REGULATION FOR MANAGEMENT SYSTEMS CERTIFICATION

Document R-001

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May 2018	section 3.3 - Update Regulation UE 679/2016 – Data Protection	F. Banfi (Technical Director)	R. Cusolito (Managing Director)

1 PURPOSE AND PREMISE

This Regulation lays down the procedures followed by ITALCERT to manage the certification of management system in the following contexts:

- certification according to UNI EN ISO 9001 (QMS scheme)
- certification according to UNI EN ISO 13485 (MD scheme)
- certification according to UNI EN ISO 14001 (EMS scheme)
- certification according to standards series UNI EN ISO 3834 (Variant of QMS scheme)

Further details, such as cheap fares, not specified in this Regulation, are defined in the Agreement of Certification drawn up for each specific Customer.
ITALCERT is accredited by ACCREDIA to issue the Certifications above and therefore is subject to compliance with the rules laid down in the rules and regulations applicable. In particular ITALCERT must comply with technical regulations (RT) and / or technical documents (DT) issued by ACCREDIA for some specific areas of certification, which contain additional requirements for Customers compared to certification standards. Is the Customer's responsibility to be aware of the applicability of these documents to its own situation and adapt its management system in order to comply with these additional requirements.
Accreditation is valid for a certain number of IAF sectors and / or technical areas; if the certification request includes an IAF sector or a technical area for which ITALCERT is not accredited, ITALCERT will however apply the rules laid down in this Regulation.

2 DEFINITIONS

For the purposes of this procedure, the following definitions apply:
Requirement: Need expressed in the reference standard for Certification or due to it.
Non-Conformity (NC): Non-compliance of a requirement.
Non-Conformity Class 1: Non-compliance of a requirement that represents a significant limitation of the management system compliance with the reference standard.
Non-Conformity Class 2: Any non-compliance of a requirement that is not configured as Class 1.
Recommendation (REC): Non-binding indication about improvement and/or consolidation areas of the management system. Reports of situations that can potentially generate NC, belong to this area.
Observation: Situation related to one or more documents of the management system which, though not a non-conformity, requires an updating and/or change of the document itself.
Customer: Organization that requires (or has obtained) the Certification. *(In some parts of this Regulation it may also be referred to as "Organization").*
For any definition not mentioned is as defined in the certification rules and in standards ISO 9000, ISO 14050 and ISO 19011.

3 PRINCIPLES OF CERTIFICATION

3.1 Sampling

The Certification process mainly involves the collection of information at the Customer's head office, evaluating some applicable examples. The audit is by its nature an activity that is performed by sample and with particular attention to the management system and not to the conformity of the product. This aspect must be taken into account for a correct use of the certification by the Customer towards the market and other interested parties.

3.2 Independence and impartiality

ITALCERT is required to comply with the rules established by the standards for accreditation. In particular ITALCERT is required to guarantee the principles of independence and impartiality. As a result, ITALCERT cannot offer support services intended as consulting on management systems.

3.3 Confidentiality and Data Protection

According to Regulation UE 2016/679 and to applicable Italian legislation about *Data Protection*, the personal data provided by the owner to ITALCERT will be processed by ITALCERT (internal staff and external collaborators/professionals involved - the latter designated as external data processing managers) exclusively for the purpose of ensuring the correct execution of the contractual relationships and of the management of the service.
In relation to the aforementioned purposes, the processing of personal data takes place through IT, manual and telematic tools with logics strictly related to the purposes themselves and, in any case, in order to guarantee the security and confidentiality of the data. The provision of the customer's personal data is therefore essential in relation to the proper conduct of contractual relationships with the consequence that any refusal to supply them will determine the impossibility for ITALCERT to proceed with the same relationships.

The data of the Organization may be communicated by ITALCERT, as far as their respective and specific competence is concerned, to Bodies and in general to any public and private entity, as well as to the internal designated subjects, responsible and in charge of data processing, as well as to those external parties responsible and / or appointed by ITALCERT to whom the communication is necessary for the execution of the services provided by ITALCERT, and with respect to whom there is an obligation or need for communication for ITALCERT.
With the exemption of the publication of the data related to the certified Organizations through the website - www.italcert.it - (see also Register of Certified Organizations on the ACCREDIA website), the personal data of the Organization will not be disclosed.
The personal data (for example: company name, address, VAT number, name of the contact persons, telephone and fax numbers, email addresses) are collected and processed by ITALCERT with the exclusive purpose of managing and coordinating the planned activities according to this regulation and in order to carry out administrative / accounting procedures. The data related to products / services (Audit Reports, Manuals, Evaluation Documents, etc.) are collected and processed in order to comply with the requirements that ITALCERT shall fulfill as an Accredited Body.
When applying for a certification, ITALCERT will provide the Customer with information about EU Regulation 679/2016 and the Italian legislation applicable to Data Protection, as a consequence the Customer may give his consent to the processing of data.
Not all the required information are detailed in this regulation.
Remember that:
- the "Data Controller" is ITALCERT S.r.l., in the person of the Legal Representative, address: Viale Sarca 336, Milan (ITALY)
- The Customer has the right, at any time, to have access to his personal data processed by ITALCERT, for example in order to request its updating, correction or integration, without prejudice to the obligations and provisions of law that bind ITALCERT as an Accredited Body for the conservation of specific information.
The provided data are collected by ITALCERT for the unique purpose of carrying out administrative / accounting procedures and to comply with the duties requested by ACCREDIA as a Certification Body.
Following the issuance of the certification, the customer data are entered in the "Register of Certified Companies", which is periodically transmitted to the Bodies to whom this information is due.
The register is also made available to any applicants who make a written request; in the same way ITALCERT makes available to those who request it the eventual renunciation, suspension or revocation of the certification.
ITALCERT guarantees also the confidentiality of all information that will be collected during the audits, including the results recorded in the audit reports. The persons, in charge by ITALCERT are also bound by specific confidentiality restrictions in relation to all the information they will be aware of during the certification process.

4 BEGINNING OF THE PROCEDURE

4.1 Request for Quotation

Any Customer can request a quotation for the process of management system certification. Some information are necessary to arrange the quotation and the Customer must make them available to ITALCERT. The Customer should identify the rules for which the certification is required.
The customer must identify the standards for which requires certification and the scope of the management system including operational premises in which it is applied. The activities that have not been subject to verification by ITALCERT shall not be included in the certificate scope.
In the definition of the purpose and scope, the organization shall consider the amount of control or influence that can have on activities, products and services. The definition of the purpose and scope should not be used to exclude activities, products, services or premises and facilities in order to escape its obligations for compliance. The purpose and scope definition shall represent the organization's operations included within the boundaries of its management system that should not be misleading to stakeholders.
As regards in particular the certification according to the standards of series UNI EN ISO 3834 is the Customer's responsibility to propose the standard of this series it deems most appropriate for the nature of its business. In the absence of an explicit indication ITALCERT shall schedule the audit on the basis of the certification according to standard EN ISO 3834-2. In any case, during the audit of stage 1 the Audit Team has the possibility and the authority to confirm / modify the audit criteria and the reference standard to be used to continue the certification process.
The quotation, including a section about the audit program and one about the amounts provided, will be arranged according to the information received by the Customer; whether the information sent is incorrect,

ITALCERT will perform a new practice review, and if appropriate, an update of the audit program and economic conditions.
The audit program is arranged according to the rules and regulations that regulate the accreditation of ITALCERT.

4.2 Places for conducting Audits

In the offer, ITALCERT identifies the locations subject to certification as well as any other locations which are deemed to be included in the audit program (e.g. locations of suppliers or temporary locations such as construction sites, etc..). The Customer should ensure the access to such locations.
The need to implement part of the audit in other locations in addition to the premises subject to certification is at the discretion of ITALCERT, on the basis of the field of certification required by the Customer. If such a need is evident after the start of the certification process due to an incorrect communication from the Customer about the activities subject to certification or subsequent amendments, ITALCERT may, at its discretion, apply an increase of the audit time; this extension will appear as an unplanned surveillance audit.

4.3 Acceptance of quotation and formalization of the Agreement.

The acceptance of the offer by the Customer requires the transmission of the "application for certification" attached to the offer itself, following which the certification practice is opened and to the Customer are sent the following documents:
a) this Regulation R 001
b) the Regulation for the use of the mark R 002
c) the Certification Agreement
The Regulations and the Agreement must be returned signed for acceptance. The request must be returned completed. Without the above documents ITALCERT cannot release the Customer the certificate of conformity.
At the opening of the practice the Customer is given the name of the Audit Team Manager expected for the certification audit. The Customer has the right to request the replacement, within a defined time, if there are motivated conflicts of interest. ITALCERT nevertheless reserves the possibility to replace afterwards the Audit Team Manager.
If the Customer were to accept the offer and sign the contract but not available to conduct the audits, ITALCERT will close the practice after one year following written notice by registered post. Nothing will be due by ITALCERT of the amount already paid by the Organization - Customer.

5 CONDUCTING AUDITS – GENERAL PRINCIPLES

5.1 Audit operating procedures

The definition of the date of audits is agreed by the secretariat of ITALCERT with the Customer, according to the Customer's availability and the auditors in charge.
The date of audit execution and the Audit Team composition are formally notified (by fax or e-mail) to the Customer. The Customer has the right to request the replacement of one or more members of the Audit Team, within a defined time, if there are motivated conflicts of interests.
About 5 days before the audit, ITALCERT sends the Customer an audit plan, with the operational detail, specifying the sequence of activities related to processes and/or to environmental aspects of the Management System as well as to the regulatory obligations.
The plan always includes an opening meeting, during which the Customer may request clarification or suggest any operational changes to the plan. The plan always provides a closing meeting, during which the Audit Team presents the audit results, explaining to the Customer the context of the identified results. The plan may not be formalized in case of unplanned surveillance audit.
The audits are conducted at the Customer's sites / productive location; they may be held even outside the Customer's head offices to verify the performance of activities included within the subject of certification; for example installation activities at the Customer's head office fall in this area. The activities performed at other Organizations' sites fall within this area of type "building sites".
During the audit, the Audit Team will collect the information needed to express its opinion on the management system through:
- examination of the Customer's documentation;
- interviews with staff;
- evaluation of examples about activities carried out previously (based on documents) or current activities during the audit.
  - Definition of the customer's organization context
  - Identification of stakeholders
  - Identification of legal compliance obligations

- Examination of the Organization's customer documentation
- Interviews with staff
- Evaluation of examples of previously carried out activities (on documentary basis) or assets outstanding during the audit

The Customer shall ensure the Audit Team the opportunity to examine examples of activities carried out for all processes for which certification is required, including those processes performed outside the Customer's head office. For this reason, the Customer must provide access to all its departments and the opportunity to interview any person employed in activities related to the certification request.
When the customer operates in shifts, in the development of the audit program and audit plans, ITALCERT must consider the activities that occur during work shifts. For this reason, the Customer must ensure access to all rounds and a chance to interview each person assigned to activities linked to the certification required in all rounds present.
The Customer shall ensure the presence of a guide in the audit, or a person designated by the Customer to assist the Audit Team.
Where applicable, before the Audit the Customer must notify to ITALCERT a list of external activities/building sites that can be verified during the audit, including location, type of activity and progress.
If deemed appropriate and necessary ITALCERT may, at its sole discretion, require to check the Management System of the Customer's outsourcers at their head offices; such verification may be considered as unplanned audit (overtime) or be included in the planned audit time, to sole discretion of ITALCERT. The lack of opportunity for ITALCERT to verify the Management System of a Customer's outsourcer can be considered as sufficient cause by ITALCERT to determine a negative result as regards the issue of certification or be cause of suspension of the certificate issued.
At the end of each audit the Audit Team Leader releases a report (hereinafter referred to letters "RRC") in which NC, recommendations and observations are formalized.

5.2 Management of findings detected

For each NC the Customer is asked to notify to ITALCERT within 15 days an assessment of the causes of NC and what actions intends to implement in order to eliminate the NC, in the expected time of implementation; ITALCERT may consider not acceptable a time of implementation exceeding 90 days. Corrective actions must be related to the causes and should consider the possibility that the promptly detected NC may also be present in other similar situations.
The corrective Actions suggested are evaluated by ITALCERT; the outcome of the assessment is formally communicated to the Customer, including any additional requests.
ITALCERT requires documentary evidence of the implementation of the NC grade I within a defined time (normally not exceeding 90 days from the date of the audit); after this period ITALCERT will proceed with the suspension of the certificate. In case of NC grade I detected during a certification audit (stage 2) or renewal, the certificate can not be issued until the Organization has not given evidence of resolution of Non Conformity.
If ITALCERT not have the opportunity to verify the corrections and the corrective actions taken by the organization taken in response to major non-conformity within 6 months after the last day of Stage 2, ITALCERT must conduct another Stage 2 audit (with additional cost for the client) before recommending granting certification.
The implementation of NC grade II is examined at the next audit. However, according to various situations, ITALCERT may apply, formally notifying the Customer, a different management of the verification of corrective actions taken by the Customer.
The closure of the NC requires the verification that the suggested corrective actions have been implemented and that they are effective. In the event that the Audit Team does not have evidence of implementation of corrective actions planned in response to the detected NC, the grade of NC can be increased, from grade II to grade I.
The recommendations are not binding; however the Customer must handle them in documented form, implementing appropriate improvement and/or preventive actions or, otherwise, documenting the arguments in support of the non-implementation of subsequent actions. The relevant documentation is normally verified during the following audit; ITALCERT may require, by formal request to the Customer, documented evidence about recommendations management before the following audit.
The observations related to change requests of system documents must be taken within the next audit, unless otherwise communicated by ITALCERT.

6 TYPES OF AUDIT

6.1 Type of audits applicable

During the certification process and its subsequent maintenance, ITALCERT may require the implementation of the following audits:

• Preliminary Audit
• Certification Audit stage 1
• Certification Audit stage 2
• Planned surveillance Audit
• Renewal Audit
• Unplanned surveillance Audit (overtime)
• Short notice or without notice Audit

All audits are carried out against payment for the Customer, according to the fares specified in the certification Agreement.

6.2 Preliminary Audit

In the period between the acceptance of the offer and the conduct of the first audit, Customer may require a preliminary audit to ITALCERT. This audit is conducted at the Customer's premises using the same recording documents provided for ordinary audit activities, except for the audit plan that is not formalized.
The preliminary audit can not be longer than 2 days and aims to determine the level of preparation of the Customer's management system to deal with the certification process.
The preliminary audit is not part of the certification process.
Any anomalies that emerge are expressed only in the form of recommendation and NC are not formalized.

6.3 Certification Audit Stage 1

6.3.1 *Purpose*

The audit stage 1 may have different purposes depending on the type of certification required, as detailed below:

a) To verify that the Customer's management system documentation complies properly with the requirements of the reference standard; evaluate that the documentation, including risks, opportunities and procedures, covers all the requirements of the standard and is in conformity with them;
b) To verify that the Organization has developed a complete, conscious and organic analysis of the context and acquire, directly from the Management, evidence that ensures confidence that the analysis of the context is effective in giving the management system the ability to obtain the expected results, and recording detailed information on the checks performed;
c) To verify that the Organization has all the necessary authorizations to perform the activity subject to certification;
d) To collect the necessary information about the purpose of the client's management system, processes and locations; the Audit Team shall perform the relevant and necessary inspections, in order to obtain an overall description of the context and activities and, where applicable, the environmental impacts of the Organization;
e) To verify the knowledge and correct management by the Organization of the regulatory requirements applicable with the certification required and that have an impact on the compliance of the management system subject to certification;
f) To apply as regards any ongoing legal proceedings as provided by the RT 09 Accredia and R001 Regulations for the ITALCERT certification in force;
g) To discuss, verify and examine with the Organization the correctness of the certification scope requested and possible exclusions. The certification field shall be expressed in a way that not present any ambiguity regarding the parts of the activity that are not included in the certification scope.
h) To verify, also taking into account the audit program, the presence of outsourced processes and evaluate, based on the degree of control exercised on them and their criticality, the need to include the verification of one or more outsourcers in the verification of stage 2;
i) To evaluate the degree of preparation for the audit stage 2, verifying whether the internal audits and the management system review have been planned and carried out and that the level of the management system implementation provides adequate trustiness that the Customer is prepared for the audit stage 2;
j) To schedule/confirm/modify the planning of the stage 2, defining where appropriate any details (such as the location of external activities to be verified);
k) (only EMS scheme) To verify that "within the scope defined for the environmental management system" the organization has identified and evaluated all "environmental aspects of its activities, products and services that may keep under control and those on which it can exert influence, and their environmental impacts, considering a life-cycle perspective ", in order to identify which are the significant ones on which to develop their EMS;

l) (EMS scheme only) To verify that the organization has all the necessary authorizations of an environmental nature relating to all activities directly or indirectly related to the certification purpose and verify its validity, completeness and correctness;
m) (Medical Device scheme only) To verify that the customer has prepared one or more technical dossiers for the medical devices of which he is manufacturer.

In case of EMS certification scheme the stage 1 is always held at the Customer's headquarters (or a sample of it). In case of schemes QMS and MD, in special circumstances, the stage 1 or a part of it could not be carried out at the Customer.
The report of Stage 1 identifies the following possible actions to be implemented:

- request for modifications and updating of the quality system documentation
- identification of situations that could lead to a potential level determine a non conformity during the audit stage 2 if not properly managed and improved
- identification of situation which, if not solved, will determine a non conformity during the audit stage 2

Furthermore, the Audit Team expresses in this report a judgment on whether or not to perform the audit stage 2 as originally planned. In case of failure, the Customer must provide evidence of having solved the findings identified before planning the audit stage 2.

6.3.2 *EMS scheme: authorizations check during Stage 1*

In case of environmental certification (EMS), the Audit Team must verify the presence of all the authorizations required by the applicable legal provisions.
As a general principle, may be acceptable also situations formally not conform to the dictates of current legislation, provided it is clear that the Customer has, however, did everything in its power to obtain the authorization itself, for example by submitting the application for authorization complete and correct (containing all the relevant information accurately) with adequate advance notice or that the Organization have done what is requested in chapter 4.2 of document UNI7TR 11331.
Failing the application for authorization or application submitted without the proper advance, the Audit Team will issue a NC of grade 1.
In case of application to which the public Body has requested additions or other actions by the Customer, the Audit Team shall have the right to assess which of the following two cases you fall in:

a) the integration is required because the application was incomplete or inaccurate and in this case the adequate advance count of 6 months restarts from the date of submission of the application complete and correct;
b) the request for additional information is not due to deficiencies in the application, but to special needs, or to clarifications not attributable to an incorrect or incomplete submission of the application itself. In that case, the date of submission of the original application attests.

However, the Audit Team verifies that the Customer waiting for the authorization:

- demonstrate the completeness and correctness of the application submitted;
- properly implement all the planned steps for the authorization process or subsequent requests from the competent Administration;
- solicit with reasonable continuity and timeliness in a documented way the public Body for the authorization issue.

Without the authorization, or application not submitted or presented without adequate advance, the Audit Team will issue a remark that could, if not entirely solved, should be a non conformity of grade 1 during stage 2 audit.
In case of an application submitted well in advance, but in which there are elements of non-conformity (for example, about the completeness of the application), the Audit Team will issue a remark that, if not entirely solved, should be a non conformity of grade 1 or 2 during stage 2 audit, under audit team consideration.
The conducting of stage 2 is not allowed, unless derogations justified and formalized, until the Customer's confirmation to have solved all the remarks that, if not entirely solved, should be a non conformity of grade 1 during stage 2 audit.

6.3.3 *Certification ISO 3834*

In case of certification according to standards ISO 3834, during the stage 1 the Audit Team will verify the correctness of the standard identified as reference for the certification by the Customer, through an examination of relevant documents and interview with the management.
The Audit Team will also test the complete takeover of the requirements of standard section ISO 3834 identified as a certification standard.
On this occasion will be also carried out an initial assessment of the competence of people holding key positions in the system ISO 3834.

6.4 Certification Audit Stage 2

The purpose of the audit stage 2 is to evaluate the implementation of the Customer 's management system, including its effectiveness. The audit stage 2 must take place at the Customer's head office(s).
During the audit the Audit Team has to:

- Collect evidences about compliance with all standard requirements or other regulatory document of the management system applicable
- Verify that the Customer has implemented a monitoring, measurement and recording system as well as a management system review of key targets and goals
- Verify that the Customer's management system assures the legislative compliance, as far as pertinent and relevant to the object of the certification required
- Verify that the system guarantees the operational control of processes and that the records ensure the traceability, where it is provided or required
- Review the system of internal audits and the review by the management, in terms of effectiveness and completeness, as well as management's responsibility for customers policies
- Assess the links between regulatory obligations, policy, performance objectives and targets, applicable legal requirements, responsibilities, competence of staff, operations, procedures, performance and findings of the internal audit and the conclusions
- Confirm (or change) the certification purpose
- Only schemes QMS and MD: confirm (or change) the presence of any standard requirements not applicable.

Stage 2 should be conducted within 6 (six) months from stage 1, but no longer than 12 months; after this time ITALCERT shall perform again the stage 1 audit. If the company is not available to carry out the audit stage 2, 12 months after the conducting of stage 1, ITALCERT will have the faculty to close the certification practice after written notice by registered post.

6.4.1 *Certification ISO 3834*

In case of certification according to standards of series ISO 3834, in addition to what already provided in the previous paragraph, the Audit Team will verify the effective competence of the coordinator of the weld (where its presence is provided) by an interview and examination of its activities previously performed.
The competence assessment of the coordinator of the weld is also based on evidence of training. The training meeting the specifics outlined in Appendix A (informative) of standard ISO 3834-5 is to be intended appropriate. In case of different levels of training it's up to the Customer to demonstrate the adequacy of the training level attained, which will however be evaluated by the Audit Team also taking into account the applicable part of standard ISO 3834.
The Customer shall make available to the Audit Team all documents and records necessary to carry out the conformity assessment, including: welding processes, welding sequences, heat treatment, staff qualification, traceability, subcontracting and acceptance criteria. The Customer must also take account of the documents listed in standard ISO 3834-5 § 2.2, in order to demonstrate the compliance with the procedures adopted.

6.5 Planned surveillance Audit

Surveillance audits are carried out at Customer's head offices, in order to verify if the certified management system continues to meet the specified requirements.
In the first three years of certification two planned surveillance audits are provided:

- the first surveillance audit must be carried out no later than 12 months from the issue date of the certificate. For this reason ITALCERT normally schedules the first planned surveillance audit at a distance of 10 months from the issue date of the certificate.
- the second surveillance audit is planned at 12 months away from the first surveillance audit.

Over the next three-year certification:

- the first surveillance audit is carried out at about 12 months from the renewal audit
- the second surveillance audit is planned at 24 months from the renewal audit.

The non-compliance with the rules about the planned surveillance audit performance, due to Customer's unavailability, involves the suspension of the certificate.

6.5.1 *Certification ISO 3834*

In case of certification according to standard of series ISO 3834, in addition to what already provided in the previous paragraph, the Audit Team will check during every surveillance the confirmation of the conditions that led to the certification, identifying any significant changes that might lead to a modification of the certification field or reference standard, taking into account, for example: change in the application of welding processes, increase of the material thickness, changing of the welding coordinator.

6.6 Renewal Audit

The certification renewal is the result of a renewal audit (or recertification), whose purpose is to ensure that the efficacy of the whole management system has been maintained, in light of internal and external changes and its continued relevance and applicability to the subject of certification and that the management system has actually contributed to the achievement of the Customer's policy and targets.
The renewal audit is planned and conducted to evaluate the continued fulfillment of all requirements of the relevant normative document. The purpose of the recertification audit is to confirm the maintenance of compliance and effectiveness of the whole management system as well as the maintenance of its usefulness and applicability for the certification purpose.
This audit considers the management system performances during the certification period; therefore the Customer must make available to the Audit Team data and/or information that give evidence of the improvement achieved by the management system during the previous period (generally three years), as well as the efforts made to maintain the effectiveness and improvement of the management system in order to strengthen the overall performances.
Exceptionally, ITALCERT may conduct a renewal audit in two stages (1 and 2), for example in case of significant changes in the management system, about the Customer, or the operational context wherein the management system is operating (e.g. changes in the legislative context or Customer's requests about extensions/variations of the certification field).
The renewal audit is normally scheduled at least two months before the expiry of the certificate.
If recertification process starts before certificate date of expires, and the audit begin before the end of validity of the certificate, but it was not completed in time (for example, a delay of remedial actions) the certificate temporarily loses its value, starting from its expiration date.
Instead, when the renewal audit begins after the expiry of the certificate, but no later than six months after the expiry of the same, ITALCERT will reassess the assumed duration of the audit; it may in some cases be increased compared to what is expected, with increasing of costs. In addition, the certificate, which loses its value by the maturity date, must compulsorily bear as "before the issue date" the date of actual renewal, thus losing the "historic". Also the effective date of the certificate will last less than three years, having to maintain the former frequency expiration.
If the certificate has lost its value, the customer is obliged to:

a) Do not use the certificate and certification logo to the re-issuance of the certificate;
b) Make yourself available to perform the audit no later than six months after the expiry date of the certificate.

If it is not possible to carry out the audit results within 6 months above the certification file is closed and will be necessary, if required, the customer submits a new application for certification.

6.7 Unplanned surveillance Audit

Unplanned audits can be resolved by ITALCERT in the following cases:

- request for extension of certification by the Customer
- particularly critical situations requiring an increase of field monitoring by ITALCERT
- particularly serious reports by the "customer system" of the certificated Customer
- need to examine the management system of a Customer's outsourcer
- need to examine processes or locations outside the usual audits planning
- failure to send of corrective actions in response to the detected NC
- no evidence of implementation of the actions planned, following the detected NC

The unplanned surveillance audits can be performed in a simplified manner, according to their purpose, and may not provide a detailed audit plan.

6.8 Short notice or without notice Audit

In very particular situations ITALCERT may conduct a short notice audit, meaning that as a notice of less than 15 calendar days. ITALCERT may require the Customer to conduct this audit in the following cases:

- Request by ACCREDIA to ITALCERT to conduct a short notice or without notice audit
- Particularly serious reports by the "customer system" of the certificated Customer.

The short notice or without notice audit can be performed with a simplified manner, according to its purpose, and may not provide a detailed audit plan.
The short notice or without notice audit are not subject to cost to the Customer, with the following exceptions:

a) the reporting by the customer system is completely motivated and fully justified; in this case from the contractual point of view the audit is comparable to a surveillance overtime
b) the short notice audit may actually be considered as "replacement" of a planned surveillance audit; in this case from the contractual point of view the audit is comparable to a planned surveillance audit.

6.9 Market Surveillance Visit

The Market Surveillance Visits are regulated by the disclosure document IAF ID04 (available online at *http://www.iaf.nu/upFiles/IAFID42012_Market_Surveillance_of_Certified_Organizations_Word_R2.pdf*).
Market Surveillance visit is carried out with the Organization certified by ITALCERT but conducted directly by ACCREDIA staff, and not by ITALCERT.
The visit is intended to ensure that the method of valuation adopted by ITALCERT comply with the applicable standards; the Accreditation Body (Accredia) may require the conduct of visits to the certified organization, directly through the use of its own staff.
About scheduling, ACCREDIA will inform ITALCERT with at least 7 working days notice; the visit plan will be prepared by ACCREDIA in accordance with IAF document ID04 and will be sent by ACCREDIA to ITALCERT within 3 working days before the visit.
The contact with the organization to be verified will be taken directly by ITALCERT and not by Accredia.
In these visits is not expected to also visit external site or external services.
If the organization does not grant its approval the visit, the validity of the certificate will be is suspended until it is not given the approval to verify, for a maximum period of 3 months.
Expired three months, in the absence of approval for the verification, certification is withdrawal.
The assessment methods used by the accreditation bodies, are included in special regulations and / or communications / circular available on the websites of the same.
The Organization shall make available to the ACCREDIA personnel its system documentation that ITALCERT has seen as a reference during the previous audit.
The visit led by GVI Accredia takes place with the support of a questionnaire (you can find an example in the Annex to the document IAF ID 04), and the presence of the organization's staff (usually the Quality System Manager and the Management Representative) and ITALCERT (if possible with the participation of a member of the review team that conducted the latest audit).
Visit Market Surveillance is not subject to cost to the client organization.

7 RELEASE OF CERTIFICATE

7.1 Issue of certificate

The certificate of conformity has a maximum validity of three years. The issuance of a certificate with a validity less than three years is possible in some specific cases, including the following:

- the certificate was issued as a result of an extension / modification of the certificate, which is not coincident with the renewal of the same.
- the standard against which the certificate is issued is in process of transition with a new edition of the standard itself.

The certificate of conformity is issued by the Resolution Committee of ITALCERT, based on the documentation collected during audits. The Resolution Committee has the power to:

a) deliberate the issue of the certificate without comments
b) deliberate the issue of the certificate with request of specific actions for the Customer
c) deny the certificate

Among the actions that the Resolution Committee may ask the Customer, there are:

- request to performance of an unplanned surveillance
- request to anticipate the first planned surveillance audit expected
- request to implement obligatorily an action following a recommendation detected during the audit.

In case of negative judgment in relation to the issuance of the certification, must be paid an additional audit, with extent and duration determined by the Committee of Resolution.
The certificate and certification logo may be used only by the Customer in accordance with the rules laid down in the Regulation of ITALCERT R-002.
The use of the certificate and the certification logo is prohibited during periods of non-validity of the certificate (certificate expired, not released, suspended, revoked, etc..).
ITALCERT, once assessed the misuse of the certificate, takes the appropriate measures to prevent it and to protect, though including publication, its own interests (warning, suspension or revocation of certification, legal actions).

7.2 Change, extension or reduction of certification field

The Customer may request a change, extension or reduction of the application field of the certificate.
This request must be expressed by written notice (letter, fax or e-mail).
In case of formal change or request of reduction of the certification field, it is not expected to conduct e specific audit.

In case of request for extension of the certification field or substantial change, the updating of the certification field may only take place as a result of an audit; as appropriate and in accordance with Customer needs, it may be necessary to conduct an unplanned surveillance audit.
Following each type of change request, extension or reduction of the application field of the certificate, ITALCERT will have the opportunity to review and update as appropriate the audits planning, in terms of their duration, and consequently update the fees related.
The approval of substantial changes, reductions and extensions of the certification field should always be the result of an assessment by a Resolution Committee.

7.3 Certification standard modification

In case of modification of the certification standards, ITALCERT will inform its client, giving the necessary instruction about transferring the certification; with regard to transferring procedures, it is very likely that they are established at international level, and ITALCERT is forced to follow them.
ITALCERT have no obligation to inform its client if other standard, that could be use as a support of the management system (guide lines …); if these standards have been used by the certified organization or mentioned in its documentations, it has been necessary to adopt the appropriate updating.

8 REQUEST FOR SHIFTS OF PLANNED AUDIT

ITALCERT communicates in advance to the Customer the period of the next planned audit.
Any shift may be requested by the Customer, provided that:

- the obligation to conduct at least one audit in a solar year is guaranteed
- the obligation to conduct the first surveillance audit before 12 months from certificate date of issue.
- the Customer requests the shift in a formal way, if this shift exceeds 2 months, giving further evidence of having implemented the corrective actions proposed for the management of NC, if applicable
- the shift does not lead to an interval between two consecutive audits exceeding 18 months.

ITALCERT, however, reserves the right not to accept the requested shift.
In case of shift of a renewal audit it shall be necessary to take in account of the previous paragraph “Renewal audit”

9 SUSPENSION, REVOCATION OR RESTRICTION OF CERTIFICATION

9.1 Suspension and revocation

The suspension of certification may be generally considered when:
a) the Customer’s management system has persistently or seriously failure to meet the certification requirements, including requirements for the effectiveness of the management system
b) the Customer certified does not allow to be conducted surveillance or renewal audits at the required frequencies
c) it is not possible to carry out audits at the Customer’s outsourcers, as explicitly requested by ITALCERT
d) the Customer has not given evidence to have carried out on time the actions planned as a result of an NC grade 1
e) the Customer is not up to date with payments
f) the Customer uses incorrectly the certificate and certification logo
g) the certified Customer has voluntarily requested the suspension
Before applying the sanction of suspension, ITALCERT communicates via fax to the Customer such a possibility, indicating mode and actions necessary to prevent such action.
The adoption of the suspension of the certification is formally communicated to the Customer by registered letter, with possible anticipation via fax. In the communication ITALCERT indicates the condition for the re-establishment of certification and the maximum time allowed (however no more than 6 months).
During the period of suspension, the certificate is not valid to all effects; so in this period, the Customer must refrain from further publicize its certification and can not use the certificate or certification logo to third parties.
The lack of resolution within the stipulated time of the factors that led to the suspension results in the automatic revocation of certification. The order revoking is communicated by registered letter, with possible anticipation via fax.
Following the revocation of the certificate the Customer must stop using all advertising means containing any reference to a state of certification.
ITALCERT may, at the request of any party, declare the state of certification of a Customer’s management system and if it is suspended or revoked.

9.2 Restriction of the certification subject

It may be necessary or appropriate that the certification purpose is reduced, before the expiry of the certificate itself.
This may occur when it has evidence that a part of the certification purpose:

a) is no more active
b) does not meet the applicable requirements in a critically and repeated manner

Before implementing the reduction of the certification purpose, ITALCERT warns the Customer giving it the faculty to submit any counter-evidence.
The reduction of the certification purpose is decided by the Resolution Committee of ITALCERT.

10 MULTISITES CERTICATES

Whether the object of certification includes more than an operational headquarters, ITALCERT shall be able to manage the certificate according to the multi-site rule if is detected a homogeneity between the activities performed in the various locations and that there is evidence that the quality system has an adequate degree of control over all the seats (if the multi-site is applied at holding or consortia level, and in any case between Organizations with different corporate names, the central Organization will have to establish a contract between the parties of acceptance of the system (e.g. identifying the leader, the rules of the common system, etc.. understood that in case of severe NC the certificate may be suspended and / or revoked for the entire group).
In case of multi-site certification ITALCERT will examine, according to the rules of sampling in different audits, the peripherals operational headquarters, however always verifying the principal headquarters. Generally the sampling program is normally communicated to the Customer at the certification offer. ITALCERT can however make subsequent amendments to that program.
As is standard practice ITALCERT issues a single certificate, including the list of premises subject to certification and in some cases ITALCERT may issue an annex to the certificate stating that list. In special cases ITALCERT may consider whether to issue a certificate for each premises, however ensuring the link between all the certificates.

11 TRANSFER OF CERTIFICATION

The Customer may request to transfer to ITALCERT a certificate in its name, but issued by another Certification Body. The transfer is done by carrying out an audit by ITALCERT at the Customer's premises; normally for such audit ITALCERT follows the same rules established for renewal audits and the certificate is reissued with a duration of three years. Any different modes can be evaluated case by case, in compliance with the applicable documents IAF.
The transfer can be implemented if:

a) The certificate was issued by a Notified Body in EA / IAF context
b) The audit of transfer is carried out in conditions of validity of the certificate to be transferred

The Customer must provide evidence of having successfully managed the findings emerged during the last audit received by the previous Certification Body and make available to ITALCERT the reports of audits underwent during the period of validity of the certificate as well as a copy of the certificate in force.
If it appears that the conditions for the transfer of the certification are actually invalid, ITALCERT carry out a new review of the certification practice; the result of this review, which will be formally communicated to the Customer, may include, for example, the following measures:

- increase in the time of planned audit to be charged to the Customer.
- conduct of an unplanned audit
- suspension of the certificate issued

12 OBLIGATION OF CERTIFIED CLIENTS

12.1 Transfer of information

The Customer, once achieved the certification, must promptly inform ITALCERT of the changes occurred in relation to:

a) legal, commercial, organizational aspects or related to property
b) organization and management (for example managers with key roles, staff with decision-making power or technical staff);
c) contact addresses and websites;
d) application field of the Organization's activities included in the certified management system;
e) significant changes to the management system and processes.

In the event of proven non-disclosure of such information ITALCERT may deliberate, based on the criticality observed, to:

- conduct an unplanned audit
- implement the suspension of the certificate issued

12.2 Use of the certificate

The Customer agrees to use the certificate and certification logo according to the rules laid down in Regulation R-002 of ITALCERT. Any use which does not comply will be considered as NC and may, in certain cases, lead to the suspension of the certificate.

12.3 Presence of ACCREDIA

ACCREDIA, as Accreditation Body and within the checks and inspections performed on all certification Bodies may apply to ITALCERT to participate, with its responsible, to audits conducted by ITALCERT at the Customer. The responsible of ACCREDIA participates to the audit as an observer and does not cause an increase in costs for the Customer; also he can not express judgments about the Customer's management system.
ACCREDIA can communicate to ITALCERT its presence with notice or with short notice; the notice ITALCERT will give to the Customer is therefore a consequence of this.
The Customer may not refuse the presence of the responsible of ACCREDIA during audits carried out by ITALCERT; in case of refusal, ITALCERT will not issue the certificate (in case of certification or renewal audit) or will provide the suspension of the certificate in other cases until the acceptance of the presence of the responsible of ACCREDIA; in case of persistent failure over 6 months of refusal, the certificate will be revoked.

12.4 Legal Proceedings in progress

The client shall communicate to ITALCERT any legal proceedings in progress or any judicial ruling that relates to the object of certification, providing the appropriate updates.
ITALCERT will check, during the audits or through specific requests on the progress of the dispute, how the organization has identified the causes and possible repercussions on its management system.
ITALCERT will collect all available and accessible information related to the current procedure and will conduct an independent review.
The client can not refuse to make sufficient evidence available to ITALCERT for an adequate and systematic monitoring of the specific problem and its monitoring; in case of refusal, ITALCERT will not issue the certificate (in the case of certification audit or renewal or transfer) or will proceed with the suspension of the certificate in other cases until the receipt of the appropriate information; in case of persistent non-compliance beyond 6 months from the refusal, the certificate will be revoked.

13 APPEALS

The Customer may appeal against a decision made by ITALCERT in relation to its certification through written communication transmitted by fax or by registered letter R.R.. To be eligible, the appeal must:

a) contain a description of the disputed decision
b) be supported by a clear and detailed reason
c) be sent to ITALCERT within 45 days from the date of the notified decision, subject of the appeal.

Upon receipt of the appeal, ITALCERT formally communicate to the Customer within 7 days if the application was deemed to be eligible or not and, in case of eligibility, the date by which a decision is made (within 30 days from receipt of the application).
The eligible appeals are evaluated by a Resolution Committee, independent from the staff involved in the actions that led to the decision subject of the appeal.
The decisions taken on the appeal by the Resolution Committee, on which no further appeal can be filed, shall be communicated to the Customer by fax and / or registered letter R.R.

14 COMPLAINTS

The Customer can make a complaint to ITALCERT for the activities performed relative to its certification.
ITALCERT formally manages any complaint received in writing (letter, fax or e-mail); any verbal complaint will be handled in a documented way, if deemed appropriate.
The management of the complaint states:
a) written response (letter, fax or e-mail) within 7 days from receipt of the complaint, with the analysis of the complaint and any actions planned for its management, with its timing;
b) written response (letter, fax or e-mail) upon completion of the planned actions.

15 ACCEPTANCE AND REGULATION UPDATE

The Customer applying for certification must formally accept the contents of this Regulation, by signature with stamp on the last page of the regulation itself. In case of future updates and changes, ITALCERT will

make available the Regulation on its web site www.italcert.it and will notify the Customer by fax, registered letter R.R. or e-mail. The Customer has 60 days to formally communicate the non-acceptance of the amendments, an act that involves the recess of the certification. After 60 days without any communication from from the Customer, the new edition of the Regulation R-001 will be deemed accepted for silent-consent.