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Electromagnetic compatibility and Radio spectrum Matters (ERM); A guide to the production of Harmonized Standards for application under the Radio & Telecommunication Terminal Equipment Directive 1999/5/EC (R&TTE) and a first guide on the impact of the Radio Equipment Directive 2014/53/EU (RED) on Harmonized Standards

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Contents

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Foreword

This ETSI Guide (EG) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The drafting of the present document has been triggered by the publication of the Radio Equipment Directive (RED) i.e. Directive 2014/53/EU [i.1].

In the present document the major differences between the R&TTE Directive [i.2] and the RED [i.1] and their impact in the drafting of Harmonized Standards have been highlighted. This approach has been followed as ETSI is working, at the moment when the present version of the Guide is being written, on a work programme whereby the Harmonized Standards supporting the R&TTE Directive [i.2] will be converted to support the RED [i.1]. It is therfore necessary to have the elements identifying what should be changed when converting the Harmonized Standards.

Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

Introduction

Earlier versions of the present document had 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.2]) only. In addition, the present document addresses the first guidance on the impact on the drafting of Harmonized Standards for application under the Radio Equipment Directive (RED) [i.1]; furthermore, it supports a consistent interpretation of the technical (and possibly non-technical) requirements needed to implement the essential requirements of these Directives.

ETSI has published more than two hundred Harmonized Standards in relation to the R&TTE Directive. Therefore, the present document includes detailed comparisons of the two Radio Directives [i.2] and [i.1] (in particular in clause 4).

Aspects relating to the transition between the R&TTE Directive [i.2] to the RED [i.1] are covered in clause 7.3 of the present document.

Annex C to the present document gives some background to the R&TTE Directive [i.2] and to the RED [i.1]. Reference is made to the framework of legal documents implementing these Directives, but the present document should not be taken as an interpretation, amplification, or restatement of any other documents. 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 these Radio Directives [i.2] and [i.1], and/or the present document as well as their answers is provided in annex G.

NOTE: At the time of drafting the present document, TCAM had not yet had the opportunity of offering clarifications on the RED. A TCAM guide on the RED is planned to be prepared.

1 Scope

The present document gives guidance to ETSI Technical Bodies and Rapporteurs on the production of Harmonized Standards (HSs) produced by ETSI for application:

- under the R&TTE Directive [i.2] (article 5); and
- a first guide under the RED [i.1] (articles 16 and 17).

NOTE: In the present document, where "the Radio Directives" is written, this means the R&TTE Directive [i.2] and/or to the RED [i.1], as appropriate.

2 References

2.1 Normative 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 referenced 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.

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

Not applicable.

2.2 Informative 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 referenced document (including any amendments) applies.

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

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 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

NOTE: The "RED".

[i.2] 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.

NOTE: The "R&TTE Directive".

[i.3] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast).

NOTE: The "Directive LVD" of 2014.

[i.4] Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to Electrical Equipment designed for use within certain voltage limits.

NOTE: The "LV Directive".

[i.5] 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.6] Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast).

NOTE: The "EMC Directive" of 2014.

[i.7] 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.

NOTE: The "EMC Directive".

[i.8] 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.9] ETSI Directives: "ETSI Drafting Rules (EDRs)" and "Technical Working Procedures (TWP)".

NOTE: The version of ETSI Directives used for preparation of the present guide is v.33 of May 2014.

[i.10] Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards.

[i.11] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (Text with EEA relevance).

[i.12] 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.13] ETSI TR 100 028 (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

[i.14] ETSI ECC MoU.

NOTE: Available at http://webapp.etsi.org/agreementview.

[i.15] ETSI EN 301 489 (all parts): "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services".

[i.16] ETSI Harmonized Standard skeleton document.

NOTE: Available at https://portal.etsi.org/Services/editHelp!/Standardsdevelopment/Drafting/Skeletons.aspx.

[i.17] Document RSPG08-246: "Radio Spectrum Policy Group Opinion on "Streamlining the regulatory environment for the use of spectrum"".

[i.18] ETSI TR 102 914: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Aspects and implications of the inclusion of receiver parameters within ETSI standards".

[i.19] Commission Decision 2000/299/EC of 6 April 2000 establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers.

[i.20] Blue Guide of 2014.

NOTE: Available at http://ec.europa.eu/DocsRoom/documents/4942/attachments/1/translations/en/renditions/pdf.

[i.21] Guide to the R&TTE Directive 1999/5/EC Version of 20 April 2009.

NOTE: Available at http://ec.europa.eu/enterprise/sectors/rtte/files/guide2009-04-20_en.pdf.

[i.22] 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.23] 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.24] ETSI TR 103 265 (V1.1.2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Definition of radio parameters".

[i.25] ETSI TErms and Definitions Database Interactive (TEDDI).

NOTE: Available at http://webapp.etsi.org/Teddi/.

[i.26] ITU Radio Regulations.

[i.27] Decision No 676/2002/EC of the European Parliament and of the Coucil of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision).

[i.28] 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.29] Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation) (Text with EEA relevance).

[i.30] Guide to the implementation of directives based on the New Approach and the Global Approach, European Commission, 2000.

NOTE: Available at http://www.netinform.net/Vorschriften/pdf/BlueGuide_en.pdf.

[i.31] 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.

NOTE: The "NLF".

[i.32] Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive).

[i.33] "Vademecum".

NOTE: Available at http://ec.europa.eu/enterprise/policies/european-standards/documents/vademecum/index_en.htm.

[i.34] ETSI TR 102 070-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Guide to the application of harmonized standards to multi-radio and combined radio and non-radio equipment; Part 1: ElectroMagnetic Compatibility".

[i.35] ETSI TR 102 070-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Guide to the application of harmonized standards to multi-radio and combined radio and non-radio equipment; Part 2: Effective use of the radio frequency spectrum".

[i.36] Recommendation ITU-T K.44 (05/2012): "Resistibility tests for telecommunication equipment exposed to overvoltages and overcurrents - Basic Recommendation".

NOTE: Available at http://www.itu.int/rec/T-REC-K.44/en.

[i.37] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

[i.38] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

[i.39] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating implantable medical devices.

[i.40] Council Directive 72/245/EEC of 20 June 1972 on the approximation of the laws of the Member States relating to the suppression of radio interference produced by spark-ignition engines fitted to motor vehicles.

[i.41] Council Directive 92/61/EEC of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles.

[i.42] Council Directive 96/98/EC of 20 December 1996 on marine equipment.

[i.43] Council Directive 93/65/EEC of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air-traffic- management equipment and systems.

[i.44] Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC.

[i.45] Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation.

[i.46] Regulation (EC) No 717/2007 of the European Parliament and of the Council of 27 June 2007 on roaming on public mobile telephone networks within the Community and amending Directive 2002/21/EC.

[i.47] Regulation (EC) No 544/2009 of the European Parliament and of the Council of 18 June 2009 amending Regulation (EC) No 717/2007 on roaming on public mobile telephone networks within the Community and Directive 2002/21/EC on a common regulatory framework for electronic communications networks and services.

[i.48] Directive 2009/140/EC of the European Parliament and of the Council of 25 November 2009 amending Directives 2002/21/EC on a common regulatory framework for electronic communications networks and services, 2002/19/EC on access to, and interconnection of, electronic communications networks and associated facilities, and 2002/20/EC on the authorisation of electronic communications networks and services.

[i.49] Commission Directive 2008/63/EC of 20 June 2008 on competition in the markets in telecommunications terminal equipment (Codified version).

[i.50] ETSI EN 300 220: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW".

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in R&TTE Directive [i.2], the RED [i.1] and the following apply:

equipment class: has the same meaning as *equipment class* in the R&TTE Directive [i.2], 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 1: Apparatus may belong to more than one equipment class.

NOTE 2: See also Commission Decision 2000/299/EC of 6 April 2000 [i.19].

essential radio test suite: one or more **essential** test procedure(s), referred to in annex III of the R&TTE Directive [i.2]

NOTE: In the RED, the term "essential radio test suite" is not used. Term to be replaced by "method of measurement" or "test", as appropriate (see clause 7.2.10, annex F and "Q6" in annex G) in HSs under the RED.

essential requirement: requirement identified in article 3 of the R&TTE Directive [i.2] and in article 3 of the RED [i.1]

NOTE: See also the Blue Guide clause 4.1.1 [i.20].

harmful interference: is "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"

NOTE 1: Source: R&TTE Directive [i.2], article 2i.

NOTE 2: The definition of "Harmfull interference" is also defined in the RED (article 2(7)) through a reference to the Framework Directive.

Harmonized Standard (HS): has the same meaning as *harmonized standard* in the R&TTE Directive [i.2], 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.12] for the purposes of establishing a European requirement, compliance with which is not compulsory" and as in the RED [i.1], article 2 (18)

NOTE 1: Unless the context indicates otherwise, this is restricted to those Harmonized Standards within the scope of the present document.

NOTE 2: Directive 98/34/EC [i.12] has been replaced by Regulation 1025/2012/EU [i.11], where the new definition of Harmonized Standard is provided in point 1 of article 2 as "(c) 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonization legislation".

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

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

other test suite: other test procedure(s) not referred to in annex III of the R&TTE Directive [i.2]

NOTE: In the RED, the term "essential radio test suite" is not used. Term "other test suite" to be replaced by "method of measurement" or "test", as appropriate (see clause 7.2.10, annex F and "Q6" in annex G) in HSs under the RED.

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

NOTE: This term has been defined in a different way in the RED [i.1], as follows, and is 4 fold:

(1) "'radio equipment' means an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination [i.1];

(2) 'radio communication' means communication by means of radio waves [i.1];

(3) 'radiodetermination' means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves [i.1];

(4) 'radio waves' means electromagnetic waves of frequencies lower than 3 000 GHz, propagated in space without artificial guide [i.1]".

recital: "whereas" in the RED [i.1]

resistibility: resistibility is the ability of telecommunication equipment or installations to withstand, in general, without damage, the effects of overvoltages or overcurrents, up to a certain specified extent, and in accordance with a specified criterion

NOTE 1: Source: Recommendation ITU-T K.44 [i.36].

NOTE 2: Resistibility is considered to cater for the needs of the whole of the telecommunication network, i.e. all types of networks, public and private, as well as any equipment installed in or connected to this network. The resistibility requirements are based on the following electromagnetic phenomena: lightning, power induction, earth potential rise and low-voltage power contact.

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

TB: the ETSI Technical Body responsible for the development of the HS being considered

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

NOTE: TTE equipment is not covered by the RED [i.1].

3.2 Symbols

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

kHz	kiloHertz
V	Volt

3.3 Abbreviations

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

ATM	Air Traffic Management
BEM	Block Edge Mask
CCF	Call Control reception Failure
CCR	Control Channel correctly Received
CEN	Comité Européen de Normalisation
CENELEC	European Committee for Electrotechnical Standardization
CEPT	Conference Européenne des Postes et Télécommunications
DOA	Date Of Announcement
DOW	Date Of Withdrawal
EC	European Commission (often refered 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.2], articles 4.1 and 11.1 and Commission Decision 2000/299/EC of 6 April 2000 [i.19].

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

NOTE: See also "new" EMC Directive 2004/108/EC [i.7].

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.4], more recently replaced by 2006/95/EC [i.5] and subsequently replaced by Directive 2014/35/EU [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.2].

RE Radio Equipment
RED Radio Equipment Directive

NOTE: See Directive 2014/53/EU [i.1].

RIS Radio Interface Specification
RSCom 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.2], articles 13, 14 and 15 and the RED [i.1] article 45.

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 Radio Directives

4.1.1 Background to the R&TTE Directive

The R&TTE Directive [i.2] conforms to the EC Council Resolution of 7 May 1985 [i.10]. 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.2] 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.2], 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.

4.1.2 Background to the RED

Some changes with respect to the R&TTE Directive were required in order to facilitate and simplify its application and enforcement and so improve the level of compliance; there was also the need to bring the text in line with other legislation, such as:

- Decision 768/2008/EC (the NLF) [i.31] (which has triggered the inclusion of many new articles),
- Regulation (EU) No 182/2011 [i.37].

The RED also includes a few additional elements articulating the relation with national regulation on the use of radio spectrum.

The objectives of the proposal were:

a) To achieve improved enforcement and compliance with the Directive.

b) To make available a sound legal basis for the implementation of the essential requirements:

- To adapt the scope of the Directive so that it includes all equipment for article 3(2) as relevant.
- To facilitate the application of the Directive to some specific cases, e.g. interoperability with chargers, software defined radio.
- To improve the coherence of definitions and requirements with other Internal Market legislation, the Radio Spectrum Decision and the regulatory framework for electronic communications.
- To modify or suppress a number of administrative obligations which create burden but bring in only limited value-added.

See also annex C (and in particular clause C.1.2).

4.1.3 Major changes from the R&TTE Directive to the RED

The main changes:

1. Scope:

- Sound and TV broadcast receivers, previously excluded, will now fall within the scope of the Directive.
- Equipment operating below 9 kHz, previously excluded, will now fall within the scope of the Directive.
- Radio-determination equipment becomes explicitly included.
- Fixed-line terminals cease to fall within the scope of the Directive.

- ISM equipment continues not to fall within the scope of the Directive + The Commission may adopt implementing acts to ensure consistent application of the definition of radio equipment.

2. Essential requirements:

- Article 3(2) has been clarified so as to ensure that it includes requirements for the performance of radio receivers (see also clause 6.4 of the present document).
- Article 3(3)(a) can be invoked to cover interoperability between radio equipment and accessories such as chargers for mobile telephones.
- Article 3(3)(i) can be invoked to ensure that radio equipment can only upload software if the compliance of the combination of the software and the radio equipment has been demonstrated.
- Concerning article 3(3), see also clause 6.5 of the present document.
- For the assessment of compliance with the essential requirement set out in point (a) of article 3(1), the manufacturer also takes into account reasonably foreseeable conditions of use.

3. New instruments:

- Article 4 may be invoked to ensure transparency on the compliance of combinations of software and radio equipment, so as to avoid barriers to competition in the market for third-party software.
- Article 5 may be invoked to require registration within a central system of products within categories affected by low levels of compliance.

4. Alignment with Decision 768/2008/EC [i.31] on a common framework for the marketing of products, including:

- The definitions set out in chapter R1 of Decision 768/2008/EC [i.31].
- The obligations of economic operators (manufacturers, importers, distributors) set out in chapter R2 of Decision 768/2008/EC [i.31].
- Three of the modules for conformity assessment set out in annex II of Decision 768/2008/EC [i.31].
- The obligations for the notification of conformity assessment bodies set out in chapter R4 of Decision 768/2008/EC [i.31].
- The simplified safeguard procedures set out in chapter R5 of Decision 768/2008/EC [i.31].

5. Alignment with the Treaty on the Functioning of the European Union and with Regulation No 182/2011 [i.37] on the Commission's exercise of implementing powers:

Installation of radio equipment

The installation of radio equipment is mentioned, in particular, in "recitals" (10) and (30) of the RED [i.1].

Time-plan

- Products have one extra year of transition period, i.e. products complying with current EU legislation can be placed in the market up to 36 months after the date of entry into force of the RED.

4.1.4 Comparison of the Scopes of the R&TTE Directive and of the RED

Table 1

	R&TTE [i.2]	RED [i.1]
Scope (article 1)	Scope and aim *1. This Directive establishes a regulatory framework for the placing on the market, free movement and putting into service in the Community of radio equipment and telecommunications terminal equipment.*	Subject matter and scope *1. This Directive establishes a regulatory framework for the making available on the market and putting into service in the Union of radio equipment.* *2. This Directive shall not apply to equipment listed in annex I.*

	R&TTE [i.2]	RED [i.1]
	2. Where apparatus as defined in article 2(a) incorporates, as an integral part, or as an accessory: *(a) a medical device within the meaning of article 1 of Council Directive 93/42/EEC [i.38] of 14 June 1993 concerning medical devices ([1]); or* *(b) an active implantable medical device within the meaning of article 1 of Council Directive 90/385/EEC [i.39] of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ([2]), the apparatus shall be governed by this Directive, without prejudice to the application of Directives 93/42/EEC [i.38] and 90/385/EEC [i.39] to medical devices and active implantable medical devices, respectively.* *3. Where apparatus constitutes a component or a separate technical unit of a vehicle within the meaning of Council Directive 72/245/EEC [i.40] ([3]) relating to the radio interference (electromagnetic compatibility) of vehicles or a component or a separate technical unit of a vehicle within the meaning of article 1 of Council Directive 92/61/EEC [i.41] of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles, the apparatus shall be governed by this Directive without prejudice to the application of Directive 72/245/EEC [i.40] or of Directive 92/61/EEC [i.41] respectively.* *4. This Directive shall not apply to equipment listed in annex I.* *5. This Directive shall not apply to apparatus exclusively used for activities concerning public security, defence, State security (including the economic wellbeing wellbeing of the State in the case of activities pertaining to State security matters) and the activities of the State in the area of criminal law.*	*3. This Directive shall not apply to radio equipment exclusively used for activities concerning public security, defence, State security, including the economic well-being of the State in the case of activities pertaining to State security matters, and the activities of the State in the area of criminal law.* *4. Radio equipment falling within the scope of this Directive shall not be subject to Directive 2014/35/EU [i.3], except as set out in point (a) of article 3(1) of this Directive.*

	R&TTE [i.2]	RED [i.1]
Some key definitions (from article 2)	*(a) "apparatus" means any equipment that is either radio equipment or telecommunications terminal equipment or both;* *(b) "telecommunications terminal equipment" means a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services);* *(c) "radio equipment" means a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/space radiocommunication;* *(d) "radio waves" means electromagnetic waves of frequencies from 9 kHz to 3 000 GHz, propagated in space without artificial guide.*	*(1) 'radio equipment' means an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination;* *(2) 'radio communication' means communication by means of radio waves;* *(3) 'radiodetermination' means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves;* *(4) 'radio waves' means electromagnetic waves of frequencies lower than 3 000 GHz, propagated in space without artificial guide.*
Annex I	*EQUIPMENT NOT COVERED BY THIS DIRECTIVE AS REFERRED TO IN ARTICLE 1(4)* *1. Radio equipment used by radio amateurs within article 1, definition 53, of the International Telecommunications Union (ITU) radio regulations unless the equipment is available commercially. Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.* *2. Equipment falling within the scope of Council Directive 96/98/EC [i.42] of 20 December 1996 on marine equipment ([1]).* *3. Cabling and wiring.* *4. Receive only radio equipment intended to be used solely for the reception of sound and TV broadcasting services.* *5. Products, appliances and components within the meaning of article 2 of Council Regulation (EEC) No 3922/91 [i.45] of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation ([2]).* *6. Air-traffic-management equipment and systems within the meaning of article 1 of Council Directive 93/65/EEC [i.43] of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air-traffic-management equipment and systems ([3]).*	*EQUIPMENT NOT COVERED BY THIS DIRECTIVE* *1. Radio equipment used by radio amateurs within the meaning of article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations [i.26], unless the equipment is made available on the market. The following shall be regarded as not being made available on the market:* *(a) radio kits for assembly and use by radio amateurs;* *(b) radio equipment modified by and for the use of radio amateurs;* *(c) equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio.* *2. Marine equipment falling within the scope of Council Directive 96/98/EC [i.42] ([1]).* *3. Airborne products, parts and appliances falling within the scope of article 3 of Regulation (EC) No 216/2008 [i.44] of the European Parliament and of the Council ([2]).* *4. Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.*
NOTE: The meaning of notes such as "([n])" can be found in the corresponding article of the appropriate Directive.		

4.1.5 Examples of changes in the terminology used in the RED

The term and potential obligation for "Relevant components" (article 2(b) of the R&TTE Directive [i.2]) do not appear in the RED [i.1].

"R&TTED" ➔ "RED".

"apparatus" ➔ "equipment".

Note that "apparatus" was used in the R&TTE Directive as it covered both radio and terminal equipment.

"Test suites" ➔ "methods of measurement".

A number of changes in terminology are the effect of the NLF Decision [i.31].

4.1.6 Further information on the timeline

Manufacturers may face with the situation where equipment will "migrate" from the scope of one Directive to the scope of another Directive, in the coming years.

An example of such a situation in relation to the RED [i.1] is broadcast receiver equipment:

- until 13 June 2016 manufacturer can use Harmonized Standards under EMCD [i.6] and LVD [i.3] to claim compliance with the essential requirements of these directives;
- from 13 June 2016 until 13 June 2017 manufacturers can choose either regime: EMCD [i.6] + LVD [i.3] or RED [i.1];
- as of 13 June 2017 the only regime in place is RED [i.1].

4.1.7 Multi-module equipment

It is worth to note the differences in limits resulting from the application of the new LVD [i.3] and RED [i.1]:

- 50V equipment for LVD [i.3];
- and 0V for RED [i.1].

This means that manufacturers of equipment operating below 50V have to declare compliance with Art.3.1(a) of the RED [i.1] and not with the LVD [i.3] as before.

ETSI developed ETSI TR 102 070-1 [i.34] (EMC) and ETSI TR 102 070-2 [i.35] (radio) in order to addressmulti-radio and combined radio equipment. These documents have to be revised as a result of the publication of the RED.

4.1.8 European Standardization systems : different approached for the development of standards

The European standardization system is based on the EC Regulation 1025/2012 [i.11] and lead by three European standardization bodies:

- CEN - European Committee for Standardization.
- CENELEC - European Committee for Electrotechnical Standardization.
- ETSI - European Telecommunications Standards Institute.

The European standardization is based on two key principles:

- national delegations one for CEN and CENELEC; these two European standardization organizations made up of national standards bodies (NSBs), which are members of CEN and of CENELEC; and
- direct participation of economic operators (without NSBs or other intermediaries) in ETSI supported by national votes on European Standards (including, therefore, Harmonized Standards) as appropriate.

CEN and CENELEC closely cooperate with their international counterparts, respectively the International Organization for Standardization(ISO) and the International Electrotechnical Commission (IEC). This close cooperation has been materialized by the signature of the Vienna Agreement (ISO-CEN) and the Dresden Agreement (IEC-CENELEC). The main objectives of these agreements are to provide a:

- Framework for the optimal use of resources and expertise available for standardization work;
- Mechanism for information exchange between international and European Standardization Organizations (ESOs) to increase the transparency of ongoing work at international and European levels.

When CEN or CENELEC elaborate a new European Standard, they set up a European technical committee under the responsibility of one of its national members, and consisting of other national members (NSBs). At the same time NSBs create the so-called "National Mirror Committees" (reflecting the European technical committee on the Member State level), which enable all interested parties (enterprises, consumers, public authorities, NGOs, etc.) to participate in the creation of the standard at national level and in their own language.

These National Mirror Committees elaborate a national position for the drafting and voting of a European standard, which is then presented at the European technical committee.

The work done by ETSI is carried out in committees and working groups with direct participation of technical experts representing different economic operators (administrations, NSOs, Industries, Associations). These committees are often referred to as "Technical Bodies".

4.2 Role of Harmonized Standard in Presumption of Conformity

The Radio Directives identify essential requirements that are to be met. Conformity with the Essential Requirements in article 3 of the Radio Directives [i.2] and [i.1] is declared by the manufacturer, and may be based on HSs (see R&TTE Directive [i.2], article 5.1 and/or RED [i.1], article 16) 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 article 3(1)(a) of the RED [i.1] the manufacturer is also required to take into account reasonably foreseeable conditions of use.

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.

See also "The Blue Guide" [i.20], clause 4.1.2.

5 Procedure for generation of Harmonized Standards

5.0 Introduction

In broad lines, the procedures valid for the RED [i.1] follow those which were in force for the R&TTE Directive [i.2].

5.1 Standardization Requests

NOTE: The term "Standardization Mandate", that was used in Directive 98/34 [i.12] has now been replaced by "Standardization Request" in Regulation 1025/2012/EU [i.11].

"Harmonized standards are European standards, which are adopted by European standards organizations, prepared in accordance with the General Guidelines agreed between the Commission and the European standards organizations, and follow a mandate issued by the Commission after consultation with the Member States" [i.30].

The "NLF" Decision, Reference [i.31] states, "*Products which are in conformity with harmonized 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 request through the European Commission's Regulation 1025/2012/EU [i.11] procedures;

- 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.2], 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.

A Standardization Request in support of the RED is expected and ETSI has been working on the corresponding work programme.

The Draft of the "Vademecum" [i.33] that is in drafting stage at the time of drafting the present document provides details of the foreseen procedures.

ENs cannot be quoted in the OJEU as HSs unless they have been developed under an EC Standardization Requests (or mandate). Where a Standardization Request (or 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 Standardization Request (or 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 issue a new Standardization Request. Such a decisions require approval by the Committee established under the terms of Regulation 1025/2012 [i.11].

5.2 The drafting process

Guidance of the drafting process is addressed separately in clause 7.

5.3 Adoption of Harmonized Standards

HSs are adopted according to specific procedures under the ETSI TWP.

Before a HS is submitted to the voting procedure, the standard should be finally examined to ascertain that the conditions imposed by the Radio Directives [i.2] and [i.1], 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.

5.4 Submission to EC and Publication in the OJEU

Once adopted by ETSI, HSs developed under a Standardization Request are presented to the Commission by the ETSI Secretariat. It has been agreed between the Commission and ETSI that the presentation will be accompanied by the translation of the ***title*** of the document into the official languages of the EU and EFTA.

The Commission will decide whether or not the HS is acceptable in whole or in part as suitable for establishing a presumption of conformity against the relevant essential requirements. The EC may decide whether or not to cite the HS or its revision (the whole or parts thereof) in the OJEU.

The ETSI Technical Working Procedures, clause 2.4 states, "*ENs shall be transposed by the National Standards Organizations (see article 13.7 of the Rules of Procedure).*" [i.9].

The ETSI Secretariat will set the Date Of Withdrawal (DOW) to eighteen months after Date Of Announcement (DOA) unless the relevant ETSI TB advises otherwise.

ETSI TBs may add a note in the OJEU listing of HS (e.g. for explaining the transfer of one (set of) standard(s) to another number). The note will appear across a whole row of the OJEU. The ETSI TB should provide this information to the ETSI Secretariat if this possibility is chosen.

5.5 Revision of Harmonized Standards

Publication of the revised standard in the OJEU is necessary to amend the requirements which give a presumption of conformity with the Radio Directives [i.2] and [i.1].

The TB should consider the cost and other implications on industry and other parties before proposing revisions to HSs. If an ETSI TB considers that technical (and possibly non-technical) modifications to a HS are required, it should raise a work item according to the ETSI TWP.

According to the MoU [i.14] between CEPT-ECC and ETSI, any modification of the HS which would require a modification of ECC deliverables should lead to a coordination process between the two bodies. The same would apply if ECC envisages a change in its deliverables which would require a modification of HSs.

Adoption and submission of revisions of HSs are as explained in clauses 5.1 to 5.4.

5.6 Withdrawal of Harmonized Standards

The withdrawal process is defined in the ETSI TWP clause 2.2.1.3.

The ETSI Secretariat will ensure that the standard is archived so as to remain available if requested, including traceability that the standard had been published in the OJEU, with the relevant dates of publication and withdrawal.

6 Formulation of technical requirements in Harmonized Standards

6.0 Introduction

At the time of drafting the present version of the present document the last version of the EDRs was version 33 of May 2014 [i.9].

6.1 Guiding principles

6.1.0 Introduction

It had been agreed, years ago, that a way to make the difference between the requirements in the Directives and in the HSs was to:

- refer to the requirements in the Directives with the words used in the Directives themselves i.e. "essential requirements";
- refer to the requirements in the HSs with the words "technical requirements".

NOTE: "EN-R" (for "EN requirement") can also be found in documents related to the Vademecum [i.33].

6.1.1 General

In general compliance with the essential requirements of the Radio Directives [i.2] and [i.1] is achieved by meeting technical requirements. However there may be a need to also include non-technical requirements in the HS for supporting the compliance with the essential requirement of the Radio Directives [i.2] and [i.1]: hence the usage of the words "technical (and possibly non-technical)" in the present Guide.

As a matter of principle, the decision of precisely how to draft the harmonized standard related to an essential requirement should remain the duty of the appropriate TB. However, it is important that a common set of principles be made available to guide the TB when making decisions on content: TC ERM and the OCG R&TTE should be informed in case of difficulties.

6.1.2 Innovation

In producing HSs for application under the Directives, ETSI should ensure that the standards do not inhibit technological innovation.

6.1.3 Choice of parameters

6.1.3.0 General

HSs should be written to address the parameters necessary to allow a presumption of conformity to the essential requirements of article 3 of the Radio Directives [i.2] and [i.1]. See also the Blue Guide [i.20].

6.1.3.1 Transmitter parameters

From the point of view of the transmitter, the essential requirement in article 3.2 of the RED, requires that *"… radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference*".

Further information is given in Recital 10 of the RED: "*In order to ensure that radio equipment uses the radio spectrum effectively and supports the efficient use of radio spectrum, radio equipment should be constructed so that: in the case of a transmitter, when the transmitter is properly installed, maintained and used for its intended purpose it generates radio waves emissions that do not create harmful interference, while unwanted radio waves emissions generated by the transmitter (e.g. in adjacent channels) with a potential negative impact on the goals of radio spectrum policy should be limited to such a level that, according to the state of the art, harmful interference is avoided.*" See also Recitals 26 and 73 of the RED.

The "support of the efficient use of radio spectrum" in the RED is a different requirement than the "effective use of spectrum … so as to avoid harmful interference" as was expressed in the essential requirement 3.2 in the R&TTE Directive. Therefore, ETSI Technical Bodies will need, in the light of the list provided in table B.2, to consider if the present parameters in existing harmonized standards under the R&TTE Directive are appropriate for publication in harmonized standards under the Radio Equipment Directive. If needed, the ETSI Technical Bodies will need to incorporate additional technical (and possibly non-technical) requirements that are necessary to demonstrate compliance with the essential requirement to support efficient use of spectrum, as set out in recital 10 of the RED.

New harmonized standards will need to include appropriate technical (and possibly non-technical) requirements derived, for example from table B.2, for radio transmitters that are necessary to demonstrate compliance with the essential requirement that they "effectively use and support the efficient use of radio spectrum and avoid harmful interference".

6.1.3.2 Receiver parameters

In relation to receivers, article 3.2 in the RED requires that "*…radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference*".

Further information is given in Recitals 10, 26 and 73 of the RED. See also clause 6.1.3.1. Recital 11 of the RED [i.1] further states: "Although receivers do not themselves cause harmful interference, reception capabilities are an increasingly important factor in ensuring the efficient use of radio spectrum by way of an increased resilience of receivers against harmful interference and unwanted signals on the basis of the relevant essential requirements of Union harmonization legislation".

The "support of the efficient use of radio spectrum" in the RED is a different requirement than the "effective use of spectrum … so as to avoid harmful interference" as was expressed in the essential requirement 3.2 in the R&TTE Directive. Therefore in the case of radio equipment that have a harmonized standard under the R&TTE Directive, ETSI Technical Bodies will need, in the light of the list provided in table B.2, to consider:

- either if the present parameters in existing harmonized standards under the R&TTE Directive are appropriate for publication in harmonized standards under the Radio Equipment Directive; or
- develop a new standard following the same principles.

If needed, the ETSI Technical Bodies will need to incorporate additional technical (and possibly non-technical) requirements that are necessary to demonstrate compliance with the essential requirement to support efficient use of spectrum, as explained in recitals 10 and 11 of the RED.

NOTE 1: Under the R&TTE Directive Radio receiver parameters (other than spurious emissions) have not always been specified in HSs.

ETSI TR 102 914 [i.18] shows the specific receiver parameters that TBs have included in ETSI HSs under the R&TTE Directive at the time of publication of ETSI TR 102 914 [i.18].

Harmonized standards for radio equipment that did not have a harmonized standard under the R&TTE Directive but now under the RED will need to include appropriate technical requirements for radio receivers that are necessary to demonstrate compliance with the essential requirement that they "effectively use and support the efficient use of the spectrum and avoid harmful interference" according to article 3.2 of the Radio Equipment Directive [i.1], as above.

NOTE 2: For a given link budget, good receiver parameters (including sensitivity) allow lower transmitter powers of the corresponding transmitters which, in turn, is supportive of European Green Agendas. As the level of transmitter spurious emissions is generally depending on the actual transmitted power, good receiver parameters also support the reduction of the "overall noise" (i.e. spurious emissions, etc.) created by transmitters.

6.2 Article 3.1(a): Protection of health and safety (and protection of property)

Please refer to the relevant clause of the EDR (e.g. Clause 5.8 of the EDR in version 33 of May 2014).

6.3 Article 3.1(b): EMC

ETSI TC ERM should be consulted concerning EMC statements to be included in HSs.

The essential requirements for EMC under the Radio Directives [i.2] and [i.1] are the protection requirements published in the EMC Directive [i.7], [i.6] and its successors.

There are several product EMC standards already available from ETSI and CENELEC that have been published in the OJEU in connection with the EMC Directive [i.7]. HSs published in the OJEU referencing the EMC Directive [i.7] either before or after the R&TTE Directive [i.2] is in force are allowed to be used under article 3.1(b) of the R&TTE Directive [i.2] (see article 18).

[Resistibility requirements as defined in some ITU-T K series Recommendations should not be included in HSs under R&TTE Directive [i.2] as requirements.]

Under the RED [i.1] regime, equipment covered by the RED is not covered by the EMC Directive.

6.4 Article 3.2 of the R&TTE Directive and of the RED

6.4.0 Introduction

It has to be noted that there has been a clear evolution in the precise terms used in article 3.2 of the R&TTE Directive [i.2] and subsequently in the RED [i.1].

While in the case of the R&TTE [i.2] article 3.2 would read:

"…the effective use of the radio spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference",

in the case of the RED [i.1] would read:

"*Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference*".

6.4.1 General

"*Where Community harmonisation legislation sets out essential requirements, it shall provide for recourse to be had to harmonized standards, adopted in accordance with Directive 98/34/EC, which shall express those requirements in technical terms and which shall, alone or in conjunction with other harmonized standards, provide for the presumption of conformity with those requirements, while maintaining the possibility of setting the level of protection by other means."* (article 3 of [i.12]).

NOTE: Directive 98/34/EC [i.12] has been amended by Regulation 1025/2012 [i.11].

The above text provides the requirements concerning how and which technical (and possibly non-technical) requirements have to be included in Harmonized Standards addressing article 3.2 of the R&TTE Directive [i.2].

In turn, the following is found in article 3.2 of the RED [i.1]:

"*Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference*".

Requirements necessary to provide a presumption of conformity to the Directive may have been a subset of those used for spectrum management under the R&TTE [i.2], but this does not need to be the case, any more, under the RED [i.1].

It is expected that the parameters that are not included in the HS are available or will be made available to the public in other documents. Technical Bodies writing HSs may consider it appropriate to make reference to 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 HS for the purposes of conformity assessment.

6.4.2 Co-operation with ECC and EC (regulatory environment) / usage of spectrum

ETSI develops 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, an MoU [i.14] has been agreed between ETSI and the CEPT Electronic Communications Committee (ECC), for co-operation in the development of radio technical specifications. In the development of HSs containing technical specifications for radio equipment, the provisions of the ETSI-CEPT/ECC MoU [i.14] will be applied.

The attention of those drafting Harmonized Standards is drawn to the fact that there may be both ECC and EC Decisions.

Harmonized Standards, CEPT/ECC deliverables and Commission Decisions are not expected to contain the same level of technical details.

For further information on ECC and EC deliverables (in particular those developed under Decision 676/2002/EC [i.27]).

- www.ecodocdb.dk;
- http://europa.eu/legislation_summaries/information_society/radiofrequencies/l24218a_en.htm.

6.4.3 Parameters forming the basis of regulation

Certain types of radio equipment have previously been regulated under Directive 98/13/EC [i.8]. Article 5(e) of this Directive required terminal equipment (as defined under Directive 98/13/EC [i.8]) to satisfy 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 [i.2], article 3.2 had a slightly different wording from Directive 98/13/EC [i.8], the technical (and possibly non-technical) specifications elaborating the essential requirements for "effective use of the spectrum so as to avoid harmful interference" were essentially the same as those under Directive 98/13/EC [i.8] for equipment falling within the scope of that Directive.

It is important to note that the essential requirements under the RED are broader than under the R&TTE, in particular in relation to receiver parameters (see, in particular, "Recital" (10) and (11)).

6.4.4 Particular cases

6.4.4.1 Installation of radio equipment

Installation of radio equipment is mentioned by the RED. See recital (30) of the RED [i.1].

6.4.4.2 Antennas

See annex B of the present document and recital (30) of the RED.

6.4.4.3 Antenna mast amplifiers

Antenna mast amplifiers are covered by the RED which addresses receivers and installations.

6.4.4.4 Software Defined Radios (SDRs)

SDRs (and software for SDRs) are the topic of article 3(3)(i) and of article 4 of the RED [i.1].

See also Annex VII of the RED.

This is subject to a delegated act by the EC.

NOTE: Dynamic DoC (Declaration of Conformity) mechanisms (for example directing to a Web-Site for the DoC) have been discussed in meetings of TC-RRS.

6.4.4.5 Radiodetermination equipment

Radiodetermination equipment is explicitly mentioned in the scope of the RED. See clause 4.1.4 of the present document.

6.4.4.6 Chargers

As already stated in clause 4.1.3, article 3(3)(a) of the RED [i.1] can be invoked by the EC to cover interoperability between radio equipment and accessories such as chargers for mobile telephones.

6.4.4.7 Other particular devices

How to handle many other particular cases and particular pieces of equipment has been discussed in TCAM in the past years, and further information can be found on EC web site, in particular in relation to the R&TTE:

- http://ec.europa.eu/enterprise/sectors/rtte/faq/index_fr.htm.

NOTE: There is not yet a similar site for the RED.

6.5 Article 3.3: Additional requirements

The activation of article 3.3 requirements, under the R&TTE Directive, needed an action from the European Commission.

NOTE 1: The existing EC Decisions applicable under the R&TTE will also be applicable under the RED, those Decisions can be found in http://ec.europa.eu/enterprise/sectors/rtte/documents/legislation/decisions/.

Article 3.3 of the R&TTE [i.2] reads:

"*In accordance with the procedure laid down in Article 15, the Commission may decide that apparatus within certain equipment classes or apparatus of particular types shall be so constructed that:*

(a) it interworks via networks with other apparatus and that it can be connected to interfaces of the appropriate type throughout the Community; and/or that

(b) it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; and/or that

(c) it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected; and/or that

(d) it supports certain features ensuring avoidance of fraud; and/or that

(e) it supports certain features ensuring access to emergency services; and/or that

(f) it supports certain features in order to facilitate its use by users with a disability."

Article 3.3 of the RED [i.1] states, in turn, that "*Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:*

(a) radio equipment interworks with accessories, in particular with common chargers;

(b) radio equipment interworks via networks with other radio equipment;

(c) radio equipment can be connected to interfaces of the appropriate type throughout the Union;

(d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;

(e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;

(f) radio equipment supports certain features ensuring protection from fraud;

(g) radio equipment supports certain features ensuring access to emergency services;

(h) radio equipment supports certain features in order to facilitate its use by users with a disability;

(i) radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated."

Under the RED [i.1], "*the Commission shall be empowered to adopt delegated acts in accordance with Article 44 specifying which categories or classes of radio equipment are concerned by each of the requirements set out in points (a) to (i) of the first subparagraph of this paragraph*."

Under the RED [i.1] if the Commission decides that any of the above requirements should be invoked, it will carry out a "delegated act" (see article 44 of the RED [i.1]).

NOTE 2: Article 4 addresses "**Provision of information on the compliance of combinations of radio equipment and software**", which may be used together with the provisions in article 3.3 (i).

7 Guidance for drafting Harmonized Standards

7.1 General drafting considerations

7.1.1 The HS skeleton

Each Harmonized Standard is developed in accordance with the ETSI TWP by the TB which is responsible for the document. The skeleton document [i.16] is available on the ETSI Portal or from ***editHelp!*** (edithelp@etsi.org).

NOTE: At the time of publication of the present document, skeleton documents can be found in:
http://portal.etsi.org/Help/editHelp!/Standardsdevelopment/Drafting/Skeletons.aspx
where the skeleton for the Harmonized Standards can be found in the list.

The skeleton document includes a number of "guidance notes" to assist the drafting of the HS, but these are expected to be removed before publications. Optional text is enclosed in "<..>" symbols. Such text may be retained, modified or deleted as required, but the symbols "<..>" are expected to be removed before publication.

7.1.2 Informative material in HSs

Informative text and illustrations in the main body of the HS or in annexes may be included at the discretion of the TB when it is felt that this improves understanding, and provided that such material is clearly indicated as being informative.

In particular, where the relationship between a requirement or test and the corresponding essential requirement of Directives [i.2] and [i.1] is not self-evident, then an informative annex could be added presenting the rationale for inclusion of the requirement or test.

7.1.3 Material to be avoided in HSs

The TB drafting a HS should avoid including statements beyond ETSI area of competence and so the following should be avoided:

1) Statements referring to the role of national authorities in general, for example indicating that national authorities may relax the standards requirements, ignore them or make them more severe. This limitation does not apply to informative text.

NOTE 1: It is within the rights of national licensing authorities to specify certain parameters such as maximum permitted radiated power, bandwidth, frequency etc. when putting equipment into service.

2) Statements concerning the legal responsibilities or legal roles of parties involved (manufacturers, operators, authorities, etc.).

3) Statements referring to sales restrictions, legal sanctions, obligations for entering the market, ban of sales, contractual arrangements/ relations between parties.

4) Statements imposing obligations outside the scope of the standards, for example an obligation to perform tests in locations defined by non-technical parameters, such as manufacturers' premises or third party laboratories.

5) Statements related to cases of dispute.

6) Statements including dates of regulatory application (when possible).

NOTE 2: If ETSI Technical Bodies find it useful to give advice in such matters, it should be done in separate documents and not be included in the text of standards. This does not apply to information about national transposition of standards.

7) Statements introducing provisional or interim limits or requirements.

8) Statements related to normative information related to other Directives beyond the scope of the HS. However, informative references to such other Directives are permitted provided that no impression is given that compliance with the HS gives a presumption of conformity with any other Directive than the Radio Directives [i.2] and [i.1].

7.1.4 Difficulties with implementation of the present document

Where a TB considers deviation from the present document is necessary or desirable, this fact should be reported to TC ERM, the ETSI Secretariat, and OCG R&TTE.

7.2 Contents of the Harmonized Standard document

7.2.0 Introduction

This clause of the present document contains further guidance for the use of the clauses in the HS EN skeleton document [i.16].

7.2.1 The Title Page and "page 2"

The title should follow the format specified in the skeleton:
https://portal.etsi.org/Services/editHelp!/Standardsdevelopment/Drafting/Skeletons.aspx.

7.2.2 The Contents List

See the ETSI Drafting Rules in the ETSI Directives [i.9].

7.2.3 The "Intellectual Property Rights" clause

The TB drafting the HS has no discretion to change the text of this clause from the text in the skeleton.

7.2.4 The "Foreword" clause

The mandatory wording of the skeleton document should be adhered to so far as it is applicable. Where the HS is part of a multipart EN, text should be included to indicate the relationship between the present part and the other parts of the same document. The TB may include any other relevant non-normative information appropriate to a foreword as explained in ETSI Directives (clause 2.5 of the ETSI Drafting Rules) [i.9].

The transposition table should be included as specified in the skeleton document, but the TB should advise the Secretariat if the default transposition dates are inappropriate for the particular HS.

Major technical (and possibly non-technical) changes since previous versions of the deliverable may be highlighted at this stage.

7.2.5 The "Introduction" clause

The standard text in the skeleton document should be included. The TB may include any other appropriate information in the introduction as as explained in ETSI Directives (clause 2.8 of the ETSI Drafting Rules) [i.9].

7.2.6 The "Scope" clause

The Scope statement limits what equipment can claim presumption of conformity under the HS. The TB should exercise considerable judgement over the way the scope is defined. As noted elsewhere in the present document, the standard should remain as technology independent as possible, should be defined without undue limitation of application, should be as general in operating frequencies as possible, and should not address national or other regulatory restrictions.

There should be the minimum number of HSs, each one having the widest possible product application. One HS is typically applicable to different types of equipment sharing similar characteristics.

7.2.7 The "References" clause

See the ETSI Directives (clauses 2.13 and 8.4 of the ETSI Drafting Rules) [i.9] for the requirements on normative and informative references in Harmonized Standards.

7.2.8 The "Definitions, Symbols and abbreviations" clause

See the ETSI Directives (clause 2.11 of the ETSI Drafting Rules) [i.9] for the requirements on normative and informative references in Harmonized Standards.

ITU Radio Regulations [i.26] provides many terms and definitions for the characteristics of emissions and radio equipment. There may be requirements in the ITU Radio Regulations [i.26] which use these terms and definitions. It therefore could be necessary to use the same terms and definitions in the ETSI Harmonized Standards.

Therefore, where possible, definitions from the ITU Radio Regulations [i.26] should be used. If there is not a definition in the ITU Radio Regulations [i.26], wherever possible, existing definitions in the ETSI TEDDI [i.25] or ETSI TR 103 265 [i.24] and those for receiver parameters in ETSI TR 102 914 [i.18], and those from relevant EC and ECC documentation should be used rather than creating new ones.

Note that many radio definitions are currently not part of TEDDI since TEDDI only includes definitions from clause 3 of the ETSI deliverables, and the definitions in many ETSI Harmonized Standards are not in clause 3. Therefore it may also be necessary to consult Harmonized Standards for similar products to find the desired definitions; ETSI TR 103 265 [i.24] includes a large number of definitions found in clauses addressing "Technical requirements" in ETSI Standards.

A total harmonization of definitions may not be possible, for example, because the definition is specific to a certain group of equipment or because it is desired to keep the same definition as a base standard developed in another standardization development organization.

It is important to note that while general definitions can be usually found in clause 3, the definitions corresponding to the parameters addressed in the Harmonized Standard are often found in clauses addressing "Technical requirements", as shown in clause E.1, see also clause 7.2.9.

It is important that a term is used consistently throughout and is only defined in one place in a document.

7.2.9 The "Technical requirements specifications" clause

For formulation of technical (and possibly non-technical) requirements see clause 6.

The preferred structure is shown in the skeleton document [i.16] and in annex E.

Every technical (and possibly non-technical) requirement in a HS for application under the Directives [i.2] and [i.1] should relate to one or more essential requirements of the Directives [i.2] and [i.1].

Every technical (and possibly non-technical) requirement should be expressed so as to be capable of objective verification. However, it is not mandatory that the method of verification be explicitly defined in the HS unless the outcome is considered dependent upon the method of verification or evaluation.

Should manufacturers choose not to apply parts of a HS, then for the parts omitted, the provisions of article 10.5 of Directive 1999/5/EC [i.1] or article 17.4 of the RED [i.1] apply. This does not preclude the possibility of a HS having within it alternative technical solutions for meeting an essential requirement. It is recommended that alternative technical (and possibly non-technical) solutions should be identified (by letters or numbers or by separation of the HS into parts) within HSs, to simplify conformity declaration, licensing and surveillance.

Harmonized Standards not for Marine Radio Communication Equipment covered by Commission Decision 2004/71/EC [i.23] should use the following guidance:

- A standard "Environmental Profile" clause should be included which indicates that technical requirements should be met throughout the environmental range indicate by the manufacturer. Explicit environment conditions should not be specified in the HS.

Harmonized Standards for Marine Radio Communication Equipment covered by Commission Decision 2004/71/EC [i.23] should use the following guidance:

- An "Environmental Profile" clause should be included which indicates that technical requirements should be met throughout the environmental range indicated by the manufacturer, but as a minimum, is expected to be that specified in the test conditions contained in the Harmonized Standard.

Air Traffic Management (ATM) ground radio equipment is presently under the R&TTE Directive [i.2] (and ETSI has been working on it under the Commission Mandate M/405); ETSI TR 102 579 [i.28] provides guidance for the production of Community Specifications for application of Interoperability Regulation EC 552/2004 [i.29].

Radio equipment subject to RED may not be permitted to be operated on board an aircraft. This equipment may require EASA certification or aircraft operator approval before being used onboard an aircraft.

NOTE 1: All airborne equipment that is intended to be used for the operation or control of the aircraft is excluded from the scope of the RED.

This clause should define the "conformance requirements" - which is the set of individual technical requirements (including limiting values of parameters where applicable) which are necessary and sufficient to meet the essential requirements referred to in the Scope clause.

NOTE 2: The preferred method of clearly separating the technical requirements which have to be met from the method of testing for compliance with those requirements is to have separate top-level clauses entitled "Technical requirements specifications" and "Testing for compliance with technical requirements". Historically, some HSs have interleaved "requirements" and "test procedures". Where there is a strong argument to adopt or retain this approach, then it remains acceptable provided that a sharp and clear distinction between "requirement" and its "test procedure" is maintained.

The technical (and possibly non-technical) requirements (including any limiting values of parameters) may be specified in any of the following ways at the discretion of the TB:

a) Explicit stand-alone complete specification of the requirement.

b) Reference to one or more explicitly identified clauses through a normative reference, in which case the ETSI Drafting Rules for the use of normative references in Harmonized Standards apply.

c) A combination of a) and b) above.

EXAMPLE: Where the technical requirement is described elsewhere but the limiting values are defined explicitly in the HS.

In all cases, clause numbering should be such that individual technical (and possibly non-technical) requirements may be unambiguously referenced as there is need for specific test specifications to be related to specific requirements both within the body of the HS and within the HS-RTT annex.

Annex E provides examples of structures for the technical requirements specifications clauses.

See also clause 7.2.8 on definitions.

7.2.10 The method of measurements and "Testing for compliance with technical requirements" clause

The preferred structure is shown in the skeleton document.

Where alternative test methods are provided, the principle should be that compliance with the requirements may be demonstrated by either or any of the methods described in the Harmonized Standard.

Harmonized Standards for Marine Radio Communication Equipment covered by Commission Decision 2004/71/EC [i.23] should include the "Environmental conditions for testing" clause in the skeleton document which indicates that testing should be carried out at representative points within the boundary limits of the declared operational environmental profile which, as a minimum, is expected to be that specified in the test conditions contained in the Harmonized Standard. As technical performance varies subject to environmental conditions, tests are expected to be carried out under a sufficient variety of environmental conditions as specified in this HS to give confidence of compliance for the affected technical requirements. These environmental conditions represent those required by article 2 of EC Decision 2004/71/EC [i.23] (which should also be within the boundary limits of the declared operational environmental profile)".

For other Harmonized Standards, the standard "Environmental profile" clause as shown in the skeleton document [i.16] should be included. This indicates that testing should be carried out at representative points within the boundary limits of the environmental profile but makes no reference to explicit environmental limits.

For HSs addressing article 3.2 of the R&TTE Directive [i.2], the test specifications were expected to indicate whether it falls within the Essential Radio Test Suite (see annex III of the R&TTE Directive [i.2]). The preferred method of achieving this was to list all such test specifications under an "Essential Radio Test Suite(s)" clause heading with all other test specifications listed under an "Other test suite(s)" heading. The RED [i.1] does not lead to a need of making such a separation.

Where compliance with the specification requires the value of a parameter to be assessed, the responsible ETSI TB writing the HS should consider whether the value obtained may vary according to the method of measurement employed.

The measurement method should be defined in the minimum detail required to ensure reproducibility of results between different laboratories. This could be done by dated reference to other relevant standards. However it should be made very clear what requirements (or tests) are considered included in the HS. Tests and test methods should not be identified in themselves as technical requirements. Methods of measurement providing the numerical value for the parameter being measured are preferred to methods providing as a result just a binary value "pass" or "fail" (i.e."tests").

Where a test is needed to determine whether equipment meets the technical requirement, that test should be specified unambiguously within the HS. This test may be specified in any of the following ways at the discretion of the TB:

a) Explicit stand-alone complete specification of the test method and procedure.

b) Reference to one or more explicitly identified clauses through a normative reference, in which case the ETSI Drafting Rules for the use of normative references in Harmonized Standards apply.

c) A combination of a) and b) above.

Test specifications may be described in non-harmonized standards. Such standards may be normatively referenced within a HS for the purpose of defining relevant test specifications.

Where testing for compliance requires measurement, the issue of interpretation of measurement results and maximum measurement uncertainty should be addressed. The preferred method of addressing this topic is shown in the skeleton document as a separate clause with appropriate text and with a table indicating the maximum measurement uncertainty for each relevant parameter. However, alternative means of addressing this may be adopted by the TB. For example, the matter can be addressed in a referenced document or the uncertainty may be addressed in the individual test suite clauses described below.

Measurement uncertainties are calculated in accordance with ETSI TR 100 028 [i.13]. The maximum acceptable level of measurement uncertainty is expected to be specified.

HSs should be written on the assumption that interpretation of the measurement results is in accordance with the principles contained in ETSI TR 100 028 [i.13].

7.2.11 The "Abstract Test Suite" clause

HSs may choose to define abstract test suites using TTCN notation. For those cases, the preferred method for introducing and presenting such test suites in TTCN Graphical or Machine processable forms is indicated in the skeleton document.

7.2.12 The " HS Requirements Table (HS-RT) Table" annex

The HS are expected to include an annex comprising an HS-RT table which lists all technical (and possibly non-technical) requirements and relates all test specifications to them. HSs in support of the R&TTE Directive [i.2] include an HS-RTT (HS Requirements and conformance Test specifications) table.

This annex should follow or be a super-set of the skeleton document. The initial version of the HS-RTT table annex as included in the skeleton document for the R&TTE Directive [i.2] has been simplified for the RED [i.1] and is reproduced as annex F to the present document. The completed annex is expected to be included as the first normative annex of the HS.

The purpose of this annex is to provide a consistent, concise set of references to all technical (and possibly non-technical) requirements and to their corresponding test specifications. Where a technical requirement depends upon conditions, this should also be clarified in this annex.

The annex is made available to be used as a check list when considering the compliance of particular equipment and therefore the copyright generally associated with ETSI deliverables is lifted for this annex of the HS.

The HS-RT should be completed by the TB so that it provides a standard means of:

- identifying all the technical (and possibly non-technical) requirements in words and by cross reference to a specific clause in the present document or to a specific clause in a specific referenced document;
- identifying any test procedure corresponding to each technical requirement by cross reference to specific clause(s) in the HS itself or to specific clause(s) in specific referenced document(s).

Where the scope of the HS includes different equipment types (for example a portable handset and a corresponding base station), it is preferred that separate HS-RTs be included for each equipment type.

NOTE: In the case where the main body clauses of the HS dealing with "Technical Requirements" and "Testing for compliance" comprise nothing but references to other documents, it is possible that those references could appear in the HS-RT and the clauses could be reduced to the environmental matters and a reference to the HS-RT.

7.2.13 Translation of the titles into the official languages

Translations of the titles of the Harmonized Standard into all languages of the member states of the European Union and of EFTA can be consulted using the "e-Approval Application".

An annex with such information is no longer part of the skeleton document.

7.3 Effects on the Harmonized Standards of the transition from the R&TTE to the RED

7.3.0 Introduction

The R&TTE Directive is repealed by article 50 of the RED:

> *"Article 50* ***Repeal***
>
> *Directive 1999/5/EC is repealed with effect from 13 June 2016.*
>
> *References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VIII."*

For completeness of the present guide, table VIII of the RED [i.1] can be found as annex A.

Article 48 of the RED provides the transitional provisions:

> *"Article 48* ***Transitional provisions***
>
> *Member States shall not impede, for the aspects covered by this Directive, the making available on the market or putting into service of radio equipment covered by this Directive which is in conformity with the relevant Union harmonisation legislation applicable before 13 June 2016 and which was placed on the market before 13 June 2017."*

7.3.1 Naming/numbering of Harmonized Standards

In order to allow a better consistency and a smooth transition from the R&TTE to RED regime, the numbering of the Harmonized Standards should not be changed due to the change from R&TTED to RED. The relevant changes (e.g. the inclusion of the appropriate receiver parameters) can be made in new revisions of the HS and made visible thanks to the version numbering (possibly incrementing "m", the "major version number" (see annex B (normative): "Numbering of deliverables", in ETSI Technical Working Procedures (i.e. page 126 in the version of 19 September 2013)); the "major version number" has often been used, so far, to indicate a new "release" of the HS).

In the text, e.g. in the title, of the Harmonized Standard, the Directive referenced will be changed when changing from the R&TTE Directive to the RED.

According to a recent clarification from the EC, the same version of a Harmonized Standard addressing article 3.2 cannot be cited in the OJEU under both the R&TTE Directive and RED ("because the Essential Requirements are different").

Concerning version numbeing schemes during the transition period, see clause 7.3.3.

7.3.2 Effect of the change from the R&TTE to the RED

7.3.2.1 Choice of the parameters

Article 3(2) of the RED [i.1] has been clarified so as to ensure that it includes requirements for the performance of radio receivers and in article 2(1) of the RED [i.1], radio equipment has been defined as follows:

"*'radio equipment' means an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination …/…*".

Article 3(2) of the RED [i.1] also addresses explicitly the use of radio spectrum "*Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference*".

7.3.2.2 Value of the parameters

Article 3(2) of the RED [i.1] addresses explicitly the need for an efficient use of radio spectrum "*Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference*".

7.3.3 Transposition dates, Transition periods and effect on new (versions of) Harmonized Standards

As the RED [i.1] had already been published at the time of publication of the present version of the present Guide, new Harmonized Standards and new versions of already published Harmonized Standards are expected to be written in view of the RED [i.1], (i.e. taking into account, in particular, the revised Scope and the revised Essential Requirements of the RED [i.1]), and to follow the guidance provided in the present document for HSs written for the RED.

Whenever convenient, Technical Bodies may consider revising the current standards (under the R&TTE Directive [i.2]) into a new version under the RED, taking into account the fact that for the purpose of market surveillance of equipment assessed and deployed under the R&TTE [i.2] regime the relevant versions will continue to be used, as appropriate.

While there is a need for flexibility in the numbering of the versions of the Harmonized Standards in order to deal with specific situations, it is also desirable to have a certain level of coherence: there are many users who handle ETSI standards for different products (test houses, frequency managers, surveillance authorities, even the European Commission). If every TB "organize the numbering scheme in their own way", it becomes difficult to maintain any form of coherence, and the body of ETSI standards become more difficult to use.

Therefore, possible numbering schemes are proposed below. Others might be envisaged by the relevant TBs in order to take into consideration specific needs.

7.3.4 Particular case of HSs being drafted at the time of publication of the RED

In the general case, it can be considered that technical (and possibly non-technical) requirements covering the Essential Requirements found in article 3.2 of the R&TTE [i.2] are comparable to or a sub-set of the technical (and possibly non-technical) requirements covering from the Essential Requirements found in article 3.2 of the RED [i.1].

More precisely, it can be expected that a HS covering the Essential requirements of article 3.2 of the RED [i.1] will include, in particular, requirements corresponding to receiver parameters and installations (when appropriate), requirements in support of the efficient use of radio spectrum and possibly also requirements in support of spectrum sharing (see, in particular, recitals 10, 11, 30 and 60 of the RED [i.1]).

Therefore, a HS written for the RED [i.1] could with "only minor" changes become also a HS for the R&TTE [i.2] Directive.

Hence a possible way forward, during the transition period, for the particular case of HSs being drafted at the time of publication of the RED [i.1] (and also at the time of drafting of version 3.1.1 of the present guide):

- to draft v <n>.1.1 of an HS for publication under the R&TTE [i.2];
- to draft v <n+1>.1.1 of the same HS (i.e. same HS number) for publication under the RED [i.1];

where, typically, n would have been equal to 1 for the very first time a Harmonized Standard would have been published.

Presumably between these two versions, there would be:

- a change of title (and possibly in the wording of Sections relating to it, possibly Foreword, Scope, etc.);
- a change in the wording of annex A - the HS-RT(T) table (see annex F of the present document);
- possibly changes of dates (d.o.w., etc.); and
- perhaps, some changes of the technical parameters included (and the corresponding limits).

As a result, ETSI would propose to the Commission:

- a listing of standards for citation under the R&TTE [i.2] Directive which would include version <n>.1.1 of the HS; and
- a listing for citation under the RED [i.1] which would include version <n+1>.1.1 of the HS.

7.3.5 Particular case of HSs being revised at the time of publication of the RED

For the reasons detailed in the section above, a possible way forward, during the transition period, for the particular case of HSs being revised at the time of publication of the RED [i.1] (and also at the time of drafting of version 3.1.1 of the present guide) is:

- to draft v <n>.p.q of an HS for publication under the R&TTE [i.2];
- to draft v <n+1>.p.q of the "same HS" (i.e. same HS number) for publication under the RED [i.1].

Annex A:
"Correlation table"

The source material for the table provided in this annex can be found in annex VIII of the RED [i.1].

Table A.1

Directive 1999/5/EC [i.2]	This Directive (i.e. the RED: 2014/53/EU) [i.1]
Article 1	Article 1
Article 2	Article 2
Article 3 (1) and (2)	Article 3 (1) and (2)
Article 3 (3) and Article 15 a	Article 3 (3), with the exception of Article 3 (3) (i) and Article 44
Article 4 (1) and Articles 13 to 15	Articles 8 and 45
Article 4 (2)	- -
Article 5 (1)	Article 16
Article 5 (2) and (3)	--
Article 6 (1)	Article 6
Article 6 (2)	--
Article 6 (3)	Article 10 (8), (9) and (10)
Article 6 (4)	--
Article 7 (1) and (2)	Article 7
Article 7 (3), (4) and (5)	--
Article 8 (1) and (2)	Article 9
Article 8 (3)	--
Article 9	Article 39 to 43
Article 10	Article 17
Article 11	Article 22 to 38
Article 12	Article 19 and 20 and Article 10(6) and (7)
Article 16	--
Article 17	Article 47
Article 18	Article 48
Article 19	Article 49
Article 20	Article 50
Article 21	Article 51
Article 22	Article 52
Annex I	Annex I
Annex II	Annex II
Annex III	--
Annex IV	Annex III
Annex V	Annex IV
Annex VI	Article 26
Annex VII (1) to (4)	Articles 19 and 20
Annex VII (5)	Article 10 (10)

Annex B:
Technical parameters and essential requirements

B.1 Typical technical requirements

Tables B.1 to B.3 provide a non exhaustive list of technical requirements (phenomena/parameters) associated with specific essential requirements that should be considered by ETSI technical bodies.

Table B.1

Essential Requirement	Phenomena
3.1 (a)	Requirements regarding the protection of the health and safety of the user and any other person are described in clause 6.2.
3.1 (b)	Requirements for EMC are already identified in a number of published EMC Harmonized Standards and are described in clause 6.3.

Table B.2

Essential Requirement	Phenomena
3.2 (Transmitting)	Frequency error/stability, and designation of channels Transmitter power Adjacent channel power Spurious emissions Inter-modulation attenuation Attack time Release time Transient behaviour of the transmitter Modulation Accuracy Duty cycle
3.2 (Directional characteristics of radio equipment)	Off-axis EIRP density Antenna gain Antenna X-polar discrimination Antenna pointing accuracy/control Active antenna spurious emissions (see guidance from TCAM below this table)
3.2 (Receiving)	(Maximum usable) sensitivity (inc. duplex) Co-channel rejection Adjacent channel selectivity Spurious response rejection (inc. duplex) Inter-modulation response rejection Blocking or desensitization (inc. duplex) Spurious emissions Multipath sensitivity

Essential Requirement	Phenomena
3.2 (TDM: CDM: Software, Control and Monitoring Functions and protocols)	Enabling Signalling Sharing Protocols Network interface bit errors Error control by coding and decoding of logical channels Logical channel arrangement Control of communication in logical channels Correct interpretation of Network control information Network interface addressing Control of basic link communication Control of random access Control of radio resource allocation Monitoring functions for cell selection Control functions for usage of cells Control of group attach/detach Tx enable/disable control Tx Call set up control Control of call maintenance Control of call disconnect Authentication control Encryption control procedures
NOTE: See also clauses 6.1.3 and 6.4.	

Table B.3

Essential Requirement	Phenomena
3.3	Currently there are some essential requirements defined under article 3.3 covered in Harmonized ENs.
NOTE: See clause 6.5.	

B.2 Antenna requirements and assessment

B.2.1 Background

The RED does not explicitly include "relevant components" of radio equipment that were explicitly included in the R&TTED scope; however, some may still be relevant to the "essential requirement".

Typical examples are antennas for some radio systems (e.g. radio systems applications in the fixed service, where the antenna directivity plays significant role in the "efficient use of the spectrum").

Therefore, whenever directional requirements are considered relevant techical phenomena, it is assumed that the radio system should be assessed as a whole with its antenna.

Antennas can be "passive" (i.e. without electronic components inside as are e.g. common parabolic dish in P-P applications) or "active" (i.e. containing electronic circuitry for e.g. beam forming features). While passive antennas affect only "directional" phenomena, active antennas may affect also transmitting and/or receiving phenomena (e.g. spurious emissions, intermodulation attenuation or blocking).

Also, antennas can be "integral/integrated" or "dedicated" (see note 1) to the radio equipment (i.e. they are generally supplied by the same equipment manufacturer, even if designed and manufactured by a different company) or can be "stand alone" (with standard antenna port interface in waveguide or coaxial connections; typical for large antennas); in the latter case, provided that, in most cases, radio equipment and antenna manufacturers are different, the user is free to buy them separately on the market.

NOTE 1: In this text "integral" or "integrated" means an antenna that is not physically separable from the equipment, unless it is returned to the manufacturer premises. "Dedicated" means an antenna specifically designed for being attached to the radio equipment (i.e. with special mechanical fixing), but can be separated from the equipment (typically for transport purpose) using normal tools.

NOTE 2: Version 2.2.1 of the present document provides more information on the situation under the R&TTE regime.

B.2.2 Guidelines

If the TB considers that there is a reasonable risk of failure to meet the essential requirements due to undefined antenna characteristics, they may include antenna requirements within the radio equipment HS.

Those requirements may be directly defined in the equipment HS or can be separately defined in a specific ETSI EN, which is referred in the normative references of the equipment HS.

Equipment using active antennas are assumed to be assessed together, unless the TB would define another suitable procedure for guaranteeing that the essential requirements are met.

Directional requirements of passive antennas are also assumed to be part of the equipment assessment as follows:

- When integral/integrated or dedicated typology is concerned (i.e. equipment and antenna are supplied through the same supplier) the assessment of directional requirement in the HS would be included in the radio equipment assessment and the relevant declaration of conformity. Equipment and antenna manufacturers are assumed to establish a commercial agreement for defining the mutual responsibilities towards the RED provisions and market surveillance procedures.

- When equipment is sold without an antenna (i.e. the user may separately purchase antenna on the market), the equipment would still meet the essential requirements only if attached to an antenna that respects the directional requirements of the HS.
  RED article 17.1 states, inter alia, that "*the assessment shall take into account all intended operating conditions*" and article 10.8 says that "*Manufacturers shall ensure that the radio equipment is accompanied by instructions and safety information. Instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components……."*; moreover annex VI of the RED, describing the content of declaration of conformity, specifically mentions that *"Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended;"*
  Therefore, when applicable, the HS should require that the equipment manufacturer takes appropriate measures to ensure that only compliant antennas are used.

Article 50 of the RED [i.1] calls for a certain continuity. It is also noted that installations are mentioned in the RED and in the Blue Guide [i.20].

Annex C: Background

C.1 The legislative background

C.1.1 The "New approach"

The most significant aspect of the introduction of the R&TTE Directive [i.2] was that it conformed originally to the EC Council Resolution of 7 May 1985 [i.10]. It was introduced in order to support a market-led approach into the Radio and Telecommunications Terminal Equipment sector, and removed the regime of type approvals. Conformity with the Essential Requirements in article 3 of the R&TTE Directive [i.2] became by manufacturer's declaration, and could be based on Harmonized Standards (or using other means).

C.1.2 The "NLF" Decision

"This Decision sets out the common framework of general principles and reference provisions for the drawing up of Community legislation harmonizing the conditions for the marketing of products (Community harmonization legislation)" (quote from article 2, "Subject matter and scope" of the NLF Decision [i.31]).

C.1.3 The "Framework Directive"

The Framework Directive and its evolution:

Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive) [i.32] has, in the mean time, been modified as follows:

- Regulation (EC) 717/2007 [i.46];
- Regulation (EC) 544/2009 [i.47];
- Directive 2009/140/EC [i.48].

Article 2(7) of the RED defines harmful interference through point (r) of article 2 of Directive 2002/21/EC [i.32] through the amendments found in Directive 2009/140/EC [i.48].

C.2 Scope of the Radio Directives

C.2.1 R&TTE Directive

The R&TTE Directive [i.2] covers apparatus that is either TTE or RE, as defined in its articles 2(b) and 2(c), or that is both TTE and RE (for example, cellular phones).

TTE was previously covered by Directive 98/13/EC [i.8], although there are differences in the definition of "TTE" between the two Directives.

RE was not previously covered by a specific Directive, although there were provisions on RE included in the EMC Directive [i.6].

For the products within its scope, the R&TTE Directive [i.2] 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 Directives are taken over into the R&TTE Directive [i.2], although the manufacturer has the option of using the procedures in these earlier Directives, for equipment which falls within their scope (R&TTE Directive [i.2], article 10.2), as a means to demonstrate conformity to the requirements of articles 3.1(a) and 3.1(b) in the R&TTE Directive [i.2].

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.

C.2.2 RED

The scope of the RED can be found in clause 4.1.4.

C.3 Implications for Telecommunications Terminal Equipment (TTE)

C.3.1 R&TTED

The definition of TTE given in the R&TTE Directive [i.2] 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 [i.8], article 1.2, interworking with the network is not part of the definition for indirectly connected terminals.

Under the R&TTE Directive [i.2], TTE is no longer subject to type approval. Products can be placed on the market under the responsibility of the manufacturer. The manufacturer makes a Declaration of Conformity to the essential requirements of the Directive, and is expected to keep this declaration, together with supportive product technical documentation, as outlined in R&TTE Directive [i.2] 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 [i.2], article 10.3 allows manufacturers 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.

Manufacturers are responsible for ensuring that each item of TTE produced meets the essential requirements. If a manufacturer has an accredited full quality assurance system, R&TTE Directive [i.2], article 10.3 allows annex V to be used, instead of annex II or IV, at the manufacturer's choice.

There is no simple relationship between the "new" essential requirements of the R&TTE Directive [i.2] and the "old" essential requirements applied to TTE under Directive 98/13/EC [i.8], except for satellite earth stations, for which the essential requirements are effectively the same.

Article 6.3 of the R&TTE Directive [i.2] addresses the information to be provided to the user of the equipment.

C.3.2 RED

TTE equipment is not within the scope of the RED [i.1].

Requirements related to the declaration of interfaces for TTE equipment are within the scope of Directive 2008/63/EC [i.49]. Product requirements are covered by the EMC and LVD.

C.4 Implications for Radio Equipment (RE)

C.4.1 R&TTE Directive

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

"*Radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference*" (article 3.2 of [i.2]), where harmful interference is 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 are required by article 6.4 of the R&TTE Directive [i.2] to 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 are required by annex III of the R&TTE Directive [i.2] to be carried out for the product. If the test suites are not defined in Harmonized Standards, article 10.5 of the R&TTE Directive [i.2] applies. The manufacturer's Declaration of Conformity to the essential requirements is expected to state that the essential radio transmitter tests have been carried out.

Article 6.3 of the R&TTE Directive [i.2] addresses the information to be provided to the user of the equipment.

C.4.2 RED

Under the RED [i.1] a few differences have been introduced in particular:

- regarding the 'relevant components' (e.g. some cases of directional antennas) which has now been specifically not included in the RED;
- inclusion of receivers, including broadcast receivers (and therefore, the corresponding receivers parameters);
- inclusion of radiodetermination equipment;
- inclusion of provisions for Software Defined Radios.

More precisely, the definition of "radio equipment" under the RED is as follows:

"*(1) 'radio equipment' means an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination;*".

C.5 Equipment classes and equipment class identifiers

The definition of Equipment Class given in the R&TTE Directive [i.2] 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".

This is further elaborated in the guide to the R&TTE Directive [i.21], where section 4 covers "equipment classes".

(See http://ec.europa.eu/enterprise/sectors/rtte/files/guide2009-04-20_en.pdf).

Equipment Class Identifiers are assigned by the Commission after consultation of TCAM (R&TTE Directive [i.2], article 4.1). R&TTE Directive [i.2], article 12.1 states, "*Radio equipment shall in addition be accompanied by the equipment class identifier where such indentifier 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.

Article 3.3 of the R&TTE Directive [i.2] states: "*In accordance with the procedure laid down in article 15, the Commission may decide that apparatus within certain equipment classes or apparatus of particular types shall be so constructed that*" it meets the additional essential requirements 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.

The concept of equipment classes has been further developed by TCAM. CEPT/ECC WG RR has also been involved in this work.

Commission decision 2000/299/EC of 6 April 2000 [i.19] further elaborates on this topic.

Further information on the various sub-classes may be found on the web site of ECO:

- www.ecodocdb.dk.

As the concept of equipment classes and sub-classes has been used in conjunction with the R&TTE Directive [i.2], is it recommended that other terms are used when making categorization of equipment. For example, the term "Receiver category" has been used in ETSI EN 300 220 [i.50] (in particular in ETSI EN 300 220-1 V2.2.1) in order to avoid confusion.

NOTE: The RED does not explicitly address classes and sub-classes as the R&TTE Directive did.

C.6 Notified interfaces

C.6.1 R&TTED

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 [i.2], article 4.1). Under Directive 98/34/EC [i.12] 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 necessarily be published in the OJEU, would not relate necessarily to essential requirements under the R&TTE Directive [i.2], and hence would possibly not be Harmonized Standards within the meaning of the present document.

As a result of the TCAM-RSCom RIG II group, a template to describe such interfaces has been defined: it is the Radio Interface Specification (RIS) template.

C.6.2 RED

With the RED [i.1] there is no change in this aspect.

C.7 Specification of interfaces offered by public telecommunications operators

C.7.1 R&TTED

Public Network Operators are expected to be obliged by their Member State's legislation to publish technical specifications of the interfaces that they offer to telecommunications terminal equipment before they provide the corresponding services (R&TTE Directive [i.2], article 4.2). "*The specifications shall be in sufficient detail to permit the design of telecommunications terminal equipment capable of utilising all services provided through the corresponding interface.*" Although it may be helpful to the operators if European standards were to be produced for certain interfaces, such standards would not necessarily be published in the OJEU under the R&TTE Directive [i.2], would not necessarily relate to essential requirements under the R&TTE Directive [i.2], and hence would possibly not be Harmonized Standards for application under the R&TTE Directive [i.2] within the meaning of the present document.

Please note that further historical information in this area can be found in the previous version of the present document, i.e. in its version 2.2.1.

C.7.2 RED

The RED [i.1] does not address TTE equipment.

Under the RED, there is no need for operators to declare their interfaces (as was the case in article 4.2 of the R&TTE Directive). These requirements are covered by Directive 2008/63/EC [i.49].

C.8 Other relevant Directives for radio equipment

Table C.1 shows key dates relating to both the RED and other Directives that manufacturers may have to take into consideration when designing equipment.

See also clause 4.1.6.

Table C.1: Key Directives for radio equipment

Directive "nick name":	"Old Directive" (repealed)	"Old Directive" repealed on:	New version (or "new Directive")	Date of publication (+ other relevant docs)	"New Directive": date of entry into Force (etc.)	Comments
R&TTE ➔ RED ("Radio Equipment" Directive)	**1999/5/EC:** **« R&TTE »** Directive	*Article 50 Repeal:* *2 years after EIF ➔ Directive 1999/5/EC is repealed with effect from 13 June 2016.* "References to the repealed Directive shall be construed as references to this Directive … table in Annex VIII."	**RED** (approved by the EP in March and Council in April) **2014/53/EU** of **16 April 2014** **(see 2012/0283 (COD))**	publication on the OJ 22 May 2014 (see also Decision 676/2002/EC [i.27] and Directive 2002/21/EC [i.32] (as modified))	*Article 49* *Transposition;* *(2 years after EIF) ➔ before 12 June 2016* *to be applied by:* *13 June 2016* *Article 51* *Entry into force:* twentieth day following that of its publication	TV equipment no longer excluded from the Scope by Annex I **Essential requirements** to be found in Art 3 (**3.2 ➔ "radio HSs")**
EMC Directive It addresses the various environments for equipment	2004/108/EC [i.7] (that already repealed Directive 89/336/EEC see whereas #1)	Directive 2004/108/EC [i.7] is repealed with effect from 20 April 2016 (Art 45)	**2014/30/EU** **of** **26 February 2014**	29.3.2014	twentieth day following that of its publication (Article 46)	Essential Requirements to be found in Annex I. Covers explicitly **installations**
LVD ("Low Voltage" Directive)	2006/95/EC [i.5]	Directive 2006/95/EC [i.5] is repealed with effect from 20 April 2016 (Art 27)	**2014/35/EU** **of** **26 February 2014**	29.3.2014	twentieth day following that of its publication (Article 28)	**Topic:** protection of health and safety of persons, and of domestic animals and property

Table C.2

Directive "nick name":	Scope	Annex I	Implications
RED ("Radio Equipment" Directive) **2014/53/EU**	*Article 1* **Subject matter and scope** *1.This Directive establishes a regulatory framework for the making available on the market and putting into service in the Union of radio equipment.* *2.This Directive shall not apply to equipment listed in Annex I.* *3.This Directive shall not apply to radio equipment exclusively used for activities concerning public security, defence, State security …/…* *4.Radio equipment falling within the scope of this Directive shall not be subject to Directive 2014/35/EU [i.e. the LVD], except as set out in point (a) of Article 3(1) of this Directive.*	*ANNEX I* ***EQUIPMENT NOT COVERED BY THIS DIRECTIVE*** *1.Radio equipment used by radio amateurs …/…* *2. Marine equipment falling within the scope of Council Directive 96/98/EC [i.42] (1).* *3. Airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 [i.44] …/…* *4. Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.*	The RED, in particular: - covers broadcast equipment as "all" other radio equipment (as specified in the Scope) - addresses receiver and transmitter parameters in a more balanced way than the R&TTE Directive - paves the way to the usage of common chargers …
EMC **2014/30/EU**	*Article 2* ***Scope*** *1. This Directive shall apply to equipment as defined in Article 3.* *2. This Directive shall not apply to: …/…* *Article 3* ***Definitions*** *1. For the purposes of this Directive …/…* *(1) 'equipment' means any apparatus or fixed installation;* *(2) 'apparatus' means …/…*	*ANNEX I* *ESSENTIAL REQUIREMENTS* *1.* ***General requirements*** *Equipment shall be so designed and manufactured, …/… as to ensure that:* *(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications …/… cannot operate as intended;* *(b) it has a level of immunity to the electromagnetic disturbance …/…* *2.* ***Specific requirements for fixed installations*** *…/…* *A fixed installation shall be installed applying good engineering practices …/…*	Installations are to be handled with care as it may be insufficient to use individual pieces of equipment that comply with the EMC Directive in order to obtain an installation complying with the EMC Directive ((EMC Compliant) + (EMC Compliant) =/=> (EMC Compliant)).

Annex D:
The modular nature of ETSI's R&TTE and RED Harmonized Standards

D.0 General

NOTE: In the figures below, some of the Harmonized Standards shown have been published by different organizations (for example, CENELEC, in the case of article 3.1(a)).

D.1 Under the R&TTE

NOTE: The following text has been adapted (and brought up to date) from standard introductory text which appeared in early Harmonized Standards. Although it is no longer felt desirable to include this text in every such standard the principles are still valid.

ETSI HSs are designed to fit in a modular structure to cover all radio and telecommunications terminal equipment under the R&TTE Directive [i.2]. Each standard is a module in the structure. The modular structure is shown in figure D.1.

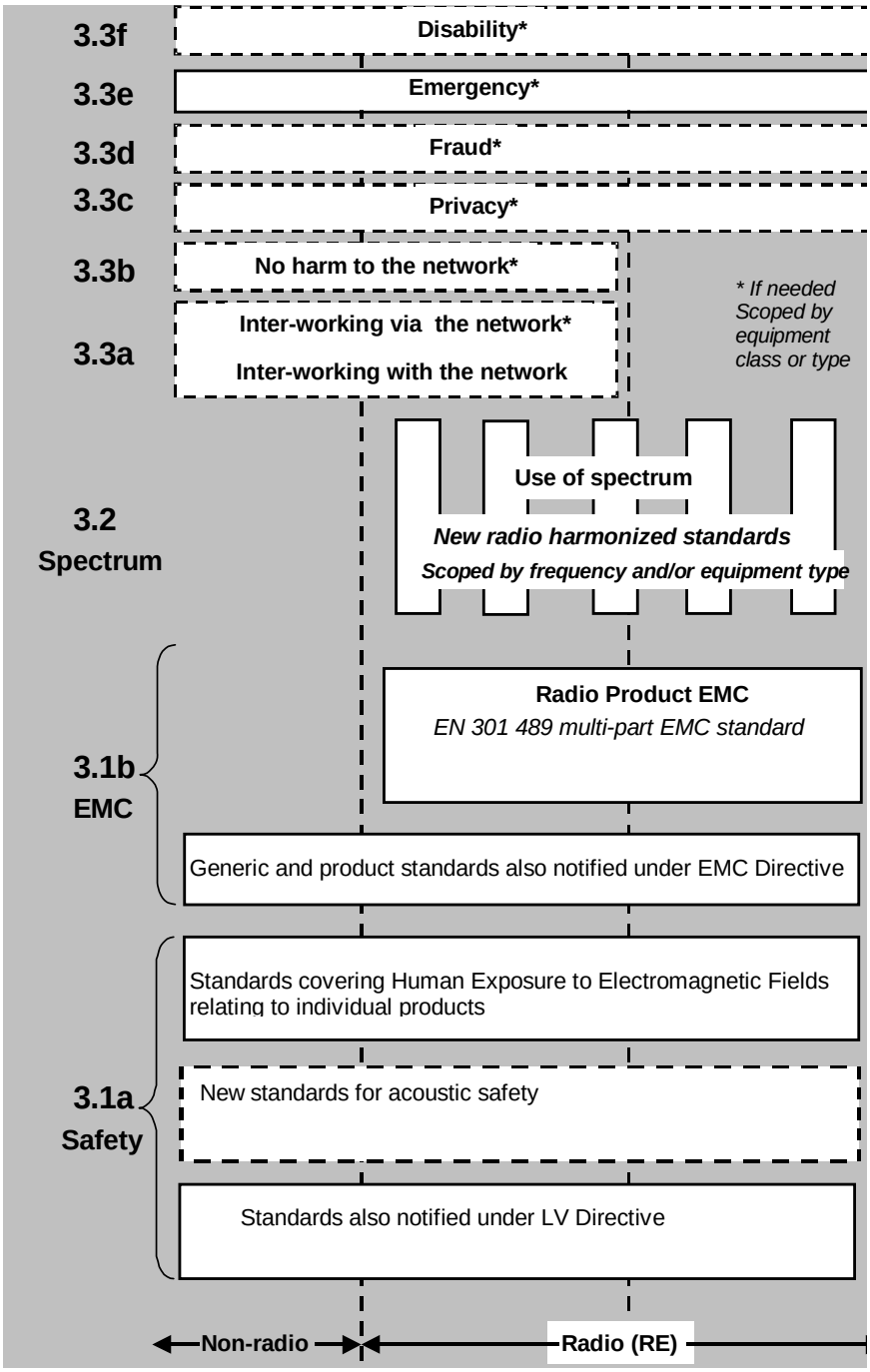

Figure D.1: Modular structure for the various standards used under the R&TTE Directive [i.2]

The left hand edge of figure D.1 shows the different clauses of article 3 of the R&TTE Directive [i.2].

For article 3.3 various horizontal boxes are shown. Dotted lines indicate that at the time of publication of the present document, essential requirements in these areas have to be adopted by the Commission. If such essential requirements are adopted and as far and as long as they are applicable, they will justify individual standards whose scope is likely to be specified by function or interface type.

The vertical boxes show the standards under article 3.2 for the use of the radio spectrum by radio equipment. The scopes of these standards are specified either by frequency (normally in the case where frequency bands are harmonized) or by radio equipment type.

For article 3.1b the diagram shows ETSI EN 301 489 [i.15], the multi-part product EMC standard for radio used under the EMC Directive.

For article 3.1a the diagram shows the existing safety standards currently used under the LV Directive and new standards covering human exposure to electromagnetic fields. New standards covering acoustic safety may also be required.

The bottom of the figure shows the relationship of the standards to radio equipment and telecommunications terminal equipment. A particular equipment may be radio equipment, telecommunications terminal equipment or both. A radio spectrum standard will apply if it is radio equipment. An article 3.3 standard will apply as well only if the relevant essential requirement under the R&TTE Directive [i.2] is adopted by the Commission and if the equipment in question is covered by the scope of the corresponding standard. Thus, depending on the nature of the equipment, the essential requirements under the R&TTE Directive [i.2] may be covered in a set of standards.

The modularity principle has been taken because:

- it is expected that it minimizes the number of standards needed. Because equipment may, in fact, have multiple interfaces and functions it is not practicable to produce a single standard for each possible combination of functions that may occur in an equipment;
- it provides scope for standards to be added:
  - under article 3.2 when new frequency bands are agreed; or
  - under article 3.3 should the Commission take the necessary decisions;

  without requiring alteration of standards that are already published;
- it is expected that it clarifies, simplifies and promotes the usage of Harmonized Standards as the relevant means of conformity assessment.

D.2 Under the RED

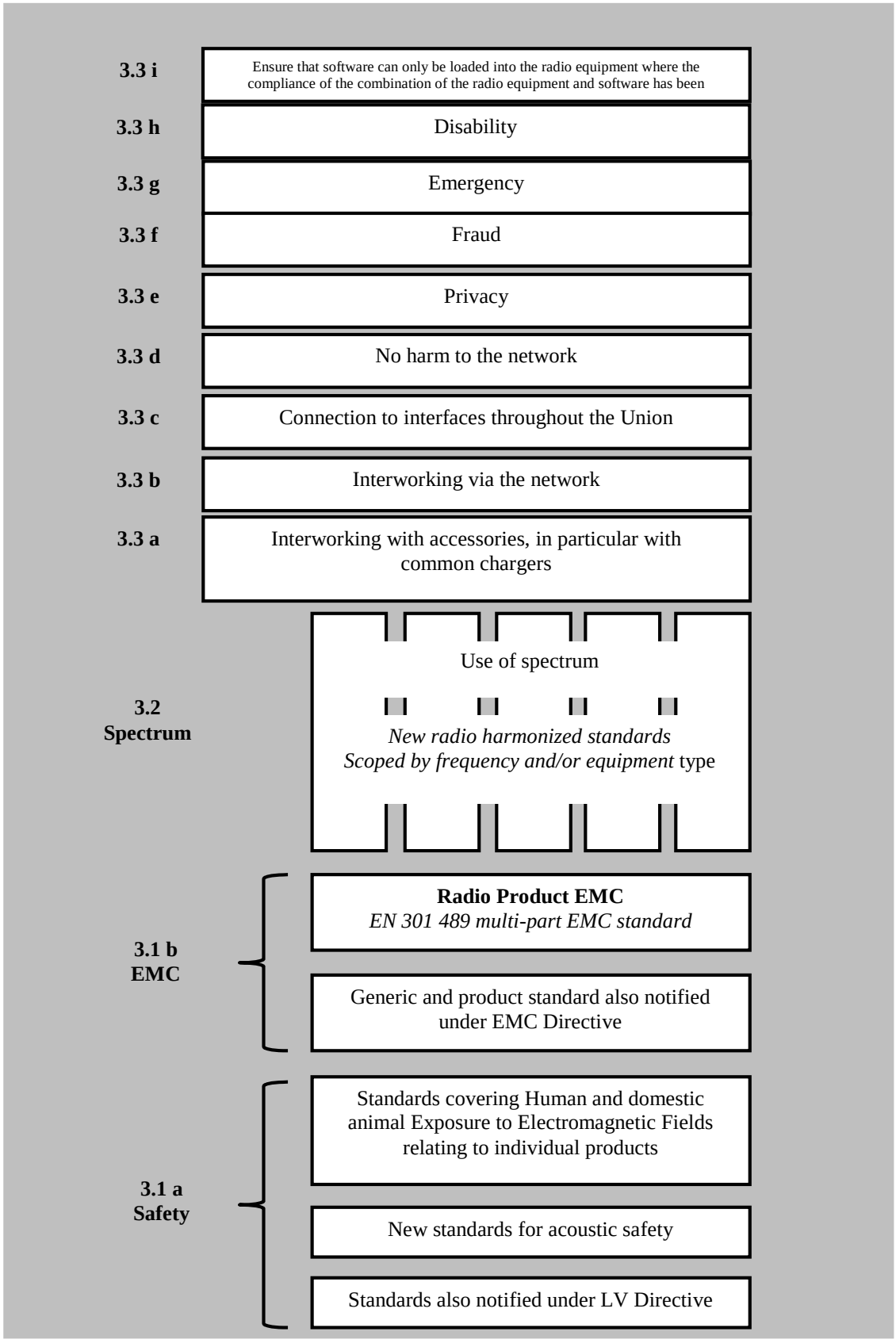

Figure D.2: Modular structure for the various standards used under the RED [i.1]

The basis of the modular structure is as much valid under the RED [i.1] as under the R&TTE Directive [i.2].

However, several major differences are relevant for the drawing and interpretation of the figure D.2 above, in particular:

- TTE equipment is not under the Scope of the RED [i.1].
- There are more possibilities of requirements in the article 3.3 of the RED [i.1] than in the case of the R&TTE Directive [i.2], and the associations " number ← → name" are different.
- Article 3(1)(a) has been expanded.

NOTE: Different horizontal boxes may correspond to different standard parts of the same multipart-standard.

Annex E:
Examples showing how to structure clauses addressing technical requirements

E.1 Example of structure

For a particular parameter P, addressed in section "Sp", the following structure in 3 clauses is often used:

Sp.1 Definition of the parameter P and applicability (see note 1).

Sp.1.1 Definition.

Sp.1.2 Applicability of the measurement (see note 1).

Sp.2 Method of measurement.

Sp.3 Limit.

The structure above suggests, in particular, that the "conditions of applicability of a particular measurement" are expected to be located in a specific clause (i.e. in Sp.1.2), rather than in the "definition" (e.g. in Sp.1.1), as it may be found, to date, in some Harmonized Standards.

The contents of "Definitions, Symbols and abbreviations" are specifically addressed in clause 7.2.8.

NOTE 1: ETSI HSs have frequently been drafted according to the approach "Part 1/Part 2" where:

- Part 1 is a "standard" (i.e. the "product standard") including most of the relevant technical material.
- Part 2 is the "Harmonized Standard" and includes a large number of pointers to Part 1.

In the case of Part 1, Sp.1 to Sp.3 are often found in the same clause/ sub-clause.

In the case of Part 2, Sp.1, Sp.2 and Sp.3 may be found in two different clauses sometimes with pointers from one clause to the other.

NOTE 2: ETSI HS have been drafted with two different structures:

- One where the requirements and measurement methods are in one clause.
- One where the requirements and measurement methods are in different clauses.

NOTE 3: HS-RTT table of the ETSI Harmonized EN skeleton [i.16] shows the conditions under which requirements are applicable and tested.

E.2 Example of structure for the description of a method of measurement

In a number of methods of measurements found in HSs already published, structures for the description of the methods of measurement correspond to the following pattern (the following items may have to be selected on a case-by-case basis):

a) description of the conditions under which the test should be performed including set up (e.g. details of test equipment to be used and of the corresponding interconnections), if necessary;

b) initial set-up of the equipment for the test (e.g. initial signal levels);

c) sequence of switching on of the various devices(e.g. of the signal generators);

d) running of the test in steps;

e) evaluation of intermediate measurement values;

f) gathering of intermediate results;

g) details on the associated measurements (e.g. measurement on other frequencies);

h) evaluation of the final result of the measurement (i.e. how to consolidate the various intermediate results obtained in step f);

i) measurements under extreme test conditions, when applicable.

The use of these steps can be selected on a case-by-case basis depending on the complexity of the test in order to ensure the understanding and the repeatability of the test.

Table E.1 shows how this regular pattern has been implemented in a set of standards offered to meeting 31 of TC-ERM for approval.

Table E.1: Example of implementation of step h of the method of measurement pattern

In Clause	h) Begins by …
8.5.2.1	h) the co-channel rejection ratio of the equipment
8.5.2.2	h) the co-channel rejection of the equipment
8.6.2.1	h) the adjacent channel selectivity …/… shall be expressed as the lower …
8.6.2.2	h) the adjacent channel selectivity …
8.7.4	h) the spurious response rejection of the equipment
8.7.5	h) the spurious response rejection of the equipment
8.8.2.1	h) the intermodulation response rejection of the equipment
8.8.2.2	h) the intermodulation response rejection of the equipment …
8.9.2.1	h) the blocking or desensitization of …
8.9.2.2	h) the blocking or desensitization of the equipment …

This regular pattern is common to a number of standards; for example h) of clause 9.7.2 of ETSI EN 300 296-1 [i.22] (PMR 446 - analogue equipment having an Integral Antenna) reads:

"h) The blocking or desensitization of the equipment under test shall be expressed as the level in dBμV/m of the field strength of the unwanted signal, at the receiver location, corresponding to the lowest value recorded in step f)."

Annex F:
HS-RT

Please check ***editHelp!*** page for the latest information on the skeleton at: https://portal.etsi.org/Services/editHelp!.aspx.

Or direct link to the harmonized standard skeleton.

NOTE: Available at https://portal.etsi.org/Services/editHelp!/Standardsdevelopment/Drafting/Skeletons.aspx.

Annex G:
"Frequently Asked Questions (FAQ)" relating to Harmonized Standards under the R&TTE Directive, the RED and/or relating to the present document

G.1 Introduction

A number of questions about Harmonized Standards (HSs) drafted by ETSI, in particular in relation to the R&TTE Directive [i.2] and RED [i.1], can and have been asked.

The text included in the present set of "FAQs" (Frequently Asked Questions) has been drafted in an endeavour to answer some of these questions. It is intended to be made available on the ETSI website and/or as an annex to the present document.

More specifically, the present annex "FAQs" focuses on questions relating to HSs under the R&TTE Directive [i.2] and/or the RED [i.1].

Further information intended to support ETSI Technical Bodies, in order to support them when drafting Harmonized Standards, can be found in the main body of the present document.

It is hereby emphasized that the main body of the present document has been drafted in support of the ***ETSI TBs*** drafting harmonized standards, whereas the text "FAQs" is intended to support both the TBs and the ***users*** of harmonized standards.

G.2 FAQs relating to the R&TTE Directive, the RED and the corresponding HSs

Disclaimer

These FAQs and corresponding answers do not replace the text of the Radio Directives [i.2] and [i.1] nor the text in the corresponding Guides [i.21] and [i.20], nor the material included in the various HSs published by ETSI.

Q1 How are the drafts for HS under the R&TTE and/or RED prepared?

Draft HSs under the Radio Directives [i.2] and [i.1] are drafted and approved for publication by ETSI under the responsibility of the ETSI TB in charge of that area (standards intended to be harmonized have to go through a public enquiry process).

In order to ensure that the formats (and contents) of HSs are as much uniform as possible, ETSI has:

- prepared the present document, for the production of HSs under the RED [i.1] and R&TTE Directive [i.2];
- draft skeletons; and
- set up the R&TTE sub-group (under the OCG).

See also:

- Q2 Why are there differences between HS under the R&TTE?
- Q4 What is meant by the term "modular approach"?

Q2 Why are there differences between the various HSs under the R&TTE?

A number of reasons may explain differences in terms of structure and in terms of choice of parameters to be included in the HS, in particular:

- special needs (e.g. particular requirements corresponding to various technologies);
- differences in the context (e.g. structure of the related product standards);
- differences in the choices of which parameters have to be harmonized in the case of a particular product, in order to fulfil the R&TTE Directive [i.2] essential requirements (choices to be made by the ETSI TBs).

To support agreements between the EC and ETSI at a certain point in time, a number of HSs may also include or have included an annex with the title in the various Community languages.

See also:

- Q3 Can receiver requirements be essential under the R&TTE [i.2]?

Q3 Can receiver requirements be essential under the R&TTE [i.2]?

A number of receiver requirements have been considered essential under the R&TTE Directive [i.2], for a number of products.

Below are some of the various reasons taken in account:

- because receivers may generate interference "directly" (e.g. spurious emissions (see note));
- because receivers may generate interference via an associated transmitter (e.g. in the case of "listen before talk" applications).

NOTE: Receiver spurious emissions are always essential requirement although there are not always corresponding "Essential Radio Test Suites", by definition.

This was discussed in an ETSI task group (TG 18) and endorsed by TCAM.

Inclusion of receiver parameters in HSs has also been discussed by RSPG whose position is outlined in the RSPG opinion [i.17]. RSPG considers that the receiver parameters should be included in Harmonized and/or product standards for all equipment. In the past ETSI TBs, on a case-by-case basis, have included the receiver parameters they believed essential, under the R&TTE Directive [i.2], in the various HS.

More recently the technical report ETSI TR 102 914 [i.18] has shown that receiver parameters, in some cases, may need to be included to respect the essential requirements of article 3.2 of the R&TTE Directive [i.2].

It can also be noted that it is usually at the level of a receiver that interference may be observed.

Receiver parameters may also have to be included, in relation to essential requirements relating to article 3.3 (e.g. article 3.3 e).

This is also explained further in clause 6.1.3.

The essential requirements in the RED have clarified the situation: see clauses 4.1.4 and 7.3 of the present document.

See also:

- Q4 What is meant by the term "modular approach"?

Q4 What is meant by the term "modular approach"?

Industry has often supported the view that HSs should not change too often.

It was felt that avoiding cross-references between various HSs could help to achieve this goal (it would allow for the evolution of one particular HS without any necessary effect on the others).

As a result, in order to comply with the various essential requirements of the R&TTE Directive [i.2], equipment has to comply with a number of HSs, each one focusing on one particular aspect (e.g. essential requirements of the R&TTE Directive [i.2] and RED [i.1]:

- article 3.1;
- article 3.2;
- possibly article 3.3 (when activated for a particular product), etc.

Hence the recommendation to usa a "modular approach" (see annex D).

According to the principles of the modular approach, each of the corresponding HSs deals with a set of parameters and other particular features to be harmonized for a particular product (as defined in the scope of the HS). The selection of these parameters and other particular features is performed by the appropriate TB. The present document contains tables in order to guide the TBs in their choices, and hopefully helps to avoid unnecessary differences between the various ETSI HSs.

See also:

- Q1 How have the drafts for HS under the R&TTE been prepared?
- Q2 Why are there differences between HS under the R&TTE?

Q5 What are the relations between "requirements" and "test suites" or "test specifications"?

According to the skeleton:

- Clause 4 of an HS often contains the technical requirements (e.g. characteristics of the power in the adjacent channel).
- Clause 5 often provides details concerning the way in which the technical requirement is assessed (e.g. environmental conditions, measurement uncertainties, test suites or specifications, etc.).

These normative clauses take precedence over any informative annex of the HS (they are in the main body of the HS).

Q6 What are the relations between "essential test suites" and "other test suites"?

According to version 2.2.1 (and previous versions) of the present document which would only address the R&TTE Directive [i.2] and to the skeletons published before mid-2014, there are different "test suites":

- Some test suites are "essential".
- While some "test suites" are referred to as "Other test suites".

Under the R&TTE Directive [i.2], this distinction was due to article III.

As under the RED [i.1] this distinction is not made anymore, it is hereby proposed to keep the structure of the Harmonized Standards as much unchanged in this respect, as practical, and rename "Essential Test Suites" as "Test suites relating to the transmitter" while the "Other test suites" would be renamed "Test suites relating to the receiver". Such an approach should minimize the amount of reorganization of the Clauses in the Harmonized Standards, while supporting clarity.

Under the RED there is no longer a distinction between "Essential Test Suites" and "Other Test Suites". Therefore the term "method of measurement" or "tests" should be used when appropriate.

Annex H: Bibliography

- The EC webpage where EC Decisions including BEMs can be found is:
  - https://ec.europa.eu/digital-agenda/en/news/radio-spectrum-decisions.
- ECC Rec (12) 03 and Rec (11) 06 on BEMs can be found in "http://www.ecodocdb.dk/".
- RSPG 13-527 rev1 final (Brussels, 07 June 2013): Radio Spectrum Policy Group - Report on Furthering Interference Management through exchange of regulatory best practices concerning regulation and/or standardisation".
- A guide in support of the writing of Test Report Forms had been published by ETSI EG 202 150.
- Several Test Report Forms had also been published by ETSI for particular products, for example ETSI TR 102 475 or ETSI TR 102 749:
  - ETSI TR 102 475 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband Transmission Systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Test Report form for testing to EN 300 328 (V1.6.1) covering essential requirements of article 3.2 of the R&TTE Directive".
  - ETSI TR 102 749 (V1.2.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Test Report Template for testing to EN 300 220-2 V2.3.1 (R&TTE)".
- Previously, test report forms had been drafted jointly by ETSI and ERC and many of them can still be found on the ECO server: www.ecodocdb.dk.
- CENELEC EN 60950 (all applicable parts): "Information technology equipment - Safety".
- CENELEC TR 62102: "Electrical safety - Classification of interfaces for equipment to be connected to information and communications technology networks".
- 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".
- ERC Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".
- 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)".

History

Document history		
V1.1.1	January 2000	Publication
V1.3.1	January 2003	Publication
V2.1.1	December 2005	Publication
V2.2.1	August 2010	Publication
V3.1.1	January 2015	Membership Approval Procedure MV 20150320: 2015-01-19 to 2015-03-20
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