**Purposes**

To define the process for auditing the client's management system against the requirements of the applicable audit criteria.

**Scope**

Pre-audits, document reviews, initial audits (Stage I and Stage II), surveillance, re-certification, special surveillance, extension, short-notice and transfer audits and all other type of audits. Applies to IndiaGHP & IndiaHACCP certification scheme and FSMS certification audits.

**Responsibility:**

The Auditor(s) shall ensure audit processes is in accordance with this process.

**Input**

Assignment letter

**Output**

**Audit report as per IndiaGHP & IndiaHACCP Scheme**

- INDIAGHPREPORT.F01
- INDIAHACCPREPORT.STAGE1.F01
- INDIAHACCPREPORT.STAGE2.F02
- Audit report as per FSMS Auditreport.F01 FSMS Audit report

**KPI**

- Auditor performance
- Client Satisfaction data
- Results of technical review (# of defects report)

**Reference documents**

- System User Guide

## 1.0 Audit Process

### 1.1 General

Once the assignment letter is received the Auditor shall prepare the audit plan in accordance with the requirements of IndiaHACCP AUDITPLAN.F01, IndiaGHP AUDITPLAN.F01 & ARPL-QP-20 Audit Planning Process.

### 1.2 Opening Meeting

Upon arrival at the client's site, the Lead Auditor shall chair the opening meeting; details are provided by work instruction; IndiaGHPPLAN.W01, IndiaHACCPPLAN.W01 & ARPL-WI-02 Opening and Closing Meeting Work Instruction.

### 1.3 Collecting and verifying information

During the audit, the team members shall collect and record objective evidence to demonstrate that the client's system is both implemented and effective. Information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be collected by appropriate sampling and verified to become audit evidence. Such evidence shall be obtained from interviews, review of documentation and records, observation of processes and activities and conditions in the processes audited. Records shall identify personnel interviewed.

**1.4 Remote Auditing**

The Audit records shall identify location, interviewed personnel and remote audit activities completed. Regardless of whether the remote segment take place at a different time than the on-site audit, all documents are to be submitted together at the end of the activity. Remote auditing techniques include, but are not limited to:

- Teleconferencing
- Web meetings
- Interactive web-based communications
- Remote electronic access to the management system and/or process documentation

**1.5 Audit Progress Assessment and Exchange of Information**

1.5.1 The Lead Auditor will ensure that there are regular meetings with the team throughout the course of the audit to ensure that issues identified are discussed and if necessary the course of the audit is modified to accommodate any changes necessary. These issues should be brought to the attention of the client's representative at the time that they are identified.

1.5.2 Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the Lead Auditor shall report this to the client and to the ARPL (Certification Division) Office to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The Lead auditor shall also:

- Maintain the information collected to this point in time;
- Provide the client with a report and the non-conformity(ies) leading to the interruption of the audit, if applicable.
- Indicate in the audit report the reason for the interruption of the audit.

1.5.3 The Lead Auditor shall conduct a daily debrief meeting as necessary to discuss the progress of the audit and the concerns with the client. As a result of the meeting, the audit plan may be modified.

1.5.4 The Lead Auditor shall review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the ARPL (Certification Division) Office.

**1.6 Preparing Audit Report**

The Lead Auditor is responsible for the preparation of its content as per the requirements. The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made. The audit report shall be prepared and issued by Auditors during the meeting; if no internet connection is available the report shall be prepared and issued off-line. The audit team may identify opportunities for improvement but shall not recommend specific solutions.

1.6.1 Audit Plan – As executed

As deemed necessary, the Lead Auditor amend the original version of the audit plan to reflect the real timing and sequence of the audit events

1.6.2 Three-Year Audit Programme

The Lead Auditor shall prepare or update the 3-Year Audit Programme

- At Initial certification, the lead auditor shall populate the document
- At recertification, the lead auditor shall create a new version of the programme to cover the new cycle.
- Any subsequent revisions are to be documented as appropriate by the auditor.
- As specified in ARPL-QP-17 Audit Programme Process, the audit programme shall include the initial certification or re-certification audit, the surveillance visits and the re-

certification audit at the end of the current certification cycle.

- For multi-site organizations, the sampling plan is to be used by the lead auditor to correctly identify all locations and the functions/activities at each site.
- The lead auditor, for the determination of the audit programme and for any subsequent adjustments, shall consider the size of the client organization, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits.
- Any changes to Audit Programme need to be clearly identified to in the Audit Report.

1.6.3 Nonconformities

1.6.3.1 General

- There are two types of nonconformities – Major and Minor
- Non-conformity shall be substantiated by objective evidence or absence of objective evidence such as: witnessed, recordable, verifiable, and quantitative collection of facts
- The Lead Auditor, shall review the findings and record them
- For each nonconformity, the author shall identify the following:
  - Finding: a clear description of the nature of the nonconformity; it could be in terms of insufficient implementation, unsuitability, inadequacy, ineffectiveness, etc. or in terms of lack identification of the evidence which conflicts with the requirement.
  - Requirement: The quote of the requirement of the audit criteria against which the nonconformity is being reported. This may include a reference to the audit criteria and/or the client's documentation. In the case of an Integrated Management System audit, it may refer to more than one audit criteria and/or other normative document
  - Objective Evidence: The objective evidence observed that supports the statement of nonconformity: the specific occurrence, supported by the identification of the evidence collected (e.g. - direct reference to the document being reviewed, the work station, etc.)

1.6.3.2 Major nonconformity

Major non conformity: failure to fulfil one or more requirements of the management system that raises doubt about the capability of the management system to achieve the expected outcomes or to effectively control the process for which it was intended.

Characteristics of a major nonconformity are:

a) An extensive breakdown or the absence of evidence of effective implementation of a process and/or documented procedure required by the applicable audit criteria and expected outcome.

b) Probable shipment of non conforming product to the client

c) The absence of, or total systemic breakdown of, a management system process specified in the applicable audit criteria; or any nonconformity where the effect is judged to be detrimental to the integrity of the product, processes, or service.

d) The absence of, or failure to implement and maintain, one or more management system requirements; or a situation which would, on the basis of objective evidence, raise significant doubt as to the capability of the management system to achieve its policy and objectives.

e) If there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;

f) A number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

g) A situation that is a significant real or imminent threat to the environment
h) A situation that is a significant real or imminent threat to the to human health and safety
i) A situation that could lead to a major compliance issue (compliance processes compromised, resulting in fines and/or sanctions from regulatory agencies)

**Note:** A major nonconformity usually represents a material risk to product quality, human health and safety, or impact to environment, and raises doubt about the capability of the management system to achieve its policy and objectives.

1.6.3.3 Minor nonconformity

Minor non conformity: failure which does not impact the capability of the management system to achieve the expected outcomes.

Characteristics of a minor nonconformity are:

a) A failure to fully satisfy a requirement of the audit criteria with a documented procedure, when required.
b) a situation that is a minor real or potential threat to the environment
c) a situation that is a minor real or potential threat to the to human health and safety
d) a situation that could lead to a minor compliance issue (minor issues not compromising overall compliance processes and resulting in no significant fines and/or sanctions from regulatory agencies)
e) A breakdown in the effective implementation of a documented procedure in isolated incidents.

**Notes**

- A minor nonconformity usually does not represent a material risk to product quality, human health and safety, or impact to environment, and does not raise doubt about the capability of the management system to achieve its policy and objectives.
- A number of minor non conformities associated with the same requirement or issue could demonstrate a systematic failure and thus constitute a major non conformity.

1.6.3.4 Opportunities for Improvement (OFI)

- Definition: an opportunity to enhance the existing work process/practice/method that conforms to the requirement of the audit criteria and/or of the organization, but may not represent the current state-of-the-art approach, or best practice, but may represent a potential for a nonconformity.
- The auditor should identify the area for improvement but cannot offer a specific solution
- Audit findings, however, which are nonconformities, shall not be recorded as opportunities for improvement.

1.6.3.5 Areas of Concern for Stage II

- Definition: Findings identified during the Stage I audit that could be classified as nonconformity during the stage II audit. The classification for areas of concern is as follows.
- Area of concern-minor: This would be a concern that potentially at the stage 2 audit could result in a non-conformity.
- Area of concern-major: This would be defined as if not addressed by the client

prior to stage 2 this would result in non-certification recommendation at stage 2.

1.6.3.6 Time line for submission of corrective action plans & implementation of corrective actions

1.6.3.6.1 Corrective Action Plans
All corrective action plans, including evidence of correction shall be submitted within 30 calendar days from the last day of the activity unless the client's certificate expires prior to that date; in such case the corrective action plan shall be submitted prior to certificate expiring.

1.6.3.6.2 Minor Nonconformities
For minor nonconformities, all corrective actions shall be implemented (including verification of effectiveness) within 90 calendar days from the last day of the activity. Effective implementation of corrections and corrective actions will take place at the next visit.

1.6.3.6.3 Major nonconformities
For major nonconformities, all corrective actions shall be implemented (including verification of effectiveness) within 60 calendar days from the last day of the activity unless the client's certificate expires prior. In such a case the client's due date should be not less than 30 calendar days before the expiry certificate

An onsite special visit to close out majors will always be scheduled unless certificate authority has approved it to be offsite. The date for scheduling the special visit shall be within 90 days following the audit or prior to certificate expiry whichever comes first.

1.6.4 The findings of non-conformities are addressed ARPL-F-44 and send to client for corrective action.

**1.7 Closing Meeting**

Prior to the closing meeting, the audit team under the responsibility of the audit team leader shall:

a) review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities;
b) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process;
c) agree any necessary follow-up actions;
d) confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence).

Prior to leaving the client's site, the Lead Auditor shall undertake the closing meeting, details are provided by work instruction; IndiaGHPPLAN.W01, IndiaHACCPPLAN.W01 & ARPL-WI-02 Opening and Closing Meeting Work Instructions.

**2.0 Additional requirements**

**2.1 Pre-Audits/Gap Analysis**

2.1.1 Unless otherwise specified in the assignment letter, the only documents to be produced are the Finding reports.

2.1.2 The results of the pre-audit are not binding. Therefore:

2.1.2.1 Responses are not required to the findings
2.1.2.2 The results of this activity are to be ignored during the performance of the initial audit.

**2.2 Stage I Audits**

**Note: Initial audits shall be conducted in 2 stages. Stage I, and stage II. Requirements for each are below.**

2.2.1 For FSMS, the stage 1 shall be carried out at the client's premises in order to achieve the objectives stated above. In exceptional circumstances, part of stage 1 can take place off-site and shall be fully justified. The evidence demonstrating that stage 1 objectives are fully achieved shall be provided. Exceptional circumstances can include very remote location, short seasonal production.

2.2.2 The client shall be informed that the results of the stage 1 may lead to postponement or cancellation of the stage 2.

2.2.3 Any part of the FSMS that is audited during the stage 1 audit, and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during the stage 2 audit. However, Lead Auditor shall ensure that the already audited parts of the FSMS continue to conform to the certification requirements. In this case, the audit report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

2.2.4 The Stage I shall include:

- The review of the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;
- The audit of the client's management system documentation;
- The evaluation of the client's location and site-specific conditions;
- The collection of the necessary information regarding the scope of the management system, processes, and location(s) of the client, and related statutory and regulatory aspects and compliance (i.e. quality, environmental and safety legal aspects of the client's operations, associated risks, etc.); processes and equipment used; levels of controls established (particularly in case of multisite clients)
- The preparation of the first version of ARPL-F-03 Audit Programme
- The evaluation of the client's preparedness for Stage II activity based on:
  a) Discussions with the client's personnel;
  b) Evaluation that the internal audits and management review are being planned and performed;
  c) The level of implementation of the management system based on the sampling of processes and relevant records;

The purpose of the Stage I audit is:

- To provide a focus for planning the stage 2 audit by gaining an understanding of the client's management system and site operations in the context of possible significant aspects
- To review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit and to evaluate and validate the need for auditing work shifts other than the main work shift.
- To verify and confirm the level of integration of integrated management system, if applicable.
- To identify any areas of concern that could be classified as nonconformity during the Stage II audit
- To reach an agreement with the client regarding the details of the Stage II audit,

including interval between stage 1 and stage 2 on the basis of needs of the client to resolve area of concerns identified, if applicable.

2.2.5 The auditor's conclusion will include the fulfilment of the stage 1 objectives and the readiness for stage 2

2.2.6 If any significant changes which would impact the management system occur, the need to repeat all or part of stage 1 may be considered.

2.2.7 The client shall be informed that the results of stage 1 may lead to postponement or cancellation of stage 2.

2.2.8 The interval between stage 1 and stage 2 shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed.

**2.3 Stage II**

2.3.1 The audit shall include at least the following:

a) Information and evidence about conformity to all requirements of the applicable management system standard or other normative 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) The client's management system and performance as regards legal compliance;

d) Internal Auditing and Management Review

e) Operational control of the client's processes;

f) Management responsibility for the client's policies;

g) Links between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

h) Validation of the scope of the management system and any stated permissible exclusion.

i) Audit findings and/or conclusions from the Stage 1 audit.

2.3.2 The Lead Auditor shall confirm ARPL-F-03 Audit Programme for three-years.

2.3.3 The auditor's conclusion and recommendation for initial certification will include an analysis of stage 1 and stage 2 audit results

**2.4 Accelerated Audit (Back-to-back Stage I/Stage II)**

2.4.1 For Accelerated audits follow the instructions in 2.2 above for the Stage I segment. Please take note that a desk review of documentation needs to take place first.

2.4.2 At the end of the Stage I segment, the audit team shall have a formal meeting with the organization in order to inform client's management about the decision is to carry-on with the Stage II segment; in the case that the decision is not to proceed with the Stage II segment the audit team shall immediately notify the ARPL (Certification Division) office. The client is also to be reminded that it will incur any additional cost associated to the audit team travel arrangement, if applicable.

2.4.3 Conditions not to proceed to stage 2 include but are not limited to:

1) If the results of the Stage I activity indicate that information provided by the client regarding the scope of the management system, processes, location(s)/site(s), work shifts, number of employees of the client, and related statutory and regulatory aspects and compliance (i.e. quality, environmental and legal aspects of the client's operations, associated risks, etc) is inaccurate to the point that the activity cannot take place as per the preliminary plan;

2) If the results of the Stage I activity provide a clear indication of a significant misunderstanding by the client of the requirements of the audit criteria (certification standard), indicating that the client is not ready for the Stage II activity;
3) If the corrective actions deemed necessary as a result of the above-mentioned off-site review activity have not been satisfactorily implemented;
4) If the applicable legal and regulatory requirements have not been properly identified;
5) In the case of integrated management system audits, failure to satisfy one of the conditions specified above for any of the standards/audit criteria covered by the scope of the management system may lead to the interruption of the audit after the Stage I activity

2.4.4 Failure to satisfy the requirements specified in section 2.4.3 above should be identified as a Major Area of Concern against the appropriate certification requirement.

2.4.5 If the decision is to proceed with the Stage II segment, this activity is to be performed in accordance with the requirement of par.2.3 above

**2.5 Multi-Site Audits**

2.5.1 Multi-site audits shall be carried out in accordance with section 1 above and follow the requirements below.

2.5.2 Prior to the beginning of the multi-site audit, the Lead Auditor shall review the sampling plan to appropriately cover locations as specified. He/she shall also communicate changes to the office if different then specified on sampling plan.

2.5.3 Internal audit of the client shall demonstrate that all sites are included in the internal audit plan.

2.5.4 At the conclusion of multi-site audits, the Lead Auditor shall also ensure that all locations as identified by the sampling plan have been audited during the certification audit and conform to all applicable requirements.

2.5.5 The Lead Auditor shall conduct an official closing meeting to communicate the results of the entire audits activities

2.5.6 The Lead auditor shall prepare a consolidated report that covers all sites

2.5.7 At the conclusion (see para1.6) of multi-site audits, the Lead Auditor shall also determine if the current site sampling plan is adequate or if it should be amended.

2.5.8 The annual internal audit programme shall include all sites of the organization.

**2.6 Surveillance audits**

ARPL (Certification Division) has maintain certification based on demonstration that the client continues to satisfy the requirements of the management system standard. It may maintain a client's certification based on a positive conclusion by the audit team leader without further independent review and decision, provided that:

**a)** For any major nonconformity or other situation that may lead to suspension or withdrawal of certification, the certification body has a system that requires the audit team leader to report to the certification body the need to initiate a review by competent personnel and different from those who carried out the audit, to determine whether certification can be maintained;

**b)** Competent personnel of ARPL (Certification Division) monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

Surveillance activities shall include on-site auditing of the certified client's management system's fulfilment of specified requirements with respect to the FSMS/ISO 22000:2018 standard to which the certification is granted.

Surveillance audits are on-site audits, but are not necessarily full system audits, and shall be planned together with the other surveillance activities so that the certification body can maintain confidence that the client's certified management system continues to fulfil requirements between

recertification audits e.g. annual cycle of surveillance audit in the 3 years certification cycle may covers minimum ~50% of the entire system activities ensuring that all management system requirements are covered in the 3 years audit cycle once again (apart from Stage 2). However, surveillance for the FSMS standard shall include following in all surveillance audits:

a) internal audits and management review;
b) a review of actions taken on nonconformities identified during the previous audit;
c) complaints handling;
d) effectiveness of the FSMS w.r.t achieving the certified client's objectives and the intended results of FSMS;
e) progress of planned activities aimed at continual improvement;
f) continuing operational control;
g) review of any changes;
h) use of marks and/or any other reference to certification.

For the last surveillance prior to recertification audit the lead auditor shall review the performance of the management system over the certification cycle by performing a review of all reports issued during the certification cycle as well as any other available information, such as complaints, in order to identify repetitive failures or improvement/degradation of the management system. Results of this review shall be recorded in the audit report.

If deemed necessary, a recommendation that could include the performance of a stage I activity at re-certification and/or increase or reduction of the audit time for the re-certification activity, based on significant changes, or performance issues with the client in the current cycle shall be documented under "Other or additional lead auditor recommendation if applicable.

Other surveillance activities may include:
a) enquiries from the certification body to the certified client on aspects of certification;
b) reviewing any certified client's statements with respect to its operations (e.g. promotional material, website);
c) requests to the certified client to provide documented information (on paper or electronic media or social media);
d) other means of monitoring the certified client's performance such as announced or unannounced site visits, feedback from site or their customers, confidential reporting system, complaint investigation, observing or witnessing an audit on request etc.

**2.7 Recertification audits**

A recertification audit shall be planned and conducted to evaluate the continued fulfilment of all of the requirements of the relevant management system standard or other normative document.

This shall be planned and conducted in due time (well in advance i.e. 2-3 months before the due date, if possible) to enable for timely renewal before the certificate expiry date.

Recertification audit shall include:
- A Stage I activity if recommended per 2.6 above or in situations where there have been significant changes to the management system, the client or the context in which the organization operates (e.g.: changes to the legislation, the major processes, etc.)
- The evaluation of the continued fulfillment of all of the requirements of the relevant audit criteria. The purpose is to confirm the continued conformity and effectiveness of the food safety management system as a whole, and its relevance and applicability for the scope of certification.
- A demonstrated commitment to maintain the effectiveness and improvement of the

management system in order to enhance overall performance

- The verification of whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives.
- The assessment of all processes identified in ARPL-F-03 Audit Programme (Three-Year).

**2.8. Transfer Audits**

Transfer audits follows general audit process defined above with regards to type of audit identified by Audit programme of previous Certification Body. The Lead Auditor shall also consider the instructions, if any, provides in the assignment letter.

**2.9. Combined Audits**

- The audit shall be performed according to section 1.0 above
- The audit plan and programme shall provide adequate coverage of all requirements of all requirements of the applicable audit criteria
- There should be an audit report for each audit criteria

**2.10. Audits of integrated systems**

- The audit shall be performed according to section 1.0 above
- The audit plan and programme shall provide adequate coverage of all requirements of all requirements of the applicable audit criteria
- There should be one integrated report produced after the audit

**NOTE:** The auditor shall confirm the level of integration of the management system during the audit. In case of a change or reduced level of integration the auditor shall document the change.

**2.11 Special visits**

The scope and objective of the special visits shall be specified in the assignment letter and the audit plan

2.11.1 Scope extension:
An application for the scope extension is required from the existing certificated site. ARPL (Certification Division) under take review of this application to determine the requirement of any audit activity i.e. Desktop review/On-site audit for deciding whether certification can be extended or not. This audit activity may be conducted with the surveillance audit or as a separate audit. (for guidance or condition refer to ARPL-QM-2.0 FSMS Manual)

2.11.2 Follow-up visit:
Visits being performed in order to close nonconformities issued during a preceding visit.

2.11.3 Short-notice/Unannounced audit:
Visits being performed to investigate complaints, in response to changes, or as follow-up on suspended clients. It may be necessary for the certification body to conduct audits of certified clients at short notice or unannounced. In such cases:

a. the certification body shall describe and make known in advance to the certified clients the conditions under which such audits will be conducted e.g. time, cost, expectations, outcomes etc.
b. the certification body shall exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members. Selection of appropriate audit team members who are competent and free from any potential conflict of interest are required to be selected.

**Records:**

INDIAGHPREPORT.F01
INDIAHACCPREPORT.STAGE1.F01
INDIAHACCPREPORT.STAGE2.F02
FSMS Auditreport.F01

ARPL-F-03 Audit Programme
ARPL-F-44 Finding Details
ARPL-F-19 Audit Process Annexure