Procedure for audit planning, conducting and reporting

Quality Techno Certification

ISO/IEC 17021: 2015
Code: QTC -CMP-01

0.1 Amendments history:

No.	Issue / Revision	Issue / Revision description	Issue/Rev No.	Issue / Rev date
0	First issue	Issue of procedure	01 /Rev0	01/12/2023

0.2 Table of contents:

1- Purpose, scope and users:

The purpose of this procedure is to describe audit planning, conducting the audit at client premises, preparation and submission of audit reports related to the fulfilment of ISO/IEC 17021-1.

This procedure is applied to all audit planning, execution of audit and reporting for all types of audits as listed below:

- Adequacy or Stage 1 audit
- Registration or stage 2 audit
- Follow up audit
- Surveillance audit
- Recertification audit
- Transfer visit

Users of this document are Certification Manager and Audit Team Leaders/ Auditors of **Quality Techno Certification (QTC).**

2- Reference documents:

- ISO 17021-1:2015, clause 9
- IAF MD 1:2018
- Management System Manual

3- Description of Activity:

3.1 Introduction:

The objective is to provide consistent service delivery norms. Audit Team leaders and auditors are responsible for ensuring the objectives of their assigned audits are fully met. The various activities needed to be carried out are:

- Document review/ Adequacy Audit (Stage 1 Audit)
- Registration Audit (Stage 2 Audit)
- Follow Up Audit
- Surveillance Audit
- Recertification Audit
- Special Visit

The term Management System as applied in this procedure includes management system in accordance to ISO 9001, ISO 14001 and ISO 50001 standard(s).

3.2 Audit Visit:

3.2.1 Calculation of the Audit man/days are calculated in (QTC- SMWI – 01). Manday Calculation based on IAF MD 5 and IAF MD 11.

The purposes of the audit visits are to provide reasonable assurance that the auditee organization's Management System conforms to the requirements of standard applied, as stated in the Certification Contract, and to verify that the documented system has been implemented. The audit also serves to verify that the Management System is appropriate to auditee organization's activities.

Certification Manager or his designee is responsible for selection of the audit team, using Auditor qualification summary (QTC-HRF - 01 – 11, QTC-HRF - 01 – 12 and/ or QTC-HRF - 01 – 13) Competence Review Form. Unless required for technical reasons and logistics, care shall be taken to ensure that same auditor does not visit the client more than three consecutive visits. This shall ensure "no bias" and a fresh look at the system. All auditors/ subcontractors are responsible for identifying any conflict of interest with the specified client and report to Certification Manager. Certification Manager shall review the same and take necessary decision which may include replacing the person with some other auditor.

4.2.2 The team leader leads the audit in accordance to the referenced instructions. A set of updated documents pertaining to audit like client details, open non conformances, surveillance plan and comments from prior visits as applicable) is provided to every audit team. Activities include the opening meeting with the auditee organization, team briefings, audit interviews, nonconformance issuance, auditee organization briefings, and the closing meeting with the auditee organization. The team leader issues an audit report reflecting the recommendation concerning registration based on the team findings.

If nonconformance is found, the recommendation will be on hold until suitable corrective action has been taken and evidenced.

4.2.3 During the audit if the auditor finds a breach of legislation i.e. legal/ regulatory/ statutory requirement not having been followed, the auditor will communicate his finding to the team

leader who in turn will notify the auditee organization's management of the violation. The auditor will further investigate the same and check as to why the auditee organization's management has failed to detect and address the same. If and when after proper investigation, it is clear that the auditee organization's management system has short comings/ the infringement of ISO standard is established, a major/ minor nonconformance as appropriate will be raised. Follow-up visits are made to verify that major nonconformance(s) are effectively remedied before registration is granted. In case of legal/ statutory / regulatory requirements by the auditee organization, the following policy shall be applied:

In the event of the auditee organization conducting a violation of the legal requirement, the auditee organization, as a part of the rules and regulations of **Quality Techno Certification (QTC)** Certification, will inform **Quality Techno Certification (QTC)** on its own pro-actively and voluntarily. This pro- active information communication by the auditee organization is not to be confined to onsite-audit activity but is applicable to the complete registration period which the auditee organization is entitled to by way of **Quality Techno Certification (QTC)** certification. In case of violation of legal requirements that is observed during the course of a Registration Audit (Stage 2 Audit) or Surveillance Audit(s), **Quality Techno Certification (QTC)** audit team will notify the auditee organization's management about the observation. Further the audit team will conduct a proper investigation on the issue and check as to why the auditee organization's management system has failed to detect and address the same. Based on the investigation of the audit team, if it is established that the management system has shortcomings / an infringement of ISO standard is observed, a major or minor non-conformance note will be issued.

Additionally, the auditee organization has to ensure and to provide evidence to that effect to **Quality Techno Certification (QTC)** that the appropriate authorities have been notified of the violation of legal requirements, as per the prescribed procedure instituted by the relevant authorities.

3.3 Audit program:

Certification manager shall prepare the Audit program (QTC-CMF – 01 – 03) for the full certification cycle to clearly identify the audit activity/ activities required to demonstrate that the client's MS fulfils the requirements for certification to the selected standard(s) or other normative document(s). The audit program for the certification cycle shall cover the complete MS requirements.

The audit program for the initial certification shall include a two-stage initial audit, surveillance audits in the first and second years following the certification decision, and a recertification audit in the third year prior to expiration of certification. The first three-year certification cycle begins with the certification decision. Subsequent cycles begin with the recertification decision. The determination of the audit program and any subsequent adjustments shall consider the size of the client, the scope and complexity of its MS, products and processes as well as demonstrated level of MS effectiveness and the results of any previous audits.

Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.

Where taking account of certification already granted to the client and to audits performed by another CB, it shall obtain and retain sufficient evidence, such as reports and documentation on corrective actions, to any nonconformity. The documentation shall support the fulfilling of the requirements of ISO/IEC 17021. **Quality Techno Certification (QTC)** shall, based on the information obtained, justify and record any adjustments to the existing audit program and follow up the implementation of corrective actions concerning previous nonconformities.

Where the client operates shifts, the activities that take place during shift working shall be considered when developing the audit program and audit plans.

3.4 Adequacy Audit (Stage 1 audit):

Stage 1 Audit is a part of the registration procedure and not an optional activity. Stage 1 is carried out onsite. Adequacy audit term is used for ISO 14001, ISO 50001,ISO 45001,ISO22000 and Document review is used for ISO 9001.

3.4.1 Objectives of Stage 1 audit:

During the Stage 1, it is to be established that the requirements of the standard(s) are being met by the auditee organization. This can be done by review of the available evidence. This evidence may take many forms and some cases need not be "documented". The objectives of stage 1 are to:

a) Review the client's management system documented information;

b) Evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2;

c) Review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;

d) Obtain necessary information regarding the scope of the management system, including:

- the client's site(s);
- processes and equipment used;
- levels of controls established (particularly in case of multisite clients);
- applicable statutory and regulatory requirements;

e) Review the allocation of resources for stage 2 and agree the details of stage 2 with the client;

f) Provide a focus for planning stage 2 by gaining a sufficient understanding of the client's management system and site operations in the context of the management system standard or other normative document;

g) 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.

3.4.2 When carrying out a review the auditor shall note his/her findings in the Stage 1 audit report and record this against the relevant topic if such fails to satisfy the requirement of the standard. Special requirements are listed in the Stage 1 audit report for that company i.e. guidance documents, legislation etc. for reference at the audit.

The Document reviews are a part of the stage 1 audit and include at least the following:

- Documentation including procedures with links to related requirements of respective standard. If client has integrated systems (e.g. QMS, OHSMS), the documentation shall be reviewed w.r.t. interfaces with other systems.
- The documentation must have been issued and would normally have been in place for a minimum of three months.
- Description of organization and its on-site procedures
- Environmental aspects, impacts and determination of significant aspects (for EMS)
- Means and system for realizing continual improvement.
- An overview of applicable regulations and agreements with authorities.
- Internal audit program, identified nonconformities and records.
- Records of incidents breach of regulation and relevant correspondence and EM/ EMS related communications with action taken.
- Records for management review
- Details of identified non conformities and corrective actions taken in last 12 months.

3.4.3 Procedure steps for Stage 1 audit:

The assigned team leader is responsible for managing and documenting the results of the adequacy audit. However, responsibilities for conducting the document review may be delegated to the other audit team member. The procedure for the stage 1 audit can be briefly described as follows:

1. Technical Expert may advises the concerned auditor / Team Leader of the assignment.
2. Team Leader prepares the audit schedule and intimates the client normally a week before the planned audit date. Audit Schedule contains auditor name. Auditor details are provided to client on request.
3. An opening meeting is held to put the auditee organization at ease, advise him/ her of objectives of the document review and obtain the auditee organization's cooperation.
4. Generally, only one person is needed to perform the adequacy audit, but where a team is used or an auditor under training is present, then a team briefing may be necessary.
5. In order to prepare a detailed program for the audit, a tour of the facility to provide familiarization with the auditee's organization is essential.
6. The main objective is to review the auditee organization's readiness with respect to the points listed above. Documents are reviewed only to the level necessary to establish compliance with relevant standard. A record of documents reviewed is made.
7. The auditor shall review for any discrepancy in any information provided in Application questionnaire and contract review. This shall be reviewed by Certification Manager and may result in change in man-days assigned for the contract.
8. Auditee organization debrief meeting is held to discuss the audit findings and obtain any further information necessary to program the audit and decide on further action.

9. The findings are collated and an audit report (QTC- CMF – 01 – 07, QTC- CMF – 01 – 09 and/ or QTC- CMF – 01 – 11) is prepared for handing over at the closing meeting. On the basis of the findings, a recommendation is made to proceed/ defer/ cancel the registration. The auditor shall explain the reason for considering the documentation or system unsatisfactory. In case of many or larger issues, the stage 1 audit may need to be carried out again. This shall be discussed with the auditee and suitable date decided. This may require working out an amendment to the contract.

10. The visit ends with a closing meeting where points agreed with the auditee organization are confirmed. The Scope of Registration for audit is confirmed. Audit report is handed to the auditee organization and a copy forwarded to **Quality Techno Certification (QTC)** for review and procedure.

11. The client will be informed by the auditor that any discrepancies not closed out prior to the audit will result in automatic non-conformance notices being raised. The discrepancies include non-completion of scheduled internal audit programs and management reviews.

12. The Stage 2 audit shall be conducted within 3 months of stage 1 audit. Any further delay shall require stage 1 audit to be carried out again. There is no restriction on minimum time duration; however the general practice is at least 7 days, depending on the findings of the stage 1 audit and client readiness.

3.4.4 Non Conformity and Sentencing of major and minor non-conformances:

A non-conformity is defined as failure to fulfil one or more requirements of the management system standard or a situation that arises serious doubts about a client's management system to achieve its intended output. Non conformities will be classified in two categories: Minor and Major.

3.4.3.1 During an audit a minor non-conformity shall be deemed present when any activity is <u>not</u> undertaken, and which is stipulated in the clients management system as a requirement or which was undertaken and is relevant but is not controlled within the

system, and is deemed to be of a minor nature (of little importance to the quality of the firm's product or service). Several non-conformities in any one section, or procedure, shall constitute a major breakdown of the system.

3.4.3.2 A major non-conformance shall be declared when a system or procedure is not working at all, or where there is complete failure to fulfil one or more requirements of the management system, or where there is significant doubt that the client's system can achieve the intended output, or where a serious cumulative number of minor non-conformities are found overall, or when there is a complete lack of system control. Several non- conformities may be grouped together as one major non- conformity.

3.4.3.3 If all non-conformities have been rectified within three months of the audit, then the award will be recommended. If not, a complete re-audit is to be carried out at the discretion of the Certification Manager. If on a follow-up visit it is found that the major nonconformity has not been satisfactorily addressed, then another visit is to be made within two weeks. If this fails then a full re-audit must take place. All visits will be charged at the standard rate and the client invoiced. The Certification Manager will confirm the time and auditors for the close out visit and will consult the Technical Expert about the invoicing.

3.4.3.4 In all cases of "follow-up" the auditor must complete a continuation sheet indicating the areas covered. Head the sheet "Close out Visit". Any small points not fully closed out may be re-raised as minor discrepancies at the discretion of the Lead Auditor. After a "follow up" visit the audit report will be completed again by the auditor. Clients whose systems are rejected on initial audit and are accepted on "follow up" partial audit may have surveillance visits set at one extra to that stated on the Contract Review for the first year of registration, if considered necessary by the Lead Auditor i.e. depending on the severity of the major non-conformance. The time (half a day minimum) for 'follow-up' partial re-audit is indicated by the Lead Auditor on the audit report along with the suggested re-audit date.

3.5 Registration Audit (Stage 2 Audit):

The objective of the Registration Audit (Stage 2 Audit) is:

(a) To confirm that the auditee organization adheres to its own policies, objectives and procedures.

(b) To conform that the management system of the auditee organization conforms to all the requirements of the current version of respective standard(s), normative document and achieving the organization's policy & objectives.

(c) To evaluate compliance to applicable legal and regulatory requirements.

3.5.1 The following activities will be carried out to meet the objectives of Stage 2 Audit:

- Assess that the (auditee) organization's Management System has been implemented and objective evidence is available to demonstrate its effective implementation in line with its policies, objectives and procedures.
- Establish that all requirements of the standard are addressed where they apply to the activities covered by the scope of registration.
- Confirm that Management System is appropriate to the product, procedure or service provided by the auditee, with the capability of managing and improving performance.
- Encourage auditee organizations to improve their management system on an on-going basis.

While accomplishing this, the registration audit must be conducted to satisfy the needs of the auditee organization and maintain the integrity of the registration procedure as a whole. The team leader is responsible for managing and documenting the results of the registration audit. He may delegate specific responsibilities for conduct of audit activities to assigned audit team members.

3.5.2 The registration audit (Stage 2 audit) addresses the implementation of all the elements in the standard and focuses on at least the following:

a) Information and evidence about conformity to all requirements of the applicable management system standard or other normative documents;

b) Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document);

c) The client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;

d) Operational control of the client's processes;

e) Internal auditing and management review;

f) Management responsibility for the client's policies.

If there are combined systems in place, e.g. QMS, OHSMS and EMS, then emphasis must be placed to ensure that both standards are adequately addressed and monitored. Records and auditor notes must demonstrate that adequate time has been given to each standard.

3.5.3 Procedure steps for Stage 2 Audit:

1) Certification Manager or designee schedules the audit and informs the Audit team leader (TL). A set of necessary documents like client details, Stage 1 audit report etc. is given to TL. On receiving the audit schedule from the Technical Expert and TL discuss the logistics and audit plan (QTC- CMF – 01 – 05) with auditee organization. TL prepares the audit Plan and intimates the client normally a week before the planned audit dates and the same is agreed upon prior to the audit. In case of any changes required by the client the same is captured as part of the Incident Report and necessary actions taken. In case of any changes in the audit plan during the audit the same is captured as part of the audit report. Auditor details are provided to client on request.

2) During the audit planning, the EGAC sector specific guidelines and audit trails is used to identify critical procedures. At least 60% of audit time shall be used for auditing critical procedures.

3) Where the assignment is complex (multi-site, has specific technological requirements, and/or utilizes a large audit team etc.), a team briefing may be planned before the scheduled audit date to coordinate details.

4) An opening meeting is held to advise the auditee organization of the objectives of registration audit, details of the audit and schedule and obtain for the auditee organization's cooperation.

5) Where more than one person has been assigned, daily team meeting may be scheduled after the auditee organization meeting/ site visit to plan the day's strategy and cover any points not included in the pre-visit team meeting.

6) Changes to the auditee organization's documentation since the previous visit is reviewed and outstanding non-conformance(s) followed-up. The auditee organization's Management System is assessed according to the schedule and audit trails identified during adequacy audit. Documents reviewed, personnel interviewed and other pertinent data is recorded in the auditor's note pads. Non-conformances are raised after proper investigation against activities found non-compliant. The Observations are issued identifying areas of improvement only. The caution will be observed in recording the Observations so that the issues pertaining to non-conformance are not reflected as observations and vice versa. The recording of observations will be strictly confined to areas of improvement only.

7) When audit is for more than a day, daily team debrief meeting is used to discuss findings, followed by auditee organization debrief to present the findings of day.

8) On the final day of the audit, the team discusses overall performance during the audit, review of stage 1 report and prepares the audit report (QTC- CMF – 01 – 08, QTC- CMF – 01 – 10 and/ or QTC- CMF – 01 – 12). The team decision to approve or defer registration is recorded in the report. Program for the next visit is also prepared (follow-up visit/ surveillance plan). An organization can be recommended only if no major non-conformance is found.

9) In case of a major non-conformance complete/ limited audit is necessary and the audit time requirement is estimated by the auditor in discussion with Director – Operations. The audit schedule for the special audit is detailed and agreed upon with the client.

10) The visit ends with a Closing Meeting where the recorded findings and team recommendations are formally presented to the auditee organization and any follow-up actions agreed upon. Auditee submits the corrective action plan for all non-conformances issued. Also, during the Closing Meeting the Team Leader informs the Client for submitting the evidences of Corrective Action taken for review and closure of the Minor Non Conformances identified. In case of major non-conformances identified the client is informed whether an additional full audit or an additional limited audit is necessary depending on the impact of the major non- conformance identified.

11) The audit report is handed to the auditee organization and a copy forwarded to **Quality Techno Certification (QTC)** for review and procedure. The audit-trails are exclusive notes strictly for use of auditors to carry out the audit and the team leader shall ensure that they are never given out to the auditee.

12) The report is submitted only after satisfactory verification of corrective actions taken for the non- conformance(s). The client shall submit the evidences of corrective actions taken within 3 months of the audit. Failure to satisfactory closure shall result in complete re-audit.

3.6 Follow-up Audit (FA):

3.6.1.1 The purpose of follow-up audits is to conduct the follow-up of non-conformance(s) of an auditee organization's management system, identified during a visit, that were determined to require corrective action. Follow-up audit is required where a major non- conformity is raised. Minor non-conformity does not require formal follow-up visit and may be closed off site based on evidence submitted. The time required for follow-up audit shall be determined based on number and nature of major non- conformities issued.

3.6.2 The team leader will plan and determine the type of follow-up that is required. An off-site follow-up may only be conducted when the corrective action can be objectively evaluated on the basis of documented evidence sent to **Quality Techno Certification (QTC)** by the auditee organization. If the follow-up audit is not performed within three months of the registration audit, a partial Re-audit has to be performed (the time required shall be about 50% of that of stage 2 audit). A complete Re-audit will be carried out if the follow-up audit is not performed within 6 months.

3.6.3 The non-conformances should be updated to reflect the new status, where the corrective actions are verified. These are reviewed by the team leader and then the Certification Committee. Certification Manager initiates withdrawal/ suspension procedures, if auditee organization fails to effectively respond to a corrective action request or if the corrective action is not satisfactory. Audit report for Follow-up audit shall be the same as for Registration Audit.

3.7 Surveillance Audit (SA):

Calculation of the Audit man/days are calculated in (QTC- SMWI – 01). Manday Calculation based on IAF MD 5 and IAF MD 11.

The registered Management System should continue to meet the requirements of specific standard and should be managed effectively by the auditee organization. Surveillance Audit is intended to verify the continued effective maintenance of the auditee organization's quality management system, satisfy the needs of the auditee organization and maintain the integrity of the registration procedure as a whole.

3.7.1 Surveillance Audit is intended to:

- Assess that the auditee organization's registered Management System has been maintained.
- Verify that changes to Management System subsequent to the previous visit are in compliance with respective standard and that objective evidence is available to substantiate implementation.

- Re-confirm that Management System is appropriate to auditee organization's product, procedure or service provided, with the capability of managing and improving performance.
- Promote the effectiveness of quality management system.
- Assess major changes in auditee organization's operations, technology that could affect the certification / registration.

3.7.2 Surveillance audits are on-site audits, but are not necessarily full system audits, and shall be planned together with the other surveillance activities so that **Quality Techno Certification (QTC)** can maintain confidence that the client's certified management system continues to fulfil requirements between recertification audits. Each surveillance for the relevant management system standard shall include:

a) Internal audits and management review;

b) A review of actions taken on nonconformities identified during the previous audit;

c) Complaints handling;

d) Effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);

e) Progress of planned activities aimed at continual improvement;

f) Continuing operational control;

g) Review of any changes;

h) Use of marks and/or any other reference to certification.

The surveillance audit may be combined with the audits of other management systems. The report should clearly indicate the aspects relevant for each management system.

3.7.3 Procedure steps for Surveillance Audit:

The team leader is responsible for managing and documenting the results of Surveillance Audit. The team leader may delegate specific responsibilities for conduct of audit activities to assigned audit team members.

Certification Manager is responsible for review of audit report to assess effectiveness. The procedure steps for the Surveillance Audit are:

1) Certification Manager or designee schedules the audit and informs the Audit team leader (TL). Care is taken that the audit is scheduled within 12 months interval, date being Certification decision date. A set of necessary documents like client details, earlier audit report etc. is given to TL. On receiving the audit schedule, TL discusses the logistics and audit plan with auditee organization.

2) TL shall review the functions/ procedures audited in the earlier surveillances before finalizing the audit plan. TL shall ensure that all critical procedures are audited at least twice and rest at least once in the three year period.

3) Where an assignment is particularly complex (i.e. begins at several different locations, has particular technological requirements, and/ or utilizes a large number of team members, etc.), it may be beneficial to call a team briefing some time before the scheduled surveillance date to coordinate details.

4) An opening meeting is held to advise the auditee organization of the objectives of audit, details of the audit and schedule and obtain auditee organization's cooperation. Auditee organization brief may be conducted if audit extends beyond a day.

5) Where more than one person has been assigned, a daily team meeting is scheduled immediately following the auditee organization meeting to plan the day's strategy and cover any points not included in the pre-visit team meeting. Changes to the auditee organization's documentation since the previous visit are reviewed and outstanding non-conformances followed-up. The scope on the certificate will be checked against the scope of activities being carried out by the company. If these are not the same, the auditor will discuss this with the company and inform the Certification Manager or appointed person for further consideration.

6) The auditee organization's Management System is assessed using the Audit Program. Documents reviewed, personnel interviewed and other pertinent data is recorded in the auditor's note pads. This information is confidential and not part of the formal audit report. Non-conformances are raised after proper investigation against activities found non-compliant. The observations are issued identifying areas of improvement only. The caution will be observed in recording the observations so that the issues pertaining to non-conformance are not reflected as observations and vice versa. The observations will be strictly confined to areas of improvement only.

7) On the final day of the surveillance, the team discusses overall auditee organization performance and determines the recommendation (registration to continue or follow-up is required). The team prepares the audit report (QTC- CMF – 01 – 08, QTC- CMF – 01 – 10 and/ or QTC- CMF – 01 – 12). The team decision is recorded on the Audit Report. Areas to be reviewed at the next visit are also detailed.

8) The visit ends with a Closing Meeting where the findings and team recommendation are formally presented to the auditee organization and any follow-up actions agreed upon. The Record of Findings is handed to the auditee organization and a copy forwarded to Certification Manager for review and procedure.

9) At least one half of the management system will be checked by the auditor at each surveillance visit. It is essential to ensure that the full system (as a minimum) is covered over a three year period by two surveillances. At each visit complaints, audits, registration marks, documentation changes, and evidence of improvement will be reviewed.

10) Any auditee organization has to notify **Quality Techno Certification (QTC)** in writing of any major change in the management system and/ or the scope of activities. Certification Manager decides if the verification of changes can be assessed during next surveillance audit or if a special visit has to be scheduled.

11) The performance of the special visit shall be similar to normal surveillance and Certification Manager shall inform the assigned auditor to audit the required changes in system.

3.7.4 Maintaining of Certificates:

Certificates will be maintained provided that the certified clients continue to satisfy the management system standard and based on positive recommendation from the audit team leader during routine surveillance audits provided that any non-conformity or any other situations which may lead to withdrawal/ suspension of certification. In such cases the audit team leader reports to the Certification Committee to initiate a review by competent personnel, independent from those who carried out the audit.

3.8 Recertification (Triennial Audits):

3.8.1 The purpose of the recertification audit is confirm the continued and effective management system as a whole is followed and the continued relevance and applicability of the scope of certification, commitment to enhance and maintain overall effectiveness and improvement of the management system and whether the operations of a certified client contributes to the achievement of the clients policy and objective.

3.8.2 The following steps should be followed when planning three-year re-approval visits:

- The planning and extent of the visit are in accordance with the accreditation board requirements and that determined at the last surveillance visit. The triennial visit is planned based on client's performance during the certification period, previous surveillance audit reports, trends in NC raised, complaints received during the period and corresponding investigation reports etc.
- Triennial audit may include stage 1, if there is considerable internal/ external change in MS, activities, location and scope of certification.
- During recertification, Certification Manager shall ensure auditor rotation in case the complete cycle is carried out by a same auditor as Team Leader.

- Triennial audit shall include review of effectiveness and improvements in the MS performance.
- The triennial audit is a full audit of the auditee organization's Management System and generally follows the same procedure as the Stage 2 Audit.
- Triennial audits and review follow the same instructions as those for initial audits. Care should be taken for review of changed scope or activities of the client.

3.8.3 Decision on renewing the certificate will be made by **Quality Techno Certification (QTC)** based on results of recertification audit (review of report), review of the certified clients system over the period of certification and any complaints received against the certified client over the certification period.

3.8.4 In accordance to ISO 17021, the triennial audit, closure of all issues and certification committee decision need to be completed prior to expiry date of the current certificate. The new certificate shall then be considered as continuation of certification. "Certified since…." date shall be the initial certification date. (The triennial audit should be completed about
2 months before certificate expiry). In case of situation that corrective action is not submitted in time to complete certification decision, an additional surveillance shall be planned after 6 months (for 12 months surveillance schedule) or 1 day is added to first surveillance (for 6 / 9 months surveillance schedule).

3.8.5 Where the activity cannot be completed before certificate expiry, the client shall be considered as a fresh case and man- days for stage 1, stage 2 and surveillance audit shall be given. Also if the surveillances are not done as per schedule, the client shall be considered as a fresh case.

3.9 Special Purpose Visits:

3.9.1 Registered Management System must continue to comply with the current version of specific standard and any changes to the system must also continue to comply. Also, the scope of registration must continue to be appropriate to the auditee organization's objectives and appropriate for the auditee organization's products and services.

3.9.2 On the other hand, complaints, appeals, request for change in scope, additional accreditation, audit visits, or surveillance visits may disclose reasons for undertaking an additional visit.

- If there are grounds for undertaking a special purpose visit, Certification Manager determines what level of review will be required to maintain or extend registration, including but not limited to normal surveillance, unplanned surveillance, partial re-audit, or full re-audit.
- Before undertaking any visit, which is not under any contractual agreement, the auditee organization must agree in writing to the new terms.
- The scope of the audit shall be pre-determined and shall depend on the reason for the visit. In case of any complaint/ appeal/ any information resulting in doubt on the effectiveness of system, the audit of concerned and other related activity may be carried out.
- Visit/ audit report shall be recorded similar to initial audit. The report shall also be reviewed for risk to **Quality Techno Certification (QTC) .** Certification committee may also discuss the findings with the audit team.

3.9.3 Extensions to scope change in management for clients already registered with Quality Techno Certification (QTC) :

- Questionnaire should be completed by the client and returned to **Quality Techno Certification (QTC)** .
- Contract Review will always be carried out by the Certification Manager or appointed person to determine whether a full or partial Stage 1 is required.
- An off-site Stage 1 must be completed and sent to the Certification Manager or appointed person for review. Under exceptional circumstances an on-site Stage 1 may be required.
- Under no circumstances must the above visit be carried out at the same time as surveillances unless extra time or extra auditor has been allocated. However, Stage 1 shall be completed before the on-site audit.

Audits for the above reasons will be carried out in the same way as the initial audit. An Audit Report must be completed in the normal way and submitted to the Certification Committee for approval.

If successful, a new certificate will be issued by **Quality Techno Certification (QTC)** .

Note: After certification, if the client changes anything which significantly affects the registration, then **Quality Techno Certification (QTC)** must be informed. **Quality Techno Certification (QTC)** reserves the right to re-assess.

3.9.4 A special visit may be carried out on request of the client for additional accreditation. Client may request for additional accreditation any time prior to certification audit or during the three year period. In case the request is prior to stage 2 audits, the request shall be reviewed by Certification Manager and verified if the client's activities are within the **Quality Techno Certification (QTC)** scope of accreditation. Stage 2 audit is carried out as described above. If the request is within the three year period, an additional visit may be required to verify compliance. The commercials shall be communicated with the client. The visit may be merged with planned surveillance. Additional accreditation shall be effected only after successful completion of the audit. The certificate shall be accordingly amended, however the expiry date shall be the same. Fees may be charged towards additional accreditation and new certificate issue.

3.9.5 Short Notice audits for clients registered with Quality Techno Certification (QTC) :

These audits are necessary to investigate any complaints, changes in management systems, follow up on suspended clients. Requirements of short notice audits are informed to client at time of contract finalization through Client Agreement.

Special care will be taken in assigning the audit team for short notice audits.

3.10 Transfers:

3.10.1 This applies only to transfers from other accredited certification bodies. Only transfers from companies which have certificates covered by an accreditation of an IAF signatory should be eligible for transfer. Certificates which are not accredited as below shall be treated as new clients.

3.10.2 Pre-transfer review:

- Carry out the normal contract review procedure, Quotation Preparation and Staff Allocation, and possibly visit the client. There is no need for a document review, unless an extension is involved.
- Check that the client's scope on their certificate is as stated on the questionnaire.
- Confirm the client's certificated activities are compatible with that of **Quality Techno Certification (QTC)** .
- Try to establish the reason for the client wanting to transfer.
- Check that all of the sites that the client wants transferring are covered by their current registration and not just Head Office.
- Check that the certificate is **VALID** and has not expired and that it is accredited. Certificates that have been suspended or withdrawn or are out of date shall not be considered for transfer. (Note: If the certification body has ceased trading or had its accreditation withdrawn then the transfer can still go ahead on the basis of this review procedure).
- Check the status in their current certificate cycle, i.e., is we to take over the surveillance program or are they due for a triennial re-audit etc. If a triennial is due we must carry out a full triennial audit including planning and site visits. Any extensions to scope will result in visits.
- Request reports/ checklists, non-conformances etc. from the previous certification body. The status of any outstanding non-conformance notices must be known. Non-conformances must be closed out by the previous certification body or sent to **Quality Techno Certification (QTC)** with evidence of corrective actions taken for **Quality Techno Certification (QTC)** to close out.
- Request verbal confirmation of the effectiveness of the complaint system. Request details of any major problems.
- For EMS or OHSMS, request details of any legal engagement with statutory bodies.

If no further outstanding problems from the above review are identified, then a certificate may be issued after authorization by the Certification Committee.

3.10.3 The program of surveillance visits/ triennials is to be adopted from the previous certification body if applicable. Appendix Document is signed by the Chairman of the Certification Committee, General Manager and Technical Expert (if applicable) to authorize issue of the certificate.

Note: If, as a result of the review, some of the criteria are not met, then a site audit will be required to give confidence to certify by **Quality Techno Certification (QTC)** .

3.11 Opening and Closing Meetings:

3.11.1 The Opening and closing meeting are a critical part of the audit procedure. Opening meeting ensures that all parties understand what is going to happen and how best they can cooperate and coordinate their efforts. Closing meeting ensures that all parties understand the relevance of findings, what they need to do and what happens next. The meeting agenda contains a number of essential requirements which must be advised to the auditee organization in addition to other useful items which make for a clearer understanding of what is expected from both parties. It is hence essential that all the agenda items covered in this instruction, as appropriate and applicable to the situation.

No.	Subject	Opening	Closing
1	Thank client for selecting **Quality Techno Certification (QTC)** . Mutual Introduction of auditors and auditee.	●	
2	Thank auditee for hospitality. Thank guides for their support.		●
3	Circulate attendance sheet.	●	●
4	State and confirm the contracted scope for certification and objectives of audit.	●	●
5	Determine auditee representative and guides.	●	
6	Confirm the audit plan and verify no conflicts with the plan. Reconfirm time and location for closing meeting. Make necessary amendments on request.	●	
7	Explain the terms non-conformance (major & minor) and observation.	●	●
8	Communicate the policy of notification by auditee for legal / statutory violation.	●	●

No.	Subject	Opening	Closing
9	Request sufficient sets of documentation, suitable room and office support.	●	
10	Explain auditor's responsibility to comply with code of conduct and confidentiality.	●	●
11	Explain that audits are sampling exercises and other issues may exist. Refer to the need of ongoing internal audit and ongoing surveillance. Stress that the audit does not guarantee to identify all areas of non-conformance.	●	●
12	Request advice on safety requirements and availability of safety equipment.	●	
13	Explain the findings. Highlight strengths. State non-conformances and observations. Explain the expectation of corrective action for non-conformances, including how lack of corrective action will impact on registration.		●
14	State conclusion and recommendation of audit team. Explain that the team can only make recommendation. Explain the concept of Certification committee. Explain that appeals procedure exists and is available on request.		●
15	Obtain auditee organization's signature on the audit report. Request auditee to state the corrective action plan. Explain auditee's responsibility of submission of evidence for non-conformances identified. Request for safekeeping of audit reports.		●
16	Invite questions	●	●

3.12 Multi-site audits:

3.12.1 General:

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 of the organization and be subject to a single management system, which is laid down, established and subject to continuous surveillance 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.

3.12.2 Eligibility of a multi-site organization for certification:

- The organization shall have a single management system.
- The organization shall identify its central function. The central function is part of the organization and shall not be subcontracted to an external organization.
- The central function shall have organizational authority to define, establish and maintain the single management system.
- 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 program.
- 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).

3.12.3 Methodology for Auditing of a Multi-site Organization Using Site Sampling:

- Conditions:
  - Sampling of a set of sites is permitted where the sites are each performing very similar processes /activities.
  - Not all organizations fulfilling the definition of "multi-site organization" will be eligible for sampling.
  - **Quality Techno Certification (QTC)** will restrict sampling where site sampling is inappropriate to gain sufficient confidence in the effectiveness of the management system under audit.

- Such restrictions shall be with respect to:
  - scope sectors or processes/ activities (i.e. based on the assessment of risks or complexity associated with that sector or activity);
  - size of sites eligible for multi-site audit;
  - variations in the local implementation of the management system to address different processes/activities or different contractual or regulatory systems; and
  - Use of temporary sites that operate under the management system of the organization even if they are not listed in the certification documents.

- Sampling:
  - The sample shall be partly selective based on the factors set out below and partly random, and shall result in a representative range of different sites being selected, ensuring all processes covered by the scope of certification will be audited.
  - At least 25% of the sample shall be selected at random.
  - Taking into account the provisions mentioned below, the remainder shall be selected so that the differences among the sites selected over the period of validity of the certificate is as large as possible.
  - The site selection shall consider, among others, the following aspects:
    - results of internal site audits and management reviews or previous certification audits;
    - records of complaints and other relevant aspects of corrective and preventive action;
    - significant variations in the size of the sites;
    - variations in shift patterns and work procedures;
    - complexity of the management system and processes conducted at the sites;
    - modifications since the last certification audit;

- maturity of the management system and knowledge of the organization;
- environmental issues and extent of aspects and associated impacts for environmental management systems;
- differences in culture, language and regulatory requirements;
- geographical dispersion; and
- Whether the sites are permanent, temporary or virtual.

- This selection does not have to be done at the start of the audit process. It can also be done once the audit of the central function has been completed. In any case, the central function shall be informed of the sites to be included in the sample. This can be on relatively short notice, but shall allow adequate time for preparation for the audit.

- Sample Size:
  - When determining the sample size, **Quality Techno Certification (QTC)** shall take into account all the factors described in this section.
  - **Quality Techno Certification (QTC)** shall have records on each application of sampling for each multi-site organization, justifying it is operating in accordance with this document.
  - The minimum number of sites to be visited per audit is:
    - Initial audit: the size of the sample shall be the square root of the number of sites: ($y=\sqrt{x}$), rounded up to the next whole number, where y = number of sites to be sampled and x = total number of sites.
    - Surveillance audit: the size of the annual sample shall be the square root of the number of sites with 0.6 as a coefficient ($y=0.6\ \sqrt{x}$), rounded up to the next whole number.
    - Re-certification audit: the size of the sample shall be the same as for an initial audit. Nevertheless, where the management system has proved to be effective over the certification cycle, the size of the sample

could be reduced to, y=0.8 √x, rounded up to the next whole number.

- The central function shall be audited during the initial certification and every recertification audit and at least once a calendar year as part of surveillance.
- The size or frequency of the sample shall be increased where the **Quality Techno Certification (QTC)** 's risk analysis of the process/ activity covered by the management system subject to certification indicates special circumstances in respect of factors such as:
  - the size of the sites and number of employees;
  - the complexity or risk level of the process/activity and of the management system;
  - variations in working practices (e.g. shift working);
  - variations in process/ activities undertaken;
  - records of complaints and other relevant aspects of corrective and preventive action;
  - any multinational aspects; and
  - Results of internal audits and management review.
- When the organization has a hierarchical system of branches (e.g. head office, national offices, regional offices, local branches), the sampling model for initial audit as defined above applies to each level.

  Example:

  1 head office: visited at each audit cycle (initial or surveillance or recertification)

  4 national offices: sample = 2: minimum 1 at random

  27 regional offices: sample = 6: minimum 2 at random

  1700 local branches: sample = 42: minimum 11 at random
- The sample of regional offices should include at least one regional office controlled by each national office. The sample of local branches should include at least one local branch controlled by each regional office. This may result

in the sample size at each level exceeding the minimum sample size calculated before.

- The sampling process shall be part of the management of the audit program. At any time (i.e. before planning the surveillance audit, or when any organization site changes its structure, or in case of acquisition of new site(s) which will be added into the certification boundary), **Quality Techno Certification (QTC)** shall review the sampling foreseen in the audit program in order to establish the need to adjust the sample size prior to auditing the sample with a view to maintaining certification.

- Additional Sites:

On the application of inclusion of new sites or a new group of sites to join an already certified multi-site organization, **Quality Techno Certification (QTC)** shall determine the required activities to be performed before including the new site(s) in the certificate. This shall include consideration of whether or not to audit the new site(s). After inclusion of the new site(s) in the certificate, the sample size for future surveillance or recertification audits shall be determined.

3.12.4 Methodology for Auditing of Multi-site Organizations Where Site Sampling is not appropriate:

- The audit program shall consist of an initial audit and recertification audit of all sites. In surveillance audits, 30% of sites, rounded up to the whole number, shall be covered in a calendar year. Each audit will include the central function. The sites selected for the second surveillance audit will normally be different from the sites selected for the first surveillance audit.

- The audit program shall be designed to ensure that all processes covered by the certification scope are audited over each cycle.

- Additional Sites:

On the application of a new site to join an already certified multi-site organization, the site shall be audited before being included in the certificate, in addition to the planned surveillance in the audit program. After inclusion of the new

site in the certificate, it shall be cumulated with the previous ones for determining the audit time for future surveillance or recertification audits.

3.12.5 Methodology for Auditing Multi-site Organizations that Include a Combination of Sites that can be Sampled and Other Sites that Cannot be Sampled:

The audit program shall be established using Section 3.11.3 for those sites that can be sampled and Section 3.11.4 for the remaining part of the organization where Section 3.11.3 is not appropriate.

3.12.6 Audit and certification:

3.12.6.1 Application and Application Review:

Quality Techno Certification (QTC) shall obtain necessary information concerning
the applicant organization to:

- confirm that a single management system is deployed across the organization;
- determine the scope of the management system being operated and the requested scope of certification and, if applicable, sub-scopes;
- understand the legal and contractual arrangements for each site;
- understand “what happens where” i.e. processes/ activities provided at each site and identify the central function;
- determine the degree of centralization of process/activities which are delivered to all sites (e.g. purchasing);
  - determine interfaces between the different sites;
- determine which sites may be applicable for sampling (i.e. where very similar processes/ activities are provided) and those that are not eligible;
  - Take into consideration other relevant factors.
  - determine the audit time for the organization;
  - determine the audit team(s)’ competence required; and
  - Identify the complexity and scale of the processes/ activities (e.g. one or many) covered by the management system.

3.12.6.2 Audit Program:

In addition to the requirement in ISO/IEC 17021-1:2015 clause 9.1.3, the audit program shall at least include or refer to the following:

- processes/ activities provided on each site;
- identification of those sites which are liable to be sampled, and which are not; and
- Identification of sites which are covered by sampling, and which are not.

When determining the audit program, **QTC** shall allow sufficient additional time for activities which are not part of the calculated audit time, such as travelling, communicating among audit team members, post-audit meetings, etc. due to the specific configuration of the organization to be audited. Where audit teams consisting of more than one member are used at any point, it shall be the responsibility of **Quality Techno Certification (QTC)** , in conjunction with the team leader, to identify the technical competence required for each part of the audit and for each site and to allocate appropriate team members for each part of the audit.

3.12.6.3 Calculation of Audit Time:

An organization that satisfies the eligibility criteria may consist of sites that can be sampled, sites that cannot be sampled or a combination of both. The audit time must be sufficient to undertake an effective audit irrespective of the makeup of the organization.

Unless precluded by specific schemes, the reduction of audit time per sampled site shall not be greater than 50%.

For example, 30% is the maximum reduction in audit time allowed by IAF MD 5 while 20% is to be considered the maximum reduction allowed for the single management system processes performed by the central function and any potential centralized processes (e.g. purchasing).

The audit time per selected site, including elements of the central function if applicable, shall be calculated for each site using the applicable IAF documents (e.g. IAF MD 5 QMS, EMS and OHSMS, IAF MD 11 for integrated management systems).

3.12.6.4 Audit Plan:

In addition to the requirement in ISO/IEC 17021-1:2015 clause 9.2.3, **Quality Techno Certification (QTC)** shall at least consider the following when preparing the audit plan:

- certification scope and sub-scopes for each site;
- management system standard for each site, if multiple management system standards are being considered;
- processes/activities to be audited;
- audit time for each site; and
- Allocated audit team.

3.12.6.5 Initial Audit: Stage 1:

During Stage 1, the audit team shall complete the information to:

- confirm the audit program;
- plan Stage 2, taking into account the processes/ activities to be audited in each site; and
- Confirm that the Stage 2 audit team has the required competence.

3.12.6.6 Initial Audit: Stage 2:

At the outcome of the initial audit, the audit team shall document which processes were audited on each site visited. This information will be used to amend the audit program and audit plans for subsequent surveillance audits.

3.12.6.7 Nonconformities and Certification:

When nonconformities, are found at any individual site, either through the organization's internal auditing or from auditing by **Quality Techno Certification (QTC)** , investigation shall take place to determine whether the other sites may be affected. Therefore, **Quality Techno Certification (QTC)** shall require the organization to review the nonconformities to determine whether or not they indicate an overall system deficiency applicable to other sites. If they are found to do so, corrective action shall be performed and verified both at the central function and at the individual affected sites. If they are found not to do so, the organization shall be able to demonstrate to **Quality Techno Certification (QTC)** the justification for limiting its follow-up corrective action.

Quality Techno Certification (QTC) shall require evidence of these actions and increase its sampling frequency and/ or the size of sample until it is satisfied that control is re-established.

At the time of the decision-making process, if any site has a major nonconformity, certification shall be denied to the whole multi-site organization of listed sites pending satisfactory corrective action.

It shall not be admissible that, to overcome the obstacle raised by the existence of a nonconformity at a single site, the organization seeks to exclude from the scope the "problematic" site during the certification process.

3.12.6.8 Certification Documents:

The certification document shall reflect the scope of certification and the sites and/ legal entities (where applicable) covered by the multi-site certification.

Certification documents shall contain the name and address of all the sites, reflecting the organization to which the certification documents relate. The scope or other reference on these documents shall make it clear that the certified activities are performed by the sites on the list. However, if a site's activities only include a subset of the organization's scope, the certification document shall include the site's sub-scope. When temporary sites are shown on the certification documents, such sites shall be identified as temporary.

Where certification documents for one site are issued, they shall include:

- that it is the management system of the whole organization which is certified;
- the activities performed for that specific site/ legal entity which are covered by this certification;
- traceability with the main certificate, e.g. a code; and
- A statement saying "the validity of this certificate depends on the validity of the main certificate".

Under no circumstances, can this certification document be issued to the name of the site/ legal entity or suggest that this site/ legal entity is certified (the one certified is the client organization), nor shall it include a declaration of conformity of the site processes/ activities to the normative document.

The certification documentation will be withdrawn in its entirety if any of the sites does not fulfil the necessary provisions for the maintenance of the certification.

3.12.6.9 Surveillance Audits:

Surveillance of multi-site organizations that can be sampled shall be audited in accordance with Section 3.11.3. The audit time per site shall be calculated in accordance with Section 3.11.6.3 above. Surveillance of multi-site organizations that cannot be sampled in accordance with Section 3.11.3 is based on auditing 30% of the sites plus the central function. The sites selected for the second surveillance of a certification cycle shall normally not include any sites sampled as part of the first surveillance audit. The audit time per site shall be calculated in accordance with Section 3.11.6.3 above.

3.12.6.10 Recertification Audits:

Recertification of multi-site organizations that can be sampled shall be audited in accordance with Section 3.11.3. The audit time per site shall be calculated in accordance with Section 3.11.6.3 above.

Recertification of multi-site organizations that cannot be sampled shall be audited as per initial audit, i.e. all sites audited plus the central function. The audit time per site and central function shall be calculated in accordance with Section 3.11.6.3 above.

4- List of forms used on the basis of this procedure:

No.	Form	Code
1	Work Order	QTC- CMF – 01 – 01
2	Audit Notification	QTC- CMF – 01 – 02
3	Audit program	QTC- CMF – 01 – 03
4	Audit Plan Stage 1	QTC- CMF – 01 – 04
5	Audit Plan Stage 2	QTC- CMF – 01 – 05
6	Audit Attendance Sheet	QTC- CMF – 01 – 06
7	Stage 1 Audit Report - QMS	QTC- CMF – 01 – 07
8	Stage 2 & Surveillance Audit Report – QMS	QTC- CMF – 01 – 08
9	Stage 1 Audit Report - EMS	QTC- CMF – 01 – 09
10	Stage 2 & Surveillance Audit Report - EMS	QTC- CMF – 01 – 10
11	Stage 1 Audit Report - 50001	QTC- CMF – 01 – 11

No.	Form	Code
12	Stage 2 & Surveillance Audit Report - 50001	QTC- CMF – 01 – 12
13	Nonconformity report	QTC- CMF – 01 – 13
14	File Content Checklist	QTC- CMF – 01 – 14
15	Stage 1 Audit Report - 45001	QTC- CMF – 01 – 15
16	Stage 2 & Surveillance Audit Report - 45001	QTC- CMF – 01 – 16
17	Stage 1 Audit Report - 22000	QTC- CMF – 01 – 17
18	Stage 2 & Surveillance Audit Report - 22000	QTC- CMF – 01 – 18