Are you ready for RE D?

1) Are you a manufacturer* of radio equipment?

2) Do you supply equipment containing a radio device into the European Union?

If the answer to either of these questions is YES then read on: the legislative requirement for radio equipment is changing and you will need to ensure you are compliant with this new requirement.

*Note: authorised representatives, importers and distributors also have responsibilities for ensuring equipment complies with the Directive.

Abstract

From 13 June 2017, manufacturers of radio equipment will need to ensure that their products meet the requirements of the Radio Equipment Directive. The Directive clearly defines radio equipment and the obligations of all economic operators in the supply chain with regard to conformity; it also instructs member states as to their obligations with regard to market surveillance and defines the specific criteria for notified bodies.

This document focuses on the aspects within the Directive that are pertinent to manufacturers clarifying their obligations, the technical and administrative changes that they will have to address, and the options available to them during the transition period. If you are the manufacturer of radio equipment read on...

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Introduction

The Radio Equipment Directive (RE D) came into force on 13 June 2016; manufacturers of any product containing a radio device that can be used for radio communication or radio determination have been given until the 12 June 2017 to address the new requirements that the RE D contains. From 13 June 2017 manufacturers will need to demonstrate that the equipment they place on to the market conforms with the Radio Equipment Directive.

WHAT'S THE REASON FOR CHANGING?

The Radio Equipment Directive addresses a number of aims:

- To provide greater emphasis on the responsible use of radio spectrum; radio spectrum is a finite resource and needs to be regulated to enable greater use of the spectrum
- To increase the traceability of equipment
- To increase the requirements for EU Member States to perform market surveillance
- To improve the quality of notified bodies
- To align with the New Legislative Framework

SCOPE OF THE DIRECTIVE

One of the fundamental changes to the RE D is the requirement for the performance of receivers to be considered, therefore equipment capable of receiving a radio signal such as broadcast receivers now fall within the scope. Telecom Terminal Equipment, (the TTE bit of R&TTE D) has been removed from the Directive as the protection requirements of the EMC Directive adequately cover this type of equipment.

Essentially all equipment that is used for radio communication or radio determination purposes fall within the scope of the Directive. If a product contains a radio function then it now falls under the scope of the Directive – for example a washing machine with an integrated ZigBee radio module now falls exclusively into the RE D.

There are however some exceptions: military and marine equipment are excluded, as are bespoke development kits.

RESPONSIBILITIES OF ECONOMIC OPERATORS (CHAPTER II)

All economic operators in the supply chain now have clearly defined responsibilities. Manufacturers have the most responsibility for ensuring that equipment is in compliance with the Directive including:

- Performing the conformity assessment procedure
- Compiling and maintaining the technical documentation
- Ongoing compliance
- Labelling the equipment
- Identifying restrictions on use
- Complying with national authorities with regard to market surveillance

However, authorised representatives, importers and distributors are also responsible for ensuring equipment is in compliance with the Directive.

TRANSITION PERIOD

Although the RE D came into force on 13 June 2016, manufacturers were given a one year transition period during which they could either declare against the R&TTE or RE Directives.

On 13 June 2017 the R&TTE D will be repealed and manufacturers have a responsibility to ensure that all products being placed on to the market meet with the requirements of RE D. Declarations of conformity against R&TTE D (1999/5/EC) will need to be updated to RE D (2014/53/EU) as they will no longer be valid.

The route to compliance

In order to CE mark radio equipment, the manufacturer has a responsibility to ensure that their equipment meets with the requirements of the Directive. In general this is achieved through the application of harmonised standards which, when applied successfully, provide a 'presumption of conformity'. Whilst this is the most common route, the manufacturer does not necessarily need to use harmonised standards; they may choose to use alternative evidence to support their claim. If this is the case then a notified body must be used (if related to the radio aspects) to review the evidence.

IDENTIFY AND ADDRESS RISKS

A new requirement for the Directive (to align it with other CE Marking Directives) is to perform a risk analysis. This risk analysis has to take into account all phenomena of the Directive and adequately address the associated risk through mitigation and evidence. This will normally be demonstrated through the application of harmonised standards, however it may also cover additional assessments if the standards do not address all the risks (i.e. if the radio product is being used in an environment which is different to, or more severe than the standard covers).

PERFORM AN ASSESSMENT: THE ESSENTIAL REQUIREMENTS, HARMONISED STANDARDS AND PRESUMPTION OF CONFORMITY

The Directive lists the essential requirements in Article 3; these requirements can be met through the application of harmonised standards. Only standards listed in the Official Journal of the European Union (OJEU) for the RE D provide a presumption of conformity. Application of a standard that is not listed on the Official Journal will not provide presumption of conformity and will require the manufacturer to document why they believe the actions they have taken are acceptable for demonstrating compliance to the essential requirements.

COMPILE TECHNICAL DOCUMENTATION

The technical documentation must include a description of the equipment and its intended purpose, the risk assessment, manufacturing information, illustrations or photographs, a list of the harmonised standards that were applied, test standards and a copy of the EU declaration of conformity and EU-type examination certificate (where applicable). The full list is given in Annex V.

PERFORM A CONFORMITY ASSESSMENT PROCEDURE (ARTICLE 17 & ANNEX II, III, IV)

There are three conformity assessment procedures that can be followed:

ANNEX II – INTERNAL PRODUCTION CONTROL

This conformity assessment procedure is applied when the manufacturer has successfully applied the appropriate harmonised standards that are listed in the OJEU for the RE D. They will bring together the relevant technical documentation and generate a declaration of conformity.

Whilst the application of harmonised standards provides presumption of conformity and use of a notified body is not mandatory, manufacturers may request that all aspects of their technical file (Radio, EMC and Safety of Electrical Equipment) are reviewed though an EU-type examination process. Gaining an EU-type certification underwrites the manufacturers' responsibility and they gain an endorsement from an independent and competent technical authority that the equipment meets with the relevant requirements.

ANNEX III – EU-TYPE EXAMINATION AND CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

This conformity assessment procedure is applied when the manufacturer has not applied, or applied in part, the Article 3.2 harmonised standard(s). The manufacturer presents the evidence to the notified body for review; should the notified body agree that the evidence supports the requirements of the Directive then an EU-type examination certificate is issued. The manufacturer commits to ensuring that all subsequent equipment is identical to that which was certificated. The manufacturer is obliged to inform the notified body of any changes to the equipment and the notified body is obliged (legally required) to inform the manufacturer of any changes to the 'state of the art' that concern the certification.

ANNEX IV – FULL QUALITY ASSURANCE

This conformity assessment procedure requires a notified body to evaluate the manufacturer's quality system which must demonstrate how conformity with the Directive is ensured, how the procedures implemented will provide sufficient evidence to cover the essential requirements and how the manufacturer will maintain state of the art.

GENERATE A DECLARATION OF CONFORMITY

The EU declaration of conformity is a legal document that indicates that the manufacturer has fulfilled their obligations with regard to the applicable Directives. Annex VI of the Directive lists the information that must be present in the declaration of conformity, including equipment identifier, name and address of the manufacturer, references to the harmonised standards, details of accessories and software, and a signature of the person responsible for the conformity of the product.

Once the declaration of conformity is in place the product can be placed on the market.

RE D Technical Changes

The main technical difference between the RE D and its predecessor, the R&TTE D, is that the new Directive now requires that receivers are resilient to interference. The preface of the RE D states:

> *Although receivers do not themselves cause harmful interference, reception capabilities are an increasingly important factor in ensuring the efficient use of radio spectrum by way of an increased resilience of receivers against harmful interference and unwanted signals on the basis of the relevant essential requirements of Union harmonisation legislation.*

RADIO CHANGES

There is a subtle, but significant, change in the wording of Article 3.2 of the R&TTE D which required that:

> *Radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference.*

and the RE D which requires that:

> *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.*

To put it simply, the R&TTE Directive required transmitters to effectively use spectrum whereas the RE Directive not only requires transmitters to effectively use spectrum, but also requires that spectrum is used efficiently, thus both the transmitters and receivers need to have appropriate level of performance.

MEASURING RECEIVER PERFORMANCE

Radio harmonised standards are being re-written so that receiver tests are now included in the list of tests that need to be applied to gain presumption of conformity; these tests vary from standard to standard but in the main include:

- Receiver Sensitivity
- Receiver Blocking

There will be certain categories (low performance) of receiver that will be phased out under the new Directive in due course.

EMC CHANGES

Although the technical EMC requirements in the RE D have not changed (compared with the R&TTE D), standards are constantly being updated. As a result, a new series of EMC standards for radio products is being rolled out which includes an extension of the frequency range from 2.7 GHz to 6 GHz for radiated electric field immunity (although EN 301 489-3 remains at 2.7 GHz for the time being).

As all equipment that incorporates a radio function is now deemed as radio equipment for the purposes of the RE D, many standards that are suitable for host equipment are not suitable for assessing the radio EMC performance. As a consequence, the European standards body, ETSI, has produced a guide on the application of the RE D for host equipment that integrates a radio function.

A further series of standards is being prepared that provides detailed guidance to integrators of radios of the procedures that need to be followed to ensure compliance with the Directive and at the same time remaining sympathetic to any test evidence that is provided by either the host equipment or embedded radio module. These new ETSI standards will become available during 2017 and make reference to many of the traditional EMC standards that would be applied if the product was supplied without the radio function.

SAFETY CHANGES

There are no changes to the technical requirements for safety. Like EMC however, the standards that are listed for the Low Voltage Directive need to be copied across for use in the RE D OJEU. Not all standards will be copied across and therefore manufacturers will need to check that the standards they have used to demonstrate the safety of their products are listed for the RE D.

It should be noted that the RE D requires that the risk of RF exposure from radio products is assessed. This may be a new requirement for some manufacturers and hence careful consideration of all the safety standards needs to be undertaken.

RE D ADMINISTRATIVE CHANGES

In addition to the technical changes there are a number of non-technical changes relating to documentation and labelling that align the RE D with the New Legislative Framework (as applicable to most other CE marking directives).

INSTRUCTIONS – ARTICLE 10.8

The manufacturer must provide instructions and safety information. The instructions will include a list of the frequency bands in which the radio equipment operates, the maximum RF transmitted power and also details of any restrictions that apply to putting into service.

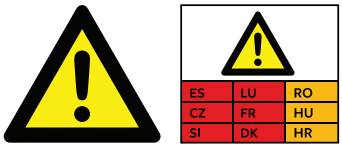
LABELLING – ARTICLE 10.6 / 10.7

The label must include the type, batch or serial number allowing identification, the name/trade name/ trademark of the manufacturer and the postal address at which they can be contacted. All information needs to be in a language that is easily understood by market surveillance authorities.

RESTRICTIONS – ARTICLE 10.10

The manufacturer is required to indicate both on the package and in the accompanying documentation any restrictions on use.

An implementing act is in preparation that, if approved, will require a warning triangle with either red or amber colours to be used with each Member State country code to indicate if the product can be used in that given country with restrictions or not allowed at all.



DECLARATION OF CONFORMITY (ANNEX VI)

Manufacturers are required to compile a RE D (2014/53/EU) declaration of conformity. This is a legal document that indicates that the manufacturer has fulfilled their obligations with regard to the Directive.

Should a product be subject to more than one Directive (for example, a medical product containing a radio would be subject to both MD D and RE D), then a single declaration of conformity would be generated covering the requirements from both Directives.

Annex VI of the RE D proves clear guidance on the structure and content of the declaration of conformity.

The declaration of conformity must either be provided in full with the radio equipment or the manufacturer is permitted to provide a simplified EU declaration of conformity giving an internet URL from which the full declaration of conformity may be obtained.

How do you demonstrate that you meet with the requirements of the Directive?

It is no secret that with six months to go until the end of the transition period, many of the harmonised standards that enable presumption of conformity are yet to be published on the OJEU for RE D. So what routes are available to manufacturers at the moment?

FOR RADIO (ARTICLE 3.2)

The routes available are:

- Route #1: Where there are Article 3.2 harmonised standards available the manufacturer may apply these, gain a presumption of conformity by testing to the standard, and perform the internal production control conformity assessment procedure.
- Route #2: Where the Article 3.2 harmonised standards are not available the manufacturer may apply the latest version of the draft standard; many of the harmonised standards are at 'On Approval' state.

Wait for the standard to be published in the OJEU for the RE D

- If the existing compliance against R&TTE is still valid, the manufacturer can continue to use that, safe in the knowledge that they have covered any RE D requirements and are ready to switch across as and when the RE D standard becomes listed on the OJEU.

Perform an EU-Type Examination

- If the existing R&TTE D compliance is not in date and RE D drafts have been applied, the manufacturer can go through the type examination route and declare their products against RE D.

FOR EMC (ARTICLE 3.1(b))

The guidance here is to apply the state of the art. The guidance from EG 203 367 is that a combination of the standard covering non-radio functionality and the EMC for radio standard (EN 301 489 series) is applied to the product; this guidance will be formalised when the ETSI EMC standard is published as a European Norm (EN 303 446).

FOR HEALTH AND SAFETY (ARTICLE 3.1(a))

The expectation is that the standards in the Low Voltage Directive that cover safety of electrical equipment will map directly into the OJEU for RE D; manufacturers are guided to apply the appropriate Low Voltage Directive standards in lieu of article 3.1 (a) RE D standards.

USE OF A NOTIFIED BODY

Whilst the use of a notified body is only mandatory where there is no Article 3.2 standard listed in the RE D OJEU, manufacturers may request that all aspects of their technical file (Radio, EMC and Safety of Electrical Equipment) are considered during the EU-type examination. Gaining an EU-type certification underwrites the manufacturers' responsibility and they gain an endorsement from an independent and competent technical authority that the equipment meets with the relevant requirements.

Still Confused?

The changes highlighted in this document are numerous and varied. Some of the changes are a major change to the test and approval requirements and it is appreciated will leave some manufacturers unclear of what the requirements are and how to proceed.

Element provide an advice service (Early Stage Qualification – ESQ) that works with manufacturers and all operators in the supply chain to help understand their compliance strategy and what needs to be done to remain compliant with these, and other CE marking requirements. This service also provides guidance on how testing can be rationalised when looking to approve the same radio product in multiple markets.

If you would like advice or need further guidance please don't hesitate to contact Element using the details shown in the footer below.