Description of the certification process

ISO 9001, ISO 14001, ISO 29001, ISO 45001, ISO 50001, ISO 37001, ISO 37301, ISO 55001, ISO 56001, SCC/SCP, ISO 13485, ISO 19443, ISO 21001

The certification process of a management system according to ISO 9001, ISO 14001, ISO 29001, ISO 45001, ISO 50001, SCC-VAZ, ISO 37001, ISO 37301, ISO 55001, ISO 56001, ISO 13485, ISO 19443 or ISO 21001 consists of an initial certification, surveillance and recertification.

1. INITIAL CERTIFICATION AUDIT

The initial certification audit of a management system shall be conducted in two stages: stage 1 and stage 2. Both audits are conducted on site at the client's site.

1.1. Audit preparation

After the certification agreement is signed, the auditor plans the audit.

1.2. Stage 1

Objectives of stage 1:

- review of the client's management system documentation,
- evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2,
- review the client's status and understanding regarding requirements of the standard, with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system,
- obtain necessary information regarding the scope of the management system, the client's processes and site(s), compliance obligations, as well as the quality, environmental, energy, and occupational health and safety aspects/risks,
- planning of stage 2,
- evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2,
- evaluate if the OH&S management system according to SCC-VAZ is in force for three months.

If areas of concern are identified in stage 1, the client shall resolve these prior to stage 2.

Unless it cannot be positively assessed after stage 1 that the customer is ready for stage 2, the certification is terminated.

The lead auditor shall provide an audit report (stage 1) and additional records (e.g. audit questionnaire and handwritten notes).

The lead auditor is responsible for the proper conducting of stage 1 and communication concerning audit team members.

1.3. Stage 2

The audit plan of stage 2 shall be communicated and the dates of the audit shall be agreed upon, in advance, with the client.

The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's management system. This is based on the standards ISO 9001, ISO 14001, ISO 29001, ISO 45001, SCC-VAZ, ISO 37001, ISO 37301, ISO 50001, ISO 13485, ISO 55001, ISO 56001, ISO 19443, ISO 21001. This can be achieved by interviews of employees, verifying relevant information during the audit and auditing relevant processes and areas of the organization.

A formal closing meeting, where attendance shall be recorded, shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting is to present the audit conclusions, including the recommendation regarding certification. Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed

The lead auditor shall provide an audit report (stage 2) and additional records (e.g. audit questionnaire and handwritten notes) or objective evidence. The audit report is sent to the client.

1.4 Issue of certificate

The certification body shall review prior to making a certification decision that the information provided by the audit team is sufficient and the correction and corrective actions for any nonconformities are accepted.

Based on the certification decision the certificate is issued.

2. SURVEILLANCE AUDITS

During preparation of the surveillance audits, the client is obliged to inform the certification body of any major changes to the management system and processes.

Within the period of validity of the certificate (3 years) surveillance audits shall be conducted at least once per calendar year, except for the years in which a recertification audit is conducted.

The first surveillance audit following the initial certification must be conducted by the planning-relevant date, at the latest 12 months after the date of the certification decision. All subsequent surveillance audits are scheduled based on the planning-relevant date and must be conducted at least once per calendar year.

After the surveillance audit, the audit report is sent to the client.

3. RECERTIFICATION AUDIT

During preparation of the recertification audit, the client is obliged to inform the certification body of any major changes to the management system and processes

The recertification audit, the verification of corrective actions and the certification decision shall be completed prior to the expiry date of the current certificate.

The recertification audit shall include an on-site audit that addresses the effectiveness of the management system and the results of the previous audit program. All standard requirements shall be audited.

Activities related to re-certification audits may require a stage 1 audit if there are significant changes in the management system or in the context of the company's activities (e.g. changes in compliance obligations).

The audit methodology for the recertification audit is equivalent to the methodology of stage 2.

4. EXTENSION AUDIT

If it is intended to extend the scope of an existing certificate, this may be conducted in conjunction with an extension audit. An extension audit can be conducted within the framework of a surveillance audit, a recertification audit or a separate audit.

The validity of a current certificate will not change.

5. SHORT-NOTICE OR UNANNOUNCED AUDITS

It may be necessary to conduct short notice announced or unannounced audits, for example, to investigate complaints or serious incidents, because of changes, or as a result of suspended certifications. In such cases, the certification body shall the conditions under which such audits will be conducted.

6. TRANSFER OF CERTIFICATIONES FROM OTHER CERTIFICATION BODIES

Only valid accredited management system certifications may be transferred.

The issuing certification body is informed about the planned transfer. As soon as no reasons are known from the issuing certification body and the customer that exclude a transfer of the valid certificate according to IAF MD 2, the transfer can be carried out.

A "pre-transfer review" shall be conducted by a competent auditor. This review shall be conducted by means of a documentation review and, if necessary (e.g. outstanding major nonconformities), shall include a pre-transfer visit at the site of the client.

Once the pre-transfer review has been positively completed, TN CERT or the TN subsidiary, in the function as the accepting certification body, can transfer the certification and plan the audit programme.

The certification cycle of the transferred certification shall be based on the previous certification cycle.

Where the pre-transfer review identifies issues that prevent the completion of transfer, TN CERT shall conduct an initial certification.

Certifications which are known to be suspended shall not be accepted for transfer.

The issuing certification body is informed as soon as the certification has been successfully transferred.

7. CERTIFICATION OF MULTI-SITE ORGANIZATIONS

Auditing of organizations with a number of sites (multi-site organizations) may be conducted using site sampling.

A multi-site organization need not be a unique legal entity, but all sites shall have a legal or contractual link with the central function (see below) of the organization and be subject to a single management system, which is laid down, established and subject to continuous surveillance by management review and internal audits by the central function. This means that the central function has rights to require that the sites implement corrective actions when needed in any site. Where applicable this should be set out in the formal agreement between the central function and the sites.

Eligibility of a multi-site organization for certification

- Single management controlled by the central function.
- Very similar processes/activities at the sites.
- The central function shall have organizational authority to define, establish and maintain the single management system.
- Similar processes/activities across all sites.
- 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:
  - system documentation and system changes,
  - management review,
  - complaints,
  - evaluation of corrective actions,
  - internal audit planning and evaluation of the results, and
  - statutory and regulatory requirements pertaining to the applicable standard(s).

8. MANAGEMENT OF NONCONFORMITIES

The client shall analyse the cause of each nonconformity and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate stated nonconformities, within a defined time. The root cause analysis, corrective actions with action plan and, if necessary, objective evidence, shall be submitted by the client within six weeks following the last day of the audit. If the nonconformities are not closed within the specified time, no certificate can be issued, or an existing certificate is withdrawn.

9. ADDITIONAL REQUIREMENTS FOR CERTIFICATION ACCORDING TO ISO 19443

The defined time for analyzing the causes of nonconformities and determining corrective actions by the audited organization shall be no more than 45 calendar days from the end of the on-site audit.

When the nature of the nonconformity needs immediate containment action, the audit team leader shall require the organization to

- describe the immediate actions ('fix now' actions) taken to contain the nonconforming situation/conditions and to control any identified nonconforming products (correction shall always be recorded),
- report within 7 calendar days, after the audit, the specific containment actions, including correction, and reach agreement on those actions with the audit team leader within the next 14 calendar days.