Rules for the EC conformity assessment of interoperability constituents

In force since 01.05.2023

RC/C 23

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2 List of terms and associated definitions

- *Agency* means the European Union of Railway Agency
- *Audit* means a systematic, independent, and documented process for obtaining objective evidence and evaluation it objectively to determine the extent to which the audit criteria are fulfilled.
- Assessment of suitability for use means the process demonstrating whether requirements for suitability for use specified in the relevant TSI relating to an interoperability constituent have been fulfilled.
- *Authorized representative* means any natural or legal person established within the Union who has received a written mandate from a manufacturer or a contracting entity to act on behalf of that manufacturer or contracting entity in relation to specified tasks.
- conformity assessment means the process demonstrating whether requirements specified in the relevant TSI relating to an interoperability constituent have been fulfilled.
- *Essential requirements* mean all the conditions set out in Annex III of the Directive (EU) 2016/797 which must be met by the Union rail system, the subsystems, and the interoperability constituents, including interfaces.
- *Interoperability constituents* means any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the rail system depends directly or indirectly, including both tangible objects and intangible objects.
- *Manufacturer* means any natural or legal person who manufactures a product in the form of interoperability constituents, subsystems, or vehicles, or has it designed or manufactured, and markets it under his name or trademark.
- *Organization* means the Entity who asked for a certification service and on behalf of whom RINA performed the requested activities.
- *Placing on the market* means the first making available of an interoperability constituent on the Union market; *Technical specification for interoperability* (TSI) means a specification adopted in accordance with this Directive by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and ensure the interoperability of the Union rail system.

3 Background and context of this document

This document contains the general procedures applied by RINA Services (railway certification organizational unit) to verify the conformity of railway interoperability components (as described in chapter III of the Directive (EU) 2016/797) to the essential requirements to ensure railway interoperability of those. RINA is Notified Body under the EU Directive 2016/797 listed in NANDO (New Approach Notified and Designated Organizations) EU Information System with registration number 0474.

The following rules and provisions define the request for a certification, the certification achievement, its maintenance, extension, renewal, and a certificate suspension or withdrawal.

At the conclusion (with positive results) of a certification, an EC certificate of conformity will be issued stating:

- the conformity of the component(s) to the essential requirements addressed in the relevant Technical Specification to apply to the component concerned (including any other standard is pointed out within a TSI). In this case such certificate is known as EC certificate of conformity.

RINA Services is a Conformity assessment Body (CAB). RINA is accredited CAB from ACCREDIA (The National Accreditation Body) as:

- Inspection Body (Type A) in railway sector according to ISO/IEC 17020 standard
- Certification Body in railway sector for railway subsystems (including the so – called interoperability components as defined with the corresponding TSI to apply to the railway subsystem concerned)

Certification service is oriented towards all Organizations (intended as Organisation of Organisation or Contracting Entity), and it's not influenced by a membership organization or a specific group. To realize this service RINA will adopt its applicable fees, providing an equity and uniformity implementation. RINA could not accept certification requests by organizations that are or have been subject to restriction, suspension, or disqualification by any Public Authority.

Regarding any other aspect that it is not included within this document, please refer to General terms and conditions for the certification of systems, products, personnel and inspection activities available at the following link: https://scresources.rina.org/resources/Documents/general_contract_conditions.pdf

Certification activities are executed by RINA according to the ISO/IEC 17065, as detailed in Quality Manual and in its related documents.

The Organisation must take the necessary measures to allow RINA's personnel to perform the certification activities in complete safety. Regardless the nature of the performed certification service by RINA or by any other people acting on behalf of RINA within the certification framework, the Organisation acts taking care of any responsibilities that an Employer has towards its employees to meet all the requirements of the applicable and relevant legislation. Normally, during the visit(s), the staff of Organisation must constantly accompany RINA personnel.

The Accreditation Body may require the participation as observer to the relevant certification activities carried out by RINA at any sites should be involved in the certification framework. The main objective is the evaluation that RINA's methods of assessment are in compliance with applicable rules within the accreditation framework.

The participation of any Accreditation Body observer(s) (as relevant as) will be previously agreed between RINA and the Organisation.

4 Procedure for Procedure for 'EC' declaration of conformity or suitability for use

4.1 Introduction

Interoperability components are placed on the market only if they enable interoperability to be achieved within the Union rail system while at the same time meeting the essential requirements.

Member States and the Agency shall consider that an interoperability constituent meets the essential requirements if it complies with the conditions laid down in the corresponding TSI or the corresponding European specifications developed to comply with those conditions. The 'EC' declaration of conformity or suitability for use shall attest that the interoperability constituents have been subject to the procedures laid down in the corresponding TSI for assessing conformity or suitability for use.

Where the TSI so requires, the 'EC' declaration shall be accompanied by:

(a) a certificate, issued by a notified body or bodies, of the intrinsic conformity of an interoperability constituent considered in isolation, to the technical specifications to be met.

(b) a certificate, issued by a notified body or bodies, of the suitability for use of an interoperability constituent considered within its railway environment, particularly in the case of functional requirements concerned.

In order to establish the 'EC' declaration of conformity or suitability for use of an interoperability constituent, the manufacturer or his authorized representative shall apply the provisions laid down by the relevant TSIs.

Where the corresponding TSI so requires, assessment of the conformity or suitability for use of an interoperability constituent shall be carried out by the notified body with which the manufacturer or his authorized representative has lodged the application.

4.2 EC conformity assessment procedure/suitability for use

The procedures for conformity assessment for the interoperability constituents covered by the TSIs shall be chosen among the modules set out in Annex I of the EU Decision 2010/713, in accordance with the following criteria:

a) whether the module concerned is appropriate to the type of interoperability constituent.
b) the nature of the risks entailed by the interoperability constituent and the extent to which conformity assessment corresponds to the type and degree of risk.
c) the need for the manufacturer to have a choice between quality management system and product certification modules set out in Annex I.
d) the need to avoid imposing modules which would be too burdensome in relation to the risks.

The TSI(s) shall specify the modules for conformity assessment to be applied for the interoperability constituents. Where necessary, the TSI(s) may clarify and complement them due to the specificity of the component concerned.

Where the TSIs so require, the procedure for assessment of suitability for use of the interoperability constituents shall be done in accordance with the instructions set out in the module CV set out in Annex I Annex I of the EU Decision 2010/713.

4.3 Conformity assessment process

Whenever RINA will be involved as NoBo within and procedure for establishing an EC declaration of conformity for an interoperability constituent a corresponding conformity assessment process applies considering the following steps:

1) Phase 1: A phase where the Organisation lodges an Application to RINA asking for the execution of a conformity assessment service(s) concerned

2) Phase 2: A Phase where RINA reviews the submitted application asking for any further clarification or request of additional documentation concerning the service to be provided to support the preparation of a suitable tender package. Once the tender has been approved, acknowledged, and accepted by all Parties involved a Contract is established ruling the conformity assessment services to be provided.

3) Phase 3: Following on the finalization of the contracting phase, the evaluation phase starts

4) Phase 4: Once the evaluation is completed (with positive outcomes) the certification decision phase follows.

4.3.1 Phase 1 – Application

An Organisation lodges and application where the following information should be provided:

- the product(s) to be certified.
- the railway standards and/or other normative documents for which the Organisation is seeking certification.
- the general features of the Organisation, including its name and the address(es) of its physical location(s), significant aspects of its process and operations and any relevant legal obligations
- general information concerning the Organisation, relevant to the field of certification for which the application is made, such as the Organisation' activities, its human and technical resources, including laboratories and/or inspection facilities, and its functions and relationship in a larger corporation, if any
- information concerning all outsourced processes used by the Organisation that will affect conformity to requirements; if the Organisation has identified a legal entity/entities for producing the certified product(s) that is different from the Organisation, then the certification body can establish appropriate contractual controls over the legal entity/entities

concerned, if necessary for effective surveillance; if such contractual controls are needed, they can be established prior to providing formal certification documentation .

- all other information needed in accordance with the relevant certification requirements, such as information for initial evaluation and surveillance activities, e.g., the locations where the certified product(s) are produced and contact personnel at these locations
- The adopted certification module for carrying out the certification concerned according to the relevant TSI provision and any further one contained in EU Decision 2010/713
- In case of adoption of QMS – based certification module such application shall also include:
    a) the presence of in force and valid ISO 9001 previous certification covering the QMS concerned
    b) Number of effective personnel involved in the organization function object of the QMS to be assessed and further approved by RINA
    c) Number of the Organization's site where the design and production and testing activities apply and are object and in the scope of the QMS to be approved
    d) the breakdown structure of the project management and the name and address of each involved entity
    e) the documentation concerning the quality management system
- The contact point of the Organisation in charge to maintain relationship with RINA
- A written declaration/declaration that the same application has not been lodged with any other notified body.

In order to facilitate the preparation of the most completed application from the Organization concerned, RINA will submit to the it a questionnaire to fill – in with the main aim to collect the most relevant information for carrying out the assessment of the interoperability constituent concerned.

Once the questionnaire is filled by the Organization and revert to RINA with any additional documentation allowing the understanding of the IC design, manufacturing, installation, and operation, RINA will review all the packages

4.3.2 Phase 2 – Application review

When the Application and any associated documents are received, RINA shall conduct a review on the received Application and the related obtained information to ensure that:

- The information received are complete.
- the information about the Organization and the product is sufficient for the conduct of the certification process.
- any known difference in understanding between RINA and the Organization is resolved, including agreement regarding standards or other normative documents.
- the scope of certification sought is defined.
- the means are available to perform all evaluation activities.
- RINA has the competence and capability to perform the certification activity.

RINA informs Organisation its decisions and provides the necessary information to continue the certification process.

RINA shall decline to undertake a specific certification if it lacks any competence or capability for the certification activities it is required to undertake.

If RINA relies on certification(s) it has already granted to the Organization, or has already granted to other Organizations, to omit any activities, then the certification body shall reference the existing certification(s) in its records. If requested by the Organisation, RINA shall provide justification for omission of activities.

Once the application has been considered as satisfactory and complete RINA will prepare a tender covering the EC conformity assessment to be performed according to the Organization's specifications and requirements. The tender will consist of a financial and a technical proposal and will be submitted to the Organization.

Following – on rounds of tender negotiation and follow -up between RINA and the Organization concerned once the Tender is accepted and approved from all involved Parties a Contract to perform the conformity assessment will be established.

4.3.3 Phase 3 – Evaluation

RINA shall receive the technical documentation from the Organization. The documentation shall make it possible to assess the interoperability component(s) conformity with the requirements of

the relevant TSI(s) to apply. The technical documentation shall specify the requirements of the relevant TSI(s) and cover, as far as relevant for the assessment, the design and operation of the subsystem.

RINA shall ensure all necessary information and/or documentation is made available for performing the evaluation tasks.

In the case of a lacking in the technical documentation or any part/annex of this documentation is not compliant to the relevant rules, the Organization will be duly informed, and the certification process will be suspended until the elimination of found deficiencies.

The evaluation shall be carried out considering:

- the adoption of a suitable certification module for the subsystem concerned according to the TSI(s) provisions
- Following on such adoption the evaluation will be carried out considering the rules and steps to be applied ad contained in the corresponding module.

The TSI(s) shall specify the modules for conformity assessment to be applied for the interoperability constituents. Where necessary, the TSI(s) may clarify and complement them due to the specificity of the component concerned. The list of the allowed modules (involving a NoBo) is the following:

NAME OF THE MODULE	SHORT DEFINITION (EU Decision 2010/713)
MODULE CA1	Internal production control plus product verification by individual examination
MODULE CA2	Internal production control plus product verification at random intervals
MODULE CB	EC-type examination
MODULE CD	Conformity to type based on quality management system of the production process
MODULE CF	Conformity to type based on product verification
MODULE CH	Conformity based on full quality management system
MODULE CH1	Conformity based on full quality management system plus design examination

Table 1 Modules for the procedures for assessment of conformity of interoperability constituents

4.3.3.1 Module CA1

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the interoperability constituent's conformity with the requirements of the TSI.

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, maintenance, and operation of the interoperability constituent.

Wherever applicable, the technical documentation shall also give evidence that the design of the interoperability constituent, already accepted before the implementation of the applicable TSI is in accordance with the TSI and that the interoperability constituent has been used in service in the same area of use.

For each individual product manufactured, one or more tests on one or more specific aspects of the interoperability constituent shall be carried out in order to verify conformity with the type described in the technical documentation and the requirements of the TSI. At the choice of the manufacturer, the tests are carried out either by an accredited in-house body or under the responsibility of RINA chosen by the manufacturer.

RINA shall issue an EC certificate of conformity in respect of the examinations and tests carried out.

4.3.3.2 Module CA2

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the interoperability constituent's conformity with the requirements of the TSI. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, maintenance, and operation of the interoperability constituent.

Wherever applicable, the technical documentation shall also give evidence that the design of the interoperability constituent, already accepted before the implementation of the applicable TSI is in accordance with the TSI and that the interoperability constituent has been used in service in the same area of use.

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals.

All interoperability constituents shall be available for verification in the form of homogeneous lots. A random sample shall be drawn from each lot. All interoperability constituents in a sample shall be individually examined and appropriate tests shall be carried out to ensure the product conformity with the type described in the technical documentation and the requirements of the TSI that apply to it and to determine whether the lot is accepted or rejected.

RINA shall issue an EC certificate of conformity in respect of the examinations and tests carried out.

4.3.3.3 Module CB

EC-type examination may be carried out in either of the following manners:

1) examination of a specimen, representative of the production envisaged, of the interoperability constituent (production type),
2) assessment of the adequacy of the technical design of the interoperability constituent through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the interoperability constituent (combination of production type and design type),
3) assessment of the adequacy of the technical design of the interoperability constituent through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

The manufacturer shall lodge an application for EC-type examination with RINA.

The EC conformity assessment will be carried out by RINA following module CB points 4.1 and 4.2, 4.3, 4.4, 4.5 and 4.6 (as relevant as according to the selected type – examination (1), (2) or (3).

RINA shall draw up an evaluation report that records the activities undertaken and their outcomes in accordance with the selected type -examination. Without prejudice to its obligation's vis-à vis the notifying authorities, RINA shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

Where the type meets the requirements of the TSI that apply to the interoperability constituent concerned, RINA shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

4.3.3.4 Conformity to type based on quality management system of the production process (module CD)

Whenever the TSI so requires for the conformity assessment of the interoperability constituent concerned this module applies in combination with the module CB.

The manufacturer shall operate a quality management system for design, manufacture and final product inspection and testing of the interoperability constituents that will be approved by RINA, and it shall be subject to surveillance.

The manufacturer shall lodge an application for assessment of his quality management system with RINA, for the interoperability constituents concerned. RINA shall assess such application performing audit visit at the relevant sites of the manufacturer where the production process takes place. The excepted audit(s) will be programmed and planned and communicated to the manufacturer concerned.

The quality management system shall ensure that the interoperability constituents are in conformity with the type described in the EC-type examination certificate and comply with the requirements of the TSI that apply to them.

When the manufacturer operates a certified quality management system certified by an accredited certification body, for the manufacturing of the relevant interoperability constituent, the RINA shall take this into account in the assessment. In this case, RINA will make a detailed assessment of quality management system specific documents and records of the interoperability constituent only. RINA shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.

Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in module CD point 3.2 are met, RINA shall issue a quality management system approval to the applicant.

4.3.3.4.1 Surveillance under the responsibility of RINA

RINA shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality management system and shall provide the manufacturer with an audit report.

The frequency of the periodic audits shall be at least once every 2 years.

When the manufacturer operates a certified quality management system, RINA shall take this into account during the periodic audits.

4.3.3.5 Conformity to type based on product verification (module CF)

Whenever the TSI so requires for the conformity assessment of the interoperability constituent concerned this module applies in combination with the module CB.

RINA shall carry out appropriate examinations and tests in order to check the conformity of the interoperability constituents with the approved type described in the EC-type examination certificate and with the requirements of the TSI.

The examinations and tests to check the conformity of the interoperability constituents with the requirements of the TSI shall be carried out, at the choice of the manufacturer either:

- by examination and testing of every interoperability constituent as specified in module CF point 4 or,
- by examination and testing of the interoperability constituents on a statistical basis as specified in module CF point 5.

4.3.3.6 Conformity based on full quality management system (module CH)

The manufacturer shall operate a quality management system for design, manufacture and final product inspection and testing of the interoperability constituents that will be approved by RINA, and it shall be subject to surveillance.

The manufacturer shall lodge an application for assessment of his quality management system with RINA, for the interoperability constituents concerned. RINA shall assess such application performing audit visit at the relevant sites of the manufacturer where the production process takes place. The excepted audit(s) will be programmed and planned and communicated to the manufacturer concerned.

The quality management system shall ensure compliance of the interoperability constituents with the requirements of the TSI that apply to them.

When the manufacturer operates a certified quality management system certified by an accredited certification body, for the design and manufacturing of the relevant interoperability constituent, RINA shall take this into account in the assessment. In this case, RINA will make a detailed assessment of quality management system specific documents and records of the interoperability constituent only. RINA shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.

Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in module CH point 3.2 are met, RINA shall issue a quality management system approval to the applicant.

4.3.3.6.1 Surveillance under the responsibility of RINA

RINA shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality management system and shall provide the manufacturer with an audit report.

The frequency of the periodic audits shall be at least once every 2 years.

When the manufacturer operates a certified quality management system, RINA shall take this into account during the periodic audits.

4.3.3.7 Conformity based on full quality management system plus design examination (module CH1)

CH1 is a module where:

1) The manufacturer shall operate a quality management system for design, manufacture and final product inspection and testing of the interoperability constituents that will be approved by RINA, and it shall be subject to surveillance.

2) The adequacy of the technical design of the interoperability constituents shall have been examined by RINA.

The manufacturer shall lodge and application for:

- Assessment of his quality management system

- Examination of the design

RINA shall assess the QMS application performing audit visit at the relevant sites of the manufacturer where the production process takes place. The excepted audit(s) will be programmed and planned and communicated to the manufacturer concerned.

When the manufacturer operates a certified quality management system certified by an accredited certification body, for the design and manufacturing of the relevant interoperability constituent, RINA shall take this into account in the assessment. In this case, RINA will make a detailed assessment of quality management system specific documents and records of the interoperability constituent only. RINA shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.

Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in module SH1 point 3.2 are met, RINA shall issue a quality management system approval to the Organization.

4.3.3.7.1 Surveillance under the responsibility of RINA

RINA shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality management system and shall provide the manufacturer with an audit report.

The frequency of the periodic audits shall be at least once every 2 years.

When the manufacturer operates a certified quality management system, RINA shall take this into account during the periodic audits.

4.4 Phase 4 – NoBo certification decision

Once the evaluation phase is concluded with positive outcomes in terms of conformity to relevant TSIs to apply to the interoperability constituent concerned, a decision about to grant or not to grant a certification is taken. It applies according to ISO/IEC 17065 clause 7.6.

RINA will adopt the certification decision considering the use of a Committee (a group of people) named Railway Certification Committee (RCC) who applies in the role of Decision Maker according to ISO/IEC 17065 clause 7.6.

RINA shall notify to the Organisation of a decision not to grant certification and shall identify the reasons for the decision.

In case of granting a certification, RINA will prepare the accompanying documentation as described in the Directive (EU) 2016/797 Annex IV clause 2.4 and clause 3.3.

4.4.1 Conditions for maintaining a certification

During the period of the certificate validity for the subsystem concerned, the Organisation who has granted a certification by RINA, shall maintain the conditions that allowed delivering the certificate itself.

During the period of certificate validity, the Organisation shall perform all required activities (as relevant as according to the certification module applied) to maintain the released certification. RINA can access to the Organisation requesting any additional checks and examinations should be required to demonstrate maintenance of the released certification.

4.4.1.1 Modifications to an interoperability constituent holding a certificate

4.4.1.1.1 Type – examination certificate (CB)

The manufacturer shall inform RINA that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the interoperability constituent with the requirements of the TSI or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC-type examination certificate. Only those examinations and tests that are relevant and necessary to the changes shall be performed.

4.4.1.1.2 Quality management approval (CD, CH and CH1)

The manufacturer shall keep RINA that has approved the quality management system informed of any intended change to the quality management system having impact on the interoperability constituent, including changes of quality management system certificate.

RINA shall evaluate any proposed changes and decide whether the modified quality management system will continue to satisfy the requirements referred to in point 3.2 (module CD, module CH and module CH1) or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4.4.1.1.3 Module CF

In case of modification of a constituent holding an EC certificate of conformity issued applying a module CF such certificate will be withdrawn.

4.4.1.1.4 Design examination certificate (module CH1)

The manufacturer shall keep RINA that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the requirements of the TSI or the conditions for validity of the certificate until the expiry of the validity of the certificate. Such modifications shall require additional approval — from RINA that issued the EC design examination certificate — in the form of an addition to the original EC design examination certificate. Only those examinations and tests that are relevant and necessary to the changes shall be performed.

4.4.2 Condition for extending a certificate

An Organisation, who received a Certificate by RINA, in order to extend the certification to:

- other IC(s) of the product family, produced in in the same establishment/,
- or to already certified IC(s), which must be produced in another factory
- or after some modifications to entire product family
- must produce a request indicating Certificate extremes, as showed in the attached fac-simile

RINA performs necessary checks and then it releases the required certificate extension, as Additional document of the first certificate. This Additional document will have the number code and also, where applicable, the same deadline date of first certificate regardless the issued date.

4.5 Certification validity and renewal

4.5.1 Validity (NoBo EC certificate of conformity)

The validity of the issued certification by RINA covering a railway subsystem applies considering the provisions stated in the relevant TSI to apply, in the EU Decision 2010/713 and considering what stated in the NB rail RFU – STR – 060 available at the following link: http://nb-rail.eu/co/nbrail/RFU/RFU-STR-060%20Validity%20of%20Certificates.pdf

4.5.2 Renewal of the certification

An issued certification can be renewed following the provisions stated in Chapter 3.6.1.1consiering the adopted certification module.

4.5.3 QMS recertification

Whenever RINA adopts a QMS – based certification module (CD, CH and CH1) a recertification applies at the end of QMS certification cycle of two years from the previous released approval. Before expiring that period, a recertification audit applies to the Organisation relevant sites of interest for the development of the subsystem concerned.

4.5.4 Certification suspension

For any valid reasons RINA may suspend the validity of an issued certificate.

Apart from the cases expressly referred to in the Rules or Guidelines, RINA may suspend validity of the certificate whenever it has reason to believe that the system (or product or personnel) no longer complies with the requirements of the reference standard document, as well as in the following cases:

a) failure to adapt to the modifications in the rules or standard document communicated by RINA
b) failure to accept periodic or supplementary audits requested by RINA
c) failure to communicate modifications to the Organization's organisation, or to the characteristics of the subsystem subject to certification
d) failure to provide information about convictions, legal proceedings, complaints, or controversies concerning the legally binding requirements of the product or system or technical and professional requirements of the certified personnel.
e) failure to pay the fees due to RINA within the deadlines indicated in the contract.
f) if the Organisation improperly uses or makes public the obtained certificate
g) if the essential requirements are not met

The suspension shall be notified to the Organisation by written notice (certified e-mail or equivalent method) which will set out the conditions for the reinstatement of the certification and established the deadline to execute them.

During the suspension period, the Organization's certification is temporarily invalid.

If the Organization wants to interrupt the certification, it must send to RINA a suspension request, indicating the reasons and the period for which the suspension is required.
RINA communicate to the Organization the acceptance of the suspension request and the suspension period, after an evaluation of indicated reasons which caused the suspension request.

The Certification is restored after an assessment of suspension conditions. Assessments could include an inspection to verify any found deficiencies have been eliminated and the compliance with the relevant regulations is restored.

During the suspension period the Organisation/Applicant cannot use the certification about interested subsystem.

The maximum of suspension period is 180 days. If conditions, which caused the suspension, are not eliminated before this period, it will be applied a withdrawal procedure.

4.5.5 Withdrawal of a certification

The issued Certificate could be withdrawn due to serious not compliances to the relevant requirements object of the certification.

In particular, the withdrawal could be applied in the following cases:

a) There's a relevant not compliance with requirements after a performed assessment.
b) no adequate action after the suspension of the certification validity.
c) after a certification suspension any remedial actions, required by RINA, are not adopted before 15 days from the request.
d) the Organisation does not respect the economic and financial terms with RINA
e) there's a relevant no compliance with essential requirements, in particular regarding safety.
f) the Organisation considers itself not able to adapt to new regulation whenever applicable regulation/requirement modifications are requested.
g) a component within a subsystem is no longer produced.

The withdrawal is notified to the Organization by a written note with a return request for the Conformity Certificate, considering 15 days from the withdrawal communication; the withdrawal also makes the certificate impossible to use and prescribes actions that the Organization must provide for subsystem already in stock or on trade or under installation.

The Organisation/Applicant, that received a withdrawal notification, could produce a new certification request after 180 days from the withdrawal.

The certification withdrawal is also regulated by chapter 16 of the General terms and conditions for the certification of systems, products, personnel and inspection activities available at the following link: https://scresources.rina.org/resources/Documents/general_contract_conditions.pdf.

4.5.6 Certification waiver

In case of certification waiver, the Organization concerned will send a formal communication to RINA before certificate deadline.

4.6 Publication

RINA must periodically publish relevant information concerning:

a) 'EC' certificates for suitability for use issued or refused.

4.7 Modification of certification requirements

RINA will notify to the Organisation the modifications that were eventually performed on the certification requirements.

RINA will define the date within which subsystems will have to be adapted to the updated/new requirements considering modifications consequences on the essential requirements the necessity not to accidentally promote on marketing a particular Organisation or a component.

Assessments and tests will be performed on a prototype and/or samples, taken from the production/installation, within the defined date by RINA, in order to verify the compliance with the new regulation.

At the good ending of assessments RINA will issue an updated Certificate in compliance with the new certification requirements.

If the Organisation does not provide to modify subsystems in accordance with new certification requirements of the evaluations are not positive within the defined date, the certificate will be withdrawn.

If the Organization wants to adopt a new certification requirement(s), it must notify to RINA this decision before it could apply modification to subsystems.

4.8 Management of claims

The Organization could claim against RINA decisions, explaining its reasons, within 30 days from the date of notification of the decision in question

RINA will evaluate the claim within 60 days from its submission.

Any costs related to the claim are under the Organization's responsibility, excluding cases base on appropriate reasons.

4.9 Management of impartiality

RINA shall be responsible for the impartiality of its certification activities and shall not allow commercial, financial, or other pressures to compromise impartiality.

RINA shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, from its relationships, or from the relationships of its personnel.

If a risk to impartiality is identified, RINA shall be able to demonstrate how it eliminates or minimizes such risk. RINA shall have a mechanism for safeguarding its impartiality.