Guide to the Radio Equipment Directive 2014/53/EU

Version of 19 December 2018

Contents

Disclaimer

This Guide is intended to serve as a manual for all parties directly or indirectly affected by the Radio Equipment Directive 2014/53/EU[1] (RED). It should assist in the interpretation of the RED 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.

This Guide will be reviewed periodically to be kept up to date.

This Guide is publicly available, but is not binding in the sense of a legal act adopted by any of the EU institutions, even if the word 'shall' is used in many parts of this Guide. In the event of any inconsistency between the provisions of the RED and this Guide, the provisions of the RED prevail.

The services of the European Commission undertake to maintain this guide to ensure that the information is accurate and up to date. Errors brought to the Commission's attention, will be corrected. 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 has no control and for which the Commission assumes no responsibility;*
- *does not constitute legal advice.*

Finally, attention is drawn to the fact that all references to the CE marking and EU Declaration of Conformity relate to the RED only and radio equipment only benefits from the free circulation in the Union market if the product complies with the provisions of all the applicable Union legislation. Reference is therefore made, whenever necessary but not always, to other EU legal acts.

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[1] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p 62).

Introduction

The purpose of this document is to give guidance, subject to the preceding disclaimer, on certain matters and procedures pertaining to the Radio Equipment Directive 2014/53/EU[2] (hereinafter referred to as 'the RED'), which is applicable as of 13th June 2016. This Guide brings together information previously available in several TCAM documents and related Commission's websites.

The Guide is based on the RED and on the "New Legal Framework[3]" described in the "Blue Guide 2016" (the "Blue Guide") [4] and does not duplicate what is already contained in the Blue Guide which addresses horizontal issues. Hence, this Guide should be read in conjunction with the Blue Guide. Moreover, other more specific guidance or documents might be issued by the Commission services, TCAM or ADCO RED[5] providing guidance or information on specific issues or items, for example:

-Supplementary Guidance on the LVD/EMCD/RED (combined equipment);[6]
-Subclasses: class 1 equipment;[7]
-Notification of draft interface regulations;[8]
-National language requirements of the national implementation of the RED.[9]

This version replaces the previous versions of 19 May 2017 and 5 June 2018.

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[2] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p 62).

[3] 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).

[4] The 'Blue Guide' on the implementation of EU product rules 2016:

http://ec.europa.eu/DocsRoom/documents/18027/

[5] ADCO RED documents do not necessarily represent the opinion of the Commission or TCAM.

[6] What the Commission is doing - European Commission

[7] Radio Equipment Directive (RED) - European Commission

[8] Radio Equipment Directive (RED) - European Commission

[9] ADCO RED

1 Scope

1.1 General

The RED covers radio equipment as described in Chapter 1.6 and is applicable from 13th June 2016.

Member States shall not impede, for reasons relating to aspects covered by the Directive, the making available on the market in their territory of radio equipment which complies with the RED.

It is noted that the RED applies in relation to the aspects it covers. Hence, radio equipment can be prohibited if it falls also within the scope of another legislation, regulating other aspects (such as environmental risks), and that radio equipment is not compliant with that other legislation (see also Chapter 9).

1.2 Geographic application

1.2.1 *Application in non-EU States, countries & territories*

The geographical application is described in Chapter 2.8 (geographical application) of the Blue Guide.

The RED also applies in the EEA-EFTA States (Liechtenstein, Iceland, and Norway) and will apply in Turkey.

Therefore, in the context of this Guide, the terms “European Union”, “Union”, “territory” or 'Member States' also cover the EEA-EFTA States (Liechtenstein, Iceland, and Norway) and Turkey, once Turkey's alignment is confirmed by the EU-Turkey Customs Union Joint Committee.

1.2.2 *Mutual Recognition Agreements (MRAs)*

MRAs are agreements established between the Union and the third countries for the purpose of mutual recognition of conformity assessment of regulated products. It is noted that it depends on the scope of each MRA, before deciding if it relates with the RED.

Specific information on MRAs may be found in Chapter 9.2 (Mutual Recognition Agreements - MRA) of the Blue Guide and the relevant Commission’s website[10].

1.2.2.1 MRA with Switzerland

The MRA concluded with Switzerland, which entered into force on 1 June 2002,[11] is a comprehensive agreement.

[10] List of mutual recognition agreements

[11] OJ L 114, 30.4.2002, p. 369.

According to the Blue Guide, 'despite the MRA, there is no customs union between the EU and Switzerland'.

A product placed on the market in Switzerland is not considered as being placed on the EU market.

Annex 1, Chapter 7, of the Agreement as amended by Decision No 1/2017 of the Committee established under the Agreement contains adaptations on the RED. In addition, the Swiss legislation on Radio Equipment is adapted to the RED.

The RED and this Guide shall be read in conjunction with the adaptations in the MRA. The most important adaptations which relate with the obligations of the economic operators are the following:

(a) for the purpose of the obligations in Articles 10(7) and 12(3) of the RED and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In cases where the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Articles 10(4) and 12(8) of the RED and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity for 10 years after the radio equipment has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the radio equipment has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Article 10(5), second subparagraph, and 12(6) of the RED and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

(d) manufacturers shall ensure that radio equipment shall be so constructed that it can be operated in at least one Member State or Switzerland without infringing applicable requirements on the use of the radio spectrum. In cases of restrictions on putting into service or of requirements for authorisation of use of radio equipment, information on the packaging shall identify restrictions existing in Switzerland, Member States or geographical areas within their territory.

(e) for the purpose of the obligation in Article 11(2) of the RED and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 11(1) of the RED or the corresponding Swiss provisions.

1.2.3 *Agreements on Conformity Assessment and Acceptance (ACAAs)*

Agreements on Conformity Assessment and acceptance of industrial products are intended to be established between the Union and the government of EU Neighboring countries (for more details see Chapter 9.1 of the Blue Guide).

1.3 **Placing on the market**

The RED applies to radio equipment placed on the market and then to any subsequent operation which constitutes making available until it reaches the end-user.

A product is placed on the market when it is made available for the first time on the Union market. Placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series.

Radio equipment shall comply with the legal requirements that were in place at the time of its placing on the market.

In some Member States, restrictions for putting into service of radio equipment may exist (see Article 7 of the RED and Chapter 1.4). In cases where all Member States have introduced restrictions preventing the use of the equipment, manufacturers have an obligation not to place the equipment on the market.

When radio equipment is constructed for own use or bought by a consumer in a third country while physically present in that country and brought by the consumer into the EU for the personal use of that person, it is not considered to be placed on the market. For details on the placing on the market and making available on the market, see Chapters 2.1, 2.2 and 2.3 of the Blue Guide.

1.4 **Putting into service**

Member States shall allow the putting into service and use of radio equipment if it complies with the RED when it is properly installed, maintained, and used for its intended purpose. Notwithstanding the forgoing, a Member State may introduce restrictions for the putting into service and/or use of radio equipment for reasons related to the effective and efficient use of the radio spectrum, to the avoidance of harmful interference, to the avoidance of electromagnetic disturbances or to public health. (Article 7 of the RED). This section should also be read in conjunction with Chapters 1.1 and 1.3.

1.5 **Special measures regarding radio equipment at trade fairs, etc.**

According to Chapter 2.3 of the Blue Guide, placing on the market is considered not to take place where a product is displayed or operated under controlled conditions at trade fairs, exhibitions or demonstrations.

Article 9.2 of the RED contains *the following* details on the conditions applicable at trade fairs, exhibitions or demonstrations*:*

- *A visible sign **clearly** indicates that such radio equipment may not be made available on the market or put into service until it has been brought into conformity with this Directive;*

- *Demonstration of radio equipment may only take place provided that adequate measures, as prescribed by Member States, have been taken to avoid harmful interference, electromagnetic disturbances and risk to the health or safety of persons or of domestic animals or to property.*

If the radio equipment contains a transmitter, the relevant national spectrum authorities have to be contacted if a manufacturer wishes to demonstrate the use of such equipment[12].

1.6 **Radio equipment**

1.6.1 *What is radio equipment?*

Radio equipment is defined in Article 2.1(1) of the RED as *an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radio determination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radio determination;*

The term 'radio communication' is defined in Article 2.1(2) of the RED as communication by means of radio waves.

The term ‘radiodetermination’ is defined in Article 2.1(3) of the RED as the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves.

The term 'radio waves' is defined in Article 2.1(4) of the RED as electromagnetic waves of frequencies lower than 3 000 GHz, propagated in space without artificial guide.

According to Article 2.2 of the RED, the Commission may adopt implementing acts to determine whether certain categories of electrical or electronic products meet the definition of a radio product. Therefore, the examples mentioned below do not prejudice or affect a future implementing act under Article 2.2. If an implementing act is adopted, the examples will be reviewed accordingly.

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[12] If during the development and production of a given Radio Equipment, samples or pre-production units of that equipment need to be operated in normal use locations for testing or validation purposes (so called “field tests”), then the relevant national spectrum authority also has to be contacted.

1.6.2 *What is explicitly excluded from the scope of the RED?*

Article 1.3 and Annex I of the RED, exclude explicitly from its scope the following radio equipment.

1.6.2.1 Radio equipment exclusively used for activities concerning public security, defence, State security

The Directive does not apply to radio equipment exclusively used for activities concerning public security, defence, State security, including the economic well-being of the State in the case of activities pertaining to State security matters, and the activities of the State in the area of criminal law.

Dual use equipment, i.e. equipment for civil and military use (or other activities listed above), is covered by the RED.

For example, radio equipment in TETRA systems are widely used by the police and other public authorities dealing with public security, however, they are subject to the RED because they are not exclusively used for the activities excluded from its scope.

1.6.2.2 Radio equipment used by radio amateurs

The RED excludes radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations, unless the equipment is made available on the market. The following equipment shall be regarded as **not** being made available on the market.

(a) radio kits for assembly and use by radio amateurs;

(b) radio equipment modified by and for the use of radio amateurs;

(c) equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio.

The assessment whether the transfer of radio amateur equipment between radio amateurs or intended for radio amateurs shall be considered as making available on the market shall be done on a case by case basis taken into account the regularity of the supplies, the characteristics of the product, the intentions of the supplier etc. The occasional transfer of radio equipment between radio amateurs may be considered as not making available on the market. However, if supply is regular or there is a business related context then it may be considered as making available on the market, in the course of commercial activity whether in return for payment or free of charge. (Blue Guide, Chapter 2.2).

1.6.2.3 Marine equipment

Annex I.2 of the RED refers to equipment falling within the scope of Council Directive 96/98/EC[13] on marine equipment.

[13] 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).

Directive 2014/90/EU [14] repealed as of 18 September 2016, Council Directive 96/98/EC. Article 40 of Directive 2014/90/EU provides that references to the repealed Directive shall be constructed as references to this Directive.

Thus equipment within the scope of Directive 2014/90/EU is excluded from the RED. Directive 2014/90/EU covers equipment which has to be carried on ships which are subject to International Maritime Organisation (IMO) Conventions e.g. Safety of Life at Sea (SOLAS).

Marine radio equipment intended to be used on non-SOLAS vessels (e.g. recreational craft) is thus covered by the RED (unless if another exemption of the RED is applicable).

1.6.2.4 Airborne equipment

Before the applicability of the new EU Regulation on Civil Aviation

-According to Annex I.3 to the RED, airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 as amended are excluded from the RED.

-Ground aviation radio equipment is thus covered by the RED (unless if another exemption of the RED is applicable).

-According to Annex II of Regulation (EC) No 216/2008, Article 4(1), (2) and (3) of that Regulation do not apply to 'unmanned aircraft with an operating mass of no more than 150 kg'. Therefore, it could be assumed that drones of 150 kg or less (in particular consumer drones) should be considered as radio equipment, rather than aircraft, within the scope of the RED.

Applicability of the new EU Regulation on Civil Aviation

Regulation (EU) 2018/1139, applicable as of 11/9/2018, repealed and replaced Regulation 216/2008 as amended. [15]

Articles 137 and 138 amend, respectively, Article 2(2) (b) of EMCD and Annex I (3) to the RED.

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[14] Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment (OJL 257, 28.08.2014).

[15] Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (Text with EEA relevance.)

When these amendments are applicable, the exemption of Article 2(2) (b) of EMCD and Annex I (3) to the RED shall apply as follows:

-equipment within the scope of the new Regulation (2018/1139) is excluded from the RED and EMCD other than the following aviation equipment (i.e. the following equipment is covered by the EMCD or RED even if it falls within the scope of Regulation 2018/1139):

a) electrical/radio equipment not intended for exclusive airborne use (e.g. ground aviation electrical/radio equipment);

b) drones in the 'open category' as well as the 'specific category';

c) drones in the 'certified category' if not intended to operate only on frequencies allocated by the Radio Regulations of the International Telecommunication Union for protected aeronautical use.

Without prejudice to the other exemptions of the RED/EMCD:

-the equipment mentioned in paragraph (a)-(c) above is covered by the RED if intended to emit and/or receive electromagnetic waves of frequencies below 3000 GHz for the purpose of radio communication and/or radiodetermination; in the other cases, that equipment is covered by the EMCD;

- where, for ground aviation equipment, the essential requirements set out in Annex I of the EMCD are wholly or partly laid down more specifically by other Union legislation, the EMCD shall not apply, or shall cease to apply, to that equipment in respect of such requirements.[16]

1.6.2.5 Custom-built evaluation kits

RED introduces an exemption for the custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes (Annex I.4 of the RED).

The exemption includes several elements and only if the products fulfil all the elements can be exempted, on the basis of Annex I.4 of the RED, from the scope of the RED:

- **Custom-built**
  i. A kit that has been built on the basis of a specific request from a specific customer or from a group of customers involved in a joint research and development project as for all or certain characteristics of the evaluation kit

[16] Article 2 (3) of the EMCD.

OR

ii. A kit that has been built for the specific requirements of a specific customer or a group of customers involved in a joint research and development project as for all or certain characteristics of the evaluation kit.

The unique design and characteristics of the kit makes it solely suitable for that research and development project.

If that evaluation kit is later on provided on a regular basis or once the kit is not used for that joint research and development project purpose, it can no longer be considered a custom-built evaluation kit.

- **Evaluation kits**

  A printed circuit board with an integrated circuit and support components to produce a working circuit for evaluation and development.

- **Destined for professionals (customers), to be used solely at research and development facilities**

  Research and development facilities meaning public or private research and development bodies.

- **For research and development purposes**

  Evaluation kits to be used in testing for further development/ improvement of the function of the equipment under research and development.

Non-exhaustive list of examples of evaluation kits that do not benefit from this exemption (even if there is a possibility for the user to adapt it to his specific needs or to build it himself):

- All devices/equipment used on a regular basis (such as laboratory equipment) to perform tests for the purposes of research and development or for other applications such as to demonstrate the conformity or quality of a product.
- Evaluation equipment for users in general in R&D departments (in this case, the equipment is always the same and is not "custom built").

1.6.3 *Specific cases / examples (non-exhaustive)*

1.6.3.1 Non-radio products which function with radio equipment/electrical and electronic equipment with non-electrical products

See document with title 'Supplementary Guidance on the LVD/EMCD/RED' published on the Commission website.[17]

[17] What the Commission is doing - European Commission

1.6.3.2 Infrared devices (IR)

The terms 'radio communication', 'radiodetermination' and 'radio waves', mentioned in the definition of 'radio equipment' (Article 2.1 of the RED), are defined as follows::

- Article 2.2: "radio communication" means communication by means of radio waves;
- Article 2.3: “radiodetermination” means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves
- Article 2.4: "radio waves" means electromagnetic waves of frequencies lower than 3 000 GHz, propagated in space without artificial guide.

Whereas IR conventionally extends from 300 GHz to 430 THz, devices operating in the lower part of the IR spectrum, i.e. that between 300 GHz and 3000 GHz, which corresponds to wavelengths between 1mm and 100µm (far infrared) are subject to the RED. IR devices operating solely at higher frequencies do not fall under the RED.

1.6.3.3 Products that use electromagnetic waves exclusively for other purposes than radio communication and/or radiodetermination

Products and applications that use electromagnetic waves exclusively for other purposes than radio communication and/or radiodetermination (products that propagate electromagnetic waves in space, but this propagation is not intended and not used for the purpose of radio communication or radiodetermination.) are not covered by the RED, for example:

- inductive warming and heating appliances;
- pure wireless power transfer (without any communication or radiodetermination);
- high frequency surgical equipment and systems;
- cookware suitable for inductive heating appliances;
- test equipment if intended to use radio waves, exclusively, for testing other devices .[18]

1.6.3.4 Antennas

Antennas may be subdivided into “active” and “passive” types. “Active” antennas are supplied with one or more active electronic components (as diodes, transistors) interacting with the RF-signal. All other antennas are in general considered “passive”.

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[18] Needs to be assessed on a case-by-case basis, in order to determine if a specific type of test equipment is covered (or not covered) by the RED.

Taking in account the definition of radio equipment in Article 2 of the Directive, passive antennas are not covered by RED if placed on the market as a single commercial unit.

A radio equipment with the antenna attached is subject to all the requirements of RED. The interface between the radio product and the provided antenna need not be assessed in this case, unless the radio part without the antenna is also made available on the market.

In contrast, active antennas (i.e. antennas including one or more active electronic components that interact with the RF signal as e.g. amplifier) are always covered by the RED.

1.6.3.5 Amplifiers and other equipment intended to be connected to antennas

The applicability of the RED depends on the intended use declared by the manufacturer. Therefore amplifiers and other electronic equipment (e.g. filters, splitters, convertors, transverters, antenna tuners, switches) intended to be connected to an antenna, based on the declaration of the manufacturer, are covered by the RED.

1.6.3.6 DVB receivers

Radio broadcast receivers are within scope. However, in the specific case of DVB receivers, pure DVB-C receivers which receive the signal via a wired CATV are not covered by the RED. Other DVB receivers (DVB-T, DVB-S) or DVB-C receivers with embedded radio functionality (e.g. a TV set with DVB-S, DVB-T and/or WLAN) are covered by the RED and have to fulfil all relevant requirements.

1.6.3.7 Jammers

In general jammers do not fall within the scope of the Directive due to the definition of radio equipment. Since jamming is inherent to their functional principle, it is not possible to construct jammers that fulfil the EMC and Radio essential requirements of the RED. Hence a jammer, if it falls within the scope of the RED, should be prohibited or restricted from being made available or withdrawn or recalled.

1.6.3.8 Construction kits

Construction kits that when assembled fall within the scope of the Directive and are intended to be made available on the EU market are covered by the RED. The kit manufacturer is responsible for compliance when the kit is assembled in accordance with the instructions.

The person who assembles the kits, already placed on the EU market, shall follow the instructions. He shall be considered as the manufacturer, when he makes them available on the EU market, if:

- their intended function or performance is modified; or
- the compliance is impacted because the instructions provided were not followed.

1.6.3.9 Specific components (radio)

The definition of 'radio equipment', in Article 2 of the RED, includes *an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radio determination*.

The following components meet the above definition, hence they are radio equipment and are covered by the RED:

- RF Modules (Radio Frequency Modules) as well as components that have an embedded RF Module;
- Integrated Circuits[19] if they have the capacity to receive or transmit (radio) signals once they are integrated, as such[20], into another product.[21]

When these components (radio equipment) are placed, before their integration into another product, on the EU market, the economic operator who is, or is considered to be, their manufacturer is required to:

- perform an assessment of the risks than can be possibly identified at the stage of placing the above components (radio equipment) on the EU market (i.e. can be possibly identified before their integration into another product); in any case, the intended use and, for safety aspects, reasonably foreseeable use have to be assessed as in Article 17(1) of the RED; and
- provide instructions which, if followed, will ensure that they remain compliant.

This section is without prejudice to any new obligations that might arise when the above components (radio equipment) are integrated into another product.

1.6.3.10 Radio equipment installed in vehicles

Where radio equipment is installed in vehicles such as cars, caravans, trains, etc (normally falling under a type approval legislation), the radio equipment has to comply with the RED unless the specific equipment falls within any of the exceptions of the RED. That radio equipment must comply with the requirements of both the RED and all applicable EU acts.

The person who places on the EU market the radio equipment is the responsible manufacturer, as defined in the RED and is responsible for compliance when the radio

[19] A collection of electronic components such as resistors, transistors, capacitors, etc. constructed on a single semiconductor wafer or chip or a single substrate, in which the components are interconnected to perform a given function.

[20] i.e. integrated as standalone.

[21] Includes also integrated circuits that need to be completed only with an accessory, e.g. an antenna or software, in order to receive or transmit signals.

equipment is installed in accordance with the instructions .The risk assessment of the radio equipment should take into account its intended purpose.

The person who installs the radio equipment, already placed on the EU market, shall follow the instructions. He shall be considered as the manufacturer of the radio equipment when the vehicle is made available if:

- the compliance is impacted because the instructions provided for the radio equipment were not followed; or
- the intended function or performance of the radio equipment is modified.

1.6.3.11 Fixed Installations

Fixed installations are not regulated under the RED. Since it is relevant in certain cases (through the link to the EMCD in Article 3.1.b), a distinction is made between two types of installations that are fixed. These are described below:

- Fixed installations as defined and described in the EMCD, i.e., which are unique in their build-up;
- Installations built up of mass-market equipment but are fixed in the sense that they are permanent in their place.

Fixed installations as defined and described in the EMCD, i.e., which are unique in their build-up

In the EMCD, special regulations for fixed installations and apparatus intended for incorporation in fixed installations are foreseen. As defined in Article 3.1 of the EMCD, fixed installation is defined as "a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location. An "apparatus" by definition of the EMCD means any finished appliance of combination thereof. For the purposes of market surveillance, fixed installations are thus fully covered by the EMCD.

Putting into service of radio equipment may include incorporation of radio equipment into a fixed installation. In the RED, the concept of fixed installations is not explicitly defined. However, the RED requires in Article 3.1.b that “an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU” has to be ensured. With this, not only the relevant requirements of Annex I of the EMC Directive but also all the other regulations of the EMC Directive which apply to the EMC level are relevant. This applies, in particular, to the special requirements and procedures according to Article 19.1 and Annex I (2) of the EMCD for fixed installations.

Therefore, the conformity assessment of radio equipment shall also take into account the circumstances, where radio equipment is designed for or may be used as a part of "apparatus" or "fixed installation". It is important to ensure the effective and efficient use of radio spectrum and avoidance of harmful interference are not compromised under any intended operating condition. The technical documentation accompanying radio equipment shall specify the fixed installation concerned and the precautions to be taken. A legal or private person, who is responsible for putting into service or use

of radio equipment, also has to ensure that radio equipment is properly installed, maintained, and used for its intended purpose.

Installations built up of mass-market equipment but are fixed in the sense that they are permanent in their place

Regarding radio equipment intended for inclusion in non-specific installations, Article 17.1 of the RED requires that "conformity assessment shall take into account all intended operating conditions and, for the essential requirement set out in Article 3.1.a, the assessment shall also take into account the reasonably foreseeable conditions of use. Where applicable these conditions may, when putting radio equipment into service, include combining the radio equipment with other equipment to form an installation that is fixed at its location.

Considering the types of equipment that are likely to be included in such installations, the installation instructions of the radio equipment should describe how to install the equipment to enable it to operate as foreseen and if needed, what type of components shall be used. It is then for the legal or private person, who is responsible for putting into service or use of radio equipment, to ensure that radio equipment is properly installed, maintained, and used for its intended purpose.

An installer who is a professional acting for a client shall undertake the responsibilities of the manufacturer when:

- the intended function or performance of the radio equipment, already placed on the EU market, is modified; or
- the radio equipment is or shall be considered as a new product; or
- the compliance is impacted because the instructions provided for the radio equipment were not followed.

1.6.3.12 Power plugs attached to radio equipment

The safety of domestic power plugs attached to radio equipment (for example to a laptop or television) is governed by the GPSD. Thus Member States may apply their national safety regulations or standards on plugs, even if they are attached to radio equipment.

1.6.3.13 RFID TAG

TAG are radio equipment within the scope of the RED and the manufacturer of the TAG is responsible for compliance.

Due to the nature or size of TAGs, CE marking, contact details and other required information may not be affixed on the TAG.

Non-radio products (e.g. passports, credit cards) which are tagged, other than the TAG itself (as clarified above), are not radio equipment and do not require CE marking and contact details for the purposes of the RED.

1.6.3.14 Cabling and wiring

Cabling and wiring, are not covered by the RED because they fall out of the scope of the definition of radio equipment.

2 Obligations of the economic operators

2.1 General

Union harmonisation legislation defines the manufacturer, the authorised representative, the importer and the distributor as 'economic operators'. The main responsibility is put on the manufacturer. The other operators have their obligations build on those of the manufacturer. Therefore this Chapter firstly describes these four economic operators and then concentrates on the specific obligations of the manufacturer.

If an economic operator undertakes the responsibilities of the manufacturer, he shall update/replace the DoC (insert his name and sign it). This obligation does not extend to the other certificates, documents e.t.c. However, where an economic operator undertakes the responsibilities of the manufacturer, he is assuming full responsibility for the compliance with the RED, including of all these documents.

2.2 Manufacturer

The RED defines in Article 10 a set of requirements to be met by manufacturers in order to place radio equipment on the EU market:

a) Ensure radio equipment is designed and manufactured in accordance with the essential requirements in article 3 of the RED (see Chapter 2.6.a)

b) Carry out conformity assessment procedures (see Chapter 2.6.b)

c) Ensure that the equipment can operate in at least one Member State (see Chapter 2.6.c)

d) Draw up technical documentation according to Article 21 (see Chapter 2.6.d)

e) Draw up a DoC / simplified DoC which shall accompany the product (see Chapter 2.6.e)

f) Affix CE marking and notified body number if applicable (see Chapter 2.6.f)

g) Add type or batch or serial number or other element to the equipment allowing its identification (see Chapter 2.6.g)

h) Add traceability information to the equipment (address, etc…) (see Chapter 2.6.h)

i) Add geographical information in case of restrictions (see Chapter 2.6.i)

j) Ensure that the equipment is accompanied by instructions and safety information including, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended. These instructions shall also include information about the frequency bands and power used by the radio equipment. (see Chapter 2.6. j

k) Ensure that series of production remain in conformity with the Directive (see Chapter 2.6.k)

l) When deemed appropriate, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls,

and shall keep distributors informed of any such monitoring. (see Chapter 2.6.l)

m) Take immediate actions in case of non-compliance of products already placed on the market. (see Chapter 2.6.m)

n) Cooperate with competent national authorities. (see Chapter 2.6.n)

Further obligations and details can be found in Chapter 3.1 of the Blue Guide.

2.3 **Authorised representative**

A manufacturer may, by a written mandate, appoint an authorised representative established in the EU to carry out some of his responsibilities on his behalf. Article 11 of the RED describes the requirements to be met by the authorised representative.

The manufacturer obligations described in Chapters 2.6.a), 2.6.b) and 2.6.d) of this guide shall not be part of the authorised representative's mandate.

The authorised representative's mandate shall at least contain the following:

- Keep the EU DoC and the TD at the disposal of national market surveillance authorities for 10 years after the radio equipment has been placed on the market;
- Manufacturer obligations described in Chapter 2.6.n);
- Cooperate with competent national authorities. (see Chapter 2.6.n).

Further obligations and details can be found in Chapter 3.2 of the Blue Guide.

2.4 **Importer**

According to Article 12 of the RED, the importer shall:

a) ensure that he is only placing compliant radio equipment on the market,

b) ensure that the manufacturer has:

   i. carried out conformity assessment procedures (see Chapter 2.6.b),

   ii. ensured that his equipment can operate in at least one Member State (see Chapter 2.6.c),

   iii. drawn up the Technical Documentation (Chapter 2.6.d),

   iv. affixed the CE mark (Chapter 2.6.f)),

   v. ensured that the equipment is accompanied by instructions and safety information (Chapter 2.6.j),

   vi. drawn up a DoC / simplified DoC which should accompany the product (Chapter 2.6.e),

   vii. added geographical information in case of restrictions (Chapter 2.6.i),

   viii. added a type, batch or serial number or other element to the equipment allowing its identification (Chapter 2.6.g),

   ix. added traceability information to the equipment (Chapter 2.6.h),

c) not place a radio equipment on the market if he considers or has reason to believe that radio equipment is not in conformity with the essential

requirements set out in Article 3. If the radio equipment presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

d) add additional traceability information to the equipment (their name, address, etc…)

e) ensure that, while radio equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Article 3.

f) when deemed appropriate, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring

g) take immediate actions in case of non-compliance of products already placed on the market

h) for a period of 10 years after the radio equipment has been placed on the market, keep a copy of the EU DoC at the disposal of the market surveillance authorities and ensure that the TD can be made available to those authorities, upon request[22]. The importer is advised to require formal assurance in writing from the manufacturer that the documents will be made available when requested by the surveillance authority[23].

i) cooperate with competent national authorities

Further obligations and details can be found in Chapter 3.3 of the Blue Guide.

2.5 **Distributor**

According to Article 13 of the RED, the distributor shall:

a) act with due care in relation to the requirements of this Directive when making radio equipment available on the market,

b) verify that:

   i. radio equipment bears the CE mark (Chapter 2.6.f),

   ii. radio equipment is accompanied by instructions as well as safety instructions (Chapter 2.6.j),

   iii. the manufacturer has ensured that his equipment can operate in at least one Member State (see Chapter 2.6.c),

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[22] According to the Blue Guide footnote 128, there is not an obligation for the importer to hold a copy of the TD and there is not an obligation for the manufacturer to supply the TD to the importer.

[23] The Blue Guide, in footnote 125, states: In light of these obligations, it is generally considered good practice for importers to: refer to the applicable EU legislation in the contract with his supplier (mentioning the obligations of manufacturers under Union law); ensure that he has access to the technical documentation, or ensure that the manufacturer has signed an obligation to provide the technical documentation if requested by market surveillance authorities.

iv. the manufacturer has added a type, batch or serial number or other element to the equipment allowing its identification (Chapter 2.6.g),

v. the manufacturer has added traceability information to the equipment (Chapter 2.6.h),

vi. the manufacturer has drawn up a DoC / simplified DoC which shall accompany the product (Chapter 2.6.e),

vii. the manufacturer has added geographical information in case of restrictions (Chapter 2.6.i),

viii. the importer (if he exists) has added traceability information to the equipment (Chapter 2.4.d),

c) not make radio equipment available on the market if he considers or has reason to believe that radio equipment is not in conformity with the essential requirements set out in Article 3. If the radio equipment presents a risk, the distributor shall inform the manufacturer or the importer and the market surveillance authorities to that effect.

d) ensure that, while radio equipment is under their responsibility, its storage or transport conditions do not jeopardize its compliance with the essential requirements set out in Article 3.

e) take immediate actions in case of non-compliance of products already placed on the market

f) cooperate with national competent authorities.

Further obligations and details can be found in Chapter 3.4 of the Blue Guide.

2.6 Description of the manufacturer's responsibilities

a) Ensure radio equipment design and manufacture in accordance with the essential requirements of the RED

The manufacturer is responsible for designing and manufacturing the product in accordance with essential requirements as set out in Article 3 of the RED.

b) Conformity assessment procedures (CAP)

Article 17 of the RED describes the applicability of each conformity assessment procedure (Annex II, III or IV) with a view to meet the essential requirements set out in Article 3. Manufacturers are free to choose whether or not to apply harmonised standards whose references are published in the Official Journal of the European Union (OJEU) under the RED[24].

For the essential requirements set out in Article 3 of the RED, Article 17 of the RED provides that conformity shall be demonstrated by using Modula A (Annex II of the RED), Module B+C (Annex III of the RED) or Module H (Annex IV of the RED). However, with respect to the requirements set out in Articles 3.2 and 3.3 of the RED,

[24] If manufacturers apply such harmonised standards they can benefit from the presumption of conformity with the corresponding essential requirements.

Module B+C (Annex III of the RED) or Module H (Annex IV of the RED) shall be used, if harmonised standards are partially applied or not applied or do not exist.

Hence, for the essential requirements set out in Article 3.1.a and 3.1.b of the RED, the possibility to demonstrate conformity with these essential requirements by means other than using the harmonised standards is not linked to the use of a notified body, because the manufacturer has always the discretion to use Modula A (Annex II of the RED) which does not involve a notified body.

With respect to the requirements set out in Articles 3.2 and 3.3 of the RED, a conformity assessment involving a notified body shall be used, if such harmonised standards are partially applied or not applied or do not exist, because Module B+C (Annex III of the RED) and Module H (Annex IV of the RED) involve a notified body.

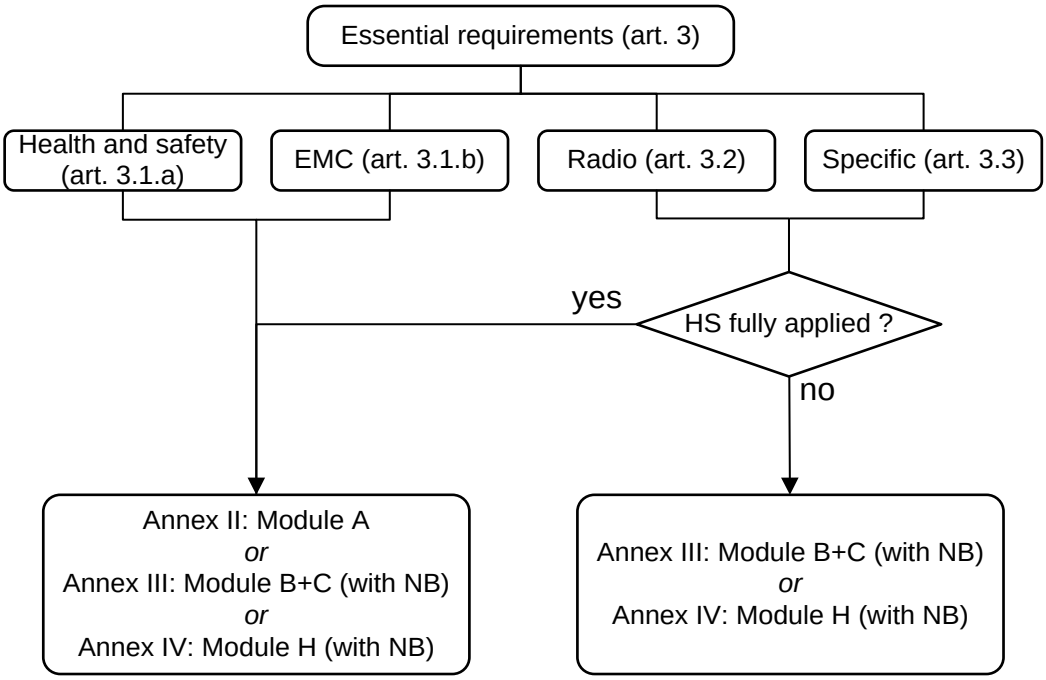

Figure 1: Overview of the different conformity assessment procedures

Under the Modules mentioned above, an assessment needs to be performed for ensuring that radio equipment complies with the essential requirements set out in Article 3 of the RED (that includes an assessment of the risks and aspects covered by Article 3). Based on the wording of Article 21 and Annex V of the RED, this assessment (whether Module A, B+C or H has been followed) shall be included in the technical documentation.

If the conformity assessment procedures require the manufacturer to perform tests, the manufacturer may seek the assistance of a third party (e.g. laboratory), but the

manufacturer remains responsible in all cases for the conformity of the radio equipment.

In its conformity assessment, the manufacturer has to "take into account all intended operating conditions" (Article 17 RED). This refers to intended operating conditions that may alter the product behaviour with respect to the conformity of the product with the essential requirements. For Article 3.1(a) the assessment shall also take into account the reasonably foreseeable conditions of use.

Where the radio equipment is capable of taking different configurations, the conformity assessment shall confirm whether the radio equipment meets the essential requirements set out in Article 3 in all possible configurations.

The manufacturer shall ensure that the radio equipment placed on the market is in conformity. In carrying out this assessment, he may use assessments performed previously for components or parts of that radio equipment, while remaining responsible for the conformity of the whole product. The reused assessment of the components or parts may not be sufficient to demonstrate conformity of the whole radio equipment.

If assessments performed previously for components or parts are used, these assessments shall be included in its technical documentation. It must be possible to make the technical documentation available to the market surveillance authorities within the Union. However, there is no obligation to keep it inside the Union. The requirement for making this technical documentation available does not mean that the person who bears this responsibility has to store it himself, as long as he is capable of presenting it on request from the national authorities. (see Chapter 7.2 of the Blue Guide).

c) Equipment can operate in at least one Member State

In addition to the essential requirements, in order to place the equipment on the EU market Article 10.2 of the RED requires manufacturers to ensure that radio equipment can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum[25]. This does not imply that it is possible to put the equipment into service or operate it in all Member States.

The requirements on the use of radio spectrum are specified by spectrum management authorities in each EU Member State and reflected in their national frequency allocation plan. Therefore, manufacturers need to check the applicable requirements on the use of the radio spectrum in all EU countries. If restrictions for the use of the equipment are applicable, the necessary information shall be provided

[25] It may be the case that a given frequency band is not regulated in any Member State (i.e. not part of any national frequency plan within the EU). In these cases, and according to Article 7 of the Directive, a radio equipment operating in that frequency band can be placed on the market throughout the Union unless all Member States have introduced national restrictions, and can be operated in Member States that have not introduced such national restrictions.

with the equipment according to Article 10.10 of the RED. Contact details of EU spectrum management authorities can be found here under "Contact points":

http://ec.europa.eu/growth/sectors/electrical-engineering/rtte-directive/

It is noted that, Member States are required, through Article 8 of the RED, to notify radio interfaces which they intend to regulate. This information provides guidance to the manufacturer regarding national spectrum plans and restrictions.

The European Communications Office (ECO) maintains a Frequency Information System (EFIS) where information regarding spectrum use in Europe is made available. This system is accessible here: http://www.efis.dk/[26]. According to recital 24, Member states are to use the Frequency Information System (EFIS) of the European Communications Office (ECO) in order to make comparable information regarding the use of radio spectrum in each Member State available to the public via the internet.

d) Technical documentation

Article 10.3 requires the manufacturer to draw up the Technical Documentation (TD) before placing radio equipment on the market. Specific requirements for the TD are contained in Article 21 of the RED.

The general principles of the TD are specified in Chapter 4.3 of the Blue Guide, this is reflected in Annex V of the RED. There are some elements in Annex V that are only requested by the RED:

- **General description of the product including:**
  - photographs or illustrations showing external features, marking and internal layout
  - version of software or firmware affecting compliance with essential requirements: the manufacturer has to provide this information only if the software or firmware has an influence on the conformity of the radio equipment (such as a change of software that would allow operation in a different frequency range or at higher output power). The manufacturer has the responsibility to assess the compliance of the radio equipment, in combination with the embedded software, with the RED. Such assessment shall be properly reflected in the TD.
  - the manufacturer shall include the user information and installation instructions referred to in Article 10.8 of the RED.
- **If applicable, a copy of the EU-type examination certificate and its annexes as delivered by the notified body involved:**
  - If the manufacturer has applied the conformity assessment procedure according to Annex III of the RED, than he has to include "a copy of the EU-type

[26] EFIS is maintained by ECO and Member States have to update their national information twice a year.

examination certificate and its annexes as delivered by the notified body involved.

- **copy of the EU- declaration of conformity**
  - a copy of the EU- declaration of conformity has to be included in the TD;
- **Explanation of the compliance with the requirement of Article 10(2) and of the inclusion or not of information on the packaging in accordance with Article 10(10):**
  - The manufacturer has to provide an explanation (such as a statement) declaring that his radio equipment has been constructed so that it can operate in at least one Member State (Article 10.2). Furthermore, he has to provide an explanation about the inclusion of information on potential restrictions of use for the putting into service of the radio equipment (Article 10.10). This could be for example a statement declaring that there are no restrictions of use. In cases where there are restrictions, such statement could for example point to the geographical information provided on the packaging and in the instruction manual.

Annex III of the RED asks to include "an adequate analysis and assessment of the risk(s)" in the TD. Chapter 4.3 of the Blue Guide provides clarification on how such assessment shall be documented.

According Article 21.4 of the RED, in cases where the TD does not comply with the requirements above and consequently fails to provide sufficient relevant data or means used to ensure compliance of radio equipment with the essential requirements of the RED, a market surveillance authority may ask the manufacturer or the importer to have a test performed by a body acceptable to that authority at the expense of the manufacturer or importer in order to verify compliance with the essential requirements of the RED.

e) EU Declaration of conformity (DoC)

The general principles of the DoC are set out in the "Blue Guide" (Chapter 4.4). The following explanations mainly concern specific obligations under the RED.

According to Article 10.3 of the RED the manufacturer is required to issue a DoC where compliance of radio equipment with the applicable requirements of the RED has been demonstrated.

The DoC has to be kept by the manufacturer for 10 years as of the date that the radio equipment was placed on the market (to be understood as the last unit of the product model placed on the market).

Annex VI of the RED defines the content and the model structure of the DoC. The RED requires under point 8 of this annex to list accessories and components including software which allow the radio equipment to operate as intended. Manufacturers only have to describe those accessories and components including software if they:

(1) have an influence on the conformity of the radio equipment, and
(2) are intended to be installed or changed by the user without the control of the manufacturer.

In those particular cases, the manufacturer can decide the format and the level of description of those pieces of accessories and components including software as long as they can be identified.

Accessories example:

- If the radio equipment is delivered without an antenna, then the technical features of the antenna that may be used in conjunction with the radio equipment shall be provided to the user. The user is responsible to operate the radio equipment and the accessories as intended and according to the description provided by the manufacturer.

  These technical features of the accessories shall therefore be mentioned in the DoC in order to enable the user to operate a compliant radio equipment. This information could be the generic characteristics of a given antenna type or a reference to a specific antenna(s) available on the market.

Software example:

- If the radio equipment has software (such as firmware, PC controlling software) that can affect its compliance with the Directive and the manufacturer intends and offers the possibility to the user to freely change it or modify it, then the software shall be named in the DoC so that it is possible for the user to put a compliant radio equipment into operation. The manufacturer can decide the format of the description of this software as long as it can be identified.

On the other hand, if the radio equipment has software that cannot affect its compliance with the Directive, even when the software is modified or replaced, then no information has to be provided in the DoC.

Manufacturers shall not confuse the DoC with other documents as e.g. conformity certificates from an (accredited) test lab, notified body certificate. These documents may be easily distinguished: the DoC is signed by the manufacturer or on his behalf by the authorised representative, while the other documents is signed by the test lab or notified body.

The designation of the radio equipment, in the DoC, has to permit a link between the product, the complete DoC and the technical documentation.

Accompany each radio equipment

A copy of the DoC or a simplified declaration of conformity has to accompany each radio equipment (i.e. at least one of them shall be in printed form). Without prejudice to other specific Union harmonisation which includes the same requirement, the RED does not prohibit the display of the DoC or the simplified DoC, when it accompanies the radio equipment, in such locations as the operating manual, a separate sheet, printed on the radio equipment, or on the packaging.

Simplified DoC

The wording of the simplified DoC can be found in Annex VII of the Directive. Some deviation of the wording may be accepted as long as the meaning does not change,

as the type designation would be indicated at the top of the page where the simplified DoC text is printed and that the text would refer to it.

The simplified DoC shall indicate the web-address where the complete DoC can be found. This web-address does not necessarily need to directly refer to the document but can lead to a specific Internet address (URL) where the DoC's are maintained by the manufacturer enabling a simple identification or search for the relevant DoC. Even if the simplified DoC refers only to RED, the complete DoC[27] located on Internet has to refer to all applicable legislation to the radio equipment.

f) CE marking

The CE marking shall be subject to the general principles set out in the "Blue Guide" Chapter 4.5.1. The following explanations mainly concern specific aspects of the RED.

Article 10.3 of the RED obliges the manufacturer to affix the CE marking to the radio equipment or its data plate when placing a product on the market unless this is not possible or not warranted on account of the nature of the radio equipment. This marking shall have a minimum height of 5 mm. The CE marking shall also be affixed visibly and legibly to the packaging.

If the nature of the radio equipment does not allow a marking of at least 5 mm, the manufacturer may affix a CE marking that is smaller than 5 mm to the product under the condition that it remains visible and legible. If it not possible or not warranted on account of the nature of the radio equipment to affix a CE marking on the product, the manufacturer may affix it visibly and legibly only to the packaging. If the radio equipment is subject to other pieces of EU legislation which do not allow the CE marking to be smaller than 5 mm, then the possibility of using a smaller CE mark cannot be used by the manufacturer (e.g. RoHS).

If a notified body was involved in the conformity assessment procedure according to Annex IV only then, according to Article 20.3 of the RED, the CE marking has to be followed by the identification number of the notified body in the same height as the CE marking.[28] This identification number of the notified body shall be affixed by the notified body itself, or under its instructions by the manufacturer or his authorised representative. This identification number consists of four digits.

Medical Devices (custom-made)

Under the EU Medical Devices Legislation[29], custom-made medical devices being placed on the market and put into service shall not bear CE marking. If these

[27] Recital 42 of the RED indicates that the complete DoC (single DoC) may be a dossier containing all relevant individual Declarations of conformity.

[28] So when the height of the CE Marking is less than 5 mm, as provided for in Article 19 (2) of the RED, the height of the identification number of the notified body will be also less than 5 mm.

[29] For the applicable legislative framework, see:

https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

custom-made medical devices contain radio equipment within the scope of RED and intended to be placed on the EU market, CE marking shall be affixed for the purposes of the RED.

Medical Devices (investigation-study)

Under the current Medical Devices Directives[30] [Article 4.2 of the AIMD and Article 4.2 of the MDD], devices intended for clinical investigations being made available to qualified medical practitioners, for that purpose, shall not bear CE marking.

Under Article 21 of Regulation 2017/745, investigational medical devices being supplied to an investigator for the purpose of a clinical investigation shall not bear the CE marking (with the exception of the devices referred to in Article 74 of that Regulation) .[31]

Under Article 19 of Regulation 2017/746, in vitro diagnostic medical devices for performance study being supplied for that purpose to laboratories or other institutions shall not bear the CE marking (with the exception of the devices referred to in Article 70 of that Regulation) .[32]

At this stage, such a device is not placed on the market, thus there is no requirement to affix the CE marking on that device even if it consists radio equipment within the scope of the RED. Once the device is intended to be placed on the market, it is subject to the requirement of CE marking in accordance with the EU Medical Devices Legislation as well as RED, if it consists of radio equipment within the scope of the RED.

Machinery Directive

Under the Machinery Directive, CE marking is not required for partly completed machinery. The partly completed machinery shall comply with the requirements set out in Article 13 of the MD. If the partly completed machinery contains radio equipment within the scope of the RED and is intended to be placed on the EU market, CE marking shall be affixed for the purposes of the RED.

Specific issues

[30] For the dates of repeal of these Directives as well as any transitional periods, see:

https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

[31] For the date of applicability of this regulation as well any transitional periods, see:

https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

[32] For the date of applicability of this regulation as well any transitional periods, see:

https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

Lastly, for specific issues relating to the affixing of CE Marking on tags, see Chapter 1.6.3.13;

g) Additional information

According to article 10.6 of the RED, the manufacturer shall ensure that their radio equipment bears a type or batch or serial number or other element allowing its identification.

In cases where the radio equipment is too small or the nature of the equipment does not allow it (if for example the surface of the equipment not suitable for printing), the above information shall be provided on the packaging or in a document accompanying the radio equipment.

Further details about this requirement can be found in Chapter 4.2.2.3 of the Blue Guide.

Lastly, for specific issues relating to tags, see Chapter 1.6.3.13.

h) Traceability information

Details about this requirement can be found in Article 10.7 of the RED and further explanation in Chapter 4.2.2.1 of the Blue Guide.

Also, for specific issues relating to tags, see Chapter 1.6.3.13.

i) Geographical information in case of restrictions

Where restrictions on putting into service or requirements for authorisation for use of radio equipment exist in the Union, Article 10.10 of the RED requires manufacturers to add information on the package that allows the identification of the Member States or the geographical area within a Member State where these restrictions or requirements exist. In addition, further information on the actual restrictions or requirements shall be completed in the instructions accompanying the radio equipment.

The Commission adopted an implementing act specifying how to present this information[33]. In particular, the implementing act provides two options on how the information can be presented on the packaging. The manufacturer may either provide, visibly and legibly, a brief written statement or a pictogram on the packaging.

[33] Commission Implementing Regulation (EU) 2017/1354 of 20 July 2017 specifying how to present the information provided for in Article 10(10) of Directive 2014/53/EU of the European Parliament and of the Council (Text with EEA relevance), OJ L 190, 21.7.2017, p. 7–10.

Examples of pictogram:[34]

		
ES	LU	RO
CZ	FR	HU
SI	DK	HR

	BG	EE	BE

In addition, the implementing act provides that detailed information shall be provided in the instructions in a language easily understood by end-users as determined by the Member State concerned.

Restrictions on putting into service relate to national frequency allocations, i.e. frequencies that are not harmonised throughout the whole European Union. Requirements for authorisation of use relate to individual licencing or conditions attached to authorisation of use (licencing conditions), e.g.indoor/outdoor use or a minimum operation distance from certain protected/restricted areas. Other examples for conditions attached to authorisation of use are the requirements to hold an operator certificate, e.g. radio amateur examination certificate, short range certificate for use of marine VHF-radio. Article 10.10 applies when these restrictions relate to the radio function of the equipment.

j) Instructions

[34] Abbreviations of Member States and other related States (see Chapter 1.2): Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE), United Kingdom (UK), Norway (NO), Iceland (IS), Lichtenstein (LI), Switzerland (CH) and Turkey (TR).

Article 10.8 of the RED requires manufacturers to accompany the equipment by instructions and safety information in a language which could be easily understood by consumers and other end- users, as determined by the Member State concerned. Furthermore, they shall be clear, understandable and intelligible.

These instructions shall also include information required to use the radio equipment in accordance with its intended use. In particular, this information shall include, where applicable, a description of accessories and components, including software:

(1) have an influence on the conformity of the radio equipment, and
(2) are intended to be installed or changed by the user without the control of the manufacturer.

Accessories example:

- If the radio equipment is delivered without an antenna, then the technical features of the antenna that may be used in conjunction with the radio equipment shall be provided to the user. The user is responsible to operate the radio equipment and the accessories as intended and according to the description provided by the manufacturer.

  These technical features of the accessories shall therefore be mentioned in the instruction manual in order to enable the user to operate the compliant radio equipment. This information could be the generic characteristics of a given antenna type or a reference to a specific antenna(s) available on the market.

Software example:

- If the radio equipment has software (such as firmware, PC controlling software) that can affect its compliance with the Directive and the manufacturer intends and offers the possibility to the user to freely change it or modify it, then the software should be named in the instruction manual so that it is possible for the user to put a compliant radio equipment into operation. The manufacturer can decide the format of the description of this software as long as it can be identified.

  On the other hand, if the radio equipment has software that cannot affect its compliance with the Directive, even when the software is modified or replaced, then no information has to be provided in the DoC.

With the objective of supporting authorities on their market surveillance activities, Article 10.8 of the RED requires manufacturers to accompany radio equipment which intentionally emits radio waves with information on the frequency bands and maximum output power with which the equipment is able to operate in the EU.

Manufacturers have different alternatives to fulfil these requirements. For example, any of the following options could be added to the instructions:

- the nominal frequency and transmitted power (radiated and/or conducted) used by the radio equipment, as reflected in the Technical Documentation, or
- for radio equipment using standardized technologies, e.g. GSM/3G/LTE, indication of the frequency band in the way they are commonly well-

known (such as GSM 900, 1800). Where different power levels are possible, the nominal maximum power would be stated.

The instructions shall also include detailed information, in a language easily understood by end-users as determined by the Member State, concerning any restrictions on putting into service or requirements for authorisation for use of radio equipment that exist in the EU (Article 10.10 RED)[35].

The Blue Guide, in Chapter 3.1.4, provides more details on how the instructions and safety information need to be provided. According to the Blue Guide, whilst the safety information needs to be provided on paper, it is not required that all the set of instructions is also provided on paper but they can also be on electronic or other data storage format, however a paper version should always be available free of charge for the consumers who request it. It is noted that the information in Article 10.8 (second sub-paragraph) and Article 10.10, as is specifically required by the RED and not directly related with the general instructions of use, shall be provided in paper.

k) Series production

The manufacturer is responsible for the conformity of every single product manufactured and placed on the market. The manufacturer, who places a product on the market, shall ensure that, at that particular point in time, the product is in conformity with the applicable legislation.

For series production it is therefore crucial that the manufacturer monitors any changes in hardware/software, developments in applicable standards and legislation and that the state of the art is taken into account adequately. In addition, the considerations given by the manufacturer to these changes shall be reported in the technical documentation. Details can be found in Chapters 3.1 and 2.3 of the Blue Guide.

l) Sample testing and register of complains

Article 10.5 (second sub-paragraph) of the RED obliges the manufacturer to carry out sample tests under certain conditions:

> "When deemed appropriate with regard to the risks presented by radio equipment, manufacturers/importers shall, to protect the health and safety of end-users, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring."

In order to protect the health and safety of end users, manufacturers shall fulfil this requirement when the radio equipment presents a risk related to the essential requirement specified in Article 3.1.a.

[35] See Chapter 2.6 i)

Further details can be found in Chapter 3.1 of the Blue Guide.

m) Action in case of non-compliance

According to Article 10.11 of the RED, in cases where the manufacturer considers or has a reason to believe that radio equipment which he has placed on the market is not in conformity with the Directive, the manufacturer shall take immediate corrective actions to:

- bring that radio equipment into conformity, or
- withdraw it, or
- recall it.

In addition, if the manufacturer considers that the radio equipment presents a risk, he shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available on the market.

The (post-placing on the market) risk assessment referred to in Article 10.11 of the RED is different to the (pre-placing on the market) risk assessment required by the RED to be part of the technical documentation (see Chapter 2.6d) .

The risk assessment referred to in Article 10.11 is the one Market Surveillance Authorities would perform in the course of their surveillance activities according to Article 40 of the RED.

Further details about this requirement can be found in Chapter 3.1 of the Blue Guide.

n) Cooperation with authorities

Manufacturers shall cooperate with competent national authority in the course of their surveillance activities according to Article 10.12 of the RED.

Further details about this requirement can be found in Chapter 3.1 of the Blue Guide.

3 Essential requirements

3.1 General

As a large part of Union harmonisation legislation, the RED lays down "essential requirements"[36], which are mandatory provisions to ensure a high level of protection of public interest.

In the RED, two sorts of essential requirements are defined:

- essential requirements applicable to all radio equipment;
- essential requirements applicable only to certain type of radio equipment pursuant to specific legal acts adopted by the Commission (delegated acts).

3.2 Essential requirements applicable to all radio equipment

All radio equipment shall be constructed so as to ensure[37]:

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

- Article 3.1.a RED: the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying;

  Therefore, battery-operated equipment, such as a GSM handset, is also subject to this essential requirement and has to ensure that, the limits for human exposure to electromagnetic fields are respected. In this respect, the manufacturer has also to take into account the reasonably foreseeable conditions of use (Article 17.1 of the RED).

  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 .

- Article 3.1.b RED: an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU.

- Article 3.2 RED: that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference (recitals 10 and 11 of the RED).

3.3 **Essential requirements applicable only to a certain type of radio equipment**

In order to make these essential requirements applicable, the Commission has first to adopt decisions, so called delegated acts[38], to specify the categories or classes of radio equipment which have to fulfil such requirements. If no delegated act is adopted by the Commission for a specific category of radio equipment, then the requirements of Article 3.3 remain not applicable.

It should be noted that Commission Decisions adopted under Article 3.3 of the R&TTED continue to be valid (see Chapter 8.1).

The essential requirements included in Article 3.3 are:

- radio equipment interworks with accessories, in particular with common chargers (Article 3.3.a);
  - *currently no delegated act*
- radio equipment interworks via networks with other radio equipment (Article 3.3.b);
  - *currently no delegated act*

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[37] Articles 3.1 and 3.2 of the RED

[38] The Treaty on the Functioning of the European Union (Article 290) allows the EU legislator to delegate to the Commission the power to adopt acts that supplement or amend certain non-essential elements of a legislative act.

- radio equipment can be connected to interfaces of the appropriate type throughout the Union (Article 3.3.c);
  - *currently no delegated act*
- radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service (Article 3.3.d);
  - *currently no delegated act*
- radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected (Article 3.3.e);
  - *currently no delegated act*
- radio equipment supports certain features ensuring protection from fraud (Article 3.3.f);
  - *currently no delegated act*
- radio equipment supports certain features ensuring access to emergency services (Article 3.3.g);
  - 2000/637/EC: Commission Decision 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
  - 2001/148/EC: Commission Decision of 21 February 2001 on the application of Article 3(3)(e) of Directive 1999/5/EC to avalanche beacons
  - 2013/638/EC: Commission Decision of 12 August 2013 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)
  - 2005/53/EC: Commission Decision 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)
  - 2005/631/EC: Commission Decision 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
- radio equipment supports certain features in order to facilitate its use by users with a disability (Article 3.3.h);
  - *currently no delegated act*
- radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the

combination of the radio equipment and software has been demonstrated (Article 3.3.i);

- *currently no delegated act.*

4 Interface regulations & specifications

4.1 Notification of radio interface specifications

Interface regulations (often called "interface specifications" or even "interface requirements") relate to the Member States' obligation under Article 8.1 to notify the Commission of the interfaces which they have regulated.

A common template has been developed with a respective guide which are available on the Commission website[39]

The relevant information may be found on the national websites of the spectrum authorities (links are available on the Commission's website) m.] or also in the EFIS database.

4.2 Assignment of radio equipment classes

The Commission has to establish, based on Article 8.2 of the RED, the equivalence between these national radio interface specifications.

The Commission shall adopt implementing acts establishing the equivalence between notified radio interfaces and assigning a radio equipment class, details of which shall be published in the Official Journal of the European Union.

Commission Decisions adopted under the R&TTED remain applicable under the RED to the extent that they are not incompatible with the RED (see Chapter 8.1). Therefore, Commission Decision 2000/299/EC of 6 April 2000 establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers, adopted under Article 4.1 of the R&TTED, remains valid with the exception of the provisions that refer to the alert sign.

The class identifier as "information sign" or "alert sign", required by the R&TTED, is not required by the RED and instead the manufacturer is required to provide information in accordance with Article 10.10 of the RED when restrictions on putting into service or of requirements for authorisation of use exist in one or more Member States.

Under Commission Decision 2000/299/EC the following classes are defined:

- Class 1: radio equipment that can be operated without any restriction in the whole EU .
- Class 2: radio equipment whose putting into service or use is subject to restrictions. Examples of such restrictions are:

[39] Radio Equipment Directive (RED) - European Commission

- frequency available and allowed for that application in certain Member States only;
- individual licence needed to use the specific radio equipment and compliance with attached conditions, as e.g. the need of an operator certificate;
- indoor use only;
- ….

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.

The manufacturer is not required to produce and place on the market radio equipment that uses the frequencies falling within the scope of 'Class 1'. If the radio equipment uses frequencies not falling within the scope of 'Class 1'will be classified as Class 2 and might be subject to restrictions.

The class 1 template may be found on the Commission's website.

5 Harmonised Standards

5.1 Introduction

Chapter 4.1.2 of the Blue guide gives information on the role and application of harmonised standards.

The application of harmonised standards is voluntary but has the advantage of giving "presumption of conformity" (if references are published in the Official Journal of the European Union under the RED) with the corresponding essential requirements that they aim to cover. Harmonised standards only address aspects related to the essential requirements. If a manufacturer chooses not to follow a harmonised standard or only partly, he has the obligation to prove that his radio equipment is in conformity with the essential requirements by other means and to provide a full technical justification.

The Commission's website[40] gives information on titles and references to harmonised standards in relation to the RED, however the only valid list is the most recent one published in the OJEU.

The 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 relevance within the concept of the RED.

The cessation of presumption of conformity applies only to those individual items which are not yet placed on the market. In other words, it does not affect radio

[40] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/rtte_en

equipment already placed on the market, neither its presumption of conformity, nor the validity of its DoC.

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

5.2 Generic harmonised standards vs product specific harmonised standard

A manufacturer which has the intention to apply a harmonised standard for the conformity assessment of its products, has to apply in priority the product specific harmonised standard and only if this one is not available, the generic one, in order to benefit of presumption of conformity with the essential requirements of the RED.

5.3 Revision of harmonised standards

Manufacturers who have applied a superseded harmonised standard which no longer provides presumption of conformity against art. 3.2 or 3.3 and do not wish to apply the new harmonised standard, need to involve a notified body in order to continue placing the radio equipment on the market.

Chapter 4.1.2.6 of the Blue Guide gives detailed information on the revision of harmonised standards.

6 Notified bodies

6.1 Introduction

If the manufacturer has not applied or not fully applied all relevant parts of the relevant harmonised standards, that are cited in the OJEU, applicable to the radio equipment in order to cover Article 3.2 and 3.3 of the Directive, the manufacturer or his authorized representative must use a conformity assessment procedure which involves a notified body (either the Annex III or the Annex IV procedure).

For the assessment of the fulfilling of the essential requirements covered by Article 3.1.a and 3.1.b of the Directive, the manufacturer has either the choice to perform the assessment without involving a NB (Annex II) or involve on a voluntary basis a NB (Annex III or Annex IV procedure).

See also Figure 1: Overview of the different conformity assessment procedures.

6.2 General concept

Notified bodies are designated by the competent authorities of the EU Member States, EEA members and other countries with which the EU has concluded Mutual Recognition Agreements (MRAs) to perform the conformity assessment tasks described in the Directive.

The Commission has a website[41] with a list of all appointed notified bodies. The lists include the address details of each body as well as the tasks for which it has been notified.

Notified bodies can be designated to perform only the Annex III or Annex IV procedure or both procedures and may be appointed to deal with all or only selected types of radio equipment. When designated for all types of radio equipment, the notified body must be able to assess all radio equipment for all of Article 3 essential requirements. When designated for selected types of radio equipment, the notified body must be able to assess only those radio equipment for all of Article 3 essential requirements.

6.2.1 *Annex III procedure — EU-type examination and conformity to type based on internal production control*

The applicant specifies which aspects of the essential requirements the notified body is to assess. As an example the manufacturer could require 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) of the Directive).

Where a notified body performs an examination of the technical documentation of an equipment that contains a radio part for which already a notified body EU type examination Certificate is available then the notified body may accept the results of that previous Examination without the need to repeat the assessment of that product part.

The Directive requires compliance when equipment is "properly installed and maintained and used for its intended purpose". The notified body shall therefore note any inconsistencies between obvious uses of the equipment and the stated intended purpose so that its EU-Type Examination may be suitably qualified and is not open to misinterpretation.
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 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 some cases, it may be necessary to liaise directly with the spectrum authority for the relevant Member State.

The notified body must base its EU-Type Examination Certificate on the requirements of the Directive and on the professional assessment of the technical documentation. They may take into account relevant other relevant EU legislation, standardisation

[41] http://ec.europa.eu/growth/tools-databases/nando/

documents, technical references as ECC reports or REDCA Technical Guidance Notes available at that time.

Annex III does not provide guidance on the format and content of the EU-Type Examination Certificate. 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.

However the notified body shall take account of the following aspects for the Certificate:

Title "Directive 2014/53/EU — Notified Body EU-Type Examination Certificate" or similar text and avoiding the use of words such as "opinion" and "declaration".

Insert on the Certificate:

- Notified body Name, address etc., (logo if relevant).
- Notified body number.
- EU-Type Examination Certificate number - this shall be the unique number of EU-Type Examination Certificate. A revision number and/or copy number shall be included if applicable.
- Date of issue of the Certificate and its Validity
- Applicant details. Name, address etc. of the party requiring the EU-Type Examination Certificate.
- Scope of examination whether the certificate is covering health & safety (Article 3(1) (a)), EMC (Article 3(1) (b)), radio spectrum use (Article 3(2)) and/or special radio features (Article 3(3) (a)-(f)).
- Clear identification of the radio equipment. 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 radio equipment, including brand/trade name, model/type designation, hardware and software (where it affect the RED conformity) revision.
    - Reference of any build status/design documentation taken into account.
    - Technical documentation identification
    - Unique identification of the documentation etc. taken into consideration irrespective of the actual physical format of the documentation
- Certification text - the text stating whether or not the radio equipment is compliant.
- Authorised signatory (signature block including printed name of the signatory).

6.2.2 *Annex IV procedure — Conformity based on full quality assurance*

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.

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

6.3 Information exchange

Article 36, Annex III (Module B, para 8)[42] and Annex IV (para 7) of the RED contain requirements for notified bodies regarding providing specific information to certain organisations such as other notified bodies, authorities, etc.

Notified bodies should check the NB coordination group: the Radio Equipment Directive Compliance Association (REDCA) whether available procedures to facilitate an easy exchange of information exists within REDCA (for example use of specific email communication and/or CIRCABC).

After having issued an EU-Type Examination Certificate the RED Notified Body is obliged to inform the Member States, in those cases where harmonised standards, if their references have been published in the OJEU, have not been applied or not been fully applied (RED Annex III point 8, paragraph 3).

6.4 Coordination between notified bodies

Recognizing that it is necessary for the conformity assessment procedures to be applied consistently by all parties in order to achieve an open and competitive market throughout Europe, the Radio Equipment Directive Compliance Association (REDCA) has been set up (see Annex 1).1)

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

The REDCA 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.

Furthermore REDCA provides Reference documents for its member containing valuable information to support the work of the notified bodies.

7 Market surveillance and enforcement

Member States are required to take all appropriate measures to ensure that radio equipment covered by the RED which is placed on the market complies with the requirements of the RED.

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[42] One of the obligations, in Annex III of the RED, is that each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the Official Journal of the European Union have not been applied or not been fully applied. This obligation to inform the Member States does not include the situation where harmonised standards do not exist.

The RED itself sets requirements for market surveillance in articles 39-43 and also it refers to Regulation 765/2008/EC[43]. Detailed provisions on how surveillance should be organised and carried out in the Member States are given in chapter 7 of the Blue Guide.

In addition to the Blue Guide other specific market surveillance guidance documents may be available.

A list of the Member State surveillance authorities can be found on the Commission's webpage[44].

8 Delegated Acts, Implementing Acts and Commission Decisions

8.1 Delegated and Implementing acts

The Directive empowers the Commission to adopt delegated and implementing acts on a number of issues[45].

8.1.1 *Delegated acts*

- Essential requirements: (Article 3.3)[46]
- Information on the compliance of combinations of radio equipment and software (Article 4)[47]
- Registration (Article 5)[48]

8.1.2 *Implementing Acts*

- Clarify the definition of radio equipment (Article 2.2)[49]
- Operational rules for the information on the compliance of combinations of radio equipment and software (Article 4) [50]

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[43] There is a proposal on 'Goods Package' (Procedure 2017/0353/COD). For market surveillance issues (if the goods package is adopted as regulation and as of the date of its applicability): the provisions of the goods package will apply for RED; the provisions of Regulation no (EC) No 765/2008 will not apply for RED.

[44] http://ec.europa.eu/growth/sectors/electrical-engineering/rtte-directive_en

[45] For more information on delegated and implementing acts, see: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:ai0032

[46] see Chapter 3.3

[47] Until the date of publication of this Guide, no delegated act has been issued; therefore this Guide does not contain analysis on Article 4.

[48] Until the date of publication of this Guide, no delegated act has been issued; therefore this Guide does not contain analysis on Article 5.

[49] Until the date of publication of this Guide, no implementing act has been adopted under this Article.

- Operational rules for Registration (Article 5) [51]
- Establish the equivalence between notified radio interfaces and assigning a radio equipment class (Article 8.2)[52]
- Information on restrictions on putting into service or requirements for authorisation of use exist (Article 10.10)[53]
- Withdrawal of a notified body (Article 33.4) [54]
- Determining whether the national measure to prohibit or restrict the radio equipment is justified or not (Article 41.1)[55]
- Compliant equipment which presents a risk (Article 42.4) [56]

8.1 Commission Decisions adopted under the R&TTED

Article 50 of the RED provides that references to the repealed Directive (i.e. R&TTED) shall be construed as references to this Directive (i.e. the RED).

As a consequence, any Commission Decisions, adopted under the R&TTED, remain applicable under the RED to the extent that they are not incompatible with the RED, until they are repealed[57].

9 Other applicable or related EU legislation

9.1 General

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[50] Until the date of publication of this Guide, no implementing act has been adopted under this Article.

[51] Until the date of publication of this Guide, no implementing act has been adopted under this Article.

[52] See Chapter 4.2

[53] See Chapter 2.2 i)

[54] Until the date of publication of this Guide, no implementing act has been adopted under this Article.

[55] This implementing act is not adopted in accordance with the procedures of Regulation (EU) No 182/2011; until the date of publication of this Guide, no implementing act has been adopted under this Article.

[56] Until the date of publication of this Guide, no implementing act has been adopted under this Article.

[57] See Chapters 3.3 and 4.2

Products can be covered by more than one Union harmonisation act. If one or more of these acts do not exclude the application of the other Union harmonisation legislation, then all relevant legislation apply simultaneously.

In this case, the manufacturer must ensure that the product complies with all applicable Union Harmonisation Legislation.

(see Chapter 2.6 "Simultaneous Application of Union Harmonisation Acts" of the Blue Guide).

9.2 **EU Environmental legislation**

Radio equipment is generally also covered by environmental legislation such as RoHS (Restrictions of Hazardous Substances), WEEE (Waste Electrical and Electronic Equipment), REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and ErP (ecodesign for Energy-Related Products).

The relevant requirements focus on the design, production and disposal phases of the life cycle of electronic products.

For more information, see the relevant links from the Commission website.[58]

9.3 **Applicability of RED with other EU acts on safety or EMC**

When RED is applicable simultaneously with any other EU legislation covering the same hazard (safety or EMC), the issue of overlap might be resolved by giving preference to the more specific EU legislation.[59]

Examples of such equipment:[60]

- radio equipment incorporated, in a fixed and permanent way, in a non-radio product at the moment of its placing on the market (i.e. in such a way that it cannot be easily

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[58] http://ec.europa.eu/environment/waste/weee/index_en.htm

http://ec.europa.eu/environment/waste/rohs_eee/index_en.htm

http://ec.europa.eu/energy/en/topics/energy-efficiency

http://ec.europa.eu/environment/chemicals/reach/reach_en.htm

[59] Conformity with the RED and with the other Union harmonisation legislation shall be assessed and declared. The declaration of conformity shall make reference to all applicable Union harmonisation legislation.

[60] For internal market legislation on specific sectors, see:

http://ec.europa.eu/growth/sectors_en

accessed and readily removed); this product is deemed to be a single radio equipment and might also be subject to the EU legislation on Medical Devices or Toys or Machinery etc.;

-ground aviation radio equipment which might also be subject to the EU legislation on Civil Aviation;

-radio equipment for vehicles which might also be subject to the EU legislation on Motor Vehicles.

9.4 **General Product Safety Directive 2001/95/EC (GPSD)**

The GPSD establishes a general obligation to place only safe consumer products on the market as well as a procedure for the adoption of standards covering risks and categories of risks. GPSD covers all risks that are not already covered by the RED.

The GPSD only applies where it contains different or more specific provisions compared to Regulation 765/2008/EC (which applies at the same time with the RED), as well as the RED (which mainly incorporates the provisions of Decision 768/2008/EC)[61].

Following a detailed comparison of the provisions of the GPSD with the Regulation 765/2008/EC as well as the RED, the following have been identified as "more specific" and apply also to harmonised consumer products (radio equipment):

- the measures provided for in Article 8(1)(b) of the GPSD;
- the measures provided for in Article 8(1)(c) of the GPSD;
- the measures provided for in Article 8(1)(d) of the GPSD;
- any accompanying measures adopted to ensure that a marketing ban is complied with, as provided for in Article 8(1)(e) of the GPSD;
- recalls and destruction of products, as provided for in Article 8(l)(f)(ii) of the GPSD, in relation to products that are dangerous without presenting a serious risk;
- encouragement and promotion of voluntary action by producers and distributors, including where applicable by the development of codes of good practice, as provided for in Article 8(2), second subparagraph, of the GPSD;
- active information of consumers and other interested parties on complaint procedures, as provided for in Article 9(2) of the GPSD;
- giving the public access to information on product identification, the nature of the risk and the measures taken, as provided for in Article 16(1), first subparagraph, second sentence, of the GPSD.

[61] There is a proposal on 'Goods Package' (Procedure 2017/0353/COD). For market surveillance issues (if the goods package is adopted as regulation and as of the date of its applicability): the provisions of the goods package will apply for RED; the provisions of Regulation no (EC) No 765/2008 will not apply for RED.

- RAPEX notification of measures restricting or imposing specific conditions on the possible marketing or use of products by reason of serious risk (not amounting to a recall, withdrawal or prohibition of being made available on the market), as provided for in Article 12(1), first subparagraph, of the GPSD.

For more details on Regulation 765/2008/EC and Decision 768/2008/EC (NEW LEGISLATIVE FRAMEWORK), see Chapter 1.2 of the Blue Guide.

9.5 Relationship between the RED and LVD[62]/EMCD[63]

Radio equipment falling under the scope of the RED are excluded from both the Low Voltage Directive (LVD) and Electromagnetic Compatibility Directive (EMCD): [64]

- Art. 1.4 RED: "Radio equipment falling within the scope of this Directive shall not be subject to Directive 2014/35/EU (LVD), except as set out in point (a) of Article 3(1) of this Directive."
- Art. 2.2(a) EMCD: "This Directive shall not apply to equipment covered by Directive 1999/5/EC."[65]

Therefore, where RED is applicable to radio equipment, the LVD and EMCD do not apply, however the RED refers to the essential requirements of the LVD and EMCD (on the essential requirements, see Chapter 3).

10 Comparison R&TTED – RED

10.1.1 *Changes between the scopes*

With regard to Directive 1999/5/EC (the R&TTE Directive), the RED has introduced the following changes:

- Pure radio sound and radio TV receive-only equipment, which has been excluded from the R&TTE Directive, falls within the scope of the RED;
- equipment operating below 9 kHz, falls within the scope of the RED;
- radio-determination equipment is now clearly included within the scope of the RED;
- Pure wired telecom terminal equipment now falls outside the scope of the RED;

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

63 Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

64 The RED, in Article 3.1, refers to the essential requirements of the LVD and the EMCD.

65 Directive 1999/5/EC (R&TTED) is replaced by the RED, according to Art. 50 RED references to the replaced Directive shall be construed as references to this Directive.

- custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes is explicitly excluded from the RED.

10.1.2 *Other changes (non-exhaustive list)*

- For the essential requirement set out in Article 3.1.a, the assessment shall also take into account the reasonably foreseeable conditions of use;
- The essential requirements set out in Article 3.2 refer also to the efficient use of radio spectrum.
- No publication of the public interfaces from network operators (Article 4.2 R&TTE was removed);
- Manufacturer's notification to member states of radio equipment that uses frequencies which are not harmonised throughout EU is no longer required (Article 6.4 R&TTED was removed);

10.1.3 *What happens with Commission Decisions taken according to R&TTED?*

Commission Decisions taken according the Article 3.3 R&TTED remain applicable under the RED to the extent that they are not incompatible with the RED. These are the following:

a) 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 (OJ L 225, 31.8.2005, p. 28);

b) 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 the Council to radio equipment intended to participate in the Automatic Identification System (AIS) (OJ L 22, 26.1.2005, p. 14);

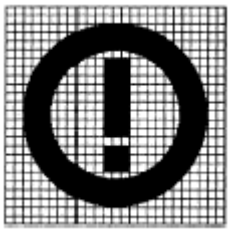
c) Commission Decision 2013/638/EU of 12 August 2013 on essential requirements relating to marine radio communication equipment which is intended to be used on non-SOLAS vessels and to participate in the Global Maritime Distress and Safety System (GMDSS) (OJ L 296, 7.11.2013, p. 22);

d) 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 (OJ L 55, 24.2.2001, p. 65);

e) 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 (OJ L 269, 21.10.2000, p. 50). Commission Decision 2005/631/EC.

In addition, Commission Decision 2000/299/EC of 6 April 2000 establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers, adopted under Article 4.1 of the R&TTED, remains valid with the exception of the provisions that refer to the 'Alert sign'.

10.1.4 *What happens with the "Alert sign"?*



The class identifier as "information sign" or "alert sign", required by the R&TTED, is not required by the RED and instead the manufacturer is required to provide information in accordance with Article 10.10 of the RED when restrictions on putting into service or of requirements for authorisation of use exist in one or more Member States. Manufacturers should avoid the use of this sign when applying the RED so that in the course of time the sign disappears from the market.

11 Transitional provisions for products falling under the scope of the RED

The RED contains the following transitional provisions in Article 48:

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

It is noted that, since the R&TTED can be applicable during the transitional period, the references of the harmonised standards for the R&TTED, as well as the notified bodies under the R&TTED will be kept during the transitional period.

11.1 **Applicability of the RED and the new LVD/EMC**

The current LVD and EMCD are in force from 18 April 2014 and are applicable as of 20 April 2016. The current LVD replaced the LVD (2006/95/EC) and the current EMCD replaced the EMCD (2004/108/EC).

The current LVD and EMCD did not modify the scopes of the previous Directives, except for to the following exclusion that has been explicitly inserted:

*'custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes'***.**

While the revision of LVD and EMCD has not changed their scope, the changes of the scope from the R&TTED to the RED, have direct consequences for the scope of the LVD and EMCD:

- The LVD and EMCD apply to products that previously were covered by the R&TTED except for the custom-built evaluation kits. In practice this means that pure wired telecommunication terminal equipment fall under the scope of the EMCD and the LVD depending on the voltage limits).
- The LVD and EMCD are not applicable to products covered by the RED.

11.2 General comments

The RED can apply to products placed on the market on or after 13 June 2016 (not before).

The LVD and EMCD applies to products placed on the market on or after 20 April 2016 (not before).

This is without prejudice to any other EU act that could also be applicable to an electrical or electronic product/equipment (for example RoHS & WEEE Directive etc.)

R&TTED, LVD and EMCD harmonised standards are not harmonised standards under RED. Only standards published in the OJEU under the RED give presumption of conformity for its requirements.

11.3 Overview of the applicability of the Directives 2014/53/EU (RED), 2014/35/EU(LVD) and 2014/30/EU(EMCD)

11.3.1 *Products within old LVD/EMCD and continue to be within new LVD/EMCD (even after applicability of RED)*

- Products placed on the market before 20 April 2016: old LVD/EMCD
- Products placed on the market on or after 20 April 2016: new LVD/EMCD

11.3.2 *Products within R&TTE that remain within the scope of RED*

- Products placed on the market before 13 June 2016: R&TTED
- Products placed on the market between 13 June 2016 and 12 June 2017: R&TTED or RED
- Products placed on the market after 12 June 2017: RED

11.3.3 *Products within old/new LVD/EMCD but then fall within RED (after applicability of RED)*

For example pure television and sound broadcasting receivers.

- Products placed on the market before 20 April 2016: old LVD/EMCD
- Products placed on the market between 20 April 2016 and 12 June 2016 : new LVD/EMCD
- Products placed on the market between 13 June 2016 and 12 June 2017: RED or new LVD/EMCD
- Products placed on the market after 12 June 2017: RED

11.3.4 *Products within R&TTED and then outside RED*

For example pure wired telecom terminal equipment.

- Products placed on the market before 13 June 2016: R&TTED

- Products placed on the market after 12 June 2016: RED is not applicable; the new EMCD and LVD depending on the voltage limit is applicable. If the LVD is not applicable than the General Product Safety Directive could be applicable provided that the equipment is a consumer product.

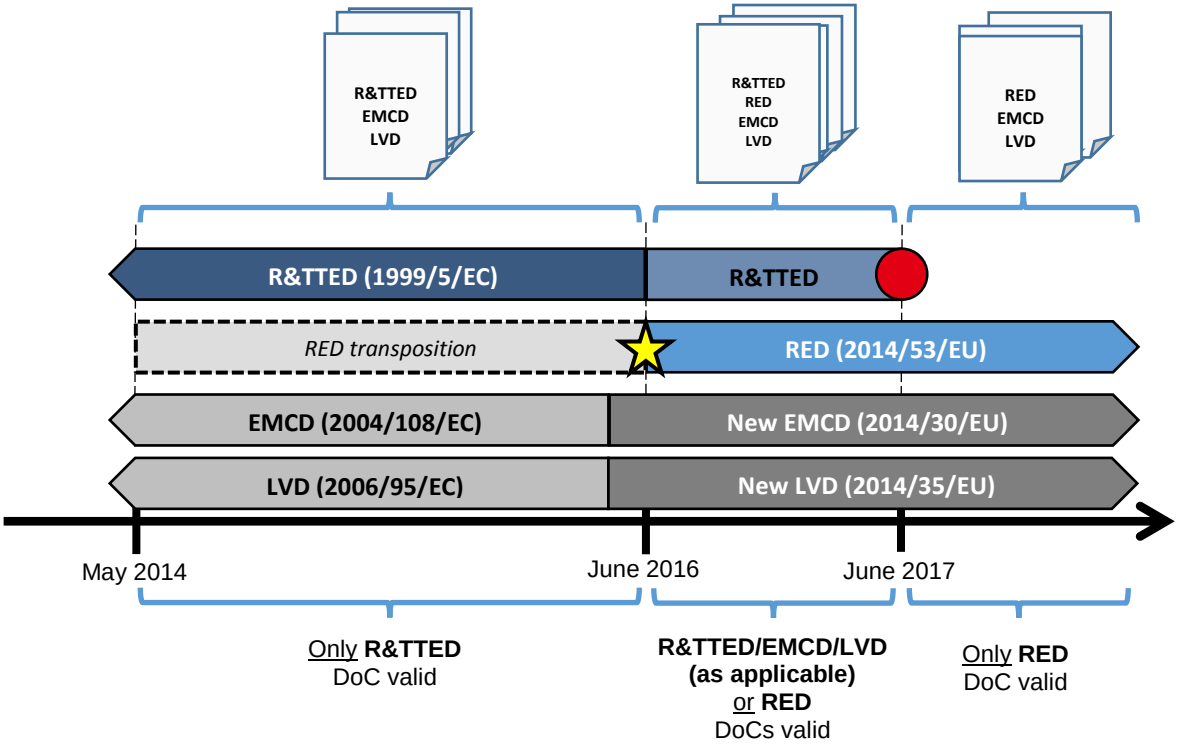


Figure 2: Summary of the transitional provisions for the placing on the market of RED products before 13 June 2017.

ANNEX 1 — Organisations and committees mentioned in this document

ADCO RED (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 [66] (http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en).

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.
https://www.cenelec.eu/
CENELEC standards may be purchased through one of the national member bodies: https://www.cenelec.eu/dyn/www/f?p=web:5.

ECO (European Communications 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 (http://www.cept.org/eco).

ETSI (European Telecommunications Standards Institute) 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/.

ETSI standards can be downloaded free of charge via the Publications Download Area application: http://www.etsi.org/standards-search.

REDCA (Radio Equipment Directive Compliance Association) provides a forum for organisations concerned with the compliance of radio equipment with regulations and technical standards in the European Economic Area, as well as in the Countries that have a Mutual Recognition Agreement with the EU, such as the USA, Canada, Japan, New Zealand, and Australia (http://www.redca.eu).

It has specific responsibilities in respect of Notified Bodies appointed under EU Directive 2014/53/EU (Radio Equipment Directive). In this context it has published a number of Technical Guidance Notes that can be accessed by following the "Download Area" link alongside.

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[66] See also Blue Guide, Chapter 7

Membership of REDCA is open to any notified body, testing, manufacturing or other organisation that is willing to follow the aims and objectives set out in the Associations Rules and Constitution. An application form and a full copy of the Rules can be found by following the "Download Area" link alongside.

The Association meets twice a year in a location within the EEA. All meetings are open for members only. These meetings are ideal to discuss matters with important players in the field such as representatives of the EU Commission, ECC, ETSI, ADCO RED and authorities from MRA countries.

REDCA operates a mail server where members can ask questions that will trigger answers and comments from the experts within the Association. These discussions provide material to be stored on the protected database for future reference by the members. Furthermore the Association has a specific protected area on the CIRCABC website, operated by the EU Commission, where all documents are stored for access by the members only.

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 (https://ec.europa.eu/digital-single-market/node/121).

TCAM + WG (Telecommunication Conformity Assessment and Market Surveillance Committee + Working Group) 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 consults the TCAM. Many TCAM documents are made publicly available after the meetings on Internet[67].

[67] https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp (> Browse categories / (European Commission)Internal Market, Industry, Entrepreneurship and SME's / RED-R&TTED: TCAM Working Group / Library / Public documents)

ANNEX 2 — Acronyms and abbreviations

ADCO RED	Group on ADministrative COoperation on RED (see Annex 1)
CATV	Community Antenna Television
CENELEC	European Committee for Electrotechnical Standardisation (see Annex 1)
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
DoC	EU Declaration of Conformity
DVB-C	Digital Video Broadcasting - Cable
DVB-S	Digital Video Broadcasting — Satellite
DVB-T	Digital Video Broadcasting — Terrestrial
ECO	European Communications Office (permanent office of the European Conference of Postal and Telecommunications Administrations [CEPT]) (see Annex 1)
EEA	European Economic Area
EMC	Electromagnetic Compatibility
EMCD	Electromagnetic Compatibility Directive (2014/30/EU)
ETSI	European Telecommunications Standards Institute (see Annex 1)
EU	European Union
GPSD	General Product Safety Directive (2001/95/EC)
ISO	International Organisation for Standardisation
LVD	Low Voltage Directive (2014/35/EU)
MRA	Mutual Recognition Agreement
MS	Member State
NB	Notified Body
NLF	New Legislative Framework
OJEU	Official Journal of the European Union
RED	Radio Equipment Directive (2014/53/EU)
RSC	Radio Spectrum Committee (see Annex 1)

R&TTED	Directive on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (1999/5/EC)
REDCA	Radio Equipment Directive Compliance Association (see Annex 1)
RF	Radio Frequency
RFID	Radio Frequency Identification
TCAM	Telecommunication Conformity Assessment and Market Surveillance Committee (see Annex 1)
TD	Technical Documentation
TETRA	Terrestrial Trunked Radio
TGN	Technical Guidance Note
URL	Uniform Resource Locator
WLAN	Wireless Local Area Network