QS QUALITY SERVICES LTD
GENERAL RULES

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Revision Register:

Date	Edit.	Rev.	Edit for	Issued	Approved
06/10/2014	1	0	First issue Rules	RSG	ADM
24/02/2015	1	1	Revision Rules	RSG	ADM
18/06/2015	1	2	Revision Rules	RSG	ADM
01/09/2016	1	3	Transition to ISO/IEC 17021-1:2015 and operative office	RSG	ADM
14/11/2016	1	4	Integration standards	RSG	ADM
29/05/2017	1	5	Cancellation of old edition ISO 17021	RSG	ADM
03/08/2018	2	1	IAF integrations and address	RSG	ADM
04/01/2021	2	2	IAF integrations	RSG	ADM
09/01/2023	2	3	Updating ISO 27001:2022	RSG	AMM
01/10/2023	2	4	Transition of ISO 50003:2021	RSG	AMM
03/06/2024	2	5	Integration Requirements IAF MD - ISO	RSG	AMM

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PRESENTATION OF QS QUALITY SERVICES

The business name is: **QS QUALITY SERVICES LTD**

Legal office: 3, Triq G. Flores, Advance Business Centre SANTA VENERA, SVR 1950 MALTA

Operative office: Shop 1 - 493 St. Paul Street SPB - San Paul Bay, SPB 3416 MALTA

QS QUALITY SERVICES is a companyfounded ontheexperiencegainedby Partners in thefieldofcertificationofmanagementsystems and productsforinternationallyrecognisedbodies

QS Quality Services Ltd isaccreditedaccordingto international standardISO 17021-1:2015requirementsforbodiesprovidingaudit and certificationofmanagementsystemsby ESYD.

QS is also accreditated ISO 17020 management system as Inspection Body type A for periodic inspections of equipments according TPED European Directive (see specific documentation and Rules uploaded also on website of QS) by NAB.

As partoftheCertification Body activity, QS Quality Services LTD providesrequestingcustomers, certificationservicesforcompliance Management Systems withrespecttovoluntarystandards in compliancewiththeprinciplesofimpartiality and independence.

In carrying out itsactivities, QS Quality Services LTD operates in accordancewiththerequirementsof ISO/IEC 17021 and itsprinciples:

-Impartiality

-Competence

-Responsibility

-Transparency

-Confidentiality

- Indipendence

-Rapidity and effectiveness in respondingtocomplaints

-Risk Mitigation Approach

1. REGULATION AND ANY CHANGES

This Regulation shall be distributed in a checked form exclusively to Accreditation Bodies. With the issuing of the offer we inform the customer of the existence of these rules as binding clause of the contract and we inform the client how to access to them. The latest version of the regulation is uploaded and published on the internet website, and its access is public. On customer's request these Rules may also be forwarded via email, mail or fax. **The Regulation forms an integral part of the contract, signing the contract implies acceptance of the present QS rules.**

Any change due to internal reorganisation of QS or any regulatory changes relating to standards and reference standards, will be communicated to already certified organisations that will be able to forward comments and observations to the proposed amendments within 30 days.At the end of 30 days, in case of not receiving any communication, the new revision of the document comes into force. The entry into force will be communicated both to certified organisations and to company on certification process that will declare their acceptance through the principle of tacit approval. The non-acceptance will entail the withdrawal of certification by QS according to the methods provided for in the contractual terms and conditions for the certification of organizations and technical systems attached to the offer and signed by the customer.

2. SCOPE AND FIELD OF APPLICATION OF THE RULES

This Regulation aims to contractually regulate the conformity assessment service agreed by the customer with QS at the moment of the signature of the Offer.

This Regulation shall apply to conformity assessment activities provided by QS as required by the customer organisation. Specifically, the general management procedures for assessing the conformity of company systems are given in this Regulation. Are present and available on the QS website, to complement this Rules, special Regulations detailing the conformity assessment modalities of the specific management systems for standard (ISO 9001, ISO 14001, /ISO 45001, ISO 22000, ISO 50001, ISO/IEC 27001, ISO 13485)

3. DOCUMENTS AND REFERENCE STANDARDS, TERMS, DEFINITIONS, ABBREVIATIONS

The standards and reference documents for the drafting of this regulation are the following:

- ISO/IEC 17021-1:2015 Conformity assessment - Requirements for bodies providing audit and certification of management systems
- ISO/IEC 17021-2:2012 Conformity assessment -- Requirements for bodies providing audit and certification of - Competence requirements for auditing and certification of environmental management systems
- ISO/IEC TS 17021-3:2013 Conformity assessment -- Requirements for bodies providing audit and certification of management systems - Part 3: Competence requirements for auditing and certification of quality management systems
- ISO/IEC TS 17021-6:2014 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 6: Competence requirements for auditing and certification of business continuity management systems
- ISO/IEC TS 17021-10 Conformity assessment -- Requirements for bodies providing audit and certification of management systems - Part 3: Competence requirements for auditing and certification of occupational health and safety management systems
- IAF MD 1:2018 Audit and Certification of Multi Site Organization
- IAF MD 2:2017 Transfer of Accredited Certification of Management Systems
- IAF MD 3:2008 Advanced Surveillance and ReCertification Procedures (ASRP)
- IAF MD 4:2008 Use of Computer Assisted Auditing Techniques (“CAAT”) for Accredited Certification of Mangement Systems
- IAF MD 5:2019 IAF Mandatory Document for Duration of QMS and EMS Audits
- IAF MD 7:2010 Mandatory Document for Harmonization of Sanctions to be applied to Conformity Assessment Bodies
- IAF MD 8:2015 Application of ISO/IEC 17011:2004 in the field of Medical device Quality Management System (ISO13485)
- IAF MD 9:2015 IAF Mandatory Document for the Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485)
- IAF MD 11:2013 Mandatory document for assessment of certification body for audit of integrated Management System
- IAF MD 16:2015 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies
- IAF MD 17:2014 Witnessing Activities for the Accreditation of Management Systems Certification Bodies
- IAF MD 21:2018 Requirements for the migration to ISO 45001:2018 from OHSAS 18001:2007
- IAF MD 22:2019 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)
- IAF MD 23:2018 Control of Entities operating on behalf of Accreditated Management Systems Certification BOdies
- IAF MD 26:2022 Transition Requirements for ISO/IEC 27001:2022
- IAF MD 1:2023 Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization.
- IAF MD 2:2023 The use of ICT is not mandatory and may be used for other types of conformity assessment activities, but if used as part of the audit/assessment methodology, it is mandatory to conform to this document.

- IAF MD 4:2023 The use of ICT is not mandatory and may be used for other types of conformity assessment activities, but if used as part of the audit/assessment methodology, it is mandatory to conform to this document.
- IAF MD 5:2023 Determination of Audit Time of Quality, Envioremental, and Occupational Health & Safety Managem ent Systems.
- IAF MD 6:2023 Applycation of ISO 14065:2013. Provides to Greenhouse Gas (GHG) programme administrators, regulators and accreditors, a basis for assessing and recognising the competence of validation or verification bodies.
- IAF MD 7:2023 Mandatory Document for the Harmonization of Sanctions and Dealing with Fraudulent Behavior.
- IAF MD 8:2023 Application of ISO/17011:2017 in the field of medical device quality management systems (iso13485).
- IAF MD 9:2023 Application of ISO/IEC17021-1 in the field of medical device quality management systems (iso 13485).
- IAF MD 11:2023 Mandatory document for the application of ISO/IEC 17021-1 for audits of integrated management systems.
- IAF MD:12:2023 Accreditation Assessment of Conformity Assessment Bodies with Activities in multiple countries.
- IAF MD 13:2023 Knowledge requirements for accreditation body personnel for information security management systems (ISO/IEC 27001).
- IAF MD 14:2023 Application of ISO/IEC 17011 in Greenhouse gas validation and verification (ISO 14065:2013).
- IAF MD 15:2023 Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance.
- IAF MD 16:2023 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies.
- IAF MD 17:2023 Witnessing Activities for the Accreditation of Management Systems Certification Bodies.
- IAF MD 20:2023 Generic Competence for AB Assessors: Application to ISO/IEC 17011.
- IAF MD 22:2023 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS).
- IAF MD 23:2023 Criteria for Evaluation of Conformity Assessment Schemes. This document contains minimum requirements for conformity assessment schemes (CAS) to be applied by IAF member accreditation bodies.
- IAF GD3:2003 Guidance on Cross Frontier Accreditation
- EA:2/13 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members
- EA:2/17 EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes
- EA:3/11 Food Safety Management Systems – Scope of Accreditation
- IAF ID 1:2014 QMS and EMS Scopes of Accreditation
- EA - 7/05:2008 EA Guidance on the Application of ISO/IEC 17021:2006 for combined audits
- ESYD RA/03/00/26-02-2015 ACCREDITATION REGULATIONS
- ACCREDITATION CRITERIA ESYD CAC/03/03/
- ESYD SUBSECTIONS/01/06/15-09-2010
- ESYD GA-H&S/01/04/02-10-2020 Guidance for the accreditation of occupational health and safety management system certification bodies
- ESYD G-22000/01/01 Guidance for the accreditation of food safety management systems certification bodies
- ISO 9001:2015 Quality management systems - requirements
- ISO 14001:2015 Environmental management systems - requirements
- ISO 45001:2018 Occupational health and safety management systems — Requirements with guidance for use.
- ISO 9001:2015/Amd 1:2024, requires organisations to actively assess and address the implications of climate change in their operations and strategic planning.
- ISO 14001:2015/Amd 1:2024, Environmental management systems — Requirements with guidance for use Amendment 1: Climate action changes
- ISO 45001:2018/Amd 1:2024, Occupational health and safety management systems — Requirements with guidance for use Amendment 1: Climate action changes

- ISO 22000:2005/2018 Food safety MS - Requirements for any organization in the food chain
- ISO 22000:2018/Amd 1:2024, Food safety management systems — Requirements for any organization in the food chain Amendment 1: Climate action changes
- ISO 50001:2011/2018/2021 Energy management systems - Requirements and guidelines for use
- ISO 50001:2018/Amd 1:2024, Energy management systems — Requirements with guidance for use Amendment 1: Climate action changes
- ISO 50003:2021- Energy Management System - Requirements for bodies providing audit and certification of energy management system.
- ISO 13485:2016 Medical devices – QM systems - Requirements for regulatory purposes.
- CEI EN 13485:2021
- ISO 50001:2018/Amd 1:2024,
- ~~ISO/IEC 27001:2013 Information technology -- Security techniques -- Information security management systems~~
- ISO/IEC 27001:2022 Information security, cybersecurity and privacy protection -- information security management systems -- Requirements
- ISO/IEC 27001:2022/Amd 1:2024, Information security, cybersecurity and privacy protection — Information security management systems — Requirements Amendment 1: Climate action changes
- ISO/TS 22003:2013 Food safety management systems - Requirements for bodies providing audit and certification of food safety management systems
- ISO/IEC 27006:2015/amd 2020 Information technology -- Security techniques - Requirements for bodies providing audit and certification of information security management systems
- ISO/IEC 20000-1:2018 Information technology — Service management — Part 1: Service management system requirements
- ISO/IEC 20000-1:2018/Amd 1:2024, Information technology — Service management — Part 1: Service management system requirementsAmendment 1: Climate action changes
- ISO/IEC 20000-6:2017 Information technology — Service management — Part 6: Requirements for bodies providing audit and certification of service management systems
- ISO 22301:2019 Security and resilience — Business continuity management systems — Requirements
- ISO 22301:2019/Amd 1:2024, Security and resilience — Business continuity management systems — RequirementsAmendment 1: Climate action changes
- ~~ISO 50003:2014 Requirements per bodies providing audit and certification of energy of management system~~
- ISO 19011:2018 Guidelines for auditing management systems
- ESG SRG 88088:2020 Social responsibility and governance

In the list above mentioned are listed only the references of the standards, laws and regulations directly aimed to define the general requirements of the management system and the general requirements of the certification process. For the list of references with all applicable standars, rules and regulations applicable to the CaB, implemented for the definition of management procedures and operating system, you shall refer to the specific Rules for each standard.

In this Regulation applies the terms and definitions given by following standards:

- EN ISO/IEC 17000

ABBREVIATIONS

QS: QS QUALITY SERVICES LTD

SG/MS: Management System

RSG/QM: Responsible Management System

RAUDT TEAM/LA: Responsible (Head) of Audit Team (Lead auditor)

AUDT TEAM: Audit Team

RVI: Report of Audit

STAGE 1: Certification auditStage 1

STAGE 2: Certification audit Stage 2

VIP: Preliminary audit (Stage 1 certification audit)

VIC: Certification audit (stage 2)

VIS: Surveillance Audit

VIR: Re-certification Audit

NC: Non Conformity

OSS: Observations

COMM: Comments

AC: Corrective Action

AP: Preventive Action

CaB: Conformity Assessment Bodies

CC: Certification Committee /Steering Committee

CS: Committee for the safeguard of Impartiality

AMM: Administrator

DT: Technical Director

RT: Technical Manager

MSGA: Company Management System Manual

4. RESPONSIBILITIES

Responsibilities and roles of parties involved in the certification process (QS and customers organizations) are defined in this regulation and in the contractual terms and conditions document for the certification of organizations and technical systems agreed by the parties at the time upon signing the contract (included the terms and conditions).

We clarify that it is the responsibility to the **customer-organization:**

- the compliance with requirements of the certification;
- the fulfillment of legislative requirements relating to the design, construction, operation of the activities covered by the evaluation;
- the fulfilment of the obligations arising from the implementation of professional activities and of any contractual obligations agreed upon with their own customers**.**

Companies that have obtained the certification shall comply in any case with legal requirements arising from the products, processes and services provided and the contractual obligations with customers.

Certified companies have however total responsibility for the damage caused to third parties caused by their activities. No responsibility can be attributed to QS.

QS is responsible for assessing the objective evidences necessary and sufficient to issue an opinion positive or negative with respect to the issuance of the certification. QS will not have any obligation with regard to the outcome of the assessment of conformity. QS is not liable for what has not been verified or not made available by the customer-organization.

The auditors employed by QS belong to Inspection Body (section)qualified by the Evaluation Committee according to the requirements defined in the standards ISO/IEC 17021 e EN ISO 19011. The auditors' responsibilities and duties are defined in the agreement signed with QS and its annexes.

As regards the responsibilities of the internal staff of QS, depending on the office duties, they are defined and subscribed by employees in the Job description.

5. COMMITMENTS AND DUTIES OFQS

QS is committed to perform with diligence, impartiality and confidentiality the service described in this regulation. Management conditions of service are defined in the terms and conditions can be consulted on the site.

QS DOES NOT PROVIDE CONSULTANCY ACTIVITIES, excluding the normal activity of information and/or assistance to certified organizations or during their certification process.

In order to ensure the complete impartiality and be free from prejudices and conflicts of interest of the personnel involved in its activities, QS issues a risk analysis document reporting the results and reasons for the deduced conclusions and the solutions adopted.

QS has a responsibility to ensure that the inspections should not be assigned to third parties or companies that have carried out advisory activities -or activities that have conflicts of interest-at the organizations supposed to be audited. To this end, at the time of signing the contract with the customer, QS requires, between the information necessary for the certification of company management systems, the name of any consultant used to prepare the System to be certified.

6. CONFIDENTIALITY

QS undertakes to maintain the confidentiality of the data acquired in accordance with the law in force and to manage the security of the data acquired.

QS is committed to maintaining the confidentiality of internal and external personnel.

The auditors, at the time of signature of the cooperation agreement with QS, sign a declaration as obligation and a commitment to treat in a strictly confidential way all information relating to the CaB, to partners companies and to customers. In this agreement there is a point pertaining to confidentiality and data protection.

QS, moreover, asks to auditor to sign an informative document on the processing of personal data, and in which is require to subscribe:

- in which it is required to sign a confidentiality commitment to managing customers data and also information pertaining QS
- a commitment to immediately communicate to QS any incompatibilities or inability to guarantee impartiality or competence in the performance of the tasks assigned to him each time during the period of collaboration.

Regarding the customer-organization, at the time of signing the contract, QS asks also to sign the Informative Form concerning the processing of personal data in order to inform the customer about the confidential management by QS of its data.

As regards the employees/collaborators of QS, they sign a declaration of confidentiality and impartiality.

Regards Partners, QS asks to the partners' employees and to their collaborators that interact to sign a confidentiality and impartiality clause and comply with the QS regulations and principles.

The signing of the contract of certification includes an option for QS to register the business names of organisations that have obtained certification of conformity in the list of certified organizations published on its website. QS is obliged to communicate the names of certified organisations to the competent Authorities.

QS undertakes to inform the customer of any renounce, suspension or withdrawal of accreditation, as well as to support the customer during the transition to another CaB. QS is not responsible in any way for any damage caused by the withdrawal or suspension of the accreditation.

Additional obligations for QS are defined in the terms and conditions for the certification of organizations and technical systems attached to the offer and integral part of the contract with the customer.

7. RIGHTSAND OBLIGATIONSOF CUSTOMER

The customer has the right to:

- use the obtained certification of management system (SG) for advertising purposes in the manner that he considers appropriate, but always limited to the object and to the limits of certification obtained and in accordance with this rules.
- submit a complaint or request an official meeting with the official direction if found a discrepancy in the application of this regulation from QS, both in the certification process through the auditing staff or by technical-administrative staff, as well as in the application of general principles of fairness, impartiality and transparency declared by QS

The customer has the obligations to:

- make sure of the compliance and operative implementation of its own management system in reference with the standard, at the moment of application for certification. Itwill be QS task toverifyitssuitability;
- declare its own commitment to maintain the ensured compliance for the duration of the contract;
- fulfill the terms and conditions of the contract signed with QS whereof this regulation is an integral part;
- keep QS updated in case of organizational relevant changes occurred after the date of the certification or of the last surveillance audit and he shall accept and incurs the expenses of any additional audit or supplementary assessments that are required;
- ensure to personnel and collaborators of QS the access to information and documents relevant for the definition of the object of the contract, for the purpose of planning and proper conduct of verification activities in the times, methods and contents indicated in official communications. Comply with the audit time agreed and determinatedaccording the reference standards
- The client shall also make available during audit anyrequired document necessary to the audit team (AUDT TEAM) for the purpose of issuing of certification without omitting any information. It is client's responsibility to ensure completeness, accuracy and compliance with the reality of the information provided;
- make possible the access to the audit team to the sites/contructions sites, to the operative productive activities/supply of the service, to eventual outsourcing activities or to the suppliers in order to verify the effective and complete way all the processes of Reference System.
- keep copies of management system documentation available to audit team and a record of all complaints and corrective actions made to management system;
- ensure to personnel and collaborators of QS safe access in the places where activities are carried out or documents are evaluated;
- accept the results of conformity assessment activities and the consequent QS decision
- make a commitment to resolve the found NCs during the audit of evaluation according to the time and manner agreed upon;
- allow the performance of additional integrative assessment audits than contractually expected whenever it is necessary to verify the resolution of major or numerous NC, or after communications or complaints received by QS about the contract and which could call into question the conformity of basic requirements. Theseadditionalinspectionwill be charged to the customer;
- declare to be certified only with respect to the activities for which the certificate was issued;

- do not use the certificate of conformity, the mark or other forms of communication or declarations in misleading way or which may cause damage or discredit and consequent loss of trust of QS (see point 8 of this rules);
- do not imply that the certification also covers activities outside the scope for which the certification was granted;
- in case of suspension, revocation or withdrawal of certification, the organization must immediately stop the use of promotional material including references to certification and return the original certificate and logo/mark. In the event of a reduction of the scope of the certification client organization must immediately provide for the adjustment of promotional material;
- immediately communicate any contrasting situations detected by supervisory Authorities, legal proceedings, definitive penal convictions, any kind of penal prosecution going on, suspensions or revocations of authorizations, concessions, etc. related to the subject of the contract and notify to QS developments of these legal actions/procedures. The customer must accept and comply with any subsequent decisions by QS to request more information or any supplementary assessments;
- if required, allow unannounced audits at already certified customer-organization: for example in the case of claims, changes or action resulting against customers whose certification has been suspended. In that case, QS communicates in advance to certified customers-organization the basic conditions to perform unannounced visits and appoints the AUDT TEAM (audit team) with particular attention due to the inability of the customer to refuse the members of the audit team;
- communicate to QS any changes that might start doubts or affect the client's ability to maintain compliance with the reference standards of obtained certification (e.g., change in ownership, company name, site location involved to the certification, etc.) (see Point 9 of this Rules);
- define procedures and responsibilities for the processing of complaints relating to products/services that are included in the requested certification scope. Records of complaints and its corrective action CA adopted shall be stored and accessible to auditors during the audit.
- In case of evaluation of QMSfor Medical Devices, allow that QS, in case of necessity, releasingtheauditinformation tocompententAuthorithiesthatrecognize ISO 13485 in caseofnecessity

Furthermore, the organization-customer has the obligation to accept, during the evaluation audit and without additional cost charged, the presence of:

- evaluators as observers or inspectors of the accreditation body whose presence is intended to ensure that the evaluation work carried out by QS complies with the requirements of accreditation. The presence of these figures and their role may be made without notification or customer will be notified in advance by QS at relatively short notice;
- auditors under training.

The refusal by the customer-organization is the same as suspending the certification process.

Further Clients obligations are defined in the document relating to contractual terms and conditions attached to the offer and an integral part of the contract with the customer.

8. USE OF THE BRAND NAME, THE LOGO AND OF THE CERTIFICATION OF CONFORMITY

An organisation which has successfully completed the certification procedure is authorised

to use the QS certification logo e the Certificatecertifying the conformity.

Both the brand and logo are property of QS and should be used only until after the transmission of the Certificate by QS and during the period of validity of the contract entered into by the parties, in the manner and according to the rules defined in this regulation.

Different or misleading application is forbidden. In these cases, QS can demand immediate corrective action by the client to restore the breach of contract.The logo cannot be modified without prior written authorization from QS.

In case of misuse of the logo and of certificate, QS will start the certification withdrawal process. From the date of the certificate and logo withdrawal, they cannot be used. The certificates must be returned and the documents having the logo must be withdrawn within 4 weeks.

The certification may be used only for management systems covered by scope of certificate issued. Operational units within the certificated SG must be defined and complete addresses indicated. Where possible, must also appear the certificate number.

In the event of a reduction of the scope of the certification the client must proceed to the adjustement of all documents and advertising materials.

The correct use is checked and verified by the auditors of QS at the time of inspection visits.

The right to use the trademark and logo terminates immediately upon termination of this agreement for any reason. If the organizations do not fulfill the contractual conditions any more, the logo has to be removed in short term and he may not apply it anymore. Therefore the customer is no longer entitled to refer to QS certificate on business documents or other application.

In the *contractual terms and conditions* attached to the offer and in the Rules for the use of the certification mark referenced are also defined further provisions for the use of the QS logo and accreditation body.

9. ORGANIZATIONAL CHANGES OF THE CUSTOMER-ORGANIZATION

Since the conclusion of the contract, the customer is obliged to communicate any relevant changes to QS compared to information provided initially, defining the nature and scope.

Changes in the corporate structure, mergers, acquisitions or divestitures of branches of the company, temporary receivership with continuation of the activity, shall be immediately communicated to QS and documented by copies of official documents. QS will assess the situation and may request any special audit agreeing amount and date with the customer.

Organizational changes which may substantially affect the organization management system (SG) must be communicated to QS that assesses the situation and may request an extraordinary audit always agreeing amount and date with the customer. Any revisions or changes to the documentation of SG that do not involve changes in the object of certification or which are small and just imply a Manual update (or equivalent document). At the time of the audit will be the (AUDT TEAM)audit leader's task to collect the new revision of the documentation to be forwarded to the Secretariat of QS for the archived documentation updating.

10. CERTIFICATION PROCESS

May apply for certification all organizations that have an implemented and operative SG, since at least three months, that meets the requirements of standard request.

10.1 APPLICATION FOR CERTIFICATION

The certification process begins by filling and sending by the applicant organisation of the documents relating to the request for quotation signed by its legal representative.

It is responsibility of the applicant organisation:

- the compilation of documents in its entirety being an indispensable condition for the correct formulation of the QS quotation;

- the truthfulness of the information communicated by filling and sending of the documents in question;
- to examine the QS regulations.

Any additions or clarifications may be required prior to issuance of the offer.

The customer must provide the following information to QS:

- company name;
- complete addesses of sites;
- certified e-mail/e-mails
- the scopeof certification required;
- number of employees full time – part time – seasoonal staff – collaborators involved in the system;
- numero di sites;
- management system implementation date and any admitted exclusions and reasons;
- consultant's name (if he exists);
- copies of any certificates in their possession
- other sector-specific requirements/scopeindicated in the particular application form (es. number of shifts, particular work conditions, IT System informationcaratheristics) see specific Rules for each standard.

Following submission of the application form for certification can be required additional information beyond those provided earlier by the Organization on the content of the same

10.2 ANALYSIS OF THE CERTIFICATION REQUEST (APPLICATION) AND ISSUANCE OF THE OFFER

On the basis of the communicated information, by adding any integrations or clarifications that may be requested by telephone to the customer, QS performs an analysis of the request and evaluates its ability to complete the task. Following the positive outcome, QS investigates the information received and send analysis results to the Administrator for permission to issue the offer.

The cost of certification activity is proportional to the number of man/days of the audit. The audit must be carried out on site, in any other sites covered by the certification, and where are any external job activities.Audit times are calculated in accordance with the IAF MD 5 document, IAF MD 9,IAF MD 22, ISO 22003, ISO 50003, ISO/IEC 27006 (according the applicable scheme) considering the total workforce of employees (effective number of personnel) of the company and the activity carried out by the same, the associated risks and complexity of the activity, any outsourcing processes.Shall be computed as additional time any transfer-times over an hour.

The effective number of personnelisusedas a basis for the calculation of audit time of management systems then it is adjusted for the significant factors applying to the client to be audited (risk category, sites, external activities,etc) , and attributing to each factor an additiveor subtractive weighting to modify the base figure.In every situation,the basis for the establishment of audit time of management systemsincluding adjustments is recorded by QS.

The effective number of personnel consists of all personnel (permanent, temporary, and part-time) involved within the scope of certification including those working on eachshift. When included within the scope of certification, it shall also include non permanent(e.g. contractors) personnel.

For OH&SMS it shall also include personnel from contractors and subcontractors performing work or work-related activities that are under the control or influence of the organization, that can have impact on the organization’s OH&SMS performance.

According each standard there is a reasoning how to calculate the effective number of personnel.

The summary of the process of calculating man-days will be reported in the offer in order to provide customers transparency and justification of that result.

The audit time for all typesofauditsincludesthe total time on-site at a client'slocation (physicalor virtual) and time spent off-site carrying out planning, document review, interactingwithclientpersonnel and reportwriting.

Together with the offer is forwarded to the customer the document relating to contractualterms and conditions for certification that are an integral part of the agreement with this regulation.

NB: The offer is formulated according to data provided by the customer. If, during the execution of the certification process, occur variations on the evaluated initial situation considered such to affect the first economic assessment, QS reserves the right to proceed to the revision of the offer.

10.3 ACCEPTANCE OF THE OFFER OF QS

The customer must send to QS the signed offer for acceptance as order. In case of discrepancies compared to the initial offer, QS will directly contact the customer for any necessary clarification. After a checking and clarified any discrepancies, QS countersigns for control and approval of changes. The acceptance of the offer represents the formalization of the contract for certification and consequent will by both parties to comply with this Rules and with the document relating contractual terms and conditions for certification.

The contract has a three-year validity. In case of will of cancellation by one of the parties, a notice must be sent at least one month before the date of expiry of the certificate, otherwise QS will issue new economic offerings in due time to ensure the continuity of the certification, valid for the next triennium.

In the new offer will be considered the renewal quotation mentioned in the previous contract in terms of proposal. If a change will be necessary, this will be communicated to the customer together with the reasons for it and it will still be subject to his written approval.

Any variation in relation to the agreed contract must be promptly communicated by the customer to QS (e.g. variation nr. employees, etc.). If the change involves a change in the planning of the Audit, any consequent change of the economic assessment will be discussed between the parties.

10.4 AUDIT PLANNING

At the time of accepting the offer contract, QS will proceed to plan of certification activites. It is agreed in advance with the Organization the possible date to perform the audit, during which there shall be present necessary company representatives/responsibles for the carrying out of the audit;

The audit activities shall be planned in such a way that the scope of certification of the company is assessed in the best possible and effective way, assensing the company during the effective activites object of the certification scope. For this purpose, it is sometimes considered the most appropriate seasons, months, dates and shifts in order to be able to perform the audit in effectively and effective way.

It is stated that in the initial evaluation (certification and recertification audit) It is not possible to issue certifications in the absence of verifications of activities.

It should be noted that in the case of organizations in whose scope the processes of delivery of services are included (e.g. provision of training courses, cleaning services, catering services, works management, etc...), QS will check with observation Always direct during the initial certification check and at least once during each subsequent certification cycle.

QS prepares and sends to the customer the audit planning letter where are communicated:

- number of audit days;
- date of STAGE 1 performanceboth according to customer demands, and on the basis of the agenda of the selected AUDT TEAM (audit team) and AUDT TEAM (lead auditor);
- the audit plan, where all activities that will be performed and the tasks of each auditor in relation to the objectives of the audit are planned;
- name of lead auditor;
- list of names of theaudit team;

- the request to transmit the documentation of the management system (SG) of the organisation-client (Manual – or equivalent document/documented information - procedures list, enviromenatl analysis, Statement of Applicability , etc..) and the documentVisura CCIAA (Chamber of Commerce company Registration) for documental analysis.

Where applicable, it is also sent an annex for the list of construction sites/activities with details of the activities available for visits provided by the customer during the offer application phase, this annex has to be up-to-date with any changes or communicated additions.

The customer, after analyzed the audit planning documentation, within 3 days, may:

- refuse, upon justified reasons, the name of RAUDT TEAM or of one or more components of audit team. QS, in case agrees the motivation given, shall designate another auditor and communicate the names to the customer by sending a new audit plan that the customer has to send back countersigned for acceptance.
- request the cancellation or to postpone the audit with one week notice. If is less than 7 days notice, it will be charged to the costumer 50% of the total amount of the audit
- If there are no issues related to the audit plan, the customer shall return the documentation for the planning of audit countersigned for acceptance. At this point QS proceeds to send the letter of assignment to the auditors of confirmed audit team, with attached documentation of customer management system and the audit plan.

If the client organisation requests the presence of its consultant, it must be allowed by the lead auditor and must cover only the role of observer, not an active part. The consultant must also submit a letter of appointment by the customer, the contract and an authorization from the company to attend during the audit.

10.5 OPTIONAL PRE-AUDIT (on customer's request)

QS may hold a pre-audit at the customer organization on request of the latter in order to assess its suitability to start the certification process. This activity can be useful to the customer to ensure suitability for the certification process and identify any remarks in the documentation and/or in the implementation of the management system.

The pre-audit activity is to be carried out before starting the certification process.

The outcomes are recorded by RAUDT TEAM and are communicated to the customer who can then decide whether to continue with the certification process, or stop it.

The outcomes of pre-audit does not in any way affect the final outcome of the certification process.

The pre-audit is not a part of the certification process, and it does not in any way condition the duration of the certification process.

The audit is to be agreed with the customer and the technical and economic assessment is to be carried out each time.

10.6 STAGE 1 OFCERTIFICATION AUDIT

The STAGE 1 audit normally takes place at the headquarter of the customer organization and consists of a preliminary assessment of the SG. Are evaluated:

- the uniformity of the management system documents kept in headquarter with those sent to QS. It also clarified any findings or remarks noticed during the prior documental examination;
- compliance with mandatory regulations or other applicable or subscribed by the customer;
- the completeness and conformity of the documentation with the standard. This documentation covers: Policy, the documentation of the SG, the description of the company and its processes and interaction, registration documents (reports of internal audits, management Reviews, etc

- prepardeness and skills of staff relating to the audit.
- The truthfulness of the data declared by the customer during the application form. In the event of a variation in relation to what declared, the QS Auditor shall inform the Body that will reassess the application review in the light of the new provided data, evaluating whether the duration of the audit will remain appropriate or it will be necessary to revise the economic offer and the duration of the audit

Furthermore:

- is formulated the text of the future certificate, that is the description of the activity and scope of application;
- is applied the evaluation of admissible exclusions and its reasons, if possible, or of the minor applicability of an aspect for some standards
- It is confirmed the location of the headquarters of the Organization and any outsourcing activities/sites to assess;
- the auditors collect all the necessary information to organize the STAGE 2 audit;
- are remarked any areas, processes, activities, services, significant or legal aspects needing particular attention;
- It is verified that were actually planned and/or carried out internal audits and Management Reviews. In particular must be already defined Policy objectives and, for the certification, must be completed at least a Management Review and a series of internal audits;
- is verified the adequacy and implementation of SG, if the level of the recordings is adequate and if SG is ready for STAGE 2,
- is reviewed the resource allocation for STAGE 2.

At the conclusion of the STAGE1 is drafted by the LA a summary report with an indication of any findings remarked. It also expressed an opinion about the management system applied and its level of application.

Furthermore, in the case of a positive evaluation of the customer organization, in the audit report is indicated by LA the option activity planning for STAGE 2.

If the proposed plan is positively evaluated by the customer, the RAUDT TEAMprocedes for the definition of it, including defined date for STAGE 2, countersigned for acceptance by the customer.

The customer has to face the any remarks found before STAGE 2 audit. If these findings were not resolved we will proceed to the formalization of the same as NC and OSS during the certification audit.

In case of any changes comparing to the information initially provided by the customer at the time of the offer application on which it was calcultated the offer (e.g. personnel declared not correct, other sistes, outsourcing process), QS reserves the right to modify its economic quotation and the review of man-days calculation.

If the client-organization demanded the presence of its consultant, this must be authorized by RAUDT TEAM and does cover solely the role of observer, not as active part in the audit. The consultant shall also submit a letter of assignment, the contract and an authorization from the company.

10.7 STAGE 2 OFCERTIFICATION AUDIT

The STAGE 2objectivies is to verify the conformity of the customer's management system to the referenced standard at the site (s) being object of certification.

Following the results of STAGE 1, it is defined the date within which STAGE 2 should be performed by considering customer needs for the resolution of any findings encountered and the of organizational needs QS.

NOTE: The STAGE 2 shall be carried out within the maximum period of 6 months from the date of STAGE 1.

The appointed staff will be the same identified for stage 1 (except any refusal by the customer). The verification plan is confirmed by LA to customer-organization at the end of stage 1.

The activities to be carried out during the stage 2 are:

- the verification of full compliance of MS to all requirements of the standard;
- the verification of the correct implementation of the SG by the customer;
- verification of legislative compliance and/or other mandatory requirements;
- checking the effectiveness of MS – implementation of the policy, objectives and improvement, responsibilities and competence, application procedures, etc.;
- checking the Internal Audit system, the management review and the related findings.

The Organization shall provide maximum cooperation to the AUDIT TEAM, shall allow access to all areas in which the activities relevant to the purpose of certification required and give the chance to interview the staff performing these activities. Also must provide to AUDT TEAM the system documentation and records as well as information that prove the application, and must guarantee the assistance of its personnel during the inspection visit.

As mentioned regarding the STAGE 1, if the customer-organization has demanded the presence of its consultant during STAGE 2, he must be authorized by AUDIT TEAM and he does cover solely the role of observer, not as active part in the audit.

At the end of STAGE 2, the RAUDT TEAM prepares the audit report where are reported the positive aspects, the comments for the improvement and any non compliace that will be recorded as follows:

Non conformity (NC): failure to comply with a requirement established by the reference standard, mandatory Law requirements, this regulation, such as to call into question or even invalidate the effectiveness and functioning of the Management System (SG);

Observation (Minor NC): they are the minor NC,failure to satisfy a requirement set by the reference standard, mandatory requirements of law, this regulation, such as to require a suitable corrective but that does not raise doubts on the effectiveness and functioning of theManagement System SG;

Comments: markings, recommendations, suggestions considered appropriate by the AUDT TEAM in order to improve the documentation and/or the implementation of Management System SG.

During the final meeting at the end of the inspection visit, the audit team presents the contents of the audit report with a summary of the activities held, comments on the strengths and weaknesses of the verified MS, the findings carried out, their classification, confirmation of the purpose of the certification with the signature of the draft of certificate and a final opinion.

The LA specifies to the customer-organisation that the contents of the audit report must still be evaluated, analyzed and approved by the Certification Committee. Also the audit team explains that the customer-organization shall define its decisions and comments with regard to the noticed findings in the course of the audit and communicate them to QS.

10.8 CONCLUSION OF CERTIFICATION PROCEDURE

During the audit the AUDT TEAM defines on specific QS document the noticed findings and assesses their level of criticality. At the end of the inspection visit RAUDT TEAM explains the findings to the organization. The customer shall take charge of the remarks made and resolve them by scheduling a plan of correcting and improving activities in order to solve the noticed problem in the determinated time.

We specify as follows:

NON CONFORMITY: the presence of these findings suspends the certification process until QS has verified their resolution in order to consider the conformity of SG.

OBSERVATIONS: the presence of these remarks force the customer to define resolutions and any AC that have to be evaluated and approved by QS in order that SG may be considered compliant.

COMMENTS: The presence of comments does not affect the judgement of conformity of SG. The customer is required to evaluate them and implement them; the resolutions and any adopted action will be evaluated during the next audit.

In particular, the Lead Auditor compiles the appropriate RAC module (Request Corrective Actions) with the indicated relief and its weight of the relief, Non Conformity (NC) or Observation (OSS); The customer will have to fill out this model indicating the cause, the treatment and the timing for the resolution of the problem emerged and eventual Corrective Action (AC) that arises.
This model shall be sent to QS within one week of the initial audit or renewal and within 30 days in the case of a surveillance audit, QS will transmit such models to the Lead Auditor to assess their taking and resolution Proposals and present the complete practice to the Certification Committee;
At the receipt QS will evaluate with the Autit team in charge of the audit as defined by the organization and if it is deemed sufficient the effectiveness of the definite will be assessed in the next audit at the organization and the organization does not receive further Communications. Otherwise the request will be sent to the customer for further explanations or any documentation to support the closure of the survey and the continuation of the certification process.

10.9 ISSUING OF THE CERTIFICATE

After checking the completeness of the documentation and following the positive opinion of the AUDT TEAM, QS submits the dossier to Certification Committee that will express a final decision on the issuing of certification.

Following approval of the Certification Committee and administrative checkings, QS will issue certificate attesting the compliance of the customer-organisation'smanagment system to reference standard. The certificate is valid for 3 years from the date of approval as long as the customer comply with the technical and economic conditions established in this Rules.

The first three-year certification cycle begins with the certification decision. The following cycles begin with the decision for renewal of certification.

The certificate is not forwarded to the client if he has not fully fulfilled the due payments.

The certificate is owned by QS and the customer has the right to use it in accordance with the rules and provisions laid down in this regulation and contractual conditions.

The Certification Committe may not approve the issuance of the certificate. In this case will be the secretariat of QS to inform the customer communicating the reasons for that decision and determining the date for a possible extraordinary audit.

Certified organizations will be included in the list available on the website of QS and registered in the register of accreditation body.

10.10 PERIODIC SURVEILLANCE AUDITS (VIS)

Surveillance audits are 2 and they are conducted annually to ensure the complete review of the MS of the organisation. The dates are calculated with reference to the date on which the Certification decision has been performed.

The first surveillance audit shall be conducted within 12 months following the day of certification decisionof initial certification or renewal certification decision. For the second surveillance the intervals can be extended up to +/-3 months to take account of any periods of inactivity of the companies involved.If there is a customer's need for a postponement (maximum of 3 months) for the execution of the second surveillance, the request must be made in writing and a valid justification must be provided. QS reserves the right to request evidence of the need for postponement. If the timing of surveillance audits is not complied with, the certificate shall be suspended.If this interval is exceeded without performing audit of surveillance, we will suspend the certificate.

You may need to vary the frequency of surveillance to facilitate such factors as seasons or having temporary management system certifications (i.e. temporary construction sites). In this case, if the normal cycle will be varied, a justification shall be provided.

Duringsurveillance audits theAUDT TEAMchecks that the conditions that have detemined the obtaining or the maintenance of certification have not been changed.

In detail are evaluated:

- the resolutions and any AC undertaken as a result of findings effected during the previous audit;
- the perfomance of internal audits and management reviews;
- handling of possible complaints received to the CAB about the certified clients;
- the effectiveness of SG in order of achievement of the goals that the organization had established;
- the progress of planned activities;
- controlled management of activities;
- any changes compared to the previous audit;
- the use of trademark, logo and certificate issued.
- Any eventual concerns of interested parties

If any findings is noticed by the AUDT TEAM, their management follows what established in the STAGE 2 provisions, considering that also after the surveillance audit may be requested the suspension or revocation of certification (see. Points14/15of this Rules).

At the end of the surveillance visit, the RAUDT TEAM produces a report with its opinion on the conformity continuity of the SG evaluated.

In case the customer organisation does not wish to perform surveillance visit without adequate justification, it must inform QS within the 11 months following the certification date (or first surveillance). In this case the contract shall be considered concluded and the certificate immediately revoked and withdrawn.In cases where the notice of contract recission is communicated in the 30 days prior to the date of execution of the annual surveillance, QS will have the right to request payment of the amount provided for in the offer concerning the surveillance audit.

In the event of recission or non-renewal of the contract with the Organization-costumer, QS will apply the procedures described in the case of suspension or withdrawal of certification (see. Points 14/15of this Rules).

10.11 EXTRAORDINARY - ADDITIONAL AUDIT

QS has the opportunity to perform of additional audit if necessary and it will communicate the reasons to the client-organization.

Some causesmay be:

- the verification of closing findings and of the treatment of any relevant NCs emerged during the last visit performed;
- any changes or changes in the Organization's management system to request a further check;
- structural changes occurred within companies or within the customer's organization;
- the receipt of news reported by/on reviews related to serious malfunctioning, complaints, misuse of brandname, logo or certificate;
- requested by the customer to extend or reduce the scope of the certificate;
- otherreasonablereasons

The communication of the extraordinary audit with its motivation and the scheduled date is forwarded to the customer. The charge of its extraordinary audit costs will be charged to the customer.

Following the visit, the AUDT TEAM produces a additional audit report. In case of a failureitwillautomatically:

- stopped the certification process for those companies on certification stage process. In this case, the customer shall reformulate the application for certification;
- suspended or revoked the certification for already certified organisations.

QS also reserves the right to, in case of need, hold any extraordinary unannounced audit.

The reasons will be explained during the audit (see. Points7 of this Rules)

10.12 UNANNOUNCED AUDIT

QS also reserves the right to perform unannounced audits than those required by the three-year program at the certified organization:
-If it receives complaints and reports, deemed to be particularly important, relating to non-compliance of MS to the requirements of the reference standard and of these Rules;
-in connection with changes in the Organization;
-for organisations whose certification has been suspended.

- if required by the Accreditation authorities

Expenses related to the audit without notice, where are found deficiencies and deviations from the applicable requirements, are the responsibility of the certified organization

11. CERTIFICATION OF MULTI-SITE ORGANIZATION AND INTEGRATED AUDIT

11.0 MULTI-SITE: GENERAL RULE

The certification procedure in situations that involve the presence of "sites with similar activities" placed in different geographic locations under the supervision and coordination of a central entity is admissible when:

- sites with similar activities are managed from a single management system under the control of one Central Management (headquarter);
- can be properly applied the same scope of certification or part thereof;
- on sites there are similar processes and similar activites are characterized by similar characteristics.

The central management shall be able to prove to have a SG in accordance with the requirements (including mandatory standards) and that the entire organization meets those requirements. It shall also be able to demonstrate the responsability of collecting and analyzing data from all sites including the head office, and to have the authority and the ability to perform any necessary organisational changes.

It is not necessary that the multi-site organization is a single legal entity (i.e. the same business name), but all locations must have a legal or contractual relationship with the headquarters of the Organisation (e.g. franchising)

11.1 INITIAL INFORMATION REQUEST

For the providing of multi-site certification service, QS applies reference IAF documents.

QS collects information of the organization asking to fill in the application form for the offer request with attached a list of secondary sites including their location and its activity.

According IAF MD1:2018 to apply a multi-site organization certification, the following requirements shall be respected:
The organization shall have a single management system.
The organization shall identify its central function. The central function is part of the organization and shall not be subcontracted to an external organization.
The central function shall have organizational authority to define, establish and maintain the single management system.
The organization’s single management system shall be subject to a centralized management review.

All sites shall be subject to the organization's internal audit programme.
The central function shall be responsible for ensuring that data is collected and analyzed from all sites and shall be able to demonstrate its authority and ability to initiate organizational change as required in regard, but not limited, to:
(i) system documentation and system changes;
(ii) management review;
(iii) complaints;
(iv) evaluation of corrective actions;
(v) internal audit planning and evaluation of the results; and
(vi) statutory and regulatory requirements pertaining to the applicable standard(s).

The customer shall specify to QS all the required information, even orally, in order to fully understand the contractual connections, the interactions between the various sites, the processes and the activities of each site.

For the purposes of the issuance of the offer QS review information saving the option to assess acceptability and methods of the certification process and economic evaluation depending on the guaranty of conformity arising from the organisational structure of the applicant organisation (e.g. risk/impact assessment) and ensuring the identification and the complexity of the list of activities covered by the management system to be evaluated, and the places where they are located.

Not all management systems standards are suitable for consideration for multi-site certification. For example, multi-site sampling would be unsuitable where the audit of variable local factors is a requirement of the standard.

After the collection of all these information QS will evaluate if the multi-site is applicable and not, and if auditing multi-site organization using site sampling or not sampling, Auditing of a multi-site Organization when sampling is not permitted.

11.2 Auditing of a Multi-site Organization Using Site Sampling: SELECTION CRITERIA
The selection of the sample of sites to inspect will be applied with a policy:

- partially selective, based on the criteria explained below;
- partially non-selective.

The sample shall result from a representative range of different selected sites, without excluding the element of randomness of the sample. At least 25% of the samples must be randomly selected. The rest of the sample must be selected so that the differences between the selected sites is the largest possible, during the period of validity of certification.

The site selection criteria should include, among others, the following aspects:

- results of internal audits of the management review or the previous certification audit, also carried out by other CaBs;
- records of complaints and other relevant aspects of AC and AP;
- relevant changes in size/importance of the sites;
- changes in shifts and working procedures or products/services provided;
- complexity of the management system and processes applied to the sites;
- changes that have taken place after the last certification audit;
- the maturity of management system and knowledge of the organisation;
- environmental issues, their influence and associated impact on the environmental management system;
- cultural differences, language, and difference of mandatory laws between the various sites;
- geographical spread factor.

The selection is made at the beginning of the audit process, at the time of drafting of the offer.

QS is committed to getting a proper understanding of where and how the organization is carrying out the various activities within the management system to plan and implement efficient and effective audits.

Any changes to the offer may be applied when the audit in Headquarters has been completed, in case that the audit team (AUDT TEAM) finds the need to reconsider the expected number of sites to assess. In any case, the QS Central Office must be informed of the sites sampled included.

The headquarters is always evaluated during each certification audit and annualy as part of surveillance, and is not counted in the sample size.

Here below the example of calculation of the minimum number of sites to visit referred to an organization with an activity considered low or medium risk and with less than 50 people involved in each site, according to the provisions of the IAF MD 1: 2018 "Mandatory Document for the Certification of Multiple Sites Based on Sampling":

- First certification: $y=\sqrt{x}$, where x is the number of sites, rounded to the higher units;
- Annual surveillance: $y = 0.6 \sqrt{x}$, where x is the number of sites, rounded to the higher units;
- Renewal: the sample size is the same as that of the initial audit. However, when the QMS has given prove of effectiveness during the period of the three previous years, the sample size may be reduced by a factor of 0.8 es. $y = 0.8 \sqrt{x}$, where x is the number of sites, rounded to the higher units.

NB: the number of branches to be inspected during the certification cycle can vary depending on the certification scheme and the sector.

QS increases the sample size or frequency of audits if risk analysis on the activity covered by the SG indicates that there are particular circumstances in relation to the following factors:

- size of sites/locations and number of employees (e.g. › 50 people on a site);
- complexity or risk level of the activities and the SGQ (QMS);
- production methods changes (e.g. shifts);
- modifiche nelle attività/processi/prodotti;
- Complaints or other relevant aspects of AC and AP;
- Any aspect linked to multinationality of organization;
- the results of internal audits and the management review.

If the organization has a hierarchical system branched (e.g. Central Executive Office, national offices, regional offices, local offices), the sample calculation model of sites must be one of the first certification applied at each level.

Auditing of a Multi-site Organization when sampling is not permitted

There are situation where sampling in not appropriate, for example: too different processes/activities (i.e. based on the assessment of risks or complexity associated with that sector or activity); high risk activities correlate at some standard; size of sites eligible for multi-site audit; variations in the local implementation of the management system to address different processes/activities or different contractual or regulatory systems, etc.;

The calculation will be made taking into consideration the relevant rules, IAF documents (principally IAF MD5) and, where appropriate, any applicable sectoral standard requirements

The audit calculation shall consist of an initial audit and recertification audit of all sites. In surveillance audits, 30% of sites, rounded up to the whole number, shall be covered in a calendar year. Each audit will include the central function. The sites selected for the second surveillance audit will normally be different from the sites selected for the first surveillance audit.

11.3 AUDIT METHODS

QS must collect the procedures that govern the multi-site testing on individual organizations selected by sampling. The nr. of man-days per site is calculated based on the calculation table audit schedules drawn up in accordance with the reference IAF documents with the possible justifications of reductions of time.

In each certification cycle, the audit programme must:
Include during each audit all the primary processes, performed on each site;
Include all evaluation and performance improvement processes during each initial audit and re-certification and at least once in each certification cycle during a surveillance audit;
Include the secondary processes as follows:
A. Control of all secondary processes in each initial audit and recertification audit, but similar secondary processes carried out in different sites can be controlled on a sampling basis;
B. During surveillance audits, secondary processes shall be monitored on the basis of sampling and depending on the outcome of the previous checks. This sampling is intended to ensure a significant sample size in order to obtain an assessment of compliance with the requirements of the management system and ensure that the selection of controlled processes during the 3-year cycle is reasonably representative management system.
Stage 1 Audits: QS may take a consideration to carry out the Phase 1 audit in several sites if necessary to meet the objectives of the Phase 1 audit dictated by the ISO standard 17021-1:2015
Recertification Audit: QS controls the complete management system in the same way as the initial audit. QS takes into account the processes that have been checked on which site during the previous cycle.

11.4 ISSUING OF THE CERTIFICATE

Following the success of the certification audit and of the approval by the Certification Committee, will be issued a certificate with the name and address of the Organization's Central Office. Will be issued the list of sites to which the certificate applies. The scope will clearly include the activities developed in the listed sites.If the scope of the certificate of the site is issued only for a part of the general scope of the Organization, its applicability is clearly reported on the certificate and on each attachment.

The certificate will be withdrawn in its entirety if the Central Office or the sites will not meet to the necessary criteria to maintain the certificate.

QS requires to organization to immediately communicate the eventual closure of one or more sites. If the organization does not provide the information required, QS will consider the omission as an abuse on the use of the certificate and will proceed accordingly.

11.5 REQUEST FOR ADDITION OF NEW SITES

Upon request to add new sites to a multi-site organization already certified, QS considers as a group in its own right for the purposes of the sample sizing new sites to analyze and proceeds accordingly to planning of audits establishing new calculation of audit duration (man-days).

Following a successful audit, the certificate will be reissued with the addition of new sites and keeping the date of expiry of the previous multi-site certification. The new sites will add to the previous sites for the purpose of the sample sizing for the next surveillances and renewal audit.

11.6 INTEGRATED AUDIT

When the management systems for different schemas are subject to audit at the same time, this is called "combined audit".

To apply the paragraph below, the systems, object of the evaluation, must be INTEGRATED into a single management system.

11.7 CALCULATION OF COMBI-AUDIT DURATION

To calculate the time of the integrated audit, QS follows, in accordance to document IAF MD 11:2013 the following procedures:

1. audit-time calculation separately for each individual certification standard (by applying each relevant factor provided by the applicable Guide to each standard): QS considers at this stage of calculating, for each schema, both the decrease and increase factors of the audit durationto

2. calculation of the sum of values thus obtained
3. where appropriate, correction of the result of the obtained sum by the increase or decrease of the time required for the integrated audit, in consideration of the factors applicable to the specific case as per Annex 1 IAF MD 11: 2013; the maximum permissible reduction, however depending on the "integration level" will be of 20%.

The factors that affect the "integration level" and therefore the audit-time reduction are:

a. the skill level of audit team
b. the level of integration of the management system (SG) of the company
c. the ability according to the declared competence of the people surveyed in answering to questions concerning of issues relating to both certification schemes (e.g. single responsible for management system, single management Delegate, etc..)
d. the complexity of integrated audits than the single audit of the management system.

What considered by QS concerning the level of integration on the basis of the declarations of the Organization during the phase of application for the offer, will be subject to review by the auditor once on site, both in STAGE 1 that during subsequent audits.

Combined audit to non-integrated systems are not subject to any kind of decrease on the audit-duration.

12. RE-CERTIFICATION (RENEWAL OF CERTIFICATION)

Renewal of certification must confirm the continued compliance and effectiveness of the management system and its relevance to the scope of certification.

Re-certification audit shall be performed within three years from the date of approval (of certification) and takes into account the performance of the SG during the entire period of certification, including the review of all reports of previous surveillance and any complaints.

Renewal involves the definition and the signing of a new contract where, in the case of variation of initial conditions, we will define new terms of reference.

The re-certification audit dates are defined with the client in accordance with the procedures established for the initial audit and shall be planned in large advance respect upon expiry date of the certificate that represents the time limit within which shall be performed.

In case the customer does not intend to proceed with renewal, he must notify it to QS at least three months before the expiry date of the certificate. In case of renounce by the customer, the certificate will be immediately withdrawn.

Recertification audit shallcomply with the following conditions:

- must be verified the application of all the requirements of the reference standard;
- Verification time shall be calculated on the basis of the IAF documentand/or the appropriate reference standard according the scheme, taking into account the total headcount of employees of the company (headoffice + external activities);
- the full review of the SG shall be perfomed in relation to the confirmation for the next three years, thus it must be completed sufficiently in advance of the expiration date;
- The recertification audit is to be considered either as final act of the three-year cycle spent, both as a basis for the next triennium. Regardless of the actual approval date of renewal of the certification that must occur anyway before the date of expiry of the certificate, will be guaranteed the temporal continuity of issued certificates.
- As regards the assessment of the "external work activities", is necessary to plan at least one audit of an operating site for each activity;
- an activity covered by the certification can be verified through the use of documentary evidence in accordance with the present document;
- in the scope of certification should be solely listed the activities that were the subject of audit, taking into consideration the verified activities in the past three years.

- The Renewal Audit is carried out in accordance with the same criteria as for PHASE 2 of the certification. In the event of substantial changes to the system, QS reserves the right to carry out a PHASE 1 audit before performing the PHASE 2 renewal audit.
- In the presence of non-conformity situations before the expiry of the certification, the treatment and corrective actions must be implemented.

If the certification body has not completed the renewal audit or it is not possible to verify the implementation of the corrections and corrective actions for each NC increased prior to the expiration date of the certification, renewal cannot be approved and the certificate validity cannot be extended. The customer will be informed of the consequences.

Following the expiry of certification, the certification body may reactivate the same within 6 months, given that you have already completed recertification pendants, otherwise it must be conduct a Stage 2. The actual date on the certificate shall correspond or be beyond the decision of recertification and expiration date must be based on the previous certification cycle. On the certificate document will be highlighted the period in which the certification was suspended (not to be).

13. EXTENSION OF CERTIFICATION SCOPE

The organization-customer can request to QS the extension of certification scope obtained following the procedure of initial request. The extension includes a new verification to be carried out on the subject of the application and that, depending on the scope of the extension request, can also involve repetition of total certification process. In case an audit for extension is required, and at the customer's request of organization, it will coincide with the annual surveillance visit.

following the positive opinion will be issued a new certificate that will imply the restitution of the obsolete certificate by the client.

QS reserves the right to restrict the field of validity of the certificate in the event of communications by the client-organization or in the presence of unresolved issues within the time limit and that affect only a specific part and not the total certified managment system.

14. SUSPENSION OF CERTIFICATION

In some cases it may be necessary to suspend the certification.

In this case (non exhaustive list):

- the management system implemented by the Organization has not secured compliance with certification requirements consistently and seriously, including the requirements of effectiveness,
- do not comply with the provisions of this regulation and/or certification contract;
- if as a result of extraordinary audit, have been found the persistence of previously reported non-conformity (AC are not undertaken or ineffective);
- If your organization does not carry out corrective action requests within the time limit;
- If serious lack inherent in the Organization's management system have been found on the basis of complaints, legal action and other objective evidence, whether or not arising from inspections;
- If they are not promptly notified corporate or organizational changes occurred within the customer organization;
- If the organization has not communicated any legal issues pending or disciplinary actions that have occurred after the last performed audit;
- If any misuse or misleading use of trademark, logo or certificate are observed;
- If due payments are not fulfilled within the period provided for in the contract;
- If the organization does not allow to perform surveillance audit with the planned time period;
- If the organization with its own behavior affects the reputation of QS;

- If there are other severe cases and motivated;
- voluntary and motivated request by the Organization.

The certificate may be suspended for up to six months after that, if the problems that led to the suspension have not been solved within the time limit defined, we will proceed to withdrawn or to the restriction of the scope for which it was issued.

Suspension of certification can also be requested voluntarily by the Organization through a formal request, motivated and signed by Top management, sent QS for a period not exceeding 6 months.

It should be noted that the period of suspension does not change the validity period of the certificate whose validity is three years.

The suspension may be applied in total or in part (e.g.: for all or part of the activities of the scope of the certificate object) or it can be partial or general (e.g.: for some or all locations/branches/factories of an organization).

During the period of suspension is not permitted use the brand, logo and certificate by the customer.

The suspension shall be withdrawn only QS evaluates the reasons which have caused it are resolved. QS reserves the right to make a additional visit if deemed necessary to carry out an inspection at the customer. In this case the cost of the visit will be totally charged to the customer-organization.

15. REVOCATION OF CERTIFICATION

In case of serious motivations communicated to the customer, QS may decide the withdrawal of certification granted. Some serious reasons that can determinate the withdrawal are (non-exhaustive list):

- the unsuccessful resolution that may have caused the suspension of certification;
- relevant findings marked during the visit which do not guarantee the application of the Management Syste or reasonably bring into question the effective functionality;
- the customer suspends the activity-which has been certified for, about a period of over 12 months;
- the bankruptcy or liquidation of the customer-organization;
- the decision by the customer not to adapt to the new contractual terms or to the new rules of regulation if QS decides to edit;
- if the Organization decide to not maintain the certification, communicated by writing;
- serious breach of the contract and the conditions and requirements contained in this regulation;
- management system does not guarantee compliance with the mandatory requirements of the product and/or service;
- repeated failure to comply with the commitments took on with QS;such asthefailureto plan theauditorthecustomer'sfailuretocooperate in theplanningoftheaudit;
- persistence of arrearage in payment situation over the terms set out in the notice posted by QS by registered mail;
- otherserious and motivatedfactors

The revocation of certification and the reasons which have caused are communicated to the customer by registered letter or other equivalent means, and made public through the cancellation of the customer-organisation from the register published on the site.

As a result of revoke, the organisation undertakes to:

- return the original QS certificate and not use any copies and reproductions;

- delete from the letterhead, advertising and technical documentation any reference or symbol of certification;
- immediately suspend the use of the QS logo and trademark.

If the customer will violate these obligations QS may act via legal action.

Even in the case of revocation, the customer shall pay what is due in case of audits already performed and still to be paid.

Revocation of certification does not give right to any refund of what previously paid to QS.

16. RENOUNCEMENT TO CERTIFICATION

The Customer organization has the right to renounce the acquired certification by sending communication to QS at least one month before the expiry date by registered means or other means of communication equivalent in the following cases

- At the expiry of the three-year period;
- In case of variation of the reference regulation;
- In case of non-acceptance of any economic changes;
- In the event of non-acceptance of any changes in the contractual conditions and/or this Regulation;
- In case of justified contractual withdrawal (e.g. cessation of activity, assignment of activity, etc.)
- In the event of a willingness on the part of the customer to transfer the certification to another OdC.

In case of waiver, the customer organization undertakes to return immediately the certificate, to suspend the use of the logo and the brand and to withdraw the documentation of any type bearing the logo and/or the mark.

The Waiver and the consequent restitution of the certificate does not imply by the customer organization the payment of any penalty unless they have already been planned and accepted the activities of future verifications or that the waiver occurs in the 30 days preceding The date of execution of the expected annual deadline, and involves only the due for any activities covered by the contract and already made/planned by QS.

17. TRANSFER OF ACCREDITED CERTIFICATES FROM OTHER CABs(TRANSFER AUDIT)

For "transfer of certification" (transfer) is meant the recognition by QS certification obtained by another CAB in order to issue an own certificate of conformity of the management system of the organisation who has requested the transfer. In particular, only the certifications issued by the accreditation obtained by a signatory to MLA agreements can be used to activate the transfer procedure.

Following receipt of aapplication for the transfer of certification by an Organisation holding a valid certificate and covered by accreditation in accordance with the foregoing, QS shall carry out a review of the application (Pre-transfer review) in order to evaluate the status of the certification.

This evaluation is carried out by:
a) Examination of the specific documents required by QS and that the Organization undertakes to transmit
b) Any cognitive visit to the requesting organisation if QS considers it necessary To better understand the organization or because the documentation received is deemed unclear or insufficient; This visit is compulsory if, during the document examination, it is shown that there are no major closed NCs issued by the preceding CaB. Any pre-Trasfer visit is not to be considered an audit.
QS requires the necessary documentation to carry out the pre-transfer review and subsequently the economic evaluation and any additions in order to issue the offer. QS carries out a documentary examination of the requested documents, namely:

- declaration by the organization that the certificate has not been suspended or withdrawn or revoked or threatened for suspension;

- declaration by the customer organization that there is no legal action or pending prosecution charged on him;
- declaration by the organization that all due payments to the precedent (transferor) CaB were fulfilled;
- audit reports issued by the transferor (precedent) CaB issued during the period of validity of the certificate;
- any other documents pertaining to the entire certification process;
- a copy of the manual (or equivalent document) in the revision into force.

At this point QS proceeds to an examination of the documentation received. The purpose of the examinationisaimed to:

- check the validity and authenticity of the certificate held by the customer;
- check the duration, scope and any permitted exclusions of the certificate;
- Verify that the organization's activities present within the scope of the certificate, are covered within areas of QS accreditation;
- ascertain the reasons for the choice of the customer to perform a transfer, analyzing the complaints/appeals received by the organization, as well as any legal or economic pending situation existing;
- analyze the current state certification/surveillance cycle;
- check the documents relating to the certification process, the previous audit of the CaB and the status of any AC on non-conformity detected;
- evaluate the implemented SG.

Following the outcome of the examination made, QS establishes as follows:

Transfer denied:QS does not find the appropriate conditions for accepting the transfer application, it shall communicate it in writing, providing the appropriate motivation.the organization is considered as a new customer applying for certification. The offer will be issued as new certification. QS will inform the customer organisation specifying the reasons.

Transfer conditioned by success of an extraordinary audit:If the above mentioned activities reveal doubts about the suitability for the transfer, the execution of the same is subject to the outcome of a site verification (pre-transfer visit), the costs and procedures of which will be included in the offer to Applicant. In case of success can be carried forward the process of transfer otherwise the Organization is considered as a new customer and will follow if it wanted the modalities of a new certification.

Accepted Transfer and reissuance of certificate by QS (in the case of a transfer during the validity of the certificate): In this case will be issued the offer for the takeover and following the subscription by the client organization QS will proceed to the activation of the transfer process and the planning of the maintenance audit respecting the timing of the process of Certification/surveillance required, with passing of the practice to the Certification Committee and following a positive resolution by the QS certification Committee, a new certificate is issued in accordance with QS formats and references, with the following Date:-

- Date of first issue: date on which the issuing CaB has issued the first certification (with the wording "from previous Cab...")
- Current issuing date: the date on which QS issues the certification following the transfer-
- Expiration date: date on which the certificate of the issuing CaB expires

The activity of transferring a certificate may not coincide with a supervisory or renewal audit. This means that you must first complete the transfer activity (documentary Exam + eventual pre-transfer visit), and only after the audit or renewal can be carried out.
Where the activity relating to transfer operations, acquisition of documentation relating to the application, review of transfer, issue offered and subsequent acceptance by the customer takes place near the expiry of the certificate (generally Less than 30 days), no intermediate certificates

will be issued, and you will proceed with the verification schedule and following a single certificate issuance.

In the event that the certificate held by the customer organization is issued by an CaB that is no longer operating (CaB suspended or revoked), the transfer can be made within six months of the time the body has lost accreditation. Over The six months you will have to manage the practice as an initial certification. In particular the following modalities will be followed:

- Transfer from OdC suspended or self-suspended: to carry out an inspection of the duration of at least one day, on site, before being able to transfer the certificate; This verification may coincide with a surveillance or renewal check. According to the results of this audi QS assesses whether to carry out additional extraordinary verifications or proceed immediately with transfer of the certificate.
- Transfer from revokedCaB or having renounced the accreditation: carrying out an inspection of the duration equal to the stage 2 if carried out within 6 months from the order of revocation of the CaB. This verification may coincide with a surveillance or renewal check

Accepted Transfer coinciding with the renewal of certification: QS issues the offer of renewal and transfer process proceeds as for normal renewal of certification of QS (re-certification), nominating a AUDT TEAM and giving them copies of the audit reports of the precedent CaB, findings issued and of their correction/management by the organization.

If the certificate held by the customer organization is issued by a CaB is no longer operating, will be QS's discretion to perform a transfer procedure or to conduct activity of new certification.

All decisions made by QS about the transfer request with the relating reasons shall be communicated in written form to the applicant organisation.

17.1 INITIATION OF TRANSFER PROCESS

To activate the transfer process, QS shall instruct an audit team for carrying out verification activities by informing the lead auditor of what emerged from the analysis of documents and delivering copies of the reports of the issuer CaB, of findings issued and of their management by the organization.

Please note that for the proper conduct of the transfer process, QS shall verify any pending NC, i.e. not yet closed CaB's issuer with a pre-transfer audit. Once performed the audit on site, the results and the recommendations of certification proposed by the appointed lead auditor will follow the normal process of analysis and approval by the Certification Committee. In the case of issuance of the certificate attesting the conformity to the reference standard, this will have the same expiration date of certificate issued by the transferor (precedent) CaB.

18. COMPLAINTS, APPEALS

Complaints and appeals can be presented in written form to QS by its customers or by certified organizations's customers about the certification activities whereby QS is responsible.

QS records any complaints and appeals on the appropriate application forms, making an analysis of situation on the local level, draw up a description of the problem with any suggestions and forwards it to the Top Management.

QS ensures full transparency, fairness and impartiality in the analysis of problems, and is committing to not use staff members or external partner/worker who may be involved.

QS shall not make public the content of the complaint or appeal without ask the full consent from the customer-organization that submitted it.

19. LITIGATION, DISPUTES

The contract signed between the customer and QS is formulated according to the maltese law, and the competent jurisdiction is that of Malta, unless otherwise specified in the contract offer and contractual terms issued by the channel of authorized partners QS.

In the case of non-payment of the QS invoice by the contracting customer-organization, QS will apply suspension procedure (see point 14) and the withdrawal procedure (see point 15) of certification.

AdditionallyQS will act judicially and extrajudicially for the collecting/recovering of unpaid credits. Also in this case the Court of exclusive jurisdiction is Malta. The costs relating to the recovery of the claim shall be entirely charged to the (insolvent) customer.

20. ACCEPTANCE CLAUSE

This rules forms part of the agreement drafted between the client-organization and QS. With the signing of the contract the customer-organization accepts all the established articles and reported in this Rules as well as in the norms, regulations, guides, technical specifications and reference documents cited therein.