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0 INTRODUCTION

Conformity assessment (certification and inspection) of products, processes, or services is a means of ensuring that they meet the requirements specified in standards and other regulatory documents (e.g., Accredia regulations). The certification and inspection schemes applied by Italcertifer and described in this document may include, individually or in combination, the following activities:

- evaluation of initial tests or type tests;
- , inspections, or assessments of products and/or systems;
- evaluation of management systems (quality, maintenance, etc.), including interfaces with suppliers and/or outsourcers;
- surveillance activities that take into account the quality management system and tests or inspections of samples taken from production and the open market (only in the case of certification and where explicitly required).

The value of certification lies in the degree of trust and credibility established through an impartial and competent demonstration, carried out by a conformity assessment body such as ITALCERTIFER S.p.A. (hereinafter also “ITCF”), of compliance with requirements

specified in standards and in the various certification and inspection schemes. The parties with an interest in certification are those listed below, although this list is not exhaustive:

- a) the clients of certification bodies;
- b) customers of organizations whose products, processes, or services are certified;
- c) government authorities;
- d) non-governmental organizations;
- e) consumers and other members of society.

In order to ensure uniform and non-discriminatory treatment of organizations that request product, process, or service certification from Italcertifer, or an inspection in the railway sectors, the rules applied for the issuance and maintenance of certification are described below.

The inspections conducted by Italcertifer are intended to provide information regarding the compliance of the items under inspection with regulations, standards, specifications, inspection schemes, or contracts. Inspection criteria may include aspects of quantity, quality, safety, fitness for purpose, and the ongoing safety compliance of products or systems in operation.

Inspection activities, subject to the clarifications set forth below, may overlap with certification activities (or be included within them), where such activities share common characteristics or refer to the same standards or regulations.

These regulations are subject to changes and updates to reflect changes in relevant regulations or standards, guidance from authorities or accreditation bodies, technical or organizational changes to processes, interpretive clarifications, and in the interest of continuous improvement. The most current version is always available on the company website www.italcertifer.it under the section: About Us > Info & Resources.

For each certification activity, the version of the regulations in effect on the date of the certification request shall apply. Should amendments to the regulations be required by mandatory regulations or binding requirements from competent authorities or bodies, such amendments may also apply to ongoing activities only to the extent strictly necessary to ensure mandatory compliance.

In the case of relationships managed under an “open-ended contract” (framework agreement), any updates to these regulations will be communicated to the customer in writing via the contact channels specified in the contract itself, or via certified email (PEC). The notification will include at least:

(i) revision and effective date; (ii) summary of the main changes; (iii) instructions on how to access the updated version. The contractual amendment resulting from the update shall be deemed accepted if no response is received within five calendar days following the date of ITCF’s notification. Any rejection of the proposed changes will prevent Italcertifer S.p.A. from proceeding with further certification activities.

1 GENERAL PRINCIPLES

ITCF recognizes impartiality and the absence of conflicts of interest as fundamental principles for conformity assessment. To this end, it has formally committed, through a statement issued by its Legal Representative and published on the company website, not to engage in activities that could give rise to conflicts of interest, such as consulting as defined in § 4.

A similar commitment is required of all its assessment personnel (whether employees or external contractors).

ITCF makes its services available to all applicants whose products, processes, and services fall within the scope of its certification and inspection activities.

ITCF does not discriminate in any way against potential clients. Access to the certification process does not depend on the client's size or membership in any association or group, nor is it influenced by the number of certifications already issued.

Additional principles considered fundamental and applied by ITCF in its activities include competence, confidentiality, transparency, accountability, and prompt response to complaints.

2 PURPOSE AND SCOPE OF APPLICATION

This regulation applies to all product certification schemes that ITCF operates under ISO/IEC 17065 accreditation, including for the purposes of its notification to the European Commission, and to inspection activities carried out under ISO/IEC 17020 accreditation in the railway sectors.

The list of certification and inspection schemes is included in the accreditation certificates available on the institutional website (<https://www.italcertifer.com/>) and in the database of the Italian accreditation body Accredia (<https://www.accredia.it/banche-dati/accreditamenti/>).

The following sets forth the general conditions and procedures applied by ITCF for product certification in accordance with the ISO/IEC 17065 standard and, as an Assessment Body (ASBO), for third-party inspection in accordance with the ISO/IEC 17020 standard. Additional provisions set forth in the standards, regulations, and circulars of the accreditation body, pertaining to the certification and inspection schemes applied by ITCF, are included in the appendices to these regulations, of which they form an integral part.

These regulations also serve, to the extent applicable, as the general reference for all product certification schemes applied by Italcertifer outside the aforementioned areas.

For its conformity assessment services, ITCF applies specific pricing, ensuring fairness and consistent treatment for all its clients. ITCF reserves the right to reject an application or terminate an existing contract with a client when there are well-founded or proven reasons, such as, for example, a client's involvement in illegal activities or a series of repeated non-conformities with certification or product requirements, or the occurrence of other similar circumstances.

The certifications and inspections referred to in these Regulations are issued and maintained pursuant to specific accreditations granted by Accredia, Italy's sole accreditation body (<https://www.accredia.it/>), to ITCF. Accredia may, at any time, conduct on-site visits to ITCF's clients to verify their operations.

By accepting the terms and conditions set forth in these Regulations, the client agrees to grant Accredia Inspectors/Technical Experts the right to access its premises, even without prior notice (accompanied by an ITCF), failing which certification will not be granted or

suspension or revocation of certification in the event of persistent failure to comply with this obligation, unless justified reasons exist.

In the event that Accredia intends to conduct an accompanied audit or otherwise perform an inspection at the premises of clients seeking certification, ITCF undertakes to promptly communicate such a request and to provide full cooperation to its clients in this regard.

Access for Accredia Inspectors/Technical Experts must also be guaranteed at any laboratories used by the client as part of the certification and inspection processes covered by Italcertifer S.p.A.'s currently valid accreditations.

3 REGULATORY REFERENCES

These Regulations are written in accordance with the following standards and/or documents, as applicable:

- UNI CEI EN ISO/IEC 17065:2012 “Requirements for bodies certifying products, processes, and services”;
- UNI CEI EN ISO/IEC 17020:2012 “Conformity assessment – Requirements for the operation of various types of bodies performing inspection”;
- UNI CEI EN ISO/IEC 17021-1 “Requirements for Bodies that provide audit and certification of management systems – Part 1: Requirements”;
- Applicable IAF/EA Mandatory Documents;
- Directive 2016/797/EU on the interoperability of the rail system within the European Union (recast);
- Legislative Decree No. 57/2019 implementing Directive 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union
- Directive 2016/798/EU on railway safety (recast);
- Legislative Decree No. 50/2019 implementing Directive 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety;
- Regulation (EU) No. 779/2019 laying down detailed provisions on a certification system for entities in charge of vehicle maintenance in accordance with Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No. 445/2011;
- MIT Decree No. 12 of March 2, 2026 “Directorate Decree on the monitoring of measures related to improving accessibility for persons with reduced mobility (PRM) at railway stations and the qualification of third parties authorized to issue certifications.”
- Regulation (EC) No. 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93;
- Technical document MNB 000MRA1044 - Requirements for conformity assessment bodies seeking notification - European Union Agency for Railways;
- Regulation (EU) No. 402/2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No. 352/2009;
- ERA 1172/003 Certification scheme for ECM and outsourced maintenance functions under Regulation (EU) 2019/779 endorsed by EA (European Cooperation for Accreditation) under ref: EA-GA (20) 11-21;

- Decision 2010/713/EU on the modules for conformity assessment procedures;
- NB-Rail RFU-STR-060 “Duration of validity of certificates and ISVs”;
- NB-Rail RFU-STR-022 “Use of test results from testing bodies other than notified bodies”;
- Regulations and circulars issued by the Certification and Inspection Department of the Italian Single Accreditation Body (ACCREDIA).

4 DEFINITIONS AND ABBREVIATIONS

Accredia	The national single accreditation body designated by the Italian government, in accordance with European Regulation 765/2008, to certify the competence, independence, and impartiality of certification, inspection, and verification bodies, as well as testing and calibration laboratories. (https://www.accredia.it)
ASBO	Risk Management Process Assessment Body (Assessment Body or CSM Assessor) pursuant to Regulation (EU) No. 402/2013
Scope of certification	Identification of: <ul style="list-style-type: none"> - product(s); process(es), service(s) for which the certification is issued; - the applicable certification scheme (); and - standard(s) and other normative document(s), including their publication date, to which the product(s), process(es), or service(s) is (are) deemed to conform.
Consulting	Participation in: <ul style="list-style-type: none"> - the design, manufacture, installation, maintenance, or distribution of a certified product or a product to be certified, or - the design, implementation, operation, or maintenance of a certified process or a process to be certified, or - the design, implementation, provision, or maintenance of a certified service or a service to be certified
Decision-making function	This refers to a person or group of people (for example, a committee) who have not been involved in the evaluation process and tasked with making the certification decision. Generally, this party is not expected to be involved in the inspection activity.
Organization	This refers to any company, public or private entity, or other institution that requests a conformity assessment service from Italcertifer S.p.A. Unless otherwise specified in this document, the term “organization” is to be understood as synonymous with the term “client”
Complaint	This refers to an expression of dissatisfaction regarding administrative, managerial, or technical aspects of the activities carried out by Italcertifer
Regulations	Unless otherwise specified, this refers to these certification regulations
Appeal	This refers to the explicit and documented expression of non-acceptance of the decisions adopted by Italcertifer in the context of audit and certification activities
Certification Scheme	A certification system for specified products to which the same requirements, specific rules, and procedures apply.

Conformity Assessment	Demonstration that specified requirements are met
EA	European Accreditation (https://european-accreditation.org/)
FD	Decision-making function
IAF	International Accreditation Forum (https://iaf.nu/en/home/)
ITCF	Italcertifer S.p.A. (https://www.italcertifer.com/)
MD	Mandatory Document (issued by IAF)

5 ASSESSMENT PROCESS

ITCF issues certificates based on the certification schemes it applies, which contain the requirements against which a client's products are assessed. The requirements subject to assessment are contained in standards and other regulatory documents identified in the agreements with the client.

5.1 Application

In accordance with accreditation standards, ITCF requires the applicant organization to provide a set of preliminary details to enable an assessment of whether the prerequisites for initiating the evaluation process are met. This information is typically included in a certification application or an information questionnaire completed by a representative of the organization. The required information includes, for example:

- the product(s) to be certified;
- the standards and/or other regulatory documents for which the client is seeking certification;
- the client's general characteristics, including its name and the address(es) of its site(s), significant aspects of its processes and activities (if required by the relevant certification scheme), and any relevant legal obligations;
- general information concerning the client, relevant to the scope of certification for which the application is submitted, such as the client's activities, its human and technical resources, including laboratories and/or inspection equipment, and, where applicable, its functions and relationships within a broader organizational structure;
- information regarding all outsourced processes used by the client that could affect compliance with the requirements;
- all other information required in accordance with the relevant certification requirements, such as information for the initial assessment and surveillance activities, including, for example, the sites where the certified product(s) is/are manufactured and the personnel to contact at these sites.

If an application for a railway inspection service is being evaluated, ITCF will request similar information, specific to the subject matter and scope of the inspection.

The applicant organization acknowledges that, as part of its railway interoperability certification activities, Italcertifer cannot conduct assessments on items for which an application has already been submitted and a contract has been entered into with another notified body.

5.2 Review of the Application and Commercial Offer

The application is reviewed by the relevant ITCF departments to determine whether it can be accepted and whether a commercial offer can be prepared.

If an application is denied for one or more of the reasons set forth in these regulations, ITCF shall notify the applicant and provide the reasons for the denial.

During the review of the application, ITCF will consider in particular whether:

- the information regarding the client and the product is sufficient to conduct the certification or inspection process;
- any outstanding differences in understanding between the firm and the client have been resolved, including agreement regarding applicable standards or other regulatory documents;
- the scope of the requested assessment has been defined;
- has the means and resources to perform the assessment activities;
- has the competence to perform the assessment activity.

If the request is accepted, ITCF prepares a commercial proposal that typically includes the following:

- ;
- a description of the activities;
- applicable regulations;
- client documentation;
- inclusions and exclusions;
- scheduling of activities (where applicable);
- commercial terms and prices;
- general terms and conditions of supply;
- validity of the offer.

The offer will generally be structured into Work Packages that are as relevant as possible to the requested evaluation process.

In the event that, during the evaluation process, the information initially provided proves to be inaccurate or out of date, ITCF reserves the right to amend its initial offer.

Unless otherwise specified by the client, the language used for assessment activities and related outputs is Italian. For the issuance of certification documents in a language other than Italian (unless explicitly requested at the time of application), ITCF reserves the right to charge the client for the costs associated with translating such documents, based on a specific quote.

By accepting ITCF's commercial offer, submitting a purchase order, or entering into a specific contract, the customer also accepts the terms and conditions set forth in these regulations and in the appendices, which constitute an integral and substantial part thereof.

5.3 Process Phases/General Information

The evaluation process is carried out through a planning phase that includes one or more of the following aspects:

- evaluation and inspection of the design and technical documentation provided by the customer;
- participation in laboratory and in-line testing activities (for railway vehicles);
- on-site inspections and checks (in the case of fixed installations);
- audits aimed at approving the quality management system applied to production;
- production surveillance activities (where applicable).

Once the assessment activities are completed, the ~~certification~~ process includes:

- a review of all information and results related to the assessment;
- issuance of the assessment report(s) and,

only if certification has been requested:

- the decision to issue the certificate by a decision-making body that is independent of the party that conducted the assessments;
- the issuance of the certificate;
- monitoring activities related to the certificate (where required and/or applicable).

Depending on the type of scheme and certificate, its validity may begin on the date of the decision or on the date of completion of the last audit.

Some types of certificates do not have an expiration date and are therefore considered valid indefinitely, provided that the conditions under which they were originally issued (e.g., project, system configuration, etc.) remain unchanged over time. As specified below, if any changes are made without notifying ITCF, the certificate is no longer considered valid.

For inspection activities conducted in accordance with ISO/IEC 17020, no certificate or attestation is issued, as the process concludes with the review and approval of the assessment report.

For each assessment project, a plan is established that includes all activities necessary for the issuance of the certificate (and for surveillance, where applicable) or the assessment report. This plan is managed by an ITCF Project Manager who handles communications with the client.

When establishing the assessment plan, factors such as the following are taken into consideration:

- scope of the assessment;
- the complexity/criticality of the product (including its design);
- design and production planning;
- necessary laboratory and in-line testing (where applicable);
- number of sites involved in production;
- whether or not certifications have already been issued for the product;
- language for conducting audits and preparing documentation (if different from Italian).

Similarly, for inspection activities carried out as an ASBO, an independent safety assessment plan is established to ensure a thorough evaluation of the modification and the results of each phase of the risk management process referred to in Annex I of Regulation (EU) No. 402/2013, as amended.

Before the assessment activities begin, a kick-off meeting is generally held with the client, during which, among other things, the assessment team is introduced. The client has the right, within 3 days of being notified of the team members' names, to recuse certain assessors involved, providing written justification for the reasons. Once this deadline has passed, the audit team is deemed to have been tacitly accepted.

To carry out the assessment activities, ITCF uses qualified and competent personnel listed in specific directories subject to Accredia's oversight. The team of assessors may be

composed of ITCF employees and/or individuals affiliated with ITCF under specific contractual arrangements.

The identified resources, regardless of the nature of their relationship with the company, operate in accordance with the procedures of ITCF's Quality Management System, demonstrating the highest level of professionalism and respect for the client. Both internal and external personnel involved in the assessment process must, in fact, meet the same requirements for competence, impartiality, and confidentiality as prescribed by the applicable accreditation standards and Accredia regulations.

For each certification or inspection scheme applied, ITCF operates in accordance with a specific procedure, the general process of which is described in the following paragraphs.

In cases where ITCF entrusts specific assessment and/or testing activities to other organizations, it ensures that such organizations meet the requirements of the standards relevant to the type of activity. Specifically:

- ISO/IEC 17025 for testing activities;
- ISO/IEC 17020 for inspections;
- ISO/IEC 17021-1 for management system audits.

Furthermore, in the case of organizations that are not accredited and/or notified, ITCF ensures that the impartiality requirements regarding the personnel of such organizations who perform the activities are always met.

Remote audits.

Audits for initial certification, surveillance, renewal, and special audits may be conducted remotely in a controlled manner and in accordance with the requirements of ISO/IEC 17065, and the reference documents IAF MD4, IAF MD5, and IAF ID12, as applicable.

For each of the types of audits listed above, ITCF will conduct an assessment of the feasibility and duration of remote audits in order to determine the cases in which an *on-site* audit can be partially or fully replaced. Similarly, the above provisions may be applied to inspection activities that involve *on-site* work, provided that the same conditions of feasibility are met.

The option to conduct remote audits applies, in principle, to all certification and inspection schemes, unless otherwise specified by the Accreditation Body, and in any case subject to confirmation by ITCF. In the context of certification activities for railway interoperability, Italcertifer applies the provisions of RFU-STR-065, which sets a minimum requirement for on-site activities equal to 50% of the entire audit program.

Remote audit techniques involve the use of tools such as teleconferencing (audio-only or audio-video) and/or computer-based access to documents and records of the system under review. Their use may replace physical presence, provided that the same effectiveness as an audit or inspection conducted using traditional techniques is ensured. This circumstance must be subject to preliminary assessment by ITCF, and upon confirmation of the client's availability of the necessary IT infrastructure.

5.3.1 Assessment Activities

The evaluation of a product generally encompasses both the design and production phases (and in some cases also management, distribution, and operation). Where applicable, the

evaluation is also extended to a phase of monitoring of production, management, delivery, or operation. In certain cases, the evaluation (and the subsequent certificate) may refer solely to design or production. The activities involved, even in these cases, are those referred to in paragraph 5.3 above.

Depending on the applicable certification scheme, the assessment procedure may be conducted based on one or more assessment modules, each of which corresponds to the relevant certificates.

Within the scope of railway interoperability (Directive 2016/797/EU and related legislation), the client has the right to choose the combinations of modules eligible for the type of product subject to certification.

The assessment activities carried out by ITCF as part of the certification process are recorded, as appropriate, in specific reports and assessment sheets or in audit and/or inspection reports. The terminology used for these documents may vary depending on the certification scheme and applicable regulations.

For inspection activities carried out as an ASBO, Italcertifer will issue the entity requesting the modification with an Assessment Report required to obtain the authorizations provided for under current regulations. Similarly, for activities carried out as a third-party inspection body pursuant to MIT Decree No. 12/2026, Italcertifer will issue a specific assessment report to the organization requesting the inspection.

Elements Subject to Evaluation

The elements subject to assessment by ITCF and which must be made available by the client include, by way of example and without limitation:

- documents demonstrating the characteristics of a specific product;
- samples: that is, products that may be prototypes, pre-production units, or items taken from a production run;
- documents on management systems applied to specific processes (e.g., production, maintenance, laboratory testing, etc.) and related records.

Documents issued as part of the assessments typically include the following information:

- unique identification and date of approval or issuance;
- identification of the items under evaluation and evidence related to each verified requirement;
- assessment(s) regarding the conformity of the evaluated items;
- any recommendations regarding the conditions/limitations of use for the evaluated items;
- additional information useful for improving understanding of the evaluation report;
- signature of the personnel responsible for the evaluation and review.

Laboratory testing activities

As part of the assessment activities described above and in accordance with applicable regulations, testing of the products subject to certification may be required. For these activities to be accepted as part of the certification process, they must be conducted by laboratories that meet the applicable requirements of the ISO/IEC 17025 standard.

In the case of laboratories accredited or qualified for the specific test, acceptance is automatic. In other cases, ITCF ensures that the testing activities and the related results meet the following requirements:

- the competence and independence of those conducting the tests;
- reproducibility and reliability of the results;
- compliance with the requirements set forth in the regulatory documents applicable to the product and its manufacturing process.

To this end, ITCF has developed specific evaluation procedures covering the following cases:

- a) tests covered by ISO/IEC 17025 accreditation;
- b) tests not covered by ISO/IEC 17025 accreditation.

Testing activities performed under ISO/IEC 17025 accreditation are used for the purpose of assessing product conformity, subject to the following formal checks:

- the activity was performed within the scope stated in the laboratory's accreditation certificate;
- the test report(s) bear the mark of an accreditation body that is a signatory to multilateral mutual recognition agreements (EA MLA, ILAC MLA, etc.)

In the case of testing activities not covered by accreditation, in order to be accepted in the certification process, they must nevertheless meet the applicable requirements of ISO/IEC 17025 and other relevant documents (ERA 000MRA1044, RFU-STR-022, etc.), but the lack of accreditation is addressed by a specific assessment conducted by a notified body prior to their performance. The costs of such an assessment are borne by the client.

In this regard, ITCF also maintains a list of laboratories it has accredited that meet the requirements of ISO/IEC 17025 and which it monitors through periodic audits. In processes where ITCF serves as the certification body, the client may utilize these laboratories without the need for a separate assessment of compliance with the requirements of ISO/IEC 17025.

For details regarding the validity of the multi-year qualification issued by Italcertifer, please refer to **APPENDIX B** to these regulations, which constitutes an integral and substantial part thereof.

Subject to compliance with the requirements applicable to testing activities, the options described in this paragraph shall be considered equivalent for the purposes of accepting the test results within the evaluation process.

It is understood that the assessment or qualification of a testing laboratory by bodies other than an accreditation body that is a signatory to multilateral mutual recognition agreements (including ITCF) shall in no case be considered equivalent to or a substitute for the specific accreditation and its meaning as described in Regulation (EC) No. 765/2008.

Approval of quality management systems related to design and production

Depending on the certification scheme, the assessment process may require an evaluation of the quality management system applied to the design and/or production of a specific product. This is to ensure that ITCF has the necessary evidence of the conformity of the products in the series with the approved type or prototype.

The evaluation process for this scope will follow the requirements set forth in Chapter 9 of ISO/IEC 17021-1 and will be conducted primarily on-site at the locations involved in the production process.

It should be noted that a customer's possession of certification for its quality management system—even if issued by a third-party body accredited by an organization that is a signatory to mutual recognition agreements—in no way replaces the assessment of the quality management system applied to the design and/or production of a specific product. This is due to the obligations and requirements arising from applicable regulations and legislation (in particular those derived from EU law). In such cases, ITCF does not re-evaluate the entire quality system but limits its assessment to those aspects of the system relevant to the design and/or production of the item to be certified.

5.3.2 Classification of Findings

ITCF classifies the results of the assessment activities described in the preceding paragraph based on the guidelines contained in the applicable regulations.

For activities performed as a Notified Body, Designated Body, and Independent Railway Body, ITCF classifies the results against the assessment requirements as follows:

Assessment	Description
Compliant	The requirements set forth in the applicable reference standards are met based on the evidence gathered and/or through risk analysis within the CSM Assessment with an “acceptable” outcome. Specific conditions and/or limitations of use may arise from the evidence gathered and/or the risk analysis and are appropriately documented
Compliant by phases or parts	The requirements set forth in the applicable reference legislation, strictly necessary for the phase or part under review, are met through the evidence collected and/or through risk analysis within the CSM Assessment with an "acceptable" outcome, from which specific conditions and/or limitations of use may arise, which are appropriately tracked
Fit for use (Interoperability constituents)	Assessment to be used in the case of EC verification of interoperability constituents, with Form CV, which has resulted in a positive outcome
Non-compliant	Failure to demonstrate compliance with one or more requirements of the applicable reference standard

Additional classifications of findings used primarily in the context of approvals for quality systems, maintenance systems, and laboratory qualifications, in addition to those mentioned above, are as follows:

OBSERVATIONS (OSS, Minor Nonconformities) Nonconformities that do not affect the management system's ability to achieve the expected results;

COMMENTS (or opportunities for improvement) when dealing with anomalies that do not currently impact the management system but could, over time, develop into potential nonconformities.

5.3.3 Root cause analysis, corrective actions, and remedies for findings

When assessments are classified as NON-COMPLIANT, TECHNICAL NOTES are opened for the specific item. The Technical Notes are sent to the client so that they can provide sufficient evidence (new design documentation, additional laboratory tests, third-party certifications, etc.) to resolve the non-conformities.

The certification process is suspended until all TECHNICAL NOTES have been closed with the necessary evidence.

In the case of assessments of management systems (quality, maintenance, etc.) and laboratories, the client identifies the causes of the findings recorded during the audits and proposes a plan of corrective actions to address them. The corrective action plan must generally be submitted no later than 30 days from the date the audit concludes. The proposed corrective actions and remedies must be commensurate with the level of severity identified and will therefore be subject to evaluation by ITCF. The outcome of this evaluation is communicated to the Organization by the Audit Team Leader via a formal notification.

Evidence of the closure or resolution of the findings is also recorded in the final assessment reports.

With regard to nonconformities, the deadline for implementing corrective actions is generally set at a maximum of three months from the date of the final closing meeting scheduled in the audit program. This deadline may be extended, at the request of the audited Organization, to a maximum of six months, only upon specific approval by ITCF. Once these deadlines have passed, if the Organization has not effectively resolved the Non-Conformity, ITCF reserves the right to repeat the assessment activities it deems most appropriate, charging the cost to the Organization.

With regard to Observations, the deadline for implementing corrective actions is generally set at a maximum of twelve months from the final closing meeting scheduled in the audit program. Once this deadline has passed without the Organization having effectively closed the Observation, ITCF reserves the right to reclassify the finding as a Nonconformity and apply the management procedures described above.

With regard to Comments, the Organization may decide to address them by initiating a corrective action or to disregard them, documenting the reasons for doing so. In this case, verification of whether the matter has been addressed is conducted during the first scheduled surveillance audit.

5.4 Review and Decision

At the conclusion of the assessment process, once all technical notes have been closed and evidence of the planned corrective actions and measures has been provided, a review of the results is conducted so that ITCF can make an informed decision regarding the issuance of the final assessment report or whether or not to grant certification.

Once the review is complete, if the issuance of a certificate is required, the Decision-Making Body (DMB) specified in the relevant scheme makes the certification decision based on all information related to the evaluation process, its review, and any other relevant information. Depending on the type of certification scheme applied, the decision may be made by a single individual or by a group of people convened in a special committee. In both cases, the decision-maker is an individual who was not involved in the evaluation process.

In the event of a negative decision, the certificate will not be issued, and ITCF will notify the client of this fact and the reasons for it, providing instructions on how to restart the process.

A client wishing to restart the certification process may submit a request; a client who disagrees may file an appeal in accordance with the procedures set forth in Section 17 below.

For inspections conducted as an AsBo, the FD is not involved at the conclusion of the evaluation process, as the process ends with the review and approval of the Evaluation Report.

5.5 Issuance of the certificate

Following a favorable decision by the FD, the certificate of conformity with the reference scheme and the scope of the certification is issued and sent to the client.

Certification is generally valid starting from the date of the FD's decision. In some cases, depending on the scheme and type of certification, the validity period begins on the date of the last audit and may be subject to periodic surveillance. Surveillance activities are conducted by ITCF at the intervals specified on the certificate.

During its surveillance activities, ITCF reserves the right to request clarifications, changes, or additions to the activities carried out in order to comply with the requirements defined by the competent authorities or the Accreditation Body, or in response to updates to the certification schemes.

Unless otherwise specified in the contract (or explicitly requested by the client), the certificate will be provided in electronic form and, generally, in a bilingual Italian/English version.

For inspection activities performed as an AsBo pursuant to Regulation (EU) No. 402/2013 and, more generally, pursuant to ISO/IEC 17020, no certificate or attestation is issued, as the process concludes with the review and approval of the Assessment Report.

5.6 Certificate Registration and Information on Certification Results

ITCF provides information on certified products regarding the following:

- product identification;
- the standard(s) and other regulatory document(s) against which conformity has been certified;
- the customer's identification.

All information regarding issued certificates is contained in a dedicated electronic registry developed and managed by ITCF.

The client acknowledges that, pursuant to specific legislative and regulatory requirements, ITCF is required to notify the competent authorities and the accreditation body of the issuance of its certificates, as well as to report data regarding the issued certificates in publicly accessible registries (e.g., ERADIS). The customer also acknowledges that, as part of its railway interoperability certification activities, Italcertifer is required to inform other notified bodies and the Notifying Authority of negative assessment results leading to the refusal, restriction, suspension, or revocation of the certificate.

6 USE OF THE CERTIFICATE AND THE INSPECTION REPORT

Upon issuance of the certification, the Organization acquires the right to use the assessment report and the certificate obtained (if applicable), the ITALCERTIFER S.p.A. logo, and, where applicable, the logo of the accreditation body and any other entities (e.g., NB-RAIL), in compliance

the conditions set forth in these regulations and in the trademark usage guidelines available at: https://www.italcertifer.com/it/chi-siamo/info_e_risorse.html.

The Organization's right to use the certificate¹ ceases immediately upon the occurrence of any of the following circumstances:

- expiration;
- suspension;
- revocation.

In any case, the use of the certificate must not be misleading or refer to regulations, standards, fields of application, or any other data and/or information other than those stated within the issued certificate. ITCF reserves the right to verify the correct use of the certificate at any time.

Similarly, the Organization may refer to the inspection report received in accordance with these regulations and those governing the use of the ITCF mark. In any case, the inspection report must be used in such a way that it is not misleading and does not refer, for example, to regulations, standards, scope of application, or other relevant information other than that contained within the document itself.

ITCF reserves the right to conduct audits at any time regarding the certificates and evaluation reports it has issued. To this end, ITCF may take any action it deems appropriate to put an end to the improper use of the certificate, its logo, or the logos of other entities (e.g., Accredia, NB-Rail, etc.).

Among the possible actions that ITCF may take as a result of the improper use of the certificate, assessment report, and/or logo, by way of example and without limitation, are:

- conducting special audits;
- requesting corrective actions;
- suspension or withdrawal of certification;
- reporting to the Accreditation Body;
- initiation of legal proceedings.

Any costs and/or expenses arising from actions taken by ITCF as a result of the improper use of the certificate and/or logo will be charged to the customer.

Upon issuance of the certification, the Organization grants ITCF the right to produce the certificate and/or an extract thereof as a reference for bidding procedures and in any other circumstance in which such references are required.

7 MAINTENANCE OF CERTIFICATION

In the event that surveillance is required by the certification scheme (e.g., ECM certifications), for the purpose of maintaining its validity, ITCF shall commence surveillance of the product(s) in accordance with the applicable rules.

¹ Including the logos associated with it.

Please note that for inspection activities carried out as an ASBO pursuant to Regulation (EU) No. 402/2013 and, more generally, pursuant to ISO/IEC 17020, no follow-up surveillance activities are required after the issuance of the Assessment Report.

7.1 Periodic Surveillance Audits

Where required by the applicable certification scheme, ITCF develops a surveillance program to verify that the certified product continues to meet the requirements of the reference scheme or any other standard against which it was certified.

Surveillance audits, where applicable, are mandatory for the certificate to remain valid and are intended to verify that the product continues to meet the required criteria.

The fact that the client, without adequate justification, does not intend to undergo a surveillance audit within the prescribed timeframe constitutes sufficient grounds for the suspension of the certificate and, should the situation persist, for its subsequent indefinite suspension or revocation by ITCF.

The procedures for conducting surveillance audits are similar to those described in par. 5.3.1 and following, with the exception—unless there are special reasons or specific requirements of the certification scheme—of the involvement of the Deliberative Body (FD).

The procedures for recording surveillance activities and managing any findings are also similar to those described in section 5.3.1.

Only exceptionally serious situations or cases of force majeure (based on the guidelines in IAF ID3 and applicable Accredia circulars) may allow for exceptions to the scheduled surveillance activities, which must be requested in writing to ITCF. Any leniency applied to the surveillance activity does not alter the frequency of any subsequent audits, which must, in any case, adhere to the original audit schedule.

The conduct of surveillance audits is contingent upon payment of the fees due for previous activities.

7.2 Renewal Audits

If requested by the client, the certificate of conformity may be renewed, based on new contractual agreements and the applicable certification scheme, following a successful renewal audit.

Before the necessary activities begin, the client must express, with sufficient advance notice (typically at least 6 months before the certificate's expiration), their intention to renew the existing certification for the duration specified by the relevant scheme. In such cases, ITCF will update the commercial offer, taking into account any changes that may have occurred in the client's organization, the product, or the certification scheme during the previous cycle.

The activities planned for the renewal audit are similar to those described in section 5.3.1 and following. Once the ITCF renewal audit phase is complete, therefore:

- it will review the information on the evaluation process;
- it will make the certification decision;
- if the outcome is positive, it will issue the new certificate of conformity.

The renewal audit must be conducted well in advance (at least 1 month prior) of the expiration of the previous certificate, in order to allow sufficient time to address and resolve any nonconformities, to conduct the review, and for the FD to make the decision.

As specified in Chapter 6 above, if the certificate has expired for any reason, the organization that holds the certificate may not use it or refer to it in any way.

With regard to the renewal and validity of certificates for laboratories qualified on a multi-year basis, the provisions contained in APPENDIX B of these regulations apply.

7.3 Special Audits

7.3.1 Extension of the scope of application

In response to a request to extend the scope of an already issued certification, ITCF conducts a new review of the request to determine the necessary audit activities and to decide whether or not the extension can be granted. The request for an extension typically involves updating the contractual terms and the need for additional verification activities beyond those already scheduled. These activities may be conducted in conjunction with a surveillance or renewal audit.

Extending the scope of the certification does not affect the certificate's expiration date.

7.3.2 Special audits

ITCF reserves the right, upon providing written justification for its decision, to conduct unscheduled inspections of the certificates it has issued. Such inspections may be carried out, in addition to those provided for in the audit program, including but not limited to, in one or more of the following cases:

- following a surveillance activity to verify the resolution of non-conformities;
- in the event of misuse of the certificate or the logos contained therein;
- in the event of reports of serious accidents, safety alerts related to the scope of the certificate, legal proceedings, or serious irregularities related to the certified product;
- following specific requests from the accreditation body or the owners of the certification scheme;
- in the event of significant modifications and changes within the Organization or its management system.

It is understood that unscheduled audits do not replace the surveillance or renewal audits referred to in paragraphs 7.1 and 7.2, but are in addition to them and are the responsibility of the Organization.

Special audits may also be scheduled on short notice based on market intelligence regarding one or more of the situations listed above or due to serious deficiencies in the management system, particularly for products related to railway safety.

7.4 Audits at the customer's suppliers

To verify the effectiveness of the customer's management system, ITCF reserves the right, at any stage of the certification process, to conduct audits of those suppliers to whom the customer entrusts critical and/or significant processes falling within the scope of the certificate.

ITCF will notify the Customer in advance of the need to conduct audits at suppliers, providing justification for such audits. To this end, the customer must take steps to ensure that its supplier

allow access to all records, data, and information related to the processes outsourced by ITCF's client that fall within the scope of the certification.

If the client does not grant such access, ITCF may suspend the certification process and take actions ranging from suspension to a reduction in the scope of certification or revocation of the certificate.

8 WAIVER OF CERTIFICATION AND AND BY BY THE ORGANIZATION

If, during the evaluation process, the client intends to withdraw from the certification process—or to cancel the certification if it has already been issued—the client must notify ITCF in writing at least 60 days prior to the scheduled start date of activities as set forth in the program, or prior to the date of initial issuance in the case of an initial certification.

If the notice period is observed, the Organization will be required to pay only for the activities performed by ITCF up to the date of receipt of the withdrawal notice; if the notice period is not observed, ITCF reserves the right to charge the full amount of the cost estimated for the scheduled verification phase.

In any case, following a request to waive certification, ITCF notifies the Organization of the suspension of activities and the revocation of the certificate, if one has already been issued.

Withdrawal from certification, in the case of valid certificates, entails:

- a prohibition on using the certificate and related logos in any way;
- the recording of the revocation in all public and internal ITCF registries.

Similarly, if the client intends to permanently terminate an inspection conducted as an AsBo pursuant to Regulation (EU) No. 402/2013 and, more generally, pursuant to ISO/IEC 17020, thereby waiving the completion of the service, the client must notify ITCF in writing at least 30 days prior to the scheduled date for the completion of the activity. If the notice period is observed, the Organization will be required to pay only for the activities performed by ITCF up to the date of receipt of the termination request; if the notice period is not observed, ITCF reserves the right to charge the full amount of the cost associated with the issuance of the inspection report.

9 SUSPENSION OF CERTIFICATION

ITCF has the right to temporarily suspend the validity of the certification at any time during the term of the contract and the certificate, by providing written notice upon the occurrence of even one of the following conditions:

- when the subject of the certification has persistently or seriously failed to comply with the certification requirements, including those relating to the effectiveness of the management system;
- when the client holding the certificate does not allow certification surveillance audits to be conducted at the required frequency;
- when the client does not accept that the ITCF audit team be accompanied by Accredia inspectors;
- if the customer has not taken the required corrective actions by the specified date;
- when the customer fails to comply with the terms and conditions set forth in these regulations and/or in the commercial offer;

- when the client refuses to implement new requirements introduced following changes to the certification scheme;
- when the client makes improper or misleading use of the certification;
- when the client has not notified ITCF of any ongoing legal proceedings relating to matters covered by the certification;
- when the customer who owns the certificate has voluntarily requested suspension;
- when a payment default persists after reminders have been sent by ITCF.

The notice regarding the suspension includes the conditions for reinstating validity (including any requirement to conduct special audits and the associated costs) and the contact person at ITCF.

The suspension, which takes effect from the date ITCF sends the notice, does not affect the contract's term of validity or the certificate's expiration date, which will remain unchanged. The suspension period may not, as a rule, exceed six months. ITCF will record the suspension in its register of certified products and, where applicable, in public registries (e.g., ERADIS).

Upon notification of the temporary suspension order, the client must immediately cease using the certificate and related logos (ITCF, Accredia, NB-RAIL, etc.).

The suspension may be lifted only after compliance conditions have been restored, including the successful completion of any extraordinary audits. The necessary actions and, more generally, the compliance conditions must be restored and completed before the suspension's expiration date. If these conditions are not restored, the certificate will be subject to a permanent suspension or revocation, where applicable.

10 PERMANENT SUSPENSION AND REVOCATION OF CERTIFICATION

ITCF may permanently suspend, or revoke where provided for by the applicable scheme, a certificate if any of the following conditions apply:

- if, upon expiration of the suspension period, the circumstances that led to the suspension have not been resolved;
- if the customer terminates the contractual relationship established with ITCF, in accordance with the provisions of these regulations and the terms contained in the commercial offer;
- if it is established in a court of law that the organization holding the certificate has failed to comply with the requirements of the scope of certification.

The decision regarding the permanent suspension or revocation of the certification is notified in writing to the client, along with the reasons for the action.

Following permanent suspension or revocation, the client is required to immediately cease all references to and use of the certificate, including any logos and trademarks contained therein.

11 USE OF CERTIFICATES ISSUED BY OTHER BODIES

In carrying out its activities, ITCF relies primarily on the results of assessments conducted within its own certification processes and using its own resources.

If the customer submits certificates issued by other bodies, ITCF will rely exclusively on certificates issued by bodies holding the accreditations and recognitions

required by the applicable certification scheme (e.g., certificates issued by other notified bodies for Directive 2016/797/EU or product certification bodies accredited to ISO/IEC 17065). Other certificates issued by bodies not holding the aforementioned accreditations and submitted by the customer, in order to be considered by ITCF for the purposes of its activities, must comply with all requirements set forth by the applicable scheme, without prejudice to ITCF's right to request or perform further verifications, the cost of which will be charged to the customer.

12 CHANGES TO THE CERTIFICATION SCHEME

In the event that the legislature, standards-setting bodies (e.g., ISO, CEN, CENELEC, UNI, CEI, etc.), or the owner of the certification scheme make changes to the standards or documents containing the requirements for the issuance and maintenance of certification, ITCF will:

- notify the affected organizations in writing;
- provide guidance and deadlines by which to bring the scope of certification into compliance;
- take into consideration any comments to changes from
from by

Changes to certification schemes may, in some cases, require additional audits to be conducted, the costs of which will be billed to the client.

If the Organization (whether certified or in the process of certification) does not intend to comply with the changes introduced, it may exercise its right to withdraw from certification in accordance with the procedures specified in Section 7 above.

13 CHANGES BY THE CLIENT

A customer holding a certificate is required to notify ITCF of any changes that may affect the certificate. Such changes include, but are not limited to, those relating to:

- the product and the related production process(es);
- production sites;
- ownership, organization and management, contact addresses, locations, and number of employees;
- the quality management system.

ITCF will assess the extent of the changes by classifying them as minor changes, which do not affect the scope of the certification, or major changes, which do affect the scope of the certification.

Minor changes, therefore, do not affect the validity of the certification and do not require additional assessment activities. Major changes, on the other hand, will be subject to additional verification, the duration and scope of which will be established in specific contractual agreements.

Failure to report changes that may affect the client's ability to meet certification requirements may result in ITCF suspending the certification.

14 FEES AND PAYMENTS

The Organization is offered a service calculated on a daily basis and inclusive of all phases provided for in the assessment program drawn up for the initial certification and, subsequently, if the client so requests, for renewal.

While acknowledging that the rates applied may be subject to change due to external macroeconomic factors, ITCF nevertheless undertakes to ensure that the rates proposed in the initial offer remain the same as of the date of issuance of the certificates.

ITCF reserves the right to notify the client of a revision to the offer if, during or following the verification process, the scope of work or the activities requested by the client are found to be inconsistent with the information provided by the client in the initial request.

Specific charges for additional activities, beyond what was agreed upon, will be applied to all activities not listed in the initial proposal and subsequently requested by the client, as well as to activities that become necessary to resolve Nonconformities or for other cases described in these regulations. Such charges may include, by way of example and without limitation, costs for:

- repeating individual steps or the entire verification program, or
- activities resulting from non-compliance with the provisions and requirements of applicable standards;
- additional activities resulting from the suspension, withdrawal, and/or reinstatement of the certificate;
- repetition of verification activities due to changes to the management system.

ITCF reserves the right to charge additional fees on top of the current rates in the event of client requests for:

- urgent execution of activities;
- cancellation or rescheduling of the activities included in the audit program.

The service rate is quoted based on the cost of one man-day of work. In this regard, an indicative rate estimate may be provided in advance upon the Customer's express request. Unless otherwise indicated, the prices quoted for individual work packages include travel expenses. Furthermore, all rates and any additional costs do not include VAT or other applicable taxes.

The billing procedures for services, along with other terms of sale, are specified in the individual financial proposals sent to and accepted by the client. Upon completion of each activity specified in the financial proposal, the purchase order, and/or the contract (if applicable), ITCF will issue a formal invoice to the client.

In the event of non-payment of issued invoices, ITCF reserves the right to suspend its activities and take action, which may include the suspension or revocation of the certificate itself if it has already been issued.

15 CONFIDENTIALITY OF INFORMATION

Through the execution of certification agreements with its clients, ITCF ensures that all information obtained during certification activities is treated as strictly confidential by all levels of its organization, unless otherwise specified.

as required by law. The confidentiality obligation applies equally to ITCF's internal staff and to any external personnel engaged in the certification processes.

In addition to the provisions already specified in these regulations, ITCF undertakes to inform the client in advance of any information it intends to make public, except as provided for in Chapter 6. Except as required by ISO/IEC 17065, ISO/IEC 17020, applicable Accredia regulations, and/or legal obligations, ITCF does not disclose information regarding its certified clients to third parties.

Please note that, in accordance with the mandatory provisions of certain certification schemes, information regarding the issuance, validity status of a certification, and the certificate holder must be made available by ITCF in designated public registries (e.g., ERADIS).

Information regarding the customer obtained from sources other than the customer themselves (for example, from a complainant or an authority) will be treated as confidential information, in accordance with the provisions of this regulation.

ITCF has processes and tools (including IT systems) in place to ensure the secure and confidential handling of the aforementioned information required for the certification process.

16 COMPLAINTS

ITCF ensures, under its own responsibility, a complaint-handling process (as defined in Chapter 4) that does not give rise to any discriminatory conduct toward the complainant. In particular, the process applied by ITCF ensures that the decision to be communicated to the complainant is made by, or reviewed and approved by, a person (or persons) not involved in the certification activities that are the subject of the complaint.

The complaint may concern any dispute regarding the certification process, with the exception of those pertaining to decisions adopted by Italcertifer in the context of audit and certification activities (see paragraph 17), and must be submitted by certified mail to ITCF's registered office, or via certified email to the address italcertifer@pec.it.

ITCF reserves the right to deem complaints inadmissible if they are submitted by means other than those specified above.

ITCF will therefore confirm receipt within five business days and initiate the process by collecting and verifying all information necessary to validate the complaint. The complaint, which must not be anonymous, must include a description of the activity in question and the process to which it refers.

Upon receipt in the manner described above, ITCF will verify, within fifteen (15) consecutive calendar days, the admissibility of the complaint with respect to its relevance to the certification activities for which it is responsible; if the complaint is deemed admissible, ITCF will proceed with the preliminary investigation phase after notifying the client. This phase will be carried out by the relevant organizational unit, which—within thirty (30) calendar days if the complaint concerns its own operations, or within sixty (60) calendar days if the complaint concerns one of its clients who holds the certificate—will respond to the submitted request. In the event that specific corrections or corrective actions are linked to the decisions made regarding the complaint, ITCF guarantees their implementation.

ITCF will also notify the certificate holder of any valid complaint concerning them in a timely manner.

ITCF will keep the complainant informed of the progress of the process. Each complaint and the corresponding resolution are kept in a dedicated archive.

Subject to legal requirements, ITCF will determine, in consultation with the certified client and the complainant, whether, and if so to what extent, the content of the complaint and its resolution should be made public.

It should be noted in this regard that ITCF is required to ensure confidentiality in all cases regarding the person who filed the complaint and the content of the complaint itself.

17 APPEALS

ITCF ensures, under its own responsibility, an objective and independent process for handling appeals (as defined in Chapter 4). In particular, ITCF guarantees that the persons involved in the appeal evaluation process (including those who make the final decision on the matter) are different from those who conducted the audits and/or made the decisions regarding certification.

The appeal may relate exclusively to decisions made by ITCF regarding the issuance, reduction, suspension, or revocation of a certification and must be filed only by the organization to which the decision was addressed, either by certified mail to ITCF's registered office or via certified email (PEC) to italcertifer@pec.it, within thirty (30) consecutive calendar days from the date the certificate subject to the appeal was issued.

ITCF reserves the right to declare appeals inadmissible if they are received after this deadline or submitted in a manner other than that specified above.

ITCF will then confirm receipt within five business days and initiate the appeal review process.

The appeal must specify the decision against which the appeal is being filed, the factual and legal grounds on which the request is based, any documents supporting the arguments presented, and the conclusions setting forth the specific relief sought from ITCF.

A properly filed appeal is submitted to the relevant organizational units, which, after obtaining the file pertaining to the certification subject to appeal and verifying its admissibility and eligibility for review, will analyze it and, within forty-five (45) calendar days of receipt, notify the organization of the decision concluding the proceedings through a specially appointed case manager.

Each appeal and the related decision are kept in a dedicated archive.

If the decisions made regarding the appeal involve specific corrections or corrective actions, ITCF will ensure that they are implemented.

ITCF will keep the organization informed of the progress of the appeal process.

ITCF ensures that the submission of appeals, their review, and the related decisions will not give rise to any discriminatory conduct toward the organization that filed the appeal.

18 CUSTOMER OBLIGATIONS

To obtain, maintain, and renew certification of a product, process, or service, the client, in accordance with the requirements of ISO 17065 and applicable Accredia Regulations, is required to:

- continuously meet the certification requirements, including implementing appropriate changes when these are communicated by ITCF;
- comply with the requirements of this regulation and those referenced herein (e.g., logo usage guidelines) when referring to the status of their certification in media such as the internet, brochures, advertising materials, or other documents
- not to make or condone references or statements that could be misleading regarding their certification;
- make statements regarding the certification that are consistent with the scope of the certification itself;
- not use, nor permit the misleading use of, a certification document or parts thereof;
- cease the use of all advertising materials that refer to the certification in the event of its revocation, as required by ITCF;
- amend all advertising materials if the scope of the certification has been reduced;
- not to use its product certification in a manner that brings ITCF into disrepute;
- ensure the necessary conditions for conducting assessments, both in terms of access to all relevant production sites and/or construction sites, and in terms of reviewing information and documentation and conducting on-site audits;
- provide all documents necessary for ITCF's assessments, in particular the construction plans and technical documentation related to the product;
- ensure that any ITCF observers and Accredia inspectors are able to participate in the audits;
- notify ITCF in the event that it is involved in legal proceedings pertaining to, related to, or connected with the certification issued.

19 ITALCERTIFER'S OBLIGATIONS

In connection with activities related to the issuance, maintenance, and renewal of certifications for products, processes, and services, and, more generally, to conformity assessment, ITCF is committed to:

- evaluate every application for certification or inspection impartially and without discrimination; however, ITCF may reject an application if it determines that the necessary conditions for completing the assessment process are not met (e.g., bankruptcy, convictions for crimes under Legislative Decree 231/01);
- provide adequate notice of the presence of any observers, whether from the organization itself or from Accredia, ensuring that the presence of the latter does not unduly influence or interfere with the audit or the client's activities;
- ensure a prompt and effective response to any complaints or appeals regarding its activities;

- assign personnel with the appropriate skills, ensuring effective mitigation of the risk of any conflicts of interest;
- base one's decisions on a review of a substantial body of objective evidence, even if obtained through a process of sampling the available information;
- ensure an effective risk management process to guarantee the impartiality of one's actions and activities;
- ensure the confidentiality of information obtained during the process.

SECTORS

**APPENDIX A: SPECIFIC CONDITIONS FOR THE CERTIFICATION OF PERSONS
RESPONSIBLE FOR MAINTENANCE.**

A.1. PURPOSE AND SCOPE

This Appendix contains the specific conditions under which Italcertifer provides certification services to entities responsible for the maintenance of railway vehicles in accordance with Regulation (EU) 2019/779, upon request.

The services described in these regulations apply to certification applications submitted by organizations that perform one of the following roles:

- Entity Responsible for the Maintenance of a Railway Vehicle;
- Entity or Organization performing one or more railway vehicle maintenance functions;

as defined in applicable legislation and that perform maintenance activities on vehicles operating on the IFN or on networks functionally isolated from the rest of the railway system, as referred to in Decree No. 347 of the Ministry of Infrastructure and Transport dated August 2, 2019. Unless expressly specified in this Appendix, the conditions contained in the general section of the Certification Regulations shall apply.

A.2 REGULATORY REFERENCES

In addition to what is already specified in Chapter 3 of the Regulations, this Appendix also refers to the following standards and/or documents:

- ERA 1172/001 V2.0 “Clarification note – Sectoral scheme for accreditation and recognition of ECM certification bodies under Commission Implementing Regulation (EU) 2019/779”;
- ERA 1172/003 V1.1 “Certification scheme for ECM and outsourced maintenance functions under Regulation (EU) 2019/779”;
- Regulation (EU) 2015/1136 “Amendment to Implementing Regulation (EU) No. 402/2013 on the common safety method for risk identification and assessment”;
- Regulation (EU) 2012/1078 “Commission Regulation (EU) No. 1078/2012 of November 16, 2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers holding a safety certificate or safety authorization, and entities in charge of maintenance”;
- ANSF Decree No. 3/2019 “Regulations governing the rules and procedures, pursuant to Article 16, paragraph 2, subparagraph bb), of Legislative Decree No. 50 of May 14, 2019, applicable to networks functionally isolated from the rest of the railway system as well as to entities operating on such networks”;
- COTIF Convention “Convention concerning International Carriage by Rail (COTIF) Appendix C - Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) Effective as of January 1, 2019”;
- MIT Decree of February 12, 2019 “Transposition of Directive (EU) No. 2018/1846 amending the annexes to Directive 2008/68/EC of the European Parliament and of the Council on the inland transport of dangerous goods, in order to take account of scientific and technical progress”;
- ANSF Decree No. 4/2012 “Regulatory Reorganization: Issuance of the ‘Responsibilities Regarding Railway Traffic Safety,’ the ‘Regulations for Railway Traffic,’ and the ‘Standards for the Qualification of Personnel Employed in Railway Traffic Safety Activities’”;

- ERA ECM Guide Ver. 9.0 “Guide for the application of Article 14 of Directive (EU) 2016/798 and Commission Implementing Regulation (EU) No 2019/779 on a system of certification of entities in charge of maintenance for vehicles in accordance with Article 19(3) of Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016”
- UNI EN ISO 19011:2018 “Guidelines for auditing management systems”.

A.3 DEFINITIONS AND ABBREVIATIONS

Additional definitions and abbreviations applicable to this Appendix:

ERA	European Union Agency for Railways
ECM	Entity in Charge of Maintenance. This refers to an entity responsible for the maintenance of a vehicle as defined below
ECM Certification Scheme	This refers to document ERA 1172/003 V1.1, which contains the mandatory requirements established by ERA for the ECM certification scheme
GdA	Audit Group
IFN	National Railway Infrastructure
RGA	Audit Group Manager
Entity in Charge of Maintenance	Entity responsible for the maintenance of a vehicle, registered as such in the vehicle register referred to in Article 47 of Directive (EU) 2016/797

A.4 CLASSIFICATION OF FINDINGS

For the purposes of the certification process described below, findings identified during audits are classified by ITCF as follows.

Non-Conformity (NC).

A Non-Conformity (NC) is a finding that occurs when a requirement of the certification scheme has not been adequately implemented, or when serious deficiencies are identified that negatively impact the effectiveness of the maintenance processes managed by the Organization.

An NC always indicates a critical deficiency in the maintenance system, as it is directly linked to potential risks of:

- operating vehicles in unsafe conditions;
- failure to meet the minimum performance targets expected for the operation of maintained vehicles.

Examples of such cases, though not limited to these, include situations where maintenance work has been repeatedly performed improperly or not carried out by the required deadline, accidents or serious operational incidents attributable to maintenance deficiencies, or other cases that could potentially result in the return to service of vehicles that are not capable of operating safely.

Observation (OSS)

An Observation (OSS) is a finding that arises when the inadequate implementation of a requirement specified by the certification scheme does not directly or immediately compromise the quality of maintenance processes or the performance achievable by the Organization.

An OSS indicates a deficiency in the maintenance system that must be corrected in any case but does not directly affect:

- vehicle operational safety,
- achievement of the minimum performance targets expected for the operation of maintained vehicles.

If it is found that a non-critical deficiency (OSS) tends to recur or is not effectively corrected within a reasonable timeframe, it may be reclassified as critical (NC).

This type of finding, however, requires the initiation of a corrective action and/or process within defined timeframes, the implementation of which will be verified during the next inspection, or evidence of its closure will be evaluated in writing by ITCF if necessary.

Please note that the number of observations, or their persistence, may lead to the issuance of nonconformities during the course of the audit program.

Comments (COM)

The type of finding classified as a Comment (COM) does not result from the identification of an objective situation of non-compliance with a requirement of the certification scheme, but is intended to prevent such a situation from occurring (as it is potentially feasible) and/or to provide useful guidance for improving the Organization's maintenance system.

A.5 GROUP ACCEPTANCE AND AUDIT PLAN

Please note that the plans submitted prior to each audit and the names of the evaluation team shall be deemed tacitly accepted by the requesting organization if, within **three business days** of notification thereof, no written and substantiated objections are received; in any case, ITCF reserves the right to assess the validity and admissibility of such objections and to notify the client of its decision.

A.6 INITIAL CERTIFICATION

ITCF applies a process for the certification of ECMs in accordance with the document ECM Certification Scheme ERA 1172/003 V1.1, which constitutes the mandatory reference framework for the issuance of certifications. The certification process follows ISO/IEC 17065 and the applicable parts of ISO/IEC 17021-1, as referenced in document ERA 1172/003 V1.1

Specifically, the process involves an initial certification audit divided into two stages (Stage 1 and Stage 2) and surveillance audits at least once every 12 months starting from the date of the certification decision. The following sections describe in detail all the stages involved in the process for obtaining initial certification, for surveillance, and for certification renewal.

A.6.1 Application

The organization seeking certification is required to submit a formal application using the forms provided by Italcertifer in accordance with Annex III of Regulation (EU) 2019/779. In addition to the client's general information, the information that Italcertifer may request to conduct the review of the application includes, but is not limited to:

- a description of the ECM's organizational structure, including, among other things:
 - general organizational chart;
 - available human and technical resources;
 - number of maintenance workshops involved and any additional sites;

- a description of the maintenance system specifying the internal organizational structures that perform the four functions described in Annex II of Regulation (EU) 2019/779;
- any outsourcing of maintenance functions or parts thereof to third parties and the relevant qualification procedures;
- the type of vehicles to which the maintenance system applies and, in the case of railcars used for the transport of dangerous goods, a list of the classes of dangerous goods that may be transported;
- the regulations applicable to the type of vehicles or goods transported, particularly dangerous goods;
- information on the maintenance policy and strategy to ensure compliance with the requirements set forth in Annex II of Regulation (EU) 2019/779;

In accordance with Regulation (EU) 2019/779, the Organization may limit its application for certification to specific categories of vehicles, which must be clearly indicated in the application, whether for an ECM or for an entity performing maintenance functions.

In the case of an application for certification as an entity performing maintenance functions, the applicant must provide the same information as above, adapted to the function(s) or parts thereof, and must additionally specify:

- the function(s) or part(s) thereof covered by the system and falling within the scope of the certification;
- the processes, sub-functions, or parts of vehicles covered by or excluded from the scope of the system and the certification.

If the information provided by the applicant organization is deemed incomplete, Italcertifer may request additional information until it has all the necessary elements to begin reviewing the application and prepare a commercial proposal.

The applicant's refusal to provide the aforementioned information or additional details constitutes sufficient grounds for Italcertifer to reject the application and decline to offer its certification services.

A.6.2 Review of the Application and Commercial Offer

The provisions of § 5.2 apply.

A.6.3 Evaluation process

Once the certification agreement has been finalized, ITCF appoints an Audit Team with the necessary expertise, whose assessment activities consist of a two-stage audit (Stage 1 and Stage 2) following a program that takes into account, among other things:

- the purpose of certification;
- the size and structure of the applicant's organization;
- the number of sites where the activities subject to certification are carried out;
- the outsourcing of part of the activities covered by the certification;
- the type of vehicles involved;
- the type of activities performed;
- the presence of special processes.

The requirements used by Italcertifer throughout the assessment process are those set forth in Reg. (EU) 2019/779, specifically those established in Annex II of Reg. (EU) 2019/779.

A.6.3.1. Stage 1 Audit

The assessment process begins upon receipt by the ECM of the complete documentation regarding its maintenance system.

The activities of Internship 1 are designed to provide participants with a thorough understanding of the organization's maintenance system and the activities it carries out, through an exchange of information with the organization and an assessment—conducted primarily on the basis of documentation by Italcertifer's GdA—regarding:

- the completeness and adequacy of the documentation in relation to the activities carried out;
- the adequacy of the human, technical, and infrastructural resources employed;
- the sites involved, their location, and the type of activities carried out;
- the type of vehicles subject to maintenance activities;
- understanding and compliance with applicable legal and regulatory requirements;
- justification for any exclusions;

During this phase, Italcertifer will verify, in particular, the consistency of the maintenance system in terms of its structure, processes, procedures, and the relationships between them, with respect to the requirements of Regulation (EU) 2019/779.

Given the complexity of the organization and its maintenance system, Italcertifer may schedule multiple audit sessions and may conduct all or part of Stage 1 activities on-site at the client's premises.

The findings of Stage 1 are communicated to the Client by the head of ITCF's Audit Group, along with an indication of whether or not to proceed to Stage 2, subject to the Client's resolution of any deficiencies and/or findings identified.

Any findings made by the Audit Group during this phase are classified according to the criteria set forth in § A.3 above.

A prerequisite for the commencement of Stage 2 is the absence of, or the resolution of, any non-compliance notices issued by the GdA to the Organization. Stage 1 must therefore be repeated, with the client being charged the applicable costs in accordance with the terms set forth in the commercial offer, until this condition is met.

Stage 2 activities must normally begin no later than three months after the conclusion of Stage 1. Beyond this deadline, ITCF reserves the right to repeat Stage 1, charging the client for the associated costs.

A.6.3.2 Stage 2 Audit

Stage 2 of the audit is intended to assess the implementation and effectiveness of the ECM maintenance system. Stage 2 takes place at the client's site(s) where the client's maintenance processes are carried out.

During this phase, the ITCF audit team will verify, in particular, the client's ability to ensure that:

- vehicles are maintained in accordance with the corresponding maintenance records and the applicable requirements of the relevant TSIs and/or other maintenance standards;
- adequate measures (including contractual ones) are taken to monitor performance for any outsourced activity that could potentially affect vehicle safety;

- the traceability of every maintenance activity is ensured;
- the performance of the maintenance system enables the achievement of its intended objectives;
- appropriate risk assessment methods defined in the relevant Common Safety Methods are implemented;
- self-monitoring processes are implemented, including internal audits and management reviews;
- Management must demonstrate the necessary commitment and involvement in the implementation of the maintenance system and in the consistent assignment of related tasks and responsibilities (including those concerning the interface with clients and/or subcontractors providing other related services).

In the case of multi-site organizations, separate audit sessions will be conducted according to a sampling program designed to ensure the representativeness of the processes and activities carried out by the Organization. Among the references adopted by ITCF for site sampling are the guidelines contained in the IAF MD 1:2023 document.

Prior to each Stage 2 audit, the RGA prepares a specific audit plan, which is shared with and sent to the client no later than three business days before the audit date, based on the information contained in the documentation reviewed during Stage 1 and the processes involved.

At the start of the audit engagement at the client's site, ITCF's RGA conducts an initial meeting with the aim of:

- introduce the members of the Audit Team;
- present the objectives and procedures of the audit, as well as the criteria for classifying findings and conclusions;
- establish official communication channels with the Audit Team, identifying a client representative to contact during the audit in the event of disputes;
- clarify any doubts and establish a climate of trust.

The Stage 2 audit continues with an assessment aimed at gathering objective evidence of compliance with the requirements of Regulation (EU) 2019/779, based on a combination of methods such as:

- staff interviews;
- observation of activities and processes;
- review of documents and records.

In general, the first part of the audit in this phase is dedicated to verifying that the issues identified during Phase 1 have been effectively resolved. If the Audit Team determines that the previously identified issues have not been resolved or have not been effectively resolved, it may suspend the audit, which may only resume after the necessary evidence has been provided. Please note that in this event, any additional costs resulting from the interruption of activities will be charged to the client in accordance with the financial terms set forth in the commercial offer.

The evidence that the GdA may verify during the audits includes, by way of example and without limitation:

- the procedures for acquiring and maintaining staff competencies, including those related to special processes;

- the availability, proper management, and implementation of applicable mandatory regulations;
- the management and monitoring of outsourced processes;
- the methods by which the ECM ensures the traceability of components used in replacement operations for safety-critical components.

During the audit, Italcertifer's audit team will inform the client of all findings and issues identified through the review of the objective evidence provided by the client.

A.6.3.3 Audit Conclusions

At the conclusion of the sessions outlined in the audit plan, the Lead Auditor conducts a final meeting, in the presence of the client's representatives, with the aim of:

- present the results and communicate any findings that have emerged;
- provide a preview of the audit report's contents
- briefly describe the continuation of the certification process, including agreements regarding the action plan for addressing any findings that have emerged;
- Distribute a copy of the audit report to the client.

Within **two weeks** of the audit's conclusion, ITCF will send the client a draft of the audit report containing a formal summary of the findings, which the ECM must address in accordance with the procedures described in the following paragraph § A.7.

A.7 MANAGEMENT OF FINDINGS

For every finding classified as a Nonconformity or Observation during audits (Stage 2, surveillance, and renewal), the client is always required to submit a plan of corrective actions, which will be evaluated by the ITCF Audit Team.

The plan must include, in particular, a root cause analysis and a description of the corrective actions the client intends to take, accompanied by realistic timelines for their effective implementation.

The action plan must be submitted to ITCF in a timely manner to allow for the development of the subsequent phases of the process, and in any case no later than **two weeks** after the submission of the draft Phase 2 audit report, surveillance report, or renewal report.

The ITCF Audit Committee will assess, in particular, the consistency of the analyses and actions contained in the plan, which must be approved by the RGA. If the plan is not approved, the client must revise it and resubmit it to the ITCF Audit Committee for approval.

The outcome of the action plan evaluation will be recorded in the audit report (Phase 2, surveillance, or renewal).

Findings classified as Comments may be addressed by the client initiating a corrective action, or they may be rejected provided that the reasons for the rejection are documented.

In general, ITCF's verification of the implementation and effectiveness of the actions established by the ECM is carried out during the first applicable surveillance audit. In the case of particularly critical non-conformities, or in the presence of a high number of observations, it may be necessary to conduct an extraordinary audit in addition to the planned surveillance audit. Please note that any additional costs resulting from the need to conduct extraordinary audits will be charged to the client in accordance with the financial terms established in the commercial offer.

During the monitoring phase, failure to manage comments properly—including failure to record the reasons for their rejection—generally results in the reclassification of the finding as an observation.

A.8 DECISION

Upon completion of the evaluation process described above, once all findings that may have been raised have been addressed by the ECM (through a specific Action Plan or by providing evidence of the corrective actions taken), ITCF reviews the results in preparation for the certification decision. The review is conducted by a dedicated Decision-Making Function (which did not participate in the assessments and is therefore independent of the Audit Team) which, based on the evidence provided and the binding opinion of a dedicated Committee, may adopt one of the following decisions:

- issue the certification;
- issue the certification with a reduced scope of application (compared to that indicated in the application);
- postpone the decision until the ECM implements the action plan;
- refuse to issue the certification.

The Decision-Making Body shall adopt its decision within two weeks (14 calendar days) of the date on which the final evaluation report becomes available internally. If the decision must be postponed pending verification by the ECM of the effectiveness of the implementations, it must be made within the time limits set forth in the last paragraph of this article.

Among the decisions made by the Decision-Making Body may also be the issuance of certification subject to the requirement that an extraordinary surveillance audit be conducted in the near future, in addition to the one provided for in the multi-year program.

In the event of a refusal to issue certification, the reasons for the decision will be provided and, only where possible, the terms and conditions for reevaluating the issuance.

In general, if an application is rejected, the client must still submit a new application if they wish to obtain certification, and the process will be restarted following a review of the new application, based on a new contractual agreement.

If the client disagrees with the decisions made by Italcertifer, they may initiate the appeal process described in Chapter 17 of the general section of these regulations.

In accordance with Article 7(5) of Regulation (EU) 2019/779, the duration of the certification process is set at **four months** from the date on which the ECM receives all the information and complete documentation to the date of the certification decision.

A.9 VALIDITY OF THE CERTIFICATE

The validity of the certification, which begins on the date of the decision by the Decision-Making Body, shall correspond to the surveillance period defined in the contractual agreement and, in any case, shall not exceed **five years**. In this regard, it is specified that, in any case, validity is contingent upon the performance of surveillance audits at least every twelve months starting from the date of the initial decision, to verify the certified entity's ability to maintain compliance with the requirements of Regulation (EU) 2019/779 over time.

In the case of certification requests submitted by newly designated ECMs—that is, entities that were not registered as such in the National Vehicle Registry prior to June 16, 2020—and that do not

cannot provide evidence of the effective implementation of the maintenance system, the initial certification process described above applies, but the validity is set at **one year**.

A.9.1 Reporting Requirements

The client acknowledges that, in accordance with applicable legislation, Italcertifer is required to notify the European Railway Agency (ERA), the Ministry of Infrastructure and Transport, the Agency for Railway and Road and Motorway Infrastructure Safety (ANSFISA), and the Italian Accreditation Body (Accredia) all certificates issued, amended, renewed, suspended, or revoked.

A.10 CERTIFICATION SURVEILLANCE

With regard to surveillance, the general provisions contained in paragraph 7.1 of these regulations apply, with the clarification that, in accordance with the provisions of Article 8(1) of Regulation (EU) 2019/779 and the ECM Certification Scheme, this must be carried out by ITCF at least once every 12 months starting from the date of issuance of the certificate. Failure to conduct surveillance audits for reasons not attributable to ITCF shall result in the suspension of the certificate.

The conduct of surveillance audits, their planning, the tools used, and the procedures for addressing any findings are similar to those described in the preceding sections of this Appendix. Unless the client notifies ITCF of significant changes to its documentation, organization, and/or maintenance system, a document review is not normally required.

In accordance with the ERA ECM Certification Scheme (Section 3.3.5.2), the Decision-Making Body is required to intervene; based on a review of the surveillance audit results, it may decide to:

- confirm the certification without reservations;
- confirm the certification with a reduction in the scope of application;
- temporarily confirm the certification by postponing the decision (for a maximum period of six months) until the action plan proposed to the client has been reviewed;
- suspend the certification (for a maximum period of six months) until the client's action plan has been verified;
- revoke the certification.

If nonconformities are identified during the surveillance audit, the provisions set forth in section A.3.8 above shall apply for their resolution, with the specific provision that, if an action plan is agreed upon, Italcertifer must be able to evaluate it and make its final decision within **six months** of the submission of the audit plan to revoke, confirm, or modify the scope of the certificate. After this period, Italcertifer reserves the right to suspend the certificate for a maximum period of **six months** in accordance with the procedures described in Section 9 above.

The results of the surveillance audit and Italcertifer's final decision are communicated to the client through the same communication channels used for the initial certification.

Please note that the certified client must submit to Italcertifer, at least **one month** prior to each surveillance audit, a report prepared in accordance with the guidelines and containing the information specified in Annex V of Regulation (EU) 2019/779. In particular, the client must inform Italcertifer of any changes that could have a significant impact on the scope of its certification.

A.11 CERTIFICATION RENEWAL

With regard to certification renewal, the general provisions set forth in Section 7.2 of these regulations apply. As a rule, Italcertifer requires that clients seeking certification renewal submit a new application in accordance with the guidelines set forth in Section A.6.1 above.

Certification renewal audits may require a Stage 1 audit if significant changes have occurred in the management system, the organization, or the context in which the management system operates (e.g., changes in legislation).

The conduct of the renewal audit, the planning, the tools used, and the procedures for addressing any findings are similar to those described in the preceding paragraphs of this Appendix.

With regard to the decision on renewal, the criteria and rules applied by ITCF are the same as those described in § A.6 of this Appendix.

For renewal as well, in accordance with applicable regulations, the Deliberative Body is involved; based on a review of the audit results, it may decide to:

- renew the certification without reservations;
- renew the certification with a reduction in the scope of application;
- postpone the decision or suspend certification (for a maximum period of 6 months), depending on the severity of the nonconformities identified, until the ECM's proposed action plan has been verified;
- revoke the certification.

A.11.1 Issuance, start, and end of validity of the renewal certificate

Regarding the validity of the renewal certificate, please note that one of the following three scenarios may occur:

- a. The renewal process (including the decision) is successfully completed **before the expiration date** of the current certificate. In this case, the new certificate is issued as a continuation, with the new expiration date based on that of the previous certificate (typically up to 5 years from the expiration date of the first issuance);
- b. The certification process (including the decision) is not completed by the expiration date of the current certificate, but in any case **no later than six months** after that date. In this case, Italcertifer may renew the certificate with an expiration date consistent with the previous cycle (see the previous case), but with an issuance date and effective date coinciding with the date of the renewal decision made after the expiration date.
- c. If the certification process (including the decision) cannot be completed **within six months** of the expiration of the current certificate, Italcertifer will not be able to renew the certificate, and the client will have to start the certification process from scratch. Please note that in this case, it will not be a renewal but rather a new certification that will not retain continuity with the previous cycle and will be subject to specific new contractual agreements.

SECTORS

APPENDIX B: VALIDITY OF THE MULTI-YEAR QUALIFICATION FOR TESTING LABORATORIES

For multi-year qualifications of testing laboratories, Italcertifer issues a certificate valid for two years following the evaluation process.

The multi-year qualification certificate may therefore be renewed upon expiration of its validity period, provided that the client has requested renewal, has previously entered into a new commercial agreement with Italcertifer, and the audit required for renewal has been conducted within 24 months of the date of the initial qualification decision.

The periodic evaluation process for the renewal of the certification is conducted using procedures and tools similar to those described in section 5.3, generally without a document review phase. This phase may be necessary if significant changes have occurred in the laboratory’s management system or in the context in which it operates (for example, changes in legislation).

The new certificate will also be valid for two years, effective from the date of completion of the renewal audit.

Before the start of the renewal audit, the client must therefore notify Italcertifer well in advance (typically at least six months before the certificate’s expiration date) of their intention to renew the current certification for the next cycle. Italcertifer will update the commercial offer, taking into account any changes to the laboratory’s organization that occurred during the previous cycle and to the scope of the certification. The new commercial offer will be drafted in accordance with the provisions of paragraph 5.4 above.

The renewal audit must normally be conducted well in advance² of the expiration date of the current certificate, so that the client has sufficient time to address and resolve any nonconformities, and so that Italcertifer can conduct the review and the FD can make its subsequent decision.

If the certificate has expired for any reason, the previously certified client may not use it and/or refer to it.

With regard to renewal procedures and situations that may affect the validity of the qualification certificate, the three scenarios described below apply.

Issuance, start, and end of validity of the renewal certificate

Case A: Completion of the renewal audit before the expiration date

The renewal audit is completed before the certificate expires, and the decision to issue the certificate is made after the corrective action plan proposed by the laboratory has been accepted (either before or after the certificate expires). In this case, the certificate will be issued to the client following the renewal decision, with a validity period of two years from the date the audit is concluded.

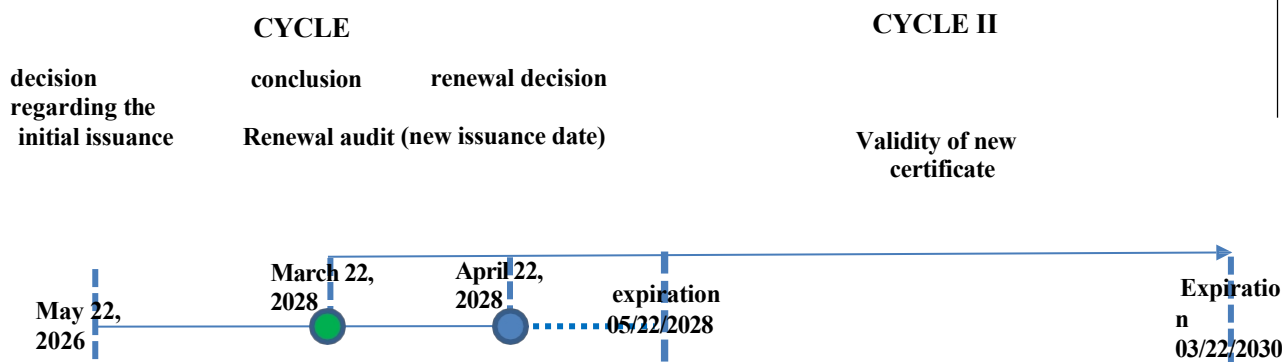


Figure 1. Example of completing a renewal audit and making a decision before the certificate expires

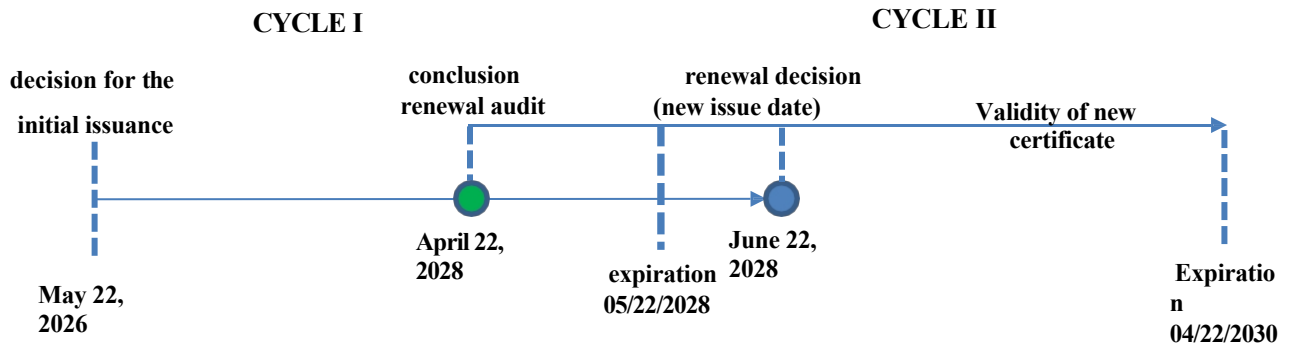


Figure 2. Example of completing a renewal audit before the certificate expires and subsequent decision

Case B: Completion of the renewal audit after the expiration date

The renewal audit is completed after the expiration date, and the decision to grant certification is made following acceptance of the corrective action plan proposed by the laboratory. The certificate will be issued to the client following the renewal decision, with a validity period of two years from the date the audit is concluded.

In this case, the continuity of the qualification's validity is interrupted. Specifically, the qualification is invalid for activities performed by the laboratory during the period beginning on the day following the expiration of the qualification certificate and ending on the day preceding the conclusion of the renewal audit, provided that the renewal decision is approved. This situation is illustrated in Figure 3.

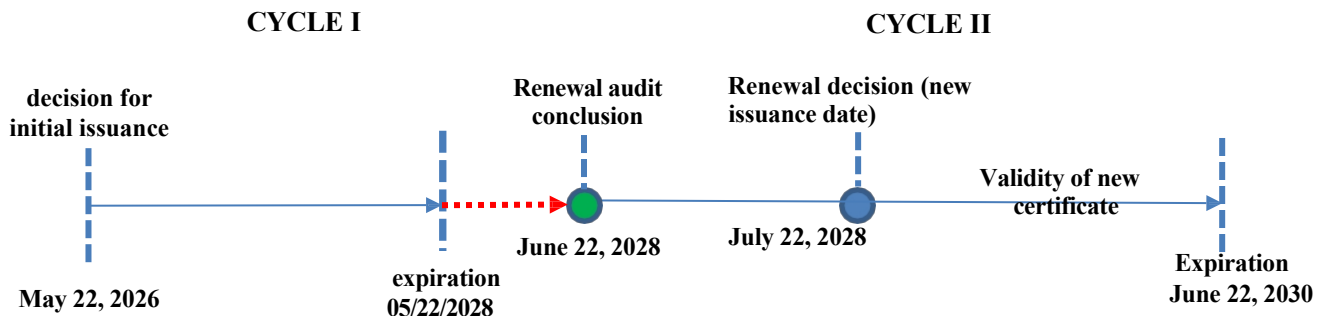


Figure 3. Audit completed by the deadline and qualification certificate issued within 6 months of the initial expiration

..... date; period not covered by the qualification

Case C: Renewal process not completed within 6 months of the expiration date of the previous certificate

If the renewal audit is not successfully completed within six months of the expiration date of the previous qualification certificate, Italcertifer must conduct a new initial audit and issue a new certificate without maintaining continuity with the previous qualification cycle. This will not be a renewal process, but rather a new qualification subject to specific contractual agreements with the client.