

REGULATIONS FOR MANAGEMENT SYSTEM CERTIFICATION

2.0	30/01/18	Added Annex B	Signed MU Q	Signed GM DT	Signed CZ AD
1.0	20/01/2017	Typos eliminated, modified para. 4.3.3 and 4.4, inserted Annex A for AMS diagram	Signed MU Q	Signed SP RQ	Signed CZ AD
0.0	13/10/2016	First issue	Signed MU Q	Signed SP RQ	Signed CZ AD
Rev.	Date	Description	Drafted by	Verified by	Approved by

Contents

1	INTRODUCTION AND SCOPE.....	3
2	GENERAL POINTS.....	3
3	NORMATIVE REFERENCES.....	4
4	CERTIFICATION PROCESS.....	4
4.1	Request for certification.....	4
4.2	Request and offer re-examination	4
4.3	Audit Process/Programme phases	5
4.4	Certification issue.....	9
4.5	Certification recording and information on the certification results.....	9
5	CERTIFICATE USE	9
6.	SURVEILLANCE	10
6.1	Periodic surveillance audit	10
6.2	Surveillance audit for recertification.....	11
6.3	Spontaneous surveillance visits	11
6.4	Audits at the suppliers of the Client organisation.....	12
7	RENOUNCEMENT OF CERTIFICATION BY THE ORGANISATION.....	12
8	CERTIFICATION SUSPENSION	13
9	CERTIFICATION REVOCATION OR REDUCTION	14
10	MODIFICATIONS TO THE CERTIFICATION PROGRAMME.....	14
11	MODIFICATIONS TO THE MANAGEMENT SYSTEM	15
12	COSTS AND PAYMENTS.....	15
13	COMPLAINTS.....	16
14	INFORMATION CONFIDENTIALITY AND ARCHIVING.....	17
15	IMPARTIALITY	17
16	APPEALS.....	17
17	CONTROVERSIES.....	18
18	RESCISSION	18
19	FORCE MAJEURE	18
20	LIMITATIONS OF RESPONSIBILITY AND REIMBURSEMENT.....	18
21	CLIENT OBLIGATIONS	19
22	CERTIFICATION TRANSFER.....	19
	ANNEX A: ASSET MANAGEMENT SYSTEM CERTIFICATION	21
	ANNEX B: MAINTENANCE SYSTEM CERTIFICATION	22

1 INTRODUCTION AND SCOPE

The scope of certification is to instil trust, in all interested parties, that a specific management system satisfies the specified requirements. The level of trust and believability of system certification derives from an expert and third-party assessment carried out and guaranteed by a Certification Organisation such as ITALCERTIFER S.p.A. (hereinafter ITCF).

This Regulation defines and describes the conditions and general procedures applied by ITCF for Company Management System certification, in accordance with national or international standards that are recognised and applied by organisations that supply products and/or services.

The conditions specified in this document are applied and taken as a reference also when assessing management systems included in other certification schemes (e.g. Product Certification, Verification of railway component and sub-system compliance, laboratory qualification, etc.).

The conditions given in these regulations can be applied to negotiations between ITCF and the physical or legal person who signs a request for Management System certification.

Particular conditions and additional procedures, if present and/or included by specific certification schemes, are specified in relevant “annexes” that integrate and complete these Regulations.

2 GENERAL

These regulations are applied by ITCF in a uniform and impartial manner to all the organisations that request certification.

In particular, potential clients are not discriminated against in any manner. In this particular case, undeserved discrimination of a financial or other nature will not be applied and is not permitted. Access to certification is not conditioned by the size of the applying company, or whether it belongs to a particular association or group, nor by the number of already- certified organisations.

Regarding certification, ITCF applies its own current costs, guaranteeing equity and treatment uniformity. ITCF reserves the legitimate faculty to refuse requests for certification coming from organisations under, or whose production or activity is under, restrictive, suspension or penalty measures by a public authority.

The Client Organisation acknowledges that by accepting the offer of certification through signing of the contract, purchase order or any similar legally binding obligation, it cannot depend on any representation, guarantee or prognostication that is outside those expressly indicated in the offer (or contract if stipulated). Any condition or prognostication included in the standard Client Organisation documents that contrasts, or implies the modification or integration of, these regulations will not be effective, unless accepted in writing by ITCF. In the contract, or other equivalent commitment, the Client must expressly accept any possible restrictive clauses, ex arts. 1341 and 1342 of the Italian Civil Code.

ITCF operates according to many acknowledgements that are issued by specific Supervisory Bodies (Ministry of Infrastructures and Transportation, Railway National Safety Authority, Italian National Accreditation Body, etc.). To maintain these acknowledgements, the Supervisory Bodies carry out periodic controls together with the ITCF auditors.

By accepting the conditions of these Regulations, the client guarantees that it will participate in the inspections carried out by the various Supervisory Bodies and that it will give its maximum collaboration. Not receiving authorisation from the Supervisory Bodies will lead to penalties that range from suspension to withdrawal of the issued certification, or interruption of the process that was started, without recognition of any indemnity from ITCF.

In the event that the aforementioned Supervisory Bodies intend carrying out a surveillance audit or carry out a check at the assessed client organisations, ITCF will quickly communicate this request and collaborate fully with its clients.

The overall framework of the acknowledgements held by ITCF is available from the company site on <http://www.italcertifer.com/riconoscimenti.php>.

Anything not expressly covered by this document will be given in the “GENERAL SUPPLY CONDITIONS” available on the company Website: <http://www.italcertifer.com/download.php>

The request for certification, together with the offer and the regulations that are an integral part of it, make up the set of agreements made between the Client organisation and ITCF regarding Management System certification.

3 REGULATION REFERENCES

These Regulations are written in accordance with the following regulations and/or documents:

- UNI CEI EN ISO/IEC 17021-1:2015 “Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements;
- Applicable mandatory IAF/EA documents (e.g. IAF ID1, ID3, MD1, MD2, MD5, MD11, etc.);
- General and Technical regulations issued by the Certification and Inspection department of the Single Italian Accreditation Body (ACCREDIA).

4 CERTIFICATION PROCESS

4.1 Application

To start the certification process, the applying Organisation makes a formal request to ITCF for the requested service. The formal request normally consists of an application for certification filled in by the applying organisation and includes minimum information, for example:

- The field of application requested for certification;
- The details pertinent to the applying organisation including the name/names and address/addresses of its location/locations, its processes and activities, technical and human resources, departments, relations and any other pertinent legal regulation;
- Identification of the processes entrusted externally by the organisation that influence conformity to the requirements;
- The regulations or other requirements on the basis of which the applicant organisation requests to be certified;
- If consultancy on the management system to be certified was supplied and, if yes, by whom.

4.2 Request and offer re-examination

The request for certification is reviewed by the competent departments of ITCF (usually the Technical Dept. + Sales & Tenders Dept.) before the offer is drawn up.¹

In the event that the request cannot be accepted as a result of one or more reasons as specified in the present document, ITCF will inform the applicant, communicating and evidencing the reasons why the request was refused.

While reviewing the application, ITCF considers the following in particular: application field of the requested certification, the location/locations of the activity of the company making the request, the time

¹ The regulations given in IAF MD5 are applied to calculate the audit time in order to draw up the offer.

needed to complete the audits and any other factor that influences certification (language, safety conditions, threats to impartiality, etc.).

In the event of application acceptance, ITCF prepares a technical-financial offer containing, at least, the following elements:

- a) The price of the requested services, made up of the following items:
 1. Certification (stage 1, stage 2 audits and first issue of the certificate);
 2. Maintenance (surveillance audit);
 3. Recertification (recertification audit and certificate re-issue);
 4. Transfer costs;
 5. Business costs traceable to additional audits (invoiced only if necessary and expressed in €/man-day).
- b) Invoice and payment conditions;
- c) Acceptance clause relative to the conditions specified in these regulations and in the supply conditions, both of which are up-to-date and available on the company Website: <http://www.italcertifer.com/download.php>

Unless otherwise specified by the applicant, the language used for communication and subsequent audits will be Italian. Where documents have to be sent to public administrations (e.g. the Ministry of Infrastructure and Transport, the Railway Safety Agency, etc.), the official language of the documents necessary for assessment and sending is the language of the member state in which the receiving administration resides.

Documents in languages other than Italian (English or French) can be delivered to accelerate the assessment, but their definitive version must be translated into Italian.

The client, by accepting ITCF's technical-financial offer, sending the purchase order or stipulating a designated contract, also accepts the conditions of these regulations.

4.3 Audit Process/Programme phases

The certification process applied by ITCF, including the relative phases, is carried out according to of UNI CEI EN ISO/IEC 17021-1.

The process phases are as follows:

- Stage 1 Initial audit (document assessment);
- Stage 2 Initial audit (certification audit in the organisation premises);
- Decision on certification;
- Certification issue;
- Surveillance audit (1st and 2nd year following certification issue);
- Recertification audit (3rd year following certification issue²);
- Decision on recertification;
- Renewed certification issue.

The certification cycle lasts for three years from the date of issue, and can be renewed upon the request of the organisation before it expires.

² According to the type of certification scheme applied (e.g. ECM Certification ex-Reg. EU 445/2011) the recertification audit is carried out at the end of a certification cycle that can last longer than three years. These cases are disciplined according to additional references given in the annexes to these regulations.

An audit programme is established for each request for certification; the programme includes the whole certification cycle and is entrusted to an Application Manager who, in addition to identifying the resources needed for assessment, takes care of contacts with the client organisation.

When establishing the audit programme, factors of the following type are taken into consideration:

- The size of the organisation;
- The application field and complexity of the Management System;
- The products, processes and efficiency level of the Management System;
- The results of previous audits, and possible certifications that have already been issued to the client, or other audits that have already been carried out.

Before Stage 1 is started, the client organisation is informed of the composition of the audit team. The organisation can refuse any assessor or technical expert involved within 5 working days, motivating the reasons in writing. After this period the audit team is considered to be implicitly accepted.

ITCF uses professionals with suitable qualifications and competences to carry out the assessment; such professionals are on a specific list that can be controlled by the Supervisory Bodies. The Audit team can include ITCF employees, people that have a specific collaboration contract with ITCF, or both.

ITCF personnel, regardless of the type of relationship that exists with the company, will operate according to ITCF's Quality Management System procedures, with maximum professionalism and full respect for the client organisation.

For each certification scheme applied, ITCF will operate according to one or more procedures or instructions³, the general process of which is described in the following paragraphs.

4.3.1 Stage 1 Initial audit

Stage 1 audit normally includes examining the organisation's documentation or documented information.

The objectives of stage 1 are, as an example that is not exhaustive, to:

- Evaluate the suitability of the management system documentation or documented information in relation to the requirements of the Standard for which certification is sought, and the identification of any possible deficiencies;
- Evaluate the position of the organisation and the specific conditions of the location/locations, and exchange information with organisation personnel in order to establish their preparation for the Stage 2 audit;
- Re-examine the organisation's identification, actuation state and understanding of the requirements of the regulation;
- Collect the necessary information on the scope (application field) of the management system, the organisation processes and location/locations, the relative statutory rules, the regulation and conformity aspects;
- Re-examine the assignment of resources for stage 2 and agree with the organisation on the details of the verification of said phase;
- Reach a sufficient understanding of the management system and the operations carried out on the site, acquiring the important aspects of the management system of the organisation seeking certification;
- Evaluate if the internal audits and re-examination by the management were planned and carried out effectively, and if the management system application level is sufficient to believe that the organisation is ready for stage 2;

³ Following a motivated request from the Organisation, ITCF will supply an extract of the assessment procedures that are applicable and used.

- Provide clarifications on the certification process details.

Upon completion of the evaluation, the result and any findings are communicated. According to the activity, communication can be in the form of an audit report or a note sent to the Organisation.

Any findings classified as NONCONFORMITY block activity continuation and evidence of their closure must be highlighted by the Organisation before Stage 2 is started. During the Stage 2 audit, closure of findings classified as OBSERVATIONS is verified, and the COMMENTS are analysed.

An initial audit can be carried out during Stage 1 if requested by the Organisation⁴.

The scope of the activity is to assess beforehand how well the Organisation's management system fulfils the requirements of the true certification audit. The initial audit is planned and developed in the same manner as a normal audit.

The findings that emerge during this phase are documented by the Audit Team in a pertinent report that is kept in the Organisation's Application file. Regardless of the reasons why the initial audit was carried out, the results will not be used for the certification procedure.

4.3.2 Stage 2 Initial audit

The Stage 2 audit is carried out in the premises of the client organisation and its purpose is to evaluate client organisation management system implementation and effectiveness. Before the Stage 2 audit, the Audit Team Leader sends a pertinent audit plan to the client organisation, specifying the dates and processes that are to be verified.

The Stage 2 audit (and in a similar manner the surveillance and recertification audits) includes these phases:

- a) Holding an opening meeting to:
 - Present the members of the Audit Team;
 - Present the purposes of the audit and how it will be undertaken, the rules for classifying anomalies and the audit result;
 - Establish formal communication channels between the Audit Team and the client organisation, and identify a manager to communicate with during the audit in the event of controversies;
 - Clarify any possible doubts and install trust.
- b) Conducting the Audit.

The effective application of the management system and its conformity to reference standards and system documentation will be evaluated during the audit. The Organisation will, in addition to collaborating actively, make the system documentation and all information and recordings that demonstrate system application available to the Audit Team.
- c) A closing meeting to:
 - present the result and inform of any findings that emerged;
 - briefly describe how the certification process continues;
 - distribute a copy of the report to the client organisation.

4.3.3 Findings classification

For certification purposes, the findings met during the various process phases are classified as:

⁴ The initial audit, if programmed, also appears in the technical-financial offer.

NONCONFORMITY (NC, Major Nonconformities), when a requirement that influences the ability of the management system to obtain the expected results is not present, or when findings classified as Observations that persists over time (or which are not resolved as agreed with ITCF) are present;

OBSERVATIONS (OSS, Minor nonconformities), nonconformities that do not influence the ability of the management system to obtain the expected results;

COMMENTS (or opportunities for improvement), when dealing with defects that do not have an impact on the management system at that moment but which could degenerate into potential nonconformities over time.

4.3.4 Treatment and corrective actions

The organisation must resolve any findings encountered by the ITCF Audit Team, applying treatment and corrective actions that are suitable for the level of the nonconformity and according to the regulations defined in the various certification programmes.

4.3.4.1 Nonconformity (NC):

The closure of any NCs found during the audit (Stage 1, Stage 2, surveillance and recertification) must be verified by ITCF in order to judge the system as conforming and to recommend issue of the certificate and/or to consider an already-issued certificate as valid. For this purpose:

- the organisation sends to ITCF, in writing and within (three) weeks from the audit date, the Corrective Action Plan and possible documentary evidence if necessary;
- ITCF verifies and approves the proposed Corrective Actions;
- within 90 (ninety) days from the audit date, the organisation implements the Corrective Actions that were communicated and ITCF verifies, with an additional audit, that the NCs have been closed and that the Corrective Actions have been applied effectively.

For the NCs that were found, the programmed closing audit must take place within the term agreed on with the Audit Team Leader (and in any case within the 90 (ninety) day timeframe). In the event that the Organisation cannot respect this term, the Initial Audit will have to be repeated or, in the case of subsequent Audits (surveillance, recertification, etc.), the certificate will be suspended.

Should the Audit Team Leader believe that the documentary evidence is sufficient for closing the Nonconformity, the closing audit is held in-house at ITCF and the supplied evidence is recorded in the documents indicated by the applicable internal procedures.

4.3.4.2 Observations (OSS)

The Corrective Action Plan proposed by the Organisation also has to be verified and approved by ITCF in the case of findings classified as OSS. This is necessary for judging the system as being conforming and for recommending issue of the certificate or considering an already-issued certificate as valid. OSS solving includes these steps:

- the organisation sends the Corrective Action Plan to ITCF, in writing and within 3 (three) weeks from the audit date;
- ITCF verifies and approves the proposed Corrective Actions;
- the organisation implements the Corrective Actions within the defined times and ITCF evaluates closing and effectiveness during the next programmed audit.

Should the Corrective Actions be found to be ineffective and/or the findings encountered remain, ITCF will do the following in the order given:

- repeat the audit, or, in the event of further inefficiency,
- suspend the certificate, or if the problem remains,

- withdraw the certificate.

4.3.4.3 Comments (COM)

As findings recorded and classified as COM are opportunities for improvement, ITCF does not formally request the sending of an action plan. The Audit Team verifies the comment analysis and any operations that were undertaken during the first programmed visit.

If there is no analysis and/or if suitable reasons for non-acceptance were not recorded, the finding classification will change from Comment to Observation.

4.4 Certification issue

After the evaluation for closing the NC (on-site at the Client or in-house at ITCF) has ended positively, the certification process continues with transmission of the documents to the Decision Body⁵ (FD) which re-examines the proposal for certification.

After the certification proposal has been approved by FD, the certification documents⁶ in relation to the reference standards and the system application field are issued and transmitted to the Organisation. Certification issue is subordinated to payment of the fees due for the audit that was carried out.

The validity start date is given on the certificate and coincides with the date on which FD made its decision. Certification validity is subordinated to periodic surveillance, and also full re-examination of the system every three years.

Surveillance frequency is generally set at 12 months, except for different indications given in some certification programmes or recommendations from FD.

While surveying, ITCF can ask for clarifications on, and that variations or integrations be made to, the activities carried out in order to comply with the requirements defined by the Accreditation Body or updates made to the certification programmes.

4.5 Certification recording and information on the certification results

All the information on the certifications that are issued is contained in a pertinent Information Register that is developed and managed by ITCF. The register gives the following information in particular:

- the identification of each certified organisation;
- the certification validity state;
- the management system reference regulation (specifying, if necessary, the exclusion of non-applicable requirements);
- the location/locations and/or premises covered by the certification;
- the type of products, processes, services to which the certification can be applied.

The information held in the register is considered as confidential and is not divulged externally. Where required by applicable programmes, regulations and laws, ITCF communicates the data on the issued certificates only and exclusively to the Supervisory bodies⁷.

5 CERTIFICATE USE

The Certificate and the logo contained in it are the property of ITCF S.p.A.

⁵ The decision can be made, in relation to the type of programme applied, by a single person (called the Decision Maker) or by a pertinent group of people (called the Certification Committee).

⁶ Except for indications and/or particular requests that must be communicated to the offer premises, the client Organisation is sent the original certificate written in Italian.

⁷ This is without prejudice to requests for information made by the competent courts and relative to ongoing legal action.

The client organisation can refer to the obtained certification in a manner that complies with these regulations and those for using the ITCF brand. The certificate cannot be used in a deceptive manner and must not indicate, for example, regulations, standards, application fields and other important information other than those given in the certificate.

The client organisation must, in particular, immediately stop making reference to the certificate:

- if it has expired;
- if it has been suspended;
- if it has been revoked or withdrawn;
- if modifications are made to the application field without having informed ITCF beforehand;
- failure to adapt to regulations introduced by the certification programme and/or notifications from ITCF.

ITCF can control correct use of the certificate at any moment, and will undertake any operation considered to be suitable, at the cost of the client, to meet incorrect use, misleading references and/or the improper certificate use. The operations that can be undertaken include but are not limited to:

- requests for corrective actions;
- certification suspension or withdrawal;
- information given to the Supervisory Bodies;
- taking legal action.

Together with the certificate, the ITCF brand can be used. The regulations for correct application and use are given in the pertinent regulations and graphic manual, available on: <http://www.italcertifer.com/download.php>

In the event of the ITCF brand being used incorrectly, the same operations described in the previous paragraphs will be applied.

6. SURVEILLANCE

During the three-year validity of certification, ITCF will carry out surveillance audits at least every year to:

- verify maintenance of conformity to the reference standard and the legal requirements applicable to the product/service/process/system;
- verify the effectiveness of any irregularities found in the previous audits;
- verify that the organisation is using the certification and relative logo correctly.

6.1 Periodic surveillance audit

Surveillance audits are obligatory for continuation of certificate validity, and they ascertain that the certified organisation maintains an effective management system that complies with the requirements of the applicable reference regulation and any other applicable regulations.

The fact that the certified organisation refuses a surveillance audit at the programmed times and without suitable reason is enough to allow ITCF to suspend and subsequently revoke the certificate.

In general, and unless otherwise specified in the individual special regulations, 2 surveillance audits per year are carried out during the three-year validity period of the certificate; the purpose of these audits is to confirm certificate validity.

The methods followed to carry out surveillance audits are similar to those of Stage 2 with the exclusion, unless in the case of special reasons, of the intervention of the Decision Body (FD).

The methods for recording the surveillance activities, and the management process for possible findings are similar to those described in paragraphs 4.3.2 – 4.3.3 - 4.3.4.

During surveillance audits the management system undergoes a partial re-examination, subject to the certificate being fully completed during its three-year validity period.

6.2 Surveillance audit for recertification

The recertification audit is obligatory and ascertains that the certified organisation has maintained an active and effective management system that complies with the requirements of the applicable reference regulation and the certification regulations.

In the event that the certified organisation does not want to have a recertification audit, this leads to the automatic suspension⁸ of the certificate, unless the organisation accepts to undergo a spontaneous audit within the limit date indicated initially.

The methods used to carry out the recertification audit are the same as those for Stage 2, with the distinction that the audit covers the whole management system.

The methods for recording recertification, management and re-issue of the certificate are the same as those described in paragraphs 4.3 – 4.4 - 4.5.

The Decision Body (FD) intervenes when the audit has been completed to decide if the certificate is to be renewed or not, according to the methods already described in the previous paragraph 4.4.

At the start of a recertification audit, the documents or documented information of the management system must be re-examined, even in relation to any changes that have been made to the management system and/or the appointed control team.

If recertification is not completed within the previously mentioned terms, the organisation, no longer having the requirements for being certified, must renounce use of the certification and the ITCF brand and, if it intends requesting certification again, it must start a new certification process, starting from what is established in point 4.1 of these regulations.

For certification renewal, the client organisation must present a new request for certification⁹ and accept the technical-financial offer formulated by ITCF.

If acceptance is refused, and if there is no formal termination, the recertification visit is carried out only to survey the valid certification, without making any proposal of recertification to the Decision Body.

6.3 Spontaneous surveillance visits

ITCF reserves the right to carry out spontaneous verifications on the certified organisation.

These audits are carried out in the presence of valid and proven motives, that are communicated to the organisation and which can include but are not limited to:

- Serious and valid complaints and/or signals received from the market and relative to the organisation;
- Judicial proceedings involving the organisation and including the scope of certification;
- Disrespect of current regulations;
- Important modifications and changes within the organisation or its management system;

⁸ Continuance of the organisation to refuse recertification leads to certificate revocation.

⁹ The request for certification is reformulated if important variations have been made at the client organisation and if the application field has been modified.

- Use of the certificate and ITCF logo contrary to these regulations and those on: <http://www.italcertifer.com/download.php>;
- A request from Accredia and the other Supervisory Bodies;
- A request by the Decision Body to intensify surveillance following re-examination of the certification file.

Spontaneous audits are also used to:

- Revoke certificate suspension;
- Extend and/or vary the application field.

The details on carrying out these audits are established according to the circumstances, and ITCF communicates them to the organisation.

It remains understood that, unless decided on differently by ITCF, spontaneous audits do not replace surveillance or recertification audits as indicated in paragraph 6.1 and 6.2, but are additional and at the cost of the client organisation.

6.4 Audits at the suppliers of the client organisation

To verify the effectiveness of the organisation's management system, ITCF reserves the right, during any phase of the certification process, to carry out audits at those suppliers to whom the organisation gives critical phases or activities included in the scope of certification.

The need to carry out verifications at the suppliers are communicated beforehand by ITCF, motivating the reasons. The client must act so that its own suppliers grant access to all the recordings, data and information relative to the processes/products object of the sub-supply that fall within the ambit of the scope of certification.

In the event that the certified organisation does not permit said access, ITCF can interrupt the certification procedure and start operations that range from suspension to revocation and/or reduction of the scope of certification.

7 RENOUNCEMENT OF CERTIFICATION BY THE ORGANISATION

The certified organisation can request waiver of the certification obtained for reasons such as, for example:

- the organisation is no longer interested in maintaining the certification when the contract expires;
- non-acceptance of the modifications to the validity conditions¹⁰ of the certification communicated by ITCF;
- Bankruptcy or compulsory winding up;
- Discontinuance of certified service and/or production realisation.

The client organisation must present ITCF with a formal request, specifying the reasons for renouncement. Notwithstanding the obligation of the organisation to pay the amounts related to the phases that have already been concluded, ITCF will accept the request without any opposition.

The organisation, under the penalty of being charged with the costs already upheld by ITCF for programming, must give a prior warning of at least 3 (three) months in relation to phases that expire (surveillance and recertification) when exercising its right to renouncement.

¹⁰ The validity conditions include modifications made to certification programmes and regulations introduced by Regulation Organisms and ITCF third-party organisations.

Following the request of renouncement, ITCF withdraws certification and cancels it from the register of certified organisations. Following communication informing of cancellation from the register, the organisation must:

- Return the original paper version of the certificate of conformity;
- Not use copies and reproductions of the certificate;
- Immediately stop using the logo and references to the certification that were granted previously;
- Settle any services carried out by ITCF and which have not yet been paid.

A new request for certification made by companies who previously renounced it can only be accepted after 1 (one) year has passed from acceptance of the request for renouncement.

8 CERTIFICATION SUSPENSION

Certification can be suspended by the FD for a maximum of 6 months, for the reasons that follow, and which are given as examples:

- If the organisation does not satisfy certification requirements seriously, including those aimed at management system effectiveness and satisfaction of the product/process/service requirements;
- If the organisation is not willing to undergo the surveillance and/or recertification audits at the programmed times, for reasons that are not specified or not justified;
- If the organisation voluntarily requests suspension;
- In the event of nonconformities that are not resolved in an effective manner and/or if the corrective actions are not implemented within the programmed/agreed times;
- If the organisation does not inform ITCF of any modifications made to its management system;
- If the organisation does not inform ITCF of any judiciary and/or administrative procedures that occur within the field of application of certification;
- If sentences are passed for facts involving disrespect of the binding requirements relative to the management system object of certification;
- if problems exist involving the binding requirements of the product/process/service that is supplied or the pertinent management system;
- If the organisation does not handle complaints and/or signals directly connected with the certified management system;
- If the organisation is not willing to undergo the audits in the presence of Accredia Inspectors and other Supervisory Bodies;
- If solutions for the improper use of certification and the ITCF logo and certificate are not satisfactory;
- If the organisation does not observe its duties as described in these regulations;
- If the system is not adapted to the new regulations communicated by ITCF;
- If the organisation is still in arrears after receiving the injunction sent by ITCF;
- If the supply activities and product/service issue activities falling within the certification field are suspended by the organisation for more than 6 months.

The organisation is notified of suspension, together with the reasons for the measure and the timescale within which the requested operations are to be implemented.

Suspension prevents the organisation from using the certificate and the ITCF/Accredia logo and is applied to all the headquarters/premises and all the activities/processes object of the suspension.

Suspension revocation is deliberated by FD only when ITCF has ensured that compliance with the requirements specified in the applicable regulations has returned in a satisfactory manner. In this case ITCF updates the validity state of certification in the Certified Organisation Register.

Further charges arising from audits that originate from suspension are at the full charge of the Organisation.

In the event that certificate validity cannot be returned within the term set by the FD, ITCF will revoke the certificate.

9 CERTIFICATION REVOCATION OR REDUCTION

FD decides on certification revocation for reasons such as:

- If the Organisation continues its dissatisfaction of certification requirements for a long period, including those requirements for management system effectiveness and satisfaction of the binding requirements of the product that was already the origin of suspension;
- If the organisation continues its non-observance of the duties undertaken with ITCF to solve the shortcomings in the management system object of certification that were found and signalled during the audits;
- If the organisation remains in arrears after the suspension period (see previous point);
- In the event of organisation bankruptcy or compulsory winding up;
- Closure of the activities for which the organisation had received certification, or activity suspension for more than 6 months;
- Organisation unavailability when carrying out the ITCF surveillance/recertification activities after the terms set during suspension;
- Ascertained non-observance of the binding regulations;
- Serious irregularities in or abuse of certificate and/or ITCF brand use;
- if the organisation is given a definitive sentence related to facts involving disrespect of the binding requirements of the management system object of certification;
- Serious violation of the contract and these regulations.

The Organisation is informed of certification revocation by a registered letter with return receipt or a message sent by certified email in which the reasons for the action taken are indicated.

Following revocation, the Organisation must:

- Return the original version of the certificate of conformity;
- Not use copies and reproductions of the certificate;
- Stop using the logo and any reference to certification.

The Organisation whose certificate has been revoked can present a new request for certification only after the problems that caused revocation have been effectively solved and documented.

In this case, subject to the opinion of FD, a new technical-financial offer is drawn up, together with the commitment involved and the methods for verifying elimination of the conditions that caused revocation if necessary.

In the event that the conditions for re-activating certification exist, the process is started again according to the methods and phases indicated in the new technical-financial offer and accepted by the Organisation.

10 MODIFICATIONS TO THE CERTIFICATION PROGRAMME

In the event that the Regulation Organisms¹¹ (ISO, CEN, CENELEC, UNI, CEI, etc.) modify any document containing the requirements for certification, ITCF will:

¹¹ What is indicated in this paragraph is also applicable when the modifications are made to standards and regulations issued by various Organisations (e.g. ACCREDIA, RFI, TRENITALIA, etc.) and against which ITCF certifies the Management System.

- inform the interested organisations;
- supply indications and dates within which to adapt the management system;
- consider possible observations on changes that are made by the certified organisations.

In the event that the organisation (certified or being certified) does not intend to adapt its management system to the changes that were introduced, it can exercise its right to renounce certification according to the methods specified in point 7 above.

All the regulations and contract documents applied by ITCF are available on: <http://www.italcertifer.com/download.php>.

In the event that the modifications to the certification programme are introduced by third parties of ITCF and require that additional audits be carried out to verify Management System adaptability, the costs are at the charge of the certified organisation.

11 MODIFICATIONS TO THE MANAGEMENT SYSTEM

Certified organisations must inform ITCF quickly about any modifications made to their Management System that influence the scope and field of application of the certificate.

ITCF must be informed of important modifications, intended as the reduction or extension of one or more of the following elements, indicated merely as examples but which are not limiting:

- Field of application;
- Operation sites;
- Special processes.

Not informing of changes made to the organisation's system is sufficient reason to begin suspension procedures and subsequent revocation.

In the event that the certificate field of application is extended, ITCF re-examines it to establish if additional audits, and as a result technical-financial offer updating, are necessary.

12 COSTS AND PAYMENTS

The Client organisation is offered a service calculated on a daily basis and which includes all the phases indicated in the assessment programme (Stage 1 and Stage 2 audits, first issue, surveillance and recertification audits).

Acknowledging that the applied costs can vary also because of external macro-economic factors, ITCF will ensure that the costs proposed during the initial offer phase are current at the certificate issue date.

ITCF can have the offer inspected if the activities requested by the Client are, subsequent to or during the on-site control, not in line with what is specified or requested by said client during the application re-examination and the initial financial negotiation phases.

Specific charges for activities that are additional to those agreed on will be inserted for all the operations that are not indicated in the initial offer and are subsequently requested by the Client, as well as for activities that are necessary following the identification of discrepancies/nonconformities. These costs can include, but are not limited to:

- the repetition of individual verification phases or the whole verification programme, or for
- activities arising from disrespect of the regulations and requirements of applicable regulations;
- additional activities resulting from certificate suspension, withdrawal and/or recovery;
- repetition of verification operations caused by modifications made to the management system;

- the judicial obligation to submit documents or proof in relation to the operations carried out by the Certification & Inspection Division of ITCF.

ITCF reserves the right to debit additional charges to the current prices in the event of:

- urgent orders from the client;
- service cancellation or reprogramming;
- partial or total repetition of the verification programme indicated in these regulations.

The Client must inform ITCF in writing, at least 10 days beforehand, if activities that have already been programmed and agreed on and requiring the presence of ITCF staff in the Client's premises are to be delayed; not informing ITCF within said period will result in the application of additional costs, equal to 50% of the cost indicated in the contract for the activity, being charged to the Client.

The fee for services is quoted on the basis of the cost of one man/day (m/d) ¹² of engagement. An indicative cost evaluation can be made available beforehand if specifically requested by the Client. Unless indicate otherwise, the costs do not include travel and accommodation. In addition, all the costs and possible additional charges do not include VAT or other applicable taxes.

Following certificate issue, ITCF will issue a regular invoice to the Client.

Invoices for operations that are additional and/or subsequent to certification will be issued when said operations have been completed. Excluding what is otherwise indicated in the offer, payment will be made 30 days from the invoice date, independently from the result of the certification process. Any use by the client organisation of the certificate or the information it contains is subordinate to punctual payment of the invoice.

Should payment be delayed, ITCF will charge the client interest on arrears starting automatically from the day following the payment date and determined by applying the bank rate of the Central European Ban increased by 8%. ITCF S.p.A. will receive a fixed amount of 40.00 euros as compensation for the damage upheld, unless it demonstrates that it upheld more serious damage (art. 6, paragraph 5, Italian Legislative Decree 231/2002). All costs related to credit recovery, including possible legal costs, will be paid by the Client.

In addition to the operations indicated in these regulations, ITCF reserves the right to interrupt the operations and to suspend and possibly revoke the certificate if the issued invoices are not paid.

13 COMPLAINTS

ITCF adheres to policies and procedures for handling complaints and signals not only coming from the certified organisations but also from the parties involved in its certification operations.

The formal, conventional channels can be used to send signals and complaints, but in addition ITCF has a specific email address (reclami@italcertifer.it), that can be used to send complaints efficiently to management. The address to send complaints and signals is also on the “contact” page of the company Website <http://www.italcertifer.com/contatti.php>.

The process and methods used by ITCF to handle complaints are described in a dedicated procedure, an extract of which is supplied to whoever legitimately requests it.

All the complaints that reach ITCF from certified organisations and important interested parties are managed and analysed to assess their validity and to establish whether additional actions are to be started.

¹² A day/man of engagement for a human resource is set at 8 working hours.

In any case and independently from the result of the internal re-examination, ITCF supplies motivated information on the validity or not of each complaint/signal that is received. ITCF supplies indications on possible measures it intends taking to solve the reasons for and causes of the complaints or signals that it believes to be valid.

14 INFORMATION CONFIDENTIALITY AND ARCHIVING

By way of contract stipulation, certification order confirmation or other documents that are a legally valid commitment, ITCF guarantees that all confidential information obtained during certification is treated in a strictly confidential manner at all company levels. The information is only made available to the Supervisory Bodies mentioned previously, and if requested by the Judicial Authorities during official procedures.

Those who do the Audit work according to regulations and in-house codes of ethics that indicate confidentiality as an essential requirement. They therefore remain bound by professional confidentiality on all the information and data they come across while carrying out their assessment duties. Excluding what is otherwise indicated by law, or upon the request of a Government or competent Jurisdictional authority, ITCF must request authorisation from the certified organisation to receive confidential information.

ITCF retains all the information and recordings on the certification process for the period of time specified by law¹³ in its paper and computer archives.

At the end of the retention period, unless otherwise indicated by the Client, ITCF will transfer, preserve and/or destroy the documents under its own discretion. The costs deriving from specific instructions given by the Client on document preservation will be paid by said Client.

15 IMPARTIALITY

Assessment activities are carried out impartially by ITCF. ITCF uses specific policies and procedures pertinent to this matter and has established a specific Mechanism for the Safeguarding of Impartiality (CSI).

The CSI is independent from ITCF and is made up of representatives of institutional bodies, category associations, client associations and associations that protect consumers; these representatives will give a fair representation of the main categories involved, without the predominance of individual interests, protecting judgement transparency and impartiality in this manner.

CSI can activate specific operations (e.g. inform the authorities, Accredia, other interested parties, etc.) if it recognises that risks for impartiality are not being handled suitably by ITCF, or if ITCF does not consider its recommendations.

16 APPEALS

The client organisation can appeal any decisions made about it by ITCF by sending a registered letter with return receipt or a certified email within 30 (thirty) days from notification of the decision, specifying the reasons for the appeal.

ITCF will re-examine the appeal received and will inform if it has been accepted or not, together with motives, within 30 days.

In the event that the appeal is accepted, ITCF will give the interested organisation its action plan, the internal interfaces that were identified and the dates within which it intends implementing the identified actions.

¹³ Barring specific laws, regulations or certification programmes, the retention period is set (ex Civil Code) at 10 years.

Appeals are managed in a similar manner to complaints and signals, namely in agreement with a specific procedure that is made available if requested by the appealing party.

17 CONTROVERSIES

The court of Florence is the competent court for any controversies arising between the Client organisation and ITCF that cannot be settled amicably.

18 RESCISSION

Unless otherwise agreed on in writing, the client can rescind from the contract ¹⁴ at any moment, giving at least 3 (three) months of prior warning in writing to ITCF.

In the event that the client rescinds from the contract, before the certificate is issued and for reasons other than that of non-fulfilment of obligations by ITCF, ITCF reserves the incontestable right to debit the Client a sum equal to 3% of the contract amount as compensation for rescission, excluding the debiting to the Client of the rates and costs relative to the operations carried out up to the date of rescission. ITCF also reserves the right to rescind from the contract at any moment before the certificate is issued, with a prior warning of no less than 3 (three) months, to be sent to the client in writing.

19 FORCE MAJEURE

In the event that ITCF is prevented from carrying out or implementing the service object of the contract for any reason or cause outside its control, the Client must pay:

- the total of the costs effectively upheld;
- the quota of the prices agreed on, in a measure that is proportional to the service effectively supplied.

It remains understood that for causes of force majeure, ITCF is relieved from any responsibility if the requested services are not carried out fully or partly.

20 LIMITATIONS OF RESPONSIBILITY AND REIMBURSEMENT

ITCF will take great care and be very proficient when carrying out its services and accepts responsibility only in the event of proven negligence.

ITCF will not accept any responsibility on behalf of the client that derives from or is connected with the contract and its execution as a result of declarations or disrespect of any expressed or implicit condition, guarantee or other law or regulation, for any indirect or special or consequential damage suffered by the client. Reimbursement payable by ITCF to the Client for other causes will be limited, for each event or series of connected events, to an amount that does not exceed the prices paid to ITCF in view of the contract (without VAT).

ITCF will not be responsible on behalf of the Client for complaints about losses, damage or costs, should said complaints not be made within one year from when the specific service carried out by ITCF and which originated the complaint was given. In the same manner, ITCF is not responsible for the presumed non-completion of the service requested if the complaint is not made within an identical period starting from the date on which said service should have been carried out. ITCF cannot be considered as an underwriter or guarantor, therefore it refuses all responsibility as such. Clients who intend protecting themselves against loss or damage must sign a pertinent insurance policy. The client acknowledges that

¹⁴ Other agreements or legally binding obligations, such as offer acceptance, purchase order, order confirmation, etc., are an integral part of the agreement.

ITCF, when drawing up a contract or carrying out the requested services, will not uphold, circumscribe, abrogate or relieve any obligation of said Client before third parties.

21 CLIENT OBLIGATIONS

In addition to what is indicated in the previous points the organisation, in order to correctly prepare the process and to reach the objectives connected with certification, must:

- Always follow the regulations that are applicable to the requested certification programme;
- Guarantee the necessary conditions for carrying out the audit, in particular regarding the availability of the documents so they can be examined, including transmission of said documents reasonably and usefully in advance¹⁵;
- Guarantee access to all areas, recordings (including the internal audit reports) and personnel availability for carrying out interviews during each audit;
- Guarantee the necessary collaboration with ITCF and the Audit Team in order to carry out the operations;
- Supply all the necessary information on the risks connected with safety during the verifications at its headquarters;
- Not use the certification in a manner that discredits ITCF and not make any declaration on the certification obtained that could be considered by ITCF and the market as misleading or unauthorised;
- use the certification only to indicate that the company management system complies with specific regulations and/or other regulatory documents and not use it to make it understood that a product or service has been approved by ITCF.

22 CERTIFICATION TRANSFER

In the event that an organisation with valid certification issued by another Management System Certifying Body that has been accredited by an Accreditation Body that adheres to the mutual recognition agreement IAF/MLA, wants to transfer its certification to ITCF, it must send a formal request¹⁶, attaching a copy of the Management System certificate.

To this purpose ITCF will verify that:

- The certificate is still valid;
- The certificate has not been suspended or revoked;
- The certifying body that issued the certificate has not been suspended or is not under sanction;
- The certified activities and the scope of the certificate are within the ITCF accreditation field;
- The organisation motivated the request for transfer.

Following re-examination of the information supplied by the applicant, ITCF will inform if it has accepted the request for transfer or not within 15 days. In the event that the request is refused, ITCF informs the applicant of the reasons for refusal.

In the event that the request is accepted, ITCF draws up a technical-financial offer that includes all the operations that have been programmed and which are necessary for transfer¹⁷.

All the evidence in the file for certificate transfer is re-examined by FD similarly to the other certification processes.

¹⁵ The time period for sending reasonably and usefully in advance is 15 days before a possible programmed verification and 7 days for a special verification.

¹⁶ Formal request means a request for certification that specifies the reasons for transfer.

¹⁷ The operations for transferring a certificate can include in-field audits, document re-examination, etc.

After positive deliberation, the transferred certificate is entered in the periodic maintenance and recertification visits programme in the methods described in these Regulations.

The date on the certificate issued by ITCF clarifies that the first issue date refers to the Certification Body that intervened previously.

ANNEX A: ASSET MANAGEMENT SYSTEM CERTIFICATION

This annex contains specific requirements for certification of the asset management system, in particular for certification of the responsibilities management system. It integrates the requirements in the general part of the Regulations.

Intangible assets: Company know-how (responsibility of the railway vehicle maintenance technicians)

The main reference for certification is given in the UNI ISO 55001:2015 Standard and in the current version of Company Communication 30 about the Trenitalia S.p.A. Safety Certificate (Abbr. COCS 30.rv). Where not specifically called for in the initial request, the two standards mentioned above will be taken as reference for the certification process.

During elaboration of the initial offer, ITCF will consider any applicant that wishes to obtain certification for additional regulations/standards/documents that contain regulations pertinent to its own Responsibility Management System.

Certificate extension to other regulations/standards/reference documents after the evaluations have been carried out and the certificate issued will be the subject of an addendum to the initial quotation.

ITCF will carry out at least one documental examination if the client organisation asks for its certificate to be extended to other regulations/standards/reference documents. Any additional in-field verifications will be considered and quoted in the technical-financial offer in relation to the additional requirements contained in the additional reference documents.

Unless otherwise indicated by the Client organisation, the requirements of new documents/reference standards will be verified during the surveillance visit.

ANNEX B: MAINTENANCE SYSTEM CERTIFICATION

B.1 SCOPE AND FIELD OF APPLICATION

This annex defines specific requirements for Maintenance Management System Certification according to EU Regulation 445/2011. The requirements in this annex are to be considered as additional to, and not in contrast with, those of these regulations.

B.2 REFERENCE DOCUMENTS

This annex refers to the following regulatory documents:

- COMMISSION REGULATION (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007
- DECREE of 21 December 2012 “Implementation of article 3, paragraph 1 of Italian Legislative Decree 43 of 24 March 2011 for the implementation of a temporary system of certification for entities in charge of maintenance for freight wagons”;
- ERA-GUI-09-2011-SAF-ECM ver.1.0 “ECM certification Application guide including explanations ECM certification scheme”
- ERA-GUI-10-2011-SAF- ECM Certification v.1.2 “ECM certification Application guide with additional explanations - Sectorial Accreditation Scheme”
- ERA-GUI-11-2011-SAF- ECM certification – guide maintenance workshop certification scheme v.1 0 - ECM certification Application guide including explanations Maintenance workshop certification scheme

A.3 TERMS, DEFINITIONS, ACRONYMS AND ABBREVIATIONS

ECM certificate: A certificate issued to a subject that is responsible for maintenance pursuant to article 14 bis, paragraph 4, of Directive 2004/49/EC.

A.4 CERTIFICATE DURATION AND SURVEILLANCE

Pursuant to art. 7, point 1 of EU Regulation 445/2011, an ECM certificate remains valid for no more than 5 years. Surveillance visits are carried out yearly.