TUVNORD

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If you should require any further information then please do not hesitate to contact us. We will be please to help you.

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DESCRIPTION OF THE EN ISO 15378 PROCEDURE

The management system certification procedure on the basis of 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 consists of the Stage 1 audit and the Stage 2 audit. Both audits are generally performed at the client's site.

1.1. Audit Preparation

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Following signing of the contract, the auditor prepares for the audit based on the questionnaire filled in by the customer and on the calculation sheet, and discusses and agrees the further procedure with the organization to be audited.

During preparation for the surveillance or recertification audit, the organizations to be audited have the duty to report fundamental changes in their organisational structure or changes in procedure to the certification body.

1.2. Audit Stage 1

The Stage 1 audit is conducted in order to

- audit the management system documentation of the customer,
- assess the site and site-specific conditions of the customer and hold discussions with the personnel of the organization in order to determine the degree of preparedness for the Stage 2 audit,
- assess the status of the customer and his understanding of the requirements of the standards, particularly with regard to identification of key performance or significant aspects, processes, objectives and operation of the management system,
- to collect necessary information regarding the scope of the management system, processes and location(s) of the client, compliance obligations as well as quality, environmental, energy, health and safety aspects and bribery risks,
- review the allocation of resources for Stage 2 audit and agree with the client on the details of the Stage 2 audit,
- to create a special focus for the planning of the Stage 2 audit, by gaining sufficient understanding of the client's management system and the activities at the site, together with possible significant aspects,
- evaluate if the internal audits and management review are both planned and performed, and that the level of implementation of the management system demonstrates that the client is ready for the Stage 2 audit,

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If weaknesses were identified in the Stage 1 audit, these must be corrected by the customer before the Stage 2 audit.

If at the end it cannot be established positively that the customer is ready for the Stage 2 audit, the audit is broken off after the Stage 1 audit.

The lead auditor is responsible for the coordination of the activities of the stage 1 audit and if necessary for coordination and cooperation of the auditors concerned amongst themselves.

1.3. Audit Stage 2 – Certification Audit

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The customer receives an audit plan at the beginning of the Stage 2 audit. The plan is agreed with the customer in advance.

The audit begins with a kick-off meeting, in which the participants are introduced to each other. The procedure to be followed in the audit is explained. Within the framework of the audit at the organization's premises, the auditors review and assess the effectiveness of the management system which has been installed. This is based on the standards EN ISO 15378.

The task of the auditors is to compare the practical application of the management system with the documented processes and to assess them in relation to fulfilment of the requirements of the standard. This is achieved by means of questioning of the employees, examining the relevant documents, records, orders and guidelines and also by visiting relevant areas of the organization.

A final meeting takes place at the end of the on-site audit. At least those employees take part in the audit who have management functions within the organization and whose areas were included in the audit. The lead auditor reports on the individual elements and explains the positive and negative results. If nonconformities are established, the lead auditor can only recommend issue of the certificate to the organization after acceptance or verification of the corrective actions by the audit team, see Section 8 "Management of nonconformities". Attention must be drawn to this fact in the final meeting.

The audit is documented in the audit report (the documentation must be separate for Stage 1 and Stage 2 audits) and is completed by means

1.4. Award of Certificate

The certificate is issued when the certification procedure has been reviewed and released by the head of the certification body or his deputy or nominated representative. The person who reviews and releases the procedure may not (i.e. is not permitted to) have participated in the audit.

The certificate can only be issued when the nonconformities have been corrected, i.e. when the corrective actions have been accepted or verified by the audit team.

Normally the certificates are valid for 3 years.

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2. SURVEILLANCE AUDIT

Surveillance audits must be conducted once per year during the period of validity of the certificate with the exception of the years when a recertification audit is performed.

The first surveillance audit which follows the initial certification has to be carried out by the planningrelevant date, at the latest 12 months after the date of the certification decision. All the subsequent surveillance audits are planned on the basis of the planning-relevant date and must be conducted at least once per calendar year.

Surveillance audits including the verification of measures for the correction of nonconformities, audit reporting and the certification decision must be completed no later than 3 or 4 months (in case of nonconformities) from the last day of the audit.

The client receives a report following the surveillance audit.

3. RECERTIFICATION AUDIT

The audit for recertification has to be conducted before the expiry date of the certificate. A tolerance period of max. 6 months is then available for evaluation of the corrective actions and for any necessary re-audits and also for the decision on recertification within the framework of the release procedure. In the recertification audit, a review of the documentation of the management system of the organization is undertaken, as well as an on-site audit. Here, the results of the previous surveillance programme(s) over the term of the certification have to be taken into consideration. All the requirements of the standard are audited.

Activities related to the recertification audit may include a stage 1 audit if there are significant changes in the management system or in connection with the activities of the organization (e.g. changes to the law).

The audit methods used in the recertification audit correspond to those used in a Stage 2 audit.

4. EXTENSION OF SCOPE AUDIT

If it is intended to extend the scope of an existing certificate, this can be implemented by means of an extension audit. An extension audit can be conducted within the framework of a surveillance audit, a recertification audit or at a time which is set independently.

The period of validity of a certificate does not change as a result. Exceptions must be justified in writing.

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5. SHORT NOTICE AUDITS

It may be necessary to perform audits at short notice to investigate complaints, in response to changes or as follow up on suspended clients.

In such cases,

- the certification body shall describe the conditions under which these short notice audits are to be conducted,
- it is not possible to object to members of the audit team.

6. TRANSFER OF CERTIFICATION FROM OTHER CERTIFICATION BODIES

In general, only certificates from accredited certification bodies can be taken over where the accreditation body is a signatory to the Multilateral Agreement (MLA) of the EA (European co-operation for Accreditation). Organizations with certificates which originate from non-accredited certification bodies are treated as new clients.

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 2:2017, the transfer can be carried out.

A "Pre-Transfer-Review" must be conducted by a competent person from the certification body which is taking over the certificate. This review generally consists of an examination of important documents and a visit to the client.

After positive completion of the pre-transfer review, TÜV NORD CERT, as the accepting certification body, can carry out the transfer of certification.

The normal certification decision making process shall be followed, including the requirement that the personnel making the certification decision are different from those carrying out the pre-transfer review.

TÜV NORD CERT, as the accepting certification body, shall take the decision on certification before any surveillance or recertification audits are initiated.

The certification cycle of the transferred certificate is based on the previous one. TÜV NORD CERT shall establish the audit programme for the remainder of the certification cycle.

Where the accepting certification body is required to treat the client as a new client as a result of the pretransfer review, the certification cycle shall begin with the certification decision.

Certificates which have been suspended, or where there is risk of suspension, may not be taken over.

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

7. CERTIFICATION OF COMPANIES WITH MULTIPLE LOCATIONS (MULTI-SITE)

A sampling procedure can be used for organizations with several sites ("multisite certification"). In this case, the client assures the certification body that the following requirements are met for all the sites which fall within the scope of the certificate. Any changes or non-fulfilment of one or several prerequisites shall (i.e. must) be communicated to the certification body immediately.

Prerequisites for multisite certification:

A multi-site organization does not have to be one single legal entity. However, all the sites shall (i.e. must) have a legal or contractual relationship with the headquarters ("central office") of the organization and be subject to a common management system, which is specified and installed by the central office and is subject to regular monitoring and internal audits by the central office. This means that the central office has the right to require the sites to implement corrective actions, if these are necessary at a particular site.

- The processes must be basically the same at all sites and must be implemented using similar methods and procedures.
- The management system of the organization must be administered under a centrally controlled plan and must be subject to a central management review. All the individual sites within the multi-site system (including the central administration (central office) function must be subject to the internal audit programme of the organization and must be audited in compliance with this programme.
- It must be demonstrated that the central office of the organisation has installed a management system in compliance with the relevant management system standard(s) which form the basis for the audit and that the entire organization fulfils the requirements of the standard.
- The organization must demonstrate its ability to collect and analyse data from all sites, including the central administration function (central office) and its management, and shall instigate any necessary organizational changes, including those related to:
 - Management review,
 - Complaints,
 - Evaluation of the corrective actions,
 - Planning of internal audits and evaluation of the results,
 - Legal requirements.
- A contract must be concluded between the client and the certification body which is legally enforceable at all branches/production sites.

8. MANAGEMENT OF NON-CONFORMITIES

An analysis of the causes must be performed for each nonconformity and corresponding corrective actions must be implemented. The organization has the duty, depending on the seriousness of the nonconformity, to inform the audit team within 6 weeks after the last day of the audit either with regard to the corrective actions which have been laid down and the dates for their implementation or that the corrective actions have been implemented. If this period is not observed, the audit is considered not to be successful, i.e. not to be passed. No certificate can be issued, or an existing certificate is withdrawn.