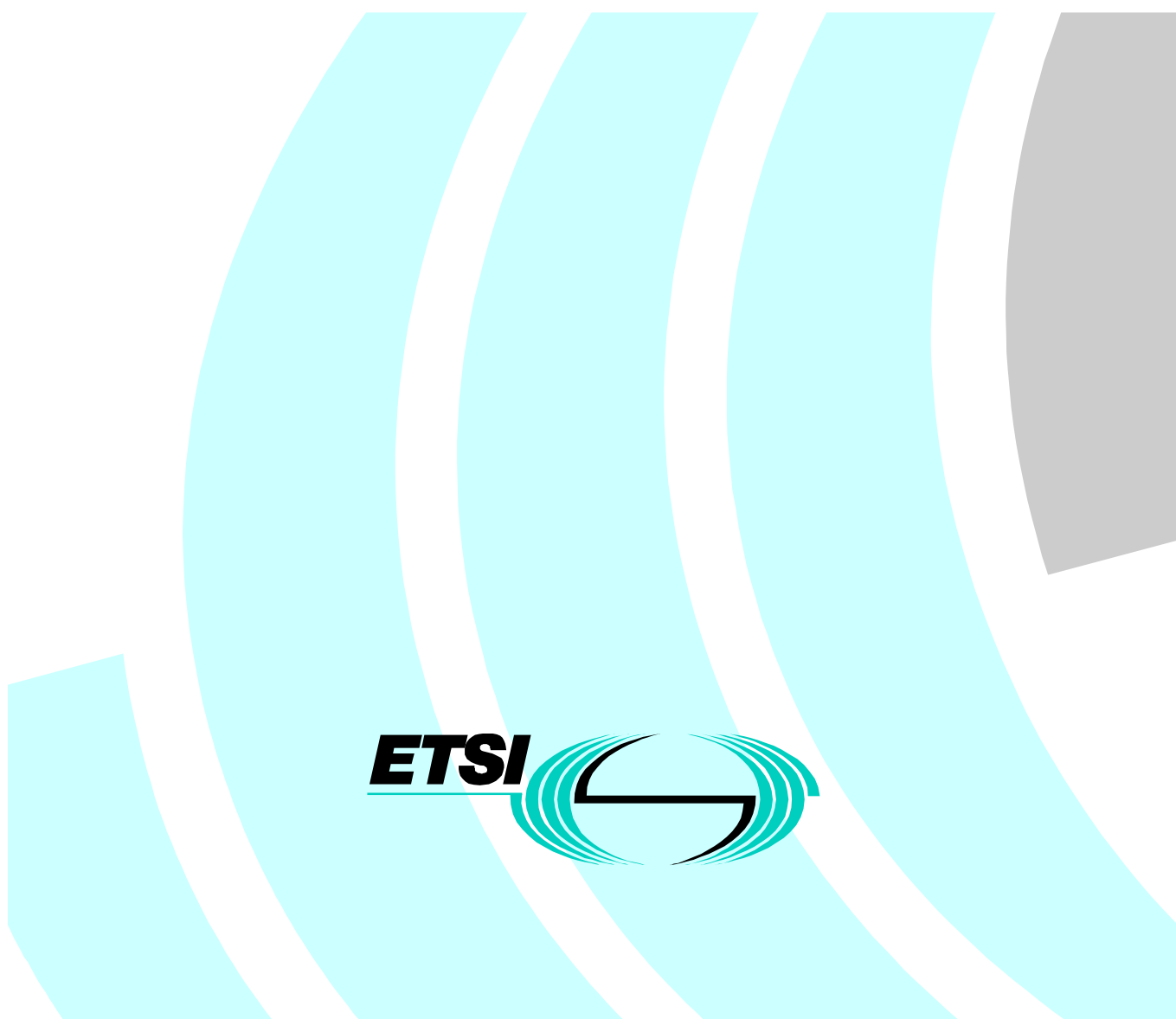


**A guide to the production of Harmonized standards for  
application under the R&TTE Directive**

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**Postal address**F-06921 Sophia Antipolis Cedex - FRANCE

---

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**Office address**

650 Route des Lucioles - Sophia Antipolis  
Valbonne - FRANCE  
Tel.: +33 4 92 94 42 00 Fax: +33 4 93 65 47 16  
Siret N° 348 623 562 00017 - NAF 742 C  
Association à but non lucratif enregistrée à la  
Sous-Préfecture de Grasse (06) N° 7803/88

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**Internet**

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secretariat@etsi.fr

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## Foreword

This ETSI Guide (EG) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the ETSI standards Membership Approval Procedure.

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## Introduction

The present document is based on and reflects the final text of the R&TTE Directive 1999/5/EC [1].

The present document is expected to result in modifications to the ETSI Drafting Rules.

The present document is one of a series of documents produced in advance of the adoption of the Directive, and the establishment of the TCAM. Other documents have been prepared in four Ad Hoc Groups established by the European Commission, namely:

- AHG A: surveillance;
- AHG B: equipment classes;
- AHG C: network interface publication;
- AHG D: essential requirements and user information.

Every effort has been made to keep the contents of the present document in line with the deliberations of the four AHGs insofar as they affect the preparation of candidate Harmonized Standards. However, readers should be aware that the Commission and TCAM are not constrained to follow the advice of the AHGs.

The status of the present document is not final. It is expected that changes will need to be made to reflect, amongst others, comments received from bodies external to ETSI, and to keep the guidance to ETSI in line with the deliberations of TCAM.

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# 1 Scope

The present document has been prepared to assist ETSI technical bodies in the preparation of candidate Harmonized Standards for application under the Radio Equipment and Telecommunications Terminal Equipment Directive (R&TTE Directive). The present document is not applicable to documents produced by other standards bodies (i.e. CEN and CENELEC) even if some of the standards they produce have application under the R&TTE Directive.

As part of its objective, the present document gives guidance on the general background to, and contents of, the R&TTE Directive, which may be of value to regulators, operators, manufacturers, users, and other interested parties. Reference is made to the framework of legal documents implementing the R&TTE Directive, but the present document should not be taken as an interpretation, amplification, or restatement of any other documents.

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# 2 References

The following documents contain provisions which, through reference in this text, constitute provisions of the present document.

- References are either specific (identified by date of publication, edition number, version number, etc.) or non-specific.
- For a specific reference, subsequent revisions do not apply.
- For a non-specific reference, the latest version applies.
- A non-specific reference to an ETS shall also be taken to refer to later versions published as an EN with the same number.

- [1] 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 (Official journal L91/10, 7.4.1999).
- [2] Council Directive 73/23/EEC on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (Official Journal L 77/29, 26.3.1973), as amended by EC Council Directive 93/68/EEC Amending Directives... 73/23/EEC. (Official Journal L 220/1, 30.8.1993).
- [3] Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility (Official Journal L 139/19, 23.5.1989) as last amended by EC Council Directive 93/68/EEC amending Directives... 89/336/EEC. (Official Journal L 220/1, 30.8.1993).
- [4] Directive 98/13/EC of the European Parliament and of the Council relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity (Official Journal, L74/1, 12.3.98) [This Directive consolidated the provisions of EC Council Directive 91/263/EEC on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity (Official Journal L 128/1, 23.5.91), EC Council Directive 93/68/EEC amending Directives... 91/263/EEC. (Official Journal L 220/1, 30.8.1993), and EC Council Directive 93/97/EEC "supplementing Directive 91/263/EEC in respect of satellite earth station equipment" (Official Journal, L 290/1, 24.11.93)]
- [5] TR 101 262: "ETSI Drafting Rules".
- [6] EC Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards" (Official Journal, C 136/1, 4.6.95).
- [7] Directive 98/34/EC (1998) laying down a procedure for the provision of information in the field of technical standards and regulations" (Official Journal L 204/37, 21.7.1998), as amended by Directive 98/48/CE (Official Journal L 217/18, 5.8.1998).

- [8] CENELEC/ETSI Technical Report ROBT-001/ETR 238: "ETSI/CENELEC standardization programme for the development of Harmonized Standards related to Electro-Magnetic Compatibility (EMC) in the field of telecommunications".
- [9] ETR 028 (1994): "Radio Equipment and Systems (RES); Uncertainties in the measurement of mobile radio equipment characteristics".
- [10] EN 60950: "Safety of information technology equipment".
- [11] EG 201 212: "Electrical safety; Classification of interfaces for equipment to be connected to telecommunication networks".
- [12] ENV 50166-2: "Human exposure to electromagnetic fields - High frequency (10 kHz to 300 GHz)".
- [13] ES 59005: "Considerations for the evaluation of human exposure to Electromagnetic Fields (EMFs) from Mobile Telecommunication Equipment (MTE) in the frequency range 30 MHz to 6 GHz".

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## 3 Definitions and abbreviations

### 3.1 Definitions

For the purposes of the present document, terms defined in the R&TTE Directive 1999/5/EC [1] shall have the definitions used in that document. In addition, the following terms and definitions apply:

**"candidate Harmonized Standard"**: draft EN, prior to its adoption by ETSI, produced under a mandate from the European Commission, and comprising only essential requirements as given in article 3 of the R&TTE Directive, and the reference of which is intended to be published in the OJEC to establish a presumption of conformity with the essential requirements of the R&TTE Directive.

NOTE: Because candidate Harmonized Standards include standards for radio equipment, they do not all fall within the category "An EN (telecommunications series) qualified as a Harmonized Standard" as currently used in the ETSI TWP.

**"supplier"**: manufacturer or his authorized representative established in the Community (R&TTE Directive annex II) *or*: the manufacturer or the person responsible for placing the apparatus on the market (R&TTE Directive article 6.3)

**"technical requirement"**: definition of certain characteristics or behaviour, within a Harmonized Standard, conformance with which allows grounds for a presumption of conformity to the relevant part of the R&TTE Directive essential requirements.

### 3.2 Abbreviations

For the purposes of the present document, the following abbreviations apply:

CCF	Control Channel Reception Failure
CCR	Control Channel correctly Received
CENELEC	European Committee for Electrotechnical Standardization
CTR	Common Technical Regulation (under Directive 98/13/EC [4])
EC	European Commission
ECI	Equipment Class Identifier (R&TTE Directive articles 4.1 and 11.1) - see subclause 4.5
EEA	European Economic Area
EIRP	Equivalent Isotropic Radiated Power
EMC	ElectroMagnetic Compatibility
ER	Essential Requirement (as defined in R&TTE Directive article 3)
ERC	European Radio Committee
ERP	Effective Radiated Power
ISM	Industrial Scientific Medical

LVD	Low Voltage Directive (Directive 73/23/EEC [2])
MoU	Memorandum of Understanding
OJEC	Official Journal of the European Communities
R&TTE	Radio Equipment and Telecommunications Terminal Equipment (Directive 1999/5/EC [1])
RE	Radio equipment (as defined in R&TTE Directive article 2(c), subject to general exclusions on the scope of the Directive - see subclause 4.2)
SMF:	System Monitoring Fail.
SMP:	System Monitoring Pass.
TCAM	Telecommunication Conformity Assessment and Market Surveillance committee (R&TTE Directive articles 13, 14, 15)
TTE	Telecommunications Terminal Equipment (as defined in R&TTE Directive article 2(b) subject to general exclusions on the scope of the Directive - see subclause 4.2)
ETSI TWP	ETSI Technical Working Procedures
TxD:	Transmission Disable command.
TxE:	Transmission Enable command.

## 4 General Background

### 4.1 New Approach

The most significant aspect of the R&TTE Directive 1999/5/EC [1] is that it conforms to the EC Council Resolution of 7 May 1985 [6]. This introduces a market-led approach into the Radio and Telecommunications Terminal Equipment sector, and removes the regime of type approvals. Conformity to the essential requirements (ERs) in article 3 of the R&TTE Directive is by supplier's declaration, and may be based on Harmonized Standards, or other means. Essential requirements are substantially reduced compared to the earlier regime.

The Directive contains essential requirements that are to be met. In producing Harmonized Standards for application under the Directive, ETSI shall ensure that the standards do not exceed the degree of regulation envisaged by the Commission (after consultation with TCAM), and shall apply discernment in order not to inhibit technological innovation or the meeting of the needs of a free-market economy.

### 4.2 Scope of the Directive

The R&TTE Directive covers Apparatus within its scope that is either TTE or RE, as defined in its article 2b and 2c, or that is both TTE and RE (for example, cellular phones).

The scope of the R&TTE Directive excludes equipment listed in its annex I (radio amateur kits, certain marine equipment, cabling and wiring, receive-only radio/TV, certain civil aviation equipment, certain air-traffic-management equipment), and equipment used exclusively for activities of the State (article 1.5). It applies only to the communication aspects of certain medical devices (article 1.2) and vehicles (article 1.3). These limitations on the scope of the Directive apply to all TTE or RE.

TTE was previously covered by Directive 98/13/EC [4], although there are differences in the definition of "TTE" between the two Directives (see comment in subclause 4.3).

RE was not previously covered by a specific Directive, although there were provisions on RE included in the EMC Directive 89/336/EEC [3].

For the products within its scope, the R&TTE Directive covers all aspects of placing on the market and putting into service, except for licensing of RE, which remains a national matter. The aspects of safety and EMC covered in other Directive 73/23/EEC [2] are taken over into the R&TTE Directive, although the supplier has the option of using the procedures in these earlier Directives, for equipment which falls within their scope (R&TTE Directive article 10.2), as a means to demonstrate conformity to the requirements of article 3.1a and 3.1b in the R&TTE Directive.

The present document relates to the introduction of the R&TTE Directive. Because of the separate backgrounds in the TTE and RE areas, they are occasionally treated separately in the present document, where this may have an effect on the production of Harmonized Standards.



## 4.3 Implications for Telecommunications Terminal Equipment

The definition of TTE given in the R&TTE Directive Directive 1999/5/EC [1] is "a product enabling communication or 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)". In contrast to the earlier Directive 98/13/EC [4] article 1.2, interworking with the network is not part of the definition for indirectly connected terminals.

Under the R&TTE Directive, TTE will no longer be subject to type approval. Products can be placed on the market under the responsibility of the supplier. The supplier makes a Declaration of Conformity to the essential requirements of the Directive, and shall keep this declaration, together with supportive product technical documentation, as outlined in R&TTE Directive annex II, for at least ten years after the last product of that type has been manufactured.

For TTE which does not use radio transmission, it is not necessary for a Notified Body to be involved in placing the product on the market. However, R&TTE Directive article 10.3 allows suppliers of TTE which does not use radio transmission to voluntarily submit their technical files to a Notified Body for assessment under annex IV, in which case that body's identification number forms part of the CE marking.

Suppliers are responsible for ensuring that each item of TTE produced meets the ERs. If a supplier has an accredited full quality assurance system, R&TTE Directive article 10.3 allows annex V to be used, instead of annex II or IV, at the supplier's choice.

There is no simple relationship between the "new" essential requirements of the R&TTE Directive and the "old" essential requirements applied to TTE under Directive 98/13/EC [4], except for satellite earth stations, for which the essential requirements are effectively the same.

## 4.4 Implications for Radio Equipment

The definition of Radio Equipment (RE) given in the R&TTE Directive, article 2(c), is "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". This definition has no lower limit on the transmitted power.

RE shall be constructed to avoid harmful interference, defined as "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". RE using frequency bands whose use is not harmonized throughout the Community shall be notified to national spectrum management authorities at least four weeks before it is placed on that national market.

For radio transmitters, including TTE which uses radio transmission, essential radio test suites shall be carried out for the product (refer to annex III of the R&TTE Directive). If the test suites are not defined in Harmonized Standards, a Notified Body of the supplier's choice shall be consulted to identify which test suites are essential for the product concerned, and that body's identification number forms part of the CE marking. The supplier's Declaration of Conformity to the ERs shall state that the essential radio transmitter tests have been carried out.

## 4.5 Equipment Classes and ECIs

The definition of Equipment Class given in the R&TTE Directive is "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."

Equipment Class Identifiers (ECIs) are assigned by the Commission after consultation of TCAM (R&TTE Directive, article 4.1). According to R&TTE Directive article 12.1, the CE conformity marking on RE shall be accompanied by the ECI where this has been assigned. The Directive does not preclude that the ECI may be a blank, i.e. no additional marking, for example for RE using harmonized frequencies.

The Commission may also decide that equipment within certain equipment classes or apparatus of particular types shall be so constructed as to meet additional ERs given in article 3.3. Such decisions are made according to TCAM's regulatory procedure (article 15). There is not necessarily any relationship between equipment classes and the need to meet additional essential requirements.

## 4.6 Notified Interfaces

Where a Member State has regulated an interface, which may be a network termination point and/or an air interface specifying a radio path, the regulated interface is notified to the Commission (R&TTE Directive, article 4.1). Under Directive 98/34/EC [7] the Member State is obliged to provide details of its regulation. Although it might be helpful to Member States for this purpose if European standards were available for certain interfaces, such standards would not be published in the OJEC, would not relate to essential requirements under the R&TTE Directive, and hence would not be candidate Harmonized Standards within the meaning of the present document.

## 4.7 Interface specifications

Network Operators will be obliged by their Member States' legislation to publish technical specifications of interfaces before they provide the corresponding services (R&TTE Directive, article 4.2). The information shall be in sufficient detail to allow design of TTE that can attach to the respective interfaces. Although it may be helpful to the operators if European standards were to be produced for certain interfaces, such standards would not be published in the OJEC under the R&TTE Directive, would not relate to essential requirements under the R&TTE Directive, and would not be Harmonized Standards for application under the R&TTE Directive within the meaning of the present document.

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# 5 Role and Purpose of Harmonized Standards

The basic role of ETSI, CENELEC and CEN standards is to provide information to be used on a voluntary basis for equipment design. Such standards should be as comprehensive as necessary to serve this purpose. The present document is not concerned with these standards, but only with Harmonized Standards produced by ETSI for application under the R&TTE Directive (article 5). In principle, these standards relate to equipment when installed and in normal use, and not under fault conditions, or when misused by the customer, deliberately or otherwise.

In accordance with the spirit of the Directive there should be the **minimum** number of Harmonized Standards, each one having the **widest possible product application. One Harmonized Standard will, in general, be applicable to a number of equipments.**

To assist this objective, the present document defines groups of products sharing similar fundamental **attributes**. Thus **Harmonized Standards should be written to address only the fundamental technical parameters** necessary to allow a presumption of conformity to the Essential Requirements of article 3 of the Directive. This has a further consequence that every effort should be undertaken to ensure that the **Harmonized Standard is drafted to be technology independent** in so far as that is possible.

**Further technical parameters should not be included in Harmonized Standards. The present document provides lists of phenomena that should be considered the maximum for each group of equipment attributes. When drafting specific Harmonized Standards, Technical Committees should consider whether requirements (up to the maximum for the attribute) are necessary. A decision tree is also provided to assist this decision process**

## 5.1 Harmonized Standards

### 5.1.1 Need for Harmonized Standards

Alternative solutions for meeting the essential requirements will be allowed under the R&TTE Directive. Harmonized Standards provide for a presumption of conformity to essential requirements when their references are published in the OJEC (see R&TTE Directive article 5.1). In certain circumstances, the Commission may also publish guidelines on the interpretation of Harmonized Standards or the conditions under which compliance with that standard raises a presumption of conformity.

Suppliers can choose to omit some applicable parts of a Harmonized Standard. For the parts omitted, they shall provide descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive. This does not preclude the possibility of a Harmonized Standard having within it alternative technical solutions for meeting an essential requirement. It is recommended that alternative technical solutions should be identified (by letters or numbers or by separation of the Harmonized Standard into parts) within candidate Harmonized Standards, to simplify conformity declaration, licensing and surveillance.

## 5.1.2 Content of Harmonized Standards

Every technical requirement in a candidate Harmonized Standard for application under the R&TTE Directive shall be justified by one or more essential requirements. The standard shall include a Table of Requirements, showing against each clause or sub-clause the corresponding article of the R&TTE Directive that justifies its inclusion.

Every technical requirement shall be expressed so as to be capable of objective verification.

Where compliance with the specification requires the value of a parameter to be assessed, the responsible ETSI technical body writing the Harmonized Standard shall consider whether the value obtained may vary according to the method of measurement employed. In this case the measurement method shall be defined in the minimum detail required to ensure reproducibility of results between different laboratories. This should preferably be by reference to other relevant standards. However it should be made very clear what requirements (or tests) are considered included in the Harmonized Standard. Tests and test methods shall not be identified in themselves as technical requirements.

An indication of the acceptable level of measurement uncertainty shall be given. Harmonized Standards shall be written on the assumption that interpretation of the measurement results is in accordance with the principles contained in annex B of ETR 028 [9].

The standard shall include a table defining the test suite for that standard, namely a list of the clauses containing specifications that shall be verified to allow conformity with the relevant parts of the standard to be claimed.

Harmonized standards for radio transmitting equipment shall include the essential radio test suites referred to in annex III of the R&TTE Directive, in order to make conformity assessment simpler for all parties concerned.

NOTE: The requirements of annex III do not apply to receiving parts of radio equipment (see R&TTE Directive, article 10.4).

## 5.2 Transition to use of Harmonized Standards

The first meetings of TCAM will be held soon after the R&TTE Directive is adopted and enters into force. The CTR regime under Directive 98/13/EC [4] will remain unchanged until the date of its repeal, 12 months later. (This date is currently expected to be March 2000). At this date, Member States will apply the provisions of their national laws transposing the Directive.

Suppliers will need the support of Harmonized Standards in the marketplace as soon as the R&TTE Directive Member State regulations take effect (and will need to know the contents well in advance, to allow for product design cycles).

Standards published under Directive 98/13/EC [4] can continue to be used to give a presumption of conformity against relevant essential requirements of the R&TTE Directive, according to its article 18.1.

Standards whose references have been published under the LVD or the EMC Directive may be used as the basis for presumption of conformity against article 3.1.a) and article 3.1.b) of the R&TTE Directive. Such standards will not be published as Harmonized Standards under the R&TTE Directive and they will consequently not have "the R&TTE Directive Foreword" (see annex B, subclause B.2.1).

NOTE: That the essential requirements of the R&TTE Directive article 3.1.a) appear to be broader than those of the LVD (see subclause 6.2).

## 5.3 Use of other technical bases for conformity

Some suppliers can be expected to use information provided by network operators, or by other technical fora, as the basis for showing conformity to the essential requirements. Such information does not provide a presumption of conformity to the Directive, nor does it obviate the involvement of a Notified Body in defining essential radio tests for the transmitting parts of transmitters and transceivers. Where network operators and terminal suppliers agree on what are appropriate requirements for a particular product/interface combination, the likelihood of challenge from other parties is small.

Documents approved by ETSI at technical level (ES, EG, TS, TR) can be used under the R&TTE Directive, but cannot be notified in the OJEC as Harmonized Standards, and therefore cannot give presumption of conformity.

## 5.4 Types of standards

Basic standards may define methods of testing for technical requirements. Basic standards are not Harmonized Standards, and therefore are not published in the OJEC, as they do not form part of the requirements for a presumption of conformity with the R&TTE Directive. However, they may be normatively referenced within a Harmonized Standard for the purpose of establishing a test method for a specification in that Harmonized Standard.

The Directive gives no grounds for different types of Harmonized Standards. It is further recognized in the present document that Harmonized Standards should always be drafted to be technology independent as far as possible. This is important to ensure the widest applicability to products coming onto the market. Notwithstanding this, there may be a few cases where it is necessary to produce Harmonized Standards containing significant technology dependence.

In all cases the supplier is free to choose the most relevant Harmonized Standard.

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# 6 Formulation of technical requirements

## 6.1 Guiding principles

The present document establishes a methodology to ensure that all ETSI technical bodies have a consistent interpretation of the technical requirements needed to implement the essential requirements of the R&TTE Directive. This methodology is based on the evaluation of applicable technical parameters for specific equipment attributes. The parameters and attributes are shown in annex A.

As a matter of principle, the decision of precisely how to demonstrate compliance with an essential requirement should remain the duty of the applicable technical body. However, it is important that a common set of principles be made available to guide the technical bodies when making decisions on content.

### 6.1.1 Level of Technological Independence

ETSI technical bodies should take note, as a principal goal, that wherever possible, harmonized standards which are technology independent are preferred. The level of technological independence shall remain the responsibility of the appropriate technical body. Means for judgement could be commonalities in equipment attributes and technical parameters as outlined below.

### 6.1.2 Equipment attributes

Equipment attributes have been defined in annex A.

A single equipment can have more than one attribute. The rules for specifying attributes are set out below, and are designed such that, if required, new attributes may be added in the future for as yet unknown applications.

There is not necessarily any fixed relationship between these equipment attributes and the Equipment Classes assigned by the Commission.

The rules for establishing equipment attributes are:

- 1) attributes should not exist to support a particular technology. They are technology independent;
- 2) attributes should not by their nature provoke questions of intellectual property rights in any form;
- 3) attributes are used to categorize fundamental technical differences;
- 4) attributes may exist due to fundamental differences in the circumstances of the *environment* as related to the essential requirements of the R&TTE Directive;
- 5) attributes may exist for the purpose of differentiating operational properties;
- 6) products having the same attribute shall have similar essential requirements in respect of that attribute.

Subject to the above constraints, the objective is to establish a small number of attributes which collectively cover all equipment falling under the R&TTE Directive.

### 6.1.3 Evaluation of parameters

For each essential requirement under the R&TTE Directive, the table in annex A.2 shows the technical phenomena related to particular equipment attributes that may need to be considered by ETSI technical bodies. These phenomena are capable of expression in terms of quantifiable technical parameters.

In applying the present document to producing a specific candidate Harmonized Standard, the responsible ETSI technical body shall use the decision tree below to evaluate which technical parameters shall be included in the standard.

The decision tree is:

- 1) For each phenomenon listed in table A2 for the attributes relevant to the particular standard under consideration, is the phenomenon meaningful in this context? If the phenomenon is meaningful.
- 2) In principle, is it necessary to include the phenomenon in order to meet the relevant essential requirement, or can the requirement be assured without addressing the phenomenon? If the phenomenon is in principle considered essential.
- 3) Are there substantial, documented and well-grounded reasons for this assessment? If so.
- 4) Can the phenomenon be expressed in terms of quantifiable technical parameters? If so.
- 5) For each technical parameter, is it necessary for this parameter to be included in the standard in order for the phenomenon to be adequately controlled, or can some technical parameters be omitted? If the parameter is in principle considered essential.
- 6) Are there substantial, documented, and well-grounded reasons for this assessment? If so.
- 7) Is there any other Community measure which already controls this parameter? If not.
- 8) Is there a need for discernment over the inclusion of a value for this parameter in order not to inhibit technological innovation or the meeting of the needs of a free-market economy (in this context, future needs should also be considered)? If not.
- 9) A value for the parameter shall be determined and included within the standard.

## 6.2 Article 3.1(a): Safety and protection of health

ETSI TC Safety shall be consulted concerning statements to be included in candidate Harmonized Standards regarding the protection of the health and the safety of the user and any other person.

No requirements in this area shall be included in candidate Harmonized Standards except under the advice of the ETSI TC Safety.

There are several product safety standards already available from CENELEC that have been published in the OJEC in connection with the LVD Directive 73/23/EC [2]. Such Harmonized Standards, either before or after the R&TTE Directive is in force, can be used to demonstrate compliance with some or all of the essential requirements of article 3.1(a) of the R&TTE Directive (see article 18).

The voltage limits within the LVD are not applied in the R&TTE Directive. This may require new or amended standards to meet the R&TTE Directive.

The essential requirements for the protection of the health and the safety of the user and any other person under the R&TTE Directive include but are not necessarily limited to the Safety Objectives published in the LVD.

**NOTE:** At the time of writing the present document, clarification of the impact of requirements on protection of health has been requested from the European Commission by ETSI TC Safety.

## 6.3 Article 3.1(b): EMC

ETSI/TC/ERM shall be consulted concerning EMC statements to be included in candidate Harmonized Standards.

The essential requirements for EMC under the R&TTE Directive are the protection requirements published in the EMC Directive 89/336/EEC [3].

There are several product EMC standards already available from ETSI and CENELEC that have been published in the OJEC in connection with the EMC Directive. Harmonized Standards published in the OJEC referencing the EMC Directive either before or after the R&TTE Directive is in force will allow their use under article 3.1(b) of the R&TTE Directive (see article 18).

Resistibility requirements, as defined in the ITU-T K series recommendations, shall not be included in Harmonized Standards under R&TTE Directive as essential requirements.

## 6.4 Article 3.2: "The effective use of the radio spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid "harmful interference"

In general, assumptions are necessary for spectrum management purposes concerning the performance of transmitters, receivers and control functions in the areas of signalling, code domain considerations and frequency resource sharing etc. In the case of article 3.2 the inclusion of technical requirements in Harmonized Standards is limited to only those necessary for the avoidance of '*harmful interference*' (which is a term defined in the Directive). Thus requirements necessary to provide a presumption of conformity to the Directive are a small subset of those used for spectrum management.

It is noted that the parameters that are not included in the Harmonized Standard are available or will be made available to the public in other documents. Technical Bodies writing Harmonized Standards may consider it appropriate to make reference to these non-essential requirements for guidance, but only with a strict clarification that such reference forms no part of the essential requirements and thus it forms no part of the Harmonized Standard for the purposes of conformity assessment.

NOTE: Radio Regulations (RR), definition of Interference:

- Interference is defined as " the effect of unwanted energy due to one or a combination of emissions, radiations, or inductions upon reception in a radio-communications system, manifested by any performance degradation".

### 6.4.1 Co-operation with ERC

ETSI is responsible for the development of standards for radiocommunications systems and equipment. Radio standards contain by their nature several requirements which relate to the efficient use of the spectrum, including compatibility between different radio services.

In order to ensure the planning of an effective use of the radio frequency spectrum, a Memorandum of Understanding has been agreed between ETSI and the European Radio Committee (ERC), for a co-operation in the development of radio technical specifications. (see CENELEC/ETSI Technical Report ROBT-001/ETR 238 [8], annex G).

In the development of Harmonized Standards containing technical specifications for radio equipment, the provisions of the ETSI-ERC MoU will be applied, to the extent that the MoU applies to the particular radio equipment.

ERC Decisions will no longer be the means of ensuring free circulation of radio products within the EEA. This role is taken over by the R&TTE Directive.

ERC Decisions will still be the general means of allocation of spectrum for the radio systems corresponding to the Harmonized Standards.

## 6.4.2 Parameters forming the basis of regulation

Certain types of radio equipment have previously been regulated under Directive 98/13/EC [4]. Article 5(e) of this Directive required that terminal equipment (as defined under Directive 98/13/EC [4]) shall satisfy the essential requirement of "effective use of the radio frequency spectrum, where appropriate". For satellite earth station equipment, this was clarified to include "the effective use of orbital resources and the avoidance of harmful interference between space-based and terrestrial communications systems and other technical systems."

Although the R&TTE Directive article 3.2 has slightly different wording from Directive 98/13/EC [4], the technical specifications elaborating the essential requirements for "effective use of the spectrum so as to avoid harmful interference" will be essentially the same as those under Directive 98/13/EC [4] for equipment falling within the scope of that Directive.

As a matter of principle, the definition of technical specifications to demonstrate compliance with an essential requirement is the duty of the applicable technical body. However, it is important that a common set of principles be made available to guide the technical bodies when making decisions on content. The inclusion of requirements is a sensitive issue and needs careful consideration on a case by case basis by the technical bodies. When requirements are included as essential, the Harmonized Standard shall include a justification derived from the decision tree in subclause 6.1.3 of the present document. Parameters shall only be considered as essential if there is a possibility of harmful interference that is unlikely to be controlled by other means.

In order to give guidance to ETSI, the relevant parts of the table in annex A show:

- 1) Radio system phenomena which might have an influence on the effective use of the spectrum, for certain types of RE. This table gives the MAXIMUM possibilities for consideration. The applicability of individual phenomena will depend on the system concerned, and is to be determined by the relevant technical body.
- 2) Initial classification of radio system types by equipment attributes.
- 3) Possible example of assignment of phenomena as essential for RE with certain attributes. This table shows the possible methodology, and shall not be taken to show the specific applicable essential requirements, which shall be determined by the relevant technical body

## 6.5 Article 3.3: Additional requirements

The "default" situation is that there will be no additional essential requirements under any of the parts of article 3.3, i.e. under:

- article 3.3(a) Interworking and Portability;
- article 3.3(b) Harm to the network or its functioning;
- article 3.3(c) Personal data and privacy;
- article 3.3(d) Avoidance of fraud;
- article 3.3(e) Emergency services access;
- article 3.3(f) Features for disabled users.

If the Commission decides, after consulting TCAM, that there should be requirements under any of these headings, it will identify the class or type of equipment to be covered under the standardization mandate, and the specific features that the standard should cover. Until this occurs, any activity of ETSI under this R&TTE Directive article should be restricted to general technical requirements.

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## 7 Procedure for generation of Harmonized Standards

### 7.1 Identification of a Work Programme

The European Commission has requested ETSI to provide a programme of standardization work it considers necessary to provide Harmonized Standards under the R&TTE Directive. This programme of standardization work will provide the basis for a standardization mandate.

### 7.2 Standardization mandate

ENs cannot be quoted in the OJEC as Harmonized Standards unless they have been developed under an EC standardization mandate. Mandates under the R&TTE Directive are proposed by the Commission, after consultation with TCAM, and approved by the Committee established under the terms of Directive 98/34/EC [7] before being presented to ETSI.

Where a standardization mandate exists and has been accepted by ETSI, a situation may occur where ETSI technical bodies consider that there is a need for a Harmonized Standard that is not covered by the mandate.

In such a situation, ETSI should adopt a work item under the ETSI TWP. The ETSI Secretariat will present the work item to TCAM with a justification covering why the Harmonized Standard is required. If regarded as justified, the EC DG XIII may decide to modify the mandate. Modifications to the mandate require approval by the Committee established under the terms of Directive 98/34/EC [7].

### 7.3 Adoption of candidate Harmonized Standards

Candidate Harmonized Standards are adopted according to specific procedures under the ETSI TWP.

Before a candidate Harmonized Standard is submitted to the voting procedure, the standard shall be finally examined to ascertain that the conditions imposed by the R&TTE Directive, the conditions of the standardization mandate, and the conditions stemming from the present document are met.

NOTE: ETSI may establish procedures to ensure that this is always the case. The details of this process are under discussion.

### 7.4 Submission to EC and Publication in the OJEC

Once adopted by ETSI, Harmonized Standards developed under R&TTE Directive mandate are presented to the Commission by the ETSI Secretariat. It is agreed between the Commission and ETSI that the presentation shall be accompanied by the translation of the *title* of the document into the official languages of the EU (currently Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish) In order that ETSI can fulfil its commitment, the ETSI Technical Body shall provide assistance, to the best of its ability, in the translation of titles to the ETSI Secretariat before the Standard is submitted to the Vote or the One-step Approval Procedure.

***The Commission will decide whether or not the Harmonized Standard is acceptable in whole or in part as suitable for establishing a presumption of conformity against the relevant essential requirements.***

NOTE: EFTA require titles in Norwegian and Icelandic if they are to be referenced in the EFTA Official Journal.

As for other ENs, Harmonized Standards developed under R&TTE Directive mandate shall be transposed by the National Standards Organizations. The relevant ETSI technical body shall advise the ETSI Secretariat of any reasons that might justify the use of other than the default transposition periods given in the ETSI TWP.



## 7.5 Revision of Harmonized Standards

Revisions of Harmonized Standards developed under R&TTE Directive mandate do not require a specific modification to the standardization mandate. However, publication of the revised standard in the OJEC is necessary to amend the requirements which give a presumption of conformity with the R&TTE Directive.

If an ETSI technical body considers that technical modifications to a Harmonized Standard are required, it should raise a work item according to the ETSI TWP. The ETSI Secretariat will present the work item to TCAM with a justification covering why the revision of the Harmonized Standard is required. The EC may decide not to cite the revision in the OJEC.

Adoption and submission of revised candidate Harmonized Standards are as specified in subclauses 7.3 and 7.4 above.

## 7.6 Withdrawal of Harmonized Standards

After consultation of TCAM, the Commission may withdraw the OJEC reference to Harmonized Standards by publication of a notice to that effect in the OJEC. Presumption of conformity through that Harmonized Standard will then cease.

If, following the Commission's action, the relevant ETSI technical body considers that the Harmonized Standard should be withdrawn, the standard shall follow the withdrawal procedures of the ETSI TWP. The ETSI Secretariat shall ensure that the standard is archived so as to remain available if requested, including traceability that the standard had been published in the OJEC, with the relevant dates of publication and withdrawal.

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# Annex A (informative): Evaluation of technical parameters according to essential requirements applicable to equipment attributes

## A.1 Equipment Attributes

Rules for establishing equipment attributes are given in subclause 6.1.2. A single equipment can have more than one attribute. Currently the following attributes are defined:

- a) RE that is unable to transmit before receiving an appropriate enabling signal under any circumstances;
- b) RE that is able to transmit without receiving an appropriate enabling signal;
- c) RE capable of receive only;
- d) apparatus intended for use in 'Emergency applications';
- e) short range radio transmitting devices;
- f) RE intended for installation in sites which may be shared with other RE without co-ordination from a single operator;
- g) RE sharing radio spectrum resources with or without operational co-ordination;
- h) TTE using an electrical interface for communication;
- i) TTE using an optical interface for communication.

The attributes are explained as follows.

### **Attribute A**

Equipment having this attribute is unable to transmit prior to receiving an enabling signal from some other equipment which co-ordinates activity in the system. This service may or may not operate on shared spectrum resource. It is believed that this attribute applies to products such as GSM mobiles, trunked radios, satellite earth stations and two-way pagers etc.

The reasoning for differentiation of this attribute is that the nature of the equipment implies the operation will be under the control of other apparatus and operating in a defined system.

### **Attribute B**

Equipment having this attribute has the potential for uncontrolled interference to other users.

Examples of such equipment are some transportable relay station devices, simple PMR equipment, Radars, and most commercially-available amateur radio equipment, including high-power transmitters.

### **Attribute C**

Equipment having this attribute cannot easily interfere with other users. This justifies the differentiation of this attribute.

Single-way pagers and Short-range receivers are examples of equipment with this attribute.

### **Attribute D**

Equipment having this attribute requires a high assurance of performance when operating. Thus it is reasonable to suppose that such equipment may need to comply with additional requirements. ***Equipment having this attribute will always have at least one other attribute.***

### **Attribute E**

Equipment having this attribute is generally accepted to be differentiated from other equipment. Short-range transmitting devices are defined in ERC Recommendation 70-03, which broadly defines this attribute. However it is noted that this ERC Recommendation also includes some devices with a power output of up to 500 mW ERP which is clearly not necessarily very short range. Much of the longer-range equipment operates on ISM frequencies.

### **Attribute F**

For equipment having this attribute there is a possibility of further phenomena acting. The justification for differentiation of this attribute is principally because the equipment is stationary and thus if any problems do arise the assumption shall be that the problem is permanent. Secondly, transmitters in close proximity should be designed to limit the transmitter intermodulation issues. Other receiver effects may become more important but the traditional solutions of antenna filters, circulators etc may be used. These are separate units and thus should not be included. Thus no change to the existing situation is proposed.

Such sites may have only one antenna that has to be shared via combining networks.

Examples of such equipment are base stations of any type, broadcast transmitters (broadcast receivers are not covered by the Directive), fixed link stations and pager stations.

*Equipment having this attribute will always have at least one other attribute.*

### **Attribute G**

Equipment having this attribute needs differentiation to allow for the difference caused by equipment such as the above (attribute F) being set to operate in shared spectrum without co-ordination. Moreover, Fixed Service systems need this attribute differentiation for coexistence with similar systems deployed in the same geographical area and using the same frequency band.

### **Attribute H**

Equipment having this attribute may or may not have other attributes concerning radio equipment. This attribute is differentiated from attribute I because it is anticipated that there may be different essential requirements for equipment with electrical or optical interfaces. Attribute H includes all equipment with electrical interfaces because it is accepted that all such equipments will have similar essential requirements under the R&TTE Directive.

There are many such equipment types so it is not necessary to provide examples.

### **Attribute I**

Equipment having this attribute may or may not have other attributes concerning radio equipment. This attribute is differentiated from attribute H because it is anticipated that there may be different essential requirements for equipment with electrical or optical interfaces. Attribute I includes all equipment with optical interfaces because it is accepted that all such equipments will have similar essential requirements under the R&TTE Directive.

## A.2 Technical Phenomena

The table that follows provides the phenomena associated with specific essential requirements that may need to be considered by ETSI technical bodies. The list of phenomena is the **MAXIMUM** for consideration, and each parameter marked 'Yes' shall be evaluated according to the methodology of subclause 6.1 of the present document.

**Table A.1**

Essential Requirement	Phenomena	Equipment Attributes								
		A	B	C	D	E	F	G	H	I
3.1 (a)	Requirements regarding the protection of the health and safety of the user and any other person are described in subclause 6.2.									
3.1 (b)	Requirements for EMC are identified in ETR 238 [8] and in the published EMC Harmonized Standards									
NOTE: ETR 238 [8] may need revision to take account of the new circumstances under the R&TTE Directive.										

Table A.2

Essential Requirement	Phenomena	Equipment Attributes								
		A	B	C	D	E	F	G	H	I
3.2 (Transmitting)	Frequency error / stability, and designation of channels	Yes	Yes			Yes		Yes		
	Transmitter power	Yes	Yes			Yes		Yes		
	Adjacent channel power	Yes	Yes			Yes		Yes		
	Spurious emissions	Yes	Yes			Yes		Yes		
	Inter-modulation attenuation						Yes			
	Release time	Yes						Yes		
	Transient behaviour of the transmitter	Yes	Yes					Yes		
	Modulation Accuracy	Yes	Yes			Yes		Yes		
	Duty cycle					Yes		Yes		
3.2 (Directional)	Off-axis EIRP density	Yes	Yes					Yes		
	Antenna gain	Yes	Yes					Yes		
	Antenna X-polar discrimination	Yes	Yes					Yes		
	Antenna pointing accuracy/control	Yes	Yes					Yes		
3.2 (Receiving)	(Maximum usable) sensitivity (inc. duplex)				Yes					
	Co-channel rejection				Yes					
	Adjacent channel selectivity	Yes	Yes	Yes		Yes		Yes		
	Spurious response rejection (inc. duplex)	Yes	Yes	Yes		Yes		Yes		
	Inter-modulation response rejection	Yes	Yes	Yes		Yes	Yes	Yes		
	Blocking or desensitization (inc. duplex)	Yes	Yes	Yes		Yes		Yes		
	Spurious emissions	Yes	Yes	Yes		Yes		Yes		
	Multipath sensitivity				Yes					
3.2 (TDM: CDM: Control and Monitoring Functions for Terminal)	Enabling Signalling	Yes								
	Sharing Protocols	Yes	Yes					Yes		
	Network interface bit errors	Yes								
	Error control by coding and decoding of logical channels	Yes								
	Logical channel arrangement	Yes								
	Control of communication in logical channels	Yes								
	Correct interpretation of Network control information	Yes								
	Network interface addressing	Yes								
	Control of basic link communication	Yes								
	Control of random access	Yes								
	Control of radio resource allocation	Yes								
	Monitoring functions for cell selection	Yes								
	Control functions for usage of cells	Yes								
	Control of group attach/detach	Yes								
	Tx enable/disable control	Yes								
	Tx Call set up control	Yes								
	Control of call maintenance	Yes								
	Control of call disconnect	Yes								
Authentication control	Yes									
Encryption control procedures	Yes									

Table A.3

Essential Requirement	Phenomena	Equipment Attributes								
		A	B	C	D	E	F	G	H	I
3.3	Currently there are no essential requirements defined under article 3.3 (see subclause 6.5). It is noted that the technical nature of the requirements may be different from requirements related to articles 3.1 & 3.2.									

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## Annex B (informative): Necessary changes to TR 101 262 in relation to production and content of Harmonized Standards for application under the R&TTE Directive

### B.1 General directions

The elements necessary for the drafting of a candidate Harmonized Standard are briefly summarized below:

- a) The standard shall be an EN (produced in accordance with the ETSI Drafting Rules (TR 101 262 [5])).
- b) The standard shall be approved by a Two-step Approval Procedure (ETSI TWP 2.2.2, under review for maintenance purposes).
- c) The standard shall be identified as a candidate Harmonized Standard, the reference of which is intended to be published in the Official Journal of the European Communities referencing the relevant Directive. This identification shall be made in the Foreword at Public Enquiry and Vote stage and when the standard is published by ETSI.
- d) The candidate Harmonized Standard shall have appropriate transposition periods specified. A Harmonized Standard confers presumption of conformity when it has been published in the Official Journal of the European Communities and transposed by a member state. The Official Journal citation gives the date of cessation of presumption of conformity of a previous standard. This is usually taken to be the date of withdrawal (dow) supplied by the standardization body.
- e) The candidate Harmonized Standard shall include all technical specifications necessary for demonstrating presumption of conformity of the products and phenomena within its scope. Products may have more than one attribute. Harmonized Standards under both attributes may be applicable.
- f) Methods of measurement may be included in the Harmonized Standard, or may be normatively referenced in the text.
- g) The standard shall contain a normative annex identifying the technical specifications with the essential requirements of the relevant Directive.

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### B.2 Text for foreword and normative annexes

In order to simplify the production of Harmonized Standards, the ETSI Secretariat has developed text for the required statements in the Foreword and normative annexes. An example of these statements are given here for information:

#### B.2.1 Foreword

"The present document has been produced by ETSI in response to a mandate from the European Commission issued under Council Directive 98/34/EC [7] laying down a procedure for the provision of information in the field of technical standards and regulations.

The present document is intended to become a Harmonized Standard, the reference of which may be published in the Official Journal of the European Communities referencing the Directive 99/.. /EC of the European Parliament and of the Council on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity ("the R&TTE Directive")."

## B.2.2 Requirements Table

The following format shall be used for this normative annex:

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**Annex <A> (normative):**  
**Subclauses of the present document relevant for compliance with the essential requirements of the R&TTE Directive**

**Table <A>.1: Subclauses of the present document relevant for compliance with the essential requirements of the R&TTE Directive**

Clause/sub-clause number and title	Corresponding article of the R&TTE Directive	Qualifying remarks

## B.2.3 Other

NOTE: Because candidate Harmonized Standards include standards for radio equipment, they do not all fall within the category "An EN (telecommunications series) qualified as a Harmonized Standard" as currently used in the ETSI TWP. This definition shall be revised.



## Annex C (informative): Alternative formulations

### C.1 Alternative formulation of requirements under article 3.2

The following alternative formulation has been proposed and may be most valuable in relation to new systems.

**Table C.1: Tests required for radio equipment to support the essential requirements  
of the R&TTE Directive**

Phenomena to test / for the state of TX	Start	Cont.	Change	Change	Stop	Justification 3.2
	TX	TX	Power	Freq.	TX	Interference
Allowed/requested to TX	X	X	X	X		X
Allowed/requested to change Power			X			X
Allowed/requested to change Frequency				X		X
Allowed/requested to stop TX				X	X	X
Inform about actions	X	X	X	X	X	X
Start TX within required time	X			X		
Stop TX within required time				X	X	X
Start at the assigned Frequency	X			X		X
Start at the assigned Power	X		X			X
Change Power within required time			X			X
Transient Frequency behaviour	X			X	X	X
Transient Power behaviour	X		X	X	X	X
Modulation accuracy		X				
Transmitter Mask		X				X
NOTE 1: Cont. TX covers continuous state of any transmitter also the conversation mode of a TDM or TDD techniques.						
NOTE 2: All requirements shall be assessed at the transmitter output. Necessary stimuli shall be applied at the network interface and/or the Man Machine Interface.						
NOTE 3: The tests to evaluate a specific phenomenon and the phenomena are selected by the product group as appropriate for the technology.						
NOTE 4: Where access to the Emergency Services is a requirement; additionally the ability to understand the message (data or voice) is required, end to end in both directions.						

### C.2 Second alternative formulation of requirements for Attribute "A"

#### C.2.1 Control and monitoring functions (CMFs) of a Terminal

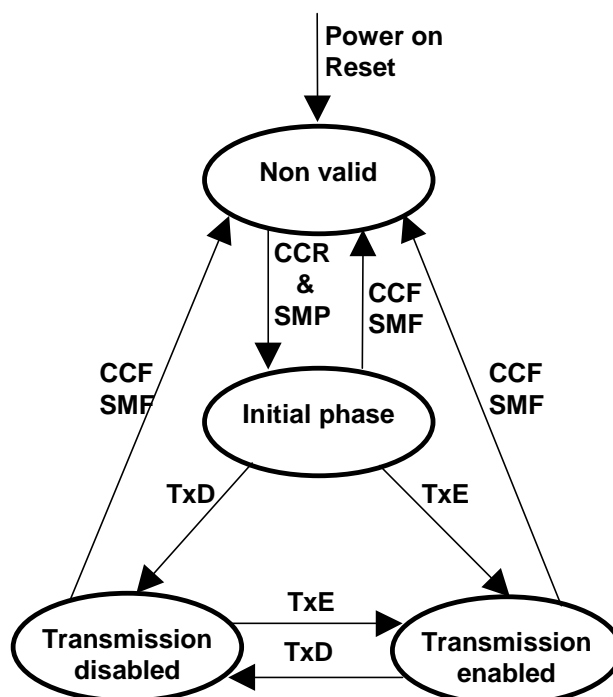
The following minimum set of Control and Monitoring Functions shall be implemented in a Terminal in order to minimize the probability that they originate unwanted transmissions that may give rise to harmful interference to other systems.

For the purpose of the present document the states of the Terminal are:

- 'non valid';
- 'initial phase';
- 'transmission disabled'; and
- 'transmission enabled'.

In the 'Non-valid' state and in the 'Transmission disable' state the Terminal shall not transmit. In the 'Transmission-enabled' state the Terminal is allowed to transmit. In the 'Initial phase' state the Terminal is only allowed to transmit initial bursts.

Under any fault condition when the Terminal transmissions are being suppressed the Harmful Interference shall not exceed the limits for the 'Transmission disabled' state specified.



**Figure C.1: State transition diagram of the control and monitoring function of a Terminal**

When the Terminal transmits several carriers having different frequencies, a Terminal state machine as described above may be associated with each carrier or each set of carriers. The events then apply to the subsystem associated with the specific carrier or the specific set of carriers, rather than the whole Terminal.

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## Annex D (informative): Template for a Harmonized Standard

It is proposed that the document should contain a template

**It is recommended that the template for a Harmonized Standard contain the following:**

The present document does not contain requirements for the protection of the health and safety of users and other persons.

NOTE: Relevant documents covering health and safety matters are produced by standards organizations, or other bodies (e.g. the World Health Organization), some examples are:

- EN 60950 [10]: the present document contains requirements for information and communications technology equipment;
- EG 201 212 [11]: the present document describes how to categorize electrical interfaces in terms of the safety characteristics specified in EN 60950 [10];
- ENV 50166-2 [12]: this provides information relating to human exposure to electromagnetic fields in the frequency range 10 kHz to 300 GHz;
- ES 59005 [13]: this specifies requirements relating to the evaluation of human exposure to electromagnetic fields from Mobile Telecommunications Equipment in the frequency range 30 MHz to 6 GHz.

The above examples contained within the "Notes" section should be selected so as to be applicable to the equipment covered by the candidate Harmonized Standard: if they are not applicable they should not be included. Additional requirements, notes and other referenced standards are not to be included without the agreement of ETSI TC Safety.

The full titles of the (undated) referenced standards in the note shall be included in the bibliography of the candidate Harmonized Standard.

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## History

<b>Document history</b>				
V1.1.1	November 1999	Membership Approval Procedure	MV 9953:	1999-11-02 to 1999-12-31