SPCR 308
Assessment and examination of marine equipment in accordance with directive 2014/90/EU MED
Foreword

A manufacturer can apply the wheel-mark on Marine Equipment after performing necessary activities as described in Directive 2014/90/EU.

Certification of products and quality systems at RISE is conducted in accordance with SS-EN ISO/IEC 17065 and SS-EN ISO/IEC 17021 respectively. The tests that are carried out as a basis for certification are conducted in accordance with SS-EN ISO/IEC 17025. Product verifications are conducted in accordance with SS-EN ISO/IEC 17020.


Directive 2014/90/EU is implemented in Swedish law by TSFS 2016:81

All evaluation and testing is carried out based on indicated standards/normative documents. The activities for certification are in line with ISO/IEC 17065.

The rules are revised as necessary to suit new and revised harmonised standards/normative documents. Revision may also be necessary if the Directive changes or as a consequence of experience gained from the application of the system, within the framework of the Directive. This issue replaces earlier issues.

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1 Scope

These rules cover procedures for assessment of marine equipment in accordance with Directive 2014/90 EU (MED) with the aim of issuing documents for the wheel-mark. The services which RISE can offer are set out below.

Module B  EC type examination
Module D  Conformity to type based on quality assurance of the production process
Module E  Conformity to type based on product quality assurance of products
Module F  Conformity to type based on product verification

The prerequisites for the respective modules are described in the following document in sections 2-5. Within certain frameworks the manufacturer chooses which modules it wants to use and, in the same manner, the manufacturer chooses which notified body/bodies should perform which task.
2 EC type examination (Module B)

2.1 General
This section describes the EC type examination (certification) of marine equipment, which is based on Directive 2014/90/EU, annex II, module B, and involves examining that the product meets the applicable requirements of the Directive. The EC type examination can be performed in one of the following ways:

- Inspection (testing) of one or more samples that are representative of the production
- Assessment of the technical design by means of review of the technical documentation as well as inspection (testing) of one or more critical parts of a sample. The sample shall be representative of the production

RISE assesses which manner is appropriate for the current product. See also below evaluation section 2.3.3. Other conditions are listed in section 5.

2.2 Required characteristics
Equipment that is manufactured in accordance with, and complies with the requirements in, the standards that have been indicated for the purpose are considered to comply with the requirements of the Directive. See the Directive’s list.

2.3 The assessment process

2.3.1 Applications
Applications for EC type examinations (certification) shall be in writing and must be accompanied by:
- The manufacturer’s name and address and, if the application is lodged by an authorised representative, his name and address as well.
- A written declaration that the application has not been submitted to another notified body
- Technical data (see below).
  - When applicable, the equipment that is representative of the type shall be placed at RISE disposal for review.
  - Documents that illustrate that the technical design is appropriate. The documents shall include or refer to the standards that are used.
  - A declaration that the equipment is representative for the planned production.

A special application form is available on RISE website.

2.3.1.1 Technical data
Technical data shall describe, among other things, the design, manufacture and working method of the equipment. This means that the appropriate sections shall contain:
- a general description of the marine equipment
- design and manufacturing drawings and charts of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for understanding the above
• a list of the requirements and testing standards that are applied, as well as
descriptions of the solutions chosen in order to comply with the requirements in
these
• results of calculations and inspections
• test reports*.

* Test reports may not be older than five years at the time of application.

All documents including drawings, product descriptions, assembly instructions, user
manuals etc. should be given a name or number and date as well as date of last revision.

2.3.2 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 manufacturer with an
explanation.
If the application is accepted, the manufacturer is notified by means of a confirmation. An
evaluation plan is prepared if this does not already exist. The standard applied
constitutes as a rule the evaluation plan. If a subcontractor must be engaged, this is
communicated to the manufacturer. The manufacturer is entitled to object to the
selected subcontractor.
If this is not done with the application, the manufacturer is asked to send test samples to
the extent that the evaluation plan requires.

2.3.3 Evaluation
During the evaluation process, the product is checked to ensure it has been
manufactured in accordance with the technical data, and that it meets the requirements
that the standard or specification requires. The evaluation process includes tests and
inspections that are carried out to the extent specified by the requirements specification
and/or evaluation plan. In some cases, previous test results can be used for the
evaluation. The requirements for these tests include that they shall have been carried out
by an accredited independent testing laboratory. The evaluation also includes a review of
marking and information to the user etc. In cases where the product and/or
documentation shows deficiencies, i.e. does not meet the requirements, the evaluation
may be cancelled.

Results of the evaluation are summarised in an assessment report, which is presented to
the manufacturer. The report is confidential and may not, in full or part, be disseminated
without the manufacturer’s consent.
If the results of the evaluation show that the product and documentation meet the
requirements of the specification, the process proceeds to review and then decision.

2.3.4 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 EC type
examination certificate is issued to the manufacturer. This can be used by the
manufacturer as a part of the documentation required for issuing a declaration of
conformity and to wheel-mark the product.
2.4 **EC type examination certificate**

2.4.1 **Validity**
EC type examination certificates for marine equipment are normally issued with a validity period of five years from the date of issue. The validity period may then be extended for five years at a time. In the event of revision of a certificate, the original validity period is retained.

2.4.2 **Extension of validity period for the issued certificate.**
Applications for extension shall be made in writing, at least 6 months before the end of the validity period. For the application, an assessment is made of the measures required for the extension. If no changes are made to the regulations, specifications, etc. the certificate can be extended without any further action. Of course, this presumes that the product is unchanged relative to the original certification or the latest revision. The applicant must certify that no changes have been made. A current set of the technical documentation shall be attached (see 2.3.1.1). Note, that test reports used as basis for the initial evaluation, may not be older than 15 years at the time of application of the extension of validity. RISE can also demand for results from assessments of the quality system according to module D/E or product verifications according to module F.

If changes are planned for the product, the application shall be supplemented with details about this. This may result in the need to conduct additional assessments and/or tests. In this case, the manufacturer must be informed thereof and will then also receive a price quotation for this.

2.5 **Changes to certified products**
Note that no changes may be made to the certified product, without this being assessed and approved by RISE. For this reason, the manufacturer must notify RISE of any planned changes to the certified product. Along with this notification, a description of the changes as well as supplementary information to the technical data must be attached. RISE will then assess what measures need to be taken in order for the certificate to remain in force after such changes have been made. The assessment may result in the need to conduct additional tests. In this case, the manufacturer is notified thereof and will 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.

2.6 **Market access and marking**
Introducing a product to the market requires that in a supplement to a valid EC type examination certificate, the manufacturer must also allow a notified body to perform any of the confirmation procedures stated in point 1.3. The manufacturer chooses the appropriate confirmation procedures to be used and the notified body that will perform each task. The procedures that are applicable are set out in the equipment list associated with the Directive. The wheel-mark must be supplemented with the identification number of the notified body that performs this task. See more on this in section 5. See section 3 and onwards for the different procedures.
3 Conformity to type based on quality assurance of the production process/products (Module D/E)

3.1 General
Directive 2014/90/EU states a number of options from which manufacturers can choose for examination of type approved/certified equipment with the aim of approving them for the market. One option is the quality assurance of the production, for which the manufacturer is responsible, and which is followed up through monitoring, for which RISE is responsible. This is based on the Directive, 2014/90/EU, annex II Module D. Following inspection, a report is issued with an assessment and proposed decision. Using this as a basis, a decision is taken to issue a certificate. Other conditions are listed in section 5. For Module D, the manufacturer must have one or more valid EC type examination certificates for the equipment that will be included.

For Module E, the same conditions apply in principle as for module D, with the exception that it is assumed in this case that there is a relevant final examination of the equipment. This means that in the examination, less importance is given to the steps that precede the final inspection.

See also document Terms for review and assessment of management systems as notified body, SP INFO 2014:35 for a more detailed description of the process

3.2 Applications
The application for examination (certification) of the quality system shall be in writing and be accompanied by:
- The manufacturer’s name and address, and if the application is lodged by an authorised representative, his/her name and address as well.
- A written declaration that the application has not been submitted to another notified body
- All information of significance for the concerned category of equipment
- Quality manual or equivalent documentation for the quality system
- The technical documentation for the type/types and a copy of the EC type examination certificate or certificates.

The application must also state if the quality system covers all or parts of the company, or all or parts of the production.

The manufacturer shall undertake to:
- Maintain the approved quality system to ensure its continuing suitability and effectiveness.
- Inform RISE about all changes that are planned in the quality system.

3.3 Quality system requirements
The requirements on the quality system are stipulated in the Directive’s annex II Module D and E respectively. The quality system shall ensure that the equipment complies with the type approval and meets applicable requirements in the Directive. The system shall be documented in accordance with point 3.4 below.
The quality assurance system of the production can be based on a quality system according to EN-ISO 9001, including examination that the measuring instruments meet the requirements of the Directive.

3.4 Documentation requirements
The documentation shall describe, for module D:
- quality objectives and the organisational structure, management responsibilities and authority with regard to product quality
- manufacturing processes, methods and techniques for quality control and quality assurance as well as the systematic measures that will be taken
- the inspections and tests that will be carried out before, during and after manufacture, including frequency
- quality documents, for example, audit reports, test results, calibration results, documentation of the expertise of staff, etc.
- the methods for monitoring that the set quality objectives are achieved and that the quality system works effectively

for module E:
- quality objectives and the organisational structure, management responsibilities and authority with regard to product quality,
- the inspections and tests that will be carried out after manufacture,
- quality documents, for example, audit reports, test results, calibration results, documentation of the expertise of staff, etc.
- the methods for monitoring that the quality system works effectively

All relevant information such as quality documents and design documents shall be kept available for RISE.

3.5 Review and assessment of quality systems, etc.
The review and assessment are conducted according to the document Terms for review and assessment of management systems as notified body, SP INFO 2014:35. For approved results, RISE issues a certificate verifying that the quality system complies with the requirements in accordance with module D and E respectively for the specified equipment. The validity period for the certificate is 5 years, and can be extended by 5 years at a time.

3.6 Monitoring of quality system
RISE will conduct audits at regular intervals, normally once a year, and submit auditor' reports. RISE may visit the manufacturer without notice and/or conduct/have tests conducted. RISE reports results in the visitation report and/or testing report.

3.7 Marking
See section 5
4  Conformity to type based on product examination (Module F)

4.1  General
The procedure entails that the manufacturer takes all necessary measures for ensuring that manufactured equipment conforms to the requirements and that RISE establishes that manufactured equipment conforms to what is stated in EC type examination certificate. For Module F, the manufacturer must have one or more valid EC type examination certificates for the equipment that will be included.

4.2  Applications
The manufacturer applies for assessment of its equipment
A list of the products that will be covered by the review, the quantity involved and, when applicable, the EC type examination certificates that exist.

4.3  Inspection
RISE conducts, or has another conduct, inspections/testing in order to check conformity with type in accordance with the description in EC type examination certificates. Testing is conducted of each piece of equipment or of a number of products that have been selected according to a statistical selection procedure.

4.4  Certificate of Conformity
RISE issues a Certificate of Conformity based on the inspections conducted. The certificate shall contain a list of the equipment that has been approved.

4.4  Marking
See section 5.

4.5  Failed products
In the case of any failed shipment, RISE will take appropriate measures to prevent release to the market. In principle, this means that the products must be destroyed or reworked. A renewed inspection/review shall be conducted following any rework.
5 General conditions

5.1 General
For section 3, more information is available in RISE Terms for review and assessment of management systems as notified body SP INFO 2014:35.

5.2 Marking
The wheel-marking of marine equipment is carried out on the manufacturer's responsibility. In those cases where RISE has participated in its capacity as of notified body, in the modules D-F, RISE ID number as notified body (0402) shall be placed adjoining the wheel-mark. Only the products that comply with the requirements in the Directive may be marked. Misuse of RISE ID number may lead to legal action.

5.3 Certificate
The validity of the certificate is based on continuous compliance with the conditions. Certificates are not transferable. Copies of certificates and associated documents may only be reproduced in their entirety, unless otherwise agreed with RISE.

5.4 Responsibility
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 products marked with the wheel-mark comply with the applicable requirements in the directive, 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.

5.5 Withdrawal of certificate
RISE, either definitely or permanently, can withdraw a certificate if:
- the product no longer meets the set requirements
- errors in the certificate come to light
- demands for continual examination are not met
- the internal examination shows serious shortcomings
- shortcomings in the internal examination are not remedied in the time prescribed
- there are failed results in examination testing in the regulatory examination
- the product is not suitable for its purpose or can cause injury or problems
- changes are made to legislation, regulations or similar.
- the competent authorities or coordinating body for a notified body recommends RISE to do so
- the holder has used the certificate or in connection with products that do not meet the requirements or are not covered by the certificate.
• fees are not paid within the prescribed deadline, the certificate holder is subject to bankruptcy, has gone into liquidation or has transferred the business
• breach of the conditions for the certificate.
If a certificate is withdrawn, the holder shall cancel all reference to the certificate and RISE name and id.no. 0402 in his EC declaration of conformity and marking. The holder may neither refer to the certificate or RISE in advertisements or other publications for the product in question.

5.6 Changes to products, quality systems, organisation
Changes to certified products, see 2.4
Regarding quality systems according to modules D and E, changes to the quality system shall be notified to RISE. Even major organisational changes or other factors which may impact the certificate should be notified.

5.7 Information obligation, confidentiality and access
As a notified body, RISE is in some cases obliged to reveal information on certificates to other notified bodies and competent authorities. RISE informs Swedac about issued certificates as well as refusals, restrictions, suspensions and withdrawals of certificates.

RISE keeps a register of certificate holders, certificates, certified products and certified quality systems, manufacturing sites, validity period for certificates etc. This information may be published, for example, on RISE websites. RISE may provide copies of or publish the certificates.

Regarding certificates issued according to the Directive 2014/90/EU, these are published in the common database, MarED. RISE is also entitled to publicise decisions on the withdrawal of certificates and the misuse of certificates or marking. Other information is classified.

The manufacturer, or its representative, should ensure that RISE, the control body that RISE has approved, or observers (e.g. from the accreditation body) have access to premises and documents that are needed to perform the duties described in the sections 2-4.

5.8 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.

5.9 Fees
Fees are set according to agreement and shall be paid by the certificate holder. Costs for work resulting from deviations in the continuous examination should be paid by the certificate holder. The fees for another examination should only be paid by the certificate holder if the examination results show that the requirements of the certification regulations are not 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 estimated to be completed within a month of the acceptance date, RISE has the right to issue regular (monthly) invoices for costs to date.
5.10 Appeals

Appeals against RISE decisions should be made in writing. Decisions on measures necessary as a result of appeals are taken by the RISE Certification board.