SPCR 307

Certification rules for EU-type examination of radio equipment according to Directive 2014/53/EU
RISE Certification Rules for EU-type examination of radio equipment according to Directive 2014/53/EU

RISE Research Institutes of Sweden AB
SPCR 307
Borås 2019

Postal address:
Box 857
SE-501 15 BORÅS
Sweden

Telephone +46 10 516 50 00
E-mail: info@ri.se
Internet: www.ri.se
Contents

Preface 4

1. Introduction 5
   1.1 General 5
   1.2 Certification and type examination in accordance with European Commission Directives 5
   1.3 EU-type examination of radio equipment 5

2. Conditions for EU-type examination of a Radio Equipment 6
   2.1 The certification process 6
      2.1.1 General 6
      2.1.2 Application 6
      2.1.3 Review of application 6
      2.1.4 Evaluation 6
      2.1.5 Review and decision 7
      2.1.6 Period of validity 7

3 Other terms and conditions for certification and assessments 8
   3.1 Application 8
   3.2 CE-marking and other product marking 8
   3.3 Certificates 8
   3.4 Liability 8
   3.5 Withdrawal of certificates 8
   3.6 Changes to products 9
   3.7 Confidentiality 9
   3.8 Revised rules 10
   3.9 Fees 10
   3.10 Appeals 10
Preface


The certification rules are based on current regulations, but may be revised in future, e.g. to harmonise them with changes in the regulations. Revision may also be necessary if new regulations are introduced or if a need for such revision is shown by the results of experience of application of the rules.

Borås, March 2019

RISE Research Institutes of Sweden AB
Certification – Notified Body no. 0402

Dag Sjöholm
1. Introduction

1.1 General
Certification involves confirmation by an independent third party that a product fulfils requirements set out in standards or some other form of specification. Certification by RISE is performed by RISE Certification, a department that is separate from the testing and inspection departments. Certification of products by RISE is performed in accordance with SS-EN ISO/IEC 17065.

1.2 Certification and type examination in accordance with European Commission Directives
Certification, type examination and other activities to obtain the CE-marking are regulated by various European directives. This means that certain sections of these rules, e.g. those regulating the requirement to make information available to other Notified Bodies and public authorities, differ from requirements in RISE general certification rules. Directives use terms such as 'EU-type examination' and 'EU-type examination certificates', which more or less approximate to the terms commonly used in RISE certification activities, 'certification' and 'certificates'.

As used in this document, the 'Directive' refers to Directive 2014/53/EU, also called "RED". Further information on the RED Directive and its application can be found on the European Commission’s website.

1.3 EU-type examination of radio equipment
The procedures are based on those specified in the Directive 2014/53/EU, for EU-type examinations that require the participation of a Notified Body. They must be carried out in accordance with the requirements of the Directive, and any other requirements specified in the Directive must also be fulfilled. In addition to these procedures, the manufacturer, the manufacturer's representative or sellers must observe the applicable requirements in the Directive, e.g. those covering the preparation of written EC Declarations of Conformity, CE-marking etc.

These rules covers EU-type examination of radio equipment, as described in annex III, section Module B, in Directive 2014/53/EU. The activities are executed by RISE in its capacity as a notified body.
2. Conditions for EU-type examination of a Radio Equipment

2.1 The certification process

2.1.1 General
The certification consists of an evaluation of the technical documentation belonging to the radio equipment concerned. If the technical documentation is found to fulfil the requirements, an EU-type examination certificate can be issued. The certificate is valid provided that the products continue to fulfil the requirements of the directive. Other terms and conditions are set out in Section 3.

2.1.2 Application
Application for certification shall be submitted in writing. An adapted application form is available, and shall be accompanied by:

- The name and address of the manufacturer and, if application is lodged by an 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 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). 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 in Annex V of Directive 2014/53/EU
- 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.

2.1.3 Review of application
When reviewing the application, RISE checks that the application is complete and that the application can be handled within RISE notification. The review may mean that RISE cannot accept the assignment, which is then communicated to the customer with a justification.

If the application is adopted, this is communicated to the customer through an order confirmation. An evaluation plan is prepared, if it does not already exist. When a standard is followed, this largely represents the evaluation plan.

2.1.4 Evaluation
During the evaluation process, the technical documentation and supporting evidence will be examined in meaning to assess that the technical design of the radio equipment is adequate to fulfil the requirements of the directive.
If the results of the evaluation show that the product and documentation meet the requirements of the specification, the process proceeds to review and decision.

However, if it is found that the technical documentation shows deficiencies, i.e. does not meet the requirements, the evaluation may be cancelled, and a certification will be refused. In that case RISE has to notify the notifying authority and other notified bodies.

2.1.5 **Review and decision**

The evaluation work is reviewed, and following successful results, the process proceeds to the decision phase. When a decision on certification has been taken, an EU-type examination certificate is issued and delivered to the customer. The certificate can be used as part of the basis required to issue a declaration of conformity and apply the CE mark the product.

2.1.6 **Period of validity**

The EU-type examination certificates are issued without any specific validity period. They are valid as long as the products are unchanged and as long as the specifications they are based on are valid and fulfil the requirements of the directive.
3 Other terms and conditions for certification
and assessments

RISE General Conditions also apply, in addition to those given in these certification rules.

3.1 Application
When an application has been made to RISE for an EU-type examination, such an
application is not allowed to be done to another notified body, according to
requirements in the Directive.

3.2 CE-marking and other product marking
Manufacturers who have obtained an EU-type examination certificate, as described in
section 2 above, are entitled to use the certificate as one of the basis to set up an EU
declaration of conformity and apply the CE-mark on products covered by the certificate.
If products are also covered by other directives, the relevant fundamental requirements
in these directives must also be fulfilled before the products may display the CE symbol.

3.3 Certificates
A certificate can be issued when assessment verifies that the product meets relevant
requirements. The validity of the certificate is based on continuous fulfilment of the
conditions. Certificates are not transferable. Copies of certificates and appertaining
documents may only be presented in its entirety, except with the prior written approval
by RISE.

3.4 Liability
The certificate holder is responsible:
• to fulfil all requirements connected to the certification including notified
changes in certification rules or conditions,
• to not provide any misleading information about the extent or conditions of the
certification which can harm the confidence for the certification or RISE
• that CE-marked products comply with the applicable requirements in one or
more directives, with corresponding national provisions and the requirements
specified in the certificate.

RISE is responsible for
• ensuring that all processing is carried out with the necessary care and in
accordance with the procedures of RISE quality system.
• the certification rules
• to inform about changes in the certification rules and conditions. RISE has no
responsibility for certified products.

RISE has no responsibility for certified products.

3.5 Withdrawal of certificates
RISE can, on temporary or permanent basis, revoke a certificate if:
• the product no longer meets the specified requirements
• errors in the certificate are discovered.
• products are not suited to their intended use or can cause injury or problems
• changes are made to legislation, directives or similar
• a harmonized specification, which the evaluation is based on, will lose its harmonization
• the authorities, or a coordinating body for Notified Bodies, recommends RISE to do so
• the holder has used the certificate for, or in connection with, products that do not meet the requirements or are not covered by the certificate
• fees are not paid as due, the holder is subject to bankruptcy, has gone into liquidation or has transferred operations
• the holder has not adhered to the conditions of certification.

If a certificate is revoked, the holder shall cancel all reference to the certificate and RISE name and id.no. 0402 in his EU declaration of conformity. The holder may neither refer to the certificate or RISE in advertisements or other publications for the product in question.

3.6 Changes to products

Note that no changes may be made to the certified product, without this being assessed and approved by RISE. The manufacturer must therefore notify RISE of any planned change to the certified product. Along with this notification, a description of the changes along with the addition of the technical data is attached. RISE will then assess what measures need to be made in order for the certificate to remain in force after such changes have been made. The assessment may result in additional examinations having to be performed. In this case, the manufacturer must be notified thereof and may then also be given a price quotation for this. If the result of the change means that the certificate is still valid, the certificate is revised with the new data.

3.7 Confidentiality

With the following exceptions, all information obtained by RISE will be regarded as commercially confidential: RISE maintains a register of certificate holders, certificates, associated documentation, certified products, manufacturing locations, certification validity periods and the use of manufacturing controls. This information may be publicised on RISE website, for example. RISE can provide copies of or publicise certificates and associated documentation. RISE also has the right to publicise decisions on the withdrawal of certificates and the misuse of certificates or marking. Other information is kept confidential.

As a notified body, RISE is in some cases obliged to reveal information about certificates to other notified bodies and applicable authorities.
• information shown on the certificate or associated appendices and supplements;
• information on certificates and associated appendices that have been refused or recalled;
• information made available after agreement with the holder of the certificate.

Information that is not commercially confidential as above may be used by RISE, or by those working with it, for such purposes as official lists of issued certificates, or as needed in order to enable RISE to fulfil its obligations as a Notified Body in respect of making available information concerning issued and recalled certificates with associated appendices and additions to other Notified Bodies.
On the request from competent authorities in EU/EES, RISE may need to submit information and documentation from commissions to such authorities.

3.8 Revised rules
RISE reserves the right to modify these rules in order to harmonise them with standards, changes to the Directive or rules for Notified Bodies, or as a result of experience of application of the system.

3.9 Fees
Fees are set by agreement and shall be paid by the certificate holder. Costs for work resulting from deviations found during regular inspection shall be paid by the certificate holder. Fees for other, essential, inspections shall only be paid by the certificate holder if the results show that the certification rules have not been fulfilled.

Application and registration fees are normally not reimbursed when an assignment is cancelled or a certificate cannot be issued. In the case of assignments that are not expected to be completed within a month of the acceptance date, RISE has the right to issue regular (monthly) invoices for costs to date.

3.10 Appeals
Appeals against RISE decisions shall be submitted in writing. Action in response to such appeals will be decided by RISE Certification Board.