Radio Equipment Regulations 2017
Schedule 3, Module B, EU-type examination, assessment guidelines

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Contents

1. Scope

This document explains the DTG Testing process for implementation Schedule 3 Module B requirements of the Radio Equipment Regulations 2017

2. Overview

Schedule 3 Module B of the regulations explains EU Type Examination. That is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 6.

This is required if no harmonised standard is available to demonstrate compliance, in which case manufacturers can self-declare conformity using test results against the harmonised standard.

Following assessment, an EU Type Examination certificate will be issued enabling UKCA marking to be affixed to the product.

If the technical documentation provided does not demonstrate conformity to the requirements then the applicant will be notified as well as other approved bodies and the notifying authority.

3. How to apply

To apply for DTG Testing Notified Body services, please complete the application form on located at www.dtgtesting.com

For further information on the booking process please contact DTG customer services: customerservices@dtg.org.uk

4. Who can apply

Applications can be made by the manufacturer or authorised representatives of the manufacturer. Details below are taken from Radio Equipment Regulations Schedule 3 section 10:

The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

As per the above requirement, DTG Testing will require a copy of the authorised representative mandate

5. What to apply for

DTG Testing are offering NB RED approval for broadcast radio products (AM/FM/DAB/DAB+) against articles 6.1a (Health and Safety), 6.1b (EMC), and 6.2 (Spectral Efficiency)

Currently there is no harmonised ETSI specification to test this category of products against which is why EU Type Examination is required to gain CE marking before placing these products on the market in Europe.

5.1. Information to include in the application.

The following are required for a EU-type examination application as specified in Schedule 3 of the Radio Equipment Regulations for Module B assessments:

□ name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

□ a written declaration that the same application has not been lodged with any other notified body;

□ the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility

□ the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s).

A risk assessment needs to assess the risks to it meeting the essential requirements. The assessment should take the form of:

Product identification – features, functions, associated accessories such as batteries, power supplies

Risk identification – with respect to the features and functions – identify the hazards and who/what would be at risk e.g. people or other equipment. Consideration needs to be given to the intended and reasonably foreseen use of the product when identifying risks.

Risk analysis – How can the hazards identified above harm the subjects

Uncontrolled risk evaluation – classify the hazard e.g. potential for harm vs likelihood that it will happen

Risk reduction - Identify how steps put in place to reduce the hazards as far as practicably possible – in this part testing that's been done can be highlighted to show it's safe, or that it meets EMC requirements

Controlled risk evaluation – Re-classify the hazards given the mitigation you've put in place to show the risk has been reduced.

See RED conformance association guidance on how to perform a risk assessment:
http://www.redca.eu/Unrestricted%20Documents/RED%20Risk%20Assessment%20introduction.pdf

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the radio equipment. The technical documentation shall contain, wherever applicable, the elements set out below and are taken from Annex V of RED.

5.2. Technical documentation:

□ a general description of the radio equipment including:

(i) photographs or illustrations showing external features, marking and internal layout;

(ii) versions of software or firmware affecting compliance with essential requirements;

(iii) user information and installation instructions;

General description guidance notes: All products covered by the technical documentation must be identified by model/type/brand etc. If more than one model etc. is covered, the relationship between them should be explained. Full user information should be provided describing how the radio equipment is intended to be used and any precautions to be observed in installing, using and maintaining it. For complex equipment, only those sections of the user information relevant to compliance are required. Where software or firmware affects compliance, it should be explicitly referenced and any user configurable options explained. If not included in the user information, photographs or illustrations showing external features and internal layout should be provided. These should be in sufficient detail to permit reliable visual identification of the equipment concerned.

□ conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;

Conceptual design guidance notes: Information is required only for those aspects which directly affect compliance. Typically, this will include circuit diagrams, PCB layouts and parts lists for all radio interface circuits, power supplies and ports for connecting other apparatus which communicates via or interacts with those interfaces. Circuit elements need only be shown in sufficient detail for an understanding of compliance issues. Components that are critical for compliance purposes (eg safety isolation or RF sources) should be specifically identified with alternatives (if any). Similar considerations apply to software and firmware as well as hardware. Note, this information may also be used to assist in identifying the equipment covered by the technical documentation particularly in cases where there is doubt arising from post-market surveillance.

□ descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the radio equipment;

Descriptions guidance notes: For simple equipment, a circuit diagram and the user information provided in response to previous sections may be sufficient. For more complex equipment, a block diagram with an outline technical description would be appropriate. In all cases, the points of connection to communications networks and to antennas (integral or external) must be clear. The network interface(s) and/or radio spectrum usage should be identified. Ports for connection of other apparatus should also be identified together with any specifications for such other apparatus required to ensure overall compliance with essential requirements.

□ a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied.

Where harmonised standards have been applied: the NB should accept [at their sole discretion] the parts of the radio equipment testing to the harmonised standards with minimal review as they should have an effective presumption of conformity in terms of state of the art, providing the harmonised standards have been followed in full[1].

Standards guidance notes: The list of standards is specifically those standards harmonised for the purposes of the RED. The particular version of each standard should be identified together with the relevant clauses or parts if it has not been applied in full. Where harmonised standards are not applied (e.g. because they are not available), other standards may be used provided some explanation of their relevance to essential requirements is given "Standards" should be interpreted broadly in this context to include requirements and recommendations issued by any recognised body competent in the field concerned. For example, decisions and recommendations by ECC and ITU-R typically include relevant requirements for spectrum use. A Notified Body assessment will be required in all such cases for the essential requirements indicated in the Articles 3.2 and 3.3 of the RED, but it is the manufacturer's responsibility, not the Notified Body's, for putting together the rationale for compliance. If no relevant standards exist to address a particular aspect of compliance with essential requirements then an assessment from first principles must be made based on good engineering practice and using the typical parameters in the production of harmonised standard, based on ETSI GUIDE "EG 203 366" requirements and typical parameters such as CEPT/ERC/RECOMMENDATION 74-01, any late draft ETSI Standards or harmonised standards that are used for equipment operating in the same frequency band or frequency band of equipment with similar usage and documented accordingly. Again, this is the manufacturer's responsibility, not the Notified Bodies. This section should deal with strategy only. Results of evaluation in accordance with the strategy identified are covered in subsequent sections.

[1] REDCA TGN28 Guidance on the RED article 3 requirements for a NB Type examination certificate covered by the RED: http://www.redca.eu/Pages/Documents%201.htm

□ a copy of the EU declaration of conformity; The DoC shall have the model structure set out in Annex VI RED

□ where the conformity assessment module in Annex III has been applied, copy of the EU-type examination certificate and its annexes as delivered by the notified body involved;

□ results of design calculations made, examinations carried out, and other relevant similar elements;

Results guidance notes: Where harmonised standards addressing all essential requirements have been applied in full and corresponding test reports are available, no further information is required here. In all other cases, an explanation of what tests and assessments have been made and how the available technical data and test results have been interpreted in order to determine compliance with the essential requirements should be provided. Typically, this might be the case where formal standards are not available, where only one model in a range of radio equipment has been tested, where reliance is placed on compliance of a sub-assembly for which a third-party holds the detailed compliance documentation, where reliance is placed on calculation rather than testing (for example, certain cases of RF exposure) or where the version manufactured differs in some way from the version to which the test results relate. It may be helpful to consider this as an exercise in risk analysis seeking to identify potential causes of non-compliance with the essential requirements and the means by which assurance has been gained that such non-compliance does not exist. This might include, for example, documenting how the installation instructions of a sub-assembly supplier have been respected, how “worst case” scenarios for selective tests on a range of models have been determined or why results on a similar but differently named/branded radio equipment can be applied.

□ any relevant test reports

Test reports guidance notes: It is recommended that testing is conducted by laboratories operating in accordance with EN ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories" and that test reports are drawn up in accordance with clause 5.10 of that standard. However, compliance with this standard is not mandatory and it remains the manufacturer's responsibility to choose a technically competent laboratory. "In-house" testing is acceptable provided it satisfies these or equivalent criteria. Test reports must unambiguously identify the apparatus to which they relate so that they can be correctly associated with the corresponding Declaration of Conformity. Test reports should be factual, reporting the actual product tested. Untested variants should not be listed in a test report. The manufacturer should provide a separate justification for the addition of partially tested or untested variants that they wish the Notified Body to considered. Partial test reports should not declare full compliance to the standard. Where special software or configuration is required for testing this must be clearly stated and the relationship with software for normal use explained. One test report may cover the whole or part of one or more essential requirements. However, it should be clear whether the report addresses the whole or only part of the essential requirements and, in the latter case, precisely which part(s). Where harmonised standards do not specify particular test suites or have not been applied in full or other standards or alternative test methods have been used, the test methods should be detailed with justifications for their relevance to the essential requirements. Opinions and interpretations given in accordance with Clause 5.10.5 of EN ISO/IEC 17025:2000 have no particular status in respect of the RED and must not be confused with a Notified Body assessment, even in cases where a test laboratory and Notified Body do business with the same trade name.

□ an explanation of the compliance with the requirement of regulation 8 (construction must allow operation in at least one Member State) and of the inclusion or not of information on the packaging in accordance with regulation 14 (information to be included where there are restrictions on putting into service or requirements for authorisation of use)..

6. DTG Testing assessment process

Once a booking form has been received and DTG Testing have confirmed all the required documentation as detailed above has been submitted with the application, DTG Customer services will schedule the assessment and confirm the date and job number.

DTG Testing will then carry out the assessment on the scheduled date and issue the certificate on successful completion.

If it is deemed that the product has met the requirements, and this is supported by the documentation provided, a report and EU Type Examination certificate will be issued to the customer.

If it is deemed the application has been unsuccessful then as per the RED requirements DTG Testing will Issue a notification to the customer to advise them of the reason for the failure

DTG Testing is required to inform the following regarding EU Type Examination certificates issued, withdrawn, refused, suspended or otherwise restricted:

- All other UK Approved Bodies
- Inform DTG Testing's Notifying Authority (UK department for Business, Energy and Industrial Strategy, BEIS)

In cases where harmonised standards the references of which have been published in the *Designated Standards: Radio Equipment* [2]have not been applied or not been fully applied. The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

7. Certification for future updates to products

In accordance with the regulations, the manufacturer needs to update DTG Testing as the issuer of certification, if modifications are made to the product following an assessment. The exact wording from Schedule 3, Module B, section 7 is:

The manufacturer must inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of these Regulations or the conditions for validity of that certificate. Such modifications require additional approval in the form of an addition to the original EU-type examination certificate

For cases where there are changes to the product which may affect the certification, the manufacturer should contact DTG Testing to discuss the validity of certification and in some cases there may be a need to re-apply for an update to the certification.

8. Future changes to requirements

DTG Testing will inform the manufacturer of changes to the UKCA requirements which may mean the approved product must be re-certified. This is detailed in Radio Equipment Regulation, Schedule 3, section 7:

The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

9. EU Type Examination records

DTG Testing and the manufacturer shall maintain a record of the product assessment and supporting documentation for 10 years from the last application. This is for both when the certificate has been issued as well as where the certificate has been refused. Below is the wording from Schedule 3, sections 8 and 9:

[2] https://www.gov.uk/government/publications/designated-standards-radio-equipment

The notified body must keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate.

The manufacturer must keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market.

10. UKCA Marking

Once it has been demonstrated that the essential requirements Article 6 of the Radio Equipment Regulations have been met, UKCA marking can be placed on the product, which allows it to be sold in the EU and EEA.

Requirements for UKCA marking are set out in https://www.gov.uk/guidance/using-the-ukca-marking#how-to-use-the-ukca-marking

11. Useful links:

DTG Testing website: http://www.dtgtesting.com/home

Readio Equipment Regulations 2017:
https://www.legislation.gov.uk/uksi/2017/1206/contents/made

'UK Designated Standards: https://www.gov.uk/government/publications/designated-standards-radio-equipment