

Applicability of the Radio Equipment Directive (RED) 2014/53/EU to CAPIEL Products

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The target audience for this guide is manufacturers of CAPIEL products, and it is assumed that the reader is already familiar with both the Radio Equipment Directive (RED) and the European Commission's "Blue Guide".

This guide is not intended to conflict with either the RED or the European Commission's Blue Guide, and the reader should be aware that the relevant national transposition of the directive is legally binding. If in doubt, the supplier of the equipment must seek his own advice on any issues and must not rely on this document alone.

Several aspects of the directive are still under discussion by the European Commission, Member States and industry, and it is therefore possible that some parts of this document may change as further information becomes available.

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1 Definitions

The following definitions are given in the RED:

- "(1) 'radio equipment' means 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;
- (2) 'radio communication' means communication by means of radio waves;
- (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;
- (4) 'radio waves' means electromagnetic waves of frequencies lower than 3 000 GHz, propagated in space without artificial guide;"

Examples of radio functionality include: RFID, GPS, Bluetooth, wireless, ...

2 Possible configurations for CAPIEL products

NOTE Further details together with an explanation of the rules that apply to radio equipment which is combined with non-electrical/electronic products is given in the European Commission's "Supplementary Guidance on the LVD/EMCD/RED" available at: https://ec.europa.eu/docsroom/documents/29121

2.1 No radio function

Nothing has changed.

The LVD/EMC/ATEX/Machinery/other Directives continue to apply.

CAPIEL supports the arguments set out in the Orgalime position paper "Inductive and capacitive proximity switches and sensors should remain outside the scope of the Radio Equipment Directive": https://www.orgalim.eu/position-papers/orgalime-position-paper-inductive-and-capacitive-proximity-switches-and-sensors

2.2 Host electrical/electronic product with optional radio module

This scenario relates to a radio module for use together with a specific industrial product (not an assembly of different products contained in a control panel, nor a machine):

- the non-radio product (i.e. a product without any radio function) shall comply with the applicable directives (e.g. LVD/EMC/ATEX/Machinery) including when the radio product is operating;
- the radio product shall comply with the RED (and any other applicable directives);

and the manufacturer of the non-radio product shall specify which radio modules are suitable for use with the non-radio product – this could be achieved by referencing specific radio modules or by specifying the requirements for the radio module (e.g. EMC environment, harmonised standards).

Where the radio module is marketed by the product manufacturer for use with their product then the manufacturer shall assess that the combination is compliant, using the principles set out in point 2.3.

The two products (including the antenna where necessary) will be assembled by a competent user (e.g. qualified electrician) according to the instructions provided by the manufacturer(s).

2.3 Host electrical/electronic product incorporating a radio module in a fixed/permanent manner

2.3.1 LVD and/or EMC product

Electrical/electronic products that traditionally did not have a radio function and were subject to the LVD and/or EMCD become a radio product in their entirety if they are equipped with radio functionality. This means that the combined equipment as a whole has to fulfil all provisions of the RED. If a manufacturer incorporates radio equipment in fixed /permanent way into a non-radio product, the manufacturer of the final product needs to assess whether the incorporated radio equipment is (continues to be) compliant with the RED, when the finished product is in operation. This assessment does not necessarily imply the need to repeat the entire conformity assessment already carried out by the manufacturer of the radio equipment. The risk assessment analysis, reports and conclusions as well as the rationale of the applied technical solutions, when required, need to be illustrated in the technical file. For the purposes of the DoC it is one single product that he places on the market.

Therefore, neither the LVD nor the EMCD apply to the combined product. Instead, the RED applies and addresses all safety and EMC aspects, as well as the radio aspects.

Product without radio function	Product with a radio function incorporated in a fixed/permanent manner	
Safety = LVD EMC = EMCD	Cofety = DED	
Safety = LVD EMC = None	Safety = RED EMC = RED Radio = RED	
Safety = None EMC = EMCD	Therefore, the DoC will reference the RED, but not the LVD nor the EMCD	
Safety = None EMC = None	but not the EVD not the EMCD	

2.3.2 ATEX and/or MD product

Products, falling under two or more separate vertical directives, namely the Machinery Directive (2006/42/EC) or the ATEX Directive (2014/34/EU) must fulfil all requirements laid down in both directives.

Therefore, the RED will apply in addition to the ATEX and/or Machinery Directive (MD).

Examples:

Safety component without radio function	Safety component with a radio function incorporated in a fixed/permanent manner	
Safety = MD EMC = EMCD	Safety = MD + RED EMC = RED Radio = RED	
Safety = MD EMC = None	The DoC will therefore reference both the MD and the RED.	

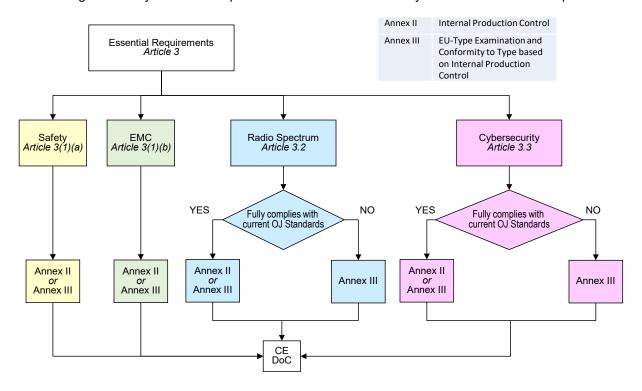
Ex product without radio function	Ex product with a radio function incorporated in a fixed/permanent manner	
Safety = ATEX EMC = EMCD	Safety = ATEX + RED EMC = RED Radio = RFD	
Safety = ATEX EMC = None	The DoC will therefore reference both ATEX and the RED.	

3 Essential Requirements, Conformity Assessment, and Harmonised Standards

NOTE: Harmonised standards that confer a presumption of conformity with the RED are available at: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/rtte_en

3.1 Introduction

The following conformity assessment procedures are those most likely to be used for CAPIEL products:



3.2 Safety

Article 3.1(a) of the RED states:

"Radio equipment shall be constructed so as to ensure: (a) 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;"

Only harmonised standards that are listed in the Official Journal under the RED confer a presumption of conformity with the corresponding essential requirements of the RED.

However, CAPIEL considers that the standards harmonised under the LVD will cover the relevant parts of this essential requirement as specified in Annex ZZ.

In addition to requirements that would apply to a non-radio CAPIEL product, the manufacturer must also address additional requirements arising from the added radio part e.g. electromagnetic fields (EMF), safety when transmitting/receiving, no upper or lower voltage limits, reasonably foreseeable conditions of use.

3.3 EMC

Article 3.1(b) of the RED states:

"Radio equipment shall be constructed so as to ensure: (b) an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU."

Only harmonised standards that are listed in the Official Journal under the RED confer a presumption of conformity with the corresponding essential requirements of the RED.

EMC standards that are listed under the EMCD do not usually take into account the influence of radio on the EMC behaviour and vice versa. For this reason, ETSI EN 303 446-2 was developed specifically for products that do not traditionally include radio (and would therefore be subject to the EMCD and LVD) but which become radio products due to the addition of radio functionality.

This EN standard takes into account the content of the existing harmonised standards for traditional non-radio equipment listed under the EMCD (e.g. EN 60947 series) and additionally specifies the conditions

under which radio-enabled versions of these products need to be assessed. It is not intended to be listed in the OJ under the RED, but contains very useful information for manufacturers.

NOTE ETSI EN 303 446-2 "ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 2: Requirements for equipment intended to be used in industrial locations" is available at: https://www.etsi.org/deliver/etsi_en/303400_303499/30344602/01.02.01_60/en_30344602v010201p.pdf

ETSI has also published a Guide (EG 203 367) which provides guidance on how to assess the compliance of a complete product based on the compliance of the non-radio product with harmonised standards listed under the EMCD, compliance of the radio product with harmonised standards listed under the RED, and an additional assessment of the combination of the two products.

NOTE ETSI EG 203 367 "Guide to the application of harmonised standards covering articles 3.1b and 3.2 of the Directive 2014/53/EU (RED) to multi-radio and combined radio and non-radio equipment" is available at: http://www.etsi.org/deliver/etsi eg/203300 203399/203367/01.01.01 60/eg 203367v010101p.pdf

3.4 Radio spectrum

Article 3.2 of the RED states:

"Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference."

Only harmonised standards that are listed in the Official Journal under the RED confer a presumption of conformity with the corresponding essential requirements of the RED.

In the absence of an appropriate harmonised standard, it is necessary to follow the conformity assessment procedure set out in Annex III "EU-Type Examination and Conformity to Type based on Internal Production Control" of the RED and thus obtain an EU Type Examination Certificate from a Notified Body.

3.5 Cybersecurity

Regulation (EU) 2022/30 sets out mandatory cybersecurity requirements for certain products that fall under the Radio Equipment Directive. The requirements apply from 01 August 2024.

NOTE The requirements of Article 3(3)(d) are the most likely to impact CAPIEL products.

RED Article	Requirement	Applicability
3(3)(d)	does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;	Any radio equipment that can communicate itself over the internet, whether it communicates directly or via any other equipment ('internet-connected radio equipment').
3(3)(e)	incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;	Any of the following radio equipment, if that radio equipment is capable of processing, within the meaning of Article 4(2) of Regulation (EU) 2016/679 [General Data Protection Regulation], personal data, as defined in Article 4(1) of Regulation (EU) 2016/679, or traffic data and location data, as defined in Article 2, points (b) and (c), of Directive 2002/58/EC [e-Privacy Directive]: (a) internet-connected radio equipment, other than the equipment referred to in points (b), (c) or (d); (b) radio equipment designed or intended exclusively for childcare; (c) radio equipment covered by Directive 2009/48/EC [Toy Safety Directive]; (d) radio equipment designed or intended, whether exclusively or not exclusively, to be worn on, strapped to, or hung from any of the following: (i) any part of the human body, including the head, neck, trunk, arms, hands, legs and feet; (ii) any clothing, including headwear, hand wear and footwear, which is worn by human beings.
3(3)(f)	supports certain features ensuring protection from fraud;	Any internet- connected radio equipment, if that equipment enables the holder or user to transfer money, monetary value or virtual currency as defined in Article 2, point (d), of Directive (EU) 2019/713.