THE RADIO EQUIPMENT DIRECTIVE
2014/53/EU: AN OVERVIEW

Products White Paper

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OVERVIEW OF RADIO EQUIPMENT DIRECTIVE

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INTRODUCTION

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

Now, as we enter the age of the (IoT) Internet of Things - where you can potentially turn your cooker at home on with your mobile phone whilst still sat in your office, you are as likely to find home appliances, medical devices, your car satellite navigation system and even your running shoes transmitting and receiving data – in short behaving like radio equipment.

The Radio Equipment Directive (RED) 2014/53/EU came into force in June 2016 for all the EU member states. With the extraordinarily increased use of the radio spectrum in our day-to-day lives and the convergence of different technologies that make our lives easier and more entertaining, and tell us where we are, the EU Commission has had to review the legislation that previously governed ‘radio equipment and telecommunications terminal equipment’ (Directive 1999/5/EC) – as now a whole range of different technology is using the radio spectrum, and this use needs to be effectively managed. The result of this review is the Radio Equipment Directive (RED) 2014/53/EU and this paper is intended to provide a brief overview of the requirements of the Radio Equipment Directive 2014/53/EU to help with your compliance planning.
RADIO EQUIPMENT DIRECTIVE (RED) 2014/53/EU

The Directive has taken into account and reflects 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; this reflects a new broader meaning of what can be 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.
As you can see from the comparative table, it 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 Notifying Bodies is explained in more detail and a robust qualification and accreditation process for these organisations is highlighted.

Provisions are also included allowing the European Commission to adopt ‘delegated acts’ at a later date - specifying what classes or categories of radio product have to 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, defence, 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

Cable and wiring equipment is no longer excluded.

Changes Summary

- All receivers (including broadcast radio & TV equipment) now fall under the scope of the RED.
- Cables and Wiring now fall under the scope of the RED.
- 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.
- 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 Radio determination.
- 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.
- Mobile phone equipment must be designed to accommodate the use of a common charger. (What this means for new charging technology such as induction chargers is yet unclear.)
- 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 undergo conformity assessment in all possible 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 as well as the name and address of the manufacturer.
- 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.
OVERVIEW OF RADIO EQUIPMENT DIRECTIVE

THE ROUTES TO COMPLIANCE

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

Via Annex II - Internal production control (Module A)
The manufacturer undertakes to compile 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 NB involvement is needed.

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 NB will be involved in examining the Technical Documentation verifying the design, testing and the issuing of an EU type Examination Certificate.

Via Annex IV - FQA agreement with a NB (Module H)
The manufacturer comes into agreement with a NB for a Full Quality Assurance programme. The NB 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 NB oversees the CE Marking and issuing of the Declaration of Conformity. The NB numerals appear on the product labelling, only under a FQA agreement with the manufacturer.

LOW COMPLIANCE REGISTER FOR RADIO EQUIPMENT

The legislation recognises 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 of the ‘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 be operated in at least one Member State without infringing applicable requirements’ (Article 10, paragraph 2).

The manufacturer 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.

The manufacturer 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 they 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 though, 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 manufacturers have to 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 harmonised 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 considering (see paragraph 47 of the introduction).
THE DISTRIBUTION CHAIN

Authorised Representatives
Authorised representatives can take on many of the manufacturers compliance tasks on their behalf, but at 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 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 jeopardise 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 that they made it available to.
They must hold documentation for 10 years and co-operate national authorities on 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 not to be in compliance, 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 on request.
Like importers they too must not jeopardise product compliance during transportation or storage.

TECHNICAL FILE 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 harmonised standards applied in full or in part, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements. Where applied, parts of partly applied harmonised 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 requirement of Article 10 (2) and of the inclusion or not of information on the packaging in accordance with Article 10 (10)
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 contents are as follows:

- Identification of object of the declaration, (the radio equipment type, batch and serial number) — and a colour photograph is permissible for clarity.
- Name and address of the manufacturer or his authorised 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 harmonisation Legislation: Directive 2014/53/EU (include other Directives as applicable)”
- Reference to the relevant harmonised 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 organisation

NON-CONFORMITY AND PENALTIES

Where non-conformity become 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 than previously, 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 organisation communicates with their customers, supply chain and the authorities.

The Directive provided one-year grace/ transitional period as a suitable window for manufacturers to ensure their existing products comply with the new requirements. However, it is worth noting that with the current rate of development of the state of the art, some technologies were obsolete by the time the directive has come into force - so arguably new products should perhaps take the focus when planning to meet the changes.

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. You may still need to consider device characteristics such as material safety under the Restriction of Hazardous Substances (RoHS) Directive, protection methods under the ATEX Directive, Performance under the Construction Products Regulation, or even perhaps the energy efficiency of the product under the EcoDesign Directive – so check which Directives apply.

Successful testing to EU harmonised 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.
HOW 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 Construction Products Regulation, ATEX, 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 have a compliance route to meet your needs and budget.

We are an EU Notified Body under a number of different Directives and Regulations, and an issuing and receiving member of the IECEE CB scheme, as well as being a Nationally Recognised Test Laboratory (NRTL) for North America (providing Product Listing).

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. So get in touch to see how we can help you with your next radio equipment assessment project.
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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