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Orgalime guidance on the manufacturer's obligations for the combination of a machine with radio equipment

1. INTRODUCTION

This paper is addressed to manufacturers of machines, which use radio equipment on the machine. In this paper it is assumed that only radio equipment bearing CE-marking according to the Radio Equipment Directive 2014/53/EU (RED) is incorporated into the final product, for example a machine.

The Guide to the Radio Equipment Directive also addresses, in the explanations provided by the RED Administrative Cooperation Group (AdCo) and the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM) the combination of radio equipment with non-radio products, in the following way:

Non-radio products (i.e. electrical or electronic products whose function is not to intentionally emit or receive radio waves)¹, may function with radio equipment.

This information paper is intended to provide guidance on the application of the Radio Equipment Directive with respect to machinery containing radio equipment. The following cases commonly occur in practice:

- Radio equipment is operated on new machinery without being attached to the machinery in a fixed way or being incorporated into the machinery
- Radio equipment is incorporated in new machinery in a fixed and permanent way
- Used machinery is retrospectively fitted with radio equipment
- Radio equipment is incorporated in partly completed machinery in a fixed and permanent way

2. CASE DIFFERENTIATION

A combination of separate products or combination of products, which is deemed to be a whole or single product within the scope of the Radio Equipment Directive are differentiated below:

2.1 Combinations consisting of two separate products

Products containing radio equipment which is incorporated in the product in a fixed way are deemed to be radio equipment within the meaning of the Radio Equipment Directive. Products

¹ For example Machines, Toys, Medical Devices, Kitchen Appliances, Luminaires.

Orgalime, the European Engineering Industries Association, speaks for 40 trade federations representing the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.9 million people in the EU and in 2015 accounted for more than €1,900 billion of annual output. The industry accounts for over a quarter of manufacturing output and a third of the manufactured exports of the European Union.

which are only attached to radio equipment are therefore not themselves radio equipment within the meaning of the Radio Equipment Directive.

It can be assumed that radio equipment is not incorporated in a fixed way, hence meaning that the products remain two separate products, if the following points apply:

- The radio equipment can be easily accessed and readily removed, or
- it is not permanently attached to the other product.

If radio equipment is only connected to the machinery via a plug-in connection which is covered by standards (e.g. USB; Ethernet, RJ 45), it is not deemed to be a case of radio equipment incorporated in a fixed way. In this case the machinery and the radio equipment remain two separate products. The radio equipment is covered by the scope of the Radio Equipment Directive, and the machinery, which is not attached to the radio equipment in a fixed way, is covered by the scope of the Machinery Directive. The radio equipment is intentionally designed for this type of operation with the machinery.

This conclusion is based on the explanation provided by the RED AdCo and TCAM, which states the following:

In the other cases, only the radio equipment is subject to RED and is deemed to be a separate product (for the purposes of the DoC, the CE Marking and the contact details). The risk assessment of the radio equipment shall address its intended use by ensuring that, when it operates in combination with the intended non-radio product, the conformity of the combination is fulfilled.

2.2 “Combined Equipment” resulting from the assembly of the radio equipment and the machinery in a fixed way

According to the Radio Equipment Directive, products containing radio equipment which is incorporated in the product in a fixed way are deemed to be radio equipment within the meaning of the Radio Equipment Directive. This Directive refers to such products as a final product. The requirements set out in chapters 2.2.1 and 2.2.2 of this information paper are also based on this assumption.

Radio equipment can be assumed to be incorporated in a fixed way if it

- cannot be easily accessed or readily removed, and
- it is permanently attached to the other product.

This is based on the explanation provided by the RED AdCo and TCAM, which states the following:

The RED is applicable to the combination of the non-radio product and the radio equipment, if the radio equipment is:

- *incorporated into the non-radio product; and*
- *permanently affixed to the non-radio product.²*

If the radio equipment is incorporated in a fixed and permanent way in the non-radio product at the moment of its placing on the market (i.e. in such a way that it cannot be easily accessed and readily removed), as specified above, this product is deemed to be a single product (for the purposes of DoC, the CE Marking and the contact details).

² The same conclusion was stated in the Guide of the repealed Directive (R&TTED) and on this point there is no modification between the provisions of the repealed Directive and the RED.

If the aforementioned final product also falls within the scope of the Machinery Directive, both the Machinery Directive and the Radio Equipment Directive apply to the final product. In terms of safety requirements, the Radio Equipment Directive refers to the safety requirements of the Low Voltage Directive (2014/35/EU). Hence, with regard to safety requirements there are areas of overlap with the Machinery Directive, which contains more specific safety requirements than the Low Voltage Directive.

As explained in the RED-Guide, the safety requirements of the directive to be applied are those which can be considered to be more specific to the final product (*lex specialis*). Given that the health and safety requirements of the Machinery Directive (2006/42/EC) are more specific, these have priority in terms of application to the final product.

This is based on the explanation provided by the RED AdCo and TCAM, which states the following:

The above product (whole product) is also subject to other Union harmonisation legislation (e.g. machinery, medical devices, toys, etc.). The RED is therefore applicable simultaneously with Union harmonisation legislation which can cover the same hazard (for example safety or EMCD).³

In such case, the issue of overlap might be resolved by giving preference to the more specific EU legislation. This usually requires a risk analysis of the product according to its intended purpose, which then determines the applicable EU legislation. See Chapter 2.6 of the Blue Guide 2016.

2.2.1 Conformity assessment for machinery containing incorporated radio equipment

If a manufacturer incorporates radio equipment in a machinery in a fixed way as defined above, this final product becomes radio equipment within the meaning of the Radio Equipment Directive. The manufacturer is therefore responsible for the conformity of the final product and draws up the EU Declaration of Conformity on the basis of all applicable directives including the Radio Equipment Directive.

The declaration of conformity shall only be drawn up if the manufacturer has carried out and documented the conformity assessment procedure in accordance with all the applicable EU-legislation. Given that radio equipment with CE-marking was used for incorporation, the manufacturer of the final product may base his assessment on the conformity assessment carried out by the manufacturer of the radio equipment. Regard must be given to the following points in connection with this:

- EU Declaration of Conformity for the radio equipment
- The installation specifications provided by the manufacturer of the radio equipment
- Incorporation must not have a negative influence on the conformity of the incorporated radio equipment with respect to the Radio Equipment Directive

Guidance on how to check that the conformity of the incorporated radio equipment with the Radio Equipment Directive is not negatively influenced and that the objectives of the EMC Directive continue to be fulfilled is provided by [ETSI Guide EG 203 367](#).

This is based on the explanation provided in chapter 2.6 b (Conformity Assessment Procedure) (version 19 May 2017) of the RED-Guide, which states the following:

³ 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.

“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 parts of that radio equipment, while remaining responsible for the conformity of the whole product. The reused assessment of the parts may not be sufficient to demonstrate conformity of the whole radio equipment.”

If the radio equipment for incorporation was subject to a conformity assessment involving a notified body (conformity assessment procedure B+C or H), the radio equipment manufacturer will have submitted to the notified body the areas that deviate from the harmonised standard. Subsequently, the assessment by the notified body must include both the assessment of the deviation from the harmonised standard and the radio equipment manufacturer’s instructions that accompany the radio equipment for its incorporation into a non-radio product. Consequently, as long as the radio equipment is incorporated according to the instructions provided by the radio equipment manufacturer it can be assumed that no further third party involvement is necessary for the incorporation into the machinery.

2.2.2 Technical file for the documentation of the conformity assessment

The manufacturer is obliged to submit to the relevant authority on reasoned request the technical file with which the performance of the conformity assessment procedure can be verified. The manufacturer of the final product will not generally be in possession of the technical file for the radio equipment, because the manufacturer of the radio equipment cannot be required under the provisions of the law to hand these documents over to other economic operators.

In order for the manufacturer of the final product to fulfil his statutory obligations, he should take the EU Declaration of Conformity, the accompanying product documentation for the radio equipment and any other applicable technical files for the radio equipment and include them with his technical file for the final product, with which the conformity of the product with the applicable EU-legislation can be verified.

This is based on the explanation provided in chapter 2.6 b (Conformity Assessment Procedure) (version 19 May 2017) of the RED-Guide, which states the following:

“The assessment performed previously for parts of the radio equipment 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).”

3. SPECIAL CASES

3.1 Retrofitting of used machinery with radio products that is made available on the market

Firstly, it is necessary to check whether there is a case of substantial modification in terms of health and safety requirements. In case of substantial modifications, the refitted machine is deemed to be a new product and a conformity assessment procedure and an EU Declaration of Conformity in accordance with the Machinery Directive are required (see per Blue Guide 2016 chapter 2.1).⁴

Where the economic operator carries out a retrofitting of a used machine with a radio equipment in the form of incorporation in a fixed way and places it subsequently on the market, the conformity of

⁴ This interpretation reflects the worst-case scenario. A majority of Orgalime members agree with this interpretation with a reservation of France.

the retrofitted machinery must be assessed and declared in accordance with the RED. The conformity assessment in accordance with the Radio Equipment Directive is to be carried out as described in chapter 2.2.1 of this paper.

3.2 Partly completed machinery with radio equipment

Where radio equipment is incorporated in partly completed machinery in a fixed way (see chapter 2.2), the final product also falls within the scope of the Radio Equipment Directive.

The manufacturer of the final product draws up a declaration of incorporation after the procedure has been completed in accordance with Art. 13 of the Machinery Directive. In addition, the manufacturer of the final product draws up an EU Declaration of Conformity in accordance with the Radio Equipment Directive after the conformity assessment procedure in accordance with the Radio Equipment Directive has been completed. Given that radio equipment with CE-marking was used for incorporation, the manufacturer of the final product may establish his assessment on the conformity assessment procedure carried out by the manufacturer of the radio equipment, as explained in chapter 2.2.1.

This is based on the explanation provided in chapter 2.6 f (CE-marking) (version 19 May 2017) of the RED-Guide, which states the following:

“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.”

As explained in the RED Guide, the safety requirements of the directive to be applied in this case are those which can be considered to be more specific to the whole product (*lex specialis*). Given that the health and safety requirements of the Machinery Directive (2006/42/EC) are more specific, these have priority in terms of application to the final product. This also applies to the provisions of Article 13 of the Machinery Directive, according to which the manufacturer of the partly completed machinery decides the essential health and safety requirements of the Machinery Directive that apply to the partly completed machinery have been complied with.

This is based on the explanation provided by the RED AdCo and TCAM, which states the following:

The above product (whole product) is also subject to other Union harmonisation legislation (e.g. machinery, medical devices, toys, etc.). The RED is therefore applicable simultaneously with Union harmonisation legislation which can cover the same hazard (for example safety or EMCD).⁵

In such case, the issue of overlap might be resolved by giving preference to the more specific EU legislation. This usually requires a risk analysis of the product according to its intended purpose, which then determines the applicable EU legislation. See Chapter 2.6 of the Blue Guide.

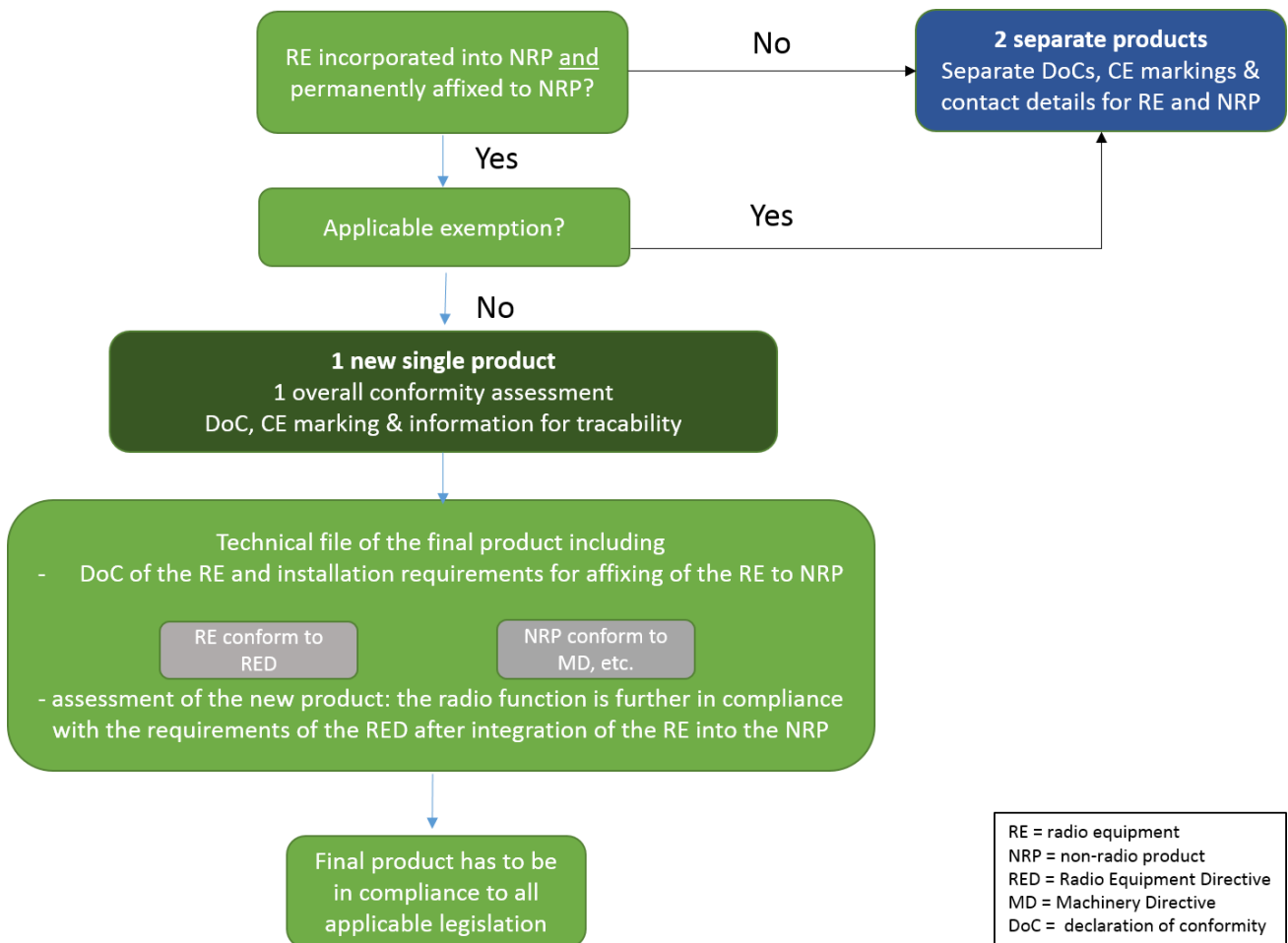
References:

- European Commission guide to the Radio Equipment Directive 2014/53/EU (English only): <http://ec.europa.eu/docsroom/documents/23321>
- ‘Blue Guide’ on the implementation of EU products rules 2016 (Published on: 28/02/2014, Last update: 28/02/2017), available in all languages: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7326

⁵ 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.

ANNEX

Picture demonstrating the most important steps a manufacturer needs to take to assess the conformity of a machine containing radio equipment.



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