Regulations for QMS certification

This document has been approved by the Director.

0. HISTORY

This Edition 27 – 25 March 2019 of the Regulations for QMS certification published by IGQ replaces the previous edition 26 of 30 June 2016 and enters into force upon its publication.

1. GENERAL

IGQ is a management system certification body competent and accredited in defined sectors of industrial, commercial and service activities.

1.1 Every organization operating within the sectors of competence IGQ has free access to IGQ certification, without any discrimination and without any undue financial or other conditions.

1.2 The certification scheme implemented by IGQ verifies and documents the compliance of quality management systems with the requirements of the reference standard UNI EN ISO 9001 - *Quality management systems – Requirements*.

1.3 Within this activity, IGQ operates in accordance with the requirements of applicable European and international standards and the applicable regulations issued by accreditation bodies (see in particular para. 15).

IGQ is responsible of all steps of the certification process, from the initial assessment to the subsequent surveillance.

IGQ may not provide consultancy services for the design and implementation of quality management systems.

All operations relating to the issue and maintenance of certifications are performed by competent and qualified personnel of IGQ with guarantee of confidentiality and no conflict of interest. Only the accreditation bodies have free access to the above mentioned information.

The issue and maintenance of certification is contingent upon payment of the charges according to the defined conditions.

IGQ may suspend the programmed audits when scheduled payments are not timely received.

2. CERTIFICATION PROCESS

2.1 APPLICATION

2.1.1 The company wishing to receive a certification shall provide an application signed by an authorized representative, supplying all the information required by the specific application documents.

2.1.2 The application shall be referred to the quality management system of a specific organizational unit of the company and to all or part of the activities performed by the unit. Such unit is hereafter referred to as the organization.

The organization includes all sites, permanent or temporary, which concur, as a single unit, to the production of the goods or services provided. The audit will take place at all such sites or at a representative sample of sites.

2.1.3 The organization shall implement a documented quality management system in compliance to the reference standard and to meet all requirements of this Regulations.

In particular the organization must ensure that:

- the responsibilities for the quality management system are clearly defined, and assigned to a person at the right level, responsible for ensuring that the rules of the system are observed and that non conformities, including those identified by IGQ, are resolved;
- all the documentation of the quality management system shall be made available to IGQ;
- management system consultants, if present during the evaluation activities or the audit, shall be limited to the role of observers.

2.2 APPLICATION ACCEPTANCE

2.2.1 IGQ, following receipt of the application:

- informs the organization of the acceptance of the application or, alternatively, explains the reasons for rejecting the application;
- describes the subsequent steps of the certification process, specifying the names of the personnel responsible;
- requests any further information necessary;
- requires the payment of the application fees.

2.2.2 The organization may object on the appointment of the persons in charge of each step of the certification process and request their substitution, explaining the reasons for such request.

2.2.3 The organization may voluntarily waive the continuation of the certification at any time by giving written notice to IGQ. The waiver implies in any case the payment of the fees for the application and for the audits which may have been already conducted.

2.3 PRE-ASSESSMENT AUDIT (PRE-AUDIT)

Upon request by the organization IGQ, before beginning the certification process, may conduct a pre-assessment audit (pre-audit). The purpose of the pre-audit is only to allow the organization to familiarize itself with IGQ assessment methods and to summarily evaluate the general state of conformity of its QMS. The audit is carried out with the same criteria of an initial audit (see below); the only difference is the extension of the audit, which may be total or partial depending on the preference of the organization being audited. The duration is determined on a case by case basis depending on the extension required.

The outcome of a pre-assessment and its findings have no influence on the assessment process and, in particular, on the extension and duration of the certification audit.

2.4 CERTIFICATION

The certification audit is carried out in two steps:

- technical meeting or stage 1 audit;
- stage 2 audit.

The audit team always includes a member competent in the sector of activity of the organization. A lead auditor is the team leader and coordinates the activities of the team.

2.4.1 In the course of the two stages:

2.4.1.1 The organization must ensure that:

- All documents and records relevant to the implementation of the QMS are made available to the audit team;
- the audit team is allowed free access to all areas involved in the activities included in the scope of certification;
- the audit team is assisted during the audit by competent personnel and by the quality manager;
- all necessary measures are put in place to ensure that the audit team may operate safely, in compliance with all applicable regulatory requirements. IGQ and accreditation bodies auditors present at the audit cannot sign declarations of discharge of liability to the organization for security issues, and should take immediate action to prevent injury, including if necessary the abandonment of the audit area and the interruption of the audit.

2.4.1.2 Before beginning the assessment, the audit team holds a meeting with the management of the organization in order to:

- introduce the audit team and explain the assessment procedure;
- establish an official channel of communication with the organization's management;
- clarify any doubts by answering specific questions;
- underline the commitment to confidentiality regarding processes, procedures, records to be examined during the audit.

2.4.2 Technical meeting – stage 1 audit

IGQ carries out the stage 1 audit at the premises of the organization, in order to:

- review the QMS documentation;

- assess the site and its specific characteristics;
- assess the awareness of the requirements of the standard within the organization;
- collect the necessary information relating to the scope of the QMS and the processes involved, including the applicable legal/regulatory requirements;
- review the allocation of resources for the stage 2 audit;
- define the stage 2 audit plan;
- verify that the internal audits and management review have been planned and conducted and that the degree of implementation of the QMS is such to allow the stage 2 audit to be carried out.

The results of the stage 1 of the audit are documented and communicated to the organization, including the identification of any problem which may be classified as a non conformity in the subsequent stage 2. For the stage 2 to take place all such problems must be solved by the organization. Verification of their effective removal will be carried out during the stage 2 audit.

If the solution of the problems identified in the stage 1 requires the organization longer than 6 months, it may be necessary to carry out an extension of the stage 1 audit. The duration of such extension shall be defined by the IGQ Certification Scheme Manager, according to the nature of the problems found, and after consulting with the RVI. If more than 12 months have elapsed, the stage 1 audit shall be repeated.

2.4.3 Stage 2 audit

2.4.3.1 The stage 2 audit always takes place at the premises of the organization. The purpose of the stage 2 audit is to assess the implementation and the effectiveness of the QMS.

2.4.3.2 The assessment includes the verification of the conformity of the procedures of the organization and of their complete and effective implementation. The following will be subject to verification:

- information and evidence about conformity to all the applicable standard's requirements;
- performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the standard);
- the QMS and performance as regards legal compliance;
- operational control of the processes;
- internal audits and management review;
- management responsibility for the organization's policies;
- links between the normative requirements, policy, performance objectives and targets, any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

2.4.3.3 At the end of its work the audit team analyses the data collected and draws its conclusions.

Then in the course of the closing meeting the audit team informs the management of the organization or its representatives of the findings, and expresses its evaluation on the conformity of the QMS to the requirements of the reference standard.

The findigs are classified as follows:

- **Non conformity** – one or more findings of this type implies a negative assessment of the conformity of the QMS; evidence of the implementation of adequate corrective actions must be provided before granting certification;
- **Minor non conformity** – this type of findings do not imply a negative assessment, however a corrective action plan must be submitted to IGQ before the certification can be granted or renewed. Evidence of the implementation of corrective action may be verified after the issue or renewal of the certification;
- **Recommendation** – this finding is an opportunity for improvement of voluntary application by the organization.

During the closing meeting the representatives of the organization may seek all necessary clarifications and, if they do not share the results of the assessment, express their objections.

The findings and any objections expressed by the organization are recorded by the audit team leader and submitted to IGQ.

2.4.3.4 At the end of the audit the audit team delivers directly to the representatives of the organization a summary of the findings with instructions for their proper management.

If any of the audit observations are modified by IGQ, the organization will receive a written notice.

2.4.3.5 In case of non conformities the organization shall analyse the causes and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate such nonconformities within the time specified in the instructions. In case it is not possible to verify the implementation of the corrections and corrective actions within 6 months of the end of stage 2 audit a new stage 2 audit will be conducted.

2.4.3.6 IGQ may then, at its discretion, conduct a new audit, partial or total, or review the documentary evidence of the implementation of the corrective actions.

Failure to implement the corrective actions results in the suspension of the certification process.

In the case of minor non conformities, the corrective actions plan shall be sent to IGQ before the issue of the certificate; the implementation of the corrective actions will be verified during the first surveillance audit.

IGQ provides a written report for each audit and for each stage of the audit. The reports are sent to the organization but remain the property of IGQ. The organization may divulge or publish them provided they are not modified and always in their entirety.

2.5 ISSUE OF THE CERTIFICATE

2.5.1 The issue of the certificate is contingent upon the favorable opinion of the IGQ Certification Commission regarding the conformity of the organization's QMS to the standards' requirements.

IGQ informs the organization that the certification has been granted and sends the certificate and the certification mark. These documents may be used under the condiions reported in the *Regulations for the use of the IGQ management systems certification mark*.

IGQ publishes and maintains on the site www.igq.it the list of all certified organizations.

3. VALIDITY OF THE CERTIFICATION

The certificate is valid three years, and precisely until the end of the thirtyfifth month from the date of the certification decision.

The period of validity of the certification may not be estended beyond these terms. In special cases, in agreement with the certified organization, IGQ may reduce the period of validity of the certification.

4. SURVEILLANCE AND RECERTIFICATION

4.1 SURVEILLANCE

4.1.1 IGQ conducts surveillance audits at least once every calendar year. The first surveillance takes place within 12 months from the date of the certification decision.

The frequency and extension of surveillance audits are decided by IGQ at its discretion, in order to ensure that the QMS is maintained in compliance with the standards' requirements.

The surveillance audit is carried out in a single stage, according to the applicable requirements of para. 2.4.

During the surveillance audit the following are verified:

- The implementation of the corrective actions and the removal of any non conformities found in the previous audit;
- Some elements of the QMS chosen by the lead auditor, but including, at least once every year, the following:
  - internal audits and management review;
  - effectiveness of the QMS with regard to achieving the organization's objectives;
  - progress of planned activities aimed at continual improvement, corrective and preventive actions;
  - continuing operational control;
- handling of complaints received by the organization;
- the use of the IGQ certification mark;

- any changes made since the last audit.

4.1.2 In the closing meeting the audit team informs the organization's management or its representatives of the findings and expresses its evaluation on the conformity of the QMS to the requirements of the reference standard.

The representatives of the organization may seek all necessary clarifications and, if they do not share the results of the assessment, express their objections.

The findings and any objections expressed by the organization are recorded by the audit team leader and submitted to IGQ.

4.1.3 At the end of the audit the audit team delivers directly to the representatives of the organization a summary of the findings with instructions for their proper management.

If any of the audit observations are modified by IGQ, the organization will receive a written notice.

In case of Non Conformities the organization shall analyze the causes and describe the specific corrections and corrective actions taken, or planned to be taken within a defined time, specified in the instructions provided, to eliminate such nonconformities, and send this corrective action plan to IGQ.

The information provided by the organization will be examined by the IGQ Certification Commission which will decide on maintenance, possibly conditioned by the successful outcome of any extraordinary or re-scheduled audits, suspension or withdrawal of certification. The Certification Commission decisions are communicated to the organization.

Non Conformities which are not removed within the defined time may imply suspension or withdrawal of the certification (see 9 and 10).

4.2 RECERTIFICATION

4.2.1 A recertification audit will be conducted before expiry of the certificate.

The recertification audit is programmed at least one month prior to the expiry date, so as to allow sufficient time for the organization to implement any necessary corrective action relating to any non conformities or minor non conformities found during the recertification audit.

4.2.2 A recertification audit implies a complete review of the QMS.

The audit is conducted according to the applicable requirements of para. 2.4 and aims to ascertain the following:

- the effectiveness of the QMS in its entirety, in the light of internal and external changes, and its continued relevance and applicability to the scope of certification;
- demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;
- whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives.

4.2.3 In the closing meeting the audit team informs the organization's management or its representatives of the findings and expresses its evaluation on the conformity of the QMS to the requirements of the reference standard.

The representatives of the organization may seek all necessary clarifications and, if they do not share the results of the assessment, express their objections.

The findings and any objections expressed by the organization are recorded by the audit team leader and submitted to IGQ.

4.2.4 At the end of the audit the audit team delivers directly to the representatives of the organization a summary of the findings with instructions for their proper management.

If any of the audit observations are modified by IGQ, the organization will receive a written notice.

In case of Non Conformities or Minor Non Conformities the organization shall analyze the causes and describe the specific corrections and corrective actions taken, or planned to be taken within a defined time, specified in the instructions provided, to eliminate such nonconformities, and send this corrective action plan to IGQ.

In case of Non Conformities the information provided by the organization will be examined by the IGQ Certification Commission which will decide on recertification, possibly conditioned by

the successful outcome of any extraordinary or re-scheduled audits, or withdrawal of certification. The Certification Commission decisions are communicated to the organization.

In case of only Minor Non Conformities the information provided by the organization will be examined by the IGQ Certification Scheme Manager who will decide on recertification. The implementation and effectiveness of the corrective actions will be verified at the next surveillance audit.

Non Conformities which are not removed within the defined time may imply the withdrawal of the certification (see 10).

4.2.5 The expired certificate can be restored within 6 months of its expiry, provided that all activities resulting from the recertification audit have been completed. In the case in which the recertification audit has not been completed within the expiry date, in order to restore the expired certificate at least one stage 2 audit must be conducted.

4.3 UNANNOUNCED OR SHORT NOTICE AUDITS

In cases when:

- IGQ receives complaints by customers of the certified organization or other stakeholders, such as for example final users of the products or services provided by the certifed organization;
- a surveillance audit finds non conformities not removed within the agreed time;
- an incorrect use of the certificate or of the certification mark has been detected;
- the organization is in a situation which severely limits the decision-making power of its management as regards the definition and implementation of the quality policy, such as in the case of insolvency proceeedings;

IGQ may conduct unannounced or short notice audits, in place of or in addition to the programmed audits. In the case of short notice audits the organization will be notified no more than three days in advance, by written notice sent by fax or other electronic means. The notice will contain all necessary information for the audit, including starting and ending dates and times, composition of the audit team and extension of the audit.

5. CHANGES AND EXTENSION OF THE CERTIFICATION

IGQ may modify the scope of the certification for clarity and completeness. IGQ will reduce the scope of the certification should processes or sites within the scope of certification be no longer active. IGQ will extend the scope to cover new activities or sites, following a request from the organization and after positive outcome of the audit activities extended to the new activities or sites.

6. CHANGES IN THE ORGANIZATION

6.1 The certified organization shall promptly inform IGQ of any changes to its QMS or any changes which may influence conformity to the requirements and in particolar of any significant changes regarding:

- the legal, commercial, organizational status or ownership;
- organization and management (e.g. key managerial, decision-making or technical staff);
- contact address and sites;
- scope of operations under the certified management system;
- major changes to the management system and processes.

6.2 IGQ will assess the extent of the changes notified by the organization and, after possible further requests for information, will decide on the necessary actions**.**

7. PUBLICATIONS

7.1 IGQ maintains and updates the list of certified organizations. The list is published on the IGQ website (www.igq.it) and on the CISQ Federation website (www.cisq.com).

7.2 The organization may:

- inform the public, with any means, of the certification;
- publish the certificate;
- use the IGQ certification mark in accordance with the requirements of the *Regulations for the use of the IGQ management systems certification mark.*

7.3 The organization whose QMS has been certified:

- must not give statements that are misleading with regards to its certification;
- must not use, or consent to the use by a third party, of a certification document, or any part of it, in a misleading way;
- must change and correct all advertising materials if the scope of certification has been reduced;
- must not allow references to the certification of its management system to be used in a way that could suggest that the certification body certifies a product, service or process;
- must not imply that the certification applies to activities which are outside the scope of certification;
- must not use its certification in such a way as to damage the reputation of the certification system or of IGQ or affect public confidence.

8. IMPROPER USE OF THE CERTIFICATE OR OF THE CERTIFICATION MARK

8.1 The improper use of the certificate or of the certification mark may imply:

- a request for corrective actions;
- the publication of the infringement in the press;
- the suspension or withdrawal of the certification (see para. 9 and 10);
- a legal action.

9. SUSPENSION OF THE CERTIFICATION

9.1 The certification may be suspended by IGQ whenever:

- it is not possible to conduct the audits;
- non conformities have been found during an audit and the organization has failed to remove them within the agreed time;
- the organization commits an infringement of the rules of the certification system or regulations of IGQ that does not entail the withdrawal of the certification;
- the organization is in a situation which severely limits the decision-making power of its management as regards the definition and implementation of the quality policy, such as in the case of insolvency proceeedings; in these cases IGQ may maintain the certification provided it can verify that the QMS is maintained in conformity to the requirements of the reference standard.

9.2 The organization may ask, by written request, a suspension of the certification.

9.3 The suspension of the certification is officially notified to the organization by registered letter which includes the conditions under which the certification may be restored.

The suspension of the certification lasts no longer than 6 months. This period may be extended for justified reasons up to a maximum of 6 more months. The suspension in any case can not be longer than 12 months.

The certification can only be restored following the positive outcome of a complete recertification audit and subject to compliance with any other specific conditions defined by IGQ depending on the circumstances that led to the suspension. Otherwise the certification will be withdrawn.

9.4 The suspension and its duration are published, during the suspension period, in the list of certified organizations.

10. WITHDRAWAL OF THE CERTIFICATION

10.1 IGQ may withdraw the certification in the following cases:

- in the case of a suspension, if the conditions for the restoration of the certification are not met within the agreed time (see para. 9.3);
- if non conformities have been found during an audit and the organization has failed to remove them within the agreed time;
- if an audit detects evidence that the QMS does not ensure systematic compliance to requirements, mandatory by law or regulations, relating to the characteristics of the product or service provided, subject to the exclusive responsibility of the organization for the possible failure to comply;

- if the organization commits an infringement of the rules of the certification system or regulations of IGQ.
- if the certification requirements are changed (see para. 12) and the organization will not or cannot ensure conformity to the new requirements;
- if the organization refuses or impedes the audits;
- if the organization fails to meet its financial obligations to IGQ;

10.2 The withdrawal implies the withdrawal of the certificate and of the authorization for the use of the certification mark, from the moment of the notification of withdrawal, by registered letter, to the legal representative of the entity to which the organization belongs.

IGQ then eliminates the organization from the list of certified organizations.

IGQ also reserves the right to publicize the withdrawal if a lack of publicity could damage the image of IGQ.

10.3 The organization which intends to obtain again a certification after withdrawal shall submit a new application and follow the entire certification process≡.

11. RENUNCIATION OF THE CERTIFICATION

11.1 The certified organization may renounce the certification at any time, with at least 90 days' advance notice sent to IGQ by registered letter.

11.2 The certified organization may renounce the certification with at least 30 days advance notice sent to IGQ by registered letter, in the following specific cases:

- non acceptance of changes to the agreed economic conditions;
- cessation of the activity subject to certification.

12. CHANGES TO THE CERTIFICATION REQUIREMENTS

12.1 Changes to the certification scheme may be necessary when:

- the standardization bodies change the QMS reference standard;
- the standardization bodies modify the standard rules governing the conduct of certification bodies;
- accreditation rules are changed (see para. 15).

12.2 In the case of changes to the certification requirements, IGQ:

- provides all necessary information to the certified organization;
- verifies that the certified organization implements the necessary changes within a specified time, defined by IGQ.

12.3 Failure by the organization to implement the necessary changes within the specified time may imply the suspension or the withdrawal of the certification in accordance to para. 9 and 10.

13. APPEALS AND COMPLAINTS

13.1 Appeals against the decisions of IGQ relating to the issue, suspension or withdrawal of the certification shall be addressed to the Director of IGQ, who is required to take them into consideration in accordance with IGQ procedures.

13.2 Complaints relating to the activities of the Auditors or of the Technical Staff shall be addressed to the Director of IGQ, who will handle such complaints in accordance to the procedures of IGQ.

13.3 Complaints received by customers of certified organizations may imply extraordinary audits.

14. CIVIL LIABILITY

IGQ does not assume any liability for damages due to defective products.

The legal entity owner of the organization remains solely responsible for the conformity of its activities with the expectations of its customers.

The legal entity owner of the organization remains solely responsible for the conformity of its activities with applicable legislation. The certification of the QMS constitutes neither a declaration nor a guarantee by IGQ that the organisation respects legal obligations and requirements.

15. OBLIGATIONS ARISING FROM ACCREDITATION

ACCREDIA is the Italian accreditation body for certification bodies.

ANAB è l'organismo statunitense di accreditamento per gli organismi di certificazione.

IGQ is accredited by ACCREDIA and ANAB for several sectors of economic activities and but may issue certifications in other sectors. The accreditation logo of ACCREDIA and/or ANAB appears on the certificate only in the case of certifications accredited by ACCREDIA and/or ANAB. For certifications issued without accreditation no accreditation logo appears on the certificate.

Additional specific rules imposed by the accreditation bodies apply to accredited certifications:

- Accreditation bodies reserve the right to conduct audits at organizations with observers accompanying the IGQ inspectors. In addition, in order to ascertain that the method of assessment adopted by IGQ comply with the applicable standards, Accredia may require visits to the certified organization, carried out by its staff. The participation in the audit by observers or the visit conducted directly by accreditation body personnel, is previously agreed upon between IGQ and the certified organization:
  - the organizations may not refuse such witness audits or visits by penalty of withdrawal of the certification;
  - The accreditation bodies ensure to the organizations the same level of confidentiality guaranteed by IGQ with respect to any information acquired during the audit;
  - Accreditation bodies auditors are mere observers during the witness audit and do not influence its results.
  - At the end of the witness audit, after the final meeting between the audit team and the representatives of the organization, a short meeting will take place between the accreditation body auditors and the IGQ auditors.
  - For ANAB accredited certifications the number of ANAB auditors who will take part in a witness audit equals the number of IGQ auditors. Each ANAB auditor will be accompanied by a translator.
  - The assessment methods used by Accredia, are included in special regulations, notices or circulars available on Accredia website.
- IGQ shall notify the accreditation bodies of all the accredited certifications issued, and notify ACCREDIA of all suspensions, withdrawals and renunciations of the certifications, specifying the reasons, even if the renunciation occurs before the issue of the certification.

  The above information are used by ACCREDIA to monitor the proper functioning of the certification system and, in particular, for the purpose of identifying situations of undue issue of certifications, and to notify the competent authorities.
- For ACCREDIA accredited certifications of construction companies additional rules are applied, as described in the document ACCREDIA RT-05, publicly available on the website www.accredia.it. Such rules are contractually binding in the case of accredited certifications in the construction sector.

16. ARBITRATION

Any dispute arising between IGQ and the organization in connection with the interpretation and application of these Regulations, with the exception of disputes deriving from the payment of fees and expenses due to IGQ, which will be settled by a Court of Justice, will be submitted to a board of three arbiters, appointed by the President of the Court of Milano.

The board of arbiters will make its decisions informally though admitting the principle of cross-examination.

The board will meet in Milano and the arbitration will be informal and legally binding.

17. REGULATION (EU) 2016/679 GDPR

IGQ, in its capacity as independent Data Controller of the personal data of individuals belonging to the client company, guarantees compliance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 concerning the protection of natural persons with regard to to the processing of personal data, as well as to the free circulation of such data (GDPR.)

IGQ's privacy policy and the information to be provided to interested parties are on the IGQ website at www.igq.it/privacy.

The organization undertakes to provide, in the name and on behalf of IGQ, the aforementioned privacy information to all its employees and collaborators.