RULES FOR MANAGEMENT SYSTEM CERTIFICATION

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Summary of changes:

- Corrected standards, standard issues, and accreditations.
- EMAS environmental statement validation activities determined in further detail.
- Deadline for the implementation of the first surveillance audit determined.
- Major and minor nonconformity determined.
- Item 7.3 Expenses supplemented.

This edition was adopted by the Board of Certification Body at its correspondence session of 2018-05-24 and replaces the 26 / 2017-05-31 edition of the Rules.

1 SUBJECT AND SCOPE

This document describes procedures for certification of management systems and related systems applied by SIQ as a certification body competent for operating the assessment and certification of conformity to management system reference documents.

This document defines a certification and verification policy and the elements of a certification procedure ensuring the implementation of this policy.

Services are performed in accordance with General terms and conditions for services GN007, which are determined in details in this Rules. In case when provisions of GN007 are contrary to the provisions of this Rules, the latter has precedence.

2 DEFINITIONS

Certification is a procedure applied by an independent third party (SIQ) to provide written evidence that a product, process or service complies with specified requirements.

A reference document is a document (standard, guide, rules and the like), issued by a recognized body, defining rules, guidelines or characteristics for described activities and their results, and is intended for common and repeated use and aimed at the achievement of the optimum degree of order and consistency in a given context.

A management system is a system for the establishment of a policy and goals and achieving these goals. A management system of an organization may include various management systems, e.g. a quality management system, environmental management system and other management systems.

A certification body is an organization that operates certification to issue certificates.

An accreditation body is an organization carrying out accreditation activities to issue accreditation certificates to conformity assessment bodies.

A certificate is a document issued in accordance with the rules for system certification that confirms the fulfilment of specific requirements as defined in a reference document.

An applicant is an organization that has submitted to a certification body (SIQ) an application for certification. As a rule, an applicant is an audited organization to which a certificate or some other relevant document is granted.

A holder is an organization that has been granted a certificate.

3 MANAGEMENT SYSTEM REFERENCE DOCUMENTS

The certification of management systems and verification are conducted in consideration of the following reference documents:

- *Quality management system – ISO 9001:2015
- *Environmental management system – ISO 14001:2015
- *Quality management system – ISO 9001:2015 taking into consideration HACCP system – FAO/WHO Codex Alimentarius, CAC/RCP 1-1969, rev. 4, 2003

- *Eco-management and audit scheme EMAS – Regulation ES 1221:2009 and Regulation 2017/1505
- *Occupational health and safety management system – BS OHSAS 18001:2007
- Occupational health and safety management system – ISO 45001:2018
- HACCP system –FAO/WHO Codex Alimentarius, CAC/RCP 1-1969, rev. 4, 2003
- *Food safety management system – ISO 22000:2005
- *Energy management system – ISO 50001:2011
- **Certification of retailer branded food products – IFS (International Food Standard), rev. 6.1, 2017
- **Certification of retailer branded food products – BRC (British Retail Consortium) Global Standard for Food Safety, issue 7, 2015
- **Certification of providers of logistics services – IFS Logistics Standard, rev. 2.2, 2018
- **Quality management systems in automotive industry – IATF 16949:2016
- **Information security management systems – ISO/IEC 27001:2013
- *Quality management systems in production of medical devices – ISO 13485:2003
- Quality management systems in production of medical devices – ISO 13485:2016
- Primary packaging materials for medicinal products - Special requirements for use of ISO 9001:2008 in relation to good manufacturing practice (GMP) (ISO 15378:2015)
- Quality in education – QE:2016
- Quality system for non-governmental organizations – NGO – Quality standard, 2008
- Verification of sustainability reports – GRI (Global Reporting Initiative)
- Social Accountability – SA 8000:2014
- Social Responsibility Management System IQNet SR 10:2015 – Social responsibility management systems requirements
- ISO 22716:2007 Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices
- **FSC CoC Scheme – Wood product traceability
- Directive EU 2008/98/EC – Council Regulation (EU) No 333/2011, No 715/2013 and No 1179/2012 establishing criteria determining when certain types of waste materials cease to be waste
- **Information technology – Service management – ISO/IEC 20000-1:2011
- **ISO 22301:2012 standard – Societal security – Business continuity management systems
- **ISO 27018:2014 standard – Information technology – Security techniques – Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors
- Asset Management System – ISO 55000:2014

- Health care services – Quality management systems EN 15224:2012 and EN 15224:2016
- GMP / DPP Food Supplements Europe Guide to Good Manufacturing Practice for Manufacturers of Food Supplements, March 2014
- 2014/32/ES Directive on measuring instruments MID (with all applicable amendments and supplements) and relevant Slovenian legislation in force
- Conformity assessment procedure according to the Rules on machinery safety, OG RS No. 75/2008, Machinery directive 2006/42/EC, Annex I (with all applicable amendments and supplements) and relevant Slovenian legislation in force
- 57/2008/EC directive on the interoperability of the rail system within the Community (with all applicable amendments and supplements) and relevant Slovenian legislation in force

* Acquired accreditation at Slovenian Accreditation

** auditing in cooperation with partner certification bodies

Other reference documents are considered in accordance with the certification policy.

4 GENERAL PROVISIONS

4.1 Legal status

SIQ is registered at the District Court of Ljubljana as an institution under the name "Slovenski institut za kakovost in meroslovje, Ljubljana, having its seat in Ljubljana, Trzaska 2. The English translation of the name is Slovenian Institute of Quality and Metrology, Ljubljana, abbreviated to SIQ Ljubljana.

SIQ is entered in the register of research organizations at the Ministry of Higher Education, Science and Technology.

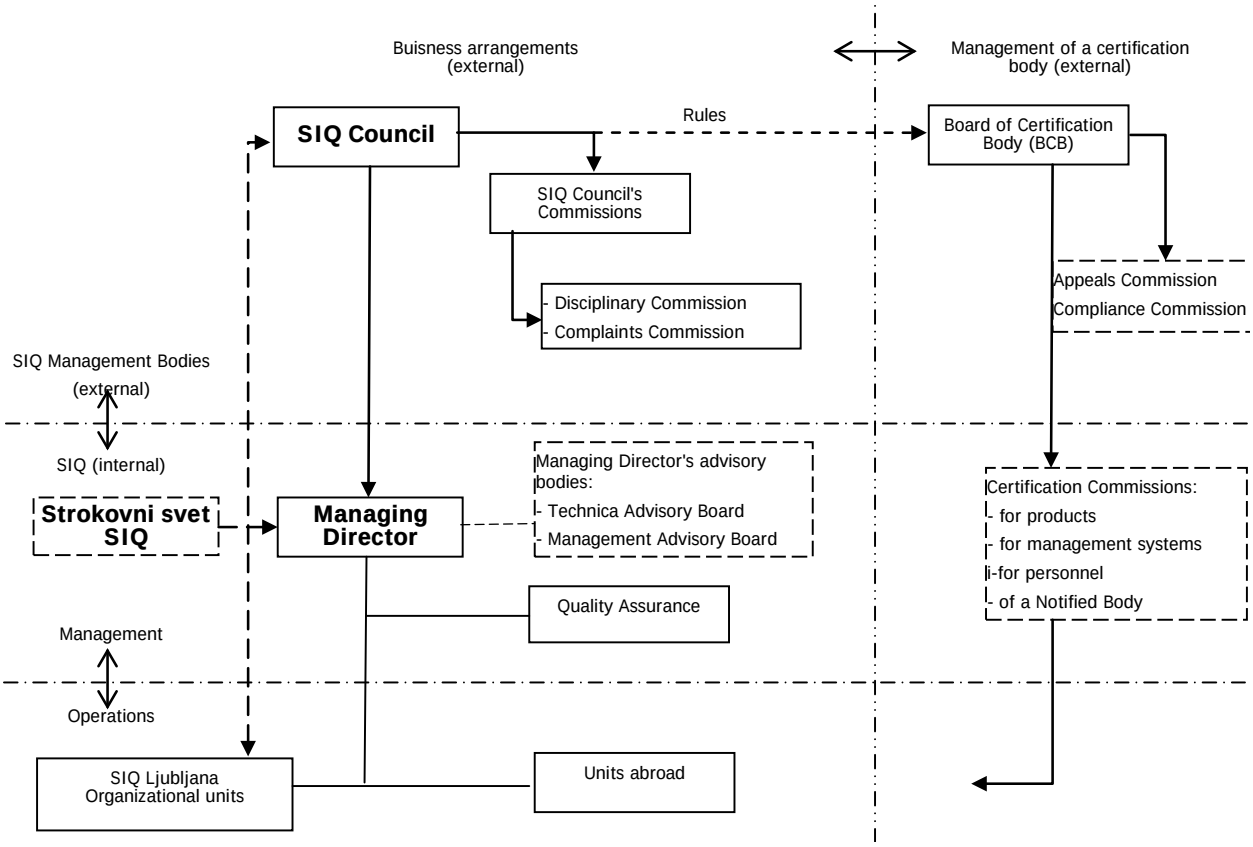
4.2 Financing

Services are charged according to the schedule of fees. The SIQ Council and/or other supervisory bodies define the policy for fees and charges for services.

SIQ is a not-for-profit institution. Current costs and investments in the development of SIQ activities are covered by the income from its fees for services.

4.3 Organization

4.3.1 Organizational scheme of SIQ as a certification body



4.3.2 Governing and management bodies

The governing and management bodies of SIQ are:

- SIQ Council
- Board of Certification Body (BCB)
- Commissions of the SIQ Council and the BCB

The SIQ Council is the governing body of SIQ and oversees the performance of all its activities.

The Board of Certification Body administers and oversees certification activities.

The powers and duties of the Board of Certification Body are defined in the Rules of the BCB and are, among others:

- to approve the certification policies and their development and to supervise their implementation;
- to appoint the members of individual certification commissions;
- to approve the certification procedures and their development;
- to approve and ratify the certification rules of individual certification commissions;
- to supervise the work of commissions;
- to determine the corrective actions and to supervise their execution;
- to approve the annual financial report of the certification body.

- to get a report on appointments of senior executives responsible for day-to-day tasks and operations related with certification and to have the power to require the exchange of these senior executives;
- to discuss and confirm the annual report on performance of internal audits and on execution of corrective actions resulting from internal audits;
- to discuss the reports on management reviews and to confirm the plan of actions defined during management review;
- to discuss impartiality policy, principles and risk assessment, including financial risks, and approve it;
- to discuss any tendency on the part of a certification body to allow commercial or other interests to impair consistent impartial provision of certification activities, or to allow openness that would present a threat to impartiality and diminish confidence in certification;
- to appoint the members of the Appeals Commission and Compliance Commission;
- to become acquainted with annual reports of the Compliance Commission;
- to perform other functions in accordance with applicable laws and regulations.

In case certain activities are not carried out, the BCB may inform the accreditation body.

The Board of Certification Body consists of the representatives of the parties involved in the certification process. One representative is elected from each of the following organizations: the Slovenian Institute for Standardization (SIST), the Chamber of Commerce and Industry of Slovenia, the Slovenian Consumers' Association, the Slovenian Quality Association, Slovene Universities, one representative of the users of Ex-apparatus in industry, delegated by the Chamber of Commerce and Industry of Slovenia, one of the manufacturers of Ex-apparatus, delegated by the Chamber of Commerce and Industry of Slovenia, one representative of SIQ, two representatives of the Electronics and Electrical Engineering Association at the Chamber of Commerce and Industry of Slovenia and one representative from the field of gaming, delegated by the Ministry of Finance. At least one of the representatives of the BCB must have the appropriate knowledge in the field covered by a relevant reference document.

The Certification Commissions are expert bodies in charge of the preparation and implementation of certification procedures. They consist of three members, the employees of SIQ. The Management Systems Certification Commission decides, among other things, on granting SIQ management systems certificates, while the Personnel Certification Commission decides on the registration of auditors and experts.

The Appeals Commission is the body of second instance and deals with complaints by applicants/certificate holders against the decisions of Managing Director/Department Director (the body of first instance) on the eligibility of their complaints against SIQ services or the work of a certificate holder, and with appeals by applicants against the decisions of the Management Systems Certification Commission. It consists of one representative of each of the following organizations: Slovene Consumers' Association, University of Maribor – Faculty of Organizational Sciences in Kranj, and SIQ (i.e., TMT Department Director). The decisions of the Appeals Commission are final. The appeals procedure is specified in document CR105 and published on SIQ website.

4.4 Certification policy

SIQ provides its services to all interested parties.

SIQ, i.e., its bodies and its personnel, deals and will deal with all applicants for its services in a non-discriminatory manner, regardless of their geographical area, size, turnover, activities, etc., and without discrimination or giving preference to anyone in any way.

SIQ binds itself to achieve and maintain international recognition in the field of certification. SIQ should endeavour to achieve greater value of its certificates in Slovenia and abroad. To this end, it has its certification activities accredited by Slovene accreditation body SA and monitored by the international association of certification bodies IQNet.

The administrative and organizational structure of SIQ is such as to prevent any influence on the staff by persons or organizations having direct commercial interests in connection with certification and to prevent any conflict of interest.

Management systems certification activities are conducted in compliance with the requirements of ISO/IEC 17021-X, ISO/IEC 17024, ISO/TS 22003 and ISO 50003 standards, as well as EMAS Regulation EC 1221:2009.

Operative activities relating to management systems certification are conducted according to the documented procedures by MSA department.

SIQ also assures its independence (impartiality) by not engaging in counselling activities for establishing and/or maintaining compliance with relevant standards.

4.5 Code of conduct for auditors and experts of SIQ

Auditors and experts operate according to relevant International, European and/or Slovene standards and regulations as well as according to pertinent documented procedures and instructions adopted by SIQ.

An auditor or expert shall act in line with the following principles and shall:

- act in a confidential and impartial manner in relation to SIQ, as well as in relation to any other organization involved in the audit they perform, or by the staff for which they are responsible;
- inform SIQ of any connection with the organization in which they are about to perform an audit before taking on any responsibilities or functions in relation with the audit in the organization;
- inform SIQ of any counselling activity performed by them in the organization in the period of three consecutive years prior to the audit;
- not accept from the organization any order for work in the field of management systems in two years after the conclusion of the audit;
- not advertise their co-operation with SIQ while providing counselling or raise the organization’s expectations to be treated differently or favourably during an audit due to their co-operation with SIQ;
- not accept from any organization in which they perform an audit, or from its representatives, or from any other person who could benefit in any way, any hints, presents, orders, discount, or any other advantage, as well as not allow any of the personnel for whom they are responsible to do so;

- not disclose, partially or entirely, any findings of the audit team, in which they took part or for which they are responsible, or any information acquired in the course of an audit procedure, to a third party, unless they are authorized in writing by the auditee and by SIQ;
- not adversely affect the reputation or interests of SIQ or of the auditee;
- co-operate in any investigation in the case of an infringement of the above principles.
- act in conformance with the Code of Ethics of SIQ.

4.6 Mutual respect of confidentiality

SIQ binds itself to treat any information and data on the applicant/certificate holder as confidential, and to use them exclusively for the implementation of the agreed activities.

Applicants/certificate holders accept that SIQ has exclusive rights to all documents handed over to the applicant by SIQ and agree not to copy these documents or reproduce them in any way, or to give them to any third party, apart from an accreditation/notification body in the accreditation/notification maintenance procedure or due to statutory requirements.

Information on the certification procedure and related activities, apart from the information on the award or cancellation of a certificate, shall be treated as business secret of the applicant/certificate holder and SIQ.

Audit reports shall be treated as business secret and may be handed over to a third party by SIQ only with a written permission from the applicant/holder and in their entirety.

SIQ reserves its right to pass to interested parties information on a cancellation of a certificate upon their request and without disclosing the reasons for cancellation or any other information on a former certificate holder.

In the case of a complaint against a certificate holder, SIQ has the right to inform the complainant of the findings of the complaint-handling process without disclosing information on the holder not necessary for the understanding of the findings. The information passed to the complainant shall be passed by SIQ to the certificate holder as well.

All the above stated obligations remain in force even after the cancellation of a certificate.

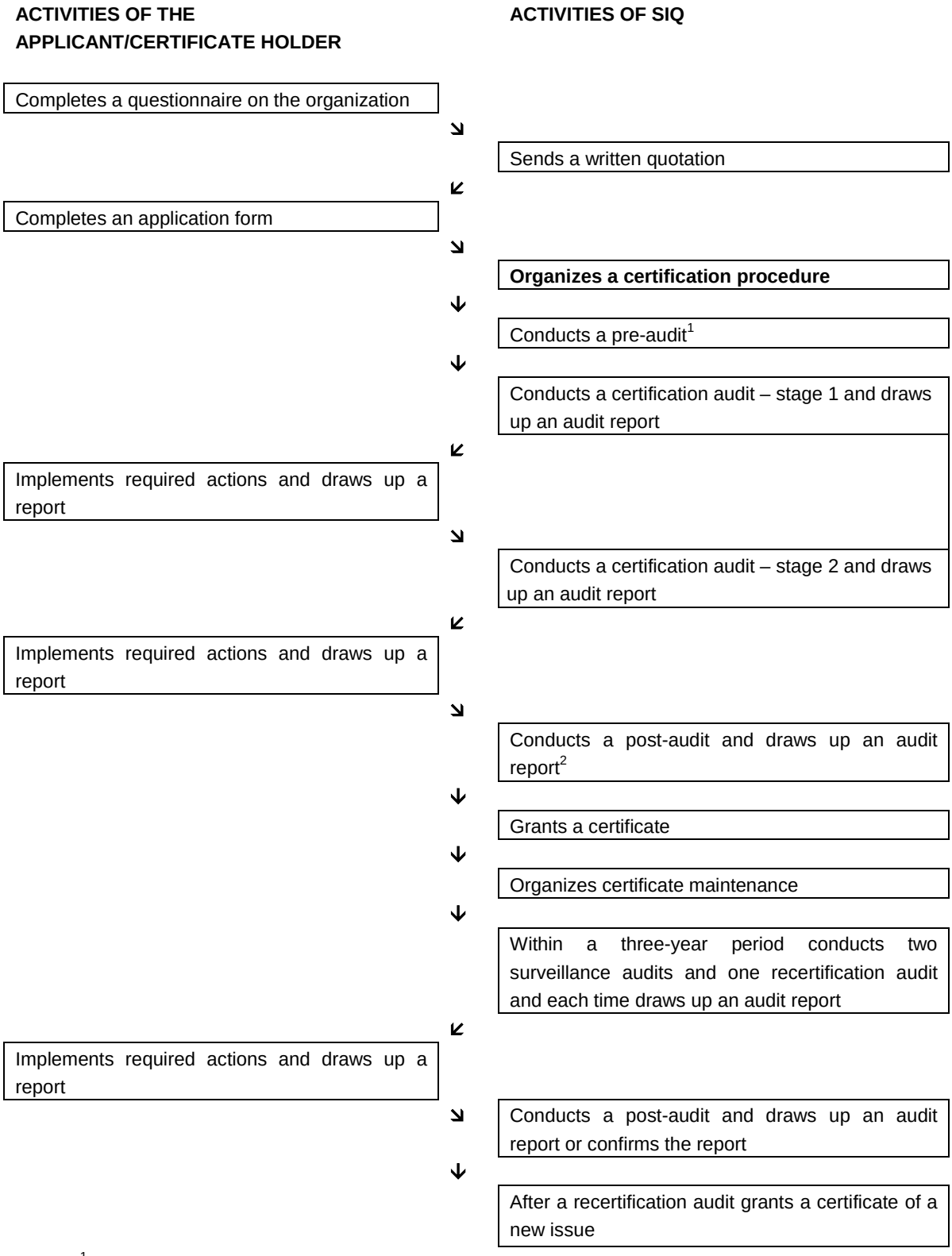
5 CERTIFICATION

A management system **certification** can be conducted:

- independently and concluded with the award of a management system certificate providing evidence of compliance with the requirements of the selected standard or some other reference document;
- as part of a registration procedure at a relevant ministry covering at SIQ an environmental management system assessment to the EMAS Regulation and validation of an environmental statement, but not the award of a certificate.

5.1 Certification and certificate maintenance procedure

The certification and certificate maintenance procedure as well as the activities of the parties involved in the procedure are shown in the following figure:



Notes: [1] conducted upon request by the applicant;
[2] conducted if nonconformities are detected during the audit

5.1.1 Questionnaire on the organization

The potential applicant for certification is made familiar with the certification procedure before the commencement of the procedure. The interested party completes the form “Questionnaire on the organization” (in continuation the Questionnaire) to provide SIQ with the information necessary to draw up a quotation.

5.1.2 Quotation

On the basis of the completed Questionnaire, SIQ defines the scope of work to provide the service and draws up a quotation covering the costs of granting and maintaining of a certificate, including certification fees. The quotation, including the information on the certification procedure and requirements for the award and maintenance of the certificate is sent to the potential applicant. The quotation is not binding

5.1.3 Application

On the basis of the quotation, the interested party applies for certification by completing the form “Application for management system certification” (in continuation the Application), thus becoming the applicant. The Application has the validity of a contract. Upon request by the applicant, a separate contract may be signed. By signing the Application or a contract, the applicants confirm that they are familiar with the procedure and the terms and conditions for the award and maintenance of a certificate.

After signing the Application or a contract, applicants can withdraw from the certification procedure. In this case, they shall cover all expenses that have arisen up to their withdrawal from the certification procedure.

5.1.4 Certification procedure

SIQ appoints an audit team to carry out a certification procedure and informs the applicant of the appointment and audit date. In the case the applicant disagrees with the appointed auditor/s, they shall inform SIQ of their disagreement and justify their decision. If their disagreement is justified/substantiated, SIQ appoints a new auditor/s. When the presence of an observer is needed during an audit (e.g. assessment of an auditor, accreditation audit, etc.), SIQ informs the applicant or/and certificate owner of this requirement prior to the audit; the applicant or/and certificate owner shall enable the observer's presence.

In agreement with the applicant, the audit team leader determines the date of the first visit on the applicant’s location, where, in line with the agreed in the quotation, it conducts the audit in question (e.g. a Pre-audit or a Certification audit – stage 1.)

5.1.5 Pre-audit or the assessment of the status of a management system

A pre-audit or the assessment of the status of a management system is optional, conducted at the applicant’s request. It points at weak elements in the management system that the applicant should eliminate to become as well as possible prepared for a certification audit. The status of a management system can be assessed prior to the receipt of the application for certification.

The scope and content of a pre-audit or the assessment of the status are defined by SIQ in accordance with the applicant’s requirements and needs and laid down in the quotation. A pre-audit may include a management system documentation audit.

The scope of a pre-audit shall not exceed the scope of a certification audit.

To be able to conduct a pre-audit or the assessment of the status, the auditor shall receive from the applicant their management system manual or some other umbrella document and other

required management system documentation. The lead auditor keeps the management system manual or some other umbrella document till the end of the certification procedure. The auditor draws up a written report for the applicant on pre-audit or assessment findings and detected management system weaknesses that need be eliminated.

The number of pre-audits of the same activities at the same auditee is limited to two. The second pre-audit can take place not earlier than 6 months after the first one.

A pre-audit cannot be prequalified into a certification audit.

5.1.6 Certification audit - stage 1

The stage 1 certification audit includes a documentation audit, assessment of the established management system and preparation for the stage 2 certification audit. The stage 1 audit is carried out by a lead auditor at the applicant's premises.

Special features of the stage 1 certification audit are the following:

- in the case of a quality management system in automotive industry, a documentation audit is carried out prior to the stage 1 certification audit and a separate documentation audit report is prepared;
- in the case of a HACCP system (without an established quality management system), Quality in education model, NGO-quality system and the verification of sustainability reports, the stage 1 certification audit includes only a documentation audit carried out by a lead auditor at their own premises;
- in the case of IFS and BRC standards for retailer branded food products and IFS Logistics standard, the stage 1 and stage 2 certification audits are combined.

A documentation audit is carried out in line with the requirements of a particular reference document. Its purpose is to assess the completeness, internal consistency and appropriateness of the documentation relating to the audited management system. As a rule, a manual or some other umbrella document is sufficient for the purpose. If a description provided in the manual or some other umbrella document is too brief, a lead auditor can require additional documents to be audited.

An audit according to the EMAS Regulation includes the evaluation of the integrity of an environmental statement.

The assessment of the established management system depends on the management system audited. As a rule, it covers the evaluation of the performance, appropriateness and understanding of internal audits and a management review, as well as the establishment and implementation of a management system.

The preparation for the stage 2 certification audit includes the identification of premises and procedures to be audited during the stage 2 certification audit and an agreement on the audit plan and schedule.

Audit findings are documented in a form of a written report and communicated to the applicant, including identification of any areas or activities of concern that could be classified as nonconformity during the stage 2 certification audit.

5.1.7 Report on required actions

Before proceeding with the certification procedure, the applicant shall implement actions to resolve areas of concern identified during the stage 1 audit and described in the report on the stage 1 certification audit. The applicant shall draw up a written report on the implemented actions and submit it to SIQ within six months, at the latest.

A lead auditor evaluates the appropriateness of the actions and determines a reasonable date to continue with the stage 2 certification audit, which shall take place within six months from the last day of the stage 1 certification audit. If this deadline is exceeded, the stage 1 certification audit shall be repeated.

5.1.8 Stage 2 certification audit

The purpose of the stage 2 certification audit is to evaluate whether the procedures are documented, established and implemented in line with the requirements of a selected standard or other reference document and whether they are effective. The audit is conducted according to the audit plan prepared by a lead auditor in cooperation with the representative of the applicant during the stage 1 certification audit.

In case of an audit according to EMAS Regulation, the environmental statement, prepared for publication, is validated.

Upon completion of the audit the auditors inform the representatives of the applicant about their findings that will be included in a written report.

If non-conformities were not detected during the audit, the report, including any other necessary documentation and information, is handed over to the Management System Certification Commission for a decision on granting a certificate.

If non-conformities with the requirements of a selected standard or other reference document were found during the audit, the audit report (the conclusion) shall include requirements for actions to be implemented by the applicant.

Non-conformity is non-fulfilment of a requirement (audit criterion): We distinguish:

- **minor non-conformity**, which is an individual encountered deviation from certain requirements (audit criteria) and the achievement of the set objectives or the quality of a product/services are not threatened as a result;
- **major non-conformity**, which is:
  - several minor non-conformities that may lead up to the failure of the system to comply with the laid-down requirements;
  - absence or failure of the system to comply with the laid-down requirements (audit criteria);
  - recurring non-compliance with statutory requirements in combination with inefficient corrective actions; or
  - a state raising considerable doubts about the ability of the management system of the auditee to achieve the set objectives and comply with the determined policy.

The certification audit cannot be prequalified into a pre-audit.

5.1.9 Implementation of actions and reporting

The applicant shall implement appropriate actions to eliminate the non-conformities found during the stage 2 certification audit and to prevent their recurrence. The applicant shall submit to SIQ a report on the implemented actions within six months after the audit, at the latest.

If non-conformities were not found during the audit and a certificate was granted but the audit report included recommendations or other requirements relating to the audited management system, the certificate holder shall act accordingly and submit to SIQ a written report on the consideration of the recommendations and stated requirements within three months after the audit, at the latest.

5.1.10 Post-audit

Upon the receipt of the report on the elimination of non-conformities, a lead auditor carries out a post-audit to check the implemented actions. The post-audit takes place at the site of the applicant or is carried out by a review of the report and the evidence received.

If the lead auditor establishes that the non-conformities were appropriately eliminated, he/she draws up a written report and hands it over, including any other necessary documentation and information, to the Management System Certification Commission for a decision on granting a certificate.

If the lead auditor cannot establish that the non-conformities were eliminated appropriately, he/she records this in a written report. If this is the case, the entire certification audit shall be repeated but not earlier than after six months have passed.

Post-audit is charged separately to the certificate holder/applicant, in relation to extent of the post-audit.

5.1.11 Granting a certificate

The decision to grant a certificate is brought by the Management Systems Certification Commission provided the audit results provide sufficient evidence of the compliance of the management system with all the requirements of a reference document and these Rules. The certificate is issued on the basis of a written decision of the SIQ MSC Commission. A certificate holder is put on the "List of SIQ Certificate Holders", publicly available on the SIQ web page www.siq.si, and on the list of certificate holders of IQNet partners, publicly available on the web page www.iqnet-certification.com. The list includes the name and address of the organization i.e. other registered address, certificate number and scope stated on the certificate.

Upon each new issue of a certificate, a certified organization is entitled to one free copy of an SIQ certificate in an A4 format. If an organization is certified according to ISO 9001, ISO 9001 according to HACCP, ISO 14001, BS OHSAS 18001, ISO 22000, ISO 13485, ISO 50001, ISO/IEC 27001, ISO/IEC 20000-1 standards, IQNet SR- 10, EN 15224, ISO 22301 and ISO/IEC 27018, it is also entitled to a free copy of an IQNet certificate. In cooperation with a lead auditor, the applicant shall provide an English translation of the certification scope on the form for the issue of a certificate. A certificate holder may order additional copies according to the currently valid schedule of fees. A certificate holder has the right to use the SIQ Certification Mark and the IQNet Certification Mark under the conditions described in the instructions that the certified organizations receive together with certification marks and which are published on the SIQ website.

In case of an audit to the EMAS Regulation, the Management System Certification Commission issues a decision on the environmental statement validation and environmental management system verification, providing the basis for the issue of the Environmental verifier's declaration on verification and validation activities. The declaration can be used by the applicant on its environmental statement only. The Commission decides also on validation of environmental information provided.

5.1.12 Certificate maintenance

A certificate holder is responsible for compliance with the requirements for certification and maintenance of a certificate by undergoing annual audits. The first two annual audits after the certification audit are surveillance audits, while in the third year a recertification audit is carried out.

SIQ appoints an audit team to carry out a certification procedure and informs the certificate holder of the appointment and audit date. In the case the certificate holder disagrees with the appointed auditor/s, they shall inform SIQ of their disagreement and justify their decision. If their disagreement is justified/substantiated, SIQ appoints a new auditor/s. When the presence of an observer is needed during an audit (e.g. assessment of an auditor, accreditation audit, etc.), SIQ informs the applicant or/and certificate owner of this requirement prior to the audit; the applicant or/and certificate owner shall enable the observer's presence.

In agreement with the representative of the certificate holder, the audit team leader draws up an audit plan.

The certificate holder obtains from the lead auditor the required audit documentation which is returned by auditors after the audit.

5.1.13 Surveillance and recertification audits

At surveillance audits SIQ checks whether the certificate holder or the holder of a validated environmental statement still meets the requirements of the selected standard or other reference document. They are carried out once a year, the first one eleven months after the certification audit and the rest in the 12-months intervals.

After the audit, the auditors inform the representatives of the applicant of audit findings that will be included in a written report. In the conclusion of the report, the auditors may state requirements to be met by the certificate holder or the holder of the validated environmental statement.

If the certification audit revealed that the system had been established shortly before the certification audit, due to which it was impossible to determine the repeatability of some processes, a post-audit can be conducted between the certification audit and the first surveillance audit.

A surveillance audit can be postponed for a maximum of three months. If an organization wishes to postpone the audit for a longer period of time than three months, a partial audit shall take place in the initially planned month during which a lead auditor shall examine only essential elements of the management system to check its performance. The date of the next audit becomes again the initial audit date (12, 24 or 36 months after the date of a certification or recertification audit). The first surveillance audit after the certification audit may be postponed provided it is implemented within 12 months after the certificate issue date at the latest.

Every third year after the certification audit, a recertification audit is performed to provide comprehensive evaluation of a three-year performance of the management system and its effectiveness, and to assess the adequacy of the audits conducted in that period. Prior to a recertification audit, SIQ checks the audit scope and, where appropriate (in the case of major changes in the organization), defines a new scope of audit activities and a new fee.

If non-conformities are not found during a recertification audit, a new issue of the certificate is granted to the certificate holder. If non-conformities are found during a recertification audit, the certificate holder shall meet the requirements given in the conclusion of the audit report before a new issue of the certificate can be granted to the holder. The compliance with these requirements is checked during a post-audit for which a post-audit report is issued.

If an organization wishes to postpone a recertification audit, a post audit shall take place in the initially planned month in the scope relative to the duration of the postponement. During the post audit, a lead auditor shall review essential elements of a management system to check its implementation. The validity of the current certificate is prolonged for the postponement period. The date of the postponed recertification audit is used to calculate the three-year validity of the new issue of the certificate and to determine the date of the next audit.

Recertification audit has to be planned and carried out in timely manner prior the expiration of the certificate, taking into account the time, necessary for possible action at any nonconformities and decision making of Management systems certification commission.

In case of an audit according to EMAS Regulation, the environmental statement, prepared for publication, is evaluated.

In case of audits to the EMAS Regulation, the Management System Certification Commission issues a decision on validation of the amendments to the environmental statement and environmental information after each surveillance audit and a decision on validation of the entire environmental statement after a recertification audit. During a surveillance or recertification audit, a correct use of the EMAS logo in line with the EMAS Regulation is verified. Should the EMAS logo be improperly used, the EMAS registration body is notified of the violation.

Post-audit is charged separately to the certificate holder, in regard to the scope of post-audit (in accordance to the extent of work performed).

5.1.14 Implementation of actions and reporting

Any non-conformity found during **a surveillance audit** shall be eliminated by the certificate holder within three months and a written report, including relevant evidence, shall be submitted to SIQ.

Any non-conformity found during **a recertification audit** shall be eliminated by the applicant within the period defined by the lead auditor in the conclusion of the audit report and a written report, including relevant evidence, shall be submitted to SIQ.

After each audit, the certificate holder shall submit to SIQ a written report on other issues identified in the audit report. This shall be done within the period defined in the conclusion of the audit report.

5.1.15 Post-audit and partial audit

A post-audit is conducted after **a surveillance audit** if this is required in the conclusion of the audit report. A lead auditor can carry out a post-audit at the site of the certificate holder or by a

review of a report received. If a lead auditor establishes that non-conformities were adequately eliminated, he/she records this in a written report, which is the evidence that the management system is appropriately maintained, on the basis of which the holder's right to the use of the certificate and certification marks is extended.

A post-audit is conducted after **a recertification audit** whenever nonconformities are found during the audit. If a lead auditor establishes that non-conformities were adequately eliminated, he/she records this in a written report on the basis of which the holder receives a new issue of the certificate for the following certification period.

Save where required in the conclusion of the report of a previous audit, a post-audit can also be conducted in the following cases: if a certificate holder wants to postpone the audit date; if a certificate holder is late with his reply to the audit report or its contents are unacceptable; if a certificate holder applies for the modification of the scope of certification; if significant changes occurred at the certificate holder due to which an audit is necessary; to investigate whether the appeals or complaints filed by an applicant/certificate holder against SIQ are justified; and when the client of a certificate holder files a complaint against the certificate holder's management system.

If a post-audit lead auditor determines that nonconformities were not adequately eliminated or that requirements from a previous audit were not adequately considered, he/she records this in a written report and submits it to the Management System Certification Commission for decision on the holder's further right to the certificate and certification marks.

An ISO 13485 post-audit is, in addition to stated, conducted also if certification body receives the information, that the data from post-marketing medical device follow-up shows defectiveness in the quality management system or other information, related to security, is gained, or due to significant regulatory changes, which may affect the compliance of the quality management system.

Post-audit is charged separately to the certificate holder, in regard to the scope of post-audit (in accordance to the extent of work performed).

A partial audit is conducted if an organization wants to postpone a surveillance audit for over three months but does not want to postpone its regular audit date. The scope of a partial audit corresponds to the postponement period.

5.1.16 Transition audit

Transition audit is performed in example of new edition of standard, usually together with surveillance or recertification audit. The scope of transition audit is determined in accordance with the guidelines for transition to the new edition of the standard. SIQ informs the certificate holder about the scope and price of transition audit.

5.1.17 Suspension of an audit

In the case of a non-conformity being found due to which the granting of a certificate will not be possible, the lead auditor shall immediately bring the matter to the attention of the auditee's contact person. If he/she deems it reasonable, the lead auditor may propose to suspend the audit, but in order to do so he/she shall obtain the written consent of the auditee's contact person. In the case of an audit being suspended, SIQ shall also be informed immediately.

If the life or health of auditors, employees or third persons is directly threatened as a result of risks ensuing from the processes audited, the lead auditor shall suspend the audit. The lead auditor shall inform the management of the audited organisation and of SIQ of the reasons underlying the suspension in writing.

After the suspension of an audit, the audit can only be resumed if the causes for the suspension have been eliminated.

6 CERTIFICATE AND CERTIFICATION MARKS

6.1 Validity of the certificate

SIQ certificate or any other relevant document states that the client has established and adequately maintains the management system in accordance with the requirements of the selected standard or other reference document stated in the certificate.

As a rule, the certificate is issued for the period of three years. The validity date is stated on the certificate. During the certificate validity period, the certificate holder shall meet the requirements of the selected standard or other relevant document and this document. Information on the valid certificates is publicly available on the SIQ web page www.siq.si. Information on invalid certificates can be obtained from SIQ upon request by the interested parties.

A validated environmental statement or its amendment or other information provided is valid for the period of twelve months.

The certificate applies only to the certified organization stated on the certificate and the scope stated therein.

6.2 Reference to the issued certificate

Appealing to the issued certificate is allowed only:

- with the name of the certified company;
- with the certificate registration number;
- with reference to the reference management system standard;
- with the stating of the scope of certification / the field of certificate validity – when only part of the organization is subjected to certification;
- by the legal first owner of the certificate;
- within the period of validity of the certificate;
- in letters, offers, informative materials, general documents of the holder, and in advertising media.

When referring to the issued certificate, the holder of the certificate shall ensure that the certificate is not being mentioned in relation to the activities which have not been certified or in the way to provide incorrect impression of products being certified.

6.3 Use of the certification mark

6.3.1 Use of the certification mark bearing the SIQ logo

The use of the certification mark is explained in the instructions available for certificate holders at the SIQ's web-site.

6.3.2 Use of the Quality in Education model certification mark and flag

The use of the certification mark is explained in the instructions available for certificate holders at the SIQ's web-site.

6.3.3 Use of the IQNet certification mark

The use of the certification mark is explained in the instructions available for certificate holders at the SIQ's web-site.

6.3.4 Use of the EMAS mark

The EMAS mark shall be used in line with Article 8 of Regulations EC 1221:2009.

6.3.5 Use of the NGO certification mark

The use of the certification mark is explained in the instructions available for certificate holders at the SIQ's web-site.

7 OBLIGATIONS OF APPLICANTS AND/OR CERTIFICATE HOLDERS

7.1 Availability of information

The applicant / holder of a certificate or other relevant certification document shall immediately inform SIQ of any changes which are in any way related to the scope of certification or to the validity of some other relevant document, e.g. changes of ownership, legal status, the name and/or address of the company, status of the company (e.g. bankruptcy, insolvency), and/or changes in the organization of the company (changes in management and contact persons, number of employees, additional changes of activities and changes related to locations etc.). In case the organization changes the environmental statement, confirmed by SIQ, it has to be resend for a review.

Prior to a surveillance or recertification audit, the certificate holder shall inform SIQ of the changes made in the management system and pertinent documentation. Based on the notified changes, SIQ determines a new scope of activities and a new price, accordingly.

The applicant/certificate holder is bound to openly inform the auditors of any issue that can be of importance to the audit. They shall facilitate the audit by ensuring that the responsible personnel are available to the auditors to provide them with the necessary information. They shall prepare the required documentation and any other evidence to ensure unimpeded auditing. The applicant/certificate holder is bound to provide safe and healthy working conditions for the audit team.

The applicant/holder of a certificate shall provide the management system documentation required for the performance of the certification procedure activities upon request expressed by SIQ.

The applicant/certificate holder shall keep records on complaints, visits by the authorities, customers' findings (e.g. audit reports by customers) as well as records on corrective actions. The auditors shall have access to these documents when conducting the audit. The applicant/certificate holder shall also keep previous issues of the manual and responses to audit findings that were submitted to SIQ to prove that the findings had been taken into consideration or nonconformities had been eliminated.

The applicant/certificate holder shall enable the auditors to conduct the audit at the organizations providing outsourced services affecting the compliance of the product with the relevant requirements or the effectiveness of the audited management system.

The certificate holder shall allow a recertification audit and shall eliminate nonconformities within the period required by SIQ or the lead auditor due to the fact that a new issue of the certificate can be granted only after a recertification audit has been successfully completed.

7.2 Reciprocity

The applicant/holders of the SIQ certificate declare that they will recognize SIQ certificates held by other companies. However, they are not obliged to forgo their own additional criteria or to conduct a post-audit of the certificate holder's management system if they have strong reasons for doing so.

The applicant/holders also declare that they will recognize certificates of IQNet partners.

The certificate holders are bound to be morally and materially concerned for the good reputation of SIQ as well as of SIQ certificates and certification marks.

7.3 Expenses

The applicant/certificate holder shall cover all costs related to the certification procedure and maintenance of certification, as defined in the quotation/contract, as well as cost of post-audits or new issues of certificates due to organizational changes (change of organization title or headquarters). In case of organizational changes (number of employees, additional activities, number of locations etc.) and changes in accreditation standards, SIQ reserves the right to determine a new price for the changed scope of activities in line with the valid SIQ list of fees.

Except in the event of force majeure, the applicant/certificate holder shall cover all costs that have arisen up to the postponement or cancellation of an audit upon the applicant/certificate holder's request less than seven days before the agreed audit date (organization of the audit, preparation of an audit programme, availability of the audit team, potential travel costs).

8 CANCELLATION OF THE CERTIFICATE

8.1 Purpose

As a rule, the validity of a management system certificate is three years.

By cancellation of a certificate or other relevant document, SIQ wishes to prevent potential mistrust in SIQ certificates and SIQ certificate holders in cases, when the requirements of these Rules are not fulfilled, or as stated below.

8.2 Grounds for cancellation

As a rule, a cancellation of a certificate is the result of infringements of the provisions of these Rules. The following reasons in particular result in cancellation of the certificate:

- declaration of insolvency or ceasing operations;
- use of the certificate and the certification mark as proof of fulfilment of the requirements of other standards which were not the basis for certification, or their use for other, uncertified business branches, etc.;
- incomplete or false information given at any kind of audit performed;
- concealment of significant changes in the management system or the company status;
- failure to implement the required corrective actions;
- failure to fulfil financial obligations;
- a written requirement of a company;
- failure to conduct a recertification audit before the expiry date of the certificate or failure to conduct a surveillance audit within 12 or 15 months from the date of the last conducted audit.

The Management Systems Certification Commission can decide on the cancellation of the certificate also in the case of a juridical decree against the certificate holder.

8.3 Procedure

The Management Systems Certification Commission makes its decision on the cancellation of a certificate on the basis of a proposal submitted by the MSA director. The certificate may be cancelled immediately, or the certificate holder is given a time limit (up to three months) by which the certificate holder shall implement adequate corrective actions.

Due to the cancellation of the SIQ certificate, the certificate holder is removed from the list of certificate holders published on web pages of SIQ and IQNet. The certificate holder is then put on the list of cancelled certificates available to interested parties at SIQ. In addition, the certificate holder is asked to make corrections to all documents bearing reference to the SIQ certificate for the management system.

9 HANDLING COMPLAINTS AND APPEALS, AND RESPONSIBILITY OF SIQ

9.1 Complaints-handling and appeals-handling processes

The applicant/certificate holder has the right to file a complaint against the work of SIQ or to file an appeal against the decision of the Management System Certification Commission.

Complaints against the work of SIQ are examined at first instance by the MSA director who informs the complainant about the receipt of the complaint and the decision, in writing. The complainant can file an appeal against the MSA director's decision to the Appeals Commission which is a body of second instance. Its decisions are final.

Complaints against the certificate holder's management system can be filed in writing by anybody and are subject to the same procedure as complaints against the work of SIQ. The complainant and the certificate holder are kept informed about the receipt of the complaint, on-going procedure and its outcome.

An appeal against the Management System Certification Commission's decision shall be filed by the appellant in writing within 15 days after the receipt of the decision. The appellant shall document the appeal appropriately. The appeal is examined by the Appeals Commission. Its decisions are final. The appellant is informed in writing about the receipt, progress and decision of the appeal.

If a complaint or an appeal is justified, the MSA director shall see to it that the reasons for the complaint/appeal are eliminated.

The appeals procedure is specified in detail in document CR105 and published on SIQ website. All other disputes fall within the competence of the Court of proper jurisdiction over the subject matter in Ljubljana. The currently valid legislation of the Republic of Slovenia is used for ruling in all relations.

9.2 Responsibility of SIQ

SIQ is not liable if a third party does not recognize the certificate issued by SIQ, or recognizes it only partially, nor is liable for damage claims by customers of the certificate holder if the customer's expectations regarding the quality have not been met.

SIQ does not accept a customer's product/service liability or liability for property damage.

SIQ holds a professional liability insurance policy, covering any damage that may occur as the consequence of faults, omissions or breaches while performing the registered activity either by its employees or its subcontractors. The insurance amount is 1.400.000 EUR.

10 FINAL PROVISIONS

A valid issue of the Rules for Management System Certification is enclosed to a quotation for the provision of services sent to the interested party.

SIQ reserves the right to modify the Rules for Management System Certification if changes are introduced to the standards or other reference documents, or guides and guidelines applicable to management system certification bodies, as well as upon request by bodies supervising the work of SIQ (accreditation bodies and IQNet), and due to changes in the organization or operation of SIQ. A valid issue of the Rules is published on the SIQ web page www.siq.si. If the applicant/certificate holder does not object to these modifications prior to the first next audit of their system, it shall be deemed that they accept them.

For settling other disputes, the relevant Court of Ljubljana is competent, unless agreed otherwise by a contract. The valid legislation of the Republic of Slovenia is applicable in all relations.