



SPCR 307

SP's rules for

EU-type examination of radio equipment according to Directive 2014/53/EU

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

**SP Sveriges Tekniska Forskningsinstitut
SP Technical Research Institute of Sweden**

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Postal address:
Box 857
SE-501 15 BORÅS
Sweden

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

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Preface

This document sets out the rules for EU-type examination (certification) of radio equipment complying with Directive 2014/53/EU of the European Parliament and of the Council.

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.

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SP Technical Research Institute of Sweden
Certification – Notified Body no. 0402

Lennart Månsson

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 SP is performed by SP Certification, a department that is separate from the testing and inspection departments. Certification of products by SP 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 SP's 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 SP 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 SP in its capacity as a notified body.

SP can also carry out the activities for conformity assessment modul H, described in a separate document

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 file belonging to the radio equipment concerned. If the technical file 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, SP checks that the application is complete and that the application can be handled within SP's notification. The review may mean that SP 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 SP has no 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

SP's General Conditions also apply, in addition to those given in these certification rules.

3.1 Application

When an application has been made to SP for an EU-type examination, such an application is not allowed to be done by 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 SP.

3.4 Liability

The certificate holder is responsible:

- for ensuring that certified products, marked with the certification mark, complies with the requirements specified in the certificate,
- to fulfil all other 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 SP
- that CE-marked products comply with the applicable requirements in one or more directives, and with corresponding national provisions.

SP is responsible for

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

3.5 Withdrawal of certificates

SP 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 SP 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 and if SP demands it, the holder is obliged to cancel all reference to the certificate in advertisements or other publications for the product in question and shall remove the certification mark from all stocked items. The holder can neither refer to the revoked certificate in his EU declaration of conformity.

When a certificate is revoked due to incorrect marking of products, i.e. products that fail to meet the certification requirements, SP can demand that the holder of the certificate pays all costs associated with replacing the substandard products with ones that meet the terms of the certificate.

3.6 Changes to products

Note that no changes may be made to the certified product, without this being assessed and approved by SP. The manufacturer must therefore notify SP 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. SP 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 SP will be regarded as commercially confidential: SP 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 SP's website, for example. SP can provide copies of or publicise certificates and associated documentation. SP 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, SP 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 SP, or by those working with it, for such purposes as official lists of issued certificates, or as needed in order to enable SP 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, SP may need to submit information and documentation from commissions to such authorities.

3.8 Revised rules

SP 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, SP has the right to issue regular (monthly) invoices for costs to date.

3.10 Appeals

Appeals against SP's decisions shall be submitted in writing. Action in response to such appeals will be decided by SP's Certification Board.