Procedure for Initial Certification
BQTL/CD/QSP/9.3/01
Standard Reference ISO/IEC 17021-1:2015 [Clause No. 9.3]

1. Purpose:

To define the method for auditing the client's management system in accordance with the applicable audit criteria.

2. Scope:

Pre-audits, document reviews, first audits (Stages I and II), surveillance, re-certification, special surveillance, extensions, short-notice and transfer audits, and all other types of audits. It applies to both FSMS and FSSC 22000 certification audits.

3. Responsibility:

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

4. Input:

BQTL/CD/FORM/24 Audit Allocation Sheet

5. Output:

BQTL/CD/FORM/05 Audit Finding Report
BQTL/CD/FORM/25 FSMS/ISO 22000:2018 Audit Checklist

6. KPI:

- Auditor Performance
- Client Feedback Form
- Results of technical review (# of defects report)

7. Audit Process:

7.1 General:

Once the BQTL/CD/FORM/24 Audit Allocation Sheet is received, the Auditor must draft the audit plan in accordance with the BQTL/CD/QSP/9.2.3/01Determination of Audit Plan.

7.2 Opening Meeting:

When the Lead Auditor arrives at the client's location, he or she will chair the opening meeting; more information is available in the work instructions; BQTL/CD/WI/02 Opening and Closing Meeting Work Instructions.

7.3 Collecting and Verifying Information:

During the audit, team members must collect and document objective data to demonstrate that the client's system is established and effective. To constitute audit evidence, information relevant to the audit objectives, scope, and criteria (including information regarding interfaces across functions, activities, and processes) must be collected and confirmed using appropriate sampling. Such evidence will be gathered through interviews, reviews of papers and records, and observations of audited processes, actions, and conditions. Personnel who have been interviewed need to be identified.

7.4 Remote Auditing:

The audit records must identify the location, interview persons, and conduct remote audit operations. Regardless of whether the remote segment occurs at a different time than the on-site audit, all papers must be presented jointly at the conclusion of the activity. Remote auditing techniques include, but are not limited to the following:

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

7.5 Audit Progress Assessment and Exchange of Information:

7.5.1 The Lead Auditor will ensure that regular meetings with the audit team are held during the audit to ensure that the concerns uncovered during the audit are discussed, and that the audit course is changed as needed to accommodate any changes. These issues should be raised with the client's representative during the audit.

7.5.2 If the available audit evidence indicates that the audit objectives are unattainable or that there is an immediate and significant risk (e.g., safety), the Lead Auditor must report this to the client and the Basil Quality Test Lab Pvt. Ltd. Certification Division office to determine the appropriate action. Such actions may include reconfirming or modifying the audit plan, changing the audit goals or scope, or terminating the audit. The lead auditor will also:

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

7.5.3 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.

7.5.4 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 Basil Quality Test Lab Pvt. Ltd. Certification Division.

7.6 Preparing Audit Report:

The Lead Auditor is responsible for preparing its material in accordance with the standards. The audit report must give an accurate, succinct, and unambiguous record of the audit, allowing an educated certification decision to be taken. Auditors will create and issue the audit report during the meeting; if there is no internet connection available, the report will be prepared and issued offline. The audit team may highlight areas for improvement, but it will not recommend particular remedies.

7.6.1 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

7.6.2 Three-Year Audit Programme:

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

- During initial certification, the lead auditor should complete the document.
- During recertification, the lead auditor will construct a new version of the software to reflect the current cycle.
- Any further adjustments must be noted as appropriate by the auditor.
- The BQTL/CD/FORM/03 Audit Programme Process requires an initial certification or re-certification audit, surveillance visits, and a re-certification audit at the conclusion of each certification cycle.
- For multi-site organisations, the lead auditor should employ a sample plan to accurately identify all sites and their functions/activities.
- The lead auditor should consider the client organization's size, management system complexity, management system effectiveness, and previous audit results when determining the audit program and making adjustments.
- Any changes to the audit program must be clearly identified in the audit report.
- At Initial certification, the lead auditor shall fill 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 BQTL/CD/FORM/03 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.

7.6.3 Non-Conformities:

7.6.3.1 General:

a) There are two types of nonconformities – Major and Minor
b) Non-conformity shall be substantiated by objective evidence or absence of objective evidence such as: witnessed recordable, verifiable, and quantitative collection of facts.
c) The Lead Auditor, shall review the findings and record them.
d) For each nonconformity, the auditor shall identify the following:
    - Finding: A clear description of the nature of the non-conformity; it could be in terms of insufficient implementation, unsuitability, inadequacy, ineffectiveness, etc. or in terms of lack of identification of the evidence which conflicts with the

requirement.

- Requirement: The quote of the requirement of the audit criteria against which the non-conformity 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 documents.
- Objective Evidence: The objective evidence observed to supports the statement of non-conformity: the specific occurrence, supported by the identification of the evidence collected (e.g. - direct reference to the document being reviewed, the work station, etc.)

7.6.3.2 Major Non-Conformity:

a) 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.

b) Characteristics of a major non-conformity are:

- 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.
- 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.
- 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.
- If there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- A number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.
- A situation that is a significant real or imminent threat to the environment
- A situation that is a significant real or imminent threat to the to human health and safety
- 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.

7.6.3.3 Minor Non-Conformity:

a) Minor Non-Conformity: Failure which does not impact the capability of the management system to achieve the expected outcomes.

b) Characteristics of a minor non-conformity are:

- A failure to fully satisfy a requirement of the audit criteria with a documented procedure, when required.
- A situation that is a minor real or potential threat to the environment.
- A situation that is a minor real or potential threat to human health and safety.
- 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)
- A breakdown in the effective implementation of a documented procedure in isolated incidents.

Notes:

- A minor non-conformity 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.

7.6.3.4 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 non-conformity.
- The auditor should identify the area for improvement but cannot offer a specific solution.
- Audit findings, however, which are non-conformities, shall not be recorded as opportunities for improvement.

7.6.3.5 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 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.

7.6.4 Time line for submission of corrective action plans and implementation of corrective actions:

7.6.4.1 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.

7.6.4.2 Minor Non-Conformities:

- For minor non-conformities, 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.
- For major non-conformities, all corrective actions shall be implemented (including verification of effectiveness) within 60 calendar days from the last day of the activity prior to the expiration of the certificate. In such a case, the due date of the certificate should be not less than 30 calendar days before the expiry certificate.
- An onsite special visit to close out major non-conformities is always scheduled, unless the certificate authority has permitted it to be offsite. The special visit must be scheduled within 90 days of the audit or before the certificate expires, whichever comes first.

7.6.4.3 The findings of non-conformities are addressed BQTL/CD/FORM/05Audit Findings Non-Compliance and send to client for corrective action.

7.7 Closing Meeting:

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

- Review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the non-conformities;
- Agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process;
- Agree any necessary follow-up actions;
- 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; BQTL/CD/WI/02 Opening and Closing Meeting Work Instructions.

8. Additional Requirements:

8.1 Pre-Audit/Gap Analysis:

8.1.1 Unless otherwise specified in BQTL/CD/FORM/24 Audit Allocation Sheet, the only documents to be produced are the BQTL/CD/FORM/42 Audit CAPA Report.

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

8.1.2.1 Responses are not required to the findings

8.1.2.2 The results of this activity are to be ignored during the performance of the initial audit.

8.2 Stage I Audits:

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

8.2.1 For FSMS AND FSSC 22000, 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.

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

8.2.3 Any part of the FSMS AND FSSC 22000 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 AND FSSC 22000 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.

8.2.4 The objectives of stage 1 are to provide a focus for the planning of stage 2 of the initial audit by gaining an understanding of the organization's FSMS and the organization's state of preparedness for stage 2 by reviewing the extent to which:

a) the organization has identified PRPs that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements).
b) the FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations);
c) the FSMS includes adequate processes and methods for the identification and implementation of relevant food safety legislation.
d) the FSMS is designed to achieve the organization's food safety policy.
e) the FSMS implementation programme justifies proceeding to stage 2;

f) the validation of control measures, verification of activities and improvement programmes conform to the requirements of the FSMS standard.
g) the FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties.
h) there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance.

8.2.5 The Stage I shall include:

a) The review of the client's management system documented information. 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.
b) The audit of the client's management system documentation. Where an organization has implemented externally developed elements of a FSMS, stage 1 shall review the documentation included in the FSMS to determine if the combination of control measures:

- is suitable for the organization.
- was developed in conformity to the requirements of ISO 22000 or other sets of specified FSMS requirements.
- is kept up to date.

c) Evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2;
d) 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)
e) The availability of relevant authorizations shall be checked when collecting the information regarding the compliance to regulatory aspects.
f) The preparation of the first version of BQTL/CD/FORM/03 Audit Programme
g) The evaluation of the client's preparedness for Stage II activity based on:
    - Discussions with the client's personnel;
    - Evaluation that the internal audits and management review are being planned and performed.
    - The level of implementation of the management system substantiates that the client is ready for stage 2.
h) 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 the management system standard or other normative document.

- 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.

NOTE: If at least part of stage 1 is carried out at the client's premises, this can help to achieve the objectives stated above.

8.2.6 The auditor's conclusion will include the fulfilment of the stage 1 objectives and the readiness for stage 2.In determining the interval between stage 1 and stage 2, consideration shall be given to the needs of the client to resolve areas of concern identified during stage 1. The certification body may also need to revise its arrangements for stage 2. If any significant changes which would impact the management system occur, the certification body shall consider the need to repeat all or part of stage 1. The client shall be informed that the results of stage 1 may lead to postponement or cancellation of stage 2.

8.2.7 Communication of Stage-1 Results to Client

The Lead Auditor shall compile and document the conclusions of the Stage-1 audit, including:

- Fulfilment of Stage-1 objectives
- Assessment of readiness for Stage-2
- Identification of any areas of concern that could be classified as a nonconformity during Stage-2

Documented conclusions regarding fulfilment of the stage 1 objectives and the readiness for stage 2 shall be communicated to the client, including identification of any areas of concern that could be classified as a nonconformity during stage 2.The communication shall clearly state that the results of Stage-1 may lead to postponement or cancellation of Stage-2 if areas of concern are not addressed.

NOTE: The output of Stage-1 is not required to meet the full requirements of an audit report.

8.2.8 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.

8.2.9 In exceptional circumstances or events, all or part of stage 1 can take place off-site or remotely through the use of ICT and shall be fully justified. The evidence demonstrating that stage 1 objectives are fully achieved shall be provided.

NOTE 1 Exceptional circumstances or events can include a very remote location, a natural disaster, a pandemic, a short seasonal production and other special situations.

NOTE 2 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, does not necessarily need to be re-audited during stage 2. In this case, the audit report includes these findings and clearly states that conformity has been established during the stage 1 of the audit.

8.3 Stage II:

8.3.1 The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's management system. The stage 2 shall take place at the site(s) of the client. It shall include the auditing of at least the following:

- Information and evidence about conformity to all requirements of the applicable management system standard or other normative document;
- 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);
- The client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;
- Internal Auditing and Management Review
- Operational control of the client's processes;
- Management responsibility for the client's policies;
- 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.
- Validation of the scope of the management system and any stated permissible exclusion.
- Audit findings and/or conclusions from the Stage 1 audit.

8.3.2 The Lead Auditor shall confirm BQTL/CD/FORM/03 Audit Programme for three-years.

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

8.4 Accelerated Audit (Back-to-Back Stage I/Stage II):

8.4.1 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.

8.4.2 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 FLPL (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.

8.4.3 Conditions not to proceed to stage 2 include but are not limited to: -

- 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;
- 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;
- If the corrective actions deemed necessary as a result of the above-mentioned off-site review activity have not been satisfactorily implemented;
- If the applicable legal and regulatory requirements have not been properly identified;
- 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.

8.4.4 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.

8.4.5 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.

8.5 Multi-Site Audits:

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

8.5.2 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.

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

8.5.4 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.

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

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

8.5.7 At the conclusion (see para0) of multi-site audits, the Lead Auditor shall also determine if the current site sampling plan is adequate or if it should be amended.

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

8.5.9 Central Function

8.5.9.1 The central function is the organizational unit responsible for planning, controlling, and managing the FSMS for all sites. It has authority from top management to define, establish, and maintain the FSMS, collect and analyse performance and complaints from all sites, and initiate continual improvement. All sites must have a legal or contractual link to the central function. The central function cannot be subcontracted externally.
A multi-site organization consists of a central function and a network of sites at which FSMS activities are fully or partially implemented.
Examples of possible multi-site organizations include:

- Organizations operating with franchises;
- Producer groups (for food chain categories A and B);
- Manufacturing companies with one or more production sites and a network of sales offices.
- Service organizations with multiple sites offering similar services.
- Organizations with multiple branches operating under a single FSMS.

The certification body shall ensure that sampling of multi-site organizations covers all activities and processes carried out across the network of sites, in accordance with the criteria specified in Clause 9.1.5.3 of ISO 22003-1:2022.

8.5.9.2 The certification body shall demonstrate that the sampling of sites does not undermine effective auditing. When multi-site sampling is undertaken, the certification body shall justify and document the rationale based on the following conditions:

a) sites are operating under one centrally controlled and administered FSMS;
b) sites subject to sampling are similar (food chain subcategory, geographical location, processes and technologies, size and complexity, regulatory and statutory requirements, customer requirements, food safety hazards and control measures);
c) the central function is part of the organization, clearly identified and not subcontracted to an external organization;
d) all sites have a legal or contractual link with the central function;
e) the central function has organizational authority to define, establish and maintain the FSMS;

f) all sites are subject to the organization's internal audit programme and have been audited;
g) audit findings at a site are considered indicative of the entire FSMS and corrective actions are implemented accordingly;
h) the central function is responsible for ensuring that outcomes of performance evaluation and customer complaints from all sites are collected and analysed;
i) the organization's FSMS is subject to central management review;
j) the central function has authority to initiate continual improvement of the FSMS.

NOTE: The central function is where operational control and authority from the top management of the organization is exerted over every site. There is no requirement for the central function to be located in a single site.

8.5.10 Sampling Rationale and Documentation

Prior to initiating multi-site audits, the Lead Auditor shall document the rationale for site sampling, including:

- Similarity of sites (food chain subcategory, processes, technologies, size, regulatory requirements, hazards and control measures)
- Verification that audit findings from sampled sites are indicative of the FSMS as a whole
- Authority and responsibilities of the central function
- Evidence that internal audits and corrective actions at sampled sites have been conducted and are effective

8.5.11 Sample Size Determination

The use of multi-site sampling is permitted for categories A and B. Sampling may be applied to multi-site organizations, with the minimum sample size being the square root of the total number of sites: $\sqrt{(x)}$, rounded up to the next whole number. The square root sample shall be taken per risk category based on production complexity of the sites (e.g. open field plant production, perennial plant production, indoor production, open field livestock production, indoor livestock production).The use of multi-site sampling is permitted for categories F and G, and only for re-heating-type facilities (e.g. event catering, coffee shops, pubs) for category E and only for facilities with limited preparation or cooking (e.g. re-heating, frying) (see Table A.1). For organizations with 20 sites or fewer, all sites shall be audited. For organizations with more than 20 sites, the minimum number of sites to be sampled shall be 20 plus the square root of the total number of other sites: $y = 20 + \sqrt{(x - 20)}$, rounded up to the next whole number. This applies to the initial certification, to surveillance and to recertification audits. The use of multi-site sampling is not permitted for any other categories identified in Annex A.

Where multi-site sampling is permitted, the certification body shall ensure (e.g. via contractual arrangements) that the organization has conducted an internal audit for each site within one year prior to certification and when applicable the effectiveness of corrective actions shall be available. Following certification, the annual internal audit shall cover all sites of the organization included in the certification scope of the multi-site organization and ongoing effectiveness of corrective actions shall be demonstrated.

Where multi-site sampling is permitted, the certification body shall define and utilize a sampling programme to ensure an effective audit of the FSMS where the following conditions apply.

a) At least annually, an audit of the central function for the FSMS shall be performed by the certification body prior to the sampled site audits.
b) At least annually, audits shall be performed by the certification body on the required number of sampled sites.
c) Audit findings of the sampled sites shall be assessed to ascertain if these indicate an overall FSMS deficiency and therefore can be applicable to some or all other sites.
d) Where audit findings of the sampled sites are considered indicative of the entire FSMS, corrective actions shall be implemented accordingly.
e) For organizations with 20 sites or fewer, all sites shall be audited.

The certification body shall increase the size of sample or terminate the site sampling where the FSMS subject to certification does not indicate the ability to achieve the intended results.

8.5.12 Internal Audit Verification

Prior to multi-site certification, the Lead Auditor shall confirm that all sites have been audited internally within the past 12 months and that corrective actions have been implemented and verified. Annual internal audits shall cover all sites included in the certification scope. Compliance with internal audit frequency and verification of corrective actions for all sites shall be ensured through contractual arrangements between Basil Quality Testing Lab Pvt. Ltd. (Certification Division) and the client organization, as defined in the Certification Agreement (BQTL/CD/FORM/43).

8.5.13 Audit Programme Requirements

For multi-site audits, the certification body shall:

- Audit the central function first each year prior to auditing sampled sites.
- Assess audit findings from sampled sites to determine if they indicate overall FSMS deficiencies and apply corrective actions accordingly.
- Adjust sample size or terminate site sampling if FSMS cannot achieve intended results.

8.5.14 Random and Selective Sampling

The sampling plan shall ensure that all processes covered by the scope of certification are audited across the certification cycle, ensuring representativeness of the FSMS implementation at each site.

The selection of the remaining sites shall ensure that the differences among sites (e.g. process type, size, production technology, and risk profile) are as large as possible over the period of validity of the certification, to ensure a comprehensive evaluation of the FSMS performance across the network of sites.

At least 25% of sampled sites shall be selected randomly. The remainder shall be selected so that the differences among the sites selected over the period of validity of the certification are as large as possible.:

- Internal audit or previous audit results
- Management review outcomes
- records of complaints, product withdrawals/recalls, and other relevant aspects of corrective action.
- Geographical location, size, complexity, processes
- Changes since last audit

8.5.15 Major Nonconformities

If any sampled site has a major nonconformity and corrective action is not satisfactorily implemented within the agreed timeframe, certification shall not be granted or maintained for the whole multi-site organization pending satisfactory corrective action.

8.5.16Certification Scope

The BQTL shall identify and include in the scope of certification the processes of the FSMS implemented at each sampled site. The consolidated audit report shall include all sampled sites, their processes, and results of audit findings.

8.6 Surveillance Audits:

Basil Quality Test Lab Pvt. Ltd. Certification Division has to 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 Basil Quality Test Lab Pvt. Ltd. Certification Division monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity are 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 AND FSSC 22000 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 AND FSSC 22000 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 AND FSSC 22000 w.r.t achieving the certified client's objectives and the intended results of FSMS AND FSSC 22000;
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.

8.7 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:

- Stage I activity if recommended as per 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 fulfilment 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 BQTL/CD/FORM/03 Audit Programme (Three-Year).

8.8 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, and provide it in BQTL/CD/FORM/24 Audit Allocation Sheet.

8.9 Combined Audits:

- The audit shall be performed according to section 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.

8.10 Audits of Integrated Systems:

- The audit shall be performed according to section 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.

8.11 Special Visits:

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

8.11.1 Scope Extension:

An application for the scope extension is required from the existing certificated site. Basil Quality Test Lab Pvt. Ltd. Certification Division undertake 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 BQTL/QM/01 Quality Manual.

8.11.2 Follow-up Visit:

Visits being performed in order to close nonconformities issued during a preceding visit.

8.11.3 Short-notice/Unannounced Audit:

8.11.3.1 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.

8.11.3.2 Where the BQTL conducts unannounced audits as part of surveillance activities. In such case:

- The BQTL shall describe and make known in advance to the certified clients the conditions under which such audits will be organized and conducted.

8.11.3.3 The BQTL 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.

Basil Quality Testing Lab Private Limited

CEO (Jan 13, 2026)