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Standards Institute**

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A guide to the production of Harmonized standards for Application under the RE&TTE Directive

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Provide sufficient information to enable a consistent interpretation of the R&TTE Directive within ETSI for the drafting of Harmonised Standards. Provide guidance that is compatible for fixed and mobile equipment, whether using radio or not. Supporting ETSI members: DTI, Nortel, Itatel, Alcatel and RegTp.

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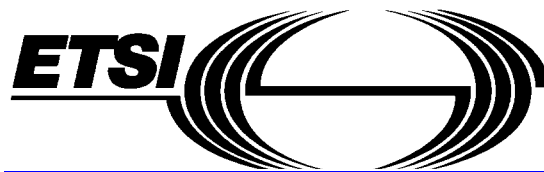
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Pursuant to the ETSI IPR policy, no investigation, including IPR searches, has been carried out by ETSI. No guarantee can be given as to the existence of other IPRs not referenced in SR 000 314 (or the updates on the ETSI Web server) which are, or may be, or may become, essential to the present document.

Foreword

This ETSI Guide (EG) has been produced by ETSI OCG TG6. Copies shall be provided to the ERC for their consideration, and to the European Commission for their legal scrutiny. This Guide is to be submitted for the ETSI Standards Membership Approval Procedure (MAP).

Introduction

This version of this ETSI Guide is based on and reflects the final text of the R&TTED [1].

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

This ETSI Guide 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 this ETSI Guide 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 this ETSI Guide is not final. It is expected that changes will need to be made to reflect comments received from bodies external to ETSI, and to keep the guidance to ETSI in line with the deliberations of TCAM.

1 Scope

This ETSI Guide has been prepared to assist ETSI committees in the preparation of candidate Harmonized Standards for application under the Radio Equipment and Telecommunications Terminal Equipment Directive (R&TTED). This ETSI Guide is not applicable to documents produced by other standards bodies (ie. CEN and CENELEC) even if some of the standards they produce have application under the R&TTED.

As part of its objective, this ETSI Guide gives guidance on the general background to, and contents of, the R&TTED, 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&TTED, but this ETSI Guide should not be taken as an interpretation, amplification, or restatement of any other documents.

2 References

The following documents contain provisions referenced in this text.

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, subsequent revisions do apply.
- 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] Final text of 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 (97/0149(COD), Brussels, 13 January 1999)
- [2] EC Council Directive 73/23/EEC "On the harmonisation of the laws of the 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] EC Council 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 of 12 February 1998 "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 harmonisation and standards" (Official Journal, C 136/1, 4.6.95)
- [7] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 "laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services" (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, "CENELEC/ETSI standardisation programme for the development of Harmonized Standards related to Electro-Magnetic Compatibility (EMC) in the field of telecommunications"
- [9] ETR 028: "Radio Equipment and Systems (RES); Uncertainties in the measurement of mobile radio equipment characteristics"

3 Definitions, and abbreviations

3.1 Definitions

In this EG, terms defined in the R&TTED [1] shall have the definitions used in that document. In addition, the following definitions apply:

Candidate Harmonized Standard: an EN produced, or to be produced, by ETSI, under a mandate from the European Commission, comprising only essential requirements as given in Article 3 of the R&TTED, 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&TTED.

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: the manufacturer or his authorised representative established in the Community (R&TTED Annex II) *or*: the manufacturer or the person responsible for placing the apparatus on the market (R&TTED Article 6.3)

Technical Requirement: A 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

In this EG, the following abbreviations apply:

ACTE	Approvals Committee for Terminal Equipment (under Directive 98/13/EC [4])
CENELEC	European Committee for Electrotechnical Standardisation
CTR	Common Technical Regulation (under Directive 98/13/EC [4])
EC	European Commission
ECI	Equipment Class Identifier (R&TTED Articles 4.1 and 11.1) - see section 4.5
EEA	European Economic Area
EIRP	
EMC	ElectroMagnetic Compatibility
ER	Essential Requirement (as defined in R&TTED Article 3)
ERC	European Radio Committee
ERP	
ISM	
LVD	Low Voltage Directive [2]
MoU	Memorandum of Understanding
OJEC	Official Journal of the European Communities
R&TTED	the Radio Equipment and Telecommunications Terminal Equipment Directive [1]
RE	Radio equipment (as defined in R&TTED Article 2(c), subject to general exclusions on the scope of the Directive - see section 4.2)
TCAM	Telecommunication Conformity Assessment and Market Surveillance committee (R&TTED Articles 13, 14, 15)
TTE	Telecommunications Terminal Equipment (as defined in R&TTED Article 2(b) subject to general exclusions on the scope of the Directive - see section 4.2)
TWP	ETSI Technical Working Procedures

4 General Background

4.1 New Approach

The most significant aspect of the R&TTE Directive[1] is that it conforms to the "New Approach to technical harmonisation" [6]. This introduces a market-led approach into the Telecommunications Terminal Equipment (TTE)

sector, and removes the regime of type approvals. Conformity to the essential requirements (ERs) in Article 3 of the R&TTED 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. For Radio Equipment (RE), the new arrangements are similar to TTE as far as receivers are concerned, but an element of *a priori* notification is introduced for transmitters and transceivers.

The Directive contains essential requirements that are to be met. ETSI must apply the Community principle of proportionality (Article 3b of the Treaty and cited also in recitals 2, 12 etc. of the Directive) that specifically limits the inclusion of requirements in Harmonized Standards to those that will not be met by other means such as market forces.

4.2 Scope of the Directive

The R&TTED 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&TTED 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 section 4.3).

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

For the products within its scope, the R&TTE Directive covers all aspects of placing on the market and taking into use, except for licensing of RE, which remains a national matter. The aspects of safety and EMC covered in other Directives [2, 3] 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&TTED Article 9.2), as a means to demonstrate conformity to the requirements of article 3.1a and 3.1b in the R&TTED.

This ETSI Guide 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 this document, where this may have an effect on the production of Harmonized Standards.

4.3 Implications for TTE

The definition of TTE given in the R&TTED[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 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&TTED 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&TTED Article 9.3 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&TTED Article 9.3 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&TTED and the "old" essential requirements applied to TTE under Directive 98/13/EC, except for satellite earth stations, for which the **essential requirements** are effectively the same.

4.4 Implications for RE

The definition of Radio Equipment (RE) given in the R&TTED, Article 2(c), is "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". 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&TTED 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&TTED, Article 4.1). According to R&TTED Article 11.1, 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, ie. 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 14). 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&TTED, 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&TTED, and hence would not be candidate Harmonized Standards within the meaning of this Guide.

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&TTED, 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&TTED, and would not be Harmonized Standards for application under the R&TTED within the meaning of this Guide.

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. This ETSI Guide is not concerned with these standards, but only with Harmonized Standards produced by ETSI for application under the R&TTED (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 it is required that ETSI produce 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, this guide defines groups of products sharing similar fundamental **attributes**. Thus **Harmonized Standards should be written to address only the fundamental 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 parameters should not be included in Harmonized Standards. This guide 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 group) 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&TTED. Harmonized Standards provide a presumption of conformity to essential requirements when their references are published in the OJEC (see R&TTED 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&TTED 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&TTED that justifies its inclusion.

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

If 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 ETR028[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&TTED, 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.

5.2 Transition to use of Harmonized Standards

The first meetings of TCAM will be held soon after the R&TTED is adopted and enters into force. The CTR regime under Directive 98/13/EC 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&TTED **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 can continue to be used to give a presumption of conformity against relevant essential requirements of the R&TTED, 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&TTED. Such standards will not be published as Harmonized Standards under the R&TTED and they will consequently not have “the R&TTED Foreword” (see annex B.2.1). Note, however, that the essential requirements of the R&TTED article 3.1.a) appear to be broader than those of the LVD (see 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&TTED, 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&TTED. 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 recognised in this guide 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 isolated cases where it is necessary to produce Harmonized Standards containing significant technology dependence.

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

6 Formulation of technical requirements

6.1 Guiding principles

This Guide 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&TTED. 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 categorise 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&TTED.
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&TTED. A single attribute may result in candidate Harmonized Standards at different levels of technological independence, where appropriate.

6.1.3 Evaluation of parameters

For each essential requirement under the R&TTED, Annex A shows the technical parameters which may apply for particular equipment attributes.

In applying this Guide to producing a specific candidate Harmonized Standard, the responsible ETSI body shall use the decision tree below which is based on the principle of proportionality (see 4.1) to evaluate whether or not the parameter should be included.

The decision tree is:

1. What is the meaning of the technical parameter for the particular attribute and candidate Harmonized Standard under consideration? If the parameter is meaningful,
2. Does the parameter in principle fall under the scope of the essential requirement as identified in the table in Annex A? If so,
3. Are there substantial, documented and well-grounded reasons why this technical parameter is significant? If yes,
4. Is it appropriate to include the parameter in the Harmonized Standard, or is it taken care of by existing market forces governing the marketplace? If considered appropriate,
5. Are there substantial, documented and well-grounded reasons for this assessment? If yes,
6. Is the parameter subject to other Community provisions, eg. horizontal or telecommunications *acquis communautaire*? If not,
7. Do the benefits of including the parameter in the standard outweigh any possible negative influence on the market? If yes,
8. A decision shall be taken to identify and include within the standard the particular technical specifications corresponding to the parameter under consideration.

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

ETSI TC **Telecommunications Equipment Safety** shall be consulted concerning safety statements to be included in candidate Harmonized Standards.

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

There are several product safety standards already available from CENELEC that have been published in the OJEC in connection with the LVD [2]. Such Harmonized Standards, either before or after the R&TTED 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&TTED (see Article 18).

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

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

~~[Conformity to the essential requirement of article 3.1a) may be assessed either using the procedures of the LVD for equipment within its scope, or the procedures of the R&TTED, at the supplier's choice.]~~

NOTE: At the time of writing this Guide, clarification of the impact of requirements on protection of health has been requested from the European Commission by ETSI TC Telecommunications Equipment 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&TTED are the protection requirements published in the EMC Directive [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&TTED is in force will allow their use under Article 3.1(b) of the R&TTED (see Article 18).

Conformity to the essential requirement of article 3.1b) may be assessed either using the procedures of the EMC Directive for equipment within its scope, or the procedures of the R&TTED, at the supplier's choice.

Resistibility requirements, ~~[as defined in the ITU-T K-series recommendations,]~~ shall not be included in Harmonized Standards under R&TTED 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 certain technical specifications. (see ref [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&TTED. ~~[However, where ERC Decisions based on a Harmonized Standard are still used for free circulation in other CEPT countries, the ERC Decision for recognition of type approval may be attached to the Harmonized Standard as an Annex.]~~

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) 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&TTED Article 3.2 has slightly different wording from Directive 98/13/EC, 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 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 clause 6.1.2 of this EG. Parameters shall only be considered as essential if there is a real possibility of harmful interference that is unlikely to be controlled by other means (i.e. market forces, operator specifications, etc).

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 standardisation mandate, and the specific features

that the standard should cover. Until this occurs, any activity of ETSI under this R&TTED Article should be restricted to general technical requirements.

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 standardisation work it considers necessary to provide candidate Harmonized Standards under the R&TTED. This programme of standardisation work will provide the basis for a standardisation mandate.

7.2 Standardisation mandate

ENs cannot be quoted in the OJEC as Harmonized Standards unless they have been developed under an EC standardisation mandate. Mandates under the R&TTED 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 standardisation mandate exists and has been accepted by ETSI, a situation may occur where ETSI technical bodies consider that there is a need for a candidate 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 Technical Working Procedures (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 standardisation mandate, and the conditions stemming from this Guide 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, candidate Harmonized Standards 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, candidate Harmonized Standards shall be transposed by the National Standards Organisations. 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 TWP.

7.5 Revision of candidate Harmonized Standards

Revisions of candidate Harmonized Standards do not require a specific modification to the standardisation 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&TTED.

If an ETSI technical body considers that technical modifications to a Harmonized Standard are required, it should raise a work item according to the 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 7.3 and 7.4 above.

7.6 Withdrawal of Harmonized Standards

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

If the relevant ETSI technical body considers that the candidate Harmonized Standard should be withdrawn, the standard shall follow the withdrawal procedures of the 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.

Annex A: Evaluation of technical parameters according to essential requirements applicable to equipment attributes

A.1 Equipment Attributes

Rules for establishing equipment attributes are given in section 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. ~~[Thus the risk of interference to other users is very much reduced.]~~

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 500mW 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.

[Spectrum sharing has two main consequences:

1. ~~Uncontrolled transmissions may directly interfere with other users unconnected with the organisation~~
2. ~~Excessive occupancy by one user may disadvantage another (duty cycle)]~~

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&TTED.

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&TTED.

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 section 6.1 of this Guide.

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 6.2										
3.1 (b)	Requirements for EMC are identified in ETR 238 [8] and in the published EMC Harmonized Standards										

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			
	Duty cycle	Yes	Yes			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 desensitisation (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						

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 section 6.5). It is noted that the technical nature of the requirements may be different from requirements related to Articles 3.1 & 3.2.									

Annex B:

Necessary changes to TR 101 262 in relation to production and content of Harmonized Standards for application under the R&TTED

B.1 General directions

The elements necessary for the drafting of a Candidate Harmonized Standard are briefly summarised below:

- a) the standard shall be an EN (produced in accordance with the ETSI Drafting Rules[5]).
- b) the standard shall be approved by a Two-step Approval Procedure (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 standardisation 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.
- h) where a radio equipment is also subject to an ERC Decision relating to national type approval regulations in CEPT countries outside the EEA, that ERC Decision may be reproduced as an annex to the Harmonized Standard.

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 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:

**Annex <A> (normative):
Sub-clauses of this EN relevant for compliance with the
essential requirements of the R&TTE Directive**

**Table <A>.1: Sub-clauses of this EN 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:

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.					

2 Second alternative formulation of requirements for Attribute "A"

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 minimise 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.

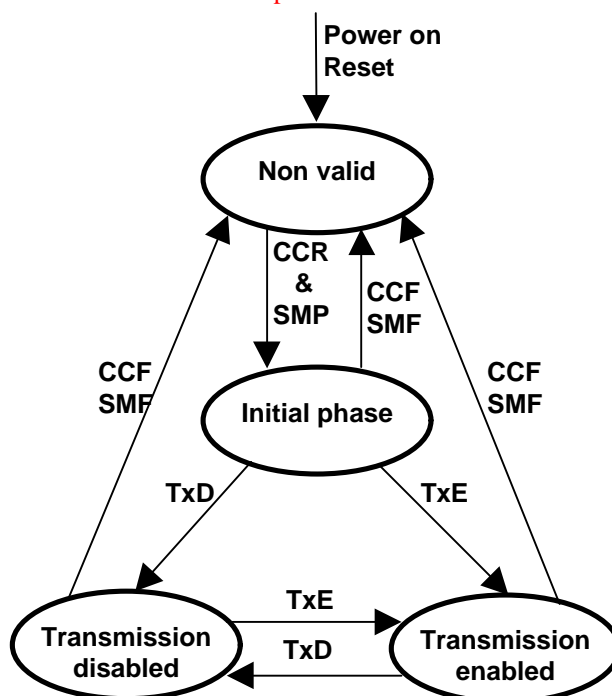


Figure 1: State transition diagram of the control and monitoring function of a Terminal

SMP: System Monitoring Pass
SMF: System Monitoring Fail

TxE: Transmission Enable command
TxD: Transmission Disable command

CCR: Control Channel correctly Received
CCF: Control Channel Reception Failure

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.

Annex D: Text of the R&TTE Directive

[If reproduction of the Directive is permitted by the Commission, the text will be included here in full, for the benefit of users of this Guide.]

Annex E: Template for a Harmonized Standard

It is proposed that the Guide should contain a template

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

This EN does not contain requirements for the protection of the health and safety of users and other persons.

Notes:

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

1. CENELEC EN 60950: this standard contains requirements for information and communications technology equipment.
2. ETSI EG 201 212: this guide describes how to categorise electrical interfaces in terms of the safety characteristics specified in EN 60950.
3. CENELEC ENV 50166-2: this provides information relating to human exposure to electromagnetic fields in the frequency range 10 kHz to 300 GHz.
4. CENELEC ES 59005: 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 Harmonised Standard: if they are not applicable they should not be included. Additional requirements, notes and other referenced standards shall not be included without the agreement of ETSI TC Telecommunications Equipment Safety.

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

History

Document history		
Draft A	1998-09	For discussion at meeting on 2 October 1998
Draft B	1998-10	For discussion at TG6 meeting on 4 November 1998
Draft C	1998-11	Revised following Guidelines meeting on 5/6 November 1998
Draft D	1999-01	Revised following Guidelines meeting 5/6 January 1999 & TG6 6/7 January 1999
Draft E	1999-03	Revised following Guidelines meeting 25/26 February 1999
