Position Paper

Brussels, 29 June 2015

Orgalime comments to the draft Guide for the application of the Radio Equipment Directive (RED)

1. INTRODUCTION

Orgalime would like to thank the European Commission and the market surveillance authorities for taking up the revision of the guide for the application of the Radio Equipment Directive (RED) to ensure that the new version should reflect a common interpretation of all the changes that the Directive's revision resulted in.

We have the pleasure of providing our comments on the first draft text that was circulated in May 2015.

2. LVD SAFETY PROVISIONS

Orgalime requests that the Guide should clarify in chapter 1.1 that the Low Voltage Directive (LVD) safety provisions apply to radio equipment, under the new RED in the same way as under the current Radio and Telecommunications Technical Equipment Directive (R&TTED), that is "*with no lower voltage limit applying*" (Recital 10).

3. RADIO EQUIPMENT DIRECTIVE SCOPE

Orgalime welcomes the clarification in chapter 1.1.3 of borderline cases of products not covered by RED.

However, we consider that the Guide should explicitly explain as well that products and applications that use electromagnetic fields for other purposes than communication and/ or radio determination are not covered by the RED. This explanation would cover all products that propagate electromagnetic waves in space, but this propagation is not intended and not used for the purpose of communication or radar determination.

Here is an indicative list of such products:

- inductive warming and heating appliances
- wireless power transfer as well as equipment using the electromagnetic field for wireless power transfer which also uses the same electromagnetic field to transmit data as a secondary function for simple communication.
- equipment using electric or magnetic near field for sensing purposes
- high frequency surgical equipment and systems

www.orgalime.org

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

- cookware suitable for inductive heating appliances
- Equipment that makes use of radio wave energy inside a closed equipment or is intended to be incorporated in a closed equipment, where a shielding ensures that the requirements of directive 2014/35/EU are fulfilled outside the equipment

4. CUSTOM-BUILT EVALUATION KITS (1.1.3.4)

"*Custom built evaluation kits, that are destined to be used by professionals solely at research and development facilities for such purposes*" are excluded from the scope of the Radio Equipment Directive.

Therefore, the guide should clarify the criteria and conditions under which custom-built evaluation kits would be excluded. A possible solution would be to adapt the guidance given on the issue in the ROHS 2 FAQ as follows:

"*A custom built evaluation kit is intended to be used in the conceptual, developmental, design or pre-production stages and is as such designed solely for R&D use. This type of equipment is supplied only from a corporation to another corporation (B2B context) or a public institution, to be used by professionals at research and / or development facilities. The purpose of these kits is to be used in facilities that include for example the test/evaluation/further development/improvement of the function under development or research*".

Therefore all devices/equipment used on a regular basis (such as laboratory equipment) to perform these evaluations are not covered by this exemption. When the research and development process is finished, the custom built evaluation kit should not be delivered to the end-user – as it is no longer covered by this exemption - unless it has been brought into conformity with the applicable harmonisation legislation.

5. DEFINING RADIO EQUPMENT

According to chapter 1.1.6 *"Non radio products incorporating radio products have to comply with the requirements of the RED".*

Moreover, chapter 1.2 states that "*when a non-radio product includes a radio part, the part or, if it cannot be separated, the whole product is subject to the provisions of the RED*".

Orgalime considers it important to further clarify these statements to avoid confusion on which legislation applies to the product. It is crucial to take into consideration that products with a radio part may be covered by other Directives, such as the Machinery Directive or the Medical Devices Directive, whose requirements are different from those of the Radio Equipment Directive. Furthermore, vehicles, such as cars and trains, which are subject to significantly different legislation, may also include radio parts.

Therefore we suggest the following re-formulation in chapter 1.1.6 instead of the current:

Non radio products ~~incorporating~~ <u>in which</u> radio products <u>are permanently incorporated and cannot be separated</u> and for which the radio interface is necessary for the primary function of the non radio product have to comply with the requirements of the RED. <u>For non radio products incorporating radio equipment which can be separated, the manufacturer can choose to apply the RED to the whole product or only to the radio part. In the latter case safety aspects of the non radio part are regulated by other relevant EU legislation.</u>

6. PRODUCTS CONTAINING MULTIPLE RADIO EQUIPMENT UNITS

Orgalime requests that chapters 1.1.6 and 1.2 explain how manufacturers should resolve the possible conflicts that may arise in products containing multiple radio equipment units, such as non-road mobile machinery products.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

7. RELATION WITH OTHER APPLICABLE LEGISLATION

Orgalime welcomes the existing clarification in chapter 1.1.7 on the relation between RED and environmental legislation.

Furthermore, we consider it important to add further clarifications in this chapter and in chapter 3.2 on the relationship between the RED and other Directives regulating health and safety aspects of equipment in a more specific way (application of the '*lex specialis*').

In particular, we suggest the following text to be added in chapter 3.2:

> *"For equipment subject to other and more specific Union harmonisation legislation and, in particular legislation regulating the health and safety aspects of this equipment, it is sufficient for the manufacturer to comply with the more specific requirements and to conduct a conformity assessment in accordance with these requirements only. Harmonised standards listed in the Official Journal that provide presumption of conformity under other more specific Union harmonisation legislation are considered to provide also presumption of conformity under the RED."*

8. DEFINITION OF ELECTROMAGNETIC WAVE AND SPACE

Radio waves can be propagated in space for purposes other than communication and/or radio determination. For example, products covered by the EMC also propagate electromagnetic waves in space, as space per definition also covers a distance <1 cm, not for the purpose of communication but for other purposes, such as for instance wireless power transfer.

Therefore, chapter 1.2 should clarify that any product making use of electromagnetic waves propagated in space for any other purpose than communication and/or radio determination is excluded from the scope of the RED.

Orgalime suggests the following definitions:

> **Electromagnetic waves**: *An electromagnetic wave in the sense of the RED is a wave that is generated and transmitted through space with the aim to carry out communication, in most cases under far field conditions. However, in cases where the frequency spectrum is used under near field conditions (as for example RFID) the equipment is covered by the Directive. Communication techniques that make use of an artificial guide (such as a cable or any conductor) in such way that the sender and/or receiver uses inductive/capacitive methods to couple the signal either into or out of that artificial guide, are not considered to be radio equipment in the sense of the RED, as long as the "far field" frequency spectrum is not utilised through that technique.*
>
> *Some products intentionally use magnetic or electric fields to serve their purpose, but the fields generated do not propagate as radio waves, as the wavelength of the signal is too long to be efficiently transmitted through the available antenna structures. Such equipment has very limited potential for interference and disturbances of the radio spectrum that is protected by Article 3 (2). Interference that may occur through near field emissions are adequately covered by the essential requirements, as set out in the EMC directive 2014/30/EU. Such equipment is therefore excluded from the scope of the RED, as it does not utilise frequency spectrum.*
>
> **Definition of space**: *Space means any area surrounding a radio equipment. If a communication technique is used that emits a radio wave (or electric/magnetic near field), but within a shielded enclosure (e.g. between a motherboard and a daughter board) then such equipment is excluded from the application of the RED. In this case the frequency spectrum is utilised only within the shielded device, whilst the RED protects the frequency spectrum only outside a device (the space) so that it can be possibly utilised by other users or services. However, the residual field strength outside the device should be in compliance with the appropriate limits that are set out in harmonised standards under the EMC Directive.*

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

9. FIXED INSTALLATIONS

Orgalime requests chapter 1.11 to provide more examples and clarification on the criteria that could lead a manufacturer to decide that his fixed installation could not be considered "*to be placed on the market as a whole*" and thereby does not require CE marking.

10. TRANSITIONAL ARRANGEMENTS

Orgalime considers it important to explain in detail the transition procedure from R&TTED to RED. It is also necessary to include a detailed overview of the three different scenarios, which could be identified for products changing from the scope of the one directive to the other, because of the implementation of the RED and the repeal of the R&TTED.

We suggest the following wording and diagram:

> "*The R&TTED (1999/5/EC) shall be used to place radio equipment on the EU market until 12 June 2016 included. The R&TTED is repealed with effect from 13 June 2016*[1]*.*
>
> *According to the Directive, the EU Member States shall transpose and publish the RED transposed national law by 12 June 2016. Consequently, the RED can be used to place radio equipment on the EU market from 13 June 2016 on*[2]*.*
>
> *In addition, during the period between 13 June 2016 and 13 June 2017 (i.e. transitional period), radio equipment falling under the scope of the RED which is in conformity with EU Directives applicable before 13 June 2016 (e.g. R&TTE, EMC, Low Voltage Directives) can also be placed on the EU market*[3]*.*
>
> *Products which have been placed on the market before 13 June.2017 applying the relevant Union harmonisation legislation, which came into force before 13 June 2016 (e.g. 1999/5/EG, 2006/95/EG and 2004/108/EG), can be made available on the market without any time limit.*

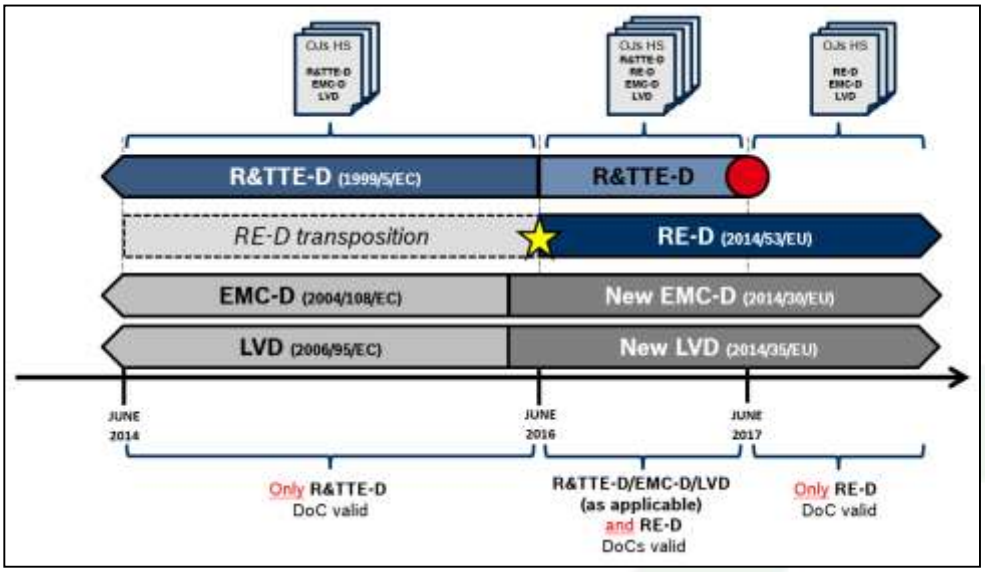

Figure 1: Timeframe for repeal, transposition and transitional provisions in RED

Moreover, considering the above, the following scenarios can be identified:

[1] Article 50 (Repeal)
[2] Article 49 (Transposition)
[3] Article 48 (Transitional provisions)

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

1. Equipment falling under the scope of the R&TTE Directive[4] which also falls under the scope of the RED[5]:

Period before 13 June 2016
- Only the R&TTED can be applied.
- Only a R&TTED Declaration of Conformity (DoC) can be issued.

Period between 13 June 2016 and 12 June 2017
- Either the R&TTED or the RED can be applied.
- Either a R&TTED DoC or a RED DoC can be issued.

Period from 13 June 2017
- Only the RED can be applied.
- Only a RED DoC can be issued.

During the period between 13 June 2016 and 12 June 2017 the EU Commission would make available a list (or lists) of references to Harmonised Standards providing presumption of conformity with both the R&TTE-D and the RED.

2. Equipment falling under the scope of the EMCD[6]/ LVD[7] which also falls under the scope of the RED (for example broadcast receivers, radio equipment operating under 9kHz):

Period before 13 June 2016
- Only the EMC-D/LVD can be applied.
- Only an EMC-D/LVD DoC can be issued.

Period between 13 June 2016 and 12 June 2017
- Either the EMC-D/LVD or the RED can be applied.
- Either an EMC-D/LVD DoC or a RED DoC can be issued.

Period from 13 June 2017
- Only the RED can be applied.
- Only a RED DoC can be issued.

3. Equipment falling under the scope of the R&TTED but not falling under the scope of the RED (e.g. telephones, fax machines, routers):

Period before 13 June 2016
- Only the R&TTED can be used.
- Only an R&TTED DoC can be issued.

Period from 13 June 2016
- Other applicable EU Directives (e.g. EMC-D/LVD) should be considered.
- A DoC according to other applicable EU Directives (e.g. EMC-D/LVD) should be issued."

11. PRODUCTS NEWLY COVERED BY RED

We propose to ensure that chapter 1.15 does not duplicate paragraph 1.12.1.1 "*What is now covered*" under chapter 1.12 "*Comparison R&TTE – RED*".
Moreover, we suggest reformulating chapter 1.16 to avoid duplicating chapter 1.12.1.2 "what is not anymore covered".

[4] 1999/5/EC
[5] 2014/53/EU
[6] 2014/30/EU
[7] 2014/35/EU

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

12. OBLIGATIONS OF ECONOMIC OPERATORS (GENERAL PART)

Orgalime welcomes the idea to draft a paragraph in chapter 2.1 on the "*Identification number of the notified body*". This paragraph should clarify that the use of a notified body is not always necessary.

13. DEFINITION OF MAXIMUM RADIO FREQUENCY POWER

Orgalime considers it is important to include an answer to the so far open question on how to define the term "radio-frequency power". In particular, it should be clarified whether it refers to the input power to the antenna or not.

14. VOLUNTARY NATURE OF STANDARDS

Orgalime considers it necessary to explain in more detail to the manufacturers the voluntary nature of standards, including harmonised standards under the RED. Therefore, paragraph 5.3.2 should clearly explain that it is not obligatory to use standards listed in the OJEU under the RED.

A reference to the relevant Blue Guide chapter could be useful.

15. POSSIBILITY TO REFER TO STANDARDS HARMONISED UNDER EMC AND LVD

Orgalime considers it important that the Guide stresses that standards harmonised under the EMC and the LVD can be referenced in the Declaration of Conformity of a product falling under the RED. Therefore, we suggest modifying chapter 5.4 as following:

> "*Harmonised standards under the LVD (2014/35/EU) and the EMCD (2014/30/EU) have the same status under the RED and can be referenced under the Declaration of Conformity of a product falling under the RED."*

16. SELECTION OF CONFORMITY ASSESSMENT PROCEDURE

Orgalime requests section 5.6.1 to delete the words "*type of the radio equipment*" because this does not determine which conformity assessment module the manufacturer may use.

Moreover, it should be clarified that the manufacturer may use more complex conformity assessment modules than the obligatory ones, if so wished. However, this is not obligatory.

17. SOFTWARE DEFINED PROPERTIES OF RADIO EQUIPMENT

Orgalime requests the Guide to explain in chapter 5.8.2 whether manufacturers of radio equipment and of software allowing radio equipment to be used as intended should provide:

- one Declaration of Conformity for all intended HW/SW combinations of radio equipment and software or
- one Declaration of Conformity for each intended combination

18. INTENDED OPERATING CONDITIONS

Orgalime requests the Guide to clarify in Chapter 5.4 that the requirement for conformity assessment to "*take into account all intended operating conditions*" (article 17) refers only to intended operating conditions that may alter the product behaviour with respect to the conformity of the product with the essential requirements. Otherwise the conformity assessment procedure would be too lengthy.

19. NOTIFIED BODIES

Orgalime considers it useful to streamline section 7.2 on notified bodies with the relevant section of the Blue Guide and delete any repetitions.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

20. MANUFACTURER

Orgalime suggests the following wording for chapter 2.2 on manufacturer's responsibilities.

Overview of responsibilities with a reference to section 5.1 of the Blue Guide

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

a) Carry out conformity assessment procedures according to Article 17
b) Ensure that the equipment can operate in at least one Member State
c) Draw up technical documentation according to Article 21
d) Draw up a DoC / simplified DoC which should accompany the product
e) Affix CE marking
f) Add type, batch or serial number or other element to the equipment allowing its identification
g) Add traceability information to the equipment (address, etc…)
h) Add geographical information in case of restrictions
i) Ensure that the equipment is accompanied by instructions including, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended. These instructions should also include information about the frequency bands and power used by the radio equipment.
j) Ensure that series of production remain in conformity with the Directive

Furthermore, the following requirements apply to manufacturers after radio equipment has been placed in the EU market:

k) 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 should keep distributors informed of any such monitoring
l) Take immediate actions in case of non-compliance of products already placed on the market
m) Cooperate with market surveillance authorities

Description of responsibilities

<u>Conformity assessment procedures (CAP)</u>

Article 17 of the RED describes the applicability of each conformity assessment procedure (Annex II, III or IV) according to the use of harmonised standards or other technical specifications. This description follows the general principles of the New Legislative Framework (Article 4, Decision 768/2008/EU).

Manufacturers are in principle free to choose whether or not to apply harmonised standards (to benefit from the presumption of conformity). If no harmonised standards are used or not used in full, then conformity will have to be assessed directly with the applicable essential requirements. Use of harmonised standards will also determine the applicable conformity assessment procedures (implying the need for involving a notified body, as the case may be).

As shown in the figure, for the essential requirements stipulated in Article 3 (2) (efficient use of radio spectrum) and Article 3 (such as interoperability, protection from fraud), the possibility to demonstrate conformity directly with these essential requirements by means other than by using the harmonised standards is linked to the use of a Notified Body.

Here is an example for the essential requirements for interoperability and efficient use of radio spectrum: If a product aims to provide a specific service that is harmonised throughout the Union, or if it uses a frequency band where radio parameters are set out in harmonised standards (such as WLAN, Data transmission equipment operating in the 2,4 GHz ISM band using wide band modulation techniques), the manufacturer will have no possibility to make his own conformity assessment and will be obliged to the make use of a Notified Body.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

As a result, harmonised standards considerably facilitate manufacturers to meet the essential requirements in the following cases:

- If they specify the requirements for interoperability or
- If they set out limits for the radio interface to protect the allocated frequency band (e.g. maximum equivalent isotropic radiation power, stability of the carrier, out of band noise)
- If they specify the interference free use of receivers/transmitters using the same frequency band or service throughout the Union (such as dynamic frequency selection, dynamic power control, communications protocol)

In some cases manufacturers may not be able to implement their own solutions in their products, which deviate from the solutions and/or limits given in the harmonised standard, such as a radio equipment that blocks all channels within a frequency band to boost the data transmission rate of their solution or increase the transmitted power above the values set out in the harmonised standard, so that other radio equipment cannot be operated effectively. Although the Directive offers various routes to assess conformity against essential requirements, the use of harmonised standards is the route providing manufacturers with “presumption of conformity”.

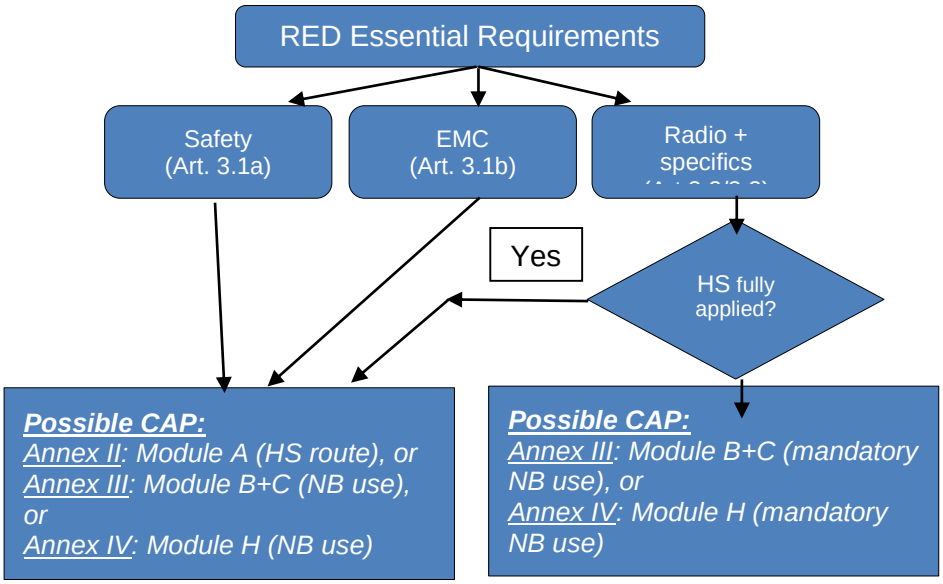

Figure 2: Overview about the different Conformity Assessment Procedures

Equipment can operate in at least one Member State

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.

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 with the respective EU spectrum management authority of the Member State, where the equipment is intended to be made available. If the equipment is intended to be made available in more than one Member State, this should be checked for each Member State. If restrictions for the use of the equipment are applicable, the necessary information should be provided with the equipment according to Article 10.10 of the RED. Contact details of EU spectrum management authorities can be found here:

http://ec.europa.eu/enterprise/R&TTE/spectr.htm (Dead link, to be updated by the Commission)

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/

Technical documentation

Article 10.3 requires the manufacturer to draw up the Technical Documentation (TD) before placing radio equipment on the market. The TD should be kept by manufacturers at the disposal of Market Surveillance Authorities for a period of 10 years after the radio product has been placed on the market.

Specific requirements for the TD are contained in Article 21 of the RED. The TD should be continuously updated, particularly in cases where a re-assessment of radio equipment being placed on the market is needed (e.g. due to the expiration of applicable harmonised standard(s) or changes in production).

Furthermore, in cases where a Notified Body (NB) is involved in the conformity assessment of the radio equipment, the TD and the correspondence relating to any EU-type examination procedure should be drawn up in the official language of the Member State in which the NB is established or in a language acceptable to that body.

Annex V of the RED sets the minimum elements to be included in the TD. The majority of these elements are mentioned in section 4.3 of the Blue Guide as they are the same across the Directives which have been aligned to the NLF. However, there are some elements in Annex V that are only requested by the RED:

- **General description of the product including**:
  - Version of software or firmware affecting compliance with essential requirements: The manufacturer should include information about software or firmware when intended changes on these elements offered by the manufacturer have impact on the compliance of the radio equipment with the essential requirements of the RED (such as, change of software would allow operation in a different frequency range or at higher output power).
  - Information about any other software or firmware not having any impact on the compliance of the radio equipment with the essential requirements of the RED is not required.
  - user information and installation instructions;
  - The manufacturer should include the user information and installation instructions referred to in Article 10.8 of the RED.

- **Copy of the DoC**: The manufacturer should include a copy of the DoC referred to in Articles 10.4 and 18 of the RED.
- **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 should 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 should 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 in the packaging and instruction manual.

Depending on the conformity assessment procedure used by the manufacturer (i.e. Annex II, III or IV), the RED asks to include “an adequate analysis and assessment of the risk(s)” in the TD. Section 4.3 of the Blue Guide provides clarification on how such assessment should be carried out.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

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 to have a test performed by a body acceptable to that authority at the expense of the manufacturer in order to verify compliance with the essential requirements of the RED.

Declaration of conformity (DoC)

The general principles of the DoC are set out in the current "Blue Guide" (Chapter 4.4; Ref. Ares(2014)1025242 - 02/04/2014). 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 all essential requirements of Article 3 of the RED has been demonstrated.

A copy of the DoC or a simplified declaration of conformity should accompany each radio equipment. The DoC should be kept by the manufacturer for 10 years as of the date that the radio equipment was placed on the market.

According to article 18 of the RED, it is possible to use a simplified DoC. The wording of the simplified DoC can be found in Attachment VII of the Directive. The simplified DoC can be displayed in such locations as the operating manual, printed on the radio equipment, or on the display of the device.

The simplified DoC should indicate a 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 an Internet address (URL) where the document is maintained by the manufacturer enabling a simple identification and search for the relevant DoC.

In case where the radio equipment is subject to more than one piece of EU legislation, the RED requires manufacturers to issue a single DoC with reference to all those applicable pieces of legislation. In order to reduce the administrative burden on economic operators, such a single DoC may be a dossier made up of relevant individual declarations of conformity.

Annex VI of the RED defines the content of the DoC. The RED requires under point 8 of this annex to list accessories and software which enable the intended operation of the radio equipment. Manufacturers should only describe those pieces of software and accessories that have an influence on the conformity of the radio equipment. In those particular cases, the manufacturer can decide the format and the level of description of those pieces of software and accessories as long as they can be identified.

This requirement does not apply to those pieces of software and accessories that do not have an influence on the conformity of the radio equipment.

Accessories example

If the radio equipment is delivered without an antenna and if the radio equipment has a maximum output power at the antenna connector then the manufacturer has to use an "exemplary" antenna in the conformity assessment procedure. The technical features (such as radiation pattern, characteristic impedance, isotropic gain) of the antenna that may be used in conjunction with the radio equipment should be clearly and unmistakably described in the user documentation. The user is responsible to operate the radio equipment and the accessories as foreseen and described in the user documentation.

These conformity-relevant, technical features of the accessories should therefore be mentioned in the instruction manual and the declaration of conformity 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:

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

If the radio equipment has software (such as firmware, PC controlling software) that intervenes in the hardware in such a way so that conformity relevant features of the device are influenced (such as transmission power, frequency) then the software should be named in the instruction manual and in the declaration of conformity 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 (such as using version names, or including only main part of software names as to allow maintenance of this software (bug fixing) without having to revise the DoC for every release).

File name (example): radio-equipmentXYZ_EU_1.x.x.x

a) Radio-equipment XYZ: Clear radio equipment type for which the software is suitable
b) EU: “Software part" radio interface (here EU for the European settings for frequency, transmission power, etc.)
c) 1: "Software part" safety function (with focus on safety and EMC aspects)
d) x.x.x: "Software part" other (look & feel, comfort functions, smaller bug fixing)

In this example, software aspects that are irrelevant for the conformity are hidden with "x" in the file name. The declaration of conformity should then only be revised when changes are made to software shares b) and c).

CE marking

The CE marking should be subject to the general principles set out in the "Blue Guide" chapter 4.5.1; Ref. Ares(2014)1025242 - 02/04/2014). The following explanations mainly concern specific aspects of the RED.

Article 10 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 should have a minimum height of 5 mm.

Exemptions are defined in Article 19 of the RED. If the nature of the radio equipment does not allow a marking of this size, the manufacturer has the choice to affix a CE marking that is smaller than 5 mm under the condition that it remains visible and legible. The CE marking may be affixed anywhere on the radio equipment. It is also permitted to affix the CE marking so that it is not visible in so far as it can be made visible without having to use tools (battery compartment lid, removing a panel, etc.).

However, one example when the CE marking on the product is not possible due to the nature of the radio equipment is a RFID transponder. Due to the type of radio equipment (size), a readable attachment of the CE marking is not possible.

The CE marking should also be affixed legibly and visibly to the packaging (if any) of the radio equipment according to Article 20 of the RED.

If a notified body was involved in the conformity assessment procedure according to Annex IV then the CE marking should be followed by the identification number of the notified body in the same height as the CE marking. This identification number of the notified body should be affixed by the notified body itself, or under its instructions by the manufacturer or his authorised representative.

Additional marking

According to article 10.6 of the RED, the manufacturer should ensure that their radio equipment bears a type, 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 should be provided on the packaging or in a document accompanying the radio equipment.

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

Traceability information

Article 10.7 of the RED requires the manufacturer to indicate on the radio equipment:

- their name,
- registered trade name or registered trade mark, and
- the postal address at which they can be contacted.

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 should be provided on the packaging or in a document accompanying the radio equipment.

Further details about this requirement can be found in section 4.2.2.1 of the Blue Guide.

Geographical information

Where restrictions on the use or putting into service of radio equipment in the EU exist, Article 10.10 of the RED requires manufacturers to add information on the package that would allow the identification of the Member States or the geographical area within a Member State where these restrictions exist. In addition, further information on the actual restrictions should be included in the instructions accompanying the radio equipment.

Typical restrictions of use in the EU are for example indoor/outdoor use or a minimum operation distance from certain protected/restricted areas. Restrictions on putting into service can refer to cases such as the need for a spectrum license or the use of frequency bands which are not harmonized in the EU.

The Directive currently provides flexibility to the manufacturer on how to fulfil the requirement to add geographical information on the packaging of the radio equipment[8]. Manufacturers can use a written description (for example in Austria, Germany, Spain), a description in abbreviated written form or a pictogram.

Instructions

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 should be clear, understandable and intelligible.

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

The requirement to include additional information about accessories and components would only apply in case those accessories or components (including software) have impact on the compliance of the radio equipment with the essential requirements of the RED.

Here are some examples:

Antenna(s) not provided with the radio equipment by the manufacturer (for example sold separately as an accessory). In this case the manufacturer should provide the user with information on the antenna(s) intended to be used in order to ensure conformity with the essential requirements of the

[8] In the future the Commission may adopt an implementing act according to Article 45(2) specifying how this geographical information should be presented (e.g. similar to the “Alert Mark” provision required by the R&TTE-D 1999/5/EC).

RED. This information could be about the generic characteristics of a given antenna type or a reference to a specific antenna(s) available on the market.

Software or firmware offered by the manufacturer or on his behalf which would have impact on the compliance of the radio equipment with the essential requirements of the RED (for example, a change of software would allow operation in a different frequency range or at higher output power). In this case the manufacturer should provide the user with information on the software or firmware (such as their version) intended to be used in order to ensure conformity with the essential requirements of the RED.

With the objective of supporting authorities on their market surveillance activities, Article 10.8 of the RED also requests manufacturers to include the following information only for radio transmitters:

- frequency band(s) in which the radio equipment operates,
- maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.

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

- specific values of the frequency and transmitting power used by the radio equipment as reflected in the Technical Documentation, or
- frequency and transmitting power limits applicable to their radio equipment instead of specific values, or
- commonly used technology names instead of specific values (such as LTE, RFID,IEEE 802.11b/g/n), or
- reference to the applicable Class 1 template instead of specific values.

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 should ensure that, at that particular point in time, the product was 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. Details can be found in section 3.1 and 2.3 of the Blue Guide.

The manufacturer has also the responsibility to ensure that series production results in every piece of radio equipment produced and placed on the market being in compliance with the requirements. It may be necessary to check each and every unit or to conduct sampling checks to demonstrate that the radio parameters of a particular device are within the limits set.

For some specific values it may be necessary not only to check the values but also to adjust them to the equipment parameter(s) during or after production. The need to check every single unit or to perform random checks (or no checks at all) depends on how close to the limits set the radio equipment is designed and on the known statistic parameters of that series of products (such as, standard deviation, distribution, confidence interval referring to a particular limit).

Risks that are covered under Article 3 (1b), 3 (2), 3 (3) should be considered in the initial product design. For example in cases where the manufacturer knows that under specific environmental/thermal condition or through aging in the expected life time particular parameters of the radio equipment may not be in conformity any more, the design of the product has to ensure that these parameters are adjusted appropriately or the user is instructed on how to use the device in a compliant manner. In some cases these conditions have already been considered in the harmonised standards.

Sample testing and register of complains

Article 10 (5) obliges the manufacturer to carry out sample tests:

“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 should fulfil this requirement when the radio equipment presents a risk related to the essential requirement specified in Article 3.1 a (same as in the Low Voltage Directive 2014/35/EU).

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

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 a radio equipment which he has put on the market is not in conformity with the Directive, the manufacturer should 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 should immediately inform the national authorities of the Member States in which they made the radio equipment available on the market to that effect.

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 section XXX of this Guide). [To be updated with the final reference to the "Technical Documentation" section]

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. Therefore, the guidance document on risk assessment under the RED prepared by the ADCO RED is a useful reference for manufacturers to fulfil the provisions of Article 10.11. [Guidance currently prepared by ADCO RED. This statement to be confirmed by the ADCO Chairman]

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

Cooperation with authorities

Manufacturers should cooperate with Market Surveillance Authorities in the course of their surveillance activities as per Article 10.12 of the RED.

In particular, the manufacturer should, upon request from authorities, provide them with the information and documentation in paper or electronic form with a view to demonstrate the conformity of the radio equipment with the RED requirements. This information should be provided in a language which could be easily understood by that authority.

Furthermore, the manufacturer should cooperate with Market Surveillance Authorities on any action they have taken to eliminate the risks posed by the radio equipment which they have placed on the market. This risk assessment would be performed by authorities in the course of their surveillance activities according to Article 40 of the RED.

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

Adviser in charge: Philippe Portalier (first name. last name@ orgalime.org)