requires new definitions of the expressions "radio equipment" and "telecommunications terminal equipment"; whereas a regulatory regime aimed at the development of a single market for radio equipment and telecommunications terminal equipment should permit investment, manufacture and sale to take place at the pace of technology and market developments;
(8) Whereas, given the increasing importance of telecommunications terminal equipment and networks using radio transmission besides equipment connected through wired links, any rules governing the manufacturing, marketing and use of radio equipment and telecommunications terminal equipment should cover both classes of such equipment;
(9) Whereas Directive 98/10/EC of the European Parliament and of the Council of 26 February 1998 on the application of open network provision (ONP) to voice telephony and on universal service for telecommunications in a competitive environment(6) calls on national regulatory authorities to ensure the publication of details of technical interface specifications for network access for the purpose of ensuring a competitive market for the supply of terminal equipment;
(10) Whereas the objectives of Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits(7) are sufficient to cover radio equipment and telecommunications terminal equipment, but with no

lower voltage limit applying;
(11) Whereas the electromagnetic compatibility related protection requirements laid down by Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of Member States relating to electromagnetic compatibility(8) are sufficient to cover radio equipment and telecommunications terminal equipment;
(12) Whereas Community law provides that obstacles to the free movement of goods within the Community, resulting from disparities in national legislation relating to the marketing of products, can only be justified where any national requirements are necessary and proportionate; whereas, therefore, the harmonisation of laws must be limited to those requirements necessary to satisfy the essential requirements relating to radio equipment and telecommunications terminal equipment;
(13) Whereas the essential requirements relevant to a class of radio equipment and telecommunications terminal equipment should depend on the nature and the needs of that class of equipment; whereas these requirements must be applied with discernment in order not to inhibit technological innovation or the meeting of the needs of a free-market economy;
(14) Whereas care should be taken that radio equipment and telecommunications terminal equipment should not represent an avoidable hazard to health;
(15) Whereas telecommunications are important to the well-being and employment of people with disabilities who represent a substantial and growing proportion of the population of Europe; whereas radio equipment and telecommunications terminal equipment should therefore in appropriate cases be designed in such a way that disabled people may use it without or with only minimal adaptation;
(16) Whereas radio equipment and telecommunications terminal equipment can provide certain functions required by emergency services;
(17) Whereas some features may have to be introduced on the radio equipment and telecommunications terminal equipment in order to prevent the infringement of personal data and privacy of the user and of the subscriber and/or the avoidance of fraud;
(18) Whereas in some cases interworking via networks with other apparatus within the meaning of this Directive and connection with interfaces of the appropriate type throughout the Community may be necessary;
(19) Whereas it should therefore be possible to identify and add specific essential requirements on user privacy, features for users with a disability, features for emergency services and/or features for avoidance of fraud;
(20) Whereas it is recognised that in a competitive market, voluntary certification and marking schemes developed by consumer organisations, manufacturers, operators and other industry actors contribute to quality and are a useful means of improving consumers' confidence in telecommunications products and services; whereas Member States may support such schemes; whereas such schemes should be compatible with the competition rules of the Treaty;
(21) Whereas unacceptable degradation of service to persons other than the user of radio equipment and telecommunications terminal equipment should be prevented; whereas manufacturers of terminals should construct equipment in a way which prevents networks from suffering harm which results in such degradation when used under normal operating conditions; whereas network operators should construct their networks in a way that does not oblige manufacturers of terminal equipment to take disproportionate measures to prevent networks from being harmed; whereas the European Telecommunications Standards Institute (ETSI) should take due account of this objective when developing standards concerning access to public networks;
(22) Whereas effective use of the radio spectrum should be ensured so as to avoid harmful interference; whereas the most efficient possible use, according to the state of the art, of limited resources such as the radio frequency spectrum should be encouraged;
(23) Whereas harmonised interfaces between terminal equipment and telecommunications networks contribute to promoting competitive markets both for terminal equipment and network services;
(24) Whereas, however, operators of public telecommunications networks should be able to define the technical characteristics of their interfaces, subject to the competition rules of the Treaty; whereas, accordingly, they should publish accurate and adequate technical specifications of such interfaces so as to enable manufacturers to design telecommunications terminal equipment which satisfies the requirements of this Directive;
(25) Whereas, nevertheless, the competition rules of the Treaty and Commission Directive 88/301/EEC of 16 May 1988 on competition in the markets in telecommunications terminal equipment(9) establish the principle of equal, transparent and non-discriminatory treatment of all technical specifications having regulatory implications; whereas therefore it is the task of the Community and the Member States, in consultation with the economic players, to ensure that the regulatory framework created by this Directive is fair;
(26) Whereas it is the task of the European standardisation organisations, notably ETSI, to

ensure that harmonised standards are appropriately updated and drafted in a way which allows for unambiguous interpretation; whereas maintenance, interpretation and implementation of harmonised standards constitute very specialised areas of increasing technical complexity; whereas those tasks require the active participation of experts drawn from amongst the economic players; whereas in some circumstances it may be necessary to provide more urgent interpretation of or corrections to harmonised standards than is possible through the normal procedures of the European standardisation organisations operating in conformity with Directive 98/34/EC of 22 June 1998 of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services(10);
(27) Whereas it is in the public interest to have harmonised standards at European level in connection with the design and manufacture of radio equipment and telecommunications terminal equipment; whereas compliance with such harmonised standards gives rise to a presumption of conformity to the essential requirements; whereas other means of demonstrating conformity to the essential requirements are permitted;
(28) Whereas the assignment of equipment class identifiers should draw on the expertise of CEPT/ERC and of the relevant European standards bodies in radio matters; whereas other forms of cooperation with those bodies is to be encouraged where possible;
(29) Whereas, in order to enable the Commission to monitor market control effectively, the Member States should provide the relevant information concerning types of interfaces, inadequate or incorrectly applied harmonised standards, notified bodies and surveillance authorities;
(30) Whereas notified bodies and surveillance authorities should exchange information on radio equipment and telecommunications terminal equipment with a view to efficient surveillance of the market; whereas such cooperation should make the utmost use of electronic means; whereas, in particular, such cooperation should enable national authorities to be informed about radio equipment placed on their market operating in frequency bands not harmonised in the Community;
(31) Whereas manufacturers should notify Member States of their intention to place radio equipment on the market using frequency bands whose use is not harmonised throughout the Community; whereas Member States therefore need to put in place procedures for such notification; whereas such procedures should be proportionate and should not constitute a conformity assessment procedure additional to those provided for in Annexes IV or V; whereas it is desirable that those notification procedures should be harmonised and preferably implemented by electronic means and one-stop-shopping;
(32) Whereas radio equipment and telecommunications terminal equipment which complies with the relevant essential requirements should be permitted to circulate freely; whereas such equipment should be permitted to be put into service for its intended purpose; whereas the putting into service may be subject to authorisations on the use of the radio spectrum and the provision of the service concerned;
(33) Whereas, for trade fairs, exhibitions, etc., it must be possible to exhibit radio equipment and telecommunications terminal equipment which does not conform to this Directive; whereas, however, interested parties should be properly informed that such equipment does not conform and cannot be purchased in that condition; whereas Member States may restrict the putting into service, including the switching on, of such exhibited radio equipment for reasons related to the effective and appropriate use of the radio spectrum, avoidance of harmful interference or matters relating to public health;
(34) Whereas radio frequencies are allocated nationally and, to the extent that they have not been harmonised, remain within the exclusive competence of the Member States; whereas it is necessary to include a safeguard provision permitting Member States, in conformity with Article 36 of the Treaty, to prohibit, restrict or require the withdrawal from its market of radio equipment which has caused, or which it reasonably considers will cause, harmful interference; whereas interference with nationally allocated radio frequencies constitutes a valid ground for Member States to take safeguard measures;
(35) Whereas manufacturers are liable for damage caused by defective apparatus according to the provisions of Council Directive 85/374/EEC(11); whereas without prejudice to any liability on the part of the manufacturer, any person who imports apparatus into the Community for sale in the course of his business is liable according to that Directive; whereas the manufacturer, his authorised representative or the person responsible for placing the apparatus on the Community market is liable according to the rules of the law of contractual or non-contractual liability in the Member States;
(36) Whereas the measures which are appropriate to be taken by the Member States or the Commission where apparatus declared to be compliant with the provisions of this Directive causes serious damage to a network or harmful radio interference shall be determined in accordance with the general principles of Community law, in particular, the principles of

objectivity, proportionality and non-discrimination;
(37) Whereas on 22 July 1993 the Council adopted Decision 93/465/EEC concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and the use of EC conformity marking which are intended to be used in the technical harmonisation directives(12); whereas the applicable conformity assessment procedures should preferably be chosen from among the available modules laid down by that Decision;
(38) Whereas Member States may request that notified bodies they designate and their surveillance authorities be accredited according to appropriate European standards;
(39) Whereas it is appropriate that compliance of radio equipment and telecommunications terminal equipment with the requirements of Directives 73/23/EEC and 89/336/EEC may be demonstrated using the procedures specified in those Directives where the apparatus is within their scope; whereas, as a result, the procedure provided for in Article 10(1) of Directive 89/336/EEC may be used where the application of harmonised standards gives rise to a presumption of conformity with the protection requirements; whereas the procedure provided for in Article 10(13) may be used where the manufacturer has not applied harmonised standards or where no such standards exist;
(40) Whereas Community undertakings should have effective and comparable access to third countries' markets and enjoy treatment in third countries similar to that offered in the Community to undertakings owned wholly, controlled through majority ownership or effectively controlled by nationals of the third countries concerned;
(41) Whereas it is desirable to establish a committee bringing together parties directly involved in the implementation of regulation of radio equipment and telecommunications terminal equipment, in particular the national conformity assessment bodies and national bodies responsible for market surveillance, in order to assist the Commission in achieving a harmonised and proportionate application of the provisions so as to meet the needs of the market and the public at large; whereas representatives of telecommunications operators, users, consumers, manufacturers and service providers should be consulted where appropriate;
(42) Whereas a modus vivendi between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty was concluded on 20 December 1994(14);
(43) Whereas the Commission should keep under review the implementation and practical application of this and other relevant directives and take steps to ensure coordination of the application of all relevant directives in order to avoid disturbance to telecommunications equipment which affects the health of humans or is harmful to property;
(44) Whereas the functioning of this Directive should be reviewed in due course in the light of the development of the telecommunications sector and of experience gained from application of the essential requirements and the conformity assessment procedures provided for in this Directive;
(45) Whereas it is necessary to ensure that with the introduction of changes to the regulatory regime there is a smooth transition from the previous regime in order to avoid disruption to the market and legal uncertainty;
(46) Whereas this Directive replaces Directive 98/13/EC, which should accordingly be repealed; whereas Directives 73/23/EEC and 89/336/EEC will no longer apply to apparatus within the scope of this Directive, with the exception of protection and safety requirements and certain conformity assessment procedures,
HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I
GENERAL ASPECTS
Article 1
Scope and aim
1. This Directive establishes a regulatory framework for the placing on the market, free movement and putting into service in the Community of radio equipment and telecommunications terminal equipment.
2. Where apparatus as defined in Article 2(a) incorporates, as an integral part, or as an accessory:
(a) a medical device within the meaning of Article 1 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices(15), or
(b) an active implantable medical device within the meaning of Article 1 of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices(16),
the apparatus shall be governed by this Directive, without prejudice to the application of Directives 93/42/EEC and 90/385/EEC to medical devices and active implantable medical devices, respectively.
3. Where apparatus constitutes a component or a separate technical unit of a vehicle within the meaning of Council Directive 72/245/EEC(17) relating to the radio interference (electromagnetic compatibility) of vehicles or a component or a separate technical unit of a vehicle within the meaning of Article 1 of Council Directive 92/61/EEC of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles, the apparatus shall be governed by this Directive without prejudice to the

application of Directive 72/245/EEC or of Directive 92/61/EEC respectively.
4. This Directive shall not apply to equipment listed in Annex I.
5. This Directive shall not apply to apparatus exclusively used for activities concerning public security, defence, State security (including the economic well-being of the State in the case of activities pertaining to State security matters) and the activities of the State in the area of criminal law.

Article 2
Definitions
For the purpose of this Directive the following definitions shall apply:
(a) “apparatus” means any equipment that is either radio equipment or telecommunications terminal equipment or both;
(b) “telecommunications terminal equipment” means a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services);
(c) “radio equipment” means a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/space radiocommunication;
(d) “radio waves” means electromagnetic waves of frequencies from 9 kHz to 3000 GHz, propagated in space without artificial guide;
(e) “interface” means
(i) a network termination point, which is a physical connection point at which a user is provided with access to public telecommunications network, and/or
(ii) an air interface specifying the radio path between radio equipment
and their technical specifications;
(f) “equipment class” means a class identifying particular types of apparatus which under this Directive are considered similar and those interfaces for which the apparatus is designed. Apparatus may belong to more than one equipment class;
(g) “technical construction file” means a file describing the apparatus and providing information and explanations as to how the applicable essential requirements have been implemented;
(h) “harmonised standard” means a technical specification adopted by a recognised standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement, compliance with which is not compulsory.
(i) “harmful interference” means interference which endangers the functioning of a radionavigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with the applicable Community or national regulations.

Article 3
Essential requirements
1. The following essential requirements are applicable to all apparatus:
(a) the protection of the health and the safety of the user and any other person, including the objectives with respect to safety requirements contained in Directive 73/23/EEC, but with no voltage limit applying;
(b) the protection requirements with respect to electromagnetic compatibility contained in Directive 89/336/EEC.
2. In addition, radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference.
3. In accordance with the procedure laid down in Article 15, the Commission may decide that apparatus within certain equipment classes or apparatus of particular types shall be so constructed that:
(a) it interworks via networks with other apparatus and that it can be connected to interfaces of the appropriate type throughout the Community; and/or that
(b) it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; and/or that
(c) it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected; and/or that
(d) it supports certain features ensuring avoidance of fraud; and/or that
(e) it supports certain features ensuring access to emergency services; and/or that
(f) it supports certain features in order to facilitate its use by users with a disability.

Article 4
Notification and publication of interface specifications
1. Member States shall notify the interfaces which they have regulated to the Commission insofar as the said interfaces have not been notified under the provisions of Directive 98/34/EC. After consulting the committee in accordance with the procedure set out in Article 15, the Commission shall establish the equivalence between notified interfaces and assign an equipment class identifier, details of which shall

be published in the Official Journal of the European Communities.
2. Each Member State shall notify to the Commission the types of interface offered in that State by operators of public telecommunications networks. Member States shall ensure that such operators publish accurate and adequate technical specifications of such interfaces before services provided through those interfaces are made publicly available, and regularly publish any updated specifications. The specifications shall be in sufficient detail to permit the design of telecommunications terminal equipment capable of utilising all services provided through the corresponding interface. The specifications shall include, inter alia, all the information necessary to allow manufacturers to carry out, at their choice, the relevant tests for the essential requirements applicable to the telecommunications terminal equipment. Member States shall ensure that those specifications are made readily available by the operators.

Article 5
Harmonised standards
1. Where apparatus meets the relevant harmonised standards or parts thereof whose reference numbers have been published in the Official Journal of the European Communities, Member States shall presume compliance with those of the essential requirements referred to in Article 3 as are covered by the said harmonised standards or parts thereof.
2. Where a Member State or the Commission considers that conformity with a harmonised standard does not ensure compliance with the essential requirements referred to in Article 3 which the said standard is intended to cover, the Commission or the Member State concerned shall bring the matter before the committee.
3. In the case of shortcomings of harmonised standards with respect to the essential requirements, the Commission may, after consulting the committee and in accordance with the procedure laid down in Article 14, publish in the Official Journal of the European Communities guidelines on the interpretation of harmonised standards or the conditions under which compliance with that standard raises a presumption of conformity. After consultation of the committee and in accordance with the procedure laid down in Article 14, the Commission may withdraw harmonised standards by publication of a notice in the Official Journal of the European Communities.

Article 6
Placing on the market
1. Member States shall ensure that apparatus is placed on the market only if it complies with the appropriate essential requirements identified in Article 3 and the other relevant provisions of this Directive when it is properly installed and maintained and used for its intended purpose. It shall not be subject to further national provisions in respect of placing on the market.
2. In taking a decision regarding the application of essential requirements under Article 3(3), the Commission shall determine the date of application of the requirements. If it is determined that an equipment class needs to comply with particular essential requirements under Article 3(3), any apparatus of the equipment class in question which is first placed on the market before the date of application of the Commission's determination can continue to be placed on the market for a reasonable period. Both the date of application and the period shall be determined by the Commission in accordance with the procedure laid down in Article 14.
3. Member States shall ensure that the manufacturer or the person responsible for placing the apparatus on the market provides information for the user on the intended use of the apparatus, together with the declaration of conformity to the essential requirements. Where it concerns radio equipment, such information shall be sufficient to identify on the packaging and the instructions for use of the apparatus the Member States or the geographical area within a Member State where the equipment is intended to be used and shall alert the user by the marking on the apparatus referred to in Annex VII, paragraph 5, to potential restrictions or requirements for authorisation of use of the radio equipment in certain Member States. Where it concerns telecommunications terminal equipment, such information shall be sufficient to identify interfaces of the public telecommunications networks to which the equipment is intended to be connected. For all apparatus such information shall be prominently displayed.
4. In the case of radio equipment using frequency bands whose use is not harmonised throughout the Community, the manufacturer or his authorised representative established within the Community or the person responsible for placing the equipment on the market shall notify the national authority responsible in the relevant Member State for spectrum management of the intention to place such equipment on its national market.
This notification shall be given no less than four weeks in advance of the start of placing on the market and shall provide information about the radio characteristics of the equipment (in particular frequency bands, channel spacing, type of modulation and RF-power) and the identification number of the notified body referred to in Annex IV or

V.

Article 7
Putting into service and right to connect
1. Member States shall allow the putting into service of apparatus for its intended purpose where it complies with the appropriate essential requirements identified in Article 3 and the other relevant provisions of this Directive.
2. Not withstanding paragraph 1, and without prejudice to conditions attached to authorisations for the provision of the service concerned in conformity with Community law, Member States may restrict the putting into service of radio equipment only for reasons related to the effective and appropriate use of the radio spectrum, avoidance of harmful interference or matters relating to public health.
3. Without prejudice to paragraph 4, Member States shall ensure that operators of public telecommunications networks do not refuse to connect telecommunications terminal equipment to appropriate interfaces on technical grounds where that equipment complies with the applicable requirements of Article 3.
4. Where a Member State considers that apparatus declared to be compliant with the provisions of this Directive causes serious damage to a network or harmful radio interference or harm to the network or its functioning, the operator may be authorized to refuse connection, to disconnect such apparatus or to withdraw it from service. The Member States shall notify each such authorisation to the Commission, which shall convene a meeting of the committee for the purpose of giving its opinion on the matter. After the committee has been consulted, the Commission may initiate the procedures referred to in Article 5(2) and (3). The Commission and the Member States may also take other appropriate measures.
5. In case of emergency, an operator may disconnect apparatus if the protection of the network requires the equipment to be disconnected without delay and if the user can be offered, without delay and without costs for him, an alternative solution. The operator shall immediately inform the national authority responsible for the implementation of paragraph 4 and Article 9.

Article 8
Free movement of apparatus
1. Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of apparatus bearing the CE marking referred to in Annex VII, which indicates its conformity with all provisions of this Directive, including the conformity assessment procedures set out in Chapter II. This shall be without prejudice to Articles 6(4), 7(2) and 9(5).
2. At trade fairs, exhibitions, demonstrations, etc., Member States shall not create any obstacles to the display of apparatus which does not comply with this Directive, provided that a visible sign clearly indicates that such apparatus may not be marketed or put into service until it has been made to comply.
3. Where the apparatus is subject to other directives which concern other aspects and also provide for the affixing of the CE marking, the latter shall indicate that such apparatus also fulfils the provisions of those other directives. However, should one or more of those directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the apparatus fulfils the provisions only of those directives applied by the manufacturer. In this case, the particulars of those directives, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by those directives and accompanying such products.

Article 9
Safeguards
1. Where a Member State ascertains that apparatus within the scope of this Directive does not comply with the requirements of this Directive, it shall take all appropriate measures in its territory to withdraw the apparatus from the market or from service, prohibit its placing on the market or putting into service or restrict its free movement.
2. The Member State concerned shall immediately notify the Commission of any such measures indicating the reasons for its decision and whether non-compliance is due to:
(a) incorrect application of the harmonised standards referred to in Article 5(1);
(b) shortcomings in the harmonised standards referred to in Article 5(1);
(c) failure to satisfy the requirements referred to in Article 3 where the apparatus does not meet the harmonised standards referred to in Article 5(1).
3. If the measures referred to in paragraph 1 are attributed to incorrect application of the harmonised standards referred to in Article 5(1) or to a failure to satisfy the requirements referred to in Article 3 where the apparatus does not meet the harmonised standards referred to in Article 5(1), the Commission shall consult the parties concerned as soon as possible. The Commission shall forthwith inform the Member States of its findings and of its opinion as to whether the measures are justified, within two months of notification of the said measures to the Commission.
4. Where the decision referred to in paragraph 1 is attributed to shortcomings in the harmonised standards referred to in Article 5(1), the Commission

shall bring the matter before the committee within two months. The committee shall deliver an opinion in accordance with the procedure laid down in Article 14. After such consultation, the Commission shall inform the Member States of its findings and of its opinion as to whether the action by the Member State is justified. If it finds that the action is justified it shall forthwith initiate the procedure referred to in Article 5(2).
5. (a) Notwithstanding the provisions of Article 6, a Member State may, acting in conformity with the Treaty, and in particular Articles 30 and 36 thereof, adopt any appropriate measures with a view to:
(i) prohibiting or restricting the placing on its market, and/or
(ii) requiring the withdrawal from its market,
of radio equipment, including types of radio equipment, which has caused or which it reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands.
(b) Where a Member State takes measures in accordance with subparagraph (a) it shall immediately inform the Commission of the said measures, specifying the reasons for adopting them.
6. When a Member State notifies the Commission of a measure referred to in paragraph 1 or 5 the Commission shall in turn inform other Member States and consult the committee on the matter.
Where, after such consultation, the Commission considers that:
- the measure is justified, it shall immediately so inform the Member State which took the initiative and the other Member States,
- the measure is unjustified, it shall immediately so inform the Member State and request it to withdraw the measure.
7. The Commission shall maintain a record of the cases notified by Member States, which shall be made available to them on request.

CHAPTER II
CONFORMITY ASSESSMENT
Article 10
Conformity assessment procedures
1. The conformity assessment procedures identified in this Article shall be used to demonstrate the compliance of the apparatus with all the relevant essential requirements identified in Article 3.
2. At the choice of the manufacturer, compliance of the apparatus with the essential requirements identified in Article 3(1)(a) and (b) may be demonstrated using the procedures specified in Directive 73/23/EEC and Directive 89/336/EEC respectively, where the apparatus is within the scope of those Directives, as an alternative to the procedures laid out below.
3. Telecommunications terminal equipment which does not make use of the spectrum allocated to terrestrial/space radio communication and receiving parts of radio equipment shall be subject to the procedures described in any one of Annexes II, IV or V at the choice of the manufacturer.
4. Where a manufacturer has applied the harmonised standards referred to in Article 5(1), radio equipment not within the scope of paragraph 3 shall be subject to the procedures described in any one of Annexes III, IV or V at the choice of the manufacturer.
5. Where a manufacturer has not applied or has only applied in part the harmonised standards referred to in Article 5(1), radio equipment not within the scope of paragraph 3 of this Article shall be subject to the procedures described in either of Annexes IV or V at the choice of the manufacturer.
6. Records and correspondence relating to the conformity assessment procedures referred to in paragraphs 2 to 5 shall be in an official language of the Member State where the procedure will be carried out, or in a language accepted by the notified body involved.

Article 11
Notified bodies and surveillance authorities
1. Member States shall notify the Commission of the bodies which they have designated to carry out the relevant tasks referred to in Article 10. Member States shall apply the criteria laid down in Annex VI in determining the bodies to be designated.
2. Member States shall notify the Commission of the authorities established within their territory which are to carry out the surveillance tasks related to the operation of this Directive.
3. The Commission shall publish a list of the notified bodies, together with their identification numbers and the tasks for which they have been notified, in the Official Journal of the European Communities. The Commission shall also publish a list of surveillance authorities in the Official Journal of the European Communities. Member States shall provide the Commission with all information necessary to keep these lists up to date.

CHAPTER III
CE CONFORMITY MARKING AND INSCRIPTIONS
Article 12
CE marking
1. Apparatus complying with all relevant essential requirements shall bear the EC conformity marking referred to in Annex VII. It shall be affixed under the responsibility of the manufacturer, his authorized representative within the Community or the person responsible for placing the apparatus on the market. Where the procedures identified in Annex III, IV or V are used, the marking shall be accompanied by the

identification number of the notified body referred to in Article 11(1). Radio equipment shall in addition be accompanied by the equipment class identifier where such indentifier has been assigned. Any other marking may be affixed to the equipment provided that the visibility and legibility of the EC marking is not thereby reduced.
2. No apparatus, whether or not it complies with the relevant essential requirements, may bear any other marking which is likely to deceive third parties as to the meaning and form of the EC marking specified in Annex VII.
3. The competent Member State shall take appropriate action against any person who has affixed a marking not in conformity with paragraphs 1 and 2. If the person who affixed the marking is not identifiable, appropriate action may be taken against the holder of the apparatus at the time when non-compliance was discovered.
4. Apparatus shall be identified by the manufacturer by means of type, batch and/or serial numbers and by the name of the manufacturer or the person responsible for placing the apparatus on the market.

CHAPTER IV
THE COMMITTEE
Article 13
Constitution of the committee
The Commission shall be assisted by a committee, the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM), composed of representatives of the Member States and chaired by a representative of the Commission.

Article 14
Advisory committee procedure
1. The committee shall be consulted on the matters covered by Articles 5, 6(2), 7(4), 9(4) and Annex VII(5).
2. The Commission shall consult the committee periodically on the surveillance tasks related to the application of this Directive, and, where appropriate, issue guidelines on this matter.
3. The representative of the Commission shall submit to the committee a draft of the measures to be taken. 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, if necessary by taking a vote.
The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.
The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account and decide within one month after having received the opinion of the committee.
4. The Commission shall periodically consult the representatives of the telecommunications networks providers, the consumers and the manufacturers. It shall keep the committee regularly informed of the outcome of such consultations.

Article 15
Regulatory committee procedure
1. Notwithstanding the provisions of Article 14, the following procedure shall apply in respect of the matters covered by Articles 3(3) and 4(1).
2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. 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.
3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.
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 a qualified majority.
If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

CHAPTER V
FINAL AND TRANSITIONAL PROVISIONS
Article 16
Third countries
1. Member States may inform the Commission of any general difficulties encountered, de jure or de facto, by Community undertakings with respect to placing on the market in third countries, which have been brought to their attention.
2. Whenever the Commission is informed of such difficulties, it may, if necessary, submit proposals to the Council for an appropriate mandate for negotiation of comparable rights for Community undertakings in these third countries. The Council shall decide by qualified majority.
3. Measures taken pursuant to paragraph 2 shall be without prejudice to the obligations of the Community and of the Member States under relevant international agreements.

Article 17
Review and reporting
The Commission shall review the operation of this Directive and report thereon to the European Parliament and to the Council, on the first occasion not later than 7 October 2000 18 months after the entry into force of this Directive and every third year thereafter. The report shall cover progress on drawing up the relevant standards, as well as any problems that have arisen in the course of implementation. The report shall also outline the activities of the committee, assess progress in achieving an open competitive market for apparatus at Community level and examine how the regulatory framework for the placing on the market and putting into service of apparatus should be developed to:
(a) ensure that a coherent system is achieved at Community level for all apparatus;
(b) allow for convergence of the telecommunications, audiovisual and information technology sectors;
(c) enable harmonisation of regulatory measures at international level.
It shall in particular examine whether essential requirements are still necessary for all categories of apparatus covered and whether the procedures contained in Annex IV, third paragraph, are proportionate to the aim of ensuring that the essential requirements are met for apparatus covered by that Annex. Where necessary, further measures may be proposed in the report for full implementation of the aim of the Directive.

Article 18
Transitional provisions
1. Standards under Directive 73/23/EEC or 89/336/EEC whose references have been published in the Official Journal of the European Communities may be used as the basis for a presumption of conformity with the essential requirements referred to in Article 3(1)(a) and Article 3(1)(b). Common technical regulations under Directive 98/13/EC whose references have been published in the Official Journal of the European Communities may be used as the basis for a presumption of conformity with the other relevant essential requirements referred to in Article 3. The Commission shall publish a list of references to those standards in the Official Journal of the European Communities immediately after this Directive enters into force.
2. Member States shall not impede the placing on the market and putting into service of apparatus which is in accordance with the provisions in Directive 98/13/EC or rules in force in their territory and was placed on the market for the first time before this Directive entered into force or at the latest two years after this Directive entered into force.
3. Apart from the essential requirements referred to in Article 3(1), the Member States may request to continue, for a period of up to 30 months following the date referred to in the first sentence of Article 19(1), and in conformity with the provisions of the Treaty, to require telecommunications terminal equipment not to be capable of causing unacceptable deterioration of a voice telephony service accessible within the framework of the universal service as defined in Directive 98/10/EC.
The Member State shall inform the Commission of the reasons for requesting a continuation of such a requirement, the date by which the service concerned will no longer need the requirement, and the measures envisaged in order to meet this deadline.
The Commission shall consider the request taking into account the particular situation in the Member State and the need to ensure a coherent regulatory environment at Community level, and shall inform the Member State whether it deems that the particular situation in that Member State justifies a continuation and, if so, until which date such continuation is justified.

Article 19
Transposition
1. Member States shall not later than 7 April 2000 adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof. They shall apply these provisions as from 8 April 2000.
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 a reference shall be laid down by Member States.
2. Member States shall inform the Commission of the main provisions of domestic law which they adopt in the field covered by this Directive.

Article 20
Repeal
1. Directive 98/13/EC is hereby repealed as from 8 April 2000.
2. This Directive is not a specific directive within the meaning of Article 2(2) of Directive 89/336/EEC. The provisions of Directive 89/336/EEC shall not apply to apparatus falling within the scope of this Directive, with the exception of the protection requirements in Article 4 and Annex III and the conformity assessment procedure in Article 10(1) and (2) of, and Annex I to, Directive 89/336/EEC, as from 8 April 2000.
3. The provisions of Directive 73/23/EEC shall not apply to apparatus falling within the scope of this Directive, with the exceptions of the objectives with respect to safety requirements in Article 2 and Annex

I and the conformity assessment procedure in Annex III, Section B, and Annex IV to Directive 73/23/EEC, as from 8 April 2000.

Article 21
Entry into force
This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 22
Addressees
This Directive is addressed to the Member States.

Done at Brussels, 9 March 1999.

For the European Parliament
The President
J. M. GIL-ROBLES

For the Council
The President
W. RIESTER

(1) OJ C 248, 14.8.1997, p. 4.
(2) OJ C 73, 9.3.1998, p. 10.
(3) Opinion of the European Parliament of 29 January 1998 (OJ C 56, 23.2.1998, p. 27), Council common position of 8 June 1998 (OJ C 227, 20.7.1998, p. 37) and Decision of the European Parliament of 6 October 1998 (OJ C 328, 26.10.1998, p. 32). Decision of the Council of 25 January 1999 and Decision of the European Parliament of 10 February 1999.
(4) OJ L 74, 12.3.1998, p. 1.
(5) OJ L 367, 31.12.1994, p. 1.
(6) OJ L 101, 1.4.1998, p. 24.
(7) OJ L 77, 26.3.1973, p. 29. Directive as amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).
(8) OJ L 139, 23.5.1989, p. 19. Directive as last amended by Directive 93/68/EEC.
(9) OJ L 131, 27.5.1988, p. 73. Directive as amended by Directive 94/46/EC (OJ L 268, 19.10.1994, p. 15).
(10) OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).
(11) OJ L 210, 7.8.1985, p. 29.
(12) OJ L 220, 30.8.1993, p. 23.
(13) OJ L 220, 30.8.1993, p. 23.
(14) OJ C 102, 4.4.1996, p. 1.
(15) OJ L 169, 12.7.1993, p. 1.
(16) OJ L 152, 6.7.1972, p. 15. Directive as last amended by Commission Directive 95/54/EC (OJ L 266, 8.11.1995, p. 1).
(17) OJ L 225, 10.8.1992, p. 72. Directive as amended by the 1994 Act of Accession.

ANNEX I

EQUIPMENT NOT COVERED BY THIS DIRECTIVE AS REFERRED TO IN ARTICLE 1(4)

1. Radio equipment used by radio amateurs within Article 1, definition 53, of the International Telecommunications Union (ITU) radio regulations unless the equipment is available commercially.
Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.
2. Equipment falling within the scope of Council Directive 96/98/EC of 20 December 1996 on marine equipment(1).
3. Cabling and wiring.
4. Receive only radio equipment intended to be used solely for the reception of sound and TV broadcasting services.
5. Products, appliances and components within the meaning of Article 2 of Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation(2).
6. Air-traffic-management equipment and systems within the meaning of Article 1 of Council Directive 93/65/EEC of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air-traffic-management equipment and systems(3).

(1) OJ L 46, 17.2.1997, p. 25.
(2) OJ L 373, 31.12.1991, p. 4. Regulation as amended by Commission Regulation (EC) No 2176/96 (OJ L 291, 14.11.1996, p. 15).
(3) OJ L 187, 29.7.1993, p. 52. Directive as last amended by Commission Directive 97/15/EC (OJ L 95, 10.4.1997, p. 16).

ANNEX II

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(3)
Module A (internal production control)
1. This module describes the procedure whereby the manufacturer or his authorised representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the products concerned satisfy the requirements of this Directive that apply to them. The manufacturer or his authorised representative established within the Community must affix the CE marking to each product and draw up a written declaration of conformity.
2. The manufacturer must establish the technical documentation described in point 4 and he or his authorised representative established within the Community must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities of any Member State for inspection purposes.
3. 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 product on the Community market.
4. The technical documentation must enable the conformity of the product with the essential requirements to be assessed. It must cover the design, manufacture and operation of the product, in particular:
- a general description of the product,
- 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, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where such standards referred to in Article 5 have not been applied or do not exist,
- results of design calculations made, examinations carried out, etc.,
- test reports.
5. The manufacturer or his authorised representative must keep a copy of the declaration of conformity with the technical documentation.
6. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

ANNEX III

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(4)
(Internal production control plus specific apparatus tests)(1)
This Annex consists of Annex II, plus the following supplementary requirements:
For each type of apparatus, all essential radio test suites must be carried out by the manufacturer or on his behalf. The identification of the test suites that are considered to be essential is the responsibility of a notified body chosen by the manufacturer except where the test suites are defined in the harmonised standards. The notified body must take due account of previous decisions made by notified bodies acting together.
The manufacturer or his authorised representative established within the Community or the person responsible for placing the apparatus on the market must declare that these tests have been carried out and that the apparatus complies with the essential requirements and must affix the notified body's identification number during the manufacturing process.

(1) Annex based on Module A with additional requirements appropriate to the sector.

ANNEX IV

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(5)
(Technical construction file)
This Annex consists of Annex III plus the following supplementary requirements:
The technical documentation described in point 4 of Annex II and the declaration of conformity to specific radio test suites described in Annex III must form a technical construction file.
The manufacturer, his authorised representative established within the Community or the person responsible for placing the apparatus on the market, must present the file to one or more notified bodies, each of the notified bodies must be informed of others who have received the file.
The notified body must review the file and if it is considered that it has not been properly demonstrated that the requirements of the Directive have been met, the notified body may issue an opinion to the manufacturer, his representative or the person responsible for placing the apparatus on the market and must inform the other notified bodies who have received the file accordingly. Such an opinion must be given within four weeks of receipt of the file by the notified body. On receipt of this opinion, or after the end of the four-week period, the apparatus may be placed on the market, without prejudice to Articles 6(4) and 9(5).
The manufacturer or his authorised representative established within the Community or the person responsible for placing the apparatus on the market must keep the file for a period ending at least 10 years after the last apparatus has been manufactured at the disposal of the relevant national authorities of any Member States for inspection.

ANNEX V

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10
Full quality assurance
1. Full quality assurance is the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned satisfy the requirements of the Directive that apply to them. The manufacturer must affix the marks referred to in Article 12(1) to each product and draw up a written declaration of conformity.
2. The manufacturer must operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and must 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 products envisaged,
- the quality system's documentation.
3.2. The quality system must 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 must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.
It must contain in particular an adequate description of:
- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
- the technical specifications, including the harmonised standards and technical regulations as well as relevant test specifications that will be applied and, where the standards referred to in Article 5(1) will not be applied in full, the means that will be used to ensure that the essential requirements of the 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 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 examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, as well as the results of the tests carried out before manufacture where appropriate,
- the means by which it is ensured that the test and examination facilities respect the appropriate requirements for the performance of the necessary test,
- 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 product 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 must presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard.
The notified body must assess in particular whether the quality control system ensures conformity of the products with the requirements of the Directive in the light of the relevant documentation supplied in respect of points 3.1 and 3.2 including, where relevant, test results supplied by the manufacturer.
The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure must 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 out of 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 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. EC 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 access for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must 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 must carry out audits at reasonable intervals 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. 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 10 years after the last product has been manufactured, keep at the disposal of the national authorities:
- the documentation referred to in the second indent 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 the final paragraph of point 3.4 and in points 4.3 and 4.4.
6. Each notified body must make available to the other notified bodies the relevant information concerning quality system approvals including references to the product(s) concerned, issued and withdrawn.

ANNEX VI

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES WHEN DESIGNATING NOTIFIED BODIES IN ACCORDANCE WITH ARTICLE 11(1)

1. The notified body, its director and the staff responsible for carrying out the tasks for which the notified body has been designated must not be a designer, manufacturer, supplier or installer of radio equipment or telecommunications terminal equipment, or a network operator or a service provider, nor the authorised representative of any of such parties. They must be independent and not become directly involved in the design, construction, marketing or maintenance of radio equipment or telecommunications 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 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 inspections must have:
- sound technical and professional training,
- satisfactory knowledge of the requirements of the tests or inspections that are carried 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 inspections.
5. The impartiality of 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 inspections.
6. The notified body must take out liability insurance unless its liability is assumed by the Member 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 Member State in which its activities are carried out) under this Directive or any provision of national law giving effect thereto.

ANNEX VII

MARKING OF EQUIPMENT REFERRED TO IN ARTICLE 12(1)
1. The CE conformity marking must consist of the initials “CE” taking the following form:
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If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.
2. The CE marking must have a height of at least 5 mm except where this is not possible on account of the nature of the apparatus.
3. The CE marking must be affixed to the product or to its data plate. Additionally it must be affixed to the packaging, if any, and to the accompanying documents.
4. The CE marking must be affixed visibly, legibly and indelibly.
5. The equipment class identifier must take a form to be decided by the Commission in accordance with the procedure laid down in Article 14.
Where appropriate it must include an element intended to provide information to the user that the apparatus makes use of radio frequency bands where their use is not harmonised throughout the Community.
It must have the same height as the initials “CE”.

Joint Declaration of the European Parliament, the Council and the Commission

The European Parliament, the Council and the Commission recognise the importance of the requirement relating to the prevention of harm to the network or its functioning which causes an unacceptable degradation of service taking into account in particular the need to safeguard the interests of the consumer.
Therefore, they note that the Commission will carry out a continuous assessment of the situation in order to evaluate whether that risk occurs frequently and, in such a case, to find an appropriate solution in the framework of the Committee acting in accordance with the procedure laid down in Article 15.
Such a solution will, where appropriate, consist of the systematic application of the essential requirement provided for in Article 3(3)(b).
Furthermore, the European Parliament, the Council and the Commission state that the procedure described above applies without prejudice to the possibilities foreseen in Article 7(5) and to the development of voluntary certification and marking schemes to prevent either the degradation of service or any harm to the network.

Commission Decision
of 6 April 2000
establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers
(notified under document number C(2000) 938)
(Text with EEA relevance)
(2000/299/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity(1), and in particular Article 4(1), thereof,

Whereas:

(1) Member States are to notify regulated interfaces, so that the equivalence between them can be established.

(2) Given that it is already known that certain radio equipment interfaces are equivalent from a regulatory perspective, the equivalence between such interfaces should be provisionally established pending notification of regulated interfaces.

(3) Experts from Member States and the sector have studied classification of interface regulations. From these studies it was concluded that it would not be in the interest of the consumer or surveillance authorities to have extensive classification or marking.

(4) Member States have not yet notified the interfaces regulated in their territories.

(5) Nonetheless a number of interfaces are known, notably those regulated through Common Technical Regulations adopted according to Directive 98/13/EC.

(6) It is appropriate to classify equipment which can be placed on the market in the whole of the Community and which can be put into service without restriction in a single class.

(7) It is appropriate for such equipment only to bear the CE mark.

(7) It is however in the interest of market surveillance authorities and consumers to be alerted through its Equipment Class Identifier where there are limitations to the placing on the market or the putting into service of radio equipment.

(8) Provisionally all equipment where there are such restrictions can be grouped in a single class.

(9) However further classes may be envisaged after Member States have notified regulated interfaces.

(10) It would be useful not to extensively describe classes in terms of equipment types in this Decision. The Commission will therefore, after consulting the Standing Committee of Directive 1999/5/EC (TCAM), publish and maintain on the web an indicative and non-exhaustive list of equipment per equipment class as guidance to manufacturers. Manufacturers are recommended to consult a notified body for products for which such guidance is not yet available.

(11) The measures provided for in this Decision are in accordance with the opinion of the TCAM Committee, HAS ADOPTED THIS DECISION:

Article 1

1. Radio Equipment and Telecommunications Terminal Equipment, which can be placed on the market and be put into service without restrictions, will constitute a class. This class will be referred to as "Class 1". An Equipment Class Identifier is not assigned for this class of equipment.

2. Radio Equipment for which Member States apply restrictions on the putting into service as foreseen in Article 7(2) of Directive 1999/5/EC or for which Member States apply restrictions on the placing on the market as foreseen by Article 9(5) of Directive 1999/5/EC will constitute a class. This class will be referred to as "Class 2". The following Equipment Class Identifier is assigned to equipment within this class:

3. The Commission will publish and maintain, in consultation with the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM), an indicative and non-exhaustive list of equipment falling within the above classes on the website containing information on Directive 1999/5/EC (http://europa.eu.int/comm/enterprise/rtte).

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 April 2000.

For the Commission
Erkki Liikanen
Member of the Commission

LIST OF HARMONIZED STANDARDS