



Regulation for the issuance of the Conformity Certificate to technical regulations relating to the functional safety of products and systems.

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

Technical regulations

Regulation for the issuance of the Conformity Certificate to technical regulations relating to the functional safety of products and systems.

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CHAPTER 1 - GENERAL

1.1

This Regulation describes the procedures followed by RINA for the Certification/Inspection of products/systems according to the reference technical standards related to the functional safety (see paragraph 1.8).

Access to the Certification is open to all Organizations and is not conditioned by their belonging or not to any Association or Group.

1.2

The activities of RINA described in this Regulation apply to industrial products/systems for which compliance with the whole, or specific parts, of the life cycle of the reference standard is required (see paragraph 1.8) including, for systems, the installation, configuration, use and maintenance phases and for shelf products the production phase.

1.3

For a given product/system, RINA issue a functional safety assessment report and the relative Conformity Certificate to the reference standard(s) (see paragraph 1.8). The Certificate is issued only if the design assessment has a positive result and the product/system tests are executed in correct way and their results are positive (see section 3.4).

1.4

Within the scope of these Regulations, RINA does not provide consultant services to Organizations.

1.5

The Accreditation Body may request the participation of its observers in the assessment processes carried out by RINA, to check that the evaluation methods adopted by RINA comply with the requirements of the reference legislation(s) (see paragraph 1.8). The participation of such observers shall be agreed in advance between RINA and the Organisation. If the Organization does not give consent to the participation, the certificate will not be issued during the first certification phase. In the presence of an existing certificate, the validity of the certificate is suspended until the consent for verification is given, for a maximum period of 3 months. After 3 months, in the absence of the consent, the certification is revoked. The methods of assessment used by the Accreditation Bodies are reported in special regulations and / or communications / circulars available on his websites. The Organization must make available to the Accreditation Body the documentation that RINA has taken as a reference during previous audits.

1.6

RINA is an accredited body for inspection activities in accordance with the CEI UNI EN ISO / IEC 17020 standard and for product certification in accordance with the CEI UNI EN 17065 standard, therefore the inspection activities and those relating to the certification of a product are carried out by RINA, in accordance with the requirements of these standards as described in detail in the Quality Manual and related documents.

1.7

The Organization must take the necessary measures so that RINA personnel can carry out any visits in complete safety. Regardless of the nature of the service provided by RINA staff or other persons acting on their behalf, the Organization assumes towards the RINA technicians any responsibility that an employer has towards its employees to comply with all the conditions of the applicable

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legislation. As a rule, during visits, RINA staff must be constantly accompanied by the Organization's staff.

1.8 – Product Reference Standard

IEC 61508 Series – Functional safety of electrical, electronic and programmable electronic systems for safety applications. (IEC 61508-1:2010, IEC 61508-2:2011, IEC 61508-3:2011)

IEC 61511 Series – Functional safety – instrument safety systems for the process industry sector. (IEC 61511-1:2017, IEC 61511-2:2016, IEC 61511-3:2016)

IEC 62061:2021 – Safety of machinery – functional safety of safety-related electrical, electronic and programmable electronic command and control systems

UNI EN ISO 13849 Series – Safety of machinery – safety-related parts of control systems (UNI EN ISO 13849-1:2016, UNI EN ISO 13849-2:2013)

[Serie UNI EN ISO 25119:2019 - Tractors and machinery for agriculture and forestry — Safety related parts of control systems

Serie ISO 26262:2018 – Road vehicles — Functional safety (part 2, 3, 4, 5, 6, 7, 8, 9, 12)

Serie IEC 62443 - Security for Industrial Automation and Control Systems (IEC 62443-2-1:2010, IEC 62443-2-3:2015, IEC 62443-2-4:2017, IEC 62443-3- 2:2020, IEC 62443-3-3:2013, IEC 62443-4-1:2018, IEC 62443-4-2:2019)

Serie EN 50126:2019 - Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS)

[EN 50128:2011/A1:2020 - Railway Applications - Communication, Signalling and Processing Systems Software for Railway Control and Protection Systems

EN 50129:2018 - Railway applications - Communication, signalling and processing systems - Safety Related Electronic Systems for Signalling

Serie - IEC 62278-2002 - Railway Applications Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS)

IEC 62279:2015 - Railway applications - Communication, signalling and processing systems - Software for railway control and protection systems

IEC 62425: 2007 - Railway applications – Communication, signalling and processing systems – Safety related electronic systems for signalling

CLC/TS 50701:2021 - Railway applications – Cybersecurity

22734:2019 Hydrogen generators using water electrolysis — Industrial, commercial, and residential applications

CHAPTER 2- DEFINITIONS

2.1

"Product Certification: act in which an independent third party declares (with the issue of a Conformity Certificate) that, with reliability, a specific product conforms to one or more regulatory documents.

"Conformity Certificate": certificate issued by an independent third party, which declares that, reliably, a given product complies with one or more regulatory documents.

"Regulatory document": document that specifies the requirements to be met by a product, process or service. The document can be issued as: rule, standard, technical specification, state law, ministerial circular, code of good practice, technical specification, etc.

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"Licensee": is the Organization that designs, manufactures or supplies a product.

"Organization": company, operator, firm, organization or association, legally recognized or not, public or private, which has its own functions and its own administration.

"Product": Equipment including electrical and/or electronic and/or programmable electronic elements and/or application software, used to perform safety functions.

"Applicant": is the Organization that requests RINA to issue the Certificate of Conformity.

"Functional safety": part of the overall safety related to the control system that depends on the proper functioning of the Electronic/ Electrical/Programmable Electronic systems implementing safety functions and other risk reduction measures (see also IEC 61508-4)

"System": Product or set of products installed and properly configured on a specific site to perform the specific security functions of the installation site.

"Security / Cybersecurity" ability of a computer-based system to provide adequate security that unauthorized persons and systems can neither modify the software nor its data nor gain access to the functions of the system, and that this is permitted to authorized persons and systems. prevention from illegal or unwanted penetrations or interference with the correct and intended operation of an industrial automation and control system.

2.2

For any other term used in this Regulation, please refer to to the UNI CEI EN ISO / IEC 17020, 17065, 45020, 17000 and reference documents for product functional safety (see section 1.8).

CHAPTER 3 - ISSUANCE OF THE CONFORMITY CERTIFICATE OF THE PRODUCT/SYSTEM or INSPECTION REPORT

3.1 Request for quotation

The Applicant must submit to RINA a specific request for an offer to obtain the issuance of the Certificate of Conformity and the relative evaluation report of the product / system to the reference standard(s) (see paragraph 1.8). In particular, the Applicant must communicate to RINA:

- (a) name and address of its head office;
- (b) production site of the product/system for which certification of conformity is required;
- (c) System installation site;
- (d) telephone and fax numbers;
- (e) indication of the possible QMS certification of the company (standard and Certification Body);
- (f) description of the product/system subject to certification such as to allow the understanding of the design, construction, installation and operation (in support of this description the applicant may attach adequate documentation);
- (g) reference regulatory document for each individual product and for the system;
- (h) number of people involved in the certification activity.
- (i) any company or consultant engaged by the Organization to perform activities on the design / manufacture / installation / maintenance / distribution of the product and / or drafting of technical documentation relating to the object of the certification.

Based on these indications, after a preliminary examination to verify the completeness of the information provided, a technical/economic offer is formulated by RINA, which will be sent together with these Regulations.

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The information referred to in point (i) allows RINA to manage possible conflicts of interest in the performance of the activity.

In the offer, RINA communicates to the Applicant a Preliminary Assessment Plan including the name of the technical staff in charge of carrying out the necessary checks for the purpose of issuing the Certificate of Conformity of the product / system. The Applicant may object to the preliminary assessment plan or the appointment of the technician team, justifying the reasons. Such objections will be duly considered in the revision of the offer or the Assessment Plan

3.2 Formalization of the order

The Applicant, in case of acceptance of the economic offer sent by RINA, formalizes the request for certification, sending RINA the specific information questionnaire, completed in all its fields.

Upon receipt of the request for certification, RINA sends the Applicant in writing the confirmation of acceptance of the request.

The request for certification and its acceptance by RINA contractually formalize RINA's interventions carried out according to these Regulations.

The start of the project involves a kick-off meeting where the official version of the Assessment Plan is discussed and approved, drawn up in accordance with the requirements of the reference standard.

3.3 Integration of product/system documentation

RINA may also request, for examination, other documents in support of the information received previously, considered important for the purposes of the certification of the product under consideration.

This documentation is assessed to verify its compliance with the provisions of this Regulation and the applicable requirements of the reference standard(s) (see paragraph 1.8).

If the documentation is incomplete or does not comply in any applicable requirement, the Applicant is informed and the certification practice can be extended over time until the deficiencies found are eliminated

3.4 Evaluation process

3.4.1 – Evaluation steps

The certification assessments by RINA consist mainly of:

- (a) evaluation of the FSM (Functional Safety Management) process (section 3.4.2) for the product/system under consideration, through examination of process documentation and audits at production premises and/or installation sites
- (b) examination of the technical documentation, proving the demonstration of the fulfilment of the functional and technical safety requirements (section 3.4.3)
- (c) tests on the product/system for which certification of conformity is required (section 3.4.4).
- (d) preparation of the Evaluation Report in accordance with the requirements of the reference standard (paragraph 3.4.5)

Further details on possible RINA analysis are contained in the product reference legislation(s) (see paragraph 1.8)

3.4.2 - FSM Functional Safety Management

FSM Functional Safety Management applied to the whole lifecycle of the product under consideration shall comply with the applicable requirements of the reference standard(s) (see paragraph 1.8).

The assessment shall include the evaluation of the FSM documents focussing mainly:

- risk analysis process applied during the entire life cycle of the product from initial conception to final use;
- product development process;
- verification and validation processes;

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- manufacturing, installation, use and maintenance processes;
- configuration management process;

To complete the assessment an audit shall be performed at the engineering department, at production site (only if the production is in the scope of the assessment) and at installation sites (only if the installation is in the scope of the assessment).

In case of assessment limited to only some specific phases of the lifecycle, the assessor will firstly identify which are the applicable FSM requirements and finally will limit the assessment only at those requirements.

3.4.3 –Examination of technical documentation

The Organization must submit to RINA, for assessment and approval, the documents that will be judged relevant for the evaluation of the product concerned.

In general, and as applicable, the documents listed below must be submitted to RINA, in the number of copies and in the detail required in each individual case. The following list is given by way of example and will be finalized with the Organization according to the specific product to be certified.

- (a) Quality plans
- (b) Functional and technical safety plan
- (c) Verification Plan
- (d) Validation Plan
- (e) Manufacturing/processing/preparation plans.
- (f) Control and test plans.
- (g) Risk analysis
- (h) Vulnerability analysis
- (i) Specifying Product/System Requirements
- (j) Project/production/installation specifications (the installation phase is for systems only).
- (k) Certifications and safety and security manuals of already certified systems or products
- (l) Descriptive technical reports of the project (hardware and software)
- (m) Construction drawings/ production specifications.
- (n) Calculation notes (e.g. Verification of the achievement of the quantitative safety targets (Safety SIL) (Security SL) and / or qualitative achieved).
- (o) Audit reports
- (p) Validation reports
- (q) Test reports carried out on the system, product.
- (r) Safety manuals
- (s) User and maintenance manuals

The technical documentation of the project, product / system, is examined by RINA expert technicians for the purpose of conformity assessments with the specific requirements of the reference standard applicable to the project.

In case that deficiencies or inconsistencies are found in this documentation, further additions or clarifications will be requested through the issuance of Technical Notes that must be taken into account in the revision of the technical documentation.

3.4.4 Product/system tests

3.4.4.1 – General requirements

The product/system must be subjected to the tests and inspections deemed necessary to verify the complete conformity of the product/system with the reference standards (see paragraph 1.8) and with the technical documentation assessed.

In particular, the tests and controls required by the reference standards must be carried out, in the number and in the manner established by it.

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3.4.4.2 Test Sites

The factory tests must be carried out (at the expense of the Organization) in an independent laboratory accredited according to the UNI CEI EN ISO / IEC 17025 standard for the specific test and / or in the laboratory of the Organization, after that RINA assess that it is suitable for the tests to be executed and that the personnel involved is competent and independent from the design unit and the project management ones of the Organization.

RINA technicians, in the case of test performances at non-accredited laboratories, will attend the execution of a subset of tests conducted by the Organization with an adequate instrumental set during one or more test sessions.

In the case of factory tests carried out at an accredited laboratory, RINA reserves the right to participate or not in some test sessions.

The compliance of the product / system, its configuration and installation and the adequacy of the laboratory will be verified on occasion of special visits to the factory and in the field. The tests at the installation site are essentially tests of system configuration and integration of the product under consideration with any other products / systems present on site and with which the system under certification must interact. Also for these types of tests, RINA technicians will be present at the execution of a subset of tests conducted by the Organization with an adequate instrumental set during one or more test sessions.

RINA must be informed in advance of all test sessions planned by the Organization both at the laboratory and at the installation site.

3.4.4.3 Re-use of previous tests and verifications

Where the product tests have already been evaluated by RINA in a previous assessment process, RINA may decide not to carry out all or part of the tests and to reuse the results of previous tests session after assessing their applicability to the product concerned.

3.4.5 Assessment reports and certificates of conformity

At the end of the assessment process referred to in the previous paragraphs, an Assessment Report is issued to the Organization drawn up in accordance with the applicable requirements of the reference standard and, if the outcome of this report is positive, after a positive review of the entire practice by the Decision Maker, the relative certificate of conformity is issued.

3.5 Management of non-conformities in relation to the reference standards

In the presence of major findings, the certification process is suspended until their complete resolution, within six months or at the request of the Organization, RINA may carry out an additional verification aimed to evaluate the correct application of the proposed corrective actions and the maintenance of the technical and organizational conditions already accepted; at the end of this verification, the certification process shall be resumed. The aforementioned time limits may be changed if the Organization gives a reasoned request.

In case of product / systems in which are still open some minor findings considered, by the assessment team, acceptable to a safe use of the product / system through the identification and implementation of appropriate mitigation measures at procedural level, the certification process can carry on. The mitigation measures shall be listed and classified as mandatory for the safe use of the system / product in the assessment report and in the conformity certificate.

RINA, agree with the applicant, can stop the assessment process at any stage if a final negative result is evident. In this case RINA charge the times and expenses incurred up to that moment. The Organization that wishes to continue with the certification of RINA must submit a new request and repeat the certification process.

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CHAPTER 4 - VALIDITY OF THE CERTIFICATE

The expiring date of the certificate is established at the contractual stage according to the specific nature of the product concerned and its context of use.

The validity of the certification is subject to the persistence of the conditions that allowed the granting of the certification itself. However, RINA reserves the right to verify the persistence of the conditions, on a case-by-case basis, through inspection visits or other means at its discretion.

CHAPTER 5 - CHANGES TO THE PRODUCT/SYSTEM

5.1

The Licensee must notify RINA of any changes he intends to make to the product/system for which he has obtained the Certificate of Conformity by submitting a new application for the certification of the new product/system as per chapter 3.

5.2

RINA may request the repetition, in whole or in part, of the assessment activities referred to in Chapter 3.4.

RINA may extend the validity of the conformity certificate to the modified product if the assessment activities repeated have positive result.

CHAPTER 6 - CONFIDENTIALITY

6.1

RINA guarantees the confidentiality of all information and documents owned by the Applicant of which its staff may become aware during relations with the same, and of all communications between RINA and the Applicant.

CHAPTER 7 - CONTRACTUAL CONDITIONS

7.1

For the contractual conditions, the provisions contained in the RINA Regulation "General conditions of contract for the certification of systems, products, personnel and for inspection activities" apply, in the edition in force, available on the website www.rina.org.

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English version

[RINA Services Joint Stock Company](#)

[Via Corsica, 12 - 16128 GENOVA](#)

[Phone +39 010 53851 - Fax: +39 010 5351555](#)

[E-mail info@rina.org](mailto:info@rina.org) - [Web www.rina.org](http://www.rina.org)

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