



ASSESSMENT REGULATION

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Management procedures Annex

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Changes	Better definition of scope and application area. Update of normative references. Eliminated the VIS term and replaced ANSF with ANSFISA.		
Status	Prepared	Verified	Approved
Role	RSQ	RCM	DG
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For the release of documents the company uses the electronic signature managed by the computer system following the assignment of a password

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1. SCOPE

This document describes the relationships between CERTIFER Italia SrlU and the Customer and the methods with which CERTIFER Italia carries out the assessment / inspection activities.

CERTIFER Italia SrlU (hereinafter CERTIFER Italia) is an independent assessment body that provides services for assessing compliance with the reference standards of the sector of projects and / or products in the railway transport sector.

2. APPLICATION AREA

It is applied to the following CERTIFER Italia activities:

- Risk management process assessment according to Regulation (EU) 402/2013 and subsequent amendments and additions
- Independent safety assessments on all subsystems and sectors (as OIF)
- Compliance assessment with European regulations concerning the compliance and safety of railway, tram and metro system (ISA)
- Compliance assessment of products with specifications (of Italian and foreign railway and other operators)

3. REFERENCES

Assessment activities will be carried out according to the following national and international reference standards and regulations:

- UNI CEI EN ISO / IEC 17020 Conformity assessment - Requirements for the operation of various types of notified bodies that perform inspections
- MNB - Assessment scheme 000MRA1044 Requirements for conformity assessment bodies seeking notification
- DIRECTIVE (UE) 2016/797 Relating to the interoperability of the European Union railway system
- DIRECTIVE (UE) 2016/798 Railway safety
- Decreto Legislativo 50,14/05/2019 Decree IT transposing directive (UE) 2016/798
- Decreto Legislativo 57,14/05/2019 Decree IT transposing directive (UE) 2016/797
- EU Regulation UE n. 779/2019 Relating to a certification system for the subjects responsible for the maintenance of vehicles
- European commission decision - Technical specifications for interoperability (TSI) applicable to the high-speed and conventional railway system
- Decrees collection and directives of the National Agency for railway Safety (ANSF)
- CEI EN 50126 The specification and demonstration of reliability, availability, maintainability and safety (RAMS)

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- CEI EN 50128 Telecommunication, signaling and processing systems, software for railway command and protection systems
- CEI EN 50129 Telecommunication systems, signaling and processing, electronic security systems for signaling
- Accredia RG-01 Regulation for the accreditation of Certification and Inspection Bodies - General Part
- Accredia RG-01-03 Regulations for the accreditation of Product Certification Bodies
- Accredia RG-09 Regulations for the use of the ACCREDIA trademark
- Accredia RG-01-04 Regulation for the accreditation of Inspection Bodies

4. TERMS AND DEFINITIONS

The definitions cited in the standards applied are:

- UNI EN ISO 9000 Quality management systems - Foundations and vocabulary, December 2005 edition.
- CEI UNI EN 45020 Standardization and related activities - General vocabulary
- UNI CEI EN ISO / IEC 17000 Conformity assessment - Vocabulary and general principles

and the following terms used in the text:

Customer: Organization that requires the activity of Inspection / assessment.

Assessor: Personnel qualified and appointed by the organization to perform the Inspection / assessment activity.

Body: company that carries out assessment activities.

Inspection: (Source 17020): Examination of a product, a process, a service or an installation, or their design and determination of its compliance with specific requirements or, based on a professional judgment, with character requirements general.

Note 1: Process inspection can include people, facilities, technologies and methodologies.

Note 2: Inspection procedures or schemes may limit the inspection to an examination only.

Nota 3: inspection results can be used as a certification support.

Assessment (Source ANSFISA): Investigation undertaken to arrive at a judgment, based on evidence, regarding compliance with specific requirements of a project, a product, a service, a process, an installation.

The terms "Inspection" and "Assessment" will be used indifferently within this document.

5. GENERAL CONDITION

1. This Regulation contains the provisions for governing the relationship between the Notify Body and the Customer. The Regulation can be supplemented by additional provisions that must be specifically included in the contract between the Body and the Customer.
2. The contractual relationship between CERTIFER Italia and its Customer will be governed exclusively by the order / contract concluded between the parties, drawn up in accordance with these Assessment Rules. In the event of discrepancies between this regulation and the contract, what is indicated on the order / contract prevails.
3. The object of assessment activity must be defined within the contract.
4. CERTIFER Italia and all the personnel performing the assessment activity are not involved in situations of: planning, realization, supply, installation, acquisition, possession, use and

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maintenance of the objects inspected or objects like these, without prejudice to the time clause (2 years).

5. CERTIFER Italia is responsible for the inspections even if the inspection activity is carried out by suitably qualified independent collaborators who carry out this activity on behalf of CERTIFER Italia.
6. Depending on the agreements that will be made, the inspection activity can be carried out, depending on the type of assessment activity, on the site, at the premises of the Customer, or even at the headquarters of CERTIFER Italia.

Note: the order / contract means the document that describes and regulates the reciprocal obligations of the Parties; it can be made up of a dedicated document specifically prepared by the Customer as well as by the formal acceptance of the offer presented by CERTIFER Italia

6. ASSESSMENT PROCESS

Assessment activities can be requested from all companies operating in the rail and tram transport sector.

6.1. *Assessment request*

To start the assessment activity, the Customer sends to **CERTIFER Italia** an offer request. The offer contains the information necessary to identify the assessment object and the specifications / standards with which to carry out the assessment.

CERTIFER Italia may request the additional documentations if they are not enough.

Furthermore, when required by applicable legislation, the offer will require a declaration in which the Customer, specifically states that no similar assessment activity has been demanded to another Body for the same object or alternatively that an assessment has already been carried out and assessment reports will be provided with results and open points (alternatively CERTIFER Italia can supply the model AP 07.1.6 "Model for univocal assignment declaration").

The contractual relationship between CERTIFER Italia and the Customer will be governed exclusively by what is indicated in the order / contract signed between the parties and by these Regulations.

As result of the signing of the order / contract, CERTIFER Italia notifies the Client of the names of the inspectors / assessors appointed (after a Start-up meeting with the interested parties).

If the offer is not issued, CERTIFER Italia informs the Customer with the reasons.

6.2. *Procedure for the documentation submission*

To carry out the assessment activities, the Customer sends to CERTIFER Italy the documentation in electronic format and, where not available, in paper form. The accepted formats are: ".xls", ".doc", ".pdf" and ".dwg" (unless otherwise agreed).

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6.3. *Assessment performing*

CERTIFER Italia notifies to the Customer the assessor names assigned and the Project Manager (**RC**) who constitutes the first interface for the Customer. The Customer has 10 days available, since the communication receipt, for a possible rejection of one or more assessors. The Customer must provide documented reasons, which will be verified by **RT (Technical Director)**. If the Customer's requests are adequate, RC will carry out the assessor(s) change.

The same approval process is also subject for the selection of the external laboratories by CERTIFER Italia, if these are necessary for the performance of the assigned activity.

CERTIFER Italia also notifies to the Customer the presence of ANSF or Accredia inspectors, as observers. The Customer has the obligation to accept the presence of such Inspectors.

The Customer has the obligation to make the assessors aware of the safety regulations and the site risks of interest for the assessment place.

In the event of an assessor prolonged absence, to maintain continuity of service, CERTIFER Italia replaces him with an assessor of equal professional competence, whose name is promptly communicated to the Customer.

The assessment, according to the procedure requirements, can be conducted by a single assessor or an assessor group. In the case of an assessor group, CERTIFER Italia will appoint a manager.

The Customer shall give available all the documentation necessary for the inspections that will be necessary for the CERTIFER Italia assessment.

RT is responsible for the technical coordination of all assessment processes. In the event of unavailability of RT or in the case of direct assessment activities as assessor, the responsibility lies with SRT (Deputy Technical Manager); in case of unavailability of SRT, the activity is suspended.

Where there is a Subsystem Coordinator, it is responsible for the technical coordination of all the assessment processes relating to the subsystem.

Where applicable, the Customer must submit a Test Plan to CERTIFER Italia, which is submitted for approval. Once approved, the Customer can perform the tests at laboratories. The tests acceptability must still be submitted to CERTIFER Italia. If the contract provides for it, CERTIFER Italia itself may organize the tests at laboratories selected in consultation with the Customer. The tests result in an independent external laboratory are transmitted to the CERTIFER Italy coordinator. If during the tests emerges a "Not-Conformity" to the applicable requirements, the assessor coordinator evaluates the opportunity to interrupt the test.

6.4. *Sub-contractor*

If CERTIFER Italia were to subcontract any part of the assessment, it will ensure and demonstrate that the selected subcontractor is competent to provide the service in question and, when applicable, is able to meet the criteria set forth in regulation 17020 or 17025.

In the event of subcontracting, CERTIFER Italia informs the Customer the intention to subcontract part of the assessment and the subcontractor will be submitted to the Customer for acceptance.

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6.5. Assessment Reports and Certificates

At the end of each assessment activity, CERTIFER Italia publishes a final assessment report, which describes, according to what is reported below, the outcome of the assessment. When required, for some types of assessment, CERTIFER Italia also issues an Assessment certificate.

The Assessment Report coincides in all cases with the Inspection Report according to the UNI CEI EN ISO / IEC 17020 standard.

The Reports and Assessment Certificates issued by CERTIFER Italia contain all the results and conclusions of the assessment activities carried out, the declaration of conformity and / or non-conformities found.

In case of corrections or changes on the Assessment Report or an Assessment Certificate made after the release, CERTIFER Italia provides for the release of a new document that cancels and replaces the previous document. Within the new document (on the Assessment Reports), the changes will be indicated and justified.

Assessment reports

The Final Assessment Report includes all the results of the examinations and the determination of conformity deriving from these results, as well as all the information necessary for their understanding and interpretation. In the case of complex assessment activities, in addition to the Final Assessment Report, Intermediate Assessment Reports can be issued, which flow together and / or are attached to the final one.

If the assessment report or the assessment certificate contains results provided by subcontractors, these results are clearly identified. Below is the detailed information:

- Documents title (Intermediate Assessment Report, Final Assessment Reports);
 - Identification code of the document and date of issue for traceability purposes;
 - CERTIFER Italia identification and its trademark;
 - Customer identification;
 - Description activity carried out for the customer;
 - Date (s) of the assessments from which the Report / Certificate is issued;
 - Identification of the object (s) of assessment (where possible, also of the individual components) and place of execution of the tests performed;
 - Brief description of the assessment methods used (specifying any variations with respect to standard procedures and methods);
 - Identification of any assessment activities and related results subcontracted to third parties;
 - Identification of the measurement or test equipment used;
 - The verification results, the declaration of conformity and / or the non-conformities found;
 - The names and signatures for the participated staff in the preparation, verification and approval of the document (internal and external);
 - Revisions index with the respective Notes / Modifications
- Assessor's opinion on compliance with the identified requirements and standards, including any observations, open points, non-conformities and relevant application conditions;
- When applicable and if not already specified in the description of the methods / procedures used, information relating to the selection criteria of the samples subject to assessment;

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- Information on the sites where the assessment activity was carried out and related environmental conditions, if relevant;
- Possible omissions of activities foreseen at the beginning of the order (and relative reasons);
- Copy right of the Assessment Report document except in the case of full approval by CERTIFER Italia and the Customer;
- Declaration for the traceability of the Assessment Report to the object (s) identified in the Report.

At the end of the assessment process, the assessor (s) draw up the Final Assessment Report, the Technical Manager approves it, verifying its consistency with the provisions of the system documents and in the contractual documents, the Legal Representative signs for authorization.

To collect all the compliance records according the requirements (intermediate reports, product test reports ...) issued by the assessor and / or the laboratories in charge and verifies their compliance with internal procedures and the applicable standards / directives.

At the end of the assessment activity, the final report is sent to the company organization and discussed in a possible final meeting with the Customer management or his representative.

Assessment certificate

Where is required, according the Final Assessment Report, an Assessment Certificate is issued attesting to the conformity of the object of the assessment carried out to a specific safety / standard specification.

6.6. Remarks, Not conformities, corrective actions

In the assessment operations, non-conformities can be detected, remarks can be made, or clarifications can be requested:

Non-conformity: they are issued in the event of failure to meet a requirement on the product, project or management system being assessed. They are also issued against a deficiency of the Customer's management system, such as not to guarantee the conformity of the product.

Remarks: they are issued against a deficiency of the Customer's product, process or management system, even if not such as not to guarantee the conformity of the product.

Comments: they are issued if a possibility of improvement of the Customer's product, process or Management system is detected, to guarantee the conformity of the product to the reference technical standard.

All Not-Conformities and Remarks are promptly communicated to the Customer and they can be documented through a technical document.

Following this communication, the Customer will inform CERTIFER Italia about the corrective actions to be taken and the times within which to execute them (decided in relation to the specific complexity of the case), times that the Customer undertakes to comply with.

The remark does not compromise the release of the Final Assessment Reports with the result of conformity and the Assessment Certificates on the condition that the Customer engage to resolve the deficiencies found, and in any case fulfills the corrective action.

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In the case of Not-Conformities that would preclude or render impracticable the continuation of the activity, CERTIFER Italia reserves the right to evaluate the temporary suspension of the activity, until the Not-Conformity is resolved.

7. ASSESSMENT REPORTS USE, CERTIFICATES, LOGO CERTIFER ITALIA, ACCREDIA BRAND

The Customer may make use permitted by the law of assessment report, which must be considered confidential documents that cannot be reproduced except for internal and official uses by the control bodies of the Agencies (European and National) and / or final Customers (users of the products being assessed).

The Companies that receive the CERTIFER Italy Certificates have the right to exhibit the Certificate and to use the reproduction, on its own bulletin boards and in its advertising documents, only in its entirety, so that it is clear which is the declared conformity and the limits of the certificate. It is forbidden the use of the Certificate outside the area for which the certification was granted, can cause the revocation or suspension of the certificate.

It is permitted to use the CERTIFER Italia logo within its own materials only if this is clearly related to the certification obtained, without the risk of misleading the user of the documentation on the type, nature and limits of the certification.

CERTIFER Italia uses the ACCREDIA trademark in its own certificates / assessment reports for the activities / services that fall under the Accreditation scheme:

UNI CEI EN ISO / IEC 17020 - as Type A Inspection Body in the sector: Railway sub systems and related components - Certificate 076E.

No other use of the ACCREDIA trademark is granted to the Customer, outside of these reports / certificates.

8. CUSTOMER RIGHTS AND DUTIES

The Customer, by accepting this regulation, undertakes to:

1. Operate as reported in the regulation.
2. Allow access to permit and make available the resources necessary for the performance of the assessment activity, to those responsible for the activities being assessed and, possibly, to the inspectors of ANSFISA and / or Accredia, in compliance with the safety regulations current.
3. Ensure all the necessary conditions to allow the optimal assessment to be carried out even in the case of third-party assessment.
4. Comply with the payments provided for in the contractual documents.

The Customer is entitled before receiving the documents, with CERTIFER Italia, to issue a confidentiality agreement.

If the customer finds discriminatory and non-impartial behavior on the part of CERTIFER ITALIA, he has the right to contact CERTIFER ITALIA's Committee for safeguarding impartiality (CSA).

9. CERTIFER ITALIA RIGHTS AND DUTIES

CERTIFER Italia undertakes to:

1. Operate as reported in this regulation.

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2. Guarantee the presence of the inspection personnel in charge during the assessment.
3. Respect the safety regulations in force in the premises owned by the Customer to which CERTIFER Italia personnel have access.
4. Respect the scheduled agreed times for the performance of the assessment activities and for the delivery of the final documentation.
5. Guarantee the confidentiality of the information received from the Customer useful / necessary for the performance of the assessment activity.

10. RESPONSIBILITY

1. The Customer undertakes to guarantee the completeness and truthfulness of the documents and information made available to CERTIFER Italia.
2. CERTIFER Italia is explicitly exempted from any liability in the event of failure or incomplete communication of data, as well as they do not correspond to the actual business situation.
3. CERTIFER Italia is responsible for verifying what has been agreed at the contractual level by not assuming any direct responsibility for the adequacy of the technical choices made for this purpose by the Principal's Organization - which remains solely responsible - nor for ascertaining the compliance with legal requirements.
4. The assessment activity by CERTIFER Italia does not exempt the Customer from the legal obligations deriving from the products, processes and services provided by it and from the contractual obligations towards its customers, with the exclusion of any liability or guarantee obligation. In particular, it is agreed that no responsibility can derive to CERTIFER Italia for defects in products, processes and services provided by the Customer to third parties, in the cases contemplated by Legislative Decree 6.09.2005 n. 206 and subsequent amendments (Consumer Code) EEC Directive 85/374 (and / or subsequent amendments or additions), concerning liability for damage to defective products and for systematic or occasional behaviors of the Customer, not aligned with Laws and / o Regulations.
5. CERTIFER Italia is not responsible for inadequacies or damages of any kind caused by the Customer during the activity or by its products, processes or services.

11. COMPLAINTS AND APPEALS

All **complaints** relating to the activities of CERTIFER Italia must be submitted in written form by registered letter with acknowledgment of receipt or fax within three months of the occurrence of the claim. All complaints so received will be analyzed by the organization. The manager of the complaint management will verify the merits of the complaint and activate the relative procedure. The results of this verification will be communicated in writing to the Customer within thirty days of receipt of the complaint. If the complaint is founded, the corrective actions will be implemented promptly by CERTIFER Italia and communicated to the Customer.

Appeals can be presented by the Customer to CERTIFER Italia within and no later than three months from the delivery of the Final Assessment Report and / or the Certificate. Appeals must be received in writing by letter registered with acknowledgement of receipt or fax.

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The appeal is taken in charge by the Legal Representative, who appoints a Responsible for the Appeal. The Complaints Manager must be a person of adequate technical skills and must be unrelated to the activity in question, independent and impartial in the expression of their judgment. The Customer will be notified in writing form for the Appeal and it will have 5 days to object, by documenting its decision in writing form.

The results of the checks are communicated by CERTIFER Italia to the Customer in written form by registered letter with acknowledgment of receipt within sixty days from the presentation of the appeal.

CERTIFER Italia notifies the Customer of the appeal results, stating the reasons, taking care to also send any documentation relating to the checks carried out about the appeal.

A more detailed description of the complaints and appeals procedure can be sent upon request.

12. DISPUTES

In the event of disputes between the Customer and CERTIFER Italia, the Court of Pisa will have the jurisdiction.

13. PRIVACY

The information and documents required for the assessment activity will be considered confidential.

Access to this documents/information will be reserved for those involved in the assessment process, the Customer and, if necessary, the accredited body.

CERTIFER Italy and its employees / external collaborators undertake to:

1. no diffusion for data dissemination and uses in any information, data, documents related to the assessment of the activities in which they participate;
2. keep and manage the documentation received from the Customer in such a way as to prevent third parties from viewing it or making a copy;
3. the assessors also undertake to return the paper copies of the documents to CERTIFER Italia and to eliminate any IT (Information Technology) versions at the end of the assessment.

The commitment takes place through the signing of confidentiality agreements, in which employees and external suppliers undertake to avoid conflicts of interest and to remain impartial and free from external influences of both economic and psychological nature.

However, CERTIFER Italia operates in full compliance with the provisions of Legislative Decree 30 June 2003 n. 196 (processing of personal data).

14. REASON OF FORCE MAJEURE

CERTIFER Italia will not be forced by this regulation and will not be held responsible if external events defined as "force majeure" on which it has no influence should occur. The term "force majeure" means all unforeseeable events independent of CERTIFER Italia which occurred after the conclusion of the contract.

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15. SAFETY REQUIREMENTS

CERTIFER Italia undertakes to comply with the Customer Safety Plan, which is previously made available for CERTIFER Italia.

Compliance with the legislation for the safety of workers is stated pursuant to Legislative Decree 81/08 and subsequent amendments and additions, in particular observing the obligations pursuant to art. 20 of the aforementioned Decree, as well as the provisions of the prevention and protection service manager.

The obligations provided by the art. 26 of Legislative Decree 81/08 and the provision of personal protective equipment (PPE), in relation to the specific risks present in the host structures, are to be attributed to the subject at the top of the host structure (article 2 DL363 / 98).

In implementation of the provisions of Legislative Decree 81/08:

In the event that there are interferences between the activities of the Customer and those of CERTIFER Italia, the personnel in charge of the Customer and that of CERTIFER Italia are to cooperate in the implementation of the risk prevention and protection measures for the activity; CERTIFER Italia draws up the document of assessment of the interferences bearing a recognition assessment of the standard risks with respect to the provision that provides derivatives from the execution of the contract. First, the beginning is foreseen for the specific risks of interaction in the places where the activity will be carried out; the integration, signed for acceptance by the executor, supplements the contractual deeds.

- Without prejudice to the fact that the coordination of the protection and prevention interventions against the risks that are the workers will always be up to the Customer, the manager in charge of the security of the Customer and that of CERTIFER Italia inform each other also in order to eliminate the risks of interference between the works of the various companies during the execution of the works contracted to CERTIFER Italia.