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
- Unannounced audit
- Recertification audit
- Transfer audit

3.0 Responsibility

3.1 **Document Management Officer** is responsible for the submission of the Audit Pack for Final review and approval. Ensuring the audit reports are received timely and submitted for review, verification, and approval.

3.2 **Audit Team Leaders/Auditors** are responsible for preparation of audit plan, submission to client, execution of audit, issuance/review/closing of audit finding, and submitting the audit pack on time.

3.3 **Shariah Expert** is independent. He is responsible for verification of Islamic compliance whenever the Team leader have doubt on the process, requirements, ingredient, and others.

3.4 **Halal Product and Management System Certification In-Charge/ Technical In-Charge** is responsible for reviewing of Audit pack submitted by Audit Team Leader and endorsement for committee verification and approval.

3.5 **Quality Assurance In-Charge / Quality Assurance Officer** is responsible for reviewing the Audit Plan prior sending to clients and ensure that the established plan includes appropriate attention to important areas and matters with regards to the criteria and scope of the audit. Responsible for monitoring the submission of the audit findings and audit report of auditors.

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 with ISO 9001, ISO 14001, OHSAS 18001, ISO/TS 22003-1, FSSC 22000, UAE.S 2055-1:2015, GSO 2055-1:2015,PNS Halal Certification Scheme of 2018 & other food safety / product 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 (e.g Philippine National Halal Certification Scheme of 2018, ISO 9001:2015) as stated in the Certification Agreement 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 In-Charge 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 In-charge. Technical In-charge shall review the same and take necessary decision which may include replacing the person with some other auditor.

In the case of Halal certification, the audit team consists of at least two personnel. One will be *halal auditor* and the other one will be a Halal Islamic affairs expert.

PCIAPI will make sure that the selection of auditors / technical experts for audit & certification for management system, Halal, product certification & EQM are based on the respective staff's qualification,

experience (industry / auditing), etc. The auditors /evaluator approved codes are mentioned in the individual (Auditor's) evaluation record.

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. PCIAPI 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 non-conformance is found, the recommendation will be on hold until suitable corrective action has been taken as evidence.

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 critical/major/minor nonconformance as appropriate will be raised. Follow-up visits are made to verify that critical and 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 PCIAPI will inform Prime Certification & Inspection 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 PCIAPI. In case of violation of legal requirements is observed during the course of a Registration Audit (Stage 2 Audit) or Surveillance Audit(s), Prime Certification & Inspection 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 Prime Certification & Inspection 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, audit shall be planned that about 60 % of the time is spent to audit the critical processes.

4.3 Adequacy Audit (Stage 1 audit)

Stage 1 Audit is a part of the registration process and not an optional activity. Stage 1 is carried out onsite or remotely , if needed. Adequacy audit term is used for QMS, EMS, GMP, HACCP, FSMS, FSSC, HALAL & 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 organization. This can be done by reviewing the available evidence. This evidence may take in 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, HALAL & HSE.

- The objective of the Stage 1 audit is to provide 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 organization
- To audit the client's management system documentation
- To evaluate the client's location and site-specific conditions and to undertake discussions with the client's 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 Prime Certification & Inspection 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 Prime Certification & Inspection 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
  - Special safety requirements
  - Security clearance requirements
  - Logistics
  - Size and complexity of the organization
  - Applicable statutory requirements & licenses
  - Technology expertise necessary
- 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.

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 with reference to 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. Documentation Management Officer advises the concerned auditor/Team Leader (Lead Auditor) of the audit assignment 10 working days before the schedule of audit.
2. Team Leader (Lead Auditor) prepares the audit plan and sends it to the client 5 working days before the planned audit date. The audit plan contains names of the audit team, scope of the audit, audit criteria, audit objective, schedule and flow of the audit and the resources required for conducting the audit. Auditor background details are provided to client on request.
3. An opening meeting is held to put the auditee organisation 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 questionnaire and contract review. This shall be reviewed by Technical In-Charge 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 is prepared for handing over at the closing meeting. Based on 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 6 months after the last day 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.
13. Halal / product certification cases PCIAPI will take random sample collection as per the specific product sampling plan. The sample will be collected from customer premises, customer outsourced presumes / market for verify the product conformity. The selection of laboratory and procedure for product sampling shall be decided by PCIAPI.
14. For product certification, during the stage 1 audit the product sample will be collected from customer end or the sample should be packed, marked and sealed by the presence of PCIAPI auditor and transferred / transported to PCIAPI agreed laboratory.

4.3.5 Non-Conformity and Sentencing of critical, major, and minor non-conformances – QMS, EMS, OHSAS, GMP, HACCP, FSMS, FSSC, Product Certification, EQM, ECAS, etc.

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 classified in two categories for (QMS, EMS, OHSAS, Product Certification, EQM, ECAS)– Minor and Major; and the non-conformities classified in to three categories for FSMS, FSSC 22000, HACCP, GMP and Halal Certification -Critical, Major and Minor non -conformities.

4.3.5.1 During an audit a minor non-conformity shall be deemed present when any activity is not 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 nonconformance 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 the specified timeframe from the last day of the audit, then the award will be taken place. If not, a complete re-audit is to be carried out at the discretion of the Certification Manager/Group Chief Executive Officer. 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 In-Charge will confirm the time and auditors for the close-out visit and will advise the sales and marketing team about the invoicing.

Note: PCIAPI requires the customer to analyses the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities, within a defined time. The customer should submit corrective action plan to PCIAPI within 7-14 working days from the last day of audit (Stage-2, Sur-1&2, Follow-up, Unannounced and Recertification audit), depending on the criticality of the non-conformity and Corrective action with objective evidences within 28-66 working days from the last day of audit (Stage-2, Sur-1&2, Follow-up, Unannounced and Recertification audit), depending on the criticality of the non-conformity.

In case of the stage-1 audit findings, the customer is not required to submit the corrective action plan and corrective action with evidence to PCIAPI. However, the customer is required to take appropriate corrective and preventive action to eliminate the identified observations prior to the stage 2 Audit.

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.

4.3.5.5 For FSMS, FSSC 22000, HACCP, GMP and Halal Certification (2055-1:2015 and 2067:2008) there are three levels of non-conformity grading/classification;

Applicable only for Stage 1

- *Major Area of Concern*
- *Minor Area of Concern*

Applicable for Stage 2 / Surveillance / Recertification

- *Critical non-conformity*
- *Major non-conformity*
- *Minor non-conformity*

Applicable for all stages of audit and standards (except for FSSC 22000 and BRC Certifications)

- *Opportunities for Improvement*

Major Area of Concern *(Applicable only for Stage 1)*

When a management system does not fulfill the requirements of one or more elements of a standard. It may affect its capability. If not addressed, this could lead to a Major Nonconformity in Stage 2.

Minor Area of Concern *(Applicable only for Stage 1)*

When a management system does not meet the expected levels of achievement for one or more elements of a standard. Hence, it will not affect its capability. Although, if not addressed, this could lead to a Minor Nonconformity in Stage 2.

Critical non-conformity

A critical nonconformity is issued when a direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/or certification integrity are at stake:

1) when a critical nonconformity is issued during an audit, the organization shall provide root cause analysis, exposed risks and the proposed corrective action plan (CAP). This shall be provided to PCIAPI

within 7 working days after the audit. PCIAPI will review the proposed corrective action plan and approve it when acceptable.

2) corrective action with evidence shall be submitted to PCIAPI within 28 working days
3) a separate audit shall be conducted by PCIAPI within 28 working days after the regular audit to verify the effective implementation of the corrective actions. This audit shall be a full on-site audit (with a minimum on-site duration of one day). After a successful follow-up audit, the certificate and the current audit cycle will be restored and the next audit shall take place as originally planned (the follow-up audit is additional and does not replace an annual audit). This audit shall be documented, and the report uploaded.
4) when a critical nonconformity is issued at a certified site the certificate shall be suspended until the critical non conformity is closed;
5) the certificate shall be withdrawn when the critical nonconformity is not effectively resolved within 28 working days;

Major non-conformity

A major nonconformity shall be issued when the finding affects the capability of the management system to achieve the intended results:

1) the organization shall provide PCIAPI root cause analysis and proposed corrective action plan (CAP) within 14 working days from the last date of audit. PCIAPI will review the proposed corrective action plan and approve it when acceptable.
2) PCIAPI shall decide to conduct a follow-up audit or a desktop audit to verify the implementation of the CA and to close the Major Non-Conformity. PCIAPI will review the corrective action plan and conduct an on-site follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, PCIAPI may decide to perform a desk review instead. Corrective Action with evidence shall be submitted within 28 working days from the last day of the audit;
3) when the major nonconformity cannot be closed in this timeframe, the certificate shall be suspended;
4) the completion of corrective actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causal factors. In such cases the corrective action plan shall include any temporary measures or controls necessary to mitigate the risk until permanent corrective action is implemented.
5) a critical NC is raised in the event of non-completion of the approved corrective action plan for the major non-conformity.

Minor non-conformity

A minor nonconformity shall be issued when the finding does not affect the capability of the management system to achieve the intended results:

1) the organization shall provide PCIAPI Audit Team the root cause analysis and proposed corrective action plan (CAP) within 14 working days from the last date of audit. PCIAPI will review the proposed corrective action plan and approve it when acceptable.
2) corrective action (CA) shall be implemented by the organization within the timeframe agreed with the PCIAPI Audit Team. Corrective Action with evidence shall be completed within 66 working days after the last day of the audit.
3) effectiveness of implementation of the corrective action shall be reviewed at the next scheduled on-site audit.
4) failure to address a minor nonconformity from the previous audit could lead to a major nonconformity being raised at the next scheduled audit.

Opportunities for Improvement

Aspects that would lead to management system optimization with respect to a requirement of the standard.

1) Basic requirement for the identification and recording of opportunities for improvement is that the requirements of the standard chapter have been fulfilled but that there are still areas for potential improvement of system effectiveness and efficiency.
2) Implementation by the organization is recommended.
3) The use of opportunities for improvement (OFI) during FSSC 22000 and BRC assessment are not allowed.

4.3.5.6 In case of BRC Certification, the Non-Conformities are categorized as Critical, Major and Minor. Observations are not at BRC assessments.

Non-conformances are raised against the clauses of the standard. The standard does not permit clustering minor non-conformances for one clause into one minor non-conformance. The standard does permit escalation from a minor to major non-conformance where there are many minor nonconformances against one clause.

In some circumstances the number or severity of non-conformances raised at the audit prevents the site being certificated following that audit.

If client organization is unclear of the information in the report, they must contact, PCIAPI Technical In-Charge / Technical representative as soon as possible.

Where non-conformances have been raised during organizations' assessment PCIAPI will provide guidance on the steps that are needed to take place to continue to certification. Such guidance may include timeframes for close out or requirement for re-assessment. PCIAPI cannot provide guidance on how to close out non-conformances.

Non-conformances identified at as assessment are required to be closed out within 28 days of the assessment.

It is client organization's responsibility to respond to the non-conformities detailed in audit report by the designated time frame. Failure to do so may result in suspension or cancellation of certification. Definitions and close-out requirements for non-conformities are defined in the BRC Global Standard for Food Safety Issue 7.

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 In-charge together with Documentation Management Officer schedules the audit and informs the Audit team leader (TL) of the audit assignment 10 working days prior the audit schedule. A set of necessary documents like client details, Stage 1 audit report etc is given to Team Leader (Lead Auditor). On receiving the audit schedule, Team Leader prepares the Audit Plan and submits it with auditee organisation within 5 working days prior the audit schedule. 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 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 (P/49A). 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 Certification Manager / TM. 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 evidence 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 (P/50A) 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 Technical In-Charge with the report. 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 evidence of corrective actions taken within the agreed timeframe of the Team Leader (Lead Auditor) and organization from the last day of audit (HACCP, FSMS, QMS, EMS OHSAS, Halal, Product certification, EQM, ECAS, etc..). Failure to satisfactory closure shall result in complete re-audit.

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 an 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 Prime Certification & Inspection by the auditee organisation. If the follow-up audit is not performed within three months of the registration audit, a partial re-audit must 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 forwarded to the Certification Committee. Technical In-Charge 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 organization, 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
- Legal regulatory compliance
- Internal audits
- Document control
- Management responsibility & review
- Use of certificate and logo
- Corrective & Preventive actions
- 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 Prime Certification & Inspection LLC

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 Team is responsible for review of audit report to assess effectiveness. The process steps for the Surveillance Audit are -

1) Technical In-Charge together with the Documentation Management Officer 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 In-Charge 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 (P/48A). 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 Prime Certification & Inspection 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 must 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 Unannounced audit for FSSC 22000

In case of FSSC 22000 certification, PCIAPI will conduct at least one unannounced audit within each 3-year period. The initial audit (stage 1 and stage 2) and the recertification audit can't be replaced by an unannounced audit. The PCIAPI decides which of the scheduled surveillance audits shall be chosen for the unannounced audit. The site shall not be notified in advance, by the PCIAPI, of the date of the unannounced audit. The unannounced audit takes place during operational working hours including night shifts. The unannounced audit is a full surveillance audit.

During the audit, the lead auditor;

1. Allow the organization half an hour to get organized for the unannounced audit.
2. Be at the shop floor within an additional one hour after arrival at the site.
3. Spend at least 50% of the time in production area (shop floor) assessing the implementation of the applicable CCPs, PRPs and OPRPs.
4. Audit the organization operating on a representative number of product lines covered by the scope of certification.

In case of multiple buildings at the site the auditor shall, based on the risks, decide which buildings/facilities shall be inspected in which order.

When there are legitimate business reasons, blackout days may be agreed in advance between the PCIAPI and the certified organization to avoid periods of extreme inconvenience during which the client would find it difficult to participate fully and/or there is no production.

The organization is requested to inform the PCIAPI about the blackout days within 2 weeks. The PCIAPI and organization will mutually agree on the blackout days, for the coming 12 months, within a further 2 weeks

The unannounced audit shall be conducted within a timeframe of 4 to 12 months after:

1. The (re-) certification decision and/or
2. The last day of the previous announced surveillance audit.

Seasonal production shall be covered by blackout days

Opening meeting:

The audit will start with an opening meeting chaired by the lead auditor.

During the opening meeting the lead auditor will confirm:

1. the scope of the unannounced audit
2. the audit plan of the unannounced audit
3. the formal communication channels
4. which key-personnel/functions shall be interviewed

Consequence of an unannounced audit

If not present during the audit the following functions shall be audited during the next scheduled audit:

1. Top-management
2. Human resources
3. Outsourced supporting services.

There shall be an appointed deputy for all other functions to be interviewed by the FSSC 22000 audit team.

Production lines that are not operated regularly (e.g., seasonal production) shall be audited during the next scheduled audit.

Exemptions:

The unannounced audit is in a so-called surprise audit. It is not always possible to organize an unannounced audit without the corporation of the FSSC 22000 certified organization.

Examples are:

1. Country specific procedures for admittance or acquiring visa
2. Country specific conditions where the auditor cannot travel to the site without a guide.

Guidance in case of an exemption situation

The organization is notified 1 month in advance of the week in which the unannounced audit shall take place. The organization is not notified about the exact date. The audited organization shall facilitate the auditor in any way possible to:

1. Acquire the necessary permission or visa for the authorities.
2. Guarantee safe accommodation and travel conditions to the site.

Sanctions:

In the event that the FSSC 22000 certified organization refuses the entry of the audit team during the unannounced audit, the certificate shall be suspended immediately by the PCIAPI.

The suspension will be lifted, and the certificate will be reinstated upon successful passing of an unannounced audit.

The *PCIAPI* withdraw the certificate, if the unannounced audit is not conducted within a six-month timeframe after the date of the refusal.

The sanction shall be confirmed within 3 working days by the PCIAPI.

If access is denied to the auditor, the FSSC 22000 certified organization will be liable for all costs.

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, 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 Prime Certification and Inspection Asia Pacific Inc. based on results of recertification audit (review of report), review of the certified client's system over the period of certification and any complaints received against the certified client over the certification period.

4.7.4 In accordance with ISO/IEC 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 PCIAPI has not completed the recertification audit or the PCIAPI 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 is not recommended, and the validity of the certification is not extended. The customer shall be informed, and the consequence is explained.

Following expiration of certification, PCIAPI 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 is on or after the recertification decision and the expiry date is based on prior certification cycle. Any renewal application submitted less than 1 month before the current Halal certificate expiry date, will be treated as a new application, and shall be subjected to the prevailing application fees and to audit certification process.

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 Prime Certification & Inspection 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 Prime Certification & Inspection

- Questionnaire should be completed by the client and returned to Prime Certification & Inspection.
- Contract Review will always be carried out by the Certification Manager / 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 Team 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 Prime Certification & Inspection

Note: After certification, if the client changes anything which significantly affects the registration, then Prime Certification & Inspection must be informed. Prime Certification & Inspection 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 Prime Certification & Inspection 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 affected 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 Prime Certification and Inspection Asia Pacific

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.

Requirements and conditions 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.

All surveillance reports are reviewed by the Technical In-Charge, should cause for a serious concern be noted, during these reviews, the Technical In-Charge may determine the need for a special visit. The Technical In-Charge shall decide the specific areas to be investigated during the special visit and will advise the company in writing. The Technical In-Charge shall then decide upon the personnel to undertake the special visit which would include an Audit Team Leader and if necessary, an Expert with expertise in the auditee company's operations.

The objective of this type of audit is to:

(a) Ensure that the client's management system has been maintained on continuous basis under changed situation,

(b) Verify and ensure that any changes to management system which might have taken place due to changed situation, meet the requirements of the standard/specification, and are implemented effectively,

(c) Ensure that the management system continues to be appropriate to the product/process/service offered by client, with the capability of managing and improving performance

The assigned team leader is responsible for conducting and managing the assessment along with another team member, if any. The Team Leader shall be of Auditor status as a minimum. As far as possible, same team should be sent for this audit as wad for the certification audit.

Based on the review above, decision regarding onsite reassessment would be made and generally concerned procedure shall be followed. If only the name of the client is changed and there are on other changes (for example there is no change in the management), decision to reissue the certificate could be taken on the basis of details (including the details regarding the legal status) provided by the client. Since this type of audit requires re-issue of certificate, the "Certification Details" in the report shall be completed and data base shall be updated. This shall be followed for verification in the next surveillance visit. On completion of the special visits, the visit leader will complete a client visit report to which assessment continuation sheets may be attached detailing the investigation and the decisions taken during the special visit. The special visit report will be reviewed by the

Technical Manager and, should the withdrawal of the client certification be recommended, a report shall be submitted to the certification manager for approval of the recommended action.

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 Prime Certification & Inspection
- Try to establish the reason for the client wanting to transfer.
- Check that all 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 Prime Certification & Inspection with evidence of corrective actions taken for Prime Certification & Inspection 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 authorization by the Certification Committee.

4.9.3 The program of surveillance visits/triennials is to be adopted from the previous certification body if applicable. Appendix Document is signed by the Certification Manager of the certification body 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 Prime Certification & Inspection.

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 customer is given opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the customer is discussed and resolved where possible. Any diverging opinions that are not resolved are recorded and referred. 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.

		Opening	Closing
A	Thank client for selecting Prime Certification & Inspection Mutual Introduction of auditors and auditee	●	
B	Thank auditee for hospitality. Thank guides for their support.		●
C	Circulate attendance sheet	●	●
D	State and confirm the contracted scope for certification and objectives of audit.	●	●
E	Confirmation of formal communication channels between the audit team and the client. And confirmation of the language used during the audit	●	
F	State that TL represents audit team. Determine auditee representative, guides and observers	●	
G	Confirm the audit plan and verify no conflicts with the plan. Reconfirm time and location for closing meeting. Make necessary amendments on request	●	
H	Information about the conditions under which the audit may pe prematurely terminated	●	

I	Confirmation that the audit team leader and the audit team representing the PCIAPI I is responsible for the audit and control / executing the audit plan including audit activities and audit trails	●	
J	Confirmation of the status of findings of previous review or audit	●	
K	The method of reporting, including any grading of audit findings & explain the terms non-conformance (critical, major & minor) and observation	●	●
L	Communicate the policy of notification by auditee for legal / statutory violation.	●	●
M	Request sufficient sets of documentation, suitable room and office support	●	
N	Explain auditor's responsibility to comply with code of conduct and confidentiality	●	●
O	Explain that audits are sampling exercises and other issues may exist. Refer to the need of ongoing internal audit and ongoing surveillance. For PA stress that the audit does not guarantee to identify all areas of non-conformance	●	●
P	Request advice on safety requirements and availability of safety equipment.	●	
Q	Explain that, during the audit the client will be kept informed of audit progress and any concerns		
R	Explain the findings /gradings of finding. 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. Time frame for client for correction, corrective active action plan and CAPA report.		●
S	State conclusion and recommendation of audit team. Explain that the team can only make recommendation. Explain the concept of Certification committee. Explain that appeals process exists and is available on request.		●
T	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		●
U	Invite questions	●	●

4.10.2 Preparing audit conclusions (Closing meeting)

The responsibility of audit team leader and prior to the closing meeting, the audit team:

a) reviews the audit findings, and any other appropriate information collected during the audit, against the audit objectives and audit criteria and classify nonconformities added;

b) agrees upon the audit conclusions, taking into account the uncertainty inherent in the audit process;

c) identifies any necessary follow–up actions;

d) Confirms the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope, audit time or dates, surveillance frequency, competence).

4.10.3 The closing meeting also includes the following elements. The degree of detail is dependent upon the familiarity of the customer with the audit process:

a) advising the customer that the audit evidence collected was based on a sample of the information; thereby introducing an element of uncertainty;

b) the method and timeframe of reporting, including any grading of audit findings;

c) the PCIAPI for handling nonconformities including any consequences relating to the status of the customer's certification;

d) the timeframe for the customer to present a plan for correction and corrective action for any nonconformities identified during the audit;

e) the PCIAPI post audit activities;

f) information about the complaint handling and appeal processes.

4.10.4 The customer is given opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the customer is discussed and resolved where possible. Any diverging opinions that are not resolved are recorded and referred to the PCIAPI.

4.10.5 The official audit findings report shall be submitted to the client by the Team Leader (Lead Auditor) within 3 working days after the last day of audit.

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 expertise. Ensure that the program 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 program 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 program 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 program, 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, coordinating the rolling program, 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 program.

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, BRC, HSE, etc.)

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:

- the results of central and internal audits
- the results of management review
- variations in the size of the sites
- maturity of the system
- existing knowledge of the organization
- shift patterns
- personnel involved
- repetitiveness of the work
- complexity of the EMS
- complexity of the sites
- variations in working practices
- variations in activities undertaken
- the significance of the aspects
- potential interaction with sensitive environments
- differing legal requirements
- communications from interested parties

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

In case for FSSC 22000 Certification, multi-site organizations and multi-site sampling is not applicable for categories like C: Food manufacturing, D: Animal feed production, I: Packaging, K : (Bio) chemicals. For these categories, every site shall have a separate audit, a separate report, a separate Certificate. If pertinent functions (Quality, Procurement) are controlled by a head office, an audit of these functions should be carried out (physically or remotely), and the results will feed all the separate reports. Certification of multi-site organizations is allowed for the categories like A: Farming of animals, E: Catering, FI: Distribution (retail / wholesale), G: Transport & storage.

In case for BRC Certification the BRC audit scope is site specific however, there are times where activities related to production of the product/s covered under the scope take place at other sites. Where the certificated organization has a head office or production is carried out over two sites these activities can be assessed and incorporated under a single report.

Note: Storage facilities, where they are on the same site as the production facility, shall be included in the audit of the site. Storage facilities located within a radius of 50km from the production site and are owned and managed by the company these sites can be included in the audit report.

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 considering 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 (P/44A or P/48A) 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, HALAL & 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 auditor's 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, HALAL, HSE. Etc. is implemented and maintained.

4.14.2 The auditor needs to perform interviews and check records and evidence during interviews. 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, HALAL, FSMS, FSSC & HSE.

Prime Certification & Inspection auditors will spend about 60% of the audit time for critical process audits.

5.0 Guidelines for Management of Extraordinary Events or Circumstances Affecting Certified Organizations

5.1 In a normal business environment, every organization is continuously exposed to opportunities, challenges, and risks. However, extraordinary events or circumstance beyond the control of the organization happen. In such a circumstance, PCIAPI have a process for the proper maintenance of accreditation and certification in accordance with the guidelines outlined as per IAF ID 3: 2011. It is important to PCIAPI to be able;

5.1.1 To demonstrate reasonable due diligence, mutual understanding, and trust and

5.1.2 To establish an appropriate course of actions in response to extraordinary events.

5.2 The objective of this clause is to provide to PCIAPI guidance on the appropriate course of action. This document is not intended to override requirements in standards or schemes. Where a standard or scheme provides no flexibility regardless of the crises that has occurred, guidance and an agreed way ahead will always be sought from the relevant accreditation body or scheme owner

5.3 Extraordinary event or circumstance - A circumstance beyond the control of the organization, commonly referred to as "Force Majeure" or "Act of God". Examples are war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters

5.4 Audit Certification Process – An extraordinary event affecting a certified organization may temporarily prevent the PCIAPI from carrying out planned audits on-site. When such a situation occurs, PCIAPI operating under recognized standards or regulatory documents need to establish (in consultation with certified organizations) a reasonable planned course of action.

5.5 PCIAPI will assess the risks of continuing certification and establish a documented policy and process, outlining the steps it will take in the event a certified organization is affected by an extraordinary event. The established policy and process of the PCIAPI will define methods for evaluating the current and expected future situation of the certified organization and define alternate potential short-term methods of assessing the organization to verify continuing effectiveness of its management systems.

6.0 Reference/Forms

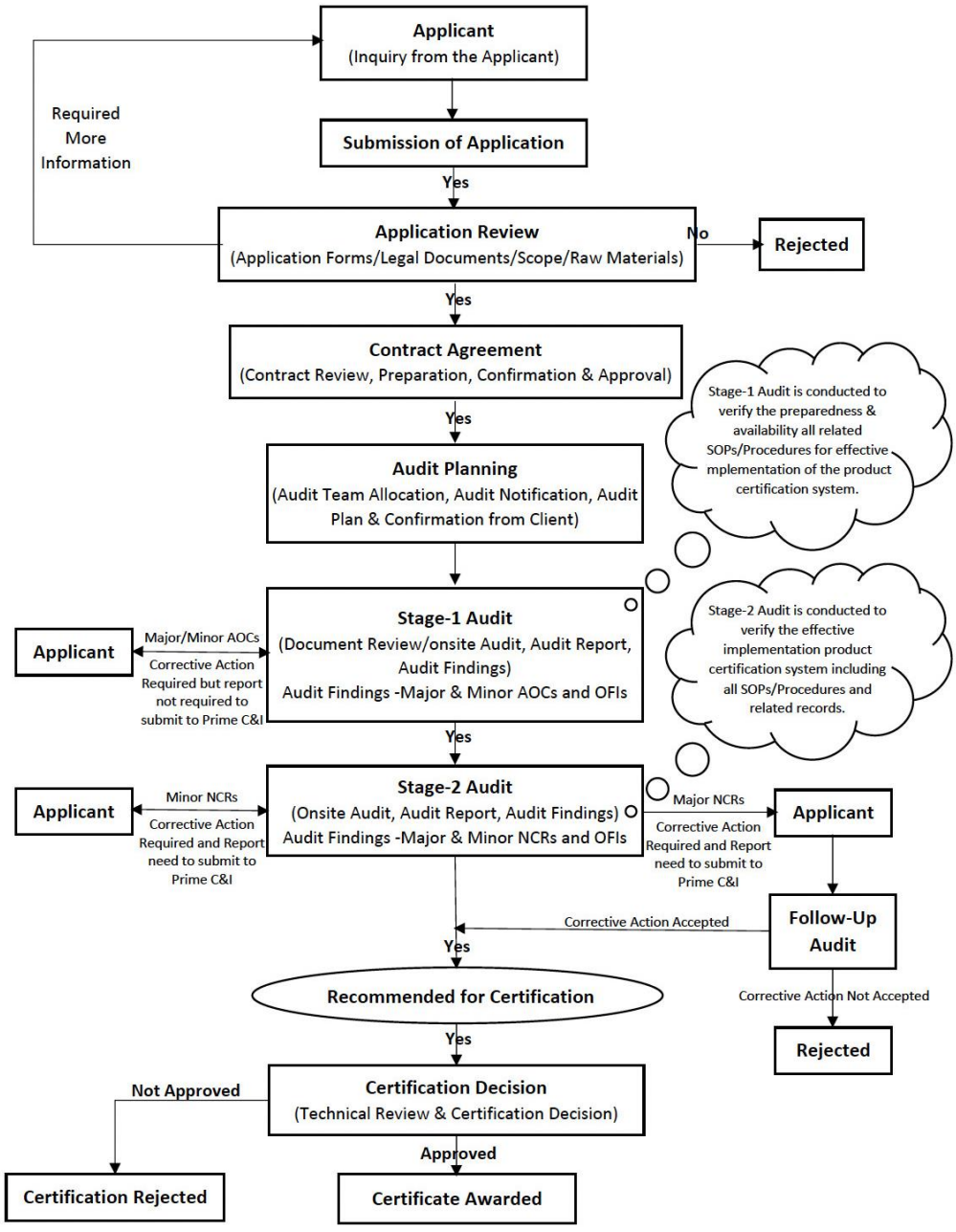
6.1 Work Instruction Auditor Qualification
6.2 Work Instruction Guidelines for GMP and HACCP Audits
6.3 Work instruction Guideline for FSMS / FSSC audits
6.4 Work instruction: Certification guideline Global standard for food safety - BRC Issue 7
6.5 Work Instruction Guidelines for ISO 9001 Audit
6.6 Work Instruction Guidelines for Halal, Product Certification Audits
6.7 Philippine National Halal Certification Scheme of 2018
6.8 ISO 19011 Auditing standard
6.9 ISO 9001 QMS standard
6.10 ISO 14001 EMS standard
6.11 ISO 22000 FSMS Standard
6.12 HACCP Codex Alimentarius Guidelines

6.13 OHSAS 18001 Standard

7.0 Formats / Exhibits

7.1 P43A – Audit Notification
7.2 P16- Basic qualification requirements
7.3 P44A Audit Programme
7.4 P45A Audit Plan
7.5 P54 Halal Audit Checklist
7.6 P-55A Halal Certification Audit Report
7.7 P-67A - Audit Notes
7.8 P51A_Audit Finding Detail
7.9 P52A_Basic Cert Info

8.0 Audit Certification Process Flow



On going Surveillance Audit & Renewal/Recertification Audit process are Similar like Stage-2 Audit.

Revision Record

Issue		Revision		Process Owner	Details of Revision
No.	Date	No	Date		
01	15.12.2020	00	-	Quality Assurance In-Charge	Initial Issuance
01	15.12.2020	01	16.04.2021	Quality Assurance In-Charge	Integrated the requirements of Philippine National Halal Certification Scheme of 2018
01	15.12.2020	02	20.04.2022	Quality Assurance In-Charge	Revised header – Change of Address
01	15.12.2020	03	17.08.2023	Quality Assurance In-Charge	Updated the procedure to comply with the requirements of ISO/TS 22003-1:2022 standard update.
01	15.12.2020	04	30.08.2023	Quality Assurance In-Charge	Revised the grading/classification of non-conformity during audit and the timeframe to close each non-conformity. Revised the responsibility and key person responsible. Updated the Audit Certification Process Flow. Updated the timeline of the submission of audit notification, audit plan and official audit findings report.
01	15.12.2020	05	05.07.2024	Quality Assurance In-Charge/ Quality Assurance Officer	Added grading/classification for Stage 1 audit which are areas of concern and opportunities for improvement. Change technical auditor to halal auditor. Align with the current function in the organization.