Rules for the EC Certification of Railway Interoperability Constituents

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RINA Services Società per Azioni
Via Corsica, 12 - 16128 GENOVA
Tel. +39 010 53851 - Fax: +39 010 5351237
E-mail info@rina.org - Web www.rina.org

Technical rules

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1 GENERALITY

1.1

The present Rules explains general procedures followed by RINA to verify the conformity and the suitability of the railway interoperability Constituents according to Directive 2008/57/EC art. 2 point f) and its further modifications, related to the interoperability of high speed and conventional community Railway System, implemented in Italy by D.Lgs 191 of 8th October 2010. About these evaluation activities, RINA has got notification by Ministry of Infrastructure and Transport. RINA is the Notified Body n°.0474.

These Rules define the procedures for certificate request, achievement, maintenance, extension and renewal, and the possible certificate suspension or revocation.

At the good ending of the conformity evaluation, a Certificate is issued declaring the conformity of the Constituent to Technical Interoperability Specifications, to theirs recalled regulations and to Norms indicated by the Applicant and accepted by RINA.

RINA is an accredited Body for the Inspection activities according to UNI CEI EN ISO/IEC 17020 and for the product certification according to UNI CEI EN 45011.

Certification service is oriented towards all applicant Manufacturers and it's not influenced by a membership organization or group. To realize this service RINA will adopt its applicable tariffs, providing an equity and uniformity implementation. RINA could not accept certification requests by organizations or its production or activities have undergone, have been subject to restriction, suspension or disqualification by a Public Authority.

Regarding what is not included in this document, look at the "CONDIZIONI GENERALI DI CONTRATTO PER LA CERTIFICAZIONE DI SISTEMI, PRODOTTI E PERSONALE" on website www.rina.org.

1.2

Inspection and product certification activities are executed by RINA according to UNI CEI EN ISO/IEC 17020 and UNI CEI EN ISO/IEC 17065, as deeply detailed in Quality Manual and in its related documents.

1.3

In relation to the product type and its production process, RINA follows what indicated in the Technical Specifications for Interoperability and in the Decision 2010/713/UE to specify applicable procedures to issue the certification and its relative maintenance.

1.4

The Applicant must take the necessary measures to allow RINA's Inspectors to perform the inspection activities in complete safety. Regardless the nature of the performed service by RINA or other people acting on behalf of RINA, the Applicant acts towards the above mentioned technical people, taking charge of any responsibilities that an employer has towards its employees in order to meet all the requirements of the applicable legislation. Normally, during the visits, RINA staff must be constantly accompanied by the staff of Applicant.

1.5

The Ministry of Transport and the Accreditation Body may require the participation of its observers to audits carried out by RINA at Manufacturer sites or at testing laboratories, to verify that RINA's methods of evaluation are in compliance with applicable rules.

The participation of the above mentioned observers will be previously agreed between RINA and the Manufacturers.

2 DEFINITIONS

2.1

Interoperability: means the ability of a rail system to allow the safe and uninterrupted movement of

trains which accomplish the required levels of performance for these lines. This ability depends on all the regulatory, technical and operational conditions which must be met in order to satisfy the essential requirements..

2.2

Subsystem: the result of the railway system division as specified in the attachment II of D.Lgs 191 of 8th October 2010. These subsystems, which have to fulfill some essential requirements as specified in the attachment III of D.Lgs 191 of 8th October 2010, could be a structural item as infrastructures, energy, command-control, signaling and rolling stock, or a functional item as the operation and management traffic, the maintenance, telematics applications for passengers and freight.

2.3

Interoperability Constituent: 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.The concept of a 'constituent' covers both tangible objects and intangible objects such as software;

2.4

Manufacturer: any subject, which has the responsibility of commercial distribution of an interoperability constituent or Subsystem or Subsystem in EC, and which could issue the EC conformity or suitability declaration to put in service.

2.5

Applicant: it could be the contracting entity or the manufacturer, or the relative authorized representative established in the Community.

It could be any entity, public or private, which orders the design and the construction or the design or construction, renovation or renewal of an interoperability constituent or Subsystem. This entity may be a railway undertaking, an infrastructure manager or a keeper, or the concession holder responsible for the put in service of a project or a manufacturer.

2.6

Essential requirements: set of conditions, described in Annex III of D. Lgs. 191 of 8th October 2010, have to be satisfy by railway system, subsystem and interoperability constituents, including interfaces.

2.7

Technical Specifications for Interoperability (TSI): means a specification adopted in accordance with this Directive by which each subsystem or part subsystem is covered in order to meet the essential requirements and ensure the interoperability of the rail system;

2.8

Notified Body: means a Body which is responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the 'EC'procedure for verification of the subsystems;

2.9

Certification: is the procedure by which a third party, such as a Notified Body, verifies that a product complies with specific requirements by providing a written statement about the success of this verification.

2.10

Certificate: is a written declaration, produced by a third party, attesting the successful completion of a certification process.

2.11 : EC Declaration of Conformity: is the declaration, issued by the Manufacturer under its own **responsibility and it complies with rules of this Regulation, attesting that a specified interoperability constituent complies with one or plus European specifications.**

2.12 EC Declaration of Suitability of Use**: is the declaration, issued by the Manufacturer under its own responsibility and it complies with rules of this Regulation, attesting that a specified**

interoperability constituent, considered within its railway environment, is able to provide and maintain requirements and performance, identified by technical specifications of a functional nature, that the constituent must comply.

3 PROCEDURE TO ISSUE A CERTIFICATION

3.1 Request

3.1.1
The applicant has to submit an appropriate request to RINA, in order to start the Certification process, using the Form annexed to this Rules.

3.1.2
The request shall contain the following data:
a) Name of the Applicant and its address;
b) Manufacturing plants for the Component;
c) Phone and fax number and aventually email address;
d) The responsible person for relations with RINA;
e) Component description;
f) Modules to be applied, as defined in Decision 2010/713/UE and in referenced TSI.
g) Reference standards for the component.

3.1.3
In the request it also shall be explained that the applicant will provide to:
a) comply with the requirements contained in these Rules and in the document entitled "CONDIZIONI GENERALI DI CONTRATTO PER LA CERTIFICAZIONE DI SISTEMI, PRODOTTI E PERSONALE", in current edition and available on website www.rina.org;
b) give the necessary assistance to RINA during audits pay fees relating to rights and costs of certification activities, regardless of the outcome of investigations carried out by RINA.

3.1.4
Documents, prescribed by rules, are in attachment with the request. Generally, the provided documentation shall allow understanding the subsystem design, construction, installation and operation, and it must be sufficient to check the component compliance with TSI requirements.

3.1.5
When the request and its annexes are received and after their preliminary examination to verify the completeness, RINA communicates to the Applicant its decisions and provides the necessary information to continue the certification process.

3.2 Certificate Assessments

3.2.1
The annex documentation is evaluated to verify the compliance with rules of this Regulation.

3.2.2
In the case that the documentation is incomplete or any part/annex of this documentation is not compliant, the applicant will be informed and the certification process will be suspended until the elimination of found deficiencies.

3.2.3
At the good ending of assessment, RINA communicates to the applicant the name of the technical responsible for certification process; the Applicant may object to the technician designation, explaining its reasons.

3.2.4
RINA investigations are defined in the implementing rules of the modules as defined in the Decision 2010/713/CE and in the relevant TSI.

3.2.5

If RINA considers all conditions for obtaining certification are not fulfilled, it will be sent to the applicant a report, in which eventual no conformities and observations are indicated and must be removed or corrected by the applicant, with a deadline for performing actions.

3.2.6

If the applicant does not provide to remove or correct the found no conformities before the defined time, RINA will communicate to applicant the request renunciation.

3.2.7

When no conformities have been removed or correct within the deadline, RINA will repeat the above investigations with the deemed necessary extent.

3.2.8

At the good ending of the above mentioned assessments, a Certificate related to the examined component will be issue, as specified in Chapter 4.

The layout and content of the Certificate are detailed in the applicable Technical Specifications for Interoperability.

3.3 Evaluation of Company Quality Management System

If the application of a module, which includes a prior approval of the Company Quality System and its supervision, is required, RINA will operate for the module in question as required by Technical Specifications for Interoperability.

3.4 Checks and tests

Evaluation procedures, performed by RINA, are referred to modules as defined in the Decision 2010/713/EC and in relevant TSI. In the absence of TSI it will be applied standards and specifications, set by the competent authority.

3.4.1 Design examination

Specifications, and if it's necessary also the component design for which the certification was required, must be submitted to a prior examination by RINA to verify the compliance with referred regulation.

The applicant must submit to RINA the documents that are considered relevant for the evaluation of the correct manufacture or installation.

Generally, as applicable, following documents must be submitted to RINA, in the number of copies and in the detail as required in each case:

a) Manufacturing drawings;
b) Calculation notes;
c) Test reports performed in laboratories;
d) Manufacturing / Installation procedures;
e) Test and calculation procedures;
f) Plans for quality control;
g) Description of any modification, performed on subsystem versions already certified;
h) Other documents considered necessary by RINA.

3.4.2 Type tests

3.4.2.1

Representative production samples must be tested and investigated, in order to verify the component compliance with the normative relevant documents.

3.4.2.2

A detailed type test program, if it is not already defined by the relevant legislation, must be provided by the Applicant to RINA in order to be agreed.

3.4.2.3

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

3.4.2.4

Any prototype samples, specially manufactured for testing activities, shall be made with the same means and assembled in accordance with the same manner of regular production. RINA reserves the right to carry out surveillance during the above mentioned prototype samples production. Some tests, in RINA opinion, can be later repeated on samples, chosen from the regular production, in order to confirm the results obtained on prototype samples. If a prototype cannot be realized,, and when permitted by the TSI reference, RINA will consider the possibility to evaluate the conformity, regarding aspects related to tests themselves, by checking design calculations produced by suitably qualified staff.

3.4.2.5

Tests must be performed (it is a cost for the Applicant) in an independent laboratory, which is in compliance with UNI CEI EN ISO/IEC 17025 for the specific field, or in others laboratories, included the Applicant's one, after a RINA assessment, proving that the laboratory is qualified to carry out specified and defined tests by RINA procedure (qualified laboratories). Tests will be performed in a qualified laboratory at RINA attention.

If tests are performed in another qualified laboratory, RINA reserves the right to take part or not at the provision and/or performance tests.

3.4.3 Series production assessment

3.4.3.1

Series production assessment is included when the Applicant must ensure compliance with the type.

3.4.3.2

Assessment can be performed over all produced subsystems or over a statistical sample. In both of case, selected subsystems shall be available to verify the conformity to TSI requirements and to carry out any tests.

4 Certificate production

At the good ending of the assessments, as mentioned at point 3 of this document, and following the CTFer discussion, RINA will produce a specific certificate in accordance with the kind of component, the provided request and the relevant regulation.

4.1

For the certification of interoperability of Components, in accordance with the Directive 2008/57/CE and following modifications and with Decision 2010/713/UE, possible Modules to be used are:

- Internal production control (Module CA)
- Internal production control plus product verification by individual examination (Module CA1)
- Internal production control plus product verification at random intervals (Module CA2)
- EC-type examination (module CB)
- Conformity to type based on internal production control (Module CC)
- Conformity to type based on quality management system of the production process (Module CD)
- Conformity to type based on product verification (Module CF)
- Conformity based on full quality management system (Module CH)
- Conformity based on full quality management system plus design examination (Module CH1)

4.2

RINA, when it is required by relevant TSI, prepares the technical documentation that is attached with the issued certificates.

4.3

If it requires by the Customer, RINA could issue a product Certificate in compliance with UNI EN 45011.

5 CONDITIONS TO PRESERVE THE CERTIFICATE VALIDITY

During the period of certificate validity, the Manufacturer, who has obtained a Certificate by RINA, shall maintain conditions that allowed delivering the certificate itself. The Manufacturer is fully

responsible of equality maintenance between the component and its relative samples, tested as point 3.4.

5.1

During the period of certificate validity, the Manufacturer must perform all required tests on production, with modalities and regularities previously defined in agreement with RINA.

5.2

During the above mentioned period, the Manufacturer 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.

5.3

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 Manufacturer must authorize RINA to take necessaries samples to perform established surveillance.

5.4

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

5.5

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.

5.6

The Manufacturer 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

6 CONDITIONS FOR CERTIFICATE EXSTENSION

6.1

The Manufacturer, who received a Certificate by RINA, in order to extend the certification to:

- other components of the product family, produced in the same factory,
- already certificated components, which must be produced in another factory

must produce a request indicating Certificate extremes, as showed in the attached fac-simile

6.2

RINA performs necessary checks and then it releases the required certificate Addition, as. This Addition to the original Certificate will have a new number code and will recall the original Certificate.

6.3 Component modifications

6.3.1

The Manufacturer, who received a certificate by RINA, must communicate to RINA about any modification that it intends to perform on an already certificated Component.

6.3.2

After the impact evaluation of suggested modifications on Component compliance with relevant rules and TSI, RINA could require a partial or total repetition of performed evaluation during certification phase.

6.3.3

After the assessment phase, RINA could extend the certificate validity to modified Component or issue a new certificate, withdrawing the previous one. The choice is made after the impact evaluation on the Component.

6.3.4

The Manufacturer/Applicant can not use RINA's certificate for modified Subsystem until it don't receive by RINA the certificate extension or renewal. RINA undertakes to notify to the manufacturer its decision, writing it within 30 days from notification of the proposed changes.

7 CERTIFICATION VALIDITY AND RENEWAL

TSI define each certificate duration, depending on the used module.
RINA reserves the right to reduce the certificate validity duration, explaining reasons to the Customer. The deadline must be indicated on the certificate.

7.1 Renewal

At deadline if the certificate holder requires it, it will have to be performed the following iter:

- The applicant submits an extension request, by a written declaration explaining that no modifications are performed or providing a technical document about no product modification.
- After this declaration RINA shall issue a report related to the renewal with the new deadline.
  - Technical specification for interoperability requires "if modifications which are defined at paragraph 6.3 are not performed, the validity of an expiring certificate could be extended for an additional period of validity. The applicant delivers the extension request by a written declaration explaining that any modifications were not performed; without contrary information, RINA allows an extension for another validity period, as mentioned ad paragraph 5. This procedure can be repeated and other evaluation activities are not planned."
  - New certificates will be issued with the same number of the expiring certificate and they will show the first emission date, the currently emission date and the new deadline.

If the Manufacturer intends to extend the dead line of an Addition Certificate, it must be issued an extension both for the original certificate and the supplement. Both of them will have and show the first emission date, the currently one and the deadline.

8 PUBBLICATION BY RINA

RINA will issue and review the list of Manufacturers/Applicant which have obtained the certificate. This list will have the following information:

- Name of the organization
- Subsystem or component must to be certificated;
- Certificate deadline.

9 PRIVACY

9.1

RINA guarantees the privacy about all information and documents owned by the Applicant, that RINA's technicians could know during the analyzed activity.

10 SUSPENSION AND RESTORING OF CERTIFICATE VALIDITY

10.1

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

10.2

In particular the suspension, related to a specified period, could be applied in the following cases:

a) If any component is no compliant with samples after RINA's assessments and if this no compliant must be immediately suspended due to its nature.
b) if the component is used in any way not compliant with the TSI requirements
c) Due to a TSI review, other new requirements could change certificate validity conditions.
d) If an interoperability subsystemt, with a EC conformity Declaration, affects the fulfillment of the essential requirements; the suspension could be required by the Ministry of transport, in compliance with art.14 of Directive 2008/57/EC.
e) If the Manufacturer improperly uses or makes public the obtained certificate.

10.3

RINA communicate to the Manufacturer/Applicant its decision by a written notification, defining the period within which the Manufacturer must undertake to provide the necessary corrective actions to restore the certification validity.

A copy of the communication shall send to competent authority, represented by the Ministry of Transports.

10.4

If the Manufacturer/Applicant 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 Manufacturer the acceptance of the suspension request and the suspension period, after an evaluation of indicated reasons which caused the suspension request.

10.5

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 regulations is restored.

10.6

During the suspension period the Manufacturer/Applicant can not use the certification about interested subsystem.

10.7

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.

11 CERTIFICATION WITHDRAWAL

11.1

The issued Certificate could be withdrawn due to serious no fulfillments.

11.2

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

a) There's a relevant no 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 Manufacturer does not respect the economic and financial terms with RINA
e) there's a relevant no compliance with essential requirements, in particular regarding the safety;
f) the Manufacturer considers itself not able to adapt to new regulation when applicable regulation/requirement modifications are performed;
g) the component is no longer produced.

11.3

The withdrawal is notified to the Manufacturer/Applicant 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 Manufacturer must to provide for subsystem already in stock or on trade or under installation.

11.4

RINA provides to communicate to the competent authority, represented by the Ministry of transport, the withdrawal.

11.5

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

11.6

The certification withdrawal is also regualted by chapter 14 of "CONDIZIONI GENERALI DI CONTRATTO PER LA CERTIFICAZIONE DI SISTEMI, PRODOTTI E PERSONALE" in current edition and

available on website www.rina.org.

12 CERTIFICATION RENUNCIATION

The Applicant could send a formal communication to RINA before certificate deadline; it's included the

13 CLAIMS

13.1
The Manufacturer/Applicant could claim against RINA decisions, explaining its reasons, within 30 days from the date of notification of the decision in question

13.2
RINA will evaluate the claim within 60 days from its submission.

13.3
Any costs related to the claim are under the Manufacturer's responsibility, excluding cases base on appropriate reasons.

14 MODIFICATION OF STANDARD REQUIRMENTS

14.1
RINA will notify to the Manufacturer the modifications that were eventually performed on standard documents and regulation which could be applied to certificated constituents.

14.2
RINA will define the date within which subsystems will have to be adapted to new regulations, considering: modifications consequences on safety, security and environment and the necessity not to accidentally promote on marketing a particular manufacturer or a component.

14.3
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.

14.4
At the good ending of assessments RINA will issue a new modified Certificate in compliance with the new regulation.

14.5
If the Manufacturer/Applicant does not provide to modify constituents in accordance with new regulation or assessments are not good within the defined date, component certificate will be withdrawn.

14.6
If the Manufacture/Applicant wants adopt a new regulation edition, it must notify to RINA this decision before it could apply modification to subsystems on manufacturing; then the above mentioned procedure will be performed, but the new document date will be chosen by the Manufacturer itself.

15 PERSONAL DATA PROCESSING

See capter 13 "Informativa ai sensi del D.Lgs 30/6/2003, n.196" of "Condizioni generali di contratto per la certificazione di sistemi, prodotti e personale" in current edition and available on website www.rina.org.

16 TERMS AND CONDITIONS

16.1
About terms and conditions provisions, which are defined in the RINA document "Condizioni generali di contratto per la certificazione di sistemi, prodotti e personale" in current edition and available on

wbsite www.rina.org , will be applied.

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RINA Società per Azioni
Via Corsica, 12 - 16128 GENOVA
Tel. +39 010 53851 - Fax: +39 010 5351555
E-mail info@rina.org - Web www.rina.org
