

Issue No : 02	Procedure for Conducting Conformance Assessments (stage-1 & 2)		
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1.0 **PURPOSE**

- 1.1 To define the procedure for planning, conducting and reporting of Stage – 1 & 2 assessments carried out by FCI

2.0 **SCOPE**

- 2.1 This procedure applies to all conformance audits conducted by FCI for ISO 22000 and HACCP Schemes.

3.0 **RESPONSIBILITIES**

- 3.1 **The Designated Person(DP) is responsible for overall implementation of this procedure.**
- 3.2 The DP shall be responsible for ensuring that the audit is planned, managed and conducted in accordance with this procedure.

4.0 **PROCEDURE**

4.1 Audit Planning and Preparation

- 4.1.1 Assessments shall be carried out in two Stages (Stage 1 & Stage 2) and both shall be carried out on site.
- 4.1.2 The DP will agree upon and schedule the assessment (Stage 1 and Stage 2) audit with the Client. The goal is to schedule the assessment requested by the Client as per the target date and conduct the audit on the target date.
- 4.1.3 The DP will decide the composition of the audit team, ensuring that assessor qualifications match audit requirements as per procedure. FCI may attach technical experts to support the audit team who are selected basing on FCI Procedure.

4.2 AUDITOR SELECTION:

- 4.2.1 DP will schedule the assessment on request from the client with the Audit mandays as per contract review meeting the Auditor Competency Requirements from the Approved Auditor/Technical expert list. The schedule is forwarded to the client and audit team.
- 4.2.2 Assessment's are performed either by one auditor or audit team basing on the budgeted & required audit man days and to maintain the technical competency of the audit. The details of qualifications with respect to sector specific scopes of the auditors are given in QMS/AN-9.

4.3 Conducting of Stage-I & II assessment.

- 4.3.1 Audit team members will assemble with downloaded documents and/or documents sent by the DP. Any missing information should be requested from the DP.
- 4.3.2 Prior to the audit or prior to the opening meeting during the scheduled assessor preparation time, the Team Leader will conduct a team briefing, if applicable. The team briefing will cover the following items as a minimum:
- Introduce all audit team members.
 - Answer any questions the team members may have about conducting the audit.
 - Review the audit plan, scope and standard.
 - Review FCI definitions of minor and major nonconformances and potential registration recommendations.
 - Stress the importance of obtaining objective evidence.

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4.4 Conducting Assessment

- 4.4.1 The Team Leader may convene with any or all assessors at any time during the audit to review their findings and determine any changes in planned activities and the audit plan.
- 4.4.2 Individual assessors are responsible for documenting non-conformances and opportunities for improvement on the Non-conformance Report and submitting them to the Team Leader before the closing meeting.
- Assessors identifying a possible "critical/major" nonconformance shall inform the Team Leader as soon as practical.
 - A nonconformance will **only** be sanctioned by the Team Leader if it is capable of being written in the words of the standard and/or documented system and is substantiated by objective evidence.
 - Assessors are encouraged to document Remark for improvement to benefit the Client.
- 4.4.3 Clearly describe the nonconformance on Nonconformance Report. Only one nonconformance may be documented on each Nonconformance Report however, multiple situations of the same nonconformance type may be documented on the same form.
- If the Client addresses a nonconformance to the assessor's satisfaction prior to the closing meeting, it may be "Approved" and "Verified" during the audit. Assessors are discouraged from this practice as it takes time from the audit and may not do justice to root cause analysis.
- 4.4.4 The Team Leader shall approve all Nonconformance Reports.
- 4.4.5 Audit Team will reconvene approximately **thirty (30) minutes** before each end-of-day meeting with the Client. They will then submit their findings to the Team Leader to determine whether non-conformances have been identified.
- 4.4.6 The Team Leader is responsible for obtaining the Client's Management Representative's signature on each Nonconformance Report.
- 4.4.7 The Team Leader will be responsible for conducting the "end-of-day" meetings, if applicable, with the Client's representatives. At these meetings the following items will be addressed as a minimum;
- The findings to date, including any nonconformances identified.
 - Additional information required from the Client to plan the remainder of the audit.
 - Any questions the Client has regarding the progress of the audit.
 - A brief description of the audit activities planned for the following day.
- 4.4.8 On the final day of the audit the Team will convene approximately **one (1) hour** before the closing meeting to finalize the non-conformances that have been identified.
- 4.4.9 The assessment team will then discuss the findings.
- 4.4.10 Ideally the decision will be unanimous but in the event of a dispute the decision of the Team Leader is final.
- 4.4.11 The Team Leader will complete the Recommendation Report containing the names of the audit team and the final audit recommendation.

4.5 Opening Meeting

- 4.5.1 The Team Leader will be responsible for conducting the opening meeting as per FSMS/G-02.
- 4.5.2 The opening meeting should be brief in an attempt to hold to the established schedule.
- 4.5.3 Following the opening meeting the Team Leader may request, if applicable, a short plant tour to familiarize the audit team with the activities carried out within the Client's facility. The plant tour should be conducted per the audit schedule.

4.6 Closing Meeting

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The Team Leader is responsible for conducting the closing meeting as per FSMS/G-03

4.7 Stage 1 Assessments:

4.7.1 The objective of Stage-1 Assessment is to focus for planning the stage-2 audit by gaining an understanding of the FSMS system in place, food safety hazard identification, analysis, HACCP Plan and PRP's, Policy and Objectives and in particular the organizations state of preparedness for audit by reviewing a minimum of the following.

For both the schemes the requirements are broadly the same. For ISO 22000 (Refer 9.2.3.1.2 of ISO/TS 22003) and for HACCP (Refer Appendix-II Phase-I Investigation)

- a. Organizations identified PRP's that are appropriate to the business.
- b. Statutory and regulatory aspects and compliances (Quality, Environmental, legal aspects of the clients operation, associated risks etc) as applicable to the scope of the management system applied.
- c. Evaluation of internal audits and Management Review are being planned and performed that substantial's readiness for Stage-2 Audit.
- d. Additional processes and methods for the identification and assessment of the organizations food safety hazards and subsequent selection and categorizations of control measures.
- e. Food Safety legislation in place for the scope of the organization
- f. Achievement of organization food safety policy.
- g. Review of the clients management system documentation.
- h. Validation, verification (Internal audit, Management Review, etc.,) and improvement programs conform to the requirements of the standard.
- i. Internal communication and communication with relevant suppliers, clients and interested parties.
- j. Any additional documentation requirements or knowledge needs to be obtained in advance.
- k. Evaluation of the client location and site-specific conditions under PRP's and to discuss with the client personnel for determining the preparedness for proceeding to stage-2 audit and allocation of resources for the stage-2 audits.

4.7.2 Audit team reports all the non conformances and hand over to the company to initiate necessary correction & corrective actions for the closure of the NCs before proceeding for Stage 2 assessment. Stage-1 report of ISO 22000/HACCP shall consists all the elements mentioned under 4.5.1. above and copy to be communicated to the client.

4.7.3 The responses to the non-conformities raised during the Stage-1 audit are to be closed by the team leader before proceeding to stage-2. In determining the interval between Stage-1 and Stage-2 audit consideration shall be given to the needs of the client to resolve areas of concerns identified in Stage-1 audit. The time gap between stage-1 and stage-2 shall not be more than 6 (Six) months. In case if it is more than Six months Stage-1 process to be repeated.

4.8 Stage 2 Assessments:

4.8.1 Stage-2 audit shall be carried out at the client location and it shall include atleast minimum of the following :

For both the scheme the requirements are broadly the same. For ISO 22000 (Refer 9.2.3.2 of ISO/TS 22003) and For HACCP (Refer Appendix II.Basics for the audit Report)

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- a. Conformity to all requirements of the applicable management system standard and other related document.
- b. Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document).
- c. Performance of the management system with reference to legal compliances
Operations control of the clients processes
- d. Internal auditing and management review.
- e. Responsibility for the implementation of the clients policies.
- f. Links between the normative requirements, policy, performance objectives and targets, any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

4.8.2 Audit team report all the nonconformance and hand over to the client to initiate necessary corrective actions for the closure of the NC's. Stage-2 Report shall consists all the elements mentioned in 4.6.1 of above.

4.9 Final Report

- 4.9.1 When the audit has been completed on the receipt of corrective actions from the client the Team Leader will produce an Assessment Report to FCI within 15 working days on closure of non-conformances. ***The report is confidential to FCI and should under no circumstances be shown or issued to third parties other than the Accreditation body/legal requirements.***
- 4.9.2 Guidelines for completing this report are documented in "Guidelines to Team Leader".

4.10 Audit Documentation

- 4.10.1 The Client can also forward corrective actions for all non-conformances to the FCI by the required "Corrective Action Response Date" and FCI will co-ordinate with the Team Leader.
- 4.10.2 Team Leader shall indicate acceptance and verification of implementation of all corrective actions on the nonconformance report. If the corrective action is unacceptable or additional information is needed for verification, the Client will be asked to resubmit.
- 4.10.3 The DP or Team Leader will submit a completed Audit File Checklist along with the documentation listed to FCI within 15 working days of the closure of non-conformance. Completed Nonconformance reports and Client corrective actions shall be included.
- 4.10.4 Window for submission of satisfactory corrective actions by the client in case of Stage-2 assessment/re-registration is 28 days from the date of audit and certification process will be completed in 42 days including 28 days. (In case of Stage-1 it is 90 days).

4.11 Follow-up Audit

- 4.11.1 If an on-site follow-up audit is necessary to verify corrective actions of nonconformances documented during the audit, then the auditor deputed will assess those evidences of conformity to NC's documented and submit his recommendation report to FCI while communicating the same to the auditee.
- 4.11.2 No more than 2 follow-up audits shall be conducted.

4.12 Registration Decision

- 4.12.1 The audit documentation is reviewed by FCI Management/Designated Reviewer. **(Refer to Para 3.3 of QMS P-04. For the purpose of review for ISO 22000 and BHC, GAP, under NABCB accreditation, ISACert assessment report forms basis for use for issuing initial registration, surveillance, Re-registration and scope extensions)**
- 4.12.2 All corrective actions must be closed with root cause analysis and corrective actions verified as

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complete before consideration by the Registration Committee.

- 4.12.3 A Registration Committee will convene with at least two members to review the audit documentation per the requirements of FCI Policy Manual & Procedures.
- 4.12.4 The Registration Committee shall review the audit documentation and record its registration decision on Recommendation Report. At a minimum they shall review;
 - a. The Company Information Sheet and contract review
 - b. The Assessment Report
 - c. Nonconformance reports and associated Client corrective action responses.
 - d. The Recommendation Report;
- 4.12.5 The Director FCI shall make the certification decision on the basis of the evaluation of audit findings and conclusions and any other relevant information provided by the registration committee.
- 4.12.6 The DP shall notify the Client by letter of the decision and establish the tentative date for the first surveillance assessment if registration is granted. The three year certification cycle begins with the certification or recertification decision.
- 4.12.7 The DP shall issue a registration packet, if registration is granted.
- 4.12.8 Should the Client appeal the decision, the Registration Committee will examine this appeal and adjudicate based upon the objective evidence submitted by both parties. If a dispute still exists upon further review, the issue will be resolved as defined in procedure Appeals.

5.0 RECORDS & Forms

- 5.1 Conformance Audit History File section in Client History File

6.0 REVISIONS

Original Issue, Rev.00, Dt: 01-08-2008

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