Rules for the EC verification of railway subsystems (fixed and mobile)

In force since 01/05/2023

RC/C22

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2 List of terms and associated definition

- *Applicant* means a natural or legal person requesting an authorisation, be it a railway undertaking, an infrastructure manager or any other person or legal entity, such as a manufacturer, an owner or a keeper; for the purpose of Article 15, the 'applicant' means a contracting entity or a manufacturer, or its authorized representatives; for the purpose of Article 19, the 'applicant' means a natural or legal person requesting the Agency's decision for the approval of the technical solutions envisaged for the ERTMS track-side equipment projects.
- "*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.
- *Certificate of verification* means the certificate delivered for a subsystem either by the notified body or by the designated body regarding the verification of conformity respectively with relevant TSIs or with relevant national rules from the design stage to the acceptance stage before the subsystem is placed on the market or in service and which covers verification of the interfaces of the subsystem in question with the system into which it is incorporated.
- *Certification decision* is the process to approve a decision for certification connected to a DeBo/NoBo/OIF conformity assessment service.
- *Conformity assessment* means the process demonstrating whether specified requirements relating to a product, process, service, subsystem, person or body have been fulfilled.
- *Conformity assessment body* means a body that performs conformity assessment activities including calibration, testing, certification and inspection.
- "EC" *certificate of verification* means the certificate delivered for a subsystem by the notified body regarding solely the verification of conformity with relevant TSIs.
- *Intermediate Statement of Verification* means the document established either by the notified body selected by the applicant, in the case of TSI requirements, or by a designated body, in the case of requirements stemming from national rules, which registers the results of a stage of the verification procedure (even of a certain part of a railway subsystem)
- *Interoperability* means the ability of a rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance.
- *Organization* means a group of people and facilities with an arrangement of responsibilities, authorities and relationships
- *Renewal* means any major substitution work on a subsystem or part of it which does not change the overall performance of the subsystem

- *Subsystems* means the structural or functional parts of the Union rail system, as set out in Annex II
- *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.
- *Upgrading* means any major modification work on a subsystem or part of it which results in a change in the technical file accompanying the 'EC' declaration of verification, if that technical file exists, and which improves the overall performance of the subsystem.

3 Background of this document

The present Rules explains general procedures applied by RINA Services (railway certification organizational unit) to verify the conformity of railway subsystems (fixed and/or mobile) as defined in the Annex II of the Directive (EU) 2016/797 (as amended) to the essential requirements to ensure railway interoperability of the subsystem concerned. 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, a certificate of verification will be issued stating:

- the conformity of the subsystem to the essential requirements addressed in the relevant Technical Specification to apply to the railway subsystem concerned (including any other standard is pointed out within a TSI). In this case such certificate is known as EC certificate of verification.
- The conformity of the subsystem to the relevant and applicable National (Technical) rules to apply for railway sector. In this case such certificate is known as certificate of verification that is issued by a Designated Body.

RINA is also Designated Body under the Directive (EU 2016)/797 according to the following table.

Railway Subsystem / Country	CCO	CCT	ENE	INF	RST
Denmark	X	NA	NA	NA	X
Greece	X	X	X	X	X
Ireland	X	X	X	X	X
Italy	X	X	X	X	X
Switzerland					X

Table 1 EU countries where RINA is DeBo

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 is 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

RINA executes certification activities according to ISO/IEC 17065, as detailed in Quality Manual and in its related documents.

In respect to the railway subsystem structural area to consider and its associated certification framework, RINA will follow rules and provisions stated in:

- The relevant TSI(s)/NTR(s) to apply to the subsystem concerned
- The EU Decision 2010/713 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability

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), RINA personnel must be constantly accompanied by the staff of Organisation.

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 EC verification procedure for subsystems

4.1 Introduction

'"EC" verification' means a procedure carried out by the Organisation within the meaning of Article 15 of the Directive (EU) to demonstrate that the requirements of the relevant Union law and any relevant national rules relating to a railway subsystem have been fulfilled and the subsystem for its further authorization to be placed in service or on the market.

The EC verification has the main goal to produce (as main outcome) an EC Declaration of verification for the railway subsystem concerned.

An Organisation shall establish the 'EC' declaration of verification of a subsystem. The Organisation shall declare on his sole responsibility that the subsystem concerned has been subject to the relevant verification procedures and that it satisfies the requirements of relevant Union law and any relevant national rule.

To establish the 'EC' declaration of verification necessary for placing on the market and placing in service referred to in Chapter V, the Organisation shall request the conformity assessment body or bodies that it has selected for that purpose to apply the 'EC' verification procedure set out in Annex IVof the Directive (EU) 2016/797.

The EC verification procedure consists of the following processes:

1) Verification by reference to TSI(s)
2) Verification by reference to the relevant National (Technical) Rules (NTR)

This is without prejudice to the obligations of the Organization to comply with the other applicable legal acts of the Union and any verifications by the conformity assessment bodies required by the other rules/acts to apply on the subsystem concerned.

The verification by reference to TSIs is the procedure whereby a Conformity Assessment Body (named as Notified Body) checks and certifies that the subsystem complies with the relevant technical specifications for interoperability.

The verification by reference to the relevant National (Technical) Rules (NTR) is the procedure whereby a Conformity Assessment Body (named as Designated Body) checks and certifies that the subsystem complies with the relevant NTR for implementing the essential requirements in the Directive (EU) 2016/797 to apply to the subsystem concerned.

The task of the NoBo or DeBo responsible for the 'EC' verification procedure of a subsystem shall begin at the design stage and cover the entire manufacturing period through to the acceptance stage before the subsystem is placed on the market or in service. It shall, in accordance with the relevant TSI/NTR(s), also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated.

The Organisation shall be responsible for compiling the technical file that is to accompany the 'EC' declaration of verification. That technical file shall contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents. It shall also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance. The technical file must contain the files compiled by each of Conformity Assessment Body (DeBo and/or NoBo) involved in the development of an EC verification procedure for the subsystem concerned.

The NoBo or DeBo may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem.

If the relevant TSI(s) allow, the notified body may issue certificates of verification for one or more subsystems or certain parts of those subsystems.

The main outcomes of a conformity assessment process carrier out by a NoBo or a DeBo are the following:

1) DeBo:

a) Certificate of verification
b) A DeBo File accompanying the certificate of verification
c) Any other DeBo technical data relevant for the assessment of the conformity of the subsystem with the relevant national rules
d) ISV: Whenever (at the request of the Organisation) the verification may be done for parts of a subsystem or may be limited to certain stages of the verification procedure.
e) In case letter d) applies a DeBo File accompanying the ISV concerned and any other DeBo technical data relevant for the assessment of the conformity of the subsystem or part of it with the relevant national rules in a certain verification stage.

2) NoBo:
a) EC Certificate of verification
b) A NoBo File accompanying the certificate of verification
c) Any other NoBo technical data relevant for the assessment of the conformity of the subsystem with the relevant TSI(s)
d) ISV: Whenever (at the request of the Organisation) the verification may be done for parts of a subsystem or may be limited to certain stages of the verification procedure.
e) In case letter d) applies a NoBo File accompanying the ISV concerned and any other NoBo technical data relevant for the assessment of the conformity of the subsystem or part of it with the relevant TSI(s) in a certain verification stage

4.1.1 Use of Intermediate statement of verification (ISV)

RINA may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem. At the request of the Organisation the verifications may be done for parts of a subsystem or may be limited to certain stages of the verification procedure. In these cases, the results of verification may be documented in an 'intermediate statement of verification' (ISV) issued by RINA. The ISV must provide reference to the TSIs/NTR(s) with which the conformity of the subsystem has been assessed. The Organisation may apply for an ISV for any part into which it decides to split the subsystem. Each part shall be checked at the following stages:

- overall design.
- production: construction, including, civil-engineering activities, manufacturing, constituent assembly and overall adjustment.
- final testing.

The Organisation may apply for an ISV for the design stage (including the type tests) and for the production stage for the whole subsystem or for any part into which the Organisation decided to split it.

The verification procedure applied by RINA is described in the Annex IV of the Directive 2016/797.

4.1.2 EC verification in case of renewal upgrading

In case of EC verification of a subsystem subject to an upgrade of renewal RINA shall receive the evidence that the works on the subsystem concerned has been considered as renewal or upgrade of the subsystem. According to the Directive (EU) Articles 18 and 21 the corresponding National Safety Authority of the Member State in which such subsystem will be authorized shall approve such works as renewal or upgrading.

If such approval is granted to the Organization, it will be shows to RINA for moving forward with the requested EC verification procedure.

In case of granting a certification, the certificate of verification shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the notified body during the verification procedure.

4.2 DeBo/NoBo conformity assessment process to issue a certification

Whenever RINA will be involved as DeBo and/or NoBo within and EC verification procedure 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 conformity assessment service(s) concerned (DeBo, NoBo or both).

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 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 designated body or notified body.

RINA may submit to the Organisation a form containing the previous bullets to be filled in by the Organisation.

Once the request is filled by the Organisation and revert to RINA with any additional documentation allowing the understanding the subsystem design, construction, installation and operation, and it must be sufficient to check the subsystem compliance to TSI/NTR requirements.

4.4 Phase 2 – Application review

RINA shall conduct a review on the received Application and the related obtained information to ensure that:

- the information about the Organisation and the product is sufficient for the conduct of the certification process.
- any known difference in understanding between RINA and the Organisation 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.

When the Application and any associated documents are received and after their preliminary examination to verify the completeness, RINA communicates to the 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 Organisation, or has already granted to other Organisations, 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.

4.5 Phase 3 – Evaluation

RINA shall receive the technical documentation from the Organisation. The documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant TSI(s)/NTR(s). The technical documentation shall specify the requirements of the relevant TSI(s)/NTR(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 Organisation 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)/NTR(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.

4.5.1 Approval of the Organization's QMS (module SD and moduleSH1)

The conformity of a railway subsystem to the requirements of the relevant TSI(s)/NTR(s) may be evaluated considering the use of a QMS – based certification module (Module SD or module SH1). RINA will carry out such evaluation according to the selected certification module with the goal to issue an approval on such QMS. The quality management system shall ensure compliance of the subsystem with the requirements of the relevant TSI(s)/NTR(s) that apply to it.

With the module SD the NoBo main goal is the approval of the Organization's quality management system covering production, final subsystem inspection and testing of the subsystem.

With the module SH1 main goal is the approval of the Organization's quality management system covering design, manufacture and final subsystem inspection and testing of the subsystem concerned.

The QMS evaluation applies considering that the relevant Organization's application for assessment of the quality management system referenced in Chapter 3.3 of this document.

When the Organisation operates a certified quality management system certified by an accredited certification body for the design, manufacturing and final testing of the relevant subsystem, 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 subsystem 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 in the adopted QMS – based certification module are met, RINA shall issue a quality management system approval to the Organisation.

4.5.2 Type – examination (module SB)

The type – examination shall be applied according to the provisions stated in the SB certification module.

The use of a type – examination shall be carried out in combination with the certification module SD or SF according to TSI indication for the subsystem object of the EC verification procedure

4.5.2.1 Design – type examination (module SB)

RINA examines the technical documentation and supporting evidence to assess whether the technical design of the subsystem is adequate to fulfil the requirements of the relevant TSI(s)NTR(s).

Where a design review is requested in the relevant TSI(s)/NTR(s), RINA examine design methods, the design tools and the design results to assess compliance with the requirements of the relevant TSI(s)/NTR(s).

4.5.2.2 Production – type examination (module SB)

RINA verifies that the specimen(s) have been manufactured in conformity with the requirements of the relevant TSI(s)/NTR(s) and with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant

TSI(s)/NTR(s), harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards.

RINA carries out appropriate examinations and tests, or have them carried out, to check whether, where the Organisation has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly.

RINA carries out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the Organisation meet the corresponding requirements of the relevant TSI(s)/NTR(s).

RINA agrees with the Organisation on a location where the examinations and tests will be carried out.

As rule of thumb, test samples must be randomly chosen by RINA from the regular production.

4.5.3 Design examination (module SH1)

Some certification modules require the use of a design examination.

RINA shall examine the application mentioned in Section 3.3 of this document. Such Application may contains as supporting evidence for assessing the design the results of tests (including those in operational conditions) carried out by the appropriate testing body of the Organisation, or by another testing body on his behalf and under his responsibility.

The application shall make it possible to understand the design, manufacture, maintenance and operation of the subsystem, and to assess the conformity with the requirements of the TSI(s)/NTR(s) that apply to it.

RINA shall examine the application and where the design meets the requirements of the relevant TSI(s)/NTR(s) that apply to the subsystem it shall issue an EC design examination certificate to the Organization.

4.5.4 Verification based on product verification (module SF)

RINA shall follow the application of SF certification module and associated rules as describe in EU Decision 2010/713.

All subsystems shall be individually examined and appropriate tests set out in the relevant TSI(s)/NTR(s), harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EC-type examination certificate and with the requirements of the relevant TSI(s)/NTR(s). In the absence of such a harmonised standard, the appropriate tests to be carried out shall be decided between the applicant and the notified body concerned.

RINA shall agree with the Organization the locations where the tests will be carried out and shall agree that final testing of the subsystem and, whenever required in the relevant TSI(s)/NTR(s), tests or validation under full operating conditions, are carried out by the applicant under direct supervision and attendance of RINA.

RINA shall have entrance for testing and verification purposes to production workshops, locations of assembly and installations, and where appropriate, prefabrication and testing facilities in order to carry out its tasks as provided for in the relevant TSI(s)/NTR(s).

4.5.5 Verification based on unit verification (Module SG)

RINA shall follow the application of SG certification module and associated rules as describe in EU Decision 2010/713.

RINA may take into account evidence of examinations, checking or tests that have been successfully performed, under comparable conditions by other bodies or, when this is specified by the relevant TSI(s)/NTR(s), by (or on the behalf of) the applicant. RINA will then decide as to whether it shall use the results of these checks or tests.

RINA shall agree with the Organisation the locations where the tests will be carried out and shall agree that final subsystem tests and, whenever required in the TSI(s)/NTR(s), tests under full operating conditions, are carried out by the Organisation under direct supervision and attendance of RINA.

In all cases, RINA keeps the responsibility of final results of the examinations, tests and checks.

4.5.6 Evaluation of testing

Whenever the evaluation of testing will be part of the RINA conformity assessment process the associated assessment procedures are referred to modules as defined in the Decision 2010/713/EC and in relevant TSI(s)/NTR(s) (as relevant as according to the module's scope). In the absence of TSI(s)/NTR(s) it will be applied standards and specifications, set by the competent authority.

RINA will follow the provisions of NB Rail RFU 022 available at the following link http://nb-rail.eu/co/nbrail/RFU/RFU-STR-022%20Test%20laboratories.pdf for Organization's consultation.

4.5.7 Management of derogations with an EC verification procedure

When the subsystem in the scope of the EC verification is subject to a TSI derogation(s) procedure according to Article 7 of Directive (EU) 2016/797, the Organisation shall inform the RINA.

The Organisation shall also provide RINA with a precise reference to the TSI(s) (or their parts) for which the derogation is requested.

The Organisation shall communicate to RINA the outcome of the derogation procedure.

4.6 Phase 4 – DeBo/NoBo certification decision

Once the evaluation phase is concluded with positive outcomes in terms of conformity to relevant TSIs or NTR(s) to apply to a subsystem 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 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.

4.6.1 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.

The Organisation shall keep the 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 relevant TSI(s)/NTR(s) 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.

The Organisation shall keep RINA that has approved the quality management system informed of any intended change to the quality management system having impact on the subsystem design, manufacture and final inspection, testing and operation, as well as of any 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 stated in the relevant QMS – certification module applied or whether a reassessment is necessary.
It shall notify the Organisation of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

The Organisation shall inform RINA that holds the technical documentation relating to the type of examination certificate of all modifications to the approved type that may affect the conformity of the subsystem with the requirements of the relevant TSI(s)/NTR(s) 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.

During the validity period, the Organisation must keep available to RINA the sample or samples which were performed by tests. RINA could allow the sale of these samples if its relative appropriate documentation is maintained and allows, in every moment decided by RINA, to verify the series production compliance with the tested sample or samples.

Production checks shall perform regularly and/or randomly, in RINA opinion, by testing Subsystem samples which are taken from the production line (as a finished or semi-finished status) or installed; consequently, the Organisation must authorize RINA to take necessaries samples to perform established surveillance.

Besides RINA reserves the right to carry out additional inspections to the Organisation/Applicant in the case of relevant claims or report about the certificated component compliance with relative requirements.

In order to perform above mentioned controls during normal working, it must be guaranteed to RINA technicians a free access to manufacturing rooms and installations/lines and archives of the certificated subsystem.

The Organisation shall maintain a record of any claims relating to certified Subsystems and of the actions taken to remedy; these are also available to RINA technicians

4.6.1.1 Modifications to a railway subsystem holding a certificate

4.6.1.1.1 Design examination certificate (SH1 – certification module)

The Organisation shall keep the 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 relevant TSI(s)/NTR(s) 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.

4.6.1.1.2 Quality management system approval (SH1 and SD certification module)

The Organisation shall keep RINA that has approved the quality management system informed of any intended change to the quality management system having impact on the subsystem design, manufacture and final inspection, testing and operation, as well as of any 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 stated in the relevant QMS – certification module applied or whether a reassessment is necessary.

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

4.6.1.1.3 Type examination certificate (SB certification module)

The Organisation shall inform RINA that holds the technical documentation relating to the type of examination certificate of all modifications to the approved type that may affect the conformity of the subsystem with the requirements of the relevant TSI(s)/NTR(s) 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.

4.6.1.1.4 Other certifications (SG and SF certification module)

With the use of other certification modules (like SG and SF) alone or in combination with other whenever a modification on the subsystem concerned applies the associated certificate of verification have to be withdrawn and a new one issued.

4.7 Condition for extending a certificate

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

- other subsystems of the product family, produced in in the same establishment/,
- or to already certificated subsystems, 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.

4.8 Certification validity and renewal

4.8.1 Validity (NoBo EC certificate of verification)

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

4.8.2 Validity (DeBo certificate of verification)

RINA applies *mutatis mutandis* the provisions contained 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

4.8.3 Renewal of the certification

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

4.8.4 QMS recertification

Whenever RINA adopts a QMS – based certification module (SD and SH1) 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.

4.8.5 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.

4.8.6 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 is 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 is 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, which 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.

4.8.7 Certification waiver

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

4.9 Publication

RINA must periodically publish relevant information concerning:

a) requests for verification and ISV received.
b) request for assessment of conformity and suitability for use of ICs.
c) ISV issued or refused
d) certificates of verification and 'EC' certificates for suitability for use issued or refused.
e) certificates of verification issued or refused.

4.10 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.

4.11 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.

4.12 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.