CERTIFICATION GENERAL PROCEDURE ISO 9001

TUV-LIMITED-CERTIFICATION

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Purpose

Procedure TUV-LIMITED-P-01 describes the roles, responsibilities and processes in a certification body **according to ISO 17021** involved in the certification of management systems (MS).

The certification process consists of the phases:

- contract review and offer preparation,
- audit preparation,
- performance of audit stage 1,
- performance of audit stage 2,
- issue of the certificate, and
- surveillance of the certified management system.

The sequence is repeated at the end of the term of validity of the audit, except for audit stage 1, which is replaced by the assessment of the previous period in the case of recertification. Recertification audit activities may need to have an audit stage 1 in situations where there have been significant changes to the management system, the client, or the context in which the management system is operating (e.g. changes in legislation).

In addition to this procedure, the requirements of the specific standards are laid down in the annexes.

Scope

This procedure applies to TUV-LIMITED and its auditors in Kingdom of Saudi Arabia.

Definition

Audit Stage 1:

On-site or off-site assessment of the readiness for certification of a company's management system and planning of audit stage 2. This includes the review of management system documentation.

The Stage 1 audit is basically performed on site. Under certain conditions (small companies) [< 50 employees] of if reasons for reductions are present)

If the Stage 1 audit is not carried out in particularly justified cases - e.g. the management system of the organization is already known through audits according to other standards - the justification must be fixed in writing and recorded in the audit file.

Audit Stage 2:

On-site assessment of the establishment, implementation and effectiveness of a management system with the final objective of issue of a certificate.

Completion of audit:

Last day of audit stage 2, typically the day of the final closing meeting.

Surveillance Audit:

Periodical (yearly, optionally half-yearly), post-certification on-site audit of management system implementation and effectiveness in representative areas and functions that are covered by the scope of the management system of the organization. The objective is maintenance of the certificate.

Re-Certification Audit:

Review of overall management system implementation and effectiveness in the organization with respect to

new issue of the certificate.

Extension Audit:

Evaluation of management system implementation and effectiveness in additional areas or at additional locations/factories. The objective is change of the scope of the certificate.

Short-notice Audit:

Audits of certified clients at short notice to investigate complaints, or in response to changes, or as follow up of suspended client certifications.

Scope of the certification

The scope of the certification includes the areas of activity, products/services and processes of the organization. Areas of activity that are 100% transferred to other locations are not included in the scope.

Nonconformity:

Non-fulfilment with respect to the certification requirements.

Major nonconformity(Characteristic 4)

A major nonconformity is a nonconformity (non fulfilment of a requirement) that affects the capability of the management system to achieve the intended results. Some examples but not exhaustive are:

- A failure of the client's system to address a specified requirement of the standard.
- A frequent or purposeful failure to follow specified requirement written within the company system.
- A failure to achieve the fundamental aim of a system requirement.
- A failure of the client's management system to achieve legal or statutory requirements*.
- Multiple minor nonconformities within the same requirement of the standard or company system.
- A purposeful failure of the company to correct nonconformities.

Correction and corrective actions are to be closed within 90 days and verified either by desktop review or where appropriate during an additional follow up visit, agreed with the client.

*Where the client has identified this system failure via their own Internal Audit and Corrective Action process and a corrective plan is in place and being implemented, then the TUV LIMITED auditor need not raise a nonconformity

4.2 Minor nonconformity(Characteristic 3)

A minor nonconformity does not affect the capability of the management system to achieve the intended results. relates to a single observed lapse in the effective implementation of a documented procedure/work instruction which indicates a deficiency requiring a corrective action

Corrective action plan approved by the team leader is acceptable and verification of implementation of corrective actions will be performed at the next visit.

4.3 Observation (Characteristic 2)

An area of concern, a process, document, or activity that is currently conforming that may if not improved, result in a nonconforming system, product or service.

Follow-up Audit:

On-site assessment of the implementation and effectiveness of corrections and corrective actions for nonconformities issued during the audit.

Evaluation of documentary evidence:

Off-site assessment of the implementation and effectiveness of corrective actions in connection with nonconformities identified during the audit. The assessment is carried out by means of documents that are submitted (documents or records).

Correction:
Action to eliminate a detected nonconformity.

Corrective Action:
Action to eliminate the cause of a detected nonconformity.

Audit day:
An audit day comprises 8 hours (net). Where it seems useful, a 10 hours audit day might be accepted.

Appointed Person:
Individuals who are appointed to perform certain, defined tasks on behalf of the head of the certification body or specialist manager, i.e. QM Managers or veto persons.

1. Responsibilities

1.1 Head of Certification Body and Specialist Manager

The Head of the Certification Body is responsible for:

- selection and appointment of auditors, senior auditors and veto persons,
- review and approval of certification files with regard to content and adherence to the rules, involving competent auditors if necessary. These auditors must not have been part of the certification process activities,
- appointment of the QM Managers in the branch offices,
- awarding the certificate.

The Head of the Certification Body is authorized to delegate responsibilities to the Specialist Managers / QM Managers for areas covered by a particular management system standard whenever applicable.

1.2 Branch Offices

The branch offices are classified into;

a. Riyadh Office

depending on their competency. The head of the certification body is responsible for the classification.

1.2.1 QM Manager

The QM manager is the representative of the certification body in the respective branch office. He is the direct superior of the local auditors and the local certification personnel in all matters concerned with management system certification.

1.2.2 Administration tasks in branch offices

Certain tasks from the certification process can be performed in the branch offices. These tasks are monitored by the local QM Manager.

1.3 Auditors

Auditors are responsible for the proper conduct of the certification process in line with this procedure.

within the audit team, the lead auditor has the following additional responsibilities:

- cost calculation of orders
- determining if the Stage 1 Audit can be performed on site during the same period as the Stage 2 Audit. Approval by the certification body is needed for this purpose. In the case of branch offices/outside locations with certification authority, the QM manager decides.

- confirmation of the updated information from the customer (no. of employees, grounds for reduction, scope) in the case or surveillance and recertification audits.

drafting of an audit plan and report for the Stage 1 audit including assessment of the MS documentation in the case of first certification

- evaluation of the previous period (last 3 years) in the case of recertification audits. In addition, evaluation of the MS documentation with report in the case of significant changes to the MS documentation,
- drafting of the audit plan and the report for the Stage 2 audit in cooperation with the audit team,
- assigning audit responsibilities during the audit,
- documentation of audit findings and any nonconformities in consultation with the audit team,
- recommendation for issue / maintenance of the certificate or required corrective action or extension of its scope,
- determination of scope of the management system in agreement with customer,
- submission of the complete certification documents to the certification body in good time for release.

Within the context of the competent certification decision, lead auditors permanently employed at TUV-LIMITED who are not involved in the audit procedure can be included in the review and release process (veto persons).

1.3.1 Experts

Experts can be employed to complete competence requirements for an audit team. They always act under the direction of an auditor and the cost for their time cannot be added to the audit time that has been calculated

1.4 Order Service

The coordination team handle the formulation of the offer and conclusion of contract as well as the implementation of the certification procedure in terms of the TUV-LIMITED-Management system. They engage the auditors in consultation with the head of the certification body / specialist manager. They monitor and organise the performance of the surveillance and re-certification audits on behalf of the certification body management.

They send the customer the audit reports along with the invoices.

1.5 Certification service

The employees of the certification service maintain and update the pool of auditors with regard to all TUV-LIMITED auditors.

On instruction from the certification body management and the specialist management, they assign certification files for release to veto persons responsible for the release. They prepare the issue of the certificates and send them to the customers. They file the certification records**.**

With the exception of updating of the pool of auditors, the activities described here are not performed for critical/certifying branch offices**.**

2.0 Procedure

The process is initiated when an applicant makes an inquiry or an order is received through sales activities. The applicant is informed of the basic certification process

The questionnaire is sent to the applicant so that an offer can be prepared and is completed either by the applicant or with the support of TUV-LIMITED staff. Based on the information from the questionnaire, the costs and times are calculated using the respective procedure of TUV-LIMITED-P-01-A. The offer is completed and after acceptance, a contract is concluded with the applicant.

In case of combined audits, the audit time shall be calculated according to the guidance given in the respective section of TUV-LIMITED-P-01-A.

Records of offers which did not lead to a contract must be kept for one year.

The audit process begins following the conclusion of the certification agreement and is divided into:

- audit preparation and planning,
- audit performance,
- documentation of the audit results.

After a positive certification decision, the certificate is granted and the process of monitoring the application of the certification and management systems, and therefore monitoring of the validity of the certificate, begins.

2.2 Audit Preparation

An audit team is appointed and the customer is informed of the team members once the contract is signed. Clients must be informed in advance that they can object against any member of the audit team (auditor or expert).

The members of the audit team must fulfil the requirements described in TUV-LIMITED-P-01-B. In the case of dependent and auditing branch offices, the audit team and the audit time has to be approved by persons appointed by the certification body prior to the audit.

The criteria for composing the audit team are:

- the audit must be performed under the leadership of a nominated lead auditor,
- for audits of less than four days on-site, the use of an audit team of at least two auditors is optional,
- for audits of four days or more on-site, the use of an audit team of at least two auditors is mandatory (for any one location),
- at least one member of the audit team must have the technical sector competence with respect to the scope of the audit. This is also required for Stage 1 audits. In audits of more than one management system by the same team, the competence requirements must be fulfilled for each standard.

The audit team leader is responsible for ensuring that technical competence is always present during the audit.

2.2.1 Stage 1 audit

The purpose of the Stage 1 audit is:

a) to audit the management system documentation of the customer,

b) to assess the location and the location-specific conditions of the customer and to discuss various aspects with staff at the customer's organization in order to determine readiness for the Audit stage 2,

c) to assess the status of the customer and also to assess the customer's understanding of the standard, particularly with regard to identification of key items which must be fulfilled and also other important aspects, processes, objectives and operation of the management system,

d) to collect necessary information with regard to the scope of the management system, the processes and the location(s) of the customer, as well as associated legal regulations and regulations related to official authorities, and to establish if the customer is fulfilling these regulations; (e.g. relating to quality, environmental and legal aspects of the customer's activities, associated risks etc.),

e) to evaluate the resources which have to be allocated to the Stage 2 audit and to discuss and agree on the details of the Stage 2 audit with the customer,

f) to create a main focus for planning the Stage 2 audit by gathering sufficient understanding of the customer's management system and of the activities carried out on site and any significant aspects relating to these,

g) to judge if internal audits and management reviews are planned and carried out and to ensure that the level of implementation of the management system proves that the customer is ready for the Stage 2 audit.

An Audit Plan is drawn up for the Stage 1 audit.

In exceptional cases, The Stage 1 audit can take place within the same period as the Stage 2 audit (see Clause 3, definitions of Stage 1 audit). The following prerequisites must be fulfilled before performance:

- The customer must be made aware of the risk that the audit may be broken off.
- A review of the management documentation must be performed before the Stage 1 audit in order to ensure than any nonconformities that are identified are rectified before the audit.
- The certification body must approve the way of proceeding.

The time interval between the two audit stages should not exceed 3 months.

In the report regarding the Stage 1 audit, the decision as to whether it is possible to perform the certification audit in the company without the need for further steps is described. The audit team leader is primarily responsible. If the requirements of the standard are not fulfilled, corrective actions are required from the customer. If all the requirements of the standard are fulfilled, detailed planning for the Stage 2 audit follows.

At the end of the Stage 1 Audit, the exact formulation of the scope of the certificate must be established in agreement with the customer not later than four weeks before the Stage 2 audit.

2.2.2 Audit planning

The audit team leader is responsible for preparing an audit plan which includes all MS requirements to be audited, the names of the relevant units within the customer`s organisation and a timescale for the audit. The audit team leader coordinates the audit plan with the audit team and the customer`s representative.

The auditors may work as a team or independently. However, if the full number of man days is to be charged for, there must be demonstrable splitting of the auditors for approx. **50%** of the audit time. The proof of splitting has to be provided in the audit plan (e. g. if 2 auditors per department/process are planned in, at least 2 representatives from the organisation to be audited must appear in the audit plan).

In TUV-LIMITED-P-01-C, the aspects of the MS that must be audited by the audit team in each audit must be defined.

If work is performed in shifts, the different shifts must be taken into consideration during audit planning (processes and control mechanisms). If every shift is not audited, the reason must be stated in the audit report.

The use of Computer Assisted Audit Techniques CAAT (e.g. document inspection, review of corrective and preventive actions, video conferences) shall be taken into consideration in the audit plan if applicable.

In situations where a customer provides a product or service at temporary sites (i.e installation sites, project locations etc.) it is important that evaluations of such sites are incorporated into the certification and surveillance program. The need for visits will depend on the relevance of these sites. The reasons for the selection of the specific sites must be documented in the audit report (reasons: special product-specific/service-relevant features, size, complexity, only site, results from previous audits).

2.2.4 Stage 2 audit

The audit commences with an opening meeting.

The task of the audit team is to review the practical application of the management system and to asses it for fulfilment of the requirements of the standard. This is carried out by means of questions put to the staff, viewing of other documents, records, orders and guidelines as well as by an on-site visit to the relevant areas. The audit questionnaire serves as a guide during this process.

At the end of the on-site audit, a final closing meeting takes place.

1.2.5 Audit Findings/Documentation of the audit

The auditors and if appropriate the expert (if used) record their findings during the audit either by hand or electronically. The findings are assigned to requirements of the standard and evaluated as regards the following:

- **conformity**,
- **opportunity for improvement**, and
- **nonconformity (Major or minor)**

The audit report is prepared based on the audit findings. Nonconformities and opportunities for improvement are documented in the audit report. Action plans for nonconformities are prepared by the customer in consultation with the audit team leader.

The corrections and corrective actions relating to nonconformities that are proposed by the client are evaluated, accepted and verified by means of follow-up-audit or submission of documentation within a maximum of 90 days, and by at the latest 3 months after the audit-relevant date. In other words, the nonconformities must be closed within this period without fail.

2.3 Certificate Issue and Surveillance

2.3.1 Certificate Issue

A review of the certification procedure by appointed persons follows. The audit team leader provides the following records for the purpose of the review:

- contract review records (calculation, certification agreement(abroad)),
- audit team and audit time approval (abroad),
- audit programme,
- audit report for audit stage 1, including review of the MS documentation,
- evaluation of the previous period
- audit plans for audit stage 1 and audit stage 2,
- hand-written notes for Audit Stage 1 and 2, which allow identification of the requirements of the MS standard and their evaluation, or audit protocol,

- audit report for audit stage 2,
- if necessary management of nonconformities,
- order placement,
- time and cost of audit,
- ordering of certificates or draft certificates,
- audit release protocol.

In general, the following documents must be submitted from the auditing branches or non-critical branches:

- contracts, certification and re-certification audit)
- audit protocol, if necessary supplemented by hand-written records
- Hand-written records which allow understanding of the relationship between the requirements of the standards and the assessments and evaluations if the audit protocol is not used.

- audit programme,
- Stage 1 audit report,
- evaluation of the previous period,
- Stage 2 audit report,
- management of nonconformity,
- release protocol,
- order of certificates (in the desired languages, in any case the scope must be defined in Arabic or English).

If the review is positive, the appointed persons release the certification file and the certificate is issued.

Release of the certification procedure must take place at the latest 105 days after the last day of the **Stage 2** audit.

2.3.2 Certificates

In general, the validity of the certificate does not exceed three years from the issue date. Expiry of validity depends on the date of certificate decision. The text on the certificates laid down in **CERT-TUV-LIMITED**.

2.3.3 Surveillance Audit

Within the period of validity of the certificate (3 years) surveillance audits shall be conducted at least once a year.

The due date of the surveillance audits ("audit-relevant date") is defined differently for new customers and registered customers

New customers:

- The audit-relevant date of the annual surveillance audit following the initial certification audit may not be later than the last day of the Stage 2 audit plus 12 / 24 months.

Existing customers (already registered)

- The date of the annual surveillance audit ("audit-relevant date") is the date of the validity of the valid certificate on day and month minus 1 month.

New and registered customers:-KSA

- The audit-relevant date is decisive for all following audits (surveillance and re-certification audits).
- All surveillance audits – including the review of corrective actions relating to identified nonconformities, audit reporting and the release process – shall be completed at the latest 3 months after the audit relevant date.

Annual surveillance audits may be performed at the earliest 3 months before the audit relevant date.

Any further delays require approval by the accreditation body or result in suspension of the certificate.

If the surveillance audit is not performed by the audit relevant date, the certificate is suspended. It is also suspended if the release has not taken place by at the latest 3 months after the audit-relevant date

An audit can be performed in order to revoke suspension up to 6 months after the audit-relevant date. this audit may require additional time. The certificate must be withdrawn 6 months after the audit due date if no audit has been performed.

Individual, documented case-by-case decisions on the part of the Certification Body remain possible.

A Lead Auditor must participate in surveillance audits. Competence for the EA scope must be present in the audit team.

During preparation of the audit, the audit team leader initiates an inquiry to the customer regarding changes in the structural and procedural organization, the size of the company and the company activities. This includes in particular a review of the current management manual. In addition, materials used for publicity (e.g. Internet, advertising material) can be used for preparation purposes. This inquiry is documented in the audit programme.

At least the following points must be taken into consideration during a surveillance audit:

- internal audits and management review,
- a review of the corrective actions undertaken in response to the nonconformities found in the previous audit,
- handling of complaints against the management system,
- effectiveness of the management system in relation to achievement of objectives and goals,
- progress with regard to planned continual improvement activities,
- process control,
- review of changes,
- use of logos and (trade) marks.

In case of nonconformities, the audit team leader should proceed as in the certification audit. The surveillance audit is documented as described under **5.2.4**. Suspensions of the certificate must also be taken into account.

The audit file is then reviewed by the appointed persons. The audit team leader makes the following documents available for the review:

- audit team and audit time approval (abroad),

- audit programme,
- audit plan,
- hand-written or electronic records which allow identification of the requirements of the MS standard and their evaluation, or audit protocol,
- audit report,
- if appropriate, management of nonconformities,
- order placement,
- audit time and costs,
- release protocol.

If the review is positive, the veto persons release the audit file.

2.3.4 Recertification audit

Recertification audits – including the review of corrective actions of identified nonconformities and auditors' recommendation either to issue, maintain, or to suspend the certificate – have to be completed prior to the expiry of the certificate.

Any exceptions must be agreed in advance with the certification body.

The audit release process shall be completed three months after the audit relevant date at the latest.

A re-certification audit shall not be performed three months prior to the audit-relevant date.

If a previous certification was performed by another accredited Certification Body, the previous certificate and audit reports have to be reviewed in the course of the evaluation of the previous period.

Competence requirements for the auditors will remain the same as for the initial audit.

Within the context of the audit preparation, a new calculation for the procedure must be carried out by the auditor, to ensure that the conditions of the contract still apply. The auditor asks the company about any changes in the structural and procedural organisation of the company, the size of the company, the company activities and the scope.

This includes among other things inspection of the current management manual. In addition, materials used to present the company to the public can be used for the preparation (e.g. Internet, advertising material). These tasks are carried out in the branch offices by a person nominated by the QM Manager.

Recertification audits include a review of management system documentation with confirmation of the review in the audit report. If there have been significant changes, the result of the review must be documented separately and an on-site audit carried out. The results of the previous surveillance programme over the course of the certificate validity shall be taken into account. All requirements of the standard must be audited.

It may be necessary to perform a Stage 1 audit in the context of a recertification audit if there have been significant changes to the management system or in relation to the activities of the company (e.g. changes in the law). The decision regarding the necessary action is made by the audit team leader in agreement with the management of the relevant specialist sector or with the QM Manager. The decision must be recorded.

The audit methodology is equivalent to the methodology of a Stage 2 audit.

Points of emphasis are at least:

- effectiveness of the interaction between all quality management elements in the management system with regard to internal or external change, and the continuing significance and applicability of the management system within the scope of the certification,
- verification that the obligation to maintain the effectiveness of the system and to improve it has been fulfilled in order to increase overall performance capacity within the organisation,
- verification that the certified management system contributes to achievement of the policies and objectives of the organisation.

Audit performance, documentation and also issue of certificates will be performed in accordance with the rules applying to certification audits.

Wherever possible, the certification decision should be made in the month in which the previous certificate expires.

2.3.5 Extension audit

An extension audit can be performed to extend the scope of an existing certificate. The extension / reduction audit may be carried out within the scope of a surveillance audit, re-certification audit or on an independently selected date.

The validity period of the certificate remains unaffected. Exceptions have to be justified in writing.

The audit team leader / audit team will review the MS documents concerning the extended areas / new locations and audit all requirements which are affected by the extension.

The further procedure with regard to the documentation and release of the audit procedure corresponds to a certification audit.

2.3.6 Transfer of certificates from other Certification Bodies

The following minimum requirements shall apply:

Prerequisites

As a general rule, only certificates issued by accredited certification bodies can be transferred. Companies with certificates from non-accredited certification bodies are to be treated as new customers.

Pre-Transfer Review

A Pre-Transfer Review must be conducted by a competent auditor: this generally comprises review of important documents and a visit to the customer. The required number of audit days has to be agreed with the specialist manager in advance.

The Pre-Transfer Review must cover the following aspects:

- confirmation that the certified activities of the customer are covered by the scope of our own accreditation.
- The reasons for transfer of the certificate:
- confirmation that a valid management system certificate with regard to term of validity and performance profile of the customer, issued by an accredited certification body, is to be transferred; if possible, the validity of the certificate and the status of any existing nonconformities should be reviewed together with the former certifier
- discussion of the two previous reports on the certification or recertification audit and the subsequent surveillance audits and of all nonconformities dealt with in these reports: this discussion should also include all other available relevant documents and records on the certification process, such as hand-written notes and checklists
- any complaints received and the action taken

- the current status of the surveillance cycle
- If the transfer is performed within the framework of a surveillance audit, the pre-transfer review can be performed within the framework of the audit.

Certificates

As a general rule, only a valid certificate issued by an accredited certification body can be transferred. If that prerequisite is not satisfied, the individual case must be judged on its merits.

It is not possible to transfer suspended certificates or certificates which are under the threat of suspension.

Any unresolved nonconformities have to be clarified with the previous certification body prior to transfer wherever practicable. Such nonconformities must otherwise be reviewed in the course of the audit.

A certificate can be issued with the date of completion of the Pre-Transfer Review as date of issue (subject to the usual release process) if there are no longer any unresolved or potential problems.

Future surveillance and recertification audits are based on the previous Surveillance and Recertification programme.

2.4 Multisite certification (Group/Matrix Certification)

Described in procedure. TUV-LIMITED-P-01-D