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WHITE PAPER

RADIO EQUIPMENT DIRECTIVE 2014/53/EU: AN OVERVIEW

CONTENTS

INTRODUCTION

Historically, almost all of the equipment that used the radio frequency spectrum to function as traditional communications and information technology: radio and television equipment, computers and telephony.

Now, as we enter the Internet of Things (IoT) age where you can turn on your oven using a mobile phone while still at your office, you are as likely to find home appliances, medical devices, your car's satellite navigation system and even your running shoes transmitting and receiving data. In short, they are behaving like radio equipment.

In addition to this extraordinarily increased use of the radio spectrum causing rapid updates to wireless standards, the EU has revised eight product directives as part of the so called Alignment package. The Alignment package aims to update these eight directives against the New Legislative Framework (NLF), two regulations and one decision, upgrading the CE marking requirements and procedures. Even though the former Radio and telecommunications terminal equipment (RTTE) directive was not formally among the eight Alignment package directives, its revision has mainly been driven by the need to align it with the NLF.

The new Radio Equipment Directive (RED) 2014/53/EU was published on April 16, 2014 and EU member states must adopt and publish the laws, regulations and administrative provisions needed to comply with the new Directive by June 12, 2016.

On June 13, 2016, 1999/5/EC will be repealed and the new requirements will come into law. However, the RED stipulates a transition period of one year from the date of adoption, which gives the following dates for when manufacturers should use either directive in their Declaration of Conformity:

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

This paper is intended to provide a brief overview of the revised requirements of the Radio Equipment Directive 2014/53/EU..

RADIO EQUIPMENT DIRECTIVE (RED) 2014/53/EU

Examining the revised legislation, much of the content has been updated to reflect the current and possible state of the art in radio-using equipment. For example, the terms "apparatus" and "telecommunications terminal equipment" (TTE) have been removed to reflect a broader meaning of what is considered "radio equipment"

The legislation has also been brought into line with other recast Directives, such as the Low Voltage Directive and EMC Directive in its use of terminology.

Old 1999/5/EC - Definitions (Article 2)	New 2014/53/EU - Definitions (Article 2)
'apparatus means any equipment that is either radio equipment or telecommunications terminal equipment or both'	No equivalent
'telecommunications terminal equipment' means a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (i.e. telecommunications networks used wholly or partly for the provision of publicly available telecommunications services);'	No equivalent
'radio equipment' means a product or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilizing the spectrum allocated to terrestrial space communications'	'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 an antenna, so as to intentionally emit/or receive radio waves for the purpose of radio communication and /or radiodetermination'
No equivalent	'radiodetermination' means the determination of the position, velocity and/or other characteristics of an object, or obtaining of information relating to those parameters, by means of the propagation properties of radio waves;'
No equivalent	'manufacturer' means any natural or legal person who manufactures radio equipment or has radio equipment designed or manufactured, and markets that equipment under his name or trade mark;'
No equivalent	'authorized representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specific tasks;'
No equivalent	'importer' means any natural or legal person established within the Union who places radio equipment from a third country on the market;'
No equivalent	'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes radio equipment available on the market;'

As you can see from the comparative table, it now uses familiar terms such as manufacturer, importer and distributor to clarify the particular conformity responsibilities of these "economic operators" in the supply chain.

The role of Notified Bodies is explained in more detail, and a robust qualification and accreditation process for these organizations is highlighted.

Provisions are also included allowing the European Commission to adopt "delegated acts" at a later date – specifying which classes or categories of radio products must meet or can be excluded from specific essential requirements (see Articles 3 and 43) – so manufacturers will need to keep a vigilant eye on the Official Journal of the European Union for additional updates.

SCOPE

The scope of the Directive applies to all radio equipment being placed on the market in the EU with the exception of:

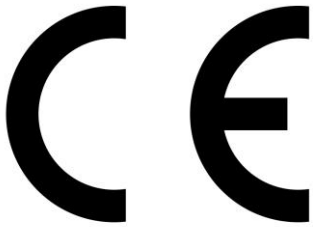
- Radio equipment used exclusively for activities concerning public security, defense, state security or for the economic well-being of the state
- Amateur radio kits
- Marine equipment
- Airborne products, parts and appliances (as regulated under Article 3 of regulation EC 216/2008)
- Custom built kits used solely for R & D

CHANGES SUMMARY

- All receivers (including broadcast radio & TV equipment) now fall under the scope of the RED instead of under the EMC directive.
- The radio frequency spectrum governed within the scope of the Directive now has no lower limit. It was previously from 9KHz up to 3000GHz.
- There are no voltage limits for radio equipment regarding LVD safety requirements.
- Many of the descriptive terms from the previous Directive have been changed or modified. “Radio equipment” now means an electrical product used for Radio communication or Radiodetermination.
- Manufacturers are solely responsible for conformity assessment, and cannot use the conformity procedures laid out in the LVD or EMC Directives to demonstrate compliance, they must use those outlined in the RED.
- The directive opens up for the possibility to require that certain equipment (f ex mobile phones) must be designed to accommodate a common charging interface.
- Radio equipment using special software to enable function must demonstrate compliance of the equipment together with the software. New versions of software must also prove compliant with the essential requirements.
- Radio equipment capable of taking different configurations must fulfill the essential requirements for all configurations.
- Class 2 labelling ‘Alert mark’ and equipment notifications are removed.
- CE Marking needs to be on both the product (where possible) and the packaging. On the product you can now use a CE Mark that is smaller than 5mm providing it is still visible and legible.
- Radio equipment must bear the type, batch, model, serial number or other element allowing identification, as well as the name and address of the manufacturer on either the product itself, on the packaging or in the manual.
- Where technical documents do not comply, the surveillance authority may ask the manufacturer or importer to have the product tested by a body accepted by the authority at the expense of the manufacturer or importer.
- Compliance documents must be presented to a surveillance authority in a language easily understood by the authority.
- The manufacturer must inform the NB of all modifications to the product that may affect compliance.
- If re-badging takes place (OEM) the company doing the OEM undertakes all responsibilities of the manufacturer.
- There are clear guidelines on market surveillance and how these authorities should operate.

THE ROUTES TO COMPLIANCE

Three options are now available for radio equipment manufacturers to prove compliance with the essential requirements. Two of those options involve the participation of a Notified Body. Let's look at the options below:



1. Via Annex II - Internal production control (Module A)

The manufacturer undertakes the compilation of the Technical Documentation (testing can be internal or external), the Manufacturing process (involving internal quality control) and the CE Marking and issuing the Declaration of Conformity. No Notified Body involvement is needed. This option can only be used if harmonized standards have been applied in full for articles 3.2 and 3.3.

2. Via Annex III - EU type examination (Modules B & C).

The manufacturer is responsible for the Technical Documentation (can be internal or external), the Internal Production control, the product CE Marking and issuing the Declaration of Conformity. The Notified Body will be involved in examining the Technical Documentation verifying the design, testing and the issuing of an **EU type Examination Certificate**.

3. Via Annex IV - FQA agreement with a Notified Body (Module H).

The manufacturer comes into agreement with a Notified Body for a **Full Quality Assurance** program. The Notified Body takes part in the auditing of the Manufacturing Process, the Quality System, the Product Design and Testing, as well as taking on Surveillance duties of the Quality system. The Notified Body also oversees the CE Marking and issuing of the Declaration of Conformity. The Notified Body's numerals appear on the product labelling, only under a **FQA** agreement with the manufacturer.

Low compliance register for radio equipment

The legislation recognizes that market surveillance of radio equipment will be significantly assisted if categories of radio products that have not achieved a high level of compliance are already registered centrally – giving surveillance authorities better visibility of what low compliance products are on the market.

The Commission will be identifying the categories of product that require registration and what documentation must be created in relation to them, as well as confirming whether they should undergo an evaluation of the risks they present in not implementing the essential requirements.

It is anticipated that the central registry will be made available by the Commission from June 12th 2018 onward.

RESPONSIBILITIES OF ECONOMIC OPERATORS

The RED gives specific compliance responsibilities to each "economic operator" in the supply chain:

Manufacturers

First and foremost, the legislation deems the compliance of radio equipment to be the sole responsibility of the manufacturer.

To be compliant the manufacturer must ensure the construction is appropriate so that 'it can operate in at least one Member State without infringing applicable requirements' (Article 10, paragraph 2).

He must also create all the appropriate documentation required for CE Marking and required by the RED and make it available for 10 years after the product has been placed on the market. This documentation must include details of the frequency band in which the equipment operates and the maximum radio frequency power transmitted frequency band(s) in which the equipment operates.

He must affix CE Marking to the product and depending on the route to conformity used, the Notified Body Number of the assessing Notified Body.

(Note: Previously in 1999/5/EC, under Article 12, paragraph 1, this was required when using the Internal Production Control plus specific apparatus tests, the technical construction file or full quality assurance routes. In the RED the Notified Body number should only be included when using the Annex IV route – Conformity based on full quality assurance – see Article 20, paragraph 3)

The manufacturer must also ensure products remain in conformity with the Directive during the period of its manufacture, and keep a record of complaints - investigating with further testing where appropriate.

Products should now also be traceable and carry a batch /serial number as well as the name and contact address of the manufacturer. If the size of the product makes this unworkable, it can be on the product's packaging or on the accompanying documentation.

As you would expect, there is also a requirement to provide instructions for use and the Declaration of Conformity in appropriate Union languages. What is particularly interesting is that there is a provision to include a simplified Declaration of Conformity instead of the "full" version.

The simplified version is outlined in ANNEX VII:

"Hereby, [name of Manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with the Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address [insert actual email address of DoC]."

In this approach, the Declaration of Conformity must be available in full at an exact web address, so users can find it easily.

In member states where particular restrictions are in place for the use of that type of equipment, the manufacturer must also provide information on these restrictions in the instructions for use.

Previously under Article 6 of 1999/5/EC, manufacturers had to notify relevant national authorities if their equipment used frequency bands not harmonized throughout the community. This requirement has been removed in 2014/53/EU.

Notes: Going forward the European Commission could potentially allow the inbuilt screens of radio equipment to show the Declaration of Conformity on starting up or for labels over the screens to carry it as an alternative to having it in the accompanying paperwork. These are options that are under consideration (see paragraph 47 of the introduction).

THE DISTRIBUTION CHAIN

Authorized Representatives

Authorized representatives can take on many of the manufacturers' compliance tasks on their behalf, but at the very least they should hold the CE Conformity Documentation for 10 years, provide the authorities with this documentation on request and cooperate with the authorities on 'eliminating risks' that the products may pose.

Importers

Importers must only place compliant products on the market and must check that the compliance work for the product has been completed.

They must provide their contact details on the products alongside the Manufacturers (to ensure traceability), or in the accompanying documentation if the product is too small.

They must ensure that instructions and information issued with the product is in a language acceptable to the member state, and they must not jeopardize the product's compliance in their storage or transportation of the product.

They also have an obligation to undertake investigative testing and corrective action where a product isn't in compliance – or if it poses a risk to report it to the national authorities in all the countries in which it is available.

They must hold documentation for 10 years and co-operate with national authorities upon request regarding risk elimination.

Distributors

Distributors must apply 'due care' concerning the Directive – basically they should verify that the product bears CE Marking, and is accompanied by the appropriate documentation in a language easily understood by the end users.

If they believe a product is not compliant, they shall not put it on the market, or if it is already on the market take corrective action, or withdraw it or recall it. If a product poses a risk, they must notify the appropriate national authority and provide the authorities with all associated documentation upon request.

Like importers they too must not jeopardize product compliance during transportation or storage.

IMPORTERS /DISTRIBUTORS REDUCE YOUR RISKS!

Many organizations forget that the judders and jolts of transportation can fracture product casings, break internal solders and cause secured components to dislodge. Similarly, the thermal shock of hot days and cold nights in storage can impact the integrity of a product. Environmental testing can identify if an importer is jeopardizing product compliance with the way they are handling and storing products.

TECHNICAL DOCUMENTATION REQUIREMENTS (SEE ANNEX V)

The technical documentation shall cover, as far as relevant, the design, manufacture and operation of the apparatus and include at least the following:

- a general description (including photographs or illustrations)
- details of firmware or software affecting the compliance of the device
- user information and installation instructions
- conceptual design and manufacturing drawings and schema
- descriptions and explanation to understand the drawings
- a list of the harmonized standards applied in full or in part, and, where those harmonized standards have not been applied, descriptions of the solutions adopted to meet the essential requirements. Where applied, parts of partly applied harmonized standards should be specified;
- a copy of the EU declaration of conformity
- EU Type examination certificate (where conformity assessment to ANNEX III has been applied).
- results of design calculations made, examinations carried out, etc.;
- test reports and results
- an explanation of the compliance with the requirements of Article 10 (2) and of the inclusion or not of information on the packaging in accordance with Article 10 (10) Be equipped with a dedicated fluorescent lamp socket connected to a high-frequency electronic ballast contained within the portable luminaire;
- Be equipped with one or more GU-24 line voltage-sockets and not rated for use with incandescent lamps of any type, including line voltage or low voltage;
- Be an LED luminaire or a portable luminaire with an LED light engine with integral heat sink, and comply with the minimum requirements for portable LED luminaires and portable luminaires with LED light engines with integral heat sink; or
- Be equipped with an E12, E17, or E26 screw-based socket and be prepackaged and sold together with one screw-based compact fluorescent lamp or screw-based LED lamps for each screw-based socket on the portable luminaire. Additionally, the compact fluorescent or LED lamps that are prepackaged with the portable luminaire must be fully compatible with the luminaire controls, i.e. portable luminaires having a dimmer control must be prepackaged with dimmable compact fluor escent or LED lamps and portable luminaires.
- Be equipped with one or more single-ended, non-screw based halogen lamp sockets (line or low voltage), a dimmer control or high low control, and be rated for a maximum of 100 watts.

DECLARATION OF CONFORMITY (SEE ANNEX VI)

The Declaration of Conformity shall have the structure set out in Annex VI. This document shall be continuously updated as required. It must also be translated into the language or languages required by the member state in which the equipment is made available.

The new contents are as follows:

- Identification of object of the declaration, (the radio equipment type, batch and serial number) – and a color photograph is permissible for clarity.
- Name and address of the manufacturer or his authorized representative.
- The statement “This declaration is issued under the sole responsibility of the manufacturer.”It should state: “The object of the declaration described above is in conformity with the relevant Union harmonization Legislation: Directive 2014/53/EU (include other Directives as applicable)”

- Reference to the relevant harmonized standards uses or references to other technical specifications used in the assessment (including their identification number and version). Details of the Notified Body name and number and a description of the assessment they undertook (and the resulting EU type examination certificate)
- Descriptions of accessories and software which allow the equipment to function as intended.
- It should be signed and dated by the responsible person in your organization

NON-CONFORMITY AND PENALTIES

Where non-conformity becomes apparent, the authorities in most instances will give the manufacturers involved an opportunity to take corrective action, to enable the product to be brought into compliance.

Where serious infringements occur, member states have the right to impose civil and criminal penalties, which are to be "effective, proportionate and dissuasive". (Article 46).

SUMMARY

CE Marking a product when it complies with all relevant Directives is not a new process, so meeting the RED requirements should be familiar ground for most companies.

"Radio equipment" is now a much bigger term, with all manner of products now covered by it – web enabled appliances, home monitoring medical devices, navigation or tracking systems and mobile phones to name a few. Anything that uses the radio spectrum to communicate (apart from those items specifically excluded in the Directive) falls within the scope of the legislation and must comply.

The Directive uses clearer language to explain the obligations of compliance and it breaks the responsibilities down by the parties in the supply chain. It leaves less room for misinterpretation and it is more explicit about how an organization communicates with its customers, supply chain and the authorities.

The deadlines for compliance are approaching, but the one year grace/transitional period relating to the compliance of existing products should be a suitable window for manufacturers to ensure their existing products comply.

When you're working to achieve compliance, remember that it is part of a suite of Directives that form the infrastructure of the CE Marking regulations – so compliance work for the RED shouldn't be undertaken in isolation. Other directives such as the Restriction of Hazardous Substances (RoHS) Directive and the EcoDesign Directive may also apply to your product.

Successful testing to EU harmonized Standards is widely used by manufacturers to provide specific evidence of conformity with Directives. Manufacturers should use an appropriately constructed technical file as a basis of their CE Marking and Declaration of Conformity activity. Getting the associated paperwork right is key, as incorrect or incomplete documentation can lead the authorities to requesting additional testing (at your expense) and then potentially to corrective actions

INTERTEK CAN HELP

For manufacturers

As CE Marking isn't just about compliance with one Directive, Intertek provides a variety of services to help you meet the requirements of all applicable Directives. From the Low Voltage Directive, the Restriction of Hazardous Substances and Energy Related Products requirements to EMC and RED, we can assist as much or as little as you need to help you get CE Marking for the EU right.

Whether you need advice on factory production control, advice on building a technical file or even how CE Marking should be applied, we can help. From evidence to support your CE Marking and Declaration of Conformity activities or for a full product certification and Marking - or even working towards international market access via the IECEE CB scheme, Intertek has a compliance route to meet your needs and budget.

We are an EU Notified Body under a number of different Directives and an issuing and receiving member of the IECEE CB scheme, as well as being a Nationally Recognized Test Laboratory (NRTL) for North America offering our ETL Listed Mark.

For Importers & Distributors

Intertek can check technical materials on your behalf to confirm that compliance has been completed.

As you have an obligation to ensure that the compliance of the equipment is not compromised in your care, Intertek can conduct vibration and temperature testing on products that you store and transport to determine their susceptibility to jolts, shocks and vibrations and to extremes of temperature.

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 42,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

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