Guide to the R&TTE Directive 1999/5/EC

Version of 20 April 2009

Contents

Disclaimer

This Guide is intended to serve as a manual for all parties directly or indirectly affected by the R&TTE Directive 1999/5/EC. It should assist in the interpretation of the Directive but cannot take its place; it explains and clarifies some of the most important issues related to the Directive's application. The Guide also aims to disseminate widely the explanations and clarifications reached by consensus among Member States and other stakeholders.

The Guide is based on the R&TTE Directive and on the "New Approach" described in the "Blue Guide". The provisions of the New Legal Framework[1] have not been taken into account in view of the difficulty of determining their impact on the R&TTE Directive. The Guide will have to be reviewed accordingly at a later date.

The text of this Guide is publicly available, but is not binding in the sense of a legal act adopted by the Community. In the event of any inconsistency between the provisions of the R&TTE Directive and this Guide, the provisions of the RTTE Directive prevail.

Finally, your attention is drawn to the fact that all references to the CE marking and EC Declaration of Conformity relate to the R&TTE Directive only and that the freedom to place an apparatus on the EU single market is only guaranteed when all relevant legislation is complied with. Reference is therefore made, whenever necessary, to other directives.

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[1] Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ L 218, 13.8.2008).

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008).

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 (OJ L 218, 13.8.2008).

INTRODUCTION

The purpose of this document is to give guidance on certain matters and procedures[2] pertaining to Directive 1999/5/EC[3] of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (the R&TTE Directive).

The main objective of the Directive is to establish a regulatory framework for the placing on the market, free movement and putting into service of radio equipment and telecommunications terminal equipment in the territory of the European Union[4]. In order to achieve that aim, a fully harmonised, high level of protection is required in the Directive, based on Article 95 (ex Article 100a) of the Treaty establishing the European Community. Article 95 enables measures to be taken with a view to establishing a single market. By virtue of the Directive, radio and telecommunications equipment compliant with a single set of requirements can be placed on the EU market. However, Member States can restrict the putting into service of radio equipment for reasons to do with the effective and appropriate use of the radio spectrum, avoidance of harmful interference, or matters relating to public health. Some radio spectrum is harmonised in the EU; the use of non-harmonised frequency bands remains a prerogative of Member States. The putting into service of radio transmitters may be restricted in some Member States.

For the vast majority of apparatus, compliance is assessed by using the customary and preferred method of conformity to the relevant European harmonised standard(s).

The present Guide brings together information previously available in several TCAM documents and related Commission websites. Nevertheless, readers can still consult

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2 The European Commission undertakes to maintain this Guide. It is our goal to ensure that the information provided is both timely and accurate. If errors are brought to our attention, we will try to correct them. However, the Commission accepts no responsibility or liability whatsoever with regard to the information in this Guide.

The information:
- is of a general nature only and is not intended to address the specific circumstances of any particular individual or entity;
- is not necessarily comprehensive, complete, accurate or up-to-date;
- sometimes refers to external information over which the Commission departments have no control and for which the Commission assumes no responsibility;
- does not constitute professional or legal advice.

3 OJ L 91, 7.4.1999.

4 In accordance with the Agreement on the European Economic Area (EEA) (Council and Commission Decision 94/1/EC of 13 December 1993, OJ L 1, 3.1.1994) the territories of Liechtenstein, Iceland and Norway have to be considered, for the implementation of Directive 1999/5/EC, in the same light as the territory of the European Union. When the term “European Union” territory is used in this guide, it therefore applies likewise to the EEA territory. Directive 1999/5/EC is also applicable in other territories where a suitable international agreement is in operation (see Section 1.1.1). However, when this Guide quotes from the current text of the Directive, it reproduces the expression “Community” where it is used in the text.

on the CIRCA site a list of interpretations[5] accepted by the TCAM. This Guide should be read in conjunction with the "Blue Guide".

The Guide has been structured in a logical manner suitable for users who need to ensure that their equipment is in conformity with the R&TTE Directive. It is divided into the following main sections:

1. **Scope**: allows manufacturers or others to quickly decide whether their apparatus falls within the scope of the R&TTE Directive;

2. **Essential requirements**: provides an overview of the mandatory technical requirements;

3. **Interface regulations & specifications**: regulatory information which Member States must publish about radio interfaces and technical characteristics available from network operators;

4. **Equipment classes**: these identify equipment which may or may not be placed on the market and put into service without restriction;

5. **Harmonised standards**: these standards give a presumption of conformity with the essential requirements. Other means are available for cases where harmonised standards have not been or cannot be applied;

6. **Conformity assessment procedures**: information about the options for conformity assessment of telecommunications terminal equipment and radio equipment;

7. **Notified bodies**: their role, selection, coordination and the treatment of complaints;

8. **Administrative requirements**: explains requirements for user information and other documentation; EC Declaration of Conformity and CE marking;

9. **Market surveillance & enforcement**: the activities of the Member States to ensure that apparatus is in compliance with the Directive.

5 http://circa.europa.eu/Public/irc/enterprise/tcam/library?l=/public_documents/tcam_3_1&vm=detailed&sb=Title.

1 SCOPE

1.1 General

The R&TTE Directive [6] applies to all radio equipment and to telecommunications terminal equipment intended to be connected to public telecommunications networks (exceptions are listed in Section 1.1.3).

1.1.1 Geographic scope

The Directive applies throughout the European Union, that is to say in all Member States of the European Union. It is also applied in non-member countries if there is a relevant agreement. For example, it applies to the Contracting States of the European Economic Area (EEA), that is to say, the 27 Member States of the EU plus Iceland, Liechtenstein and Norway. In accordance with a Mutual Recognition Agreement between Switzerland and the EU, the Directive is transposed in Switzerland. It applies in Turkey pursuant to the EU-Turkey Customs Union.

1.1.2 Mutual Recognition Agreements (MRAs)

The EU has concluded Mutual Recognition Agreements with Australia, Canada, Japan, New Zealand and the United States concerning equipment covered by the Directive. These do not in any way permit R&TTE compliant products to be used in those countries. They relate only to the formal recognition of conformity assessment procedures in the territory of one party for the purposes of regulations in the territory of the other. In the context of the Directive, this means that conformity assessment bodies (CABs) in any of these countries can seek authorisation and designation to act in the capacity of a notified body under the Directive. Quite a number have done so, particularly in the US. Details of such organisations can be found in the NANDO database by following the appropriate country link and selecting "99/5/EC Radio and telecommunications terminal equipment" in the drop-down menu on the respective country page: http://ec.europa.eu/enterprise/newapproach/nando/index.cfm.
More information about MRAs can be found at: http://ec.europa.eu/enterprise/international/index_en.htm.

1.1.3 Explicit exclusions from the R&TTE Directive

Annex I of the Directive lists equipment that is not covered by the Directive.

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[6] The Directive was adopted by the Council and European Parliament on 9 March 1999.

The Directive excludes equipment used by radio amateurs 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 falling within the scope of Council Directive 96/98/EC[7] on marine equipment is excluded from the scope of the Directive.

Cabling and wiring are excluded.

Receive-only radio equipment intended to be used solely for the reception of sound and TV broadcasting services is excluded. It should be noted that other types of radio receivers fall within the scope of the Directive.

Products, appliances and components within the meaning of Article 2 of Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation are excluded. This exclusion relates to on-board items only.

The Directive excludes air-traffic-management equipment and systems within the meaning of Article 1 of Council Directive 93/65/EEC of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air-traffic-management equipment and systems. However, that Directive has been repealed since 20 October 2005. As a consequence, ground aeronautical radio equipment now falls within the scope of the Directive.

Furthermore, since the same date, the Interoperability Regulation (EC) No 552/2004 covers some aeronautical radio equipment now within the scope of the Directive. However, its provisions concern interoperability in air traffic management. Those aspects are separate and additional to those dealt with by the Directive.

In addition, the Directive (pursuant to Article 1(5)) does not apply to apparatus exclusively used for activities concerning public security, defence, State security and activities of the State in the area of criminal law. So, for example, military radio equipment used solely by armed forces does not fall under the Directive but if this radio equipment is sold to collectors it cannot be used without being made compliant with the Directive. TETRA systems that are widely used by public authorities are subject to

[7] Council Directive 96/98/EC of 20 December 1996 on marine equipment (OJ L 46, 17.2.1997), as amended by Council and Parliament Directive 2002/84/EC (OJ L 324, 29.11.2002).

the Directive as they are not exclusively used for the activities excluded from its scope.

1.1.4 Special measures regarding equipment at trade fairs, etc.

Equipment not (yet) allowed to be placed on the EU market, on grounds of non-compliance with the Directive, may be displayed at trade fairs and exhibitions provided a visible sign clearly indicates that such equipment may not be marketed or put into service in the EU. The use of such equipment is not permitted under the Directive, but some national authorities may allow very limited use (time, location, duration). The relevant authorities in the Member State concerned should therefore be contacted if a manufacturer wishes to demonstrate the use of such equipment.

1.1.5 Second-hand apparatus

According to the Blue Guide[8], the Directive applies to products which are intended to be placed (or put into service) on the European Union market for the first time. Consequently, it applies also to new, as well as used and second-hand, products imported from third countries and placed on the EU market for the first time. However, the provisions of the EEA Agreement on the free movement of goods apply only to products originating in the Contracting Parties to the Agreement.

1.1.6 R&TTE equipment also covered by other specific legislation

Where apparatus incorporates as an integral part, or as an accessory, medical devices and active implantable medical devices, it is governed by Directives 93/42/EEC[9] or 90/385/EEC[10] as well as the R&TTE Directive. The apparatus must comply with the requirements of all relevant directives.

Where apparatus constitutes a component or a separate technical unit within the meaning of Council Directive 72/245/EEC[11] on radio interference produced by vehicles, or a component or a separate technical unit of a vehicle within the meaning of

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8 Blue Guide, Chapter 2.1.

9 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993).

10 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990).

11 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 (OJ L 152, 6.7.1972).

Article 1 of Council Directive 92/61/EEC[12] on the type-approval of two or three-wheel motor vehicles, the apparatus is governed by the R&TTE Directive without prejudice to the application of Directive 72/245/EEC or of Directive 92/61/EEC respectively. Again, these technical units or components must comply with the requirements of both the R&TTE Directive and all applicable directives.

1.1.7 Horizontal legislation

R&TTE equipment is generally also covered by environmental legislation such as RoHS (Restrictions on Hazardous Substances) [13] , WEEE (Waste Electrical and Electronic Equipment)[14], REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)[15] and EuP (ecodesign for Energy-Using Products)[16]. The relevant requirements focus on the design, production and disposal phases of the life cycle of electronic products.

1.2 Defining "apparatus"

The R&TTE Directive (Article 2) defines "apparatus" as any equipment that is either radio equipment or telecommunications terminal equipment or both.

1.2.1 Telecommunications terminal equipment

Telecommunications terminal equipment is defined as 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. An interface means a network termination point at which a user is provided with access to a public telecommunications network and/or an air interface specifying the radio path between radio

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12 Council Directive 92/61/EEC of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles (OJ L 225, 10.8.1992).

13 Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 37, 13.2.2003).

14 Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE) (OJ L 37, 13.2.2003).

15 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006).

16 Directive 2005/32/EC of the European Parliament and of the Council of 6 July 2005 establishing a framework for the setting of ecodesign requirements for energy-using products and amending Council Directive 92/42/EEC and Directives 96/57/EC and 2000/55/EC of the European Parliament and of the Council (OJ L 191, 22.7.2005).

equipment and their technical specifications. The Directive requires Member States to notify the types of interfaces offered by public telecommunications networks.

Terminal equipment that is not connected in any way to any public network is not a terminal within the meaning of the Directive.

1.2.2 Radio equipment

Radio equipment is defined as 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 radio communications. Radio waves means electromagnetic waves of frequencies from 9 kHz to 3000 GHz, propagated in space without artificial guide.

So, for example, mobile phones are both terminal equipment and radio equipment.

When a product includes a radio or telecommunications terminal component, the component or, if it cannot be separated, the whole product is subject to the provisions of the R&TTE Directive. So, for example, a PC that incorporates a WLAN falls within the scope of the Directive but in the case of a separate WLAN card attached to a PC the PC is not covered by the Directive (while the WLAN card naturally is covered by the Directive). In any event, the manufacturers' instructions must be respected when components or separate modules are connected.

1.3 TCAM opinions on the scope of the Directive

The TCAM has discussed issues to do with the scope of the Directive. The conclusions below cannot be considered legally binding but they represent the TCAM's opinion.

1.3.1 Antennas

Antennas may be subdivided into "active" and "passive" types. "Active" antennas are supplied with one or more electronic components interacting with the signal. All other antennas are in general considered "passive"

Passive antennas are not relevant components under Article 2(c) and therefore not covered by the Directive if placed on the market as a single commercial unit for distribution or final use. If they are marketed together with a radio product, the overall radio product including the antenna is subject to all the requirements of the Directive.

In contrast, active antennas (i.e. antennas including one or more active electronic components that interact with the RF signal) fall within the scope of the Directive.

Manufacturers who place on the market products without an antenna or with an antenna that is intended to allow replacement have a responsibility to provide information on the general types and/or characteristics of antennas that may be used with their equipment in order that the overall radio equipment remains compliant. The guidance of the transmitter manufacturer has to be followed when they are installed.

Where a radio system is integrated on site — as in the case of microwave point-to-point and point-to-multipoint systems — the system integrator is responsible for ensuring compliance of the system with the Directive when the system is brought into service.

However, there are a few cases where stand-alone passive antennas sold separately present a likely risk of failure to meet the essential requirements when assembled with their radio system. They thus become relevant components under Article 2(c) and must be treated as “active”. When drafting the related harmonised standard, ETSI must inform the TCAM of its intention to include requirements on such stand-alone passive antennas. Absent a contrary TCAM decision, ETSI assumes the TCAM’s agreement, and includes the requirements but also points out and explains this exception.

1.3.2 Radar

Radars fall within the scope of the Directive. In addition they may be subject to further regulations.

1.3.3 Test equipment (transmitting radio frequencies)

Test equipment used for radio equipment testing is not considered to be radio communications equipment and is thus not covered by the Directive. However, the use of the test equipment may need a permission from radio frequency authorities.

1.3.4 Jammers

This issue was specifically discussed in the context of mobile phone jammers (i.e. equipment preventing the operation of GSM handsets). Since jamming, which is inherent to their functional principle, cannot fulfil the essential requirements of the Directive, the placing on the market and putting into operation of these devices is banned.

1.3.5 Cochlear implants

Cochlear implants are not covered by the Directive as they are not regarded as radio equipment. This statement should be considered as concerning current technology and not as a generic exclusion.

1.3.6 Programmable equipment

Manufacturers need to classify equipment that can be programmed to use bands whose use is not harmonised or could be used only under special licensing conditions (Class 2 — see Section 4) and to inform users about existing restrictions.

1.3.7 Components/sub-assemblies

Components/sub-assemblies that are either telecommunications terminal equipment or radio equipment within the meaning of the Directive and are intended to be placed and/or put into service on the European Union market fall within the scope of the Directive.

1.3.8 Construction kits

Construction kits that when assembled fall within the scope of the Directive and are intended to be placed on the market are covered by the Directive. The kit manufacturer is responsible for compliance when the kit is assembled in accordance with the instructions provided. In contrast, when a product is assembled from components not intended to be part of a kit the responsibility lies with the person making the product.

Passive components/sub-assemblies are excluded from the Directive as separate items. However, when they are connected to apparatus the manufacturer's instructions must be followed. Otherwise compliance with the Directive must be shown by the responsible person incorporating the items into a final apparatus.

1.3.9 Products for own use

Where an apparatus is manufactured for own use, it is not considered to be placed on the market. The obligation to comply with the Directive occurs when it is put into service and only for provisions which, at this stage, are still necessary for ensuring the objectives of the Directive (assessment, technical file, etc., but for instance not the marking)[17].

Products imported for personal use are considered to be placed on the market at the moment they enter EU territory, and from this

[17] Blue Guide, Chapter 2.3.2.

point in time all the provisions necessary to ensure the objectives of the Directive apply[18].

1.3.10 Fixed installations

Fixed installations are not specifically mentioned in the Directive. They are not, however, excluded, so that installations that conform to the definition of Article 2(a) ("apparatus") fall within the scope of the Directive. "Fixed installation" is understood to mean a particular combination of several types of devices which are apparatus within the meaning of Article 2(a) and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a pre-defined location. However, when a fixed installation is not placed on the market as a whole, the requirements relating to CE marking and declaration of conformity are considered not to apply to the installation as a whole. The person putting an installation into service must assume the responsibilities of the manufacturer and perform the appropriate conformity assessment. The Directive does not specify which conformity assessment procedure is to be used unless the devices are sold as one complete product.

"Additional apparatus for fixed installations" is understood to mean apparatus which is specifically designed for incorporation into a given fixed installation, and which is otherwise not commercially available. The concept of placing on the market is considered not to apply to apparatus meeting the definition of "additional apparatus for fixed installations", provided that the documentation accompanying the apparatus specifies the fixed installation concerned and the precautions to be taken for the incorporation of the apparatus into the installation in order not to compromise the conformity of the installation. Hence the requirements for CE marking or declaration of conformity are likewise considered not to apply. In other cases, all the provisions of the Directive apply in full.

2 ESSENTIAL REQUIREMENTS

2.1 General

The R&TTE Directive lays down "essential requirements"[19], which are mandatory provisions for the protection of the public and the general interest and are designed to ensure a high level of protection.

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[18] Blue Guide, footnote 30.

[19] More information on the principle of essential requirements can be found in Chapter 4.1 of the Blue Guide.

A number of essential requirements apply to all equipment, while some are specific to radio equipment. The Directive also allows additional essential requirements to be imposed on specific categories of equipment. These additional requirements can only be applied by means of a Commission decision[20].

The essential requirements give the objective(s) to be met, but do not specify how. As part of the "new approach[21]" to technical legislation this allows the smooth adaptation of product design to technical progress and all technical solutions are possible insofar as they meet the objectives.

Compliance with the essential requirements is mandatory and only equipment that meets all relevant requirements can be placed and/or put into service on the European Union market.

The essential requirements must be met when the equipment is properly installed and maintained and used for its intended purpose as described by the manufacturer in the instructions for use.

The R&TTE Directive does not contain requirements concerning fitness for purpose. Contracts requiring additional "quality" requirements may be agreed; however, such additional requirements must not lead to a non-compliant product.

The manufacturer, his authorised representative established in the European Union or in some cases the person responsible[22] for placing R&TTE apparatus on the market has to declare that the equipment satisfies all essential requirements that apply.

2.2 General essential requirements

The following essential requirements[23] are applicable to all apparatus:

(a) the protection of the health and the safety of the user and any other person, including the objectives with respect to safety requirements contained in the Low Voltage Directive (LVD) – Directive 2006/95/EC[24], but with no voltage limit applying.

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20 See Section 2.3.2 "Commission decisions on additional essential requirements" for more details.

21 http://www.newapproach.org and http://ec.europa.eu/enterprise/newapproach/index_en.htm.

22 See Chapter 3.3 of the Blue Guide and the R&TTE Directive, Article 6(4), Article 12(1), Article 12(4), Annex II.3, Annex III and Annex IV.

23 Article 3(1)(a) and 3(1)(b) of the R&TTE Directive.

24 Article 3(1)(a) of the R&TTE Directive refers to Directive 73/23/EEC. This directive has since been codified by Directive 2006/95/EC, which came into force on 16 January 2007. *As no changes were made to the consolidated version of the "old" Directive 73/23/EEC as amended, references made to the repealed directive should be considered as references to the new directive* and should be read in accordance with the correlation table in Annex VI of the new LVD Directive.

Therefore, battery-operated equipment such as a GSM handset is also subject to this essential requirement.

This essential requirement covers **all** health and safety risks arising from the use of equipment, e.g. electrical, mechanical and chemical (e.g. emission of aggressive substances) as well as (but not exclusively) health aspects relating to noise, vibration and ergonomic aspects[25].

This essential requirement ensures also that equipment is constructed in such a way that, when it is used as intended, the limits for human exposure to electromagnetic fields are respected;

(b) the protection requirements with respect to electromagnetic compatibility contained in the Electro-Magnetic Compatibility (EMC) Directive – Directive 2004/108/EC[26].

The goal of this essential requirement is to ensure that:

- the electromagnetic disturbances generated by equipment do not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
- equipment has a level of immunity to electromagnetic disturbances to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

The following essential requirement[27] is applicable to radio equipment only:

(c) 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.

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[25] The risks listed here are for information purposes and are not exhaustive, as all risks need to be taken into account.

[26] Article 3(1)(b) of the R&TTE Directive refers to Directive 89/336/EEC. This directive has been revised and replaced by Directive 2004/108/EC, which came into force on 20 July 2007. The provisions of the new directive need to be followed from that date on.

References made to the repealed directive should be considered as references to the new directive and should be read in accordance with the correlation table in Annex VII of the new EMC Directive (see also the remark in Section 6 “Conformity assessment procedures”).

[27] Article 3(2) of the R&TTE Directive.

2.3 Additional essential requirements[28]

2.3.1 General principle

The R&TTE Directive allows the Commission to adopt decisions prescribing additional requirements for certain types of equipment (Article 3(3));

One or more of the additional essential requirements set out below may be imposed on apparatus of particular types. However, this is only done if the Commission deems it necessary and decides by means of a procedure in the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM)[29] that the apparatus must be so constructed that:

(a) it interworks via networks with other apparatus and 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 or 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.

The Commission and the Member States take such initiatives only *exceptionally*. Any decision about additional requirements based on Article 3(3) is published in the Official Journal of the European Union (OJEU) together with the date from which these additional requirements need to be applied.

2.3.2 Commission decisions on additional essential requirements

Decisions currently in force are detailed here.

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[28] Article 3(3) of the R&TTE Directive.

[29] The TCAM is composed of representatives of the Member States and chaired by a representative of the Commission.

Additional essential requirements are currently only in place for equipment accessing emergency services (maritime, inland waterway and avalanche beacons).

The first set of decisions came about due to the fact that there is radio equipment used on ships that does not fall within the scope of the Marine Equipment Directive 96/98/EC[30]. As safety is a fundamental requirement, it was agreed that measures were required to ensure that the laws were in place so that there was a legal obligation for such equipment to be sufficiently robust given its intended environment.

As a consequence the Commission adopted the following decisions:

- Commission Decision 2000/637/EC of 22 September 2000 on the application of Article 3(3)(e) of Directive 1999/5/EC to radio equipment covered by the regional arrangement concerning the radiotelephone service on inland waterways (applicable from 21 October 2000).

This Decision introduces an additional requirement in respect of radio equipment used on waterways covered by an arrangement concerning the radiotelephone service on inland waterways (regional inland waterway agreement) that this must be equipped with an "automatic transmitter identification system (ATIS)" and that the emitted power on specific channels must not be higher than 1 watt.

- 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).

This Decision introduces the additional requirement that the radio equipment falling within the scope of the Decision must work correctly in "emergency situations".

- Commission Decision 2005/631/EC of 29 August 2005 concerning essential requirements as referred to in Directive 1999/5/EC of the European Parliament and of the Council ensuring access of Cospas-Sarsat locator beacons to emergency services.

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[30] Equipment which meets the requirements of the Marine Equipment Directive meets the technical requirements of the R&TTE Directive. There are therefore no technical grounds that might lead to reassessment of such products for installation on other than SOLAS ships. There are no grounds to forbid the usage of equipment covered by the Marine Equipment Directive as being incompatible with the R&TTE Directive.

This Decision applies to locator beacons intended to operate on 406 MHz with the Cospas-Sarsat system that do not fall within the scope of Decision 2004/71/EC.

This Decision lays down additional requirements to be met by Cospas-Sarsat beacons. It does not require Member States to allow their use on national territory nor does it require Member States to react to distress calls from Cospas-Sarsat beacons. Manufacturers need to clarify in the product documentation any restrictions on use and are advised to inform users in which Member States emergency services will react to distress calls.

- Commission Decision 2005/53/EC of 25 January 2005 on the application of Article 3(3)(e) of Directive 1999/5/EC of the European Parliament and of the Council to radio equipment intended to participate in the Automatic Identification System (AIS).

This Decision requires that radio equipment which operates in the maritime mobile service as defined in Article 1.28 of the International Telecommunications Union (ITU) Radio Regulations, or in the maritime mobile satellite service as defined in Article 1.29 of the ITU Radio Regulations, must be designed in such a way as to ensure that it operates correctly on non-SOLAS vessels and land-stations as well. In addition, equipment of this kind must meet all the appropriate operational requirements of the Automatic Identification System (AIS).

Another decision was adopted to ensure that radio equipment intended to locate persons submerged by snow following an avalanche functions correctly under extreme conditions.

- Commission Decision 2001/148/EC of 21 February 2001 on the application of Article 3(3)(e) of Directive 1999/5/EC to avalanche beacons.

This Decision applies to equipment operating on 457 kHz and ensures interoperability and operation under harsh conditions.

3 INTERFACE REGULATIONS & SPECIFICATIONS

3.1 Member States' interface regulations

Interface regulations (often called "interface specifications" or even "interface requirements") relate to the Member States' obligation under Article 4(1) of the Directive to notify the Commission of the interfaces which they have regulated. These regulations concern only radio equipment interfaces and are issued by the spectrum management authorities of the individual Member States. They are increasingly harmonised through decisions taken under the so-called Radio Spectrum

Decision 676/2002/EC [31] . Manufacturers have to comply with the regulations of the Member States in which their equipment is intended to be used.

There is no collated source of interface regulations and reference must be made to the individual spectrum authorities. Contact details for spectrum authorities can be found here: http://ec.europa.eu/enterprise/R&TTE/spectr.htm,

and limited links to information about interface regulations here: http://ec.europa.eu/enterprise/R&TTE/weblinks.htm.

Information about national spectrum usage can also be found in the EFIS database:
http://www.efis.dk.

Radio equipment that falls into Equipment Class 1 [32] and fits the parameters set out in the relevant sub-class definition published by the ERO may be presumed consistent with the interface regulations of all Member States. The relevant information can be found here: http://www.ero.dk/R&TTE.

The template for guidance to spectrum authorities and for Commission decisions within the scope of the TCAM and the RSCOM on elements of interface regulations is set out in the table below. Additional parameters covered by harmonised standards should not be included. The list is split into a normative part, which is compulsory, and an informative part, which contains additional information that many administrations have chosen to include in their allocation tables or descriptions of regulated radio interfaces.

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[31] Decision No 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision) (OJ L 108, 24.4.2002).

[32] Class 1 concerns all radio equipment that can be used without any restriction in the entire territory of the European Union; see Section 4.

[COUNTRY]	Radio Interface Specification	[TITLE]	[REFERENCE NUMBER]	[EDITION/ DATE]

Normative part

No	Parameter	Description	Comments
1	Radiocommunication service		
2	Application		
3	Frequency band		
4	Channelling		
5	Modulation/ occupied bandwidth		
6	Direction/ separation		
7	Transmit power/ power density		
8	Channel access and occupation rules		
9	Authorisation regime		
10	Additional essential requirements pursuant to Art. 3(3) of R&TTE Directive		
11	Frequency planning assumptions		

Informative part

12	Planned changes		
13	Reference		
14	Notification number		
15	Remarks		

The full explanatory notes to the template are available in the public documents of the Radio Spectrum Committee.

Spectrum authorities are not required to make a separate notification of interface regulations to the Commission under Article 4(1) if notification has been made under Directive 98/34/EC. An explanation of the 98/34

procedure and a searchable database of notifications can be found at: http://ec.europa.eu/enterprise/tris/.

3.2 Publication of interface specifications by network operators

Under Article 4(2) of the Directive, Member States must ensure that operators of public telecommunication networks publish information about the publicly available interfaces offered in the respective Member State. This concerns new, modified and withdrawn interfaces for both radio equipment (air interfaces) and telecommunications terminal equipment (fixed network interfaces) and applies to any public network operator providing public telecommunications services over a public network.

Sufficient details must be published to permit the design of terminal equipment able to use all the services provided through the corresponding interface. This includes the information necessary to permit identification of the tests required to demonstrate compliance with the essential requirements. In addition to basic conveyance services, supplementary services or tele-services that are directly controlled by the public network operators should be published.

There may be some parts that should not be made public, such as details of encryption systems used to secure radio-based communications, e.g. GSM, and service features that may relate to lawful interception. This information should only be made available subject to non-disclosure agreements.

Links to the interface specifications of public network operators in some Member States can be found in the column “Interface Publications” at: http://ec.europa.eu/enterprise/R&TTE/weblinks.htm.

In other cases, requests for interface specifications should be addressed to the public network operator concerned. In cases where the information is not provided, assistance may be obtained from the national authority in the Member State concerned.

Guidance on contents of interface specifications:

ETSI EG 201 730 Terminals’ access to public telecommunications networks; Application of Directive 1999/5/EC (R&TTE), Article 4(2); Guidelines for the publication of interface specifications

Part 1: General and common aspects

Part 2: Analogue narrow-band wireline interfaces

Part 3: Digital wireline interfaces

Part 4: Broadband multimedia cable network interfaces

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".

The obligation to publish information does not extend to private networks or operators providing non-public services e.g. to limited groups of end-users or public service providers (a provider of publicly available service(s) who provides a service from one or more sets of apparatus connected to a public network, but does not itself operate a network). However, it does include public network operators who provide services under contract to customers but who do not themselves provide the direct interface to the terminal equipment.

4 EQUIPMENT CLASSES

4.1 Introduction

Member States notify the radio interfaces they have regulated to the European Commission[33]. These radio interfaces contain the technical characteristics which must be met by the radio equipment in order to be put into service in the Member State concerned.

The Commission has to establish, based on Article 4(1) of the Directive, the equivalence between these national radio interfaces.

Equivalent radio interfaces form an "equipment class" and an "equipment class identifier" is assigned to that class.

In addition, the Commission can draw up, in close consultation with the Member States, spectrum decisions to regulate spectrum use in Europe. These decisions also contain the technical characteristics which have to be fulfilled by the radio equipment in order to be used.

4.2 Equipment classes based on Article 6(3)

Together with the Member States the Commission has adopted a Classification Decision laying down the initial classifications and associated equipment class identifiers.

This Decision puts equipment which can be placed on the market throughout the European Union and put into service without "restrictions or requirements for authorisation of use" (Article 6(3)) into a single class (Class 1). No equipment class identifier has been assigned for this category. A "restriction or requirement" is defined as any administrative or technical step which the end user must perform before putting the equipment into service: mandatory authorisation of use, mandatory notification of use, any parameter or condition of use prior to putting into

[33] See Section 3.1 for further information.

service, which is not carried out automatically by the equipment itself and thus has to be carried out by the user (indoor/outdoor, power, azimuth, duty cycle, etc.). This Class 1 typically includes radio transmitters that function in a frequency band assigned to the same radio interface in all Member States and consequently respect the same technical parameters. In general the placing on the market[34] or putting into service[35] of such equipment is not constrained by the Member States.

Conversely, no restriction means that the end user can use the radio equipment without any preliminary precaution, whether administrative or technical.

On the other hand, all equipment whose placing on the market or putting into service is subject to restrictions is grouped into a separate class (Class 2).

Examples of such restrictions are:

- frequency available and allowed for that application in certain Member States only;
- individual licence needed to use the specific radio equipment;
- indoor use only.

The following equipment class identifier has been assigned for Class 2.

"information sign" or "alert sign"

The "alert sign" forms an integral part of the CE marking[36].

Telecommunications terminal equipment (non-radio) and receive-only equipment (radio) belongs to the first category and is thus Class 1 equipment[37].

Radio equipment may belong either to Class 1 or to Class 2 depending on the nature of its radio interface.

Radio equipment subject to restriction(s) of use belongs to Class 2.

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34 See Article 9(5) of the R&TTE Directive.

35 See Article 7(2) of the R&TTE Directive.

36 See Section 6.5 for further information on the marking.

37 TCAM 3, 13-14 October 1999.

The Classification Decision states that the Commission will publish and maintain, in consultation with the TCAM, an indicative and non-exhaustive list of equipment falling within the above classes on its website.

It has been agreed to put the following radio equipment in Class 1:

- receive-only radio equipment (even where usage restrictions exist for receivers, such restrictions are beyond the scope of the Directive[38]);
- radio transmitters which can only transmit under control of a public network and thus do not need any technical adjustment by the user (e.g. simple GSM handsets, simple UMTS handsets, non-DMO TETRA terminals);

To assist manufacturers, the Commission, in consultation with Member States, identifies subclasses of radio equipment, confirming that they belong to Class 1.

This list and templates of subclasses of "Class 1" radio equipment can be consulted on the ERO website.

The list is regularly updated.

To be considered Class 1 equipment, radio equipment must respect the technical characteristics of the subclass concerned (the radio interface). The technical parameters to be respected for a given subclass can be viewed by clicking on the number associated with that subclass.

Important note: Equipment classes (Art. 6(3)) and the need to notify or not (Art. 6(4)), are not identical concepts. The way equipment classes can combine with the need to notify or not is explained in **Section 7.4.**

5 HARMONISED STANDARDS

5.1 Introduction

Harmonised standards are standards adopted by European standards organisations, prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations (CEN, CENELEC and ETSI), and in response to a mandate issued by the Commission after consultation with the Member States.

The reference of a harmonised standard must be published in the OJEU under the R&TTE Directive in order to give a presumption of conformity to the essential requirements of the Directive.

[38] TCAM 6, 25-26 September 2000.

The application of harmonised standards is voluntary but has the advantage of giving a "presumption of conformity" with the essential requirements corresponding to its scope. If a manufacturer chooses not to follow a harmonised standard, he has the obligation to prove that his apparatus is in conformity with the essential requirements by other means and to provide a full technical justification.

If the manufacturer applies only part of a harmonised standard or where the applicable harmonised standard does not cover all the essential requirements, the presumption of conformity exists only to the extent that the applied standard corresponds to the essential requirements.

A harmonised standard has to match the essential requirements of the relevant directive. A European standard may contain parts relating not only to essential requirements as defined by the Directive but also to other provisions. In such a case, these provisions are clearly distinguished from those covering the essential requirements.

A harmonised standard does not necessarily cover all essential requirements. This would oblige the manufacturer to use other harmonised standards, relevant specifications or other standards to meet all the essential requirements relevant to his apparatus.

In the event of shortcomings in certain harmonised standards and in consultation with the TCAM pursuant to Article 5, the Commission may also publish guidelines on the interpretation of harmonised standards or define the conditions under which compliance with a standard is considered to confer a presumption of conformity.

Acting under the same procedure, the Commission may withdraw a harmonised standard if it does not ensure presumption of conformity with the relevant essential requirements. The Commission website gives a list of titles and references to harmonised standards in relation to radio equipment and telecommunications terminal equipment at: http://ec.europa.eu/enterprise/rtte/harstand.htm.

A copy of the most recent list published in the OJEU can also be downloaded from that page.

The Commission may withdraw the OJEU reference by publication of a notice to that effect in the OJEU after consultation with the TCAM. The presumption of conformity with that standard will then cease. In certain circumstances, the Commission may also publish an opinion that results in withdrawal of the presumption from certain parts of a harmonised standard.

The OJEU provides the following information for each harmonised standard:

- the reference (including the version number);

- the title;
- the reference of the superseded standard;
- the date of cessation of presumption of conformity of the superseded standard.

This date of cessation of presumption of conformity of the superseded standard should not be confused with the date of withdrawal ("dow") of a superseded standard indicated by a standards organisation, although normally both these dates are identical. The dow has no meaning within the concept of the R&TTE Directive.

The cessation of presumption of conformity applies only to those individual items which are not yet placed on the market. For an individual apparatus already placed on the market, the fact that one or more standards it conforms to no longer confer presumption does not alter its conformity, nor the validity of its DoC.

Any current reference of a standard taken from the latest valid OJEU list may be used as a harmonised standard until the date of cessation of presumption of conformity is reached.

Explanations are provided as notes attached to the list of European harmonised standards published in the OJEU.

5.2 Radio test suites

Radio test suites are defined as a series of tests providing evidence of the apparatus' compliance with the essential requirements of the R&TTE Directive.

In practice, harmonised standards describe these radio test suites.

5.3 Revision of harmonised standards

During a transitional period, both the old and the revised standards give a presumption of conformity, provided that they both meet the conditions for doing so.

If the manufacturer chooses to apply a harmonised standard, he has to ensure that his apparatus complies with the version of the harmonised standard which gives a presumption of conformity at the time of its declaration of conformity.

Manufacturers who have applied a superseded harmonised standard and do not wish to apply the new harmonised standard need to consult a notified body in order to continue placing apparatus on the market.

6 CONFORMITY ASSESSMENT PROCEDURES

6.1 Introduction

Apparatus is required to comply with the essential requirements referred to in Article 3 of the R&TTE Directive. The manufacturer has to demonstrate the compliance of apparatus by applying a conformity assessment procedure. A different conformity assessment may be used for each essential requirement. The procedures are detailed in Article 10 and Annexes II, III, IV and V of the Directive.

Technical documentation has to be prepared to provide evidence that the apparatus complies with the essential requirements. This includes evidence that the apparatus complies with the relevant harmonised standards or, if harmonised standards are not used or used only in part, a detailed technical justification.

To assess compliance with the essential requirement regarding health and safety, the manufacturer may apply the conformity assessment procedures laid down in the R&TTE Directive or, if the apparatus is within the scope of application of the LVD, the procedures laid down in that Directive.

Since the entry into force of the new EMC Directive, the assessment procedures of the EMC Directive can no longer be applied for R&TTE apparatus.

Harmonised standards under the LVD, EMC, 2006/95/EC, 2004/108/EC and 93/42/EC Directives also have the same status under the R&TTE Directive.

At the end of the conformity assessment, the manufacturer or his authorised representative in the European Union is required to complete an EC Declaration of Conformity and affix the CE marking on each apparatus.

After the conformity assessment has been carried out, the manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured apparatus with the technical documentation and with the essential requirements of the R&TTE Directive that apply to it.

6.2 Applicable conformity assessment procedures

6.2.1 Introduction

The following procedures are applicable depending on the type of apparatus and whether or not harmonised standards are used.

Procedure		Applicable to apparatus: without radio part	Applicable to apparatus: with radio part	Role of the notified body (if applicable)
II	Internal production control	Terminal equipment	Receivers	
III	Internal production control plus specific apparatus tests		Radio equipment including a transmitter complying with harmonised standards	Identification of the essential radio test suites if they are not defined in the harmonised standard
IV	Technical construction file	Terminal equipment	All radio equipment as above and also that including a transmitter not complying or only partially complying with harmonised standards	Opinion on the conformity of the equipment based on a review of the technical construction file established by the manufacturer
V	Full quality assurance	All equipment covered by the R&TTE Directive		Certification of the manufacturer's quality system

The R&TTE Directive conformity assessment procedures are ordered incrementally depending on their complexity (Annex II is simpler than Annex III, and so on). Higher conformity assessment procedures may always be applied (with the single exception that Annex III cannot be applied to terminal equipment with no radio part). For example, a receiver which has to be assessed under the procedure described in Annex II may also be assessed under the procedures described in Annexes III, IV or V. Conversely, a GSM base station which has to be assessed at least under the procedure described in Annex III cannot be assessed under the procedure described in Annex II.

The explanations of the modules set out below describe the procedures whereby the manufacturer or his authorised representative established within the European Union, who carries out the obligations laid down in the applicable descriptions, ensures and declares that the apparatus concerned satisfies the requirements of this Directive that apply to it.

6.2.2 Internal production control (Annex II)

This procedure may be applied to wired terminal equipment (wired phones, wired faxes, etc.) and to the receiving parts of radio equipment.

The R&TTE Directive stipulates that the manufacturer has to:

- ensure that apparatus fulfils the applicable essential requirements:
  - by applying in full applicable harmonised standards and performing all test suites described in the harmonised standards themselves. Results of the assessment should be recorded in test reports that are part of the technical documentation. A list of the applied harmonised standards has also to be included in the technical documentation;
  - by using other means of his own choice (for example by means of any existing technical specifications, by using partly an applicable harmonised standard, etc.). The manufacturer has to describe and explain the solutions adopted to meet the essential requirements of the Directive. This information has to be included in the technical documentation;
- prepare the technical documentation;
- draw up the declaration of conformity and keep a copy with the technical documentation;
- take all measures necessary in order that the manufacturing process ensures compliance of the manufactured apparatus with the essential requirements;
- affix the CE marking on the apparatus, on the packaging and on accompanying documents;
- identify the apparatus by type, batch and/or serial numbers and by either the name of the manufacturer or the person responsible for placing the apparatus on the market.

6.2.3 Internal production control plus specific apparatus tests (Annex III)

This procedure may be applied by the manufacturer only if he fully applies harmonised standards applicable to the apparatus.

The R&TTE Directive stipulates that the manufacturer has to apply the requirements laid down in the previous module (internal production control (Annex II) — Section 6.5.1), plus the following supplementary requirements:

- he must carry out all essential radio test suites described in the applicable harmonised standard;
- if the applicable harmonised standard does not describe all essential radio tests suites, the manufacturer has to consult a notified body that will define them.

In order to allow the notified body to analyse the radio test suites to be applied, the manufacturer should provide (but should not be restricted to) the following information:

- technical documentation;
- technical parameters of the apparatus:
  - frequency range
  - RF output power
  - type of modulation
  - channel spacing
  - duty cycle
  - simplex/duplex
  - declared (RF) interface on which the apparatus is intended to operate
  - ITU code;
- any other information relating to the identification of radio test suites as required;

- he must draw up the declaration of conformity to specific radio test suites described in Annex III, whereby he declares that these essential tests have been carried out;
- he must affix the CE marking (including notified body number and alert sign, where appropriate) on the apparatus, on the packaging and on accompanying documents.

6.2.4 Technical construction file (Annex IV)

This procedure may be applied for all apparatus falling within the scope of the R&TTE Directive, including those cases where the manufacturer has not applied or has applied only in part a harmonised standard.

The R&TTE Directive stipulates that the manufacturer has to apply the requirements laid down in the previous modules (internal production control (Annex II) — Section 6.5.1) and if

applicable internal production control plus specific apparatus tests (Annex III) — Section 6.5.2), plus the following requirements:

- he must prepare a technical construction file (technical documentation plus the declaration of conformity to specific radio test suites described in Annex III);

- he must present the technical construction file to a notified body for inspection. The same technical construction file may be presented to more than one notified body. In such a case, the manufacturer must inform all involved notified bodies of all other notified bodies consulted. The notified body must not perform any tests. It has to issue an opinion based on an evaluation of the technical documentation;

- the opinion of the notified body must be given within four weeks. On receipt of the opinion, or after the end of the four-week period, the apparatus may be placed on the market under the full responsibility of the manufacturer.

It is recommended that the manufacturer keeps a copy of the opinion of the notified body with the technical documentation.

6.2.5 Full quality assurance (Annex V)

This procedure may be applied by manufacturers that operate an approved quality system for design, manufacture and final inspection and testing of apparatus. It is available for all equipment within the scope of the Directive irrespective of whether or not harmonised standards are applied.

The manufacturer's quality system must ensure compliance of the apparatus with the essential requirements and must include a quality plan or equivalent documentation for each apparatus or family of apparatus, for example DATA, ISDN, GSM. The quality system is subject to assessment and audit by a notified body.

A manufacturer's quality system in accordance with international quality standards normally satisfies the general requirements of Annex V of the Directive. The notified body should pay particular attention to the way R&TTE regulatory obligations are handled under the quality system.

The notified body needs to be informed about significant changes to the manufacturer's organisation or quality system. The notified body will then verify the information and decide whether further audit(s) are necessary.

Findings of audits will be recorded in an audit report. The report will be made available to the applicant together with required changes and actions (if any).

The notified body will perform follow-up audits at least once a year. The frequency of follow-up audits may depend on issues such as the depth of the audit, the size of the facilities and results of previous audits. The audit results and follow-up actions must be formally documented and made available by the notified body on request.

Inspection and test records will need to be kept for a timescale agreed with the notified body and as described in the quality plan or equivalent documentation. In any event, the timescale must not be less than 2 years.

The following records are kept for at least 10 years after the last apparatus has been manufactured:

- the quality manual and quality plans or equivalent documentation including design input and verification data;
- details of any amendments to the quality system documentation together with the notification of agreement from the notified body where required;
- reports from the notified body on all routine surveillance visits and unannounced visits, and any apparatus tests arising from such visits.

A procedure must exist whereby the manufacturer provides a declaration of conformity for each apparatus produced under the Annex V arrangements.

There is no specific time limit placed on notified bodies for retention of documentation, but it seems appropriate for the notified body to retain its own records for the same period as the manufacturer.

The manufacturer must retain the declarations of conformity as a record of what he has placed on the market via the Annex V route. The notified body must have access to these documents, and to all relevant documentation supporting the declaration of conformity.

6.2.6 Using the compliance procedures of the LVD

Where apparatus falls within the scope of the LVD, the manufacturer may apply the procedures laid down in that

Directive to assess compliance with the essential requirement regarding health and safety.

This can be helpful and avoid the need for involvement of a notified body in cases where harmonised standards do not exist on all health and safety aspects for certain radio equipment within the scope of the LVD, for example exposure to electromagnetic fields.

6.3 Testing

Required tests may be carried out by the manufacturer or by a third party. No formal accreditation is required to carry out the tests. The manufacturer remains responsible in all cases for the compliance of his apparatus.

6.4 Documentation required by the conformity assessment procedures

This comprises the technical documentation and the EC Declaration of Conformity.

Records and correspondence relating to the conformity assessment procedures must be in an official language of the Member State where the procedure is carried out, or in a language accepted by the notified body involved.

6.4.1 Technical documentation

The manufacturer draws up technical documentation providing evidence of the conformity of the apparatus with the essential requirements of the Directive.

6.4.1.1 Confidentiality of the content of technical documentation

National market surveillance authorities have the legal right to obtain the necessary technical information to check conformity with the essential requirements of the Directive. National market surveillance authorities are under the legal obligation to ensure that technical information they collect remains confidential.

Manufacturers therefore have no grounds for fearing that sensitive information they provide to national market surveillance authorities in the context of market surveillance might be disclosed.

6.4.1.2 Legal basis

Annex II of the R&TTE Directive requires the manufacturer to establish the technical documentation. The technical documentation must be kept by the manufacturer or his authorised representative in the EU for at least 10 years after the last product has been manufactured, and be shown on request to the national

surveillance authorities in the Member States. In the words of the R&TTE Directive, the documentation must cover:

- a general description of the product;
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product;
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where such standards referred to in Article 5 have not been applied or do not exist;
- results of design calculations made, examinations carried out, etc.;
- test reports.

The manufacturer or his authorised representative must also keep a copy of the relevant declaration of conformity with the technical documentation.

6.4.1.3 Purpose of technical documentation

The purpose of the technical documentation referred to in Annex II of the Directive is to assess the conformity of the product with the essential requirements of the Directive (Article 3(1)(a), 3(1)(b), 3(2) and 3(3) if applicable). Even if it is not intended to be a comprehensive design and manufacturing dossier, it should contain all information necessary to identify the product(s) concerned and assess their compliance.

The nature and detail of the documents included will vary from case to case. The specific product(s) concerned must always be clearly identified. However, information about design, manufacture and operation is relevant only to the extent that it is needed to assess compliance with the essential requirements. In particular, aspects for which compliance is assessed solely by measuring how the equipment impacts its environment (e.g. measuring radio emissions around the equipment) do not justify including a description of the internal design.

Although it is not a requirement of the Directive, it is recommended that the documentation is organised in a file with sections corresponding to the elements identified in Annex II.4 of the Directive. This is the basis of the advice set out below.

International standard EN ISO/IEC 17050-2:2004 “Conformity assessment — Supplier’s declaration of conformity — Part 2: Supporting documentation”, with the exception of clause 5.2a), is generally applicable to establishing and maintaining technical documentation for the purposes of the Directive.

Modifications with potential impact on the way the product meets the essential requirements require a new assessment.

6.4.1.4 General description of the product [EN ISO/IEC 17050-2 Clause 5.1a)]

All products covered by the technical documentation must be identified by model/type/brand, etc. If more than one model etc. is covered, the relationship between the models should be clearly explained.

Full user information should be provided, describing how the product is intended to be used and any precautions to be observed in installing, using and maintaining it.

Where software or firmware affects compliance, it should be explicitly referenced and any user-configurable options explained.

If not included in the user information, photographs or illustrations showing external features and internal layout should be provided. These should be in sufficient detail to permit reliable visual identification of the equipment concerned.

6.4.1.5 Conceptual design & manufacturing drawings & schemes of components, sub-assemblies, circuits, etc. [EN ISO/IEC 17050-2 Clause 5.1b)]

Conceptual design & manufacturing drawings & schemes of components, sub-assemblies, circuits, etc. include circuit diagrams, PCB layouts and parts lists for all network or radio interface circuits, power supplies and ports for connecting other apparatus which communicates via or interacts with those interfaces.

Components that are critical for compliance purposes (e.g. safety isolation or RF sources) should be specifically identified with alternatives (if any). Similar considerations apply to software and firmware as well as hardware.

Note that this information may also be used to assist in identifying the apparatus covered by the technical documentation, particularly in cases where there is doubt arising from post-market surveillance.

6.4.1.6 Descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product [EN ISO/IEC 17050-2 Clause 5.1b)]

For simple equipment, a circuit diagram and the user information provided in response to previous sections may be sufficient. For more complex equipment, a block diagram with an outline technical description would be appropriate.

In all cases, the points of connection to communications networks and to antennas (integral or external) must be clear. The network interface(s) and/or radio spectrum usage should be identified.

Ports for connection of other apparatus should also be identified together with any specifications for such other apparatus required to ensure overall compliance with essential requirements.

6.4.1.7 List of the standards referred to in Article 5, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive, where such standards, referred to in Article 5, have not been applied or do not exist [EN ISO/IEC 17050-2 Clause 5.2b)]

The list of standards is specifically those standards harmonised for the purposes of the R&TTE Directive. The particular version of each standard should be identified together with the relevant clauses or parts if it has not been applied in full.

Where harmonised standards are not applied (e.g. because they are not available), other standards may be used provided some explanation of their relevance to essential requirements is given. “Standards” should be interpreted broadly in this context to include requirements and recommendations issued by any recognised body competent in the field concerned.

The opinion of a notified body will be required in all such cases but it is the manufacturer’s responsibility, not the notified body’s, to put together the rationale for compliance.

If no appropriate standards exist to address a particular aspect of compliance with essential requirements then an assessment from first principles must be made, based on good engineering practice, and documented accordingly. Again, this is the manufacturer’s responsibility, not that of a notified body.

This section should deal with strategy only. Results of evaluation in accordance with the strategy identified are covered in subsequent sections.

In the case of a product where the manufacturer has fully applied the applicable harmonised standard, the inclusion of a copy of the declaration of conformity (including the reference to the standards applied) is sufficient.

6.4.1.8 Results of design calculations made, examinations carried out, etc. [EN ISO/IEC 17050-2 Clause 5.1c)]

It may be helpful to consider this as an exercise in risk analysis seeking to identify potential causes of non-compliance with the essential requirements and the means by which assurance has been gained that such non-compliance is avoided. This might include, for example, documenting how the installation instructions of a sub-assembly supplier have been respected, how "worst case" scenarios for selective tests on a range of models have been determined or why results on a similar but differently named/branded product can be applied.

Typically, this might be the case where only one model in a range of products has been tested, where reliance is placed on compliance of a sub-assembly for which a third party holds the detailed compliance documentation, where reliance is placed on calculation rather than testing (for example, certain cases of RF exposure) or where the version manufactured differs in some way from the version to which the test results relate.

6.4.1.9 Test reports [EN ISO/IEC 17050-2 Clause 5.1c)]

For each product type, the manufacturer has to subject his product to compliance tests. The results of these tests should be recorded in a test report. This may be done by the manufacturer himself or by a third party, such as a test laboratory (accreditation is not required).

It is advisable that test reports are drawn up in accordance with clause 5.10 of the standard ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories". However, this is not compulsory.

Test reports must unambiguously identify the apparatus to which they relate so that they can be correctly associated with the corresponding declaration of conformity. Where special software or a special configuration is required for testing this must be clearly stated and the relationship with software for normal use explained. Information on how to set the product in test mode and the test software needed should also be available. This information should permit the assessment of controlled equipment under the same conditions used by the manufacturer in the conformity assessment procedure.

One test report may cover the whole or part of one or more essential requirements. However, it should be clear whether the report addresses the whole or only part of the essential requirements and, in the latter case, precisely which part(s).

Where harmonised standards do not specify particular test suites or have not been applied in full or other standards or alternative test methods have been used, the test methods should be detailed with justifications for their relevance to the essential requirements.

6.4.1.10 Other items [EN ISO/IEC 17050-2 Clause 5.2b)]

It is a requirement of the Directive that a copy of the declaration of conformity must accompany the technical documentation to make up a technical construction file when the opinion of a notified body is sought. It is therefore recommended that a copy of the declaration of conformity forms part of the technical documentation.

International standard EN ISO/IEC 17050-1:2004 “Conformity assessment — Supplier’s declaration of conformity — Part 1: General requirements” provides a suitable model for the declaration of conformity.

Where an opinion is obtained from a notified body in accordance with Annex IV of the Directive, it is further recommended that a copy of that opinion and annexes are added to the technical documentation.

The R&TTE Directive requires records and correspondence relating to the conformity assessment procedures (e.g. technical documentation) to be in an official language of the Member State where the procedure is carried out, or in a language accepted by the notified body involved.

The technical documentation should be kept at the disposal of the market surveillance authorities for a period of at least 10 years after the last apparatus has been manufactured.

Although the R&TTE Directive does not require the physical presence of the technical documentation in the EU, it is recommended that the importer keeps a copy of the technical documentation in the EU.

6.4.2 EC Declaration of Conformity

The compliance of apparatus with all relevant essential requirements is declared in an “EC” Declaration of Conformity (DoC) issued by the manufacturer — inside or outside the

European Union — or by his authorised representative in the European Union.

As the DoC is an "official" declaration, it must be signed by a person "empowered to bind the manufacturer or his authorised representative located in the European Union".

The layout of the DoC can take any form as long as the minimum required relevant information is provided. A recommended form in line with EN 17050 can be found in Annex 1 to this Guide.

It is left to the discretion of the manufacturer to add any information that could be useful in order to make the DoC applicable to areas outside the EU, provided that it does not conflict with the requirements of the R&TTE Directive.

Furthermore, in cases where several directives apply simultaneously to the apparatus, the manufacturer or the authorised representative is free to decide whether it might be worthwhile to merge all the DoCs into a single document. However, this may not be possible if a directive provides for a specific form of the DoC (such as the Directive relating to Personal Protective Equipment) that is not aligned with the DoC for the R&TTE Directive.

All information regarding the concept of making the DoC available to the authorities, as well as where to keep the DoC, is given in Section 6.4.3.

Manufacturers should not confuse the DoC with the opinion of a notified body, which is incorrectly called in some cases "certificate of conformity". The two documents may be easily distinguished: the DoC is signed by the manufacturer, while the other document is signed by the notified body.

6.4.3 Concept of "holding at the disposal of the authorities"

The Directive requires that:

"The manufacturer must establish the technical documentation … and he or his authorised representative established within the Community must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities of any Member State for inspection purposes."

This provision also applies to the DoC.

The concept of "holding at the disposal of the authorities" means:

1. The manufacturer or his authorised representative established within the European Union is responsible for making available the EC Declaration of Conformity and the technical documentation.

2. This person must present the EC Declaration of Conformity and the technical documentation upon request from the competent authorities, within a reasonable time (usually 2 weeks). He has to take positive actions to make it actually available to those authorities (send a copy of the file, email, etc.).

3. Failure to present the information within a reasonable period in response to a request by the authorities can constitute an infringement of one of the administrative requirements of the R&TTE Directive. This may lead to further measures because it cannot be proved that a conformity assessment was carried out before the apparatus was placed on the market.

4. The authorised representative established within the European Union does not need to be in physical possession of the documents. The documents can be kept on the manufacturer's premises, even if the manufacturer is outside the European Union.

5. Where neither the manufacturer nor the authorised representative is present in the European Union, the responsibility for the provision of this information rests with the person first placing the apparatus on the EU market (importer).

6. The manufacturer is obliged to provide the documentation and cannot argue that it contains confidential information (e.g. commercial confidentiality).

7. It has been agreed by those concerned that the information to be made available on request need not be an original document but can be a copy. In addition, the technical documentation can be kept in any format (for example in hard copy or on CD-ROM or any other electronic storage medium) which allows it to be made available within a reasonable period of time (e.g. 2 weeks). Information should be provided in an appropriate and usable form.

8. If the documents are in a language that is not understood by the competent authority, it is considered mandatory to provide the competent authority with a translation of the most important documents.

There is no obligation for the technical documentation to accompany the apparatus nor is it a legal obligation under the Directive for manufacturers to make available technical documentation to their customers.

6.5 Marking

The marking set out below must be affixed to the apparatus or to its data plate and have a minimum height of 5 mm. The elements should be easily readable and indelible. They may be placed anywhere on the apparatus case or in its battery compartment. No tool should be needed to view the marking.

This marking should also be reproduced on the packaging (if any) and on the accompanying documents. Although the word “documents” appears in plural in the text of the Directive, the intention is that the CE marking should be reproduced at least in one set of accompanying documents (e.g. instruction manual) and be easily identified by the user and/or the surveillance authorities.

Where it is “not possible or warranted on account of the nature of the apparatus” to have the marking affixed to the apparatus or to its data plate, the CE marking may be placed on the packaging, if any, and in the accompanying documents. The Blue Guide (Chapter 7.3) gives more information about the circumstances in which this exemption is allowed.

The R&TTE Directive does not forbid affixing the CE marking in more than one place, for example, on the packaging as well as inside the apparatus.

Affixing the CE marking denotes compliance with all applicable EC “new approach” directives. As a consequence, apparatus that does not fall within the scope of the R&TTE Directive or of any other directives requiring CE marking cannot bear the CE marking.

The R&TTE Directive forbids the affixing of marks that are similar to the CE marking, as well as those that are likely to mislead third parties in relation to the meaning of the CE marking, e.g. by giving the impression that they are needed in order to have free access to a Member State’s market.

For apparatus under the R&TTE Directive, the CE marking is the only marking having regulatory effect regarding R&TTE requirements within the European Union. Other directives may impose additional regulatory marking.

6.5.1 Complete CE marking

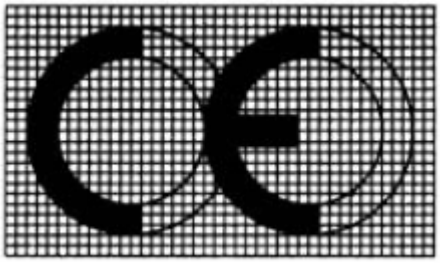
The following picture shows an example of CE marking. The “CE” mark is always required. The other elements, notified body

number ("NBnr" replaced by the four-digit identification number of any notified body involved) and class identifier (alert sign), may or may not be present depending on the particular circumstances.

CE NBnr

6.5.2 CE mark

The R&TTE Directive requires that apparatus bears the CE mark as an attestation of compliance with the R&TTE Directive. The CE mark may, however, be required to show conformity with other directives, in which case its presence attests to compliance with all applicable directives.

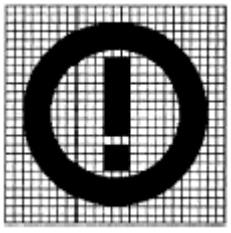


6.5.3 Identification number of the notified body

The CE marking should include the identification number of the notified body involved in the conformity assessment procedure. Where more than one notified body is involved, all the identification numbers of all notified bodies involved should be indicated. The identification number must have the same height as the CE marking.

6.5.4 Class identifier

The class identifier is the "information sign" or "alert sign" described in Section 4.2. It forms part of the CE marking and is used to inform the user that restrictions on the use of the apparatus may apply in some countries or geographic areas. It must have the same height as the CE marking.



This marking should be accompanied by information for the user on the applicable restrictions on the use of the apparatus and where these restrictions apply.

6.5.5 Other markings

The R&TTE Directive requires that apparatus be identified by:

- type;
- batch and/or serial numbers;
- the name of the manufacturer or the person responsible for placing the apparatus on the market.

This information is needed to allow the apparatus to be identified. The identification of the apparatus must unambiguously correlate with the DoC and the technical documentation.

Although not explicitly mentioned, this information needs to be on the apparatus (or its data plate). This will establish a link to the technical documentation where more information is given.

6.5.6 Marking of apparatus containing an R&TTE component

Apparatus containing an R&TTE component must be marked in the following way:

- Apparatus which at the time of placing on the market contains as an integral part one or more components that are covered by the R&TTE Directive and are not intended to be removed by the user should be marked pursuant to the R&TTE Directive. In addition, the user documentation for the apparatus should comply with the Directive and e.g. indicate geographic restrictions on use.
- Apparatus which at the time of supply has provision for later user-added components that fall under the R&TTE Directive but are otherwise not covered by the Directive (e.g. computers without an integral modem and/or wireless capability) should not be marked according to the Directive.

7 ADMINISTRATIVE REQUIREMENTS

7.1 Introduction

In addition to the conformity assessment procedure, the R&TTE Directive lays down some administrative requirements to be fulfilled.

7.2 Information for the user

The manufacturer must:

- inform the user about the intended use of the apparatus. This information has to be sufficient to avoid interferences due to misuse of the apparatus (e.g. the maximum gain of the antenna to be connected to a WLAN);

- inform the user on the packaging and in the instructions for use of the apparatus about the Member States or the geographic area within a Member State in which the apparatus is intended to be used. This information is not required for Class 1 equipment, which by definition can be used anywhere in the European Union;

- alert the user to potential restrictions or requirements regarding the authorisation to use the radio apparatus that may apply in certain Member States (e.g. use restricted indoors);

- in the case of terminal apparatus, inform the user about the interfaces of the public telecommunications networks to which the apparatus is intended to be connected;

- provide the user with a copy of the declaration of conformity. This obligation may be fulfilled by choosing one of two possibilities:

  – a copy of the original declaration of conformity is made available to the user;

  – the following informal statement on compliance with the Directive is made in any of the languages of the European Union:

    [Name of manufacturer] hereby declares that this [type of equipment] is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

    This statement has to be accompanied by the exact address (mail address or website) where a copy of the original declaration of conformity may be found or obtained.

This information has to be presented in such a way that the user can readily understand it. Typically, this will necessitate translation into every local language (required by national consumer laws) of the markets where the equipment is intended to be sold. Illustrations, pictograms and using

international abbreviations for country names may help reduce the need for translation.

7.3 Notification of radio equipment pursuant to Article 6(4)

The manufacturer or his authorised representative established within the European Union or the person responsible for placing the equipment on the market must notify the national authority responsible in the relevant Member State for spectrum management of the intention to place radio equipment using frequency bands whose use is not harmonised throughout the European Union on its national market (Art. 6(4)).

The concept of "harmonised use", for determining whether notification of a given item of radio equipment is needed or not, takes into account both the existing usage restrictions imposed by authorities and the equipment characteristics themselves. All the various restrictions on putting into service established throughout the Union have to be analysed to check how this radio equipment fits into them.

The TCAM applied the above principle to define radio equipment for which the use of frequency bands is harmonised throughout the EU. It is radio equipment which:

- does not transmit; or
- can only transmit under the control of a network or otherwise automatically adapts without user intervention so as to meet the conditions of use in every Member State and never harmfully interfere in any Member State; or
- transmits exclusively in frequency band(s) which are allocated to the same radio interface in every Member State in the following way:
  - (a) there is a common frequency allocation; and
  - (b) within this allocation, the allotment and/or assignment of radio frequencies or radio frequency channels follows a common plan or arrangement; and
  - (c) the equipment satisfies common parameters (e.g. frequency, power, duty cycle, bandwidth).

Notification of radio equipment which uses frequency bands whose use is not harmonised throughout the European Union should be made to the relevant Member States, i.e. the Member States on whose market it is intended to place the equipment.

Use of the bands corresponding to subclasses of Class 1 published on the ERO website (www.ero.dk/rtte) is harmonised. Equipment operating exclusively in one or more of those bands and fulfilling the described technical requirements for the corresponding subclasses does not need to be notified.

The notification has to be carried out at least four weeks before effective placing on the market. Although there is no obligation for national authorities to respond to a notification, most will do so if the equipment's frequency use does not correspond to the national frequency allocation table.

There has been disagreement on whether notification should be made to all Member States where the product is marketed, or only to those Member States where the frequencies used by the equipment are not available.

One group of Member States requires notification of all equipment capable of operating outside the definition of harmonised use, whereas another group requires notification only of equipment for which frequencies are not available nationally. While the latter group is acting according to the original intention, the first group is acting according to the letter of the Directive. Furthermore, the Commission does not oppose those Member States that do not require any notification.

However, the administrative burden and uncertainty of this unresolved situation has been alleviated since 1 January 2008 by a web-based notification tool. Notifications may be submitted to many Member States via the "one-stop notification" application (http://ec.europa.eu/enterprise/rtte/osn.htm). Using this web application simplifies the notification procedure. The manufacturer introduces the required information and sends it to all authorities concerned in one step. Not all Member States participate in the one-stop notification procedure. For these countries, the notification has to be sent separately. Contact points are available at "spectrum authorities" on http://ec.europa.eu/enterprise/rtte/contact.htm.

After a four-week period, the equipment may be placed on the market.

Notification is therefore the process of announcing to the national authority one's intention to place on the market telecommunications equipment using frequencies whose use is not sufficiently harmonised at European Union level for this equipment.

7.4 Comparing the need to notify or not (Art. 6(4)) to the need for an alert sign or not (Class 1 or Class 2)

The dividing line between Class 1 and Class 2 (see Section 4.2) is not the same as the dividing line between notification and no notification. Most of the time Class 2 equipment (alert sign required) needs to be notified, and Class 1 equipment (no alert sign) does not need to be notified. However, there are cases where Class 2 equipment (alert sign required) does not need to be notified. This is the case of equipment which operates in bands whose use is harmonised (e.g. GSM base stations) but is subject to some restrictions (e.g. a GSM licence), and thus must carry the alert sign.

Nevertheless, the fourth theoretical case where Class 1 equipment (no restrictions) would have to be notified because it operates in non-

harmonised bands has been eliminated by the first and second bullet of the accepted definition of harmonised use given in Section 7.3.

The table below summarises the situation:

	No restrictions on putting into service Class 1	Restrictions on placing on the market or putting into service Alert sign and Class 2
Operates exclusively in bands with harmonised use and does not have to be notified (3)	Class 1, no notification	Class 2, no notification
Does not operate exclusively in bands with harmonised use and must be notified	Not possible	Class 2, notification

8 NOTIFIED BODIES

8.1 General concept

Notified bodies are designated by the competent authorities of the Member States to perform the conformity assessment tasks described in the Directive. The Member States verify that these bodies meet the criteria given in Annex VI of the Directive, i.e. that they can demonstrate the required level of resources, competence, independence, impartiality and integrity. This is subject to surveillance at regular intervals.

The Commission publishes a list of bodies in the OJEU and keeps it up to date. There is also a website with a list of appointed EU notified bodies: http://ec.europa.eu/enterprise/newapproach/nando/index.cfm.

The lists include the address details of each body as well as the tasks for which it has been notified.

Under the R&TTE Directive the notified body may perform up to three different tasks following the procedures in Annexes III, IV and V of the R&TTE Directive.

- identify the essential radio test suites (Annex III of the Directive);
- review and give opinions on technical construction files (Annex IV of the Directive);
- assess and perform periodic surveillance of manufacturers' full quality assurance systems (Annex V of the Directive).

Bodies can be designated for one or more of these tasks and may be appointed to deal with all or only selected types of apparatus.

The body will need to have policies and procedures in place that distinguish between tasks carried out as a notified body and any other activity in which the organisation is engaged.

It should be noted that the body cannot, in its role as a notified body:

- carry out testing;
- prepare test reports;
- design equipment;
- sign or issue a manufacturer's declaration of conformity;
- act as an agent for the manufacturer;
- perform notifications pursuant to Article 6(4) of the Directive.

8.1.1 Annex III procedure — essential radio test suite

Based on the information received and the product identification in accordance with Section 6.2.3, the aspects related to Article 3(2) of the Directive are analysed by the body.

This analysis is based on checking the following parameters:

1. Technology-independent criteria;

2. No access protocol tests (unless required by a harmonised standard);

3. General frequency management items:

- RF power capabilities;
- occupied bandwidth;
- frequency stability;
- frequency error;
- (conducted) spurious emissions;
- extreme temperature and voltage behaviour (if appropriate);
- adjacent channel power (if appropriate);
- transmitter attack time/release time (if appropriate);

- transmitter intermodulation attenuation (if appropriate);
- availability of appointed air interfaces.

The result of this evaluation leads to the identification of radio test suites and the body then passes this information to the applicant.

It is the responsibility of the applicant to make sure that those radio test suites are then applied to the apparatus.

The radio test suites are only valid for the apparatus described so long as it remains unchanged or until harmonised standards are issued for the product in question containing complete and appropriate radio test suites. If the equipment is still being produced, there is a responsibility for the applicant to comply with these latter requirements.

The identification of the radio test suites by the notified body can be given in any format but the following items should at least be covered by the identification:

APPLICANT DETAILS

- Company name: < full name of the company >
- For the attention of: < name of applicant representative > and/or < function >
- Address of the applicant

PRODUCT DETAILS

- Product description: < indicate kind of equipment >
- Intended use: < describe the technical usage of the equipment and frequency of operation >
- Manufacturer: < indicate the name of the manufacturer >
- Brand: < as indicated on the product; this is important as identification information >
- Type(s): < the type identification as printed on the type identification label >
- Frequency band: < frequency band given in kHz, MHz or GHz >
- Maximum transmit power: < indicate how the power is expressed, e.g. dBm, dBm EiRP, ERP >

- Type of antenna: < indicate type of antenna, e.g. integrated, external, parabolic >
- Type of modulation: < indicate type of modulation; the ITU class of emission 7 digit code is helpful >
- Channel spacing: < as declared by the manufacturer, or with reference to e.g. CEPT rec. >
- Channel access method: < channel access method used, or protocol, or refer to ITU info >
- Bit rate: < if available, indicate bit rate used >
- Duty cycle: < related to ERC Dec 70-03E classification of duty cycle class >

ESSENTIAL RADIO TEST SUITES TO BE TESTED

- HS standard used: < indicate title and number of HS used >
- Radio test suites to be tested: < indicate e.g. clauses of proposed standards or a description of the radio test suites >
- Date of application: < in any format >
- Date of issue: < in any format >

An example is given in Annex 2.

8.1.2 Annex IV procedure — technical construction file (TCF)

The Directive requires compliance when equipment is "properly installed and maintained and used for its intended purpose". The body should therefore note any inconsistencies between obvious uses of the equipment and the stated intended purpose so that its opinion may be suitably qualified and is not open to misinterpretation.

The applicant specifies which aspects of the essential requirements the notified body is to assess. For example, the manufacturer could require only the EMC aspects to be covered (Art. 3(1)(b) of the Directive) and the effective use of the spectrum (Art. 3(2) of the Directive) and not require the safety issues to be covered (Art. 3(1)(a)).

An aspect relevant to the intended purpose may be the number of units of equipment likely to be put into service and their overall potential for harmful effects to networks or the radio spectrum. Control of the spectrum remains essentially a national matter and so it is essential to consider the spectrum plan for the intended

location(s) of use and any relevant interface regulations for the Member State(s) concerned. In this context “location” implies not only the physical placement but also any relevant environmental factors. In extreme cases, it may be necessary to liaise directly with the spectrum authority for the relevant Member State.

The notified body must review the file and, if the review concludes that the file does not properly demonstrate compliance with the requirements of the Directive, the notified body may issue an opinion to the applicant and inform the other notified bodies that have also received the file. This opinion must be given within four weeks of receipt of the file and describe on what grounds the technical documentation of the apparatus fails to demonstrate compliance with the Directive.

The Directive only indicates that an opinion may be issued by the notified body in the event that the requirements are not met. However, it is common practice among notified bodies to only issue a statement (opinion) to the applicant in the positive case where all requirements have been met.

The notified body must base its opinion regarding compliance with the requirements of the Directive on its professional assessment of the TCF taking due account of relevant standardisation, other technical references and professional opinion available at that time.

When compliance of the apparatus is confirmed the opinion of the notified body cannot generally be conditional or limited in time. An exception is made if technical requirements have to be specified in order to be compliant (such as adding a specific filter to the equipment).

The notified body should maintain records documenting the rationale used to arrive at a particular opinion. The records should identify any documents referenced in the assessment and the particular limits applied to determine compliance with the essential requirements.

Annex IV of Directive 1999/5/EC provides for the notified body to give an opinion on a TCF but does not provide guidance on the format and content of such an opinion.

The table below sets out minimum criteria for a notified body opinion. In all other respects, a notified body is free to choose its own format and may include additional information such as the manufacturer’s details, conformity assessment procedure, reference standards, intended purpose and other remarks/observations.

Title	"Directive 1999/5/EC — Notified Body Statement of Opinion" or similar text using the word "opinion" and avoiding the use of words such as "certificate" and "declaration".
Notified body details	Name, address etc., logo. Notified body number.
Opinion number	Unique number of opinion. Revision number and/or copy number if applicable.
Date	Date of issue.
Applicant details	Name, address etc. of the party seeking the opinion.
Scope of opinion	Whether the opinion is in respect of health & safety[39] (Article 3(1)(a)), EMC (Article 3(1)(b)), radio spectrum use (Article 3(2)) and/or special features (Article 3(3)(a)-(f)).
Identification of apparatus	The goal is to give the **minimum** information from the following list such that a third party would be able to uniquely identify the item in question. Description of apparatus, including brand/trade name, model/type designation, software revision. Serial number if opinion was based on testing/examination of a specific physical sample. Reference of any build status/design documentation taken into account. For TTE, network interface compatibility. For radio equipment (as appropriate): o Frequency band(s)/range o Transmit power/power range
TCF identification	Unique identification of the documentation etc. taken into consideration irrespective of the actual physical format of the TCF.
Opinion text	The text stating whether or not the apparatus is compliant (see example).
Authorised signatory	Signature block including printed name of the signatory.

Example of the text of a notified body opinion:

"Our opinion in accordance with Annex IV of Council Directive 1999/5/EC on radio equipment and telecommunications equipment and the mutual recognition of their conformity is that the apparatus identified above complies/does not comply with the requirements of that Directive stated in the above scope."

An example of a notified body letter of opinion is given in Annex 3.

[39] Note that "health & safety" includes EMF as well as electric shock and other hazards. The opinion should be clear about which hazards are included if Article 3(1)(a) is referred to in its scope.

8.1.3 Annex V procedure — full quality control

Assessments to verify compliance of the quality management system with the requirements must be performed under the responsibility of the notified body. Where the manufacturer's quality system has already been certified to related quality plans by an accredited certification body the notified body will normally not duplicate assessments of compliance with those requirements, but will seek assurance that the Directive-specific issues have been taken into account.

8.2 Subcontracting

The notified body can formally subcontract limited tasks, as long as these can be defined as substantial and coherent parts of its operation and are still under its control.

Subcontracting does not therefore entail the delegation of powers or responsibilities. Opinions are always solely issued in the name and under the responsibility of the notified body.

8.3 Coordination between notified bodies

Recognising that it is necessary for the conformity assessment routes to be applied consistently by all parties in order to achieve an open and competitive market throughout Europe, the Radio and Telecommunications Terminal Equipment Compliance Association (R&TTECA) has been set up.

The R&TTECA contributes to the effective implementation of relevant legislation in cooperation with the Committee set up under the Directive (i.e. the TCAM) and facilitates the convergence of conformity assessment practices in the regulatory sphere. The R&TTECA liaises with relevant organisations such as ETSI, the ECC and the R&TTE ADCO.

The R&TTECA issues information sheets, called Technical Guidance Notes — TGNs — which have been drawn up to assist the notified body in its task. These TGNs may also contain valuable background information for manufacturers. The approved TGNs are therefore placed in the public domain and serve as general reference (www.rtteca.com).

It is also advisable that notified bodies closely follow the developments in European standardisation.

The notified body should also:

- be fully aware of the (national) spectrum plans in Europe. These are not always harmonised!
- know the Directive and EU law;

- be able to interpret essential requirements on the basis of available harmonised standards.

8.4 Complaints regarding the service provided by notified bodies

Notified bodies are required to have a policy and procedure for the resolution of complaints received from clients or other parties.

Where a manufacturer is dissatisfied with the service performed, he should file a complaint with the notified body in question.

A complaint can also be filed by the manufacturer with the national designating authority.

Where non-compliant apparatus has been subject to the conformity assessment procedure involving the service provided by a notified body, the Member State supervising the notified body will need to take appropriate action and inform the Commission and the other Member States accordingly.

8.5 Market surveillance and enforcement

Member States are required to take all appropriate measures to ensure that equipment is placed on the market and/or put into service only if it complies, when properly installed, maintained and used for its intended purpose, with the requirements of the Directive.

The Directive does not contain provisions on how surveillance should be organised and carried out in the Member States but details are given in the Blue Guide. The legal and administrative surveillance infrastructures are therefore different from one Member State to another. A list of the Member State surveillance authorities can be found at: http://ec.europa.eu/enterprise/R&TTE/marksur.htm.

The Directive enables the surveillance authorities to gain access to information on equipment. In particular, it requires the declaration of conformity and technical documentation to be retained for inspection by them. This information must be made available by the manufacturer, by his authorised representative established within the European Union, or where neither is in the European Union, by the importer or person responsible for placing the apparatus on the market. The information cannot be withheld on the ground that it contains confidential information (i.e. commercial confidentiality). The surveillance authorities themselves have a duty to respect confidentiality.

Surveillance authorities may also, in accordance with their national laws, check and test products sampled in the market or distribution chain under their jurisdiction in accordance with national laws.

Surveillance activities may arise as a result of a complaint or random check or as part of a systematic programme. Where problems are found, the follow-up will depend on the seriousness of any non-compliance but there should first be an attempt to resolve matters nationally through direct dialogue with the manufacturer or his authorised representative.

In serious cases or where there is a failure to implement adequate remedial measures in a timely manner, withdrawal from the market may be imposed and the surveillance authority concerned will trigger the formal "safeguard" procedure under Article 9 of the Directive. Under this procedure, formal notification of the action taken and the reasons for it is made to the Commission. The Commission will then inform the other Member States, consult with the TCAM and, in due course, give an opinion on the action taken.

The surveillance authorities collaborate in the R&TTE ADCO (Group on Administrative Cooperation).

ANNEX 1 — Recommended form of declaration of conformity

R&TTE Declaration of Conformity (DoC)

Unique identification of this DoC: …….

We, ...
name and address of the manufacturer and/or if applicable of his authorised representative issuing the declaration (contact information)

.....

.....

.....

declare under our sole responsibility that the product:

product name: .....

trade name: .....

type or model: .....

relevant supplementary information: .....
(e.g. lot, batch or serial number, sources and numbers of items)

to which this declaration relates is in conformity with the essential requirements and other relevant requirements of the R&TTE Directive (1999/5/EC).
The product is in conformity with the following standards and/or other normative documents:

HEALTH & SAFETY (Art. 3(1)(a)): .....
(title and/or number and date of issue of the standard(s) or other normative document(s))

EMC (Art. 3(1)(b)): .....
(title and/or number and date of issue of the standard(s) or other normative document(s))

SPECTRUM (Art. 3(2)): .....
(title and/or number and date of issue of the standard(s) or other normative document(s))

OTHER (incl. Art. 3(3) and voluntary specs): .....
(title and/or number and date of issue of the standard(s) or other normative document(s))

Limitation of validity (if any): .....

Supplementary information:
Notified body involved: .....
.....
.....
Technical file held by: .....
.....
.....
.....

Place and date of issue (of this DoC): .....

Signed by or for the manufacturer: .....
(Signature of authorised person)

Name (in print): .....
Title: .....

ANNEX 2 — Example of radio test suite letter under Annex III of the Directive

APPLICANT DETAILS

Company name:	Transmitter company
For the attention of:	R. Designer
Address:	461 Telecom Road 12234 Telecom Valley, USA

PRODUCT DETAILS

Product description:	XYZ wireless point-to-point radio system
Intended use:	Trunk digital point-to-point radio link, 4 GHz
Manufacturer:	Transmitter Company
Brand:	Wireless One
Type(s):	WRLS 128TCM (3.4-4.2 GHz)
Frequency band:	ZZ GHz
Maximum TX power:	XXdBm at maximum settings
Type of antenna:	n.a.
Type of modulation:	128 TCM-4 dimensional
Channel spacing:	ITU-R 382.7 (3.8-4.2 GHz: CEPT 12-08)/draft 9/1005 (3.4-3.9 GHz)
Channel access method:	STM-1 (ITU-T G.703)
Bit rate:	155.22 Mbits/s (STM-1)
Duty cycle:	n.a.

ESSENTIAL RADIO SUITES TO BE TESTED

Harmonised standard available:	EN 300 xyz V1.2.1 (1998-10)/EN 301 abc V.1.1.1 (1999-10),
Radio test suites to be tested:	6.1/6.3-4/6.6/8.2/8.3.1/8.3.2, Annex A2 (EN 300 xyz) 7.1 (EN 301 abc), TX and RX spurious according to CEPT 7-01E
Date of application:	13 August 2010
Date of issue:	31 August 2010
On behalf of:	EU NB Services

Signature and name:

ANNEX 3 — Example of letter of opinion under Annex IV of the Directive

Directive 1999/5/EC — Notified Body Statement of Opinion

This opinion is given under the conformity assessment procedure referred to in Article 10(5) and Annex IV of the R&TTE Directive 1999/5/EC.

Notified body

Notified body number:	8888
Name:	Notified body xyz
Address:	P.O. Box 78392793 999 East Street, Company City, AA 083048

Statement of opinion

Opinion number:	12939317rev 1
Date of issue	31 January 2008

Applicant

Name:	ZZZ Products Manufacturing Co. Ltd.
Address:	P.O. Box 111111 125 West Street, Company City, NJ 08888 USA

Scope of opinion

This statement of opinion is given in respect of compliance of radio spectrum use (Art. 3(2) of the R&TTE Directive 1999/5/EC).

Identification of apparatus

Apparatus type:	Wireless remote control
Apparatus brand name:	ZZZ Products model line A
Apparatus identification:	JDC-9876543
Intended use:	433 MHz SRD according to CEPT 70-03 E
Network interface:	Not applicable
Frequency range:	433.050-434.790 MHz
Transmit power:	1 mW ERP
Duty cycle:	10 %

Technical construction file

Issued by:	ZZZ Products Manufacturing Co. Ltd.
Address:	P.O. Box 111111 125 West Street, Company City, NJ 08888 USA
Date:	01 January 2008
File number:	102030CC.TCF

Opinion

Our opinion in accordance with Annex IV of Council Directive 1999/5/EC on radio equipment and telecommunications equipment and the mutual recognition of their conformity is that the apparatus identified above complies with the requirements of that Directive stated in the above scope.

On behalf of:	The Director of EU Notified Body Services
Signature:	
Name:	

ANNEX 4 — Organisations and committees involved

R&TTE **ADCO** (Group on ADministrative COoperation) is a group formed by the market surveillance authorities of the Member States and countries that have implemented the R&TTE Directive. The group promotes administrative cooperation in the fields of market surveillance, joint market surveillance campaigns, exchange of information and non-conformity issues[40].

CENELEC (European Committee for Electrotechnical Standardisation) is recognised as an official European standards organisation by the European Commission and works under mandates from the Commission to prepare harmonised standards for the Directive. Membership is restricted to representatives of national standardisation bodies. CENELEC activities concerning the Directive relate to Article 3(1)(a) and 3(1)(b).
http://www.cenelec.org/Cenelec/Homepage.htm
CENELEC standards may be purchased through one of the national member bodies: http://www.cenelec.org/Cenelec/CENELEC+in+action/Web+Store/Standards/default.htm.

ERO (European Radiocommunications Office) is the permanent office supporting the ECC (Electronic Communications Committee of the CEPT), the committee that brings together the radio and telecommunications regulatory authorities of the 48 CEPT member countries. The ERO is charged by the Commission with maintaining information about the classification of equipment in accordance with the R&TTE Directive.
http://www.ero.dk/rtte

ETSI is recognised as an official European standards organisation by the European Commission and works under mandates from the Commission to prepare harmonised standards for the Directive. Membership is open to all interested parties. ETSI activities concerning the Directive relate mostly to Article 3(2), 3(3) and, in part, 3(1)(b).
http://www.etsi.org/WebSite/homepage.aspx
ETSI standards can be downloaded free of charge via the Publications Download Area application:
http://pda.etsi.org/pda/queryform.asp.

ICNIRP (International Commission on Non-Ionising Radiation Protection) has no formal link with the Directive but, in those cases where there are no harmonised standards covering EMF hazards for a particular type of radio equipment, ICNIRP guidance may be helpful in compiling a basis for compliance with this aspect of Article 3(1)(a).
http://www.icnirp.de/pubEMF.htm

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[40] See also Blue Guide, Chapter 8.6.

R&TTE CA (R&TTE Compliance Association) is an informal group for notified bodies and others interested in conformity assessment under the R&TTE Directive. Its primary concern is to ensure that notified bodies act in a coherent manner. Membership is open to all interested parties and public documentation is available at: http://www.rtteca.com.

RSC (Radio Spectrum Committee) assists the Commission in the development and adoption of technical implementing measures aimed at ensuring harmonised conditions for the availability and efficient use of radio spectrum, as well as the availability of information related to the use of radio spectrum. It has no formal remit concerning the Directive but its activities have a strong influence on the definition of equipment classes in the TCAM and their maintenance by the ERO. For this reason, joint meetings of the RSC and TCAM take place from time to time. http://ec.europa.eu/information_society/policy/radio_spectrum/activities/rsc_work/index_en.htm

TCAM (Telecommunication Conformity Assessment and Market Surveillance Committee) was set up under the R&TTE Directive to assist the Commission. It is made up of representatives of the Member States and chaired by the Commission. Representatives of industry, standards bodies, the ERO and notified bodies are also invited to participate on a non-voting basis. The Commission is obliged to consult the TCAM on matters relating to shortcomings in harmonised standards, in cases where a safeguard measure has been taken to remove a product from the market or where authorisation to disconnect equipment has been given, and on surveillance activities in general. In the case of formal decisions concerning equipment classes and essential requirements under Article 3(3), the Commission must obtain the formal opinion of the TCAM. Many TCAM documents are made publicly available after the meetings: http://forum.europa.eu.int/Public/irc/enterprise/tcam/home
(follow “library” > “public documents”).

ANNEX 5 — Acronyms and abbreviations

CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
CEPT	European Conference of Postal and Telecommunications Administrations
DoC	EC Declaration of Conformity
EEA	European Economic Area
EMC	Electromagnetic compatibility
EMCD.	Electromagnetic Compatibility Directive
ERO	European Radiocommunications Office (permanent office of CEPT)
ETSI	European Telecommunications Standards Institute
EU	European Union
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
ITU	International Telecommunication Union
MRA	Mutual Recognition Agreement
NB	Notified body
OJEU	Official Journal of the European Union
R&TTE	Radio equipment and telecommunications terminal equipment
R&TTECA	(see Annex 4)
R&TTE ADCO	(see Annex 4)
RF	Radio frequency
TCAM	(see Annex 4)
RSC	(see Annex 4)
TGN	Technical Guidance Note