Summary

0 INTRO

The certification 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 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 on samples taken from production and the free market.

The value of certification is the degree of trust and credit established through impartial and competent demonstration, carried out by a conformity assessment body such as ITALCERTIFER S.p.A. (hereinafter also referred to as "ITCF"), of compliance with requirements specified in standards and in the various certification and inspection schemes. The parties that have an interest in certification are those listed below, although this list is not exhaustive:

a) the customers 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 requesting Italcertifer to certify products, processes, or services, or to carry out inspections in the railway sector, the rules applied for issuing and maintaining certification are described below.

1 GENERAL PRINCIPLES

ITCF recognizes impartiality and the absence of conflicts of interest as fundamental principles for certification. To this end, it has formally committed itself, through a statement made by its Legal Representative and published on the company website, not to carry out activities that could generate conflicts of interest, such as, for example, consulting as defined in § 4.

A similar commitment is required of all its assessment staff (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 between potential customers. Access to the certification process does not depend on the size of the customer or its membership of any association or group, nor is it conditioned by the number of certifications already issued.

Other principles considered fundamental and applied by ITCF in its activities include competence, confidentiality, transparency, responsibility, and rapid response to complaints.

2 PURPOSE AND SCOPE

These regulations apply to all product certification schemes that ITCF carries out under ISO/IEC 17065 accreditation, including for the purposes of its notification to the European Commission, and to inspection activities under ISO/IEC 17020 accreditation carried out in the railway sector.

The list of certification and inspection schemes is included in accreditation certificates no. 0107PRD and no. 0058ISP, 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 specifies 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), with the ISO/IEC 17020 standard. Additional provisions set out in the standards, regulations, and circulars of the accreditation body relating to the certification schemes applied by ITCF are included in the appendices to these regulations, of which they form an integral part.

These regulations also constitute, where applicable, the general reference for all product certification schemes applied by Italcertifer outside the aforementioned areas.

ITCF applies specific sales prices for its certification activities, guaranteeing fairness and uniform treatment to all its customers. ITCF reserves the right to reject a certification application or terminate certification contract with a customer when there are valid or proven reasons, such as a customer's participation in illegal activities or a series of repeated non-conformities with certification/product requirements, or the occurrence of other similar circumstances.

The certifications and inspections referred to in these Regulations are issued and maintained by virtue of specific accreditations granted to ITCF by Accredia, the sole Italian accreditation body (https://www.accredia.it/). Accredia may, at any time, carry out accompanied visits to ITCF customers to verify their work .

By accepting the conditions contained in these Regulations, the client undertakes to guarantee the right of Accredia Inspectors/Technical Experts to access its premises (accompanied by ITCF), even without prior notice, under penalty of non-granting of certification or suspension or revocation of certification in the event of persistent failure to comply with this obligation, except for justified reasons.

In the event that Accredia intends to carry out an accompanied audit, or in any case to carry out an inspection at the premises of customers requesting certification, ITCF undertakes to promptly communicate this request and to provide maximum cooperation to its customers in this regard.

The right of access to Accredia Inspectors/Technical Experts must also be guaranteed at any laboratories used by the customer as part of the certification processes covered by Italcertifer S.p.A.'s accreditation no. 0107PRD.

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 providing audit and certification of management systems - part 1: requirements";
- Applicable IAF/EA Mandatory Documents;
- Directive 2016/797/EU on the interoperability of the European Union's rail system (recast);
- Legislative Decree 57/2019 implementing Directive 2016/797 of the European Parliament and of the Council of May 11, 2016, on the interoperability of the European Union rail system
- Directive 2016/798/EU on railway safety (recast);
- Legislative Decree 50/2019 implementing Directive 2016/798 of the European Parliament and of the Council of May 11, 2016, on railway safety;
- Regulation (EU) No. 779/2019 laying down detailed rules on a system for the certification of entities in charge of maintenance of vehicles under Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No. 445/2011;
- 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 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 Accreditation Body (ACCREDIA).

4 DEFINITIONS AND ABBREVIATIONS

Accredia	Single national accreditation body designated by the Italian government, in application of 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	Assessment Body or CSM Assessor for the risk management process pursuant to Regulation (EU) 402/2013
Scope of certification	Identification of: – product(s); process(es), service(s) for which certification is issued; – applicable certification scheme; and – standard(s) and other regulatory document(s), including their date of publication, with which the product(s), process(es) or service(s) are deemed to comply.
Consultancy	Participation in: - the design, manufacture, installation, maintenance, or distribution of a certified product or a product to be certified, or - the design, implementation, management, 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 persons (e.g., a committee) who have not been involved in the assessment process and are tasked with making the certification decision.
Organization	This refers to any company, public or private body, or other institution that requests a certification service from Italcertifer S.p.A. Unless otherwise specified in the document, the term "organization" is synonymous with the term "customer."
Complaint	This refers to an expression of dissatisfaction in relation to administrative, managerial, or technical aspects of the activities carried out by Italcertifer.
Regulations	Unless otherwise specified, this refers to the present certification regulations.

Appeal	This refers to the explicit and documented expression of non-acceptance of decisions taken by Italcertifer in the context of audit and certification activities.
Certification scheme	Certification system relating to 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 CERTIFICATION PROCESS

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

5.1 Certification application

In accordance with accreditation standards, ITCF requires the applicant organization to provide a series of preliminary and information to enable to assess whether the conditions for initiating the certification process are met. This information is normally contained in a certification application completed by a representative of the organization itself. The information requested includes, for example:

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

When assessing an application for a railway inspection service, ITCF will request similar information relating to the subject and scope of the inspection.

5.2 Review of the application and commercial offer

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

If the application is rejected for one or more reasons referred to in these regulations, ITCF shall notify the applicant, stating the reasons.

When reviewing the application, ITCF shall consider in particular whether:

- the information about the customer and the product is sufficient to carry out the certification process;
- any differences in understanding between ITCF and the customer have been resolved, including agreement on the applicable standards or other regulatory documents;
- the scope of the certification requested has been defined;
- it has the means and resources to carry out the assessment activities;
- it has the competence to perform the certification activity.

If the application is accepted, ITCF prepares a commercial offer that normally includes the following:

- premises;
- description of activities;
- applicable reference standards;
- customer documentation;
- assumptions and exclusions;
- activity scheduling (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 certification process requested.

If, during the certification process, the information initially provided proves to be inaccurate or out of date, ITCF reserves the right to correct its initial offer.

Unless otherwise specified by the customer, the language used for the 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 customer for the costs of translating them, based on a specific quote.

By accepting ITCF's commercial offer, sending the purchase order, or entering into a specific contract, the customer also accepts the conditions set out in these regulations and in the appendices that form an integral and substantial part thereof.

5.3 Process Stages/General Information

The certification process is carried out through an assessment plan that includes one or more of the following aspects:

- evaluation and inspection of the design and technical documentation produced by the customer;

- participation in laboratory and in-line testing (for railway vehicles);
- site visits and field checks (in the case of fixed installations);
- audits aimed at approving the quality management system applied to production;
- production monitoring activities (where applicable).

Once the assessment activities have been completed, the certification process involves:

- review of all information and results relating to the assessment;
- the decision to issue the certificate by a Decision-Making Body independent of those who carried out the assessments;
- the issuance of the certificate;
- certificate monitoring activities (where required and/or applicable).

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

Some types of certificates do not have an expiry date and are therefore considered to be valid indefinitely, provided that the conditions for the initial issue (e.g., design, system configuration, etc.) do not change over time. As specified below, in the event of changes not communicated to ITCF, the certificate shall be considered invalid.

For each certification order, an assessment plan is defined that includes all the activities necessary for issuance (and surveillance, where applicable) and is managed by an ITCF internal Order Contact who handles customer relations.

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

- scope of certification;
- complexity/criticality of the product (including design);
- design and production planning;
- necessary laboratory and in-line testing activities (where applicable);
- number of sites involved in production;
- whether or not the product has already been certified;
- language used for audits and documentation (if different from Italian).

Similarly, for inspection activities carried out as ASBO, an independent safety assessment plan is defined in order to ensure a thorough assessment of the modification and the results of each stage of the risk management process referred to in Annex I of Reg. (EU) No. 402/2013 and subsequent amendments.

Before the assessment activities begin, a kick-off meeting is generally held with the client, during which, among other things, the assessment team is presented. The client has the right, within 3 days of receiving the names, to reject certain assessors involved, giving written reasons. After this period, the audit team is considered to have been tacitly accepted.

ITCF uses qualified and competent personnel listed in specific registers subject to Accredia control to carry out its assessment activities. The team of assessors may consist of ITCF employees and/or persons linked to ITCF with specific forms of collaboration contracts.

The resources identified, regardless of the type of relationship they have with the company, operate in accordance with ITCF's Quality Management System procedures with the utmost

professionalism and respect for the customer. Both internal and external personnel employed in the certification process must comply with the same requirements of competence, impartiality, and confidentiality prescribed by the applicable accreditation standards and Accredia regulations.

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

In the event that ITCF entrusts specific assessment and/or testing activities to other organizations, it ensures that they meet the requirements of the standards relevant to the type of activity. In particular:

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

Furthermore, in the case of non-accredited and/or non-notified organizations, ITCF guarantees that the impartiality requirements relating to the personnel of those organizations performing the activities are always met.

Remote audits.

Audits for initial certification, surveillance, renewal, and special audits may be performed remotely in a controlled manner and in accordance with the requirements of ISO/IEC 17065 and the reference documents IAF MD4, IAF MD 5, and IAF ID12, as applicable.

For each of the above types of audit, ITCF will conduct an assessment of the feasibility and duration of remote audits in order to determine the cases in which it is possible to partially or totally replace an on-site audit.

The possibility of conducting remote audits is applicable, in principle, to all certification schemes, unless otherwise specified by the accreditation body, and in any case subject to confirmation by ITCF.

Remote auditing techniques involve the use of means such as teleconferencing (audio only or audio+video) and/or computer access to documents and recordings of the system to be audited. Their use may replace physical presence, provided that they guarantee the same effectiveness as an audit carried out using traditional techniques. This circumstance must be subject to preliminary assessment by ITCF, and subject to confirmation of the availability of the necessary IT infrastructure at the customer's premises.

5.3.1 Assessment activities

The assessment of a product generally includes both the design and production phases. Where applicable, the assessment is also extended to a production monitoring phase. In some cases, the assessment (and subsequent certificate) may refer only to design or production. The activities envisaged, even in these cases, are those referred to in paragraph 5.3 above.

Depending on the applicable certification scheme, the assessment procedure may be carried out on the basis of one or more assessment modules, which will correspond to the relevant certificates.

In the field of railway interoperability (Directive 2016/797/EU and related legislation), the customer has the right to choose the combinations of modules that are eligible for the type of product being certified.

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 the applicable regulations.

For inspection activities carried out as ASBO, Italcertifer will issue the proposing entity with an Assessment Report necessary to obtain the authorizations required by the current regulatory framework.

Elements subject to assessment

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

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

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

- unique identification and date of approval or issue;
- identification of the elements subject to assessment and evidence related to each requirement verified;
- assessment judgment(s) regarding the conformity of the elements assessed;
- any indications regarding the conditions/limitations of use of the objects assessed;
- additional information useful for improving understanding of the assessment report;
- signature by the personnel responsible for the assessment and review.

Laboratory testing activities

As part of the assessment activities described above and based on applicable regulations, testing activities may be necessary on the products being certified. In order to be accepted within the certification process, these activities 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 related results meet the following requirements:

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

To this end, ITCF has developed appropriate assessment procedures that include 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 product conformity assessment purposes, except for the following formal checks:

- the activity has been carried out within the scope stated in the laboratory's accreditation certificate;
- the test report(s) bear(s) 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 still meet the applicable requirements of ISO/IEC 17025 and other relevant documents (ERA 000MRA1044, RFU-STR-022, etc.), but the absence of accreditation is compensated for by a specific assessment by a notified body to be carried out prior to their execution. The costs of this assessment are borne by the customer.

In this regard, ITCF also has a list of laboratories that it has qualified as meeting the requirements of ISO/IEC 17025 and which it monitors through periodic audits. The client, in the context of processes where ITCF is the certification body, may use these laboratories without the burden of a specific assessment of compliance with the requirements of ISO/IEC 17025.

Without prejudice to compliance with the requirements applicable to testing activities, the options described in this paragraph are to be considered equivalent for the purposes of accepting the results of the testing activity within the assessment 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) cannot in any case be understood as equivalent to or a substitute for the specific accreditation and its meaning as described in Reg. (EC) 765/2008.

Approval of quality management systems related to design and production

Depending on the certification scheme, the assessment process may require the 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 to the approved type or prototype.

The assessment process for this area will follow the requirements of Chapter 9 of ISO/IEC 17021-1 and will be carried out mainly on-site at the sites involved in the production process.

It should be noted that a customer's possession of certification of its quality management system, even if issued by a third-party body accredited by a signatory to mutual recognition agreements, does not in any way replace 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 the European Union).

5.3.2 Classification of findings

The results of the assessment activities described in the previous paragraph are classified by ITCF on the basis of the indications contained in the applicable reference legislation.

For activities carried out 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 of the applicable reference standard are met through the evidence collected 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 collected and/or risk analysis, which are appropriately tracked
Compliant in phases or in parts	The requirements of the applicable reference standard, strictly necessary for the phase or part under consideration, 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.
Suitable for use (Interoperability components)	Assessment to be used in the case of EC verification of interoperability components, with CV module, which has given a positive result
Non-compliant	No evidence of compliance with one or more requirements of the applicable reference standard

In addition to the above, the following classifications of findings are mainly used in the context of quality system approvals, maintenance systems, and laboratory qualifications:

OBSERVATIONS (OSS, minor non-conformities) Non-conformities that do not affect the ability of the management system to achieve the expected results;

COM**MENTS** (or opportunities for improvement) when anomalies have no impact on the management system at the moment but could degenerate into potential non-conformities over time.

5.3.3 Analysis of causes, treatments, and corrective actions to findings

In the presence of judgments classified as NON-CONFORMING, TECHNICAL NOTES are opened on the specific element. The Technical Notes are sent to the customer so that they can produce sufficient evidence (new design documentation, additional laboratory tests, third-party certifications, etc.) to overcome 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 customer identifies the causes of the findings recorded during the audits and proposes a plan of treatment and corrective actions to remove them. The corrective action plan must normally be provided no later than 30 days after the date of completion of the audit. The proposed corrective actions and treatments must be appropriate to the level of severity found and will therefore be evaluated by ITCF. Evidence of the closure or acceptance of the findings is also recorded in the final assessment reports.

5.4 Review and decision

At the end of the assessment process, once all technical notes have been closed and evidence of the planned corrective actions and treatments has been provided, a review of the results is conducted so that ITCF can make an informed decision on whether or not to issue certification.

Once the review is complete, the Decision-Making Body (DM) provided for in the specific scheme makes a decision on certification based on all the information relating to the assessment process, its review, and any other relevant information. Depending on the type of certification scheme applied, the decision may be taken by a single person or by a group of people meeting in a special committee. In both cases, the decision-maker is a person who has not been involved in the assessment 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.

Customers who express an interest in restarting the certification process may submit a request to do so; customers who disagree may lodge an appeal in accordance with the procedures set out in section 17 below.

For inspection activities carried out as AsBo, at the end of the assessment process, there is no intervention by the FD as the process ends with the review and approval of the Assessment 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 certification is issued and sent to the customer.

The certification is normally valid from the date of the FD's decision. In some cases, depending on the scheme and type of certification, the validity of the certification starts from the date of the last audit and may be subject to periodic surveillance. The surveillance activity is carried out by ITCF at the intervals indicated on the certificate.

During its surveillance activities, ITCF has 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 with respect to updates made to the certification schemes.

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

For inspection activities carried out as AsBo pursuant to Reg. (EU) 402/2013 and ISO/IEC 17020, no certificate or attestation will be issued as the process ends with the review and approval of the Assessment Report.

5.6 Registration of the certificate and information on the results of certification

ITCF reports information on certified products with regard to the following:

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

All information relating to the certificates issued is contained in a special computerized register developed and managed by ITCF.

The customer acknowledges that, by virtue of 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 communicate the data relating to the certificates issued in publicly accessible registers (e.g., ERADIS).

6 USE OF THE CERTIFICATE AND INSPECTION REPORT

Upon issuance of the certification, the Organization acquires the right to use the certificate obtained, the ITALCERTIFER S.p.A. logo and, where applicable, the logo of the accreditation body and any other entities (e.g., NB-RAIL) in accordance with the conditions set forth in these regulations and in those for the use of the trademark available at: https://www.italcertifer.com/it/chi-siamo/info_e_risorse.html.

The Organization's right to use the[1] certificate ceases immediately upon the occurrence 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 reported in the certificate issued. ITCF reserves the right to verify the correct use of the certificate at any time.

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

ITCF reserves the right to carry out checks at any time with regard to its certificates and reports issued. To this end, ITCF may take any action it deems appropriate to terminate the improper use of the certificate, its logo, or that of other entities (e.g., Accredia, NB-Rail, etc.).

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

- conducting extraordinary audits;
- requesting corrective actions;
- suspension or withdrawal of certification;
- notification to the accreditation body;
- initiation of legal action.

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

By issuing the certification, the Organization grants ITCF the right to produce the certificate and/or an extract thereof as references for tender procedures and in any other circumstances in which they are requested.

7 MAINTENANCE OF CERTIFICATION

If surveillance is required by the certification scheme (e.g., ECM certifications), ITCF will begin surveillance of the product(s) in accordance with the rules in order to maintain its validity.

[1] Including the logos associated with it.

It should be noted that for inspection activities carried out as AsBo pursuant to Reg. (EU) 402/2013 and ISO/IEC 17020, no surveillance activity is required after the issuance of the Assessment Report.

7.1 Periodic surveillance audit

Where required by the applicable scheme, ITCF draws up a surveillance program to verify that the certified product continues to comply with the requirements of the reference scheme or any other standard or norm against which it has been certified.

Surveillance audits, where applicable, are mandatory for the certificate to remain valid and are intended to verify that the requirements for the product continue to be met.

The fact that the customer, without adequate justification, does not intend to undergo a surveillance audit within the specified time frame constitutes sufficient grounds for the suspension of the certificate and, if the situation persists, for the subsequent indefinite suspension or revocation of the certificate by ITCF.

The procedures for conducting surveillance audits are similar to those described in paragraph 5.3.1 and following, with the exception, unless there are special reasons or specific indications in the certification scheme, of the intervention of the Deliberative Function (FD).

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

Only situations of exceptional gravity or force majeure (based on the indications of the IAF ID3 document and applicable Accredia circulars) may allow for exceptions to the planned surveillance activities, which must be requested in writing to ITCF. The tolerances applied to surveillance activities do not ly change the frequency of any subsequent audits, which must in any case comply with the original audit schedule.

The performance of surveillance audits is subject to payment of the fees due for previous activities.

7.2 Renewal audit

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

Before the necessary activities are started, the client must express their intention to renew the existing certification for the duration provided for in the reference scheme well in advance (normally at least 6 months before the certificate expires). In this case, ITCF will update the commercial offer, taking into account any changes that have occurred in the client's organization, product, or certification scheme in the previous cycle.

The activities planned for the renewal audit are similar to those described in paragraph 5.3.1 and following.

Once the renewal audit phase has been completed, ITCF will:

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

The renewal audit must be carried out well in advance (at least 1 month before) the expiry date of the previous certificate, so as to allow sufficient time to manage and resolve any non-conformities, to conduct the review, and for the FD to make its decision.

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

7.3 Special audits

7.3.1 Extension of the scope

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

The extension of the scope of certification does not affect the expiry date of the certificate.

7.3.2 Extraordinary audits

ITCF reserves the right, giving written reasons for its decision, to carry out extraordinary audits in relation to the certificates issued. Such audits may be carried out, in addition to those provided for in the audit program, by way of example and without limitation, in one or more of the following cases:

- following a surveillance activity to verify the closure 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 concerning the purpose 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 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 additional to them and are at the expense of the Organization.

Extraordinary audits may also be planned at short notice on the basis of information gathered on the market regarding one or more of the above cases or due to serious deficiencies in the management system, in particular for products related to railway safety.

7.4 Audits at customer suppliers

In order to verify the effectiveness of the customer's management system, ITCF reserves the right, at any stage of the certification process, to carry out audits at those suppliers to whom the customer entrusts critical and/or relevant processes included in the scope of the certificate.

ITCF shall notify the customer in advance of the need to carry out audits at suppliers, giving reasons for doing so. To this end, the customer must take steps to ensure that its supplier allows access to all records, data, and information relating to the processes outsourced by the ITCF customer and falling within the scope of certification.

If the customer does not allow such access, ITCF may interrupt the certification process and take actions ranging from suspension to reduction of the scope or revocation of the certificate.

8 WAIVER OF CERTIFICATION AND INSPECTION BY THE ORGANIZATION

If, during the assessment process, the client intends to waive certification, or its maintenance if already issued, it must notify ITCF in writing at least 60 days before the start date of the activities scheduled in the program, or the date of first issue in the case of initial certification.

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

In any case, following the request for withdrawal, ITCF shall notify the Organization of the interruption of activities and the revocation of the certificate if already issued.

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

- a ban on using the certificate and related logos in any way;
- the registration of the revocation in all public and internal ITCF registers.

Similarly, if the customer intends to permanently interrupt an inspection carried out as an AsBo pursuant to Reg. (EU) 402/2013 and ISO/IEC 17020, waiving the conclusion of the service, they must notify ITCF in writing at least 30 days before the date set for the conclusion of the activity. If the notice period is respected, the Organization will only be required to pay for the activities carried out by ITCF up to the date of receipt of the request for termination; if the notice period is not respected, ITCF reserves the right to charge the full amount of the cost of issuing 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 giving written notice if even one of the following conditions occurs:

- 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 customer who owns the certificate does not allow the certification surveillance audits to be carried out at the required frequency;
- when the client does not accept that the ITCF verification team is accompanied by Accredia inspectors;
- when the customer has not implemented the required corrective actions by the established date;
- when the customer does not comply with the conditions set out in these regulations and/or in the commercial offer;
- when the customer refuses to implement new requirements introduced as a result of changes to the certification scheme;
- when the customer makes improper and misleading use of the certification;
- when the customer has not notified ITCF of the existence of ongoing legal proceedings relating to aspects of the subject matter of the certification;
- when the customer who owns the certificate has voluntarily requested suspension;
- when a condition of late payment persists after reminders sent by ITCF.

The notice of suspension shall contain the conditions for restoring validity (including any need to carry out extraordinary audits and the related costs) and the contact person at ITCF.

The suspension, which takes effect from the date of dispatch of the notification by ITCF, does not affect the terms of validity of the contract and the expiry of the certificate, which remain unchanged. The suspension period may not, as a rule, exceed six months. ITCF shall record the suspension in its register of certified products and, where applicable, in public registers (e.g., ERADIS).

Following notification of the temporary suspension, the customer must immediately suspend use of the certificate and related logos (ITCF, Accredia, NB-RAIL, etc.).

The suspension may only be lifted once the conditions of compliance have been restored, including the successful completion of any extraordinary audits. The necessary activities and, more generally, the conditions of compliance must be restored and completed before the expiry date of the suspension. If these conditions are not restored, the certificate will be subject to definitive suspension or revocation, where applicable.

10 DEFINITIVE SUSPENSION AND REVOCATION OF CERTIFICATION

ITCF may definitively suspend or revoke a certificate, where provided for in the applicable scheme, if one of the following conditions occurs:

- if, at the end of the suspension period, the circumstances that led to the suspension have not been removed;
- if the customer withdraws from the contractual relationship established with ITCF, in accordance with the provisions of these regulations and the conditions contained in the commercial offer;
- if it is judicially established that the organization that owns the certificate has failed to comply with the requirements of the subject of certification.

The decision on the definitive suspension or revocation of the certification shall be notified in writing to the customer, together with the reasons for the measure.

Following the definitive suspension or revocation, the customer is obliged to immediately cease all reference to and use of the certificate, including that relating to logos and trademarks contained therein.

11 USE OF CERTIFICATES ISSUED BY OTHER BODIES

For the development of its activities, ITCF relies mainly on the results of assessments carried out within its own certification processes and with its own resources.

If the customer submits certificates issued by other bodies, ITCF will rely exclusively on certificates issued by bodies that have the accreditations and recognitions required by the applicable certification scheme (e.g., certificates issued by other bodies notified for Directive 2016/797/EU or ISO/IEC 17065 accredited product certification bodies). Other certificates issued by bodies that do not hold the above accreditations and submitted by the customer must comply with all the requirements of the applicable scheme in order to be considered by ITCF for the purposes of its activities, without prejudice to ITCF's right to request or carry out further checks, the cost of which will be charged to the customer.

12 CHANGES TO THE CERTIFICATION SCHEME

In the event that the legislator, the Regulatory 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:

- inform the organizations concerned in writing;
- provide guidance and deadlines for adapting the subject of certification;
- take into consideration any comments on the changes made by the certified organizations.

Changes to certification schemes may in some cases require additional audits to be carried out, which will be charged to the customer.

If the organization (certified or undergoing certification) does not intend to comply with the changes introduced, it may exercise its right to renounce certification in accordance with the procedures specified in Chapter 7 above.

13 CLIENT CHANGES

The certified customer is required to notify ITCF of any changes that may have an impact on certification. Such changes include, but are not limited to, those relating to:

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

ITCF will assess the extent of the changes, classifying them as minor changes, which have no impact on the purpose of the certification, or major changes, which affect the purpose 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 extent of which will be established in specific contractual agreements.

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

14 FEES AND PAYMENTS

is offered a service calculated on a daily basis and including all the stages provided for in the assessment program drawn up for initial certification and, subsequently, if requested by the customer, for renewal.

Given that the fees applied may be subject to variability, including due to external macroeconomic factors, ITCF nevertheless undertakes to ensure that those proposed in the initial offer are the same on the date of issue of the certificates.

ITCF reserves the right to notify a revision of the offer if the scope or activities requested by the customer are found, subsequently or during the verification activities, to be inconsistent with the information provided by the customer in the initial application.

Specific charges for additional activities, beyond what was agreed, will be included for all activities not listed in the initial offer and subsequently requested by the customer, as well as for activities that may be necessary to close Non-Conformities or for other cases described in these regulations. These charges may include, but are not limited to, costs for:

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

ITCF reserves the right to charge additional fees to the rates in force in the event of customer requests for:

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

The rate for services is quoted on the basis of the cost of one man-day (day/man) of work. In this regard, an indicative rate assessment can be made available in advance at the express request of the customer. Unless otherwise indicated, the prices offered for individual work packages include travel expenses. Furthermore, all rates and any additional costs do not include VAT or other applicable taxes.

The terms of invoicing for services, together with other conditions of sale, are specified in the individual quotations sent to and accepted by the customer. Upon completion of each activity specified in the quotation, purchase order, and/or contract (where applicable), ITCF will issue a regular invoice to the customer.

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

15 CONFIDENTIALITY OF INFORMATION

By entering into certification agreements with its customers, ITCF ensures that all information obtained in the course of certification activities is treated as strictly confidential by all levels of its organization, unless otherwise required by law. The obligation of confidentiality applies equally to ITCF's internal staff and to any external personnel involved in the certification processes.

In addition to what is 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 other mandatory standards, ITCF does not disclose information about its certified customers to third parties.

It should be noted that, based on mandatory provisions of certain certification schemes, information on the issuance and validity status of a certification and on the owner of the certificate must be made available by ITCF in specific public registers (e.g., ERADIS).

Information about the customer originating from sources other than the customer itself (e.g., 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 tools) in place to ensure the security and confidentiality of the above-mentioned information necessary 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 towards the complainant. In particular, the process applied by ITCF ensures that the decision to be communicated to the complainant is taken 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 relating to the certification process, with the exception of those relating to decisions taken by Italcertifer in the context of audit and certification activities (see paragraph 17), and must be submitted by registered mail to the registered office of ITCF, or by certified email toitalcertifer@pec.it .

ITCF reserves the right to declare complaints received by means other than those indicated above inadmissible.

ITCF will then confirm receipt and initiate the process by collecting and verifying all the information necessary to validate the complaint. The complaint, which cannot be anonymous, must include a description of the activity being contested and the process to which it refers.

Upon receipt in the manner described above, ITCF will verify, within (15) consecutive calendar days, the admissibility of the complaint in relation to the certification activity for which it is responsible; if the complaint is admissible, after notifying the customer, it will proceed with the preliminary investigation. This phase will be carried out by the relevant organizational structure, which will respond to the request within thirty (30) calendar days if the complaint concerns its own work, or within sixty (60) calendar days if the complaint concerns one of its clients who is the owner of the certificate. If the decisions taken in relation to the complaint involve specific corrections or corrective actions, ITCF guarantees that these will be implemented.

Any valid complaint concerning a customer who is a certificate holder will also be reported by ITCF to the customer in a timely manner.

ITCF will communicate the progress of the process to the person who submitted the complaint. Each complaint and the related determination are kept in a special archive.

Except where required by law, ITCF will determine, together with the certified customer and the person who submitted the complaint, whether, and if so to what extent, the content of the complaint and its resolution should be made public.

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

17 APPEALS

ITCF ensures, under its own responsibility, an objective and independent appeals process (as defined in Chapter 4). In particular, ITCF guarantees that the persons involved in the appeals

assessment process (including those who make the final decision) are different from those who carried out the audits and/or made the decisions regarding certification.

The appeal may only concern decisions taken by ITCF in relation to the issue, reduction, suspension, or revocation of a certification and must be submitted only by the organization to which the decision is addressed by registered letter to the registered office of ITCF, or by certified email toitalcertifer@pec.it within thirty (30) consecutive calendar days of the transmission of the certificate subject to appeal.

ITCF reserves the right to declare appeals that arrive after this deadline or in a manner other than that indicated above inadmissible.

ITCF will then confirm receipt and begin the appeal review process.

The appeal must contain an indication of the decision against which the action is being taken, the factual and legal grounds on which the request is based, any documents supporting the argument put forward, and the conclusions specifying the request that ITCF is asked to accept.

The correctly notified appeal is submitted to the relevant organizational structures which, after acquiring the file relating to the certification subject to appeal and verifying its admissibility, validity, and procedur , will analyze it and, within forty-five (45) calendar days of receipt, notify the organization of the conclusion of the proceedings through a specially appointed case manager.

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

If the decisions taken in relation to the appeal involve specific corrections or corrective actions, ITCF guarantees that these will be implemented.

ITCF will communicate the progress of the appeal process to the organization.

ITCF ensures that the submission of appeals, their examination, and the related decisions will not give rise to any discriminatory conduct towards the organization that submitted the appeal.

18 CUSTOMER OBLIGATIONS

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

- continuously meet the certification requirements, including the implementation of appropriate changes when these are communicated by ITCF;
- comply with the requirements of these regulations and those referred to therein (e.g., regulations on the use of the logo) when referring to the status of their certification in media such as the internet, brochures, advertising material, or other documents
- not make or condone references or statements that may be misleading about its certification;
- make statements about certification that are consistent with the scope of the certification itself;
- not use, or allow the misleading use of, a certification document or parts thereof;
- discontinue the use of all advertising materials that refer to the certification in the event of its revocation, as requested by ITCF;
- rectify all advertising materials if the scope of the certification has been reduced;
- not use its product certification in such a way as to bring ITCF into disrepute;

- ensure the necessary conditions for the assessments to be carried out, both in terms of accessibility to all relevant production sites and/or construction sites, and in terms of the review of information and documentation and the conduct of field audits;
- provide all documents useful for ITCF assessments, in particular the work execution plans and technical documentation relating to the product;
- ensure that any ITCF observers and Accredia inspectors are able to participate in the audits;
- inform ITCF if it is involved in legal proceedings relating to, connected with, or linked to the certification issued.

19 ITALCERTIFER OBLIGATIONS

In the context of activities relating to the issuance, maintenance, and renewal of product, process, and service certifications, ITCF undertakes to:

- evaluate each certification application impartially and without discrimination, but may refuse the application if assesses that the conditions necessary for the conclusion of the certification process are not met (e.g., bankruptcy, convictions for crimes under Legislative Decree 231/01);
- communicate with adequate notice the presence of any observers, either its own or those of Accredia, ensuring that the presence of the latter does not unduly influence or interfere with the activities of the audit and the client;
- ensure a rapid and effective response to any complaints or appeals relating to its activities;
- assign personnel with the appropriate skills, ensuring effective mitigation of the risk of any conflicts of interest;
- base its decisions on the 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 for the impartiality of its actions and activities;
- guarantee the confidentiality of information obtained during the certification process.

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

A.1. PURPOSE AND SCOPE

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

The services described in this regulation apply to certification requests from organizations that perform one of the following roles:

- Entity Responsible for the Maintenance of a railway vehicle;
- Entity or Organization that performs one or more railway vehicle maintenance functions;

as defined in the applicable legislation and which carry out their own maintenance activities for vehicles running on the IFN or on networks functionally isolated from the rest of the railway system referred to in the decree of the Ministry of Transport Infrastructure No. 347 of 02/08/2019. Unless expressly specified in this Appendix, the conditions contained in the general part 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 the 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 determination 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 that have obtained a safety certificate or safety authorization, and entities in charge of maintenance";
- ANSF Decree No. 3/2019 "Regulation of rules and procedures, pursuant to Article 16, paragraph 2, letter 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) With effect from January 1, 2019";
- MIT Decree of February 12, 2019 "Transposition of Directive (EU) No. 2018/1846 amending the annexes to Directive No. 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 'Attributions in the field of 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 May 11, 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 containing the mandatory requirements set by the ERA for the ECM certification scheme
GdA	Audit Group
IFN	National Railway Infrastructure
RGA	Audit Group Manager
Entity Responsible for 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 is not adequately implemented, or if there are serious deficiencies that adversely affect the effectiveness of the maintenance processes managed by the Organization.

An NC is in any case indicative of a deficiency in the maintenance system that is considered critical because it is directly linked to potential risks:

- operation of vehicles in unsafe conditions;
- failure to achieve the minimum performance objectives expected for the operation of maintained vehicles.

Such cases, without limitation, may be detected, for example, in the presence of repeated maintenance interventions performed improperly or not carried out at the relevant deadline, accidents or serious operational incidents attributable to maintenance deficiencies, or other cases that could potentially lead to the return to service of vehicles that are not capable of operating safely.

Observation (OSS)
An Observation (OSS) is a finding that occurs when the inadequate implementation of a requirement of the certification scheme is not such as to directly or immediately compromise the quality of the maintenance processes and 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:

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

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

This type of finding requires the initiation of a corrective action and/or measure within a defined time frame, the implementation of which will be verified during the next visit, or the evidence of closure of which will be assessed in documentary form by ITCF if necessary.

It should be noted that the number or persistence of Observations may lead to the formulation of Non-Conformities during the development of the audit program.

Comments (COM)

The type of finding classified as a Comment (COM) does not result from the discovery 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 information for improving the Organization's maintenance system.

A.5 ACCEPTANCE OF THE AUDIT GROUP AND PLAN

It should be noted that the plans sent before each audit and the names of the assessment group will be considered tacitly accepted by the requesting Organization if, within **three working days** of notification, no written objections are received, for which ITCF reserves the right to assess their validity and admissibility and communicate this to the customer.

A.6 INITIAL CERTIFICATION

ITCF applies a process for the certification of ECMs in accordance with the ECM Certification Scheme ERA 1172/003 V1.1 document, which constitutes the mandatory reference scheme for the purposes of issuing certifications. The certification process follows the ISO/IEC 17065 standard and the applicable parts of ISO/IEC 17021-1 as referred to 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 from the certification decision. The following is a detailed description of all the stages involved in the process of obtaining initial certification, surveillance, and renewal.

A.6.1 Application

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

- description of the ECM's organizational structure, including, among other things:
  - general organization chart;
  - available human and technical resources;
  - number of maintenance workshops involved and any additional sites;
  - description of the maintenance system specifying the internal organizational structures that perform the four functions described in Annex II to Regulation (EU) 2019/779;

- any outsourcing of maintenance functions or parts thereof and the relevant qualification procedures;
- type of vehicles to which the maintenance system is applied and, in the case of wagons used for the transport of dangerous goods, the list of classes of dangerous goods that can be transported;
- the regulations applicable to the type of vehicles or goods transported, in particular dangerous goods;
- information on the maintenance policy and strategy to ensure compliance with the requirements set out in Annex II to Regulation (EU) 2019/779;

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

In the case of an application for certification as an entity performing maintenance functions, the applicant shall provide the same information as above, adapted to the function(s) or parts thereof, specifying in addition:

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

If the information provided by the applicant organisation is deemed incomplete, Italcertifer may request additional information until it has all the elements necessary to start reviewing the application and formulate a commercial offer.

The fact that the applicant does not intend to provide the above information or additions is sufficient reason for Italcertifer not to accept the application and not 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

Following the finalization of the certification agreement, ITCF appoints an Audit Group with the necessary expertise, whose assessment activities consist of a two-stage audit (stage 1 and stage 2) according to 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 covered by the certification are carried out;
- the outsourcing of part of the activities covered by the certification;
- the type of vehicles involved;
- the type of activities carried out;
- the presence of special processes.

The requirements used by Italcertifer throughout the assessment process are those set out in Regulation (EU) 2019/779, in particular those set out in Annex II to Regulation (EU) 2019/779.

A.6.3.1. Stage 1 audit

The assessment process begins with the ECM receiving complete documentation regarding its maintenance system.

The activities of stage 1 are aimed at acquiring adequate knowledge of the maintenance system and the activities carried out by the Organization, through an exchange of information with the same and an assessment, carried out mainly on a documentary basis by Italcertifer's GdA, concerning:

- 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 concerned, location, and type of activities carried out;
- the type of vehicles subject to maintenance activities;
- the understanding and acceptance of the applicable regulatory and legislative requirements;
- the justification of any exclusions;

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

Considering the level of complexity of the Organization and its maintenance system, Italcertifer may schedule multiple audit sessions and may carry out stage 1 activities, in whole or in part, at the customer's premises.

The conclusions of stage 1 are notified to the client by the head of the ITCF Audit Group, indicating whether or not it is possible to proceed to stage 2, subject to the client resolving any deficiencies and/or findings identified .

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

A necessary condition for the start of Stage 2 is the absence or resolution of non-conformities issued by the GdA to the Organization. Stage 1 must therefore be repeated, charging the customer the costs provided for in the commercial offer, until this condition is met.

Stage 2 activities shall normally commence no later than three months after the conclusion of Stage 1. Beyond this deadline, ITCF reserves the right to repeat Stage 1, charging the customer for the related costs.

A.6.3.2 Stage 2 audit

Stage 2 of the audit aims to assess the implementation and effectiveness of the ECM maintenance system. Stage 2 takes place at the customer's site(s) where the maintenance processes implemented by the customer are carried out.

During this phase, the ITCF GdA will verify, in particular, the customer's ability to ensure that:

- vehicles are maintained in accordance with the corresponding maintenance files and the applicable requirements of the relevant TSIs and/or other maintenance standards;
- appropriate measures (including contractual measures) are taken to monitor the performance of any outsourced activities with a potential impact on vehicle safety;
- the traceability of each maintenance activity is guaranteed;
- the performance of the maintenance system enables the achievement of the objectives expected of it;
- the 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 demonstrates the necessary commitment and involvement in the implementation of the maintenance system and in the consistent assignment of tasks and responsibilities related to it (including those concerning the interface with clients and/or subcontractors of other related services).

In the case of multi-site organisations, different audit sessions will be conducted according to a sampling programme that ensures the representativeness of the processes and activities implemented by the Organisation. Among the references adopted by ITCF for site sampling are the guidelines contained in document IAF MD 1:2018.

Prior to each stage 2 audit, the RGA prepares a specific audit plan which is shared and sent to the client no later than 3 days before the audit date, based on the information contained in the documentation examined in stage 1 and the processes involved.

At the start of the audit activity at the client's premises, ITCF's RGA holds an initial meeting with the aim of:

- introduce the members of the Audit Team;
- present the objectives and rules for conducting the audit, the criteria for classifying findings and the conclusions of the audit;
- establish official lines of communication with the Audit Team, identifying a customer representative to contact during the audit in case 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, for example:

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

In general, the first part of the audit at this stage is dedicated to verifying the effective closure of the findings that emerged during stage 1. If the GdA finds that the findings previously formulated have not been closed or have not been closed effectively, it may order the interruption of the audit, which may only be restarted after the necessary evidence has been provided. It should be noted that in this case, any additional costs due to the interruption of activities will be charged to the client based on the economic conditions established in the commercial offer.

The evidence that the GdA may verify during the audits includes, but is not limited to:

- the methods of acquiring and maintaining staff skills, including those relating to special processes;
- the availability, correct management, and implementation of the applicable version of the mandatory regulations;
- the management and monitoring of outsourced processes;
- the methods by which the ECM guarantees the traceability of components used in replacement operations in safety devices.

During the audit, Italcertifer's GdA will inform the client of any findings and elements that emerge from the examination of the objective evidence provided by the client.

A.6.3.3 Audit conclusions

At the end of the sessions scheduled in the audit plan, the RGA will hold a final meeting, in the presence of the client's representatives, with the aim of:

- present the outcome and communicate any findings that have emerged;
- preview the contents of the audit report
- briefly describe the continuation of the certification process, including agreements for the management plan for any findings that have emerged;
- distribute a copy of the audit report to the client.

Within **two weeks** of the audit completion date, ITCF will send the client a draft audit report containing the formalization of any findings, which must be managed by the ECM in accordance with the procedures described in paragraph § A.6 below.

A.7 MANAGEMENT OF FINDINGS

For each finding classified as Non-Conformity and Observation during audits (stage 2, surveillance, and renewal), the client is always required to submit a plan of corrective actions and measures, which will be evaluated by the ITCF GdA.

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

The action plan must be sent to ITCF in time to allow for the development of the subsequent stages of the process and, in any case, no later than **two weeks** after the delivery of the draft phase 2, surveillance, or renewal audit report.

The ITCF GdA 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 reformulate it and resubmit it to the ITCF GdA for approval.

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

Findings classified as Comments may be addressed by the client initiating an improvement action, or they may not be accepted, provided that the reasons for non-acceptance are recorded.

In general, ITCF's verification of the implementation and effectiveness of the actions established by the ECM is carried out during the first useful 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 carry out an extraordinary audit in addition to the planned surveillance. It should be noted that any extra costs due to the need to carry out extraordinary audits will be charged to the customer according to the economic conditions established in the commercial offer.

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

A.8 DECISION

At the end of the assessment process described above, once all findings have been managed by the ECM (through a specific Action Plan or through evidence of the treatments and corrective actions taken), ITCF reviews the results in preparation for the certification decision. The review is conducted by a specific Deliberation Function (which did not take part in the assessments and is therefore independent of the Audit Group) which, based on the evidence provided, may take one of the following decisions:

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

The Deliberation Function's decisions may also include the issuance of certification with the requirement to carry out an extraordinary surveillance audit at a short deadline in addition to that provided for in the multi-year program.

In the event of refusal to issue certification, the reasons for the decision will be provided and, where possible, the terms and conditions for re-evaluating the issue.

In general, in the event of a refusal, if the client is interested in obtaining certification, they must submit a new application and the process will be restarted, following review of the application, on the basis of a new contractual agreement.

If the customer disagrees with the decisions taken by Italcertifer, they may initiate the appeal process described in chapter 17 of the general part 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 of receipt of all information and complete documentation from the ECM to the date of the certification decision.

A.9 VALIDITY OF THE CERTIFICATE

The validity of the certification, which shall run from the date of the decision of the Deliberation Function, shall be consistent with the surveillance period defined in the contractual agreement and in any case shall not exceed **five years**. In this regard, it should be noted that, in any case, validity is subject to the performance of surveillance audits, at least every twelve months from the date of the initial decision, to verify the certified entity's ability to maintain the requirements of Regulation (EU) 2019/779 over time.

In the case of certification requests from newly designated ECMs, i.e., those submitted by entities that were not registered as such in the National Vehicle Register before June 16, 2020, and which cannot provide evidence of the effective implementation of the maintenance system, the initial certification process described above shall apply, but the validity shall be set at **one year**.

A.9.1 Communication obligations

The customer 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 the Safety of Railways and Road and Motorway Infrastructure (ANSFISA), and the Italian Accreditation Body (Accredia) of all certificates issued, modified, renewed, suspended, or revoked.

A.10 SUPERVISION OF CERTIFICATION

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 from the date of issue of the certificate. The inability to carry out surveillance audits not attributable to ITCF shall result in the suspension of the certificate.

The conduct of surveillance audits, planning, the tools used, and the management of any findings are similar to those described in the previous paragraphs of this Appendix. In the absence of significant

changes to the customer's documentation, organization, and/or maintenance system, communicated by the customer to ITCF, it is not normally necessary to carry out a document- d verification .

In accordance with the ERA ECM Certification Scheme (point 3.3.5.2), the Deliberative Function is required to intervene and, based on a review of the results of the surveillance audit, may decide to:

- confirm the certification without reservations;
- confirm the certification with a reduction in the scope of application;
- temporarily confirm the certification, postponing the decision (for a maximum period of 6 months) until the action plan proposed to the client has been verified;
- suspend the certification (for a maximum period of 6 months) until the client's action plan has been verified;
- revoke the certification.

If any findings are made during the surveillance audit, the provisions contained in point A.3.8 above shall apply for their management, 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 audit plan being sent in order 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 outcome of the surveillance activity and Italcertifer's final decision are communicated to the client through the same communication channels used for the initial certification.

It should be noted that customers in possession of certification must send Italcertifer, at least **one month** before each surveillance audit, a report drawn up in accordance with the guidelines and content specified in Annex V of Reg. (EU) 2019/779. In particular, the customer must inform Italcertifer of any changes that could have a significant impact on the scope of their certification.

A.11 RENEWAL OF CERTIFICATION

The general provisions contained in paragraph 7.2 of this regulation apply to the renewal of certification. As a rule, Italcertifer requires customers interested in renewing their certification to submit a new application in accordance with the instructions in § A.5.1 above.

Certification renewal audit activities may require a stage 1 audit if there have been significant changes 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 management of any findings are similar to those described in the previous paragraphs of this Appendix.

With regard to the renewal decision, the criteria and rules applied by ITCF are the same as those described in § A.7 of this Appendix.

Also for renewal, in accordance with the applicable regulations, the Deliberative Function is involved and, based on the review of the audit results, may decide to:

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

- revoke the certification.

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

With regard to the validity of the renewal certificate, it should be noted that one of the following three cases may arise:

a. The renewal process (including the decision) is successfully completed **before the expiry date** of the current certificate. In this case, the new certificate is issued continuously, with the new expiry date based on that of the previous certificate (normally up to 5 years from the expiry date of the first issue);
b. The certification process (including the decision) is not completed by the expiry 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 expiry date that is consistent with the previous cycle (see the previous case) but with the date of issue and the start of validity coinciding with the date of the renewal decision taken after the expiry date.
c. If the certification process (including the decision) cannot be completed **within six months** of the expiry of the current certificate, Italcertifer will not be able to renew the certificate and the client will have to start a new certification process from scratch. It should be noted that in this case it will not be a renewal, but a new certification that will not maintain the history of the previous cycle and will be subject to specific new contractual agreements.