

## 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)

Regarding UNI EN ISO 45001 certification scheme (SCR scheme), please refer to the specific regulation RS-001.

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 regulation, 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 (major):** Non-compliance of a requirement that represents a significant limitation of the management system compliance with the reference standard.

**Non-Conformity Class 2 (minor):** 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 and ISO 19011.

**Legislative Checklist:** Document prepared by ITALCERT which must be completed and kept updated at each audit by the Organization in the case of ISO 14001 and/or ISO 45001 certification. In the event of failure to complete it annually, an observation is issued with the obligation to complete it within 30 days of the performed audit.

## 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](http://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 numbers, certified mail and 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.

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 formalization of the contract between ITALCERT and the Applicant takes place in two stages.

The first formal act consists of the return of the "Application form for certification" duly filled and signed by the legal representative or by an authorized person.

The "Application form of certification" is an integral part of the offer and is placed at the end of it. With this document, the organization confirms the correctness and truthfulness of the data related to the applicant (employees, offices, outsourcers, etc.) indicated in the offer.

After the reception of the application form, ITALCERT opens the certification order, reporting the relevant charges if indicated in the offer. ITALCERT assigns a unique code to the order which will be always reported in all subsequent communications.

With the opening of the certification order, the following documents are sent to the customer.

- a) this Regulation R 001
- b) the Regulation for the use of the mark R 002
- c) the Certification Agreement

Regulations R 001 and R 002 are considered implicitly accepted with the submission of the application form of certification.

The contract, on the other hand, includes as established in the offer with more details and a signature is required for acceptance of the conditions included the clauses pursuant to the Italian Civil Code. Art 1341 highlighted therein.

The contract is established for an indefinite period with a tacit renewal. It may subsequently be updated with separate documents, for example in connection with the three-year renewals.

The return of the signed contract is a necessary condition to complete the certification process and to issue the certificate.

If the Customer accept the offer and sign the contract but is not available to be audited, ITALCERT will be able to close the contract after one year and following a written notice by registered letter or PEC. Nothing will be owed by ITALCERT beyond what has already been 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.

In the case of ISO 14001/ISO 45001 certification, the Secretariat, together with the notification confirming the audit date, sends the Organization the legislative checklist document.

The Client must make the legislative checklist available, in an updated and complete form, to the GVI during the audit during the initial meeting and deliver it in xls format to the Audit Group.

The date of audit execution and the Audit Team composition are formally notified (by certified mail 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 because 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.