

TOPAS

Traffic Open Products and Specifications

Guidance for Manufacturers and Purchasers of Products incorporation Radio Equipment

Introduction

This note provides guidance for Manufacturers and Purchasers about the regulations which govern Products containing Radio Equipment, provides background information on the relevant regulations, and outlines the responsibilities of Manufacturers and Purchasers of such Products. Guidance is also given specifically for Manufacturers of Products who are seeking TOPAS Registration.

UK Government guidance on the Regulations can be found at:

www.gov.uk/government/publications/radio-equipment-regulations-2017.

Outline of the Regulations

All equipment (Products) which contain a radio transmitter, receiver or transceiver are governed by the Radio Equipment Regulations (2017)¹, referred to as the RER. This enacts into UK law the EU Radio Equipment Directive (2014/53/EU) usually referred to as the RED. The EU Withdrawal Act 2018 preserves the Regulations and enables them to be amended, so as to function effectively now the UK has left the EU.

The RER establishes a regulatory framework and defines a set of essential requirements for placing equipment which transmits or receives radio waves, on to the Market in the UK and largely replicates the requirements of the RED.

With some minor exceptions (defined in Regulation 3 and Schedule 1 of the RER) **all Radio Equipment placed on the market in the UK must be compliant with the RER².**

***Note:** If a Radio Module (such as a Bluetooth Module) is fitted into an otherwise 'non- radio Product, the whole resulting Product is deemed to be "Radio Equipment" and the whole Product becomes subject to the Regulations.*

¹ As amended by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, Schedule 29. The amendments specifically change references from EU directives to UK Regulations, so for example the EMC directive is replaced by the "Electromagnetic Compatibility Regulations 2016" and gives some extra powers to the Secretary of State, but in general these amendments and the Regulations as a whole preserves the essential requirements of the RED, except in relation to CE marking and associated assessment procedures.

² Some of the provisions apply differently in Northern Ireland for as long as the Northern Ireland Protocol is in force. For specific guidance on placing equipment on the Northern Ireland Market see:
<https://www.gov.uk/government/publications/radio-equipment-regulations-2017>

Although this document is mainly focused on UK manufacturers, the RER applies equally to imported Radio Equipment, with several specific Regulations (Chapter 3 of the RER) covering the obligations of importers. Distributors of Radio Equipment have comparable obligations, defined in Chapter 4 of the RER. In both cases the obligations are similar to those of Manufacturers and require that due diligence is exercised before placing imported or distributed Radio Equipment on the UK market.

The Regulations also provide for market surveillance and their enforcement by a Market Surveillance Authority (Regulations 56 - 60). In the UK enforcement is the primary responsibility of the Weights and Measurement Authority³ but is designated to OFCOM, in respect of enforcement action taken to protect and manage the radio spectrum.

Penalties for failure to comply with the Regulations can be severe including, withdrawal of the Product, fines or imprisonment for Manufacturers, awarding of costs against the manufacturer (Regulation 71) and possible recall of non-compliant equipment. (Schedule 10).

Note: *Although the main impact of enforcement action is likely to be focused on the Product Manufacturer, if enforcement action leads to a Product recall this could impact significantly on Purchasers, because it may result in important traffic control and monitoring functionality, which depend on the Product, being lost.*

In addition to the RER, the Wireless Telegraphy Act (2006) requires that Radio Equipment must be licensed before it is installed or used. In practice however exemptions apply to many types of Radio Equipment which would normally be used in Traffic Control applications. These are defined in OFCOM Document IR2030 – UK Interface Requirements. Importantly this document defines frequency allocations, permitted power levels and relevant EN standards which apply to a wide range of Radio Equipment types and against which verification should be undertaken to comply with the RER.

Note: *As an example, IR2030/7 covers wide band data transmission devices such as Radio Local Area Networks (RLANs) and short-range devices such as Bluetooth. For a Product incorporating a Bluetooth module, IR2030/7/1 specifically applies (for equipment in the 2400 – 2483.5 MHz range) and explicitly references EN300 328, which is the relevant ETSI standard for Bluetooth devices. It is this standard which provides a definition of the performance requirements and the testing required for such devices.*

Testing and Assessment

As a 'framework' the Radio Equipment Regulations do not identify what actual tests are required to be compliant with the Regulations, nor do they define 'levels' of performance or how to perform a compliance assessment. (These are defined in related ETSI and other specifications referenced by IR2030 as described above).

The Regulations do however define a set of essential requirements which must be met before Products can be placed on the Market and also requires that a Conformity Assessment is undertaken (Regulation 9 and 41), resulting in a Declaration Of Conformity (Regulations 10 and 42), which is

³ In Northern Island this responsibility falls to the District Councils, but OFCOM are still responsible for the managing and protecting the radio spectrum.

supported by relevant “Technical Documentation” (Regulation 45). The content of the Technical Documentation is defined in detail in Schedule 5 of the Regulations.

Note: *The Technical Documentation is intended to be a set of “live” documents which are kept up to date for at least 10 years after a Product is placed on the market, reflecting any changes to the Product. Along with the DOC the Technical Documentation may be requested by the Enforcing Authority as evidence of compliance with the Regulations (Regulation 11).*

The essential requirements of the Regulations fall into three separate classes.

- **Product safety** (Regulation 6(1)(a)) which references the Electrical Equipment (Safety) Regulations 2016⁴.
- **EMC** (Regulation 6(1)(b)) by reference to Electromagnetic Compatibility Regulations 2016⁵. **For Traffic Products this means compliance with EN50293.**

Note: *In some cases, test limits imposed by the individual radio specifications (e.g EN300 328) may be more demanding than the standard EMC tests. For example, emissions limits may be tighter to avoid interference with sensitive radio receivers, or susceptibility limits may be higher to ensure the Product is able to function properly when intended radio transmissions are present. In these cases, the more demanding tests should be carried out. It’s also important to note that EMC testing must be undertaken with the Radio Equipment fitted and operating.*

- **Radio Performance** (Regulation 6(2)) requiring that Radio equipment must be constructed so that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference. Typically, this requires compliance with the relevant ETSI or other standards(s) for the type of Radio used.

Note: *Where an already RER compliant Radio Module** is used (for example a Bluetooth Module), it is permissible to use the published test results for that module, however it is expected that any test cases which could be affected by the installation of the module in its host equipment are retested to confirm compliance.*

It could be reasonable, for example, not to repeat tests on a Bluetooth Module which are intended to verify characteristics such as Duty Cycle, Tx Sequence or TX gap, as these are unlikely to be affected by the integration of that module in the host equipment. However, characteristics such as RF power output, unwanted spurious emissions and receiver performance would probably be required to be re-tested because they are likely to be affected by the integration of the module in the host equipment.

The decision on which published tests are to be accepted and which tests are to be repeated is the decision of the Product Manufacturer, but the rationale should be documented in the Technical Compliance Document.

⁴ The Regulations as written refer to the Low Voltage Directive (LVD 2014/35/EU), but are amended by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 to refer to the equivalent UK Regulation.

⁵ The Regulations as written refer to the EMC Directive (2014/30/EU), but are amended by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 to refer to the equivalent UK Regulation.

*** Be aware that Radio Modules (such as a Bluetooth Modules) are "Radio Equipment" and must in themselves comply with the RER and be CA marked as Radio Equipment. Module certification (such as FCC) does not demonstrate that the module is RER compliant. Also, the inclusion of an CA Marked Radio Module within an otherwise CA marked product does not automatically mean the total combination is compliant with the RER.*

There are three alternative Conformity Assessment routes provided for in the Regulations.

- a) **Internal production control as set out in Schedule 2.** This requires that the Manufacturer take sole responsibility for verifying that the Product meets all the essential requirements of the Regulations. To achieve this in an effective manner the Manufacturer must have all the necessary resources and expertise and be able to fully undertake all necessary verification testing of the final Product (EMC, Radio etc) himself.
- b) **A UK type examination that is followed by the conformity to type based on internal production control as set out in Schedule 3** This requires that the Manufacturer submit the design and supporting evidence (including testing results) to a Notified Body who will draw up an evaluation report and issue a Type Examination Certificate, confirming the conformity to the Regulations.
- c) **Conformity based on full quality assurance as set out in Schedule 4.** This requires that the Manufacturer's Quality system in design and manufacture is scrutinised on a regular basis and that they will ensure conformity with the Regulations. The Manufacturer is still required to undertake the necessary testing to verify that the product design meets the essential Requirements of the Regulations.

Note: *Where the radio equipment is covered by a Designated EN standard any of the three assessment routes may be adopted. However, if there is no Designated EN specification then only routes b) or c) may be used (Regulation 41).*

A link to a list of Designated standards is provided at the end of this guidance document.

Note: *To achieve TOPAS Registration verification testing must be undertaken by a qualified independent test facility, with the test results and if relevant, the Type Examination Certificate issued by the Notified Body, being included within the technical file submitted as part of the Registration process. - see "TOPAS Registration" later in this document.*

Note: *In all cases ongoing Production verification is also required – see "Production Verification" later in this document.*

CA Marking and labelling

Where compliance with the with the essential requirements has been demonstrated by a relevant conformity assessment procedure and the Declaration of Conformity produced, Products must, before they are placed on the UK market, be CA⁶ marked (Regulation 10).

In addition, the final equipment and / or its packaging / documentation must be labelled with explicit information required by Regulations 11 and 12. This includes but is not limited to:

- A copy of the (simplified) DOC (as set out in Schedule 6) which includes Product type, and batch or serial number.
- As part of the DOC, the name, registered trade name or registered trademark of the manufacturer and a postal address at which the manufacturer can be contacted.
- For transmitters the frequency bands in which the equipment operates and its maximum transmitted power.

Note: CA marking and labeling requirements apply to the overall Product. If a Radio Module (such as a Bluetooth Module) is fitted into an otherwise 'non-radio Product, the whole resulting Product is deemed to be "Radio Equipment" and requires appropriate CA marking and labeling. It is the responsibility of the final Product manufacturer to properly CA mark the Product (Regulation 39). It is not permissible to simply rely on the Radio Modules marking and documentation.

Production verification (Series Production)

The RER applies to each unit delivered from the production line (Regulation 17 - Series Production) and a Manufacturer must implement ongoing monitoring during manufacture to ensure the requirements of Regulations continue to be met in each instance of the Product.

Note: The exact nature of this monitoring is not specified, but it is reasonable to expect key parameters such as transmitted power and frequency, unwanted spurious emissions and receiver sensitively are checked on each Product produced.

Note: Any changes to the Product design or manufacture (including software) should be assessed and documented in the Technical Documentation, so as to confirm that the Product remains compliant with the Regulations.

TOPAS registration

TOPAS specifications provides a means for Purchasers of traffic control and related Products to easily define the technical requirements, as well as Standards and Regulation compliance, required for Products to be used on UK roads, freeing them from the need to explicitly define such detail in their own purchasing documentation and tenders – a task which would be extremely time consuming and in many cases something which Purchasers do not have the expertise to do effectively.

The TOPAS Registration process is the means by which Manufacturers are able to demonstrate compliance with the specifications, allowing Purchasers to easily verify that Products they purchase

⁶ CE marking by the manufacturer is still possible until at least the 31 December 2021 for the UK market.

are compliant. The TOPAS Registration process is defined in the TOPAS Document TOPAS 0600⁷ and requires that Manufacturers create a detailed Technical File, which is reviewed by an Independent Technical Assessor to verify compliance, before Registration is granted.

Each TOPAS specification defines the required content of the Technical File (in Appendix Z). The basic content is consistent across all the TOPAS specifications but, with some additional requirements being dependent on the individual specification.

Typically, the Appendix Z will require evidence of the manufacturers quality system, a statement of compliance against the relevant TOPAS specification, inclusion of external test results for items such as EMC, environmental and optical performance (where relevant) and CA mark documentation.

For specifications which identify specific functionality related to radio equipment, Manufacturers are required to provide explicit evidence of compliance with the RER as part of the Technical File, notably:

- A copy of the RER Declaration Of Conformity
- Reference to the RER Technical Documentation for the product (by part number and issue state).
- Copies of the results of radio testing, undertaken by an appropriately qualified independent approved test house. The test results should be those identified in the RER Technical File Pack and should cover any specific IR2030 requirements for the type of radio used.
- A copy of the Type Examination Certificate for radio equipment not covered by a Designated EN standard.

Note: *Where a Product specification does not explicitly require evidence of RER compliance in its Appendix Z, but the Product does include radio equipment, the TOPAS Technical File must include the documents and evidence outlined above, to confirm RER compliance for the whole Product. This might occur, for example, when a Product, which is to be Registered against its main specification (e.g TOPAS 2500 - which in itself does not define any radio related functionality), includes a permanently installed Bluetooth module, allowing remote access to the Products user interface.*

⁷ More details about TOPAS and access to all the TOPAS specifications, including TOPAS 0600 as well as other guidance can be found on the TOPAS website: www.topasgroup.org.uk.

References and useful documentation:

The Radio Equipment Regulation (2017)

www.legislation.gov.uk/uksi/2017/1206/contents

The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

www.legislation.gov.uk/ukdsi/2019/9780111180402/contents

Radio Equipment Regulations – Guidance

www.gov.uk/government/publications/radio-equipment-regulations-2017

IR 2030 – UK Interface Requirements 2030

www.ofcom.org.uk

Designated standards: radio equipment

www.gov.uk/government/publications/designated-standards-radio-equipment

TOPAS 0600 – The TOPAS Registration Process

www.topasgroup.org.uk