

AUDIT INFORMATION

General Requirements:

1. The organizations shall determine ALL critical processes, hazards, environmental aspects, relative objectives, performance indicators for the health and safety, food safety, quality, energy and the environment in the documented MS, in agreement with the scope of certification and according to the applicable standards and/or regulations. The determination shall be based on regulatory, consumer, interested party and internal requirements of the MS.
2. There are documented procedures for elements required by the standard.
3. The completion and record of at least one full internal audit cycle for all applicable requirements of the standard has been audited.
4. Records that prove the application and implementation of the MS shall exist
5. The completion and documentation of at least one management review which includes an assessment of the systems continuing suitability, adequacy and effectiveness and opportunities for improvement.
6. Objective evidence that the MS is monitored and measured in relation to objectives. Evidence that the MS is continuously improving.
7. Where one or more samples for test and measurement is required, the organization shall use risk assessment techniques to define the sampling method for verification and validation reasons. Records of verification and/or validation of the MS shall be requested where appropriate and feasible.

AUDIT EXPECTATIONS

Important:

All management systems' certificates have a three years' validity (if not required otherwise by the relevant scheme). The certification and the validity of the certificate for the three years' cycle is under the circumstances that the certification audit was successful as well as the two surveillance audits (once per year). If the Organization wants to continue the validity of their certification for the next cycle, then they have to plan a recertification audit before the date that the certificate expires and to follow again the surveillance audit planning.

The Certification Audit of MS is conducted in two Stages.

Stage I Audit

The objectives of the Stage I audit are to provide a focus for planning the Stage II audit by gaining an understanding of the MS in the context of the organization's programs, policies and objectives and in particular of the organization's state of preparedness for audit.

The audit team will perform the Stage I audit of a client organization's MS on-site.

Stage I audit results will be documented and communicated to the client organization, including identification of any areas of concern that could be classified as non-conformity during the Stage II audit. An audit report will be submitted to the organization. The report will include results that as minimum include:

- Evaluation of factory environment, health and safety, food safety, energy management or other conditions
- Evaluation of identified significant aspects, risks, processes, and objectives of the MS
- Evaluation of methodology of the preliminary steps for hazard and risk analysis of the processes
- Evaluation of methodology for the selected pre-requisite or operational programs
- Evaluation of methodology for justification of acceptable levels
- Reference to requirements for quality, environmental, health and safety, food safety, energy, legal, associated risks, in the manufacturing and/or service chain the organization belongs
- Evaluation of resource availability
- Results of the organization's internal audits and management review

Audit findings will be documented and submitted to the customer.

Any part of the MS that is audited during the Stage I audit and determined to be fully implemented effectively and in conformity with requirements may not need to be re-audited during the Stage II audit. In this case, the Stage II audit report will include these findings and clearly state that conformity has been established during the Stage I audit.

The Lead Auditor along with the organization will determine the time interval between the Stage I and Stage II audits by considering the needs of the client to resolve areas of concern identified during the Stage I audit. The arrangements for Stage II audit may also need to be revised. The time frame between the Stage I and Stage II of the audit cannot be greater than six (6) months. If it exceeds the six months limit, Stage I must be repeated. Stage II can be conducted back to back, provided the audit findings of Stage I allow it and the auditor and organization agree to it.

Stage II Audit

Stage 2 audit will take place at the site(s) of the client organization with the purpose to evaluate the implementation and effectiveness of the client's MS.

Any part of the MS that has been fully audited during the Stage I audit may not need to be re-audited during Stage II. The Stage II audit report still; will include findings that support conformance to requirements from audit findings during Stage I.

The audit team shall gather audit evidence that the MS conforms to the standard and other certification requirements.

The audit team shall audit a sufficient number of examples of the activities of the client organization in relation to the MS and activities to get a sound appraisal of the implementation and effectiveness of the MS.

The audit team shall address a sufficient number of the staff, including operational personnel and management of the audited facility to provide assurance that the system is implemented and understood throughout the organization.

The audit team shall analyze all information and audit evidence gathered during the Stage I and Stage II audits to determine the extent of fulfillment with all certification requirements and decide on the recommendation to be submitted to the certification manager. The audit team may propose opportunities for improvement but shall not recommend specific solutions.

Links between the normative requirements, the policy, performance objectives and targets, associated legal requirements, responsibilities and personnel competence, operations and procedures, performance data and internal audit results per critical process shall be audited.

Findings

Findings can be categorized into four levels:

1. *Conforming*
2. *Minor Non-Conforming* (requirement not met with no impact on safety, quality, hygiene, and environmental performance of the product and/or service). Does not affect the capability of the management system to achieve the intended results. The proposed corrective actions must be submitted by the Organization to the Lead Auditor and be approved within ninety (90) days. The verification of their effectiveness can be done during the next planned audit.
3. *Major Non-Conforming* (requirement not met with impact on safety, quality, hygiene, and environmental performance of the product and/or service) or (legal requirement not met with impact on safety, quality, hygiene, and environmental performance of the product and/or service). Affects the capability of the management system to achieve the intended results. The proposed corrective actions must be applied within ninety (90) days or maximum six (6) months and the objective evidence must be sent to the CB, unless the verification of the actions must be verified on site. In case that the time exceeds the time period of six months then a Stage II audit must be repeated.
4. *Opportunity For Improvement*

Audit Report

After audit completion, the Lead Auditor will compile an Audit Report. The report is confidential to QMSCERT and should under no circumstances be shown or issued to third parties other than the organization or ESYD.

Certification Decision

The CB's designee will review all the audit's objective evidence and will decide whether or not a certificate can be granted (in the second case the CB's designee with the Lead Auditor and the Organization's representative will plan the appropriate actions in order to finalize the procedure).

The certificate which will be issued shall be dated with the certification decision date, or after that date.

Surveillance Audits

Surveillance audits shall be conducted according to the requirements of Stage I and Stage II in a single Stage. The organization shall be notified with an audit schedule prior to the audit.

During the surveillance audit, parts of the Management System will be audited. All of the standard's requirements shall be audited during the first and second surveillance audits. The clauses of the standard (requirements) that will be audited during the surveillance audit will be communicated to the Organization by the Lead Auditor in the form of an audit schedule.

One surveillance audit must be conducted within a calendar year with the restriction that the first surveillance audit will be conducted one year minus one day from the date that the certification decision was made by the CB's designee.

Recertification Audit

Recertification audit shall be conducted according to the requirements of Stage I and Stage II and can fulfilled in one Stage. A recertification audit shall be conducted in two Stages provided there are significant changes in the MS that justify it.

If during the recertification audit major non conformities are raised and the corrective actions will be implemented and verified beyond the certificate's expiration date then the certificate shall not be valid. In that case and in case that the recertification audit will not be conducted within the required time frame (before the expiration date of the certificate) a time period of six months is given within which the recertification audit can be finalized. Upon successful completion of the recertification procedure the CB will issue the certificate which will have as issue date, the date that the recertification decision was made and expiration date according to the previous certification cycle.

Management Standard Specific Issues

Specifically for each MS standard the organization will receive scheme specific terms if they exist.

Notes:

- Please contact QMSCERT if you have any questions about this document