

GUIDANCE

Application of the Radio Equipment Directive 2014/53/EU and status of combined equipment



Disclaimer

This publication is only for guidance and gives an overview regarding the assessment of the application of the Radio Equipment Directive 2014/53/EU and status of "combined equipment" (non-radio product functioning with radio equipment). It shall not be considered as a binding interpretation of the existing legal framework. It neither claims to cover any aspect of the matter, nor does it reflect all legal aspects in detail. It is not meant to, and cannot, replace own knowledge of the pertaining directives, laws and regulations. Furthermore, the specific characteristics of the individual products and the various possible applications have to be taken into account. This is why, apart from the assessments and procedures addressed in this guide, many other scenarios may apply. Manufacturer's instructions and manuals must always be respected.

Apart from the Directive itself, this guidance is based on both the content of the European Commission's Guidelines, as well as the discussions and drafts that led to their adoption. In particular, the interpretation of the regime applicable to combined equipment represents a plausible scenario in view of the discussions that took place prior to the adoption of the European Commission's guidelines. The guidance may however be adapted once the European Commission's guidelines are revised and notably once the part on combined equipment is completed.

Introduction

Materials handling equipment often incorporates radio devices that are necessary for its functioning. As a result, this equipment may be covered by the Radio Equipment Directive 2014/53/EU (hereafter "RED"). This Directive is thus potentially relevant to all FEM product categories, with the exception of racking and shelving when it only consists of a metallic structure.

This FEM Guidance aims at providing further clarity about the provisions of the RED, notably regarding the obligations and practical steps to be taken by materials handling manufacturers to ensure compliance with the Directive once it becomes applicable, taking into consideration the following situations:

- a. Materials handling manufacturer also producing the radio equipment himself, and therefore bearing the responsibility for the conformity of this radio equipment to the RED
- b. Manufacturer of a non-radio product which incorporates radio equipment in a fixed and permanent manner ("combined equipment")
- c. Manufacturer of a non-radio product which incorporates radio equipment in a non-permanent manner (in other words, a radio product which may be provided separately in the package or can be easily accessed and readily removed from the main non-radio product, or can be bought by the end-user to be integrated into the non-radio product).

This document specifically elaborates on the incorporation of radio equipment, and its two scenarios (permanent and non-permanent incorporation), to give guidance on what legislation is applicable, which manufacturer is responsible for what, and what concrete requirements need to be fulfilled to ensure that the whole product is compliant with all applicable legislation for the CE marking of products.

This FEM Guidance complements the Orgalime Guide on manufacturer's obligations for the combination of a machine with radio equipment.

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1. Scope, comparison with R&TTE Directive and exclusions

1.1- What is the Radio Equipment Directive and what has changed in the new Directive compared to the R&TTE Directive 1999/5/EC?

The Radio Equipment Directive 2014/53/EU repealed the previous R&TTE Directive from 13 June 2016. The RED covers all equipment using the radio spectrum placed on the market as from 13 June 2017 (a one-year transition period is given for the application of the RED). The table below shows which Directive(s) must be referred to, according to the date of the placing on the market:

Radio equipment before 13 June 2016: R&TTE

Radio equipment placed on the market between 13 June 2016 and 12 June 2017: R&TTE or RED

Radio equipment placed on the market after 12 June 2017: RED

There are significant scope changes in the RED, compared to the previous R&TTE Directive, as listed below:

- The RED applies to equipment which <u>intentionally</u> transmits or receives radio waves for communication or radio-determination, regardless of its primary function
- Pure wired telecommunications terminal equipment now falls out of the scope of the RED
- ¹Equipment operating below 9 kHz (previously excluded by R&TTE) is now included in the RED scope (the upper limit remains at 3000 GHz)
- The RED applies to broadcast TV and radio receivers (previously excluded from R&TTE)

1.2- What is the relationship between the RED and the Low Voltage Directive 2014/35/EU (LVD) and the Electromagnetic Compatibility Directive 2014/30/EU (EMCD)?

The changes of scope from the R&TTE to the RED directly impact the relationship between the RED and the other two Directives for electrical equipment (EMCD and LVD) in terms of their scope:

- Products (e.g. pure wired telecommunication terminal equipment) previously covered by the R&TTE fall within the scope of the LVD and EMCD
- On the other hand, products which meet the definition of radio equipment and are now subject to the RED are explicitly excluded from the LVD and EMCD (RED, article 1.4 and EMCD, article 2.2.a)

¹ Frequencies below 9 kHz have not been allocated yet. <u>The CEPT report 59</u> (June 2016) specifies however that the spectrum below 9 kHz is currently used with no requirement for authorisation. If a frequency band is not regulated in any Member State (i.e. it is not part of any national frequency plan within the EU), radio equipment operating in that frequency band can be placed on the EU market in Member States that have not introduced national restrictions (article 7, RED).

• However, the RED refers to the essential requirements of the LVD and EMCD (article 3.1 (a) and (b)) in terms of health and safety, as well as electromagnetic compatibility – see question 3.1. on essential requirements.

1.3- What is 'radio equipment' under the RED?

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

1.4- What are the explicit exclusions from the RED?

The following types of equipment are excluded from the RED (Annex I of the Directive):

- Radio equipment exclusively used for activities concerning public security, defence, state security
- Radio equipment used by radio amateurs
- Marine equipment
- Airborne equipment (but drones of 150 kg or less are in the RED scope)
- Custom-built evaluation kits destined for professionals to be used exclusively at research and development facilities

Further details about these exclusions are provided in the <u>European Commission's RED Guide</u> (chapter 1.6.2).

2. Materials handling products incorporating radio equipment

Materials handling equipment may incorporate radio equipment either in a permanent and fixed manner ("combined equipment") or in a non-permanent manner.

2.1- Case differentiation and applicable legislation

To determine which Directive(s) are applicable to combined equipment, two scenarios need to be looked at:

1) <u>Incorporation of radio equipment into a materials handling product in a permanent manner</u>

The **RED** is applicable to the combination of a non-radio product and radio equipment if the following two conditions are fulfilled:

- a. The radio equipment is incorporated into the non-radio product; AND
- b. The radio equipment is permanently affixed to the non-radio product.

A non-radio product which incorporates radio equipment in a permanent way (i.e. non-plug connection) is entirely subject to the RED, in addition to **other legislation** which applies to non-radio products (e.g. Machinery Directive - MD).

2) <u>Incorporation of radio equipment into a materials handling product in a non-permanent</u> manner

As the radio equipment is not permanently incorporated into the non-radio product, , each product needs to comply with the applicable legislation: the **RED** for the radio product and **other applicable legislation** (e.g. MD) for the non-radio product. The radio equipment is not incorporated and not easily accessible:

- if it is attached non-permanently to the non-radio product/machinery, for example via the use of a plug connection (e.g. USB, RJ 45, industrial power connector), OR
- if it is easily accessible and readily removable.

In such cases the radio equipment and the machinery are two separate products.

More information about the conformity assessment obligations is provided in chapter 3.2.

2.2- Are there any RED exemptions which are relevant to materials handling equipment that incorporates radio equipment?

The two categories of exemptions described below and relevant to some types of materials handling equipment have the same effect: the RED applies only to the radio equipment, and not to the whole combined equipment. The resulting requirements are therefore the same as those applicable to combined equipment in which the radio equipment is not permanently incorporated (see chapter 3.2.2).

Vehicles

Equipment only subject to type-approval legislation benefits from **vehicle exemption** from the RED, in the case of radio equipment incorporatedinto a type-approved product. If the equipment is subject to the type approval and the legislation for the CE marking, the part of the product which is covered by the legislation for the CE marking has to be considered according to the principles in chapter 2.1 of this paper. The exemption of vehicles is described in the RED Guide (see Commission RED Guide chapter 1.6.3.11). For machinery mounted on a vehicle, the RED however applies, as explained in chapter 2.1.

→ Examples of FEM equipment that may include a type-approved vehicle

Examples within FEM product ranges: some types of mobile cranes (truck-mounted cranes and all-terrain cranes), MEWPs (truck-mounted and trailers), trucks with elevating operator

position; rough terrain forklifts if homologated for public roads: a) telehandlers; b) masted rough terrain forklifts

Fixed installations

Fixed installations are not covered by 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 under the EMCD² (unique in their build-up): the radio equipment manufacturer is responsible for the conformity of the radio equipment which should include the intended operating conditions for which the radio equipment is designed or under which it may be used as part of the fixed installation. The technical documentation must specify the fixed installation concerned and the precautions to be taken.
- Installations built up of mass market equipment ("fixed" means in this case "permanent" in their: This is a possible 'reasonably foreseeable condition of use" which should be documented in the conformity assessment together with the intended operating conditions. In this case, the radio equipment should be accompanied by the instructions describing how to install the equipment forming the installation, to ensure that it operates as foreseen.

→ Examples within FEM product ranges: intralogistic systems

Fixed installations as defined and described in the EMCD, i.e. which are unique in their build-up. Radio equipment may be integrated into a fixed installation, as described in the EMCD. Fixed installations which are unique in their build-up are fully covered by the EMCD.

When radio equipment is incorporated into a fixed installation, it is the radio manufacturer who undertakes the conformity assessment

Radio equipment can also be combined with other equipment to form an installation which is fixed at its location.

3. Requirements

3.1- What are the essential requirements of the RED?

If materials handling equipment manufacturers also manufacture their own radio equipment, they are responsible for the latter's compliance with the RED essential requirements and will therefore need to ensure:

The safety requirements laid down in the Low Voltage Directive 2014/35/EU (Article 3.1.a)

² Definition of fixed installation under the EMCD 2014/30/EC – Article 3(3): "fixed installation means 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 adequate level of electromagnetic compatibility as set out in the Electromagnetic Compatibility Directive 2014/30/EU (Article 3.1.b)
- An efficient use of the radio spectrum to avoid harmful interference (Article 3.2)

The whole product – the materials handling equipment including the permanently incorporated radio equipment, which is manufactured by the manufacturer of the materials handling equipment is subject to the RED. For other cases of the attachment of a radio product to the non- radio product see chapter 2.1 of this paper.

3.2- What are the RED requirements for materials handling manufacturers?

In the vast majority of cases where materials handling manufacturers do not manufacture radio equipment but only incorporate it into their machine, the finished materials handling product is considered a "combined equipment" from a RED point of view and is therefore covered by the RED. Two situations must then be differentiated:

- Permanent incorporation of the radio equipment into the non-radio product
- Non-permanent incorporation of the radio equipment into the non-radio product or exemption

3.2.1- Incorporation of a radio equipment into a materials handling product in a permanent manner

In this case, the manufacturer who places the final product on the market <u>needs to assess</u> that:

- a. The incorporated radio product remains compliant with the RED, when the final product is in operation.
- b. The materials handling non-radio product continues to be subject to the applicable EU legislation (e.g. the MD) when it is functioning with the radio equipment.

Main principles:

- Radio equipment combined with a materials handling product in a permanent and fixed way
 is considered a single and new product, which means that it will be placed on the market with
 one DoC referring to all the applicable legislation, including the RED 2014/53/EU a single CE
 marking, and one manufacturer's contact details.
- There is however no need to repeat the conformity assessment already carried out by the radio equipment manufacturer. It is the radio equipment manufacturer who undertakes the primary conformity assessment for the radio equipment which should include the operating conditions for which the radio equipment is designed or may be used
- The combined equipment manufacturer only needs to guarantee that the parameters of the radio and the non-radio equipment are not changed when the final product is functioning, and document the risk analysis in the technical file.

The final product manufacturer may base his assessment on the conformity assessment procedure done by the radio equipment manufacturer. The assessment of the final product should take into consideration the following aspects:

• The declaration of conformity for the radio equipment

- The installations specifications provided by the radio equipment manufacturer
- The verification that the conformity of the incorporated radio equipment with the RED is not negatively influenced following its incorporation into the non-radio product

The technical file of the final product should indicate how the combined operation of the radio and non-radio equipment fulfils the essential safety requirements of all the applicable legislation (e.g. the MD for the non-radio product, the RED for the radio equipment).

For further details, please refer to the Orgalime Guide (chapter 2.2.1).

3.2.2- Incorporation of a radio equipment into a materials handling product in a non-permanent manner

Whether a radio product is intended to be installed in a non-radio product but provided separately in the package, or easily detachable from the non-radio product (e.g. plug and play devices), or bought by the end-user to be installed in the non-radio product, each product (radio and non-radio) is considered <u>separate</u> and must therefore comply with its own legislation, as follows:

- the radio product complies with the RED and other Directives/Regulations (if applicable)
- the non-radio product complies with its applicable legislation (e.g. the MD), not the RED.

In this case, the materials handling non-radio product manufacturer is responsible only for his equipment and therefore must ensure that it complies with its applicable legislation (not the RED), even when functioning in combination with a radio product. It is the radio equipment manufacturer's responsibility to ensure the radio product's compliance with the RED.

Therefore, the non-radio product manufacturer should provide the following information:

- specify in the instructions which radio devices are suitable to be installed in materials handling equipment (an end-user who buys the radio equipment to fit into a non-radio product should follow the instructions provided by the radio manufacturer)
- illustrate in the technical file that the non-radio product and the radio equipment can optimally function together.

These requirements are the same in the case of combined equipment that benefits from an exemption (see chapter 2.2).

- 4. Acquisition of the radio equipment (single product or combined equipment)
- 4.1- What requirements does a materials handling manufacturer have to meet when they buy a radio product already placed on the EU market?

A materials handling manufacturer who acquires radio equipment which is already placed on the EU market and installs it in his non-radio product must meet the requirements explained in chapter 3 of

this Guide, depending on whether the combination of the two products is permanent or non-permanent and bearing in mind possible exemptions.

4.2- What requirements does a materials handling manufacturer have to fulfil when they import a radio equipment into the EU to install it in his non-radio product and place the finished product on the EU market?

A materials handling manufacturer who imports the radio equipment must fulfil the responsibilities of importers, according to Article 12 of the RED. These are detailed in the European Commission's RED Guidelines (chapter 2.4).

If he assembles the radio equipment with his non-radio product in Europe and places the finished product on the market, he becomes the manufacturer of the combined equipment and is therefore responsible for declaring the compliance of the combination with both the RED and other applicable legislation, as explained in chapter 3 of this Guide.

4.3- What requirements does a materials handling manufacturer have to meet when they import the whole combined equipment?

A materials handling manufacturer importing the whole combined equipment into the EU must comply with the requirements applicable to importers, according to Article 12 of the RED. The importer has the responsibility to place compliant products on the market³. Therefore, he needs to guarantee that the manufacturer has correctly fulfilled his obligations towards demonstrating compliance of the combined equipment. If there are any non-compliance issues for the product already placed on the market, the importer is held accountable for taking immediate actions (corrective measures necessary to bring the product into conformity, withdrawing or recalling it, if appropriate).

For further information, please refer to the European Commission's RED Guidelines (chapter 2.4).

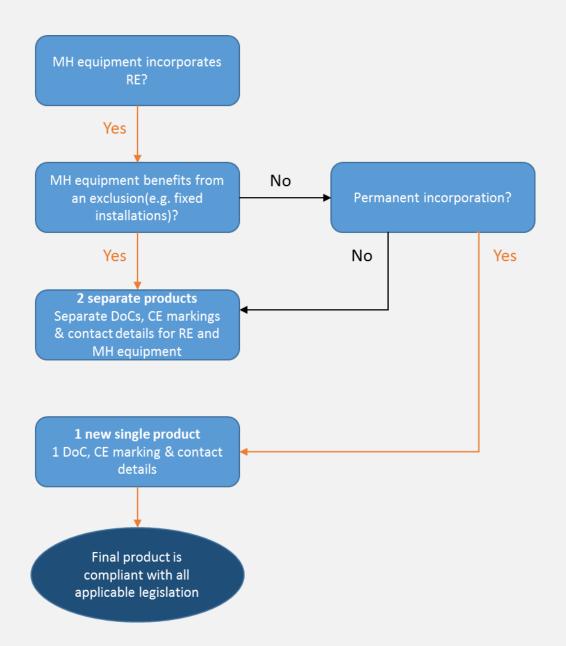
For additional special cases (retrofitting, partly completed machinery etc.) please refer to the Orgalime Guide (chapter 3).

³ See chapter 3.3 of the Blue Guide on the implementation of EU product rules (26 July 2016)

Bibliography

- <u>Directive 2014/53/EU</u> 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, 22 May 2014.
- Orgalime Guide on the Radio Equipment Directive 2014/53/EU
- European Commission Guidelines on the Radio Equipment Directive 2014/53/EU
- <u>Blue Guide</u> on the implementation of EU Product Rules, 26 July 2016.

ANNEX I – Decision chart on RED requirements





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