

**Electromagnetic compatibility
and Radio spectrum Matters (ERM);
A guide to the production of Harmonized Standards
for application under the R&TTE Directive**

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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.

The present version of the document (i.e. version 2.2.1) is a development of the previous version, in particular it has been brought up to date following recent events in TCAM, RSCoM and in the OCG R&TTE Working Group of ETSI.

Some of the major developments appearing in version 2.2.1 with respect to version 2.1.1 are:

- the modification of the environmental profile to allow for the special case for the marine environment;
- the modification of the text of clause A.3 to correspond with the TCAM guidance and decision on antennas;
- the addition of guidance on the structure of clauses i.e. applicability, method of measurement, limit;
- enhanced guidance on definitions to be used in Harmonized Standards;
- replacement of a number of deliverables due to the production of EG 201 730 [i.13] to [i.16] and withdrawal of TR 101 845 [i.34];
- precision of the text in clause C.7 on "interface specifications" in order to align it with clause 4.2 of the R&TTE Directive [i.26].

During the revision, have also been:

- introduced changes consequential to the withdrawal of SR 001 470 [i.35] containing the pro-forma for the production of Harmonized Standards and replacement by the Harmonized Standard skeleton document [i.22];
- introduced changes consequential to the withdrawal of SR 001 262 [i.36] and the inclusion of the ETSI Drafting Rules in the ETSI Directives [i.6];
- avoided duplications of ETSI Drafting Rules text, by replacing text with a pointer to the ETSI Drafting Rules;
- deleted copyright release text;
- removed the occurrences of "candidate" in "candidate Harmonized Standard" since this terminology is no longer used by ETSI;
- made modifications concerning the title translation text in order to correspond with the current practices;
- made the alignment of requirements on normative references in Harmonized Standards with the requirements of the European Commission;
- clarified the wording in annexes A and F;
- made a split within the text of the "Scope", in order have both "Introduction" and "Scope";

- added a new annex E; the previous annexes E and F became therefore F and G;
- added a reference to EC Decision 2000/299/EC [i.25];
- performed a number of editorial enhancements of text.

Introduction

The present document has been prepared to assist ETSI technical bodies in the preparation of Harmonized Standards for application under the Radio Equipment and Telecommunications Terminal Equipment Directive (R&TTE Directive [i.26]); furthermore, it establishes a methodology to allow those technical bodies to have a consistent interpretation of the technical requirements needed to implement the essential requirements of the R&TTE Directive [i.1].

Annex C to the present document gives some background to the R&TTE Directive [i.1]. Reference is made to the framework of legal documents implementing the R&TTE Directive [i.1], but the present document should not be taken as an interpretation, amplification, or restatement of any other documents. More generally, the present document reminds the reader that there are a number of regulatory requirements that Members States and the various stakeholders have to comply with. As clarified above, a number of requirements originate from the legal framework in place and not from the present document.

A short list of Frequently Asked Questions (FAQs) relating to Harmonized Standards under the R&TTE Directive [i.1] and/or the present document as well as their answers is provided in annex G.

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1 Scope

The present document addresses those HSs produced for application under the R&TTE Directive [i.1] (article 5) by ETSI (and only those; more specifically, it does not address all ETSI standards).

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 [i.1].

2 References

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the reference document (including any amendments) applies.

Referenced documents which are not found to be publicly available in the expected location might be found at <http://docbox.etsi.org/Reference>.

NOTE: While any hyperlinks included in this clause were valid at the time of publication ETSI cannot guarantee their long term validity.

2.1 Normative references

The following referenced documents are necessary for the application of the present document.

Not applicable.

2.2 Informative references

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

- [i.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 (R&TTE Directive).
- [i.2] Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (LV Directive).
- [i.3] Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.
- [i.4] Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (EMC Directive).
- [i.5] 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.
- [i.6] ETSI Directives: "ETSI drafting rules".
- [i.7] Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards.
- [i.8] 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.

- [i.9] ETSI TR 100 028 (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".
- [i.10] CENELEC EN 60950 (all applicable parts): "Safety of information technology equipment".
- [i.11] CENELEC TR 62102: "Electrical safety - Classification of interfaces for equipment to be connected to information and communications technology networks".
- [i.12] ETSI EG 201 838: "ElectroMagnetic Compatibility and Radio Spectrum Matters (ERM); Publication of interface specifications under Directive 1999/5/EC; Guidelines for describing radio access interfaces".
- [i.13] ETSI EG 201 730-1: "Terminals' access to Public Telecommunications Networks; Application of the Directive 1999/5/EC (R&TTE), article 4.2; Guidelines for the publication of interface specifications; Part 1: General and common aspects".
- [i.14] ETSI EG 201 730-2: "Terminals' access to Public Telecommunications Networks; Application of the Directive 1999/5/EC (R&TTE), article 4.2; Guidelines for the publication of interface specifications; Part 2: Analogue narrow-band wireline interfaces".
- [i.15] ETSI EG 201 730-3: "Terminals' access to Public Telecommunications Networks; Application of the Directive 1999/5/EC (R&TTE), article 4.2; Guidelines for the publication of interface specifications; Part 3: Digital wireline interfaces".
- [i.16] ETSI EG 201 730-4: "Terminals' access to Public Telecommunications Networks; Application of the Directive 1999/5/EC (R&TTE), article 4.2; Guidelines for the publication of interface specifications; Part 4: Broadband multimedia cable network interfaces".
- [i.17] ETSI EN 300 718-3: "Electromagnetic compatibility and Radio spectrum matters (ERM); Avalanche Beacons; Transmitter-receiver systems; Part 3: Harmonized EN covering essential requirements of article 3.3e of the R&TTE Directive".
- [i.18] ETSI EN 301 025-3: "Electromagnetic compatibility and Radio spectrum Matters (ERM); VHF radiotelephone equipment for general communications and associated equipment for Class "D" Digital Selective Calling (DSC); Part 3: Harmonized EN under article 3.3 (e) of the R&TTE Directive".
- [i.19] ETSI CEPT MoU.
- NOTE: See <http://webapp.etsi.org/agreementview>.
- [i.20] ERC/ECC Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".
- [i.21] ETSI EN 301 489 (all parts): " Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services".
- [i.22] Harmonized Standard skeleton document.
- NOTE: See http://portal.etsi.org/edithelp/Files/zip/ETSI_HS_EN_skeleton.zip.
- [i.23] Radio Spectrum Policy Group Opinion on Streamlining the regulatory environment for the use of spectrum (RSPG08-246).
- [i.24] ETSI TR 102 914: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Aspects and implications of the inclusion of receiver parameters within ETSI standards".
- [i.25] COMMISSION DECISION 2000/299/EC of 6 April 2000 "establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers ".
- [i.26] Guide to the R&TTE Directive 1999/5/EC Version of 20 April 2009.
- [i.27] ETSI EN 300 296-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Land Mobile Service; Radio equipment using integral antennas intended primarily for analogue speech; Part 1: Technical characteristics and methods of measurement".

- [i.28] Commission Decision 2004/71/EC of 4 September 2003 on essential requirements relating to marine radio communication equipment which is intended to be used on non-SOLAS vessels and to participate in the Global Maritime Distress and Safety System (GMDSS).
- [i.29] ETSI TErms and Definitions Database Interactive (TEDDI).
- NOTE: See <http://webapp.etsi.org/Teddi/>.
- [i.30] ITU Radio Regulations.
- [i.31] DECISION No 676/2002/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision).
- [i.32] ETSI TR 102 579: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Report providing guidance for the production of Community Specifications for application under the Single European Sky Interoperability Regulation EC 552/2004".
- [i.33] Interoperability Regulation EC 552/2004: "Regulation on the interoperability of the European Air Traffic Management network".
- [i.34] ETSI TR 101 845: "Fixed Radio Systems; Technical Information on RF Interfaces applied by Fixed Service Systems including Fixed Wireless Access (FWA) in the light of the R&TTE Directive (Article 4.2)".
- [i.35] ETSI SR 001 470: "Guidance to the production of candidate Harmonized Standards for application under the R&TTE Directive (1999/5/EC); Pro-forma candidate Harmonized Standard".
- [i.36] ETSI SR 001 262: "ETSI drafting rules".
- [i.37] Guide to the implementation of directives based on the New Approach and the Global Approach, European Commission, 2000.
- [i.38] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.
- [i.39] ETSI Directives: "ETSI Technical Working Procedures", 28 Jan. 2010.

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in R&TTE Directive [i.1] and the following apply:

equipment class: has the same meaning as *equipment class* in the R&TTE Directive [i.1], article 2f: "a class identifying particular types of apparatus which under this Directive are considered similar and those interfaces for which the apparatus is designed"

NOTE: Apparatus may belong to more than one equipment class.

See also COMMISSION DECISION 2000/299/EC of 6 April 2000 [i.25].

essential radio test suite: one or more test procedure(s), referred to in annex III of the R&TTE Directive [i.1]

essential requirement: has the same meaning as *essential requirement* in the R&TTE Directive [i.1]

harmful interference: has the same meaning as *harmful interference* as in the R&TTE Directive [i.1], article 2i: "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"

Harmonized Standard: has the same meaning as *harmonized standard* in the R&TTE Directive [i.1], article 2h: "a technical specification adopted by a recognized standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC [i.8] for the purposes of establishing a European requirement, compliance with which is not compulsory"

NOTE: Unless the context indicates otherwise, this is restricted to those Harmonized Standards within the scope of the present document.

HS Requirements and conformance Test specifications Table (HS-RTT): table annexed to a Harmonized Standard concisely setting out explicit references to the specification of each technical requirement and, where appropriate, the corresponding test procedure which may be executed to demonstrate that a particular equipment conforms with that requirement

NOTE: It also indicates whether such test is a member of the *essential radio test suite* or of the *other test suite*.

interference: effect of unwanted energy due to one or a combination of emissions, radiation, or induction upon reception in a radiocommunication system, manifested by any performance degradation, misinterpretation, or loss of information which could be extracted in the absence of such unwanted energy

manufacturer: manufacturer or his authorized representative established in the Community (R&TTE Directive [i.1], annex II), or the person responsible for placing the apparatus on the market (R&TTE Directive [i.1], article 6.3)

other test suite: test procedure(s) not referred to in annex III of the R&TTE Directive [i.1]

Radio Equipment (RE): radio equipment as defined in R&TTE Directive [i.1], article 2(c), subject to the general exclusions within the R&TTE Directive [i.1] (see its Annex I)

skeleton document: pre-built deliverable, already laid out as required and containing essential titles and text blocks

TB: unless the context indicates otherwise this refers to the ETSI TB responsible for the development of the HS being considered

Telecommunications Terminal Equipment (TTE): Telecommunications Terminal Equipment as defined in R&TTE Directive [i.1], article 2(b) subject to general exclusions within the R&TTE Directive [i.1] (see its Annex I)

3.2 Abbreviations

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

ATM	Air Traffic Management
CCF	Call Control reception Failure
CCR	Control Channel correctly Received
CEN	Comité Européen de Normalisation
CENELEC	European Committee for Electrotechnical Standardization
CEPT	Conférence Européenne des Postes et Télécommunications
DOA	Date Of Announcement
DOW	Date Of Withdrawal
EC	European Commission (often referred to as "Commission" in the present document)
ECC	Electronic Communications Committee (a committee of CEPT)
ECI	Equipment Class Identifier

NOTE: See R&TTE Directive [i.1], articles 4.1 and 11.1 and COMMISSION DECISION 2000/299/EC of 6 April 2000 [i.25].

EEA	European Economic Area
EFTA	European Free Trade Association
EIRP	Equivalent Isotropic Radiated Power
EMC	ElectroMagnetic Compatibility

NOTE: See "new" EMC Directive 2004/108/EC [i.4].

EN	European Norm
ER	Essential Requirement
ERC	European Radiocommunications Committee

NOTE: This committee of CEPT led later to ECC.

ERP	Effective Radiated Power
ETSI TWP	ETSI Technical Working Procedures
FAQ	Frequently Asked Questions
HS	Harmonized Standard
HS-RTT	HS Requirements and conformance Test specifications Table
ISM	Industrial Scientific Medical
LVD	Low Voltage Directive

NOTE: See Directive 73/23/EEC [i.2], more recently replaced by 2006/95/EC [i.3].

MoU	Memorandum of Understanding
Nb	Number
OCG R&TTE	ETSI's Operational Co-ordination Group sub-group on Radio Equipment & Telecommunications Terminal Equipment
OJEU	Official Journal of the European Union
PMR	Private Mobile Radio
R&TTE	Radio Equipment and Telecommunications Terminal Equipment

NOTE: See Directive 1999/5/EC [i.1].

RE	Radio Equipment
RIS	Radio Interface Specification
RSCCom	Radio Spectrum Committee
RSPG	Radio Spectrum Policy Group
SMF	System Monitoring Fail
SMP	System Monitoring Pass
TB	ETSI Technical Body
TCAM	Telecommunication Conformity Assessment and Market surveillance committee

NOTE: See R&TTE Directive [i.1], articles 13, 14 and 15.

TDD	Time Division Duplex
TDM	Time Division Multiplex
TTCN	Testing and Test Control Notation or (previously) Tree and Tabular Combined Notation

NOTE: Both are valid and have been used associated different version of TTCN.

TEDDI	TErms and Definitions Database Interactive
TTE	Telecommunications Terminal Equipment
TxD	Transmission Disable command
TxE	Transmission Enable command

4 Role and purpose of Harmonized Standards

4.1 Background to the R&TTE Directive

The R&TTE Directive [i.1] conforms to the EC Council Resolution of 7 May 1985 [i.7]. It introduced a market-led approach into the Radio and Telecommunications Terminal Equipment sector, and removed the regime of type approvals.

The R&TTE Directive [i.1] covers apparatus within its scope that is either TTE (Telecommunications Terminal Equipment) or RE (Radio Equipment), as defined in its articles 2(b) and 2(c), or that is both TTE and RE, but excludes equipment listed in its annex I (radio amateur kits, certain marine equipment, cabling and wiring, receive-only radio/TV, and at the time of the publication of the R&TTE Directive [i.1], certain civil aviation equipment and 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.

4.2 Role of Harmonized Standard in Presumption of Conformity

The Directive identifies essential requirements that are to be met. Conformity with the Essential Requirements in article 3 of the R&TTE Directive [i.1] is declared by the manufacturer, and may be based on HSs (see R&TTE Directive [i.1], article 5.1) or using other means.

In principle, HSs relate to equipment when installed, operated as intended, and not under fault conditions nor when misused by the customer, deliberately or otherwise.

In certain circumstances, the Commission may also publish guidelines on the interpretation of HSs or the conditions under which compliance with that standard raises a presumption of conformity.

5 Procedure for generation of Harmonized Standards

5.1 Standardization mandate

"Harmonised standards are European standards, which are adopted by European standards organisations, prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations, and follow a mandate issued by the Commission after consultation with the Member States" [i.37].

'Harmonised standard' means "a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of that Directive" [i.38].

Reference [i.38] states, "Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in ... [reference to the relevant part of the legislation]."

As a result, Harmonized Standards are distinct from other ENs, in particular, in that:

- they are produced under a formally issued standardization mandate through the European Commission's '98/34/EC procedure';
- when the standard has been adopted, a reference to it is placed in the Official Journal of the European Union with an indication of the Directive for which the presumption of conformity should apply.

With the advent of the R&TTE Directive [i.1], the European Commission requested ETSI to propose a programme of standardization work considered necessary under Directive. This programme of work provided the basis for a first standardization mandate.

ENs cannot be quoted in the OJEU as HSs unless they have been developed under an EC standardization mandate. Mandates under the R&TTE Directive [i.1] are proposed by the Commission, after consultation with TCAM, and approved by the Committee established under the terms of Directive 98/34/EC [i.8] 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 HS 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 HS is required. If regarded as justified, the EC may decide to modify the mandate or issue a new one. Such decisions require approval by the Committee established under the terms of Directive 98/34/EC [i.8].