Description of the certification procedure
MS DIN EN ISO 15378

Certification

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Do you have questions about this service description? We will be happy to assist you further.

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The management system certification procedure on the basis of **DIN EN ISO 15378** comprises the proposal and contracting phase, the preparation of the audit, the performance of the stage 1 audit incl. an assessment of the management documentation, the performance of the stage 2 audit, issue of the certificate and the surveillance/recertification regime.

The auditors are selected by the director of the TÜV NORD CERT GmbH certification body on the basis of their qualification and accreditation for the respective industry.

1 CERTIFICATION PROCEDURE

The certification audit is comprised of the stage 1 audit and the stage 2 audit. Both audits will generally be carried out on the client's premises.

1.1 Audit preparation

After the audit agreement is signed, the auditor will prepare the audit using the stakeholder questionnaire and the calculation sheet and determine the further course of action together with the company.

The company is required to notify the certification body of any significant changes in their structural and workflow organisation occurring during the preparation for the surveillance and/or recertification audit.

1.2 Stage 1 audit

The stage 1 audit is carried out with the following objectives:

- to audit the customer's management system documentation,
- to assess the site and site-specific conditions of the customer and to discuss the question of readiness for the stage 2 audit with the customer's personnel,
- to assess the customer's current status and understanding with regard to the requirements imposed by the standard, particularly with regard to the identification of key performances and/or significant aspects, processes, objectives and the operation of the management system,
- to collect necessary information with regard to the scope of the management system, the processes and site(s) of the customer, compelling obligations, as well as aspects pertaining to quality, environmental, energy and occupational safety,
- to evaluate the allocation of resources for stage 2 audits and to coordinate the particulars of the stage 2 audits with the customer,
- to establish a focus area for planning the stage 2 audit on the basis of an adequate understanding of the customer's management system, the activities at the respective site and any other potentially significant aspects,

- to assess whether the internal audits and management reviews are scheduled and carried out, whether the achieved implementation of the management system is documented and whether the customer is ready for the stage 2 audit.

Any vulnerabilities identified during the stage 1 audit shall be rectified by the customer prior to the stage 2 audit.

If it cannot be positively confirmed that the customer is ready for the stage 2 audit, the certification procedure will be terminated after the stage 1 audit.

The lead auditor is responsible for coordinating the activities of the stage 1 audit and any potentially necessary coordination between the involved auditors.

1.3 Stage 2 audit - Certification audit

The customer will be presented with an agreed audit plan at the beginning of the level 2 audit.

The audit begins with an introductory meeting, at which the participants introduce themselves. The activities that will be performed during the audit will be explained. The auditors will review and assess the effectiveness of the management system implemented by the company during their on-site audit activities. This review and assessment will be based on **DIN EN ISO 15378.**

The auditors are responsible for reviewing the practical application of the management system with the documented processes and to assess its conformity with the requirements of the standard. This will be achieved by surveying employees, reviewing applicable documents, records, orders and guidelines, as well as by the physical inspection of relevant areas.

The on-site audit will be concluded by a final meeting. At least the employees who hold management functions within the organisation and whose areas were included in the audit will attend the meeting. The lead auditor will present his report about the individual elements and explain the positive and negative findings of the audit. In the event the audit assessed any non-conformities, the lead auditor will only be able to recommend the issue of a certificate after acceptance and/or verification of the respective corrective measures by the audit team (in this respect see section 7. “Management of non-conformities”). This issue will be pointed out in the final meeting.

The documentation will take place in the audit report (separately for the stage 1 audit and stage 2 audit) and will be supplemented by additional records (e.g.: audit questionnaire and handwritten notes).

1.4 Issue of certificate

The certificate will be issued by the director of the certification body, his deputy or a designated person upon a positive review of the certification procedure. The reviewer must not have been involved in the auditing activities.

The certificate can only be issued once all non-conformities have been rectified, i.e. after the corrective measures have been accepted and/or verified by the audit team.

Certificates are generally valid for a period of three years.

2 SURVEILLANCE AUDIT

Surveillance audits must be carried out annually over the validity period of the certificate, with the exception of the years in which a re-certification audit takes place.

The first surveillance audit after the initial certification must be carried out by the prescribed date, i.e. at the latest 12 months after the date of the certification decision. All subsequent surveillance audits will be scheduled on the basis of the prescribed date and must be carried out at least once in each calendar year.

Each surveillance audit, including the review, acceptance and potentially necessary verification of corrective measures for non-conformities, the preparation of the audit report and approval by the certification body must be completed by no later than three months (or four months in the case of non-conformities) after the last day of the on-site audit.

The customer will be presented with a report at the end of the surveillance audit.

3 RECERTIFICATION AUDIT

The recertification audit must be carried out prior to the expiry date stated on the certificate. A grace period of six months is allowed for the evaluation of corrective measures and potentially necessary post-audits, as well as for the decision concerning a recertification within the approval procedure. The recertification audit comprises a review of the company's management system documentation and an on-site audit, which will give consideration to the results of the activities carried out under the surveillance regime over the validity period of the certification. All requirements imposed by the standard will be audited.

Activities associated with recertification audits might require a stage 1 audit to be carried out if there were any significant changes in the management system or in relation to the company's activities (e.g.: changes in the law).

The auditing methodology used in the recertification audit corresponds to the methodology used for a stage 2 audit.

4 EXTENSION AUDIT

Customers who wish to extend the scope of an existing certificate may do so by requesting an extension audit. Extension audits may be carried out separately on an agreed date, or during the course of a surveillance or recertification audit.

This will not change the validity period stated on the certificate. Any exceptions must be justified in writing.

4.1 Audits on short notice

It is sometimes necessary to carry out audits on short notice, e.g. to investigate complaints, in response to changes or as a consequence of a suspended certification. In these cases,

- the certification body will determine the conditions under which these on-site inspections on short notice are to be carried out;
- there is no right to object against any members of the audit team.

5 TAKEOVER OF CERTIFICATIONS ISSUED BY OTHER CERTIFICATION BODIES

As a general rule, only certificates issued by accredited certification bodies are eligible for a certification transfer. The accrediting body must be a signatory to the Multilateral Agreements by EA (European Cooperation for Accreditation). Companies with certificates issued by non-accredited certification bodies shall be treated as new customers.

A skilled person of the accepting certification body shall carry out a “pre-transfer review”, which consists of a review of important documents and, if necessary, a visit to the customer.

Suspended certificates or certificates at risk of suspension are not eligible for a certification transfer.

The further surveillance and recertification regime will be based on the previous one.

6 CERTIFICATION OF COMPANIES WITH MULTIPLE SITES

The random sampling procedure (“multi-site certification”) may be used for the certification of organisations with multiple sites. In these cases, the customer warrants that all locations covered by the scope of the certificate satisfy the conditions set out below. The certification body must promptly be notified of any change in circumstances or failure to satisfy one or a number of conditions.

Conditions for a multi-site certification:

An organisation with multiple sites does not necessarily have to be a single legal entity. It is, however, required that all sites are in a legal or contractual relationship with the organisation's head office and are subject to a common management system that is specified and implemented by the organisation’s head office and subject to a regime of regular surveillance and internal audits carried out by the organisation’s head office. This means that the head office has the right to instruct the individual sites to implement any corrective measure that is required at the respective site.

- The processes must be essentially similar at all sites and be carried out with similar methods and techniques.
- The management system of the organisation must be centrally managed on the basis of a centrally coordinated plan and be subjected to a centrally conducted management review. All

associated sites (including the central administration function) must be subjected to the organisation's internal audit regime and be audited in compliance with this regime.

- It must be demonstrated that the organisation’s head office has implemented a management system in compliance with the audited management system standard, and that the entire organisation satisfies the requirements of this standard.
- The organisation must evidence its capability of collecting and analysing data from all sites, including the central administrative function and its management, and arrange for the implementation of any necessary organisational changes:
  - management review,
  - complaints,
  - evaluation of corrective measures,
  - planning of internal audits and assessment of audit findings,
  - statutory requirements.

- Signing of an agreement between client and certification body that is legally enforceable at all branches/production sites of the company.

7 MANAGEMENT OF NON-CONFORMITIES

The company must analyse the causes of each individual non-conformity assessed by the audit and implement adequate corrective measures. Depending on the severity of the non-conformity assessed, the company must within 6 weeks from the last day of the audit inform the audit team about the corrective measures and target dates determined by it, or about the implementation of the corrective measures. The audit will be assessed as failed if this period is not adhered to. This means that a certificate cannot be issued, or that the certificate will be cancelled.