Regulation for the Independent Safety Assessment in the railway domain (Voluntary field)

In force since 19/03/2023

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1 General

1.1 Overview

This Regulation describes the procedures followed by RINA Services, Railway Certification Organizational Unit (RINA hereinafter) for the Independent Safety Assessment (ISA) of products/systems according to the reference technical standards related to the railway safety (see section 1.2.1).

The ISA process is the specific certification process considered by this regulation. "ISA" and "certification" are used as synonymous in this regulation.

Access to the ISA is open to all Applicants and is not conditioned by their belonging or not to any Association or Group. RINA could reject ISA requests received from Applicants that are or have been subject to restriction, suspension, or disqualification by any Public Authority.

ISA is a third-party evaluation process aimed *to determine whether the system/product meets the specified safety requirements and to form a judgement as to whether the system/product is fit for its intended purpose in relation to safety* (see [EN50126-1]).

The ISA process is usually performed by RINA as a Type A Inspection activity, according to the [17020] requirements. Where needed, e.g. requested by the Applicant, by the final customer, local rules, etc., the ISA process is performed by RINA as a Product Certification activity, according to the [17065] requirements.

The ISA activities (document inspection, on-site inspections, audits, test witnessing, test) described in this Regulation apply to railway, metro, light rail transit products/systems for which compliance with the whole, or specific parts, of the life cycle of the applicable reference standards is required (see section 1.2.1).

The [17065] gives requirements for product, process and service certification bodies, where "product" is the output of a process. In this regard, the [17065] "product" can represent any of the possible items to be submitted for ISA according to the CENELEC standards: system, subsystem, product, referring to the hierarchical breakdown of a system, and/or Generic Product (GP), Generic Application (GA) and Specific Application (SA), referring to the foreseen levels of characterization of a product, where Generic Product and Generic Application are items designed to be further characterized/ specialized to be used in many applications, while a Specific Application is a specific specimen, as adapted, configured, installed and meant to be put into operation. For example:

- GP: a safe computing platform (HW, operating system, digital I/O SW)
- GA: safe computing platform plus software implementing e.g.: 1) ERTMS/ETCS onboard European Vital Computer functions (EVC) or 2) trackside interlocking functions
- SA: EVC GA-1 of previous bullet, configured for (e.g.) the ETR1000 train (length, weight, brake performance, etc.) and installed, or GA-2 configured for (e.g.) Bologna station (exactly the signals, track circuits, points etc.) and installed.

GP and GA do not include final configuration and installation on field (may include a pilot case). Configuration, installation, operation and maintenance are considered just concerning the related instructions and advices that shall be included by the manufacturer in the related manuals. All the above shall be clarified in the offer, in the contract, in the ISA report and in the certificate (where issued).

SAs include final configuration and installation on field but usually do NOT include operation and maintenance. Operation and maintenance are usually considered just concerning the related instructions and advices that shall be included by the manufacturer in the related manuals. All the

above shall be clarified in the offer, in the contract, in the ISA report and in the certificate (where issued).

If the ISA activities are concluded with positive results, as reported in the ISA report, the related certificate of conformity to the reference standard(s) (see section 1.2.1) can be issued.

RINA is responsible for the impartiality of its certification activities and shall not allow commercial, financial or other pressures to compromise impartiality. The RINA strategy for ensuring impartiality is described in section 7.

The Accreditation Body may request the participation as observer in the ISA activities carried out by RINA at any site included in the ISA scope, to check that the evaluation methods adopted by RINA comply with this regulation and, therefore, with the requirements of the reference standards (see section 1.2.1). The participation of the Accreditation Body's observers shall be agreed in advance between RINA and the Applicant. If the Applicant denies the consent without a justification that is considered acceptable by the Accreditation Body, the ISA process cannot be concluded with positive results and no certificate can be issued. In presence of an existing and still valid certificate issued by RINA, the validity of the certificate is suspended until the issue is resolved (the consent is given by the Applicant or their justification is accepted by the Accreditation Body) for a maximum period of 6 months, after which the certificate is withdrawn. The methods of assessment used by the Accreditation Body are reported in special regulations and/or communications / circulars available on their websites.

RINA is a conformity assessment body accredited by ACCREDIA (the Italian Accreditation Body) as:

- Body for the Inspection (Type A) according to the [17020] standard
- Body for the Certification of Product/Service/Process according to the [17065] standard

RINA's inspection and certification activities are carried out by RINA, in accordance with the requirements of the above standards, as described in detail in the RINA Certification Quality Manual and related documents.

The Applicant 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 Applicant assumes towards the RINA technicians any responsibility that an employer has towards its employees to comply with all the conditions of the applicable local legislation and Applicants' internal rules, including HSE rules. As a general rule, during visits, RINA staff must be constantly accompanied by the Applicant's staff.

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

1.2 Reference standards

Reference standards for the ISA activities described in this regulation are reported below. The applicable version is the latest valid at the date of this regulation, including amendments.

1.2.1 Railway safety standards

1.2.1.1 European (CENELEC) standards

[EN50126-1] EN 50126-1:2017; Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 1: Generic RAMS Process

[EN50126-2] EN 50126-2:2017; Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 2: Systems Approach to Safety

[EN50128] EN 50128:2011/A1:2020/A2:2020; Railway Applications - Communication, signalling and processing systems - Software for railway control and protection systems

[EN50129] EN 50129:2018; Railway Applications - Communication, signalling and processing systems - Safety related electronic systems for signalling

[EN50159] EN 50159:2010/A1:2020; Railway applications - Communication, signalling and processing systems - Safety-related communication in transmission systems

[EN50657] EN 50657:2017; Railway Applications - Rolling stock applications - Software on Board Rolling Stock

[EN50716] EN50716:2023; Railway Applications - Requirements for software development

Note 1: the CENELEC standards are the railway sector specific application of IEC 61508 "Functional Safety of electrical, electronic and programmable electronic (E/E/PE) safety-related systems".

Note 2: The reference standards listed above are included in the scope of RINA's accreditations except for the [EN50657] and [EN50716], both very similar to the [EN50128]. The [EN50657] is the on-board equivalent of the [EN50128], RINA has applied for extension of the accreditation and the process in on-going. The [EN50716], november 2023, merges, improves and supersedes [EN50128] and [EN50716]. RINA will apply for accreditation ASAP.

1.2.1.2 International standards

The international standards listed below are based on the related CENELEC standards.

[62278] IEC 62278:2002; Railway applications - Specification and demonstration of reliability, availability, maintainability and safety (RAMS)

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

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

1.2.2 Requirements for the ISA activities

[17020] ISO/IEC 17020:2012; Conformity assessment - Requirements for the operation of various types of bodies performing inspection

[17065] ISO/IEC 17065:2012; Conformity assessment Requirements for bodies certifying products, processes and services

[17025] ISO/IEC 17025:2017; General requirements for the competence of testing and calibration laboratories

2 Terms, definitions and abbreviations

2.1 Terms and definitions

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

"**Audit**": systematic, independent and documented process for obtaining objective evidence and evaluation it objectively to determine the extent to which the audit criteria are fulfilled.

"**Certification decision**": the process to approve a decision for certification connected to a conformity assessment service.

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

"**Conformity assessment**": the process to assess (check) whether specified requirements relating to a product, process, service, subsystem, person or body have been fulfilled.

"**Conformity assessment body**": body that performs conformity assessment activities.

"**Independent Safety Assessment**": process to determine whether the system/product meets the specified safety requirements and to form a judgement as to whether the system/product is fit for its intended purpose in relation to safety (EN 50126-1:2017). It is the specific conformity assessment addressed by this regulation.

"**Inspection**": examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.

"**Organization**": group of people and facilities with an arrangement of responsibilities, authorities and relationships, e.g.: company, operator, firm or association, legally recognized or not, public or private, which has its own functions and its own administration.

"**Product**": collection of elements, interconnected to form a system, a subsystem or an equipment, in a manner which meets the specified requirements (EN 50126-1:2017). A product is the result of a process (IEC 17065:2012). The CENELEC standards classify product into three types:

- "Generic Product": product independent of applications, fulfilling predefined boundary conditions, interfaces and functionality (EN 50126-1:2017). The product is designed to be applicable to different classes of applications. Analyses are carried out within an operational context which is application-independent. E.g.: safe computing platform.
- "Generic Application": product designed to be suitable for a class of application. Analyses are carried out within an operational context which is application-dependent. Often consisting in generic product(s) adapted/customized/specialized. E.g.: safe computing platform with interlocking functions added (interlocking GA).
- "Specific Application": product designed for a specific application, including its physical implementation at the installation site. Often consisting in generic product(s) and/or application(s) configured for a specific application site. E.g.: interlocking GA configured and installed at Bologna station (Bologna station interlocking SA).

"**Process**": set of interrelated or interacting activities which transforms inputs into outputs (IEC 17065:2012).

"**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, etc.

"**Safety**": freedom from unacceptable risk (EN 50126-1:2017).

"**System**": set of interrelated elements (products) considered in a defined context as a whole. It can be considered the highest hierarchical level of a product architecture.

2.2 Abbreviations

CAB	Conformity Assessment Body
GA	Generic Application
GP	Generic Product
ISA	Independent Safety Assessment
QMS	Quality Management System
RAMS	Reliability, Availability, Maintainability and Safety
SA	Specific Application
SMS	Safety Management System

3 Independent Safety Assessment process

3.1 Introduction

The Independent Safety Assessment (ISA) is a process through which the certification body aims to determine whether a product/system meets the specified safety requirements and to form a judgement as to whether it is fit for its intended purpose in relation to safety (definition from EN 50126-1:2017).

The ISA is based on inspection/evaluation of the evidence of the safety, design, verification and validation activities undertaken by the Applicant.

The ISA shall evaluate conformity of the product/system to the applicable requirements of the railway safety standards (see section 1.2.1).

The ISA shall give a judgment on the acceptability of the safety demonstration provided by the Applicant in the safety dossier, i.e. the Safety Case and its supporting safety evidence. This includes checking that possible constraints and limitations are adequately captured, clearly exported to the receiver of the product/system through appropriate "safety-related application conditions" deemed sufficient to control the residual risk. Of course, the assessors can require additional verification and validation activities to the Applicant in support of their safety demonstration.

The main output of an ISA are:

- ISA Plan (sometimes included in the offer)
- Record of the ISA activities and findings
- ISA Report
- ISA Certificate of Conformity or Statement of Conformity (if requested)

The ISA Certificate of Conformity is always supported by the related ISA Report. In some case, just the ISA Report is requested by the Applicant.

Interim ISA Reports and related Interim ISA Statements can be issued, where so requested by the Applicant and foreseen by the contract and the ISA Plan, at intermediate stages of development or for certain parts of the product/system.

The ISA is performed with reference to the applicable requirements of the railway safety standards (see section 1.2.1). This is without prejudice to the obligations of the Applicant to comply with other applicable local/National rules, standards, legal acts, etc..

The ISA process steps are described in the next sections.

3.2 Request for quotation

3.2.1 Application

The Applicant submits a request for quotation to RINA for the ISA of a product/system, with reference to the relevant standard(s) (see section 1.2.1). In particular, the Applicant must communicate to RINA:

- Name and address of its head office;
- Production site of the product/system for which certification of conformity is required;
- System installation site (where applicable, i.e. for SA);
- Contacts of technical, commercial and administrative reference persons;
- Indication of the possible QMS certification of the company (standard and Certification Body);
- In case of adoption of QMS-based certification scheme (see section 3.6) the Applicant shall also include:
    - The presence of in force and valid ISO 9001 certification covering the relevant sites/functions/activities involved in the scope of the requested ISA (e.g. design, verification, validation, production, installation, etc.)
    - Number of effective personnel involved in the Applicant function(s) involved in the product/system submitted for assessment (lifecycle phases, product/system)
    - Number of the Applicant's sites where design, verification, testing, validation, production, installation activities are performed (as applicable in the scope of the product/system submitted for assessment)
    - the breakdown structure of the project management and the name and contacts of each involved professional/entity
    - the documentation concerning the QMS
- Identification and technical description of the product/system submitted for ISA, to allow understanding of its concept, architecture, functions, interfaces, intended use;
- Reference regulatory document for the product/system and for all his parts;
- Number of people involved in the product/system submitted for ISA.
- Any company or consultant engaged by the Applicant 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.

RINA, in particular for new product/system or new Applicant, may submit to the Applicant a form containing the previous bullets to be filled in by the Applicant.

3.2.2 Application review

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

- The information about the Applicant and the product/system is sufficient for the conduct of the ISA process.
- Any known difference in understanding between RINA and the Applicant is resolved, including agreement regarding standards or further normative documents.
- The scope of certification sought is accurately defined. In particular:
    - Type of product/system submitted for ISA (GP, GA, SA)

  - Phases of the lifecycle of the product/system submitted for ISA.
  - Type of evaluation sought for (unit, type, series production, QMS based, etc.)
- The means are available to perform all evaluation activities.
- RINA has the competence and capability to perform the ISA activity.

Based on the above indications, a technical/economic offer is formulated by RINA and sent to the Applicant.

In the offer, RINA communicates to the Applicant a Preliminary ISA Plan, possibly including the name of the technical staff in charge of carrying out the assessment activities, alternatively RINA will indicate in the offer that the names will be communicated after the contract signature. In both cases, the Applicant shall be informed that they have five days of time to reject one or more assessors if there are relevant reasons (relating to impartiality, conflict of interest and/or competence).

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

3.3 Formalization of the order

Once the offer is finalized and accepted by the Applicant, a Contract is established between the parties, formalizing and ruling the mutual commitments, obligations, etc., for the execution of the ISA activities.

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

At the ISA start, a kick-off meeting is held where the official version of the Assessment Plan is discussed and approved, drawn up in accordance with the requirements of the reference standard. Where the product submitted for ISA subject is very well-known, e.g. previous versions were already assessed by RINA, the kick-off is resolved shortly.

3.4 Integration of product/system documentation

RINA may also request, for examination, further documents in support of the information received previously, as relevant for the purposes of the ISA of the product/system 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 section 1.2.1).

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.

What above remains applicable throughout the entire evaluation process described in the next section.

3.5 Evaluation process

3.5.1 General aspects

RINA shall receive the technical documentation from the Applicant. The documentation shall make it possible to assess the product/system conformity with the applicable requirements of the reference standard(s) (see section 1.2.1).

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 Applicant will be duly informed, and the ISA process will be concluded with positive results until the of found deficiencies are eliminated by the Applicant.

The ISA team shall be defined for each ISA process, with the following roles:

Role	Description	Note
Lead Assessor	Has the overall responsibility of all ISA assessment activities.	
Assessor(s)	Supports the lead assessor.	
Technical Reviewer	Review all information and results related to the evaluation. The TR must not be involved in the evaluation process.	
Decision Maker	Person (or group of) responsible for the decision relating to certification. The DM must not be involved in the evaluation process.	[17065] only
QMS Lead Auditor	Has the overall responsibility of all ISA auditing activities.	[17065] only
QMS Auditor	Supports the QMS lead auditor.	[17065] only

Table 1 - ISA Team Main Roles

Where needed (e.g. reduced size ISA projects) and provided that the competence requirements are fulfilled, some of the roles above can be performed by the same person, in the extreme case as follows:

- Decision Maker + Technical Reviewer;
- Lead Assessor + Assessor + QMS Lead Auditor + QMS Auditor

The Applicant shall be informed by RINA that they have five days of time after communication of the ISA team to reject one or more ISA team members, if there are relevant reasons relating to impartiality, conflict of interest and/or competence.

The evaluation shall be carried out considering the adoption of a suitable certification procedure for the product/system (see section 3.6).

The scope of evaluation is often limited and does not cover all the phases of the product/system lifecycle as considered by the reference standard(s) listed in section 1.2.1, in particular [EN50126-1] that spans from concept to decommissioning. The scope of the evaluation (and its limitations) shall be clarified in the ISA Plan, ISA Report and (if issued) ISA certificate and has an impact on the duration of the certificate validity. ISA procedures are described in section 3.6, certificate duration and terms of validity are discussed in section 4.

The evaluation activities described in the next subsections and the procedures described in section 3.6 are applicable both when RINA operates as a Type A Inspection Body ([17020]) and as a Product Certification Body ([17065]). However, it is understood that in the former case, the evaluation is referred to the conformity of the product/system at the date of the inspection conclusion (issue of the ISA Report) while, in the latter case, the evaluation is referred also to the trusted capability of the Applicant to achieve the compliance with requirements.

3.5.2 Evaluation activities

The ISA process performed by RINA consist mainly of:

(a) Evaluation of the Quality and Safety Management System (QMS & SMS) as applied by the Applicant to the product/system under assessment. This activity is performed by RINA through (see section 3.5.3):
   i. examination of the Applicant's QMS processes documentation and
   ii. inspection(s) ([17020]) and/or audits ([17065]) at the Applicant's premises and/or production and/or installation sites.

(b) Examination of the technical documentation of the product/system, that provides the demonstration of fulfilment of the safety requirements (section 3.5.4)

(c) Tests (or Test Witnessing) on the product/system under assessment (section 3.5.5).

(d) Preparation of the ISA report (evaluation report) with respect to the applicable requirements of the reference standard(s) (paragraph 3.5.7)

Further details on possible RINA analysis are contained in the product reference standard(s) (see section 1.2.1).

3.5.3 Evaluation of Quality & Safety Management

QMS and SMS applied by the Applicant to the lifecycle of the product/system under consideration shall comply with the applicable requirements of the reference standard(s) (see section 1.2.1).

The assessment shall include the evaluation of the QMS planning documents and evidence of complete and correct execution of the planned activities, to be reported in the related records and reports.

The evaluation activities should address as a minimum:

- Hazard analysis and risk assessment process applied during the entire life cycle of the product/system
- Product/system development process
- Control of suppliers
- Management of competences
- Verification and Validation processes
- Manufacturing, installation processes (where applicable)
- Configuration management process
- Change control

To complete the assessment inspection(s) ([17020]) and/or audit(s) ([17065]) 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 QMS and SMS requirements and will limit the ISA to those requirements.

3.5.4 Examination of technical documentation

The Applicant must submit to RINA the relevant documents for the evaluation of the product concerned.

A reference example document list is given below. The actual product/system document list will be determined case by case, proposed by the Applicant and to be accepted by RINA that reserves the right to ask for further documentation in the course of the ISA, in case of lacks or incompleteness:

- Quality & Safety plan(s)
- Verification & Validation Plan(s)
- Hazard Identification
- Hazard Analysis & Risk Assessment
- Hazard Log
- Product/System Requirements Specification (including Safety Requirements)
- Architecture Specification
- Certifications and safety and security manuals of already certified parts or previous versions of the product/system
- Detailed design and V&V technical documentation (hardware and software)
- Calculation notes (e.g. FMEA, FTA, Verification of the achievement of qualitative (SIL) and/or quantitative (THR, TFR) safety targets)
- Internal Audit reports
- Manufacturing plans (if manufacturing is in the scope of the ISA)
- Construction drawings
- Production/installation specifications and reports (installation phase for SA only)
- Safety manuals
- User and maintenance manuals
- Validation Test Specification
- Validation Test Report
- Validation Report
- Safety Case

The technical documentation of the product/system is examined by RINA assessors for the purpose of conformity assessments with the relevant requirements of the applicable reference standard.

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 considered by the Applicant that shall implement corrective actions and/or provide clarifications to the assessors' satisfaction.

3.5.5 Product/system tests

3.5.5.1 General requirements

The product/system must be subjected to the tests and inspections deemed necessary to verify the conformity of the product/system with the relevant requirement of the reference standards (see section 1.2.1) and with the technical documentation assessed (requirements specifications, test specifications, etc.).

3.5.5.2 Test Sites

Type tests[1] shall be carried out (at the expense of the Applicant) by an independent laboratory accredited according to the [17025] standard for the specific test and/or in the laboratory of the Applicant, after that RINA assess that it is suitable for the tests to be execute and that the personnel involved is competent and independent from the design unit and the project management ones of the Applicant. Attendance of RINA on tests carried out by accredited laboratories is not necessary, however, RINA reserves the right to participate in some of the test sessions, if deemed relevant for the ISA purpose.

If type tests are performed at non-accredited laboratories, RINA will attend the execution of the tests to verify that tests are performed in accordance with the [17065] requirements. RINA reserves the right to attend all, or a subset, of the tests conducted by the Applicant, with an adequate instrumental set during the selected test sessions.

Other factory tests (e.g. software module testing, functional testing, etc.) must be carried out by the Applicant according to the product/system lifecycle required by the relevant safety standards requirements (see section 1.2.1), in compliance with the requirements there specified regarding competence and independence of the test engineers, testing and verification techniques and strategies to be adopted, validation of test tools, calibration of measurement tools, etc..

The correct execution and the results of the tests performed by the Applicant for demonstrating compliance of the product/system, its configuration and installation and the adequacy of the laboratory resources will be verified by RINA during visits at the Applicant's premises at factory and in the site of application (where included in the scope of the ISA).

Tests at the installation site are mainly tests of system configuration and integration of the product under consideration with any other equipment present on site with which the product/system under ISA must interact. RINA technicians will be present at the execution of all, or a subset of, the tests conducted by the Applicant with an adequate instrumental set during one or more test sessions.

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

3.5.5.3 Re-use of previous tests and verifications

Where some product/system tests were already evaluated by RINA in a previous ISA process, RINA may decide to reuse (all or part of) those tests and the results of the related evaluations, after assessing their applicability to the product under ISA.

3.5.6 Review and certification decision

The Technical Reviewer, person not involved in the ISA (see Table 1), shall review all information and results related to the evaluation. The Technical Reviewer shall not have been involved in the evaluation process.

If the ISA is performed by RINA as Product Certification Body ([17065]), the decision about the certification shall be taken by the Decision Maker, also not involved in the ISA (Technical Reviewer and Decision Maker can be the same person).

[1] ISO/IEC 17065:2012: *Some product, process or service certification schemes may include initial testing or inspection and assessment of its suppliers' quality management systems, followed by surveillance that takes into account the quality management system and the testing or inspection of samples from the production and the open market. Other schemes rely on initial testing and surveillance testing, while still others comprise type testing only*.

3.5.7 ISA reports and certificates of conformity

At the end of the assessment activities described in the previous paragraphs, an ISA Report is issued, drawn up in accordance with the applicable requirements of the reference standard (se section 1.2.1) and, if the outcome of this report is positive, the related certificate of conformity can be issued.

3.6 ISA procedures

3.6.1 General aspects

ISA procedures consist in a sequence of the evaluation activities described in section 3.5.2, organized and characterized for a particular ISA approach, type of product/system, ISA scope.

As anticipated in section 3.5.1, the scope of the ISA is often limited and does not cover all the phases of the a product/system lifecycle as considered by the reference standard(s) listed in section 1.2.1, in particular [EN50126-1] that spans from concept to decommissioning while the ISA scope usually does not go beyond the product/system acceptance phase (that also has a different meaning for GP, GA and SA).

The scope of the ISA (and its limitations) shall be clarified in the ISA Plan, ISA Report and (if issued) ISA certificate and have an impact on the duration of the certificate validity. ISA certificates duration and terms of validity are discussed in section 4.

The CENELEC lifecycle is reported in Figure 1 (extracted from [EN50126-1]).

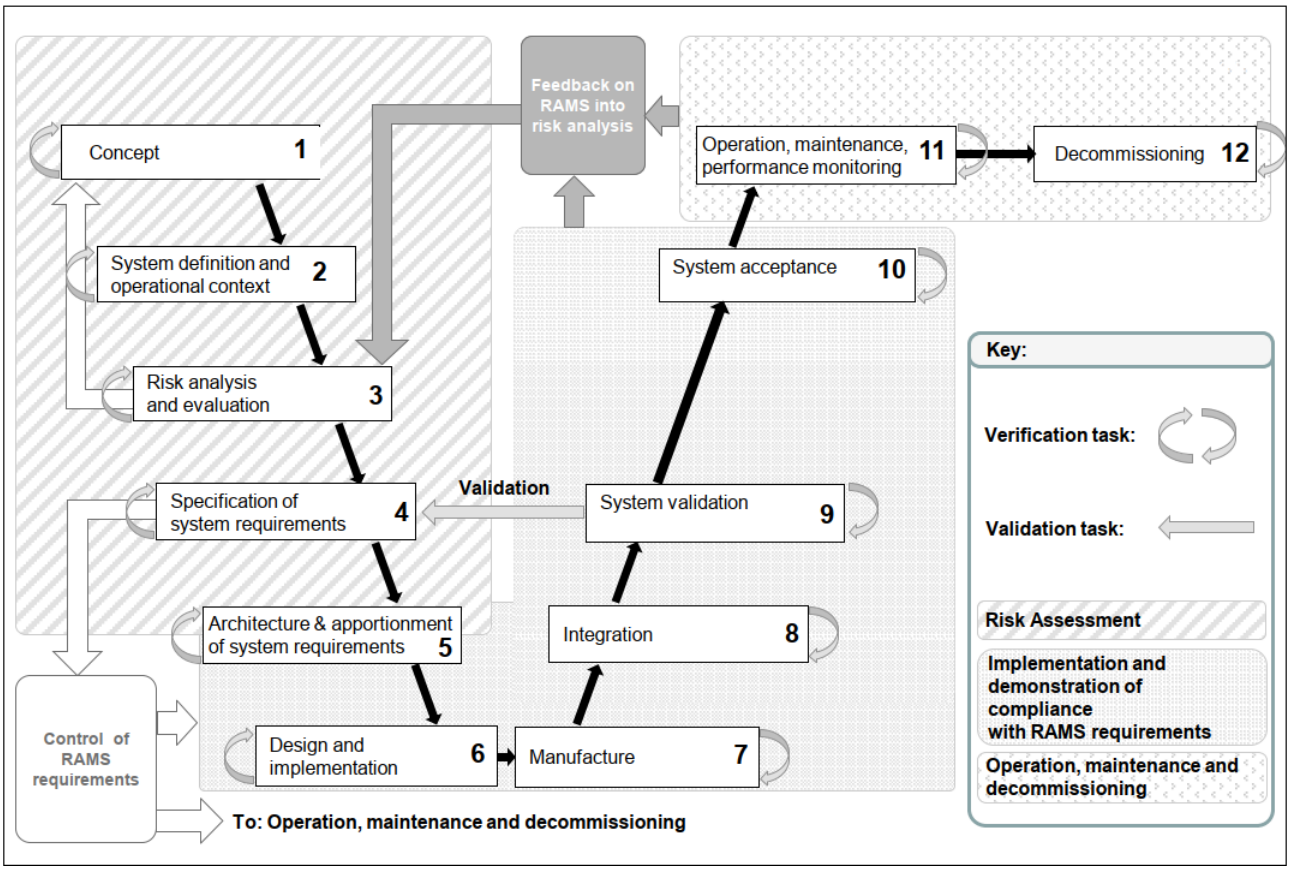

Figure 1 - CENELEC Lifecycle

With reference to Figure 1, Phase 11 "Operation, maintenance and performance monitoring" and Phase 12 "Decommissioning" are usually out of the scope of the ISA, as described in EN 50126-1:2017, Table 1 "RAMS tasks for lifecycle phases 1 to 12", where the issuing of the ISA Report is allocated to phase 10 "System acceptance". Note: manuals and instructions with advices/ requirements/ constraints for safe use and maintenance of the product/system during its operation are of course in charge of the Applicant and are subjected to ISA, but not the actual performance of phases 11 and 12. However, for better evidence to the receivers of the ISA results, the exclusion of Phase 11 and Phase 12, as well as the possible exclusion of further phases and/or requirements, if any, shall be explicitly reported in the ISA Plan, ISA Report and (if issued) ISA certificate.

A relevant distinction is to be made about Phase 7 "Manufacture" if it is intended for series production or for a single unit production. In fact, the production QMS needs to undergo surveillance /re-certification during the production period but in the case of single unit, QMS surveillance /re-certification is not applicable.

The main foreseen ISA procedures are listed in the following table and are deepened in the next sections:

#	ISA Procedure
1	Unit examination
2	Design examination + Product(s) examination

Table 2 - ISA Procedures

3.6.2 #1 - Unit examination

This procedure is adopted when production of more specimens is NOT foreseen or applicable and Phase 7 "Manufacture" is limited to one run. In this case, each individual product/installation is a single unit that undergoes dedicated ISA.

This is typical of (though not strictly limited to) Specific Applications, i.e. turnkey product/system, delivered to be put into operation (e.g.: the signalling system Specific Application of Bologna station cannot be duplicated as such for the Florence station, but another dedicated Specific Application shall be developed and assessed separately).

In this case, it is sufficient to verify the correct production just once and there is no need for production QMS certification and surveillance /re-certification.

If the Applicant's production QMS is already certified by an accredited certification body, the production QMS shall not be re-examined but just its correct application to the product/system under ISA.

3.6.3 #2 - Design examination + Product(s) examination

In this procedure, the design/development (including verification and validation) of the product/system and the manufactured product(s) are examined.

The examination of the design/development aims to verify the compliance of the product/system design with the applicable requirements of the relevant reference standards (see section 1.2.1).

The examination of the 1st product specimen aims to verify that the Applicant is able to manufacture the specimen as designed (i.e. compliant with the designed functions, characteristics and performances).

The examination of the other product specimens aims to verify that all specimens are correctly manufactured (i.e. achieving the designed characteristics and performances). Statistical approach is accepted, duly justified.

The ISA certificate can be issued as a unique document or as separate certificates, one for the design examination and one (or more) for the addressed specimen(s).

4 Validity of the Certificate

As a minimum, the following elements should be considered, as applicable, when defining the terms of validity of a certificate:

1. Accurate identification of the certified product/system, e.g.: part number and version of the product/system accompanied by the detailed list of hardware and software components, also identified by number and version, related technical documentation (requirements, specifications, architecture, technical drawings, etc.). Note: any change/modification shall make the certificate invalid.
2. Intended use for which the certificate is valid.
3. Possible limitations and constraints (e.g. environmental, electromagnetic, kind of application, etc.).
4. Possible exclusions (e.g. the exclusion of Phase 11 and Phase 12, though out of the scope of the reference standards listed in section 1.2.1, as well as the possible exclusion of further phases and/or requirements).
5. Expiry date (where applicable).

Bullet 1 is always mandatory, bullets 2 to 4 are mandatory where applicable. Related data and information shall be clearly reported in the certificate (or in its attachment).

Concerning bullet 5, expiry date:

- For certificates issued as Type A Inspection Body ([17020]), the expiry date is not foreseen. These certificates state the conformity of the product/system at the date of issue of the certificate (instant photography of the product/system safety).
- For certificates issued as Product Certification Body ([17065]), the expiry date depends on the selected examination procedure, on the scope of the certification and on the characteristics of the product/system under ISA. As a general rule, a validity of 10 years with surveillance audits should be foreseen, however:
    - For ISA procedure #1 (Unit examination, each individual product/system or installation requires a dedicated ISA process), if phase 11 of Figure 1 is out of scope (as foreseen by the [EN50126-1]), the expiry date can be omitted and the validity can be defined based on bullets 1 to 4 above.
    - For ISA procedure #2 (Design examination + Product(s) examination):
        - if the certification is limited to the specimen(s) examined during the ISA, duly identified and listed in the certificate, the expiry date can be omitted and the validity can be defined based on bullets 1 to 4 above;
        - if production of further specimens is considered and the issued certificate is meant to cover specimens going to be produced after the date of issue of the certificate, surveillance audits shall be foreseen (as a minimum every 2 years) and the certificate shall report the expiry date.

Without prejudice to the above, the actual expiry date of the certificate is definitively established case by case in the contractual phase, considering the specificities of the product concerned and

its context of use. It is understood that the expiry date shall always be inserted at the discretion of the assessor (and/or of the TR or DM) whenever deemed appropriate/necessary.

The validity of the certification is constantly subject to the persistence of the defined terms of validity of the certificate. RINA reserves the right to verify the persistence of the conditions on a case-by-case basis through inspections or other means at its discretion.

5 Changes to the product/system

As clarified in section 4, the validity of a certificate expires if any change is applied to the addressed product/system.

The Applicant shall communicate to RINA any changes they intend to apply to an already certified product/system and shall submit a new application for certification of the modified product/system, as described in section 3.2.

At the discretion of RINA, some or all of the evaluation activities referred to in section 3.5 shall be repeated. After execution of the needed activities with positive results, RINA may extend the validity of the conformity certificate to the modified product.

6 Confidentiality

RINA guarantees the confidentiality of all information, documents and intellectual property owned by the Applicant, as well as of all communications exchanged.

For details about the mutual commitments on confidentiality between RINA and the Applicant, 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

7 Impartiality and management of conflicts of interest

The management of impartiality and conflict of interest, and the measures for addressing any potential risks to impartiality, are defined in section 4.5.1 of the RINA Certification Quality Manual and in procedure PR-COARM-ERM-01.

RINA, in compliance with the requirements of the accreditation rules, analyses all the potential threats relevant to impartiality and conflicts of interest in the document RMRImp-AD-RSSE-CE.

8 Contractual conditions

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

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