1.0 Purpose

To describe a procedure for audit planning, conducting the audit at client premises, preparation of reports and submitting the reposts

2.0 Scope

This procedure covers 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 audit

3.0 Responsibility

3.1 **Technical Manager** is responsible for Planning the audit and ensuring the audit reports are received timely in the office and review of the audit reports

3.2 **Audit Team Leaders/Auditors** are responsible for execution of audit and preparation of audit and submitting the audit reports

4.0 Description of Activity

4.1 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
- Triennial Audit
- Special Visit

The term quality management system as applied in this procedure includes management system in accordance to ISO 9001, ISO 14001, OHSAS 18001, ISO 22000 & other food safety standard(s).

4.2 Audit Visit

4.2.1 The purposes of the audit visits are to provide reasonable assurance that the auditee organization's quality 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 quality management system is appropriate to auditee organization's activities.

Technical Manager or his designee is responsible for selection of the audit team, using Auditor qualification summary. 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 Technical Manager. Technical 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 with 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. QS Certification Middle East has a legal counsel for consultation, if required for ISO 14001. 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 organisation. 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 organisation, the following policy shall apply -

In the event of the auditee organisation conducting a violation of the legal requirement, the auditee organisation, as a part of the rules and regulations of QS Certification Middle East Certification, will inform QS Certification Middle East on its own pro-actively and voluntarily. This pro-active information communication by the auditee organisation is not to be confined to onsite-audit activity but is applicable to the complete registration period which the auditee organisation is entitled to by way of QS Certification Middle East 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), QS Certification Middle East 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 organisation has to ensure and to provide evidence to that effect to QS Certification Middle East that the appropriate authorities have been notified of the violation of legal requirements, as per the prescribed procedure instituted by the relevant authorities.

Work instructions for ISO 9001 audit guidelines is also available for the audit team. During the audit the audit shall be so planned that about 60 % of the time is spent to audit the critical processes.

4.3 Adequacy Audit (AA) (Stage 1 audit)

Stage 1 Audit is a part of the registration process and not an optional activity. Stage 1 is carried out onsite. Adequacy audit term is used for QMS, EMS, GMP, HACCP, FSMS, FSSC & HSE and Document review is used for ISO 9001.

4.3.1 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 organisation. This can be done by review of the available evidence. This evidence may take many forms and some cases need not be "documented". However, this does not alter the need to adhere to the requirements for documentation contained in the QMS, EMS, GMP, HACCP, FSMS, FSSC & HSE.

- The objective of the Stage 1 audit is to provide

- To audit the client's management system documentation
- a focus for the planning of the Stage 2 Audit (e.g. resources, time allocation) by review the client's status and understanding regarding the standard w.r.t objectives and operations of the management system, site activities, identification of environmental aspects and associated impacts (for ISO 14001), identification of applicable legislation and licenses matching with site and activities of auditee organization, discussions with client personnel regarding policy, objectives and the state of preparedness of the auditee organisation,
- To evaluate the client's location and site-specific conditions and to undertake discussions with the clients personnel to determine the preparedness for the stage 2 audit
- To collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance (e.g. quality, environmental, legal aspects of the clients operation, associated risks etc)
- To review the allocation of resources for stage 2 audit and agreeing with the client on the details of the stage 2 audit.
- To provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the clients management system and site operations in the context of possible significant aspects.
- To evaluate if the internal audits and management system substantiates that the client is ready for the stage 2 audit.

For Companies requiring transferring from another certification body -

- If the company has an accredited certificate by another body then the auditors need only carry out a partial (brief) Document Review in QS Certification Middle East office. However all of the paperwork still needs to be completed using the combined Stage 1 Review and Audit Schedule form.
- If the company has a non-accredited certificate, then QS Certification Middle East normal procedures must apply in full.

4.3.2 Stage 1 audit is intended to -

- Assess that the auditee has a documented management system, which is compliant to applied standard.
- Ensure that the EMS includes an adequate process for identification of environmental aspects, impacts and determination of their significance.
- Ensure that the system includes a procedure for identification of applicable regulatory requirements and that all the required environmental licenses, permits and approvals are in place.
- Ensure that the management system is designed to achieve defined policy, objectives and targets.
- Establish that internal audit conform to the requirements of respective standard and the internal audits are effective and relied upon. Seeking evidence for competence, experience, training & independence of internal auditors (ISO 19011); auditing procedure & methodology; reference & standards; resource availability; organization & planning of audits; checks & reports; timeliness & effectiveness of corrective / preventive action and management of audit follow-up.

- Establish that management reviews are conducted and cover continuing suitability, adequacy and effectiveness of management system.
- Establish that relevant communication from customers / external interested parties is documented and responded
- Establish that the management system is designed to realize the concept of continual improvement.
- Establish that the proposed scope of registration is appropriate to the auditee organization's business activities.
- Confirm the auditee organization's readiness for registration audit.
- Obtain information about the auditee organization's operations which might have an impact on the stage 2 audit including:
  - Work hours and schedules
  - Size and complexity of the organization
  - Special safety requirements
  - Applicable statutory requirements & licenses
  - Security clearance requirements
  - Technology expertise necessary
  - Logistics
- Prepare a detailed program including audit trails for the upcoming Stage 2 audit.
- Review the adequacy of audit time for Stage 2 audit. Increase the time duration if required based on the findings of audit; complexity / volume of processes; variation found from the data provided by the client in F080 Questionnaire.

4.3.3 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 processes
- 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 EMS related communications with action taken.
- Records for management review
- Details of identified non conformities and corrective/preventive action taken in last 12 months

4.3.4 Process 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 process for the stage 1 audit can be briefly described as follows:

1. AE advises the concerned auditor / TL of the assignment.

2. TL prepares the audit schedule and intimates the client normally a week before the planned audit date. Audit Schedule contains auditor name. Auditor background details are provided to client on request.
3. An opening meeting is held to put the auditee organisation at ease, advice 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 questionnaire and contract review. This shall be reviewed by Technical Manager and may result in change in man-days assigned for the contract.
8. Auditee organisation 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 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 organisation are confirmed. The Scope of Registration for audit is confirmed. Audit report is handed to the auditee organisation and a copy forwarded to head office for review and processing. The report will also include the audit program detailing expected times and duration for audit of each activity.
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 programmes 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.

4.3.5 Non Conformity and Sentencing of major and minor non-conformances – QMS, EMS, OHSAS, GMP, HACCP, FSMS & FSSC.

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

4.3.5.1 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.

4.3.5.2 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.

4.3.5.3 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 Director Ops. 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 Technical Manager will confirm the time and auditors for the close out visit and will advise the AE about the invoicing.

4.3.5.4 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.

4.4 Registration Audit (RA) (Stage 2 Audit)

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

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

(b) To conform that the management system of the auditee organisation 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.

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

- Assess that the auditee organization's quality 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 quality management system is appropriate to the product, process 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 organisation and maintain the integrity of the registration process 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.

4.4.2 The registration audit (Stage 2 audit) addresses the implementation of all the elements in the standard and focuses on –

- identification of environmental aspects & its effectiveness, defined criteria/procedure for significance and subsequent determination of their significance (for ISO 14001)
- Procedures to ensure compliance with legal & other requirements
- Inconsistencies between organization's policy, objectives & targets and its procedures to achieve them or the results of their application. The registration audit team shall appreciate that it is for the organization to define the means by which its policy commitment to continual improvement, customer satisfaction and prevention of pollution is achieved and to develop processes for achieving / measuring performance.
- Auditee's procedure & application for investigation / development of opportunities for improvement and programs for improvement.
- Auditee's process for achieving continual improvement and its effectiveness.
- Operational control to maintain consistent performance and compliance to procedures
- Performance monitoring, measuring, reporting & reviewing against the legislative requirement, objectives and targets.
- Internal auditing, identification / evaluation of non-conformities and completion of effective corrective / preventive actions.
- Management review and management responsibility for quality management system.
- Interfaces and links between policy, aspects & impacts, objectives & targets, responsibilities, programs & procedures, performance data, internal audit and management review.
- Register of regulatory requirements (for ISO 14001)
- Seeking evidence for competence, experience, training & independence of internal auditors; auditing procedure & methodology; reference & standards; resource availability; organization & planning of audits; checks & reports; timeliness & effectiveness of corrective / preventive action and management of audit follow-up.
- Staff awareness of environmental requirement

If there are combined systems in place, e.g. QMS 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.

4.4.3 Process steps for Stage 2 Audit

1) Technical 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 AE, TL discusses the logistics and audit plan with auditee organisation. TL prepares the audit Plan and intimates the client normally a week before the planned audit date 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 background details are provided to client on request.
2) During the audit planning, the EAC sector specific guidelines and audit trails is used to identify critical processes. At least 60% of audit time shall be used for auditing critical processes.
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 organisation 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 organisation 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 quality 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 organisation 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 (F48). 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. 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.

9) The visit ends with a Closing Meeting where the recorded findings and team recommendations are formally presented to the auditee organisation 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.

10) The report (F48) is handed to the auditee organisation and a copy forwarded to Head Office for review and processing. The program for next visit and auditor notes is forwarded to AE with the report. Adequacy audit report issued is also returned to AE. 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.

11) 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. If Certification body is not able to verify the implementation of corrections and corrective actions of any major non conformity within 6 months after the last day of stage-2 audit certification body need to conduct another stage 2 audit prior to recommending certification.

4.5 Follow-up Audit (FA)

4.5.1 The purpose of follow-up audits is to conduct the follow-up of non-conformance(s) of a auditee organization's quality 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.

4.5.2 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 QS Certification Middle East by the auditee organisation. 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.

4.5.3 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 Registration Committee. Technical Manager initiate withdrawal/suspension procedures, if auditee organisation 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.

4.6 Surveillance Audit (SA)

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

4.6.1 SA is intended to:

- Assess that the auditee organization's registered quality management system has been maintained.
- Verify that changes to quality 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 quality management system is appropriate to auditee organization's product, process 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.

4.6.2 The various mandatory elements to be audited at every surveillance are –

- Changes to documented system
- Management responsibility & review
- Legal regulatory compliance
- Use of certificate and logo
- Internal audits
- Corrective & Preventive actions
- Document control
- achievement of objectives and Continual improvements

- Appeals / Complaints / communication from external interested parties
- Effectiveness of quality management system to achieve auditee organization's policy, objectives & targets.
- Progress of the planned activities and continuing operational
- Follow-up on identified non-conformities (internal / certifying body)
- Appeals / complaints received by Qs Certification Middle East

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.

4.6.3 Process steps for Surveillance Audit

The team leader is responsible for managing and documenting the results of SA. The team leader may delegate specific responsibilities for conduct of audit activities to assigned audit team members. Technical Manager is responsible for review of audit report to assess effectiveness. The process steps for the Surveillance Audit are -

1) Technical 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 last day of Certification Audit. A set of necessary documents like client details, earlier audit report etc is given to TL. On receiving the audit schedule from the AE, TL discusses the logistics and audit plan with auditee organisation.
2) TL shall review the functions / processes audited in the earlier surveillances before finalizing the audit plan. TL shall ensure that all critical processes 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 organisation of the objectives of audit, details of the audit and schedule and obtain auditee organization's cooperation. Auditee organisation 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 organisation 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 Technical Manager or appointed person for further consideration.
6) The auditee organization's quality 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 organisation performance and determines the recommendation (registration to continue or follow-up is required). The team prepares the audit report (F48). 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 organisation and any follow-up actions agreed upon. The Record of Findings is handed to the auditee organisation and a copy forwarded to Technical Manager for review and processing.
9) At least one third 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 surveillances. At each visit complaints, audits, registration marks, documentation changes, and evidence of improvement will be reviewed.

Any auditee organization has to notify QS Certification Middle East in writing of any major change in the management system and / or the scope of activities. Technical Manager decides if the verification of changes can be assessed during next surveillance audit or if a special visit has to be scheduled. The performance of the special visit shall be similar to

normal surveillance and Technical Manager shall inform the assigned auditor to audit the required changes in system.

4.6.4 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.

4.7 Recertification (Triennial Audits)

4.7.1 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, commitement to enhance and maintain overall effectiveness and improvement of the manageme nt system and whether the operations of a certified client contributes to the achievement of the clients policy and objective.

4.7.2 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 QMS or FSMS, activities, location and scope of certification.
- **During recertification audit planning Technical 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 QMS performance
- The triennial audit is a full audit of the auditee organization's quality management system and generally follows the same process 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.

4.7.3 Decision on renewing the certificate will be made by QS Certification Middle East India 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.

4.7.4 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).

4.7.5 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.

4.7.6 When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the

recertification decision.

4.7.7 If **QS Certification Middle East** has not completed the recertification audit or the certification body is unable to verify the implementation of corrections and corrective actions for any major nonconformity, prior to the expiry date of the certification, then recertification shall not be recommended and the validity of the certification shall not be extended. The client shall be informed and the consequences will be explained.

4.7.8 Following expiration of certification, **QS Certification Middle East** can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date will be based prior certification cycle.

4.8 Special Purpose Visits

4.8.1 Registered quality 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. 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, Technical 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 QS Certification Middle East Certification committee may also discuss the findings with the audit team.

4.8.2 Extensions to scope change in management for clients already registered with QS Certification Middle East

- Questionnaire should be completed by the client and returned to QS Certification Middle East
- Contract Review will always be carried out by the Technical 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 Technical 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 QS Certification Middle East

Note: After certification, if the client changes anything which significantly affects the registration, then QS Certification Middle East must be informed. QS Certification Middle

East reserves the right to re-assess.

4.8.3 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 Technical Manager and verified if the client's activities are within the QS Certification Middle East 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.

4.8.4 Short Notice audits for clients registered with QS Certification Middle East

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.

4.9 Transfers

4.9.1 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.

4.9.2 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 QS Certification Middle East
- 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 programme 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 QS Certification Middle East with evidence of corrective actions taken for QS Certification Middle East to close out.
- Request verbal confirmation of the effectiveness of the complaint system. Request details of any major problems.
- For EMS only – 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 authorisation by the Certification Committee.

4.9.3 The programme of surveillance visits/triennials is to be adopted from the previous

certification body if applicable. Appendix Document is signed by the MD of the certification body and Technical Expert (if applicable) to authorise 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 QS Certification Middle East

4.10 Opening and Closing Meetings

4.10.1 The Opening and closing meeting are a critical part of the audit process. 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 organisation 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.

4.11 Multi-site audits (QMS only) (refer to IAF Guide 62 Annex 3)

4.11.1 This procedure only applies in certain circumstances, e.g. distribution companies, recruitment companies etc and it is the responsibility of the Contract Review process and the person planning the audit to determine its use. The program is particularly suited to those organizations:

- Engaged in distribution, having a number of strategically placed geographic distribution centers; or
- Operating a multi-outlet wholesale business; or
- Performing simple, repetitive processing at a number of different sites.

4.11.2 The program may be applied to the whole of the organization under an initial registration, or only part of the total number of sites may be registered initially, with others to be added later at the client's convenience.

Be particularly careful when planning audits on multi-site companies to take into consideration the working shifts and those that may require particular expertise. Ensure that the programme caters for a representative sample of the activities undertaken.

It is usual to audit the company Head Office and a sample of sites if all sites are working to the same management system and activities on each site are the same (e.g. a recruitment agency). (Company Head Office is usually where most of the system records are kept but this is not always the case, each job is to be judged individually.)

4.11.3 There may be situations where sampling is not permitted due to the nature of the work or because the activities on each site are not common to each other. In this situation, the programme would need to allow for visiting each site, and would determine the need for a full audit with resulting documentation at each site visited.

If the activities are common and a sample is taken initially, a rolling programme of surveillance visits must be established.

If additional sites need to be added, the client must be able to demonstrate that the new sites are included in a controlled manner. These will normally be treated as an extension to scope.

They must be added to the rolling programme, increasing the amount of surveillance time and costs as appropriate.

4.11.4 With large, multi-site companies it is usual to appoint a Project Leader who will be responsible for on-going liaison with the client, arranging dates for surveillances, co-ordinating the rolling programme, and dealing with any day to day queries and sorting out extensions to scope. This ensures continuity with the client and that correct sites are visited on rolling programme.

It is not necessary to raise opening and closing meeting for every site visited, but a schedule is to be available for each auditor.

4.12 Multi-site audits (EMS, GMP, HACCP, FSMS, FSSC & HSE)

4.12.1 Multiple site audits under the control of a single EMS, FSMS & HSE are carried out in accordance with the following.

All sites will be audited or the Head Office and a representative number of sites may be sampled by the audit team providing:

a) All sites have been audited in accordance with the internal audit procedures

b) A central management review has been carried out.

4.12.2 The sampling of the sites must include a representative number. The selection of the sites takes into account:

These requirements will be considered by the Certification Committee before awarding certificates.

4.13 IMS audits

4.13.1 Where there is a combined documented system the audits are carried out in accordance with this procedure with the completion of the auditor's reports showing that they have looked at the requirements of integrated management system standards in the areas allotted to them. The auditors assigned to the areas are trained in the requirements of the relevant standard(s) and if necessary two auditors cover one area to ensure all requirements are addressed.

4.13.2 The audit is carried out according to the audit plan produced at Stage 1 / Document Review, with the Lead Auditor ensuring that the appropriately trained auditors are used for each area and part of the individual standards. Care is taken to ensure that the appropriate amount of time is spent on each area in the company and for ensuring full coverage of the standard requirements. The areas covered are reported on with details of the time spent in the key areas and indications of non-conformances. Where the auditors cover the requirements of more than one standard in one area at the same time during the audit, then the report should indicate this and examples recorded should show evidence of this.

A plan for surveillance visits is produced at the end of the audit taking into account the time needed for each standard and the expertise for the various surveillance visits as well as the areas to be looked at.

4.13.3 Where a non-conformance is applicable to both standards, only one report is raised and referenced to both standards if appropriate.

4.13.4 If the recommendation is positive for both standards then one audit report (F44 or F48) is raised. Similarly, if the recommendation is negative for both standards then one audit report is raised. If the recommendation is positive for one standard and negative for the other, two audit reports will be completed separately.

4.13.5 This procedure is followed for surveillance audits with the additional EMS, GMP, HACCP,

FSMS, FSSC & HSE sections being completed in the audit report. The auditor must ensure that sufficient time is allowed in each area to cover the requirements of both standards adequately. The auditors report must show clearly that the requirements of both standards have been subjected to audit and evidence of compliance recorded.

4.14 Sampling plan and auditing time

4.14.1 As such there is no statistical or mathematical formula to establish the right number of samples to be taken during an audit. Defining the number of samples to be taken to confirm conformity to the requirements of the standard is not efficient and does not ensure conformity. Adequate sampling would refer to a level of sampling taken during on site interviews and record reviews that give sufficient confidence that the auditee's QMS, EMS, GMP, HACCP, FSMS, FSSC & HSE is implemented and maintained.

4.14.2 The auditor needs to perform interviews and check records and evidence during interview. The number of samples to be taken depends on the complexity of the processes being audited and the quality of information received from the auditee during the interview. It is also important that the auditor maintains the schedule outlined in the audit plan. At the end of the day the auditor needs to feel comfortable that the samples and the objective evidence seen are representative, in order to draw appropriate conclusions regarding the implementation of QMS, EMS, GMP, HACCP, FSMS, FSSC & HSE.

QS Certification Middle East auditors will spend about 60% of the audit time for critical process audits.