TNV System Certification Private Limited

(Management System Certification Agency) Auditor Guide (TNV-F-55)

D1.0 PURPOSE: Guidelines for Auditing Personnel to conduct audit Assignments efficiently and achieve TNV Certification objectives.

1.2 SCOPE: All certification activities undertaken by TNV

1.3 RESPONSIBILITY: CEO/Quality Manager

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(Management System Certification Agency) Auditor Guide (TNV-F-55)

Section A1 Introduction:

This Handbook describes the duties and responsibilities of TNV's auditing personnel while carrying out Assessment of Organization's (client) Management System for certification to ISO 9001/14001/45001/27001/22301/37001 standards, as applicable.

This Handbook addresses the following specific areas:

a) Code of Conduct
b) Assessment Team Responsibilities
c) Audit Guidelines
d) Conduct of Pre-Audit
e) Conduct of Assessment and Re- Assessment Conduct of Surveillance
f) Procedures for Reporting
g) Procedures referred in TNV Procedure Manual M-02

Section A2 Quality Policy

TNV System Certification Pvt. Ltd.'s Quality Policy laid down by its top Management is as under:- Top Management of the TNV shall demonstrate that

1. TNV is committed to provide Transparent, Neutral, Independent, and Competent Management System Certification Services which reveal Veritas among the Business, Government & Society and Add value to its Client's Product & Services to the ultimate customer satisfaction.
2. The Management System of TNV is Established, Maintain and continually improve in accordance with the requirements of the Accreditation Board and to meet all Statutory & Regulatory Requirements in its entire process of Services to meet Accreditation Requirement.
3. TNV System Certification Pvt. Ltd. will ensure that all possible "conflict of interest" situations arising out of its activities are identified and resolved timely and effectively.
4. TNV shall create & maintain an environment where each employee contributes to all aspects of our business process and shall strive for continual improvement to meet with Customer Satisfaction.

The above policy may be reviewed for any changes, as and when required, by the Top Management. The above policy will be prominently displayed in TNV System Certification Pvt. Ltd. office, website and brochures.

Section A3: The Certification Process

The Certification process consists of the following key stages, ENQUIRIES and QUOTATIONS, APPLICATION, Stage-I, Stage-II and SURVEILANCE VISITS. Re-Audits are also features of the certification process.

ENQUIRIES are received in several forms, by telephone, letter or facsimile. If they fall within TNV Certification scope of accreditation as allocated by Accreditation board from time to time. These result in the sending out of an Information Brochure pack, including an application form to be completed for the purpose of providing a quotation of fees for certification based upon the information made available, to be submitted to the client for acceptance.

Upon acceptance of the fee quotation, the client completes and submit the "Application Questionnaire "together with the Application fee upon receipt of which Technical Coordinator verifies the relevant details of the client's application with the fee quotation and completes a supplementary Contract Review including allocation of the scope sector of the clients activities coming under the applied scope of registration with the original Questionnaire to check that there is no discrepancy.

The Stage-I visit has two key functions. The first and most important is to review the Documented Management System (DMS) against the requirements of the relevant ISO 9001/14001/45001/27001/22301/37001 Standard. A detailed report is drawn up, and copy left with the client. The second function is to have a preliminary evaluation of the implementation based upon which a plan for the Stage-II audit of the organization is discussed with the management.

It is expected that the Management System has been in place for at least about three months before the **Stage-I** audit is considered.

A period of two-Three weeks is normally recommended between Stage-I and Stage-II visits but the certification audit is scheduled on a mutually convenient date upon client's intimation of readiness.

A pre-Audit is a trial audit which is conducted before the Certification audit at client's option to provide a macro level Audit of the status of implementation and identification of any major deficiencies in the compliance of the documented quality system with the requirements of the certification standards, for corrective actions to be taken in advance of the certification audit. It provides valuable inputs to give confidence to the clients and saves time for taking necessary corrective action, later.

All audits begin with an "Opening Meeting", at which the Team leader introduces other members of the team and runs through the Audit programme. The Team leader will also explain the methodology of the Audit such as the duties of the guides, and the confirmation of confidentiality, scope as per the requirements stated in ISO 17021-1-2015.

The purpose of the STAGE-II is to ensure that the requirements of relevant ISO standard as addressed by the documented management system are being complied with. The Auditors will be looking for objective evidence of compliance with the standards and Non-compliances are brought to the attention of the guide and noted on a report form. At the end of Audit, these NC are discussed, and the company's management representative is asked to sign the report acknowledging that he understands and accepts the findings.

The Audit is concluded with a "Closing Meeting" at which the Team Leader presents the findings and makes recommendations, either for certification to the applicable standards of ISO otherwise with a requirement for a verification audit in case of major non-conformances having been identified.

In case where non-compliances are of a minor nature, certification is recommended subject to a corrective action plan that addresses the non-compliances and observations raised in the report being submitted together with objective evidences for all non-compliances within 2 weeks. When this corrective action plan and the objective evidences are received at the TNV Certification office, the audit reports are verified for conformance against the requirements of the certification standard. The client's file is reviewed to ensure an independent verification of compliance against certification checklist as per the applicable management system and grant of certification.

Each certified organization is required to undergo a surveillance audit at minimum intervals of one year, during the term of validity of its certification. The continual conformance of the organization applicable management system with the certification standard is verified by auditing selected elements of the quality management system at each visit besides verification of the effectiveness of the corrective actions against the non-conformities raised during the previous audit.

The Auditors are required to complete the Reports in a precise and accurate manner. The justification for non inclusion of any element as per the ISO 9001 standards e.g. Design Control etc from the company's quality management system should be carefully verified and recorded in the Report.

Audit Time: Audit activities normally include:

1. Conducting the opening meeting
2. Performing document review while conducting the audit
3. Communicating during the audit
4. Assigning roles and responsibilities of guides and observers
5. Collecting and verifying information
6. Generating audit findings
7. Preparing audit conclusions
8. Conducting the closing meeting

Audit Man-Day: The duration of an audit day is normally 8 hours and may or may not include a lunch break depending upon local legislation.

TEMPORARY SITES: Typically, on-site audits of temporary sites would be performed. However, the following methods could be considered as alternatives to replace some on-site audits:

1. Interviews or progress meetings with the client and/or its customer in person or by teleconference.
2. Document review of temporary site activities.
3. Remote access to electronic site(s) that contains records or other information that is relevant to the assessment of the management system and the temporary site(s).
4. Use of video and teleconference and other technology that enable effective auditing to be conducted remotely.
5. In each case, the method of audit should be fully documented and justified in terms of its effectiveness and with prior approval of the assessment manager.

CONTROL OF EXTERNALLY PROVIDED FUNCTIONS OR PROCESSES (OUTSOURCING):

1. If any client organization outsources part of its functions or processes, it is the responsibility of the Audit Team to obtain evidence that the organization has effectively determined the type and extent of controls to be applied in order to ensure that the externally provided functions or processes do not adversely affect the effectiveness of the MS, including the organization's ability to consistently

deliver conforming products and services to its customers or to control its environmental aspects and commitments to compliance with legal requirements.

2. The Auditor shall audit and evaluate the effectiveness of the client's management system in managing any supplied activity and the risk this poses to the delivery of objectives, customer and conformity requirements. This may include gathering feedback on the level of effectiveness from suppliers. However auditing the supplier's management system is not required, considering that it is included in the scope of the organization's management system only the control of the supplied activity, and not the performance of the activity itself. From this understanding of risk any additional audit time shall be determined.
3. The CB will audit and evaluate the effectiveness of the client's management system in managing any supplied activity and the risk this poses to the delivery of objectives, customer and conformity requirements. This may include gathering feedback on the level of effectiveness from suppliers. However auditing the supplier's management system is not required, considering that it is included in the scope of the organization's management system only the control of the supplied activity, and not the performance of the activity itself. From this understanding of risk any additional audit time shall be determined.

Methodology For Determining Audit Time of OH&SMS

1. Where product or service realization processes operate on a shift basis, the extent of auditing of each shift by the CAB depends on the processes done on each shift, taking into consideration the associated OH&S risks, and the level of control of each shift that is demonstrated by the client.
2. To audit effective implementation, at least one of the shifts inside and one outside of regular office hours shall be audited during the first cycle of certification. During surveillance audits of the subsequent cycles, the CB may decide not to audit the second shift based on the recognised maturity of the organization's OH&SMS
3. Adjustments for delaying the starting time of audit are recommended whenever possible, in order to cover both shifts within the 8 hours audit time. The justification for not auditing the other shifts shall be documented taking into account the risk for not doing so.
4. The audit time of OH&SMSs determined using the tables of this Appendix shall not include the time of "auditors-in-training", observers or the time of technical experts.
5. The reduction audit time of OH&SMSs shall not exceed 30% of the times established from OHS table in TNV-F-22.

Section A4: Code of Conduct

The Auditors should understand that they are visiting the Client's premises as representatives of TNV and their conduct must reflect professional and ethical standards of the highest order.

Auditors are expected to:

a) Be smartly dressed and well groomed.
b) Be calm and polite during communication.
c) Be well prepared and objective in conducting the audits ensuring effective Time management.
d) Be direct and decisive
e) Seek objective evidence of compliance and non-compliance
f) Use only TNV documentation and follow the procedural requirements.
g) All auditors are required to declare a denial of their involvement in providing Consultancy or professional interest of any company before undertaking an Auditing assignment in the Company.
h) Be ethical , open minded, diplomatic, good observant and determined.

i) Be discerning, versatile, tenacious and self-reliant

Auditors are not expected to:

a) Correspond directly with the client unless authorized by TNV

b) Offer advice that may be interpreted as consultancy to the company being assessed.

Section A5 Auditor's Responsibilities

1.0 Auditor's Responsibilities:

For each Audit a Lead Auditor (LA) will be nominated who will be responsible for the management of the audit and the performance and conduct of each of the Auditor and/or Observers/Technical experts present on behalf of TNV. LA is responsible for preparing and submitting the audit report to the client as well as TNV, however the ownership of report lies with TNV.

The LA is responsible for planning and conduct of the Audit. LA is also responsible for ensuring that all relevant information concerning the Audit is reported. **(LA: - Lead Auditor)**

LA shall allocate tasks to each member of the audit team and LA shall ensure that the members of the team are fully prepared and capable of undertaking the auditing functions professionally and effectively. Audit recommendations are arrived at by the Audit team at the Pre-closing meeting where the LA will debrief the entire Auditor's. The final report & recommendation, however, shall be decided by the LA himself.

During the planning phase of the auditing process, the LA and other members should prepare individual Audit Check lists for evaluating quality system elements assigned to them. These lists should be filled up in a manner as to provide evidence of an in-depth probe into quality systems. These should also bring out evidence of both positive and negative findings about the company's quality management systems.

The Lead Auditor should ensure that the completed check lists through notes of each auditor are attached to the audit reports before forwarding the same to TNV.

The lead auditor shall ensure that Guide, Observer, interpreter, translator does not influence or interfere the audit process or neither shall interfere in the outcome of the audit.

Note The responsibilities of guide can include establishing contacts and timing for interviews, arranging visits to specific parts of the site or organization, ensuring that rules concerning site safety and security procedures are known and respected by the audit team members, witnessing the audit on behalf of the client, providing clarification or information as requested by an auditor.

2. CONDUCT OF AUDITS

The Lead Auditor /Audit Members will ensure that due caution is exercised in complying with the following requirements when conducting quality systems audits.

2.1 Audit Planning/Preparation

2.1.1 Audit Plan Matrix

The team has to prepare in advance a matrix of the elements of the standard against departments/functions to be audited. Tick marks the form after judicious cross reference to the auditees' activities. While making the audit plan the LA shall give consideration to below mentioned points but not restricted to this only

a) the scope and complexity of the client's management system;
b) products and processes (including services);
c) size of the client organization;
d) sites to be audited;
e) language of the client organization and languages spoken and written;
f) the requirements of sector or regulatory schemes;
g) client and their customers' requirements and expectations;
h) the number and timing of shifts;
i) audit time required for each audit activity;
j) competence of each member of the audit team;
k) the need to audit temporary sites;
l) results of the stage 1 audit or of any other previous audits;
m) results of other surveillance activities;
n) demonstrated level of management system effectiveness;
o) eligibility for sampling;
p) customer complaints;
q) complaints received by the certification body about the client; r) combined, integrated or joint audits;
s) changes to the client's organization, products, processes or its management system;
t) changes to the certification requirements;
u) changes to legal requirements;
v) changes to accreditation requirements;
w) risk and complexity;
x) organizational performance data [e.g. defect levels, key performance indicators (KPI) data, Rejection, Customer Satisfaction, Vendor Approval etc.];
y) interested parties' concerns;
z) information gained during previous audits.

2.1.2 Audit Programme

After ascertaining the geographical location of various departments/functions and the quantum of work in each, the Team Leader should allocate time and auditing function to each auditor, including allocation of technical experts, if any, for critical areas of the auditees activities, in the Audit Plan. The Team Leader is required to discuss the Audit Plan/Schedule with the Audit Team Members and the Technical Experts, during Audit Team Briefing before the commencement of the Audit.

Audit Plan and composition of Audit Team details are advised to the Auditee in advance for their acceptance and the same is explained in details at the time of opening meeting. The auditors need to communicate effectively either through their own skills or use interpreter if required.

While developing the audit plan the Audit team need to the ensure that the objectives covers Management priorities, Commercial intentions, Management system requirements, Statutory, regulatory and contractual requirements,

Need for supplier evaluation, Customer requirements, Needs of other interested parties and Risks to the organization.

The extent of an audit plan may vary and will be influenced by the size, nature and complexity of the organization to be audited also consideration must be given to scope, objective and duration of each audit to be conducted, frequency of audit, number, importance, complexity, similarly and locations of the activities to be audited, Standards, statutory, regulatory and contractual requirements and other audit criteria, Conclusions of previous audit or results of a previous audit programme review, language, cultural and social issues, concerns of interested parties (EMS & OHS), Significant changes to an organization or its operations.

2.1.3 Check Sheets/Recording of Observations/Use of TNV Reporting Documents

The Team Leader should ensure that each member prepares his individual check lists relating to his assigned function. The information gathered must be based on the type of industry and the scope of registration. Further, it is dependent upon the criticality of the function/product/process and its bearing on quality and safety. The auditor must verify the accuracy of the collected information in regard to conformity and non- conformity of any process. The evidences must be collected in a manner that it supports the audit findings and the compliance/non-compliance to lead a conclusion for the certification activity.
The auditors need to assess those processes/factors which have an effect on the dependability of the audit finding and conclusions.

While identifying and recording the audit findings the Lead Auditor/Auditor shall ensure the following points

i) Audit findings summarizing conformity and detailing nonconformity and its supporting audit evidence are recorded and reported in the audit report to enable an informed certification decision to be made or the certification to be maintained.

ii) The Opportunities for improvement identified in the audit are recorded in the audit report, unless prohibited by the requirements of a management system certification scheme. Audit findings, however, which are nonconformities in accordance with 9.1.15 b) and c) of the manual will never be recorded as opportunities for improvement.

iii) Finding of nonconformity are be recorded against a specific requirement of the audit criteria contain a clear statement of the nonconformity and identify in detail the objective evidence on which the nonconformity is based in the audit report. Discuss Nonconformities with the client to ensure that the evidence is accurate and that the nonconformities are understood. The lead auditor however shall avoid from suggesting the cause of nonconformities or their solution.

iv) Shall try to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, and unresolved points shall be recorded in the audit report.

v) Shall not recommend specific solution related to any opportunity or NC identified

2.1.4 Guidance Documents

Auditor must read the study sector specific guidance material well before the audit. Based on this, emphasize some of the clauses which become critical because of the peculiar requirements of the sector specific industry.

2.1.5 Audit Scope & Criteria

The audit scope describes the extent and boundaries of the audit, such as physical locations, organizational units, activities and processes to be audited, as well as the time period covered by the audit.

The audit criteria are used as a reference against which conformity is determined and may include applicable policies, procedures, standards, laws and regulations, management system requirements, contractual requirements or industry / business sector codes of conduct.

If the scope covers installation activities, the planning matrix should include onsite verification. If the auditee's scope includes design requirements, special care is to be taken in earmarking the team member with experience in design. Further the team leader should ensure that adequate amount of time is allotted for this function.

The auditors need to ensure the confidentiality and security if the information gathered in the audit.

The Team Leader confirms the scope of certification applied for, with the client, during the opening meeting. In the event an amended scope involving a major addition or change to the original scope is proposed by the company, the Team Leader should seek instructions from TNV office before proceeding with the Audit, as an amended scope may require additional audit man-days or sector scope competence. Minor changes in the scope of certification may, however, be accepted for Audit and reported, accordingly. Where a combined audit is to be conducted, it is important that the audit team leader ensures that the audit objectives, scope and criteria are appropriate to the nature of the combined audit.

3. AUDIT EXECUTION

3.1 Time Management

TNV auditors follow good planning for management system certification audit by preparation of Audit Plan Matrix, TNV Programme sheet and check sheets prior to the commencement of the audit will ensure that team does not waste any time during the execution of the audit. An itinerary will be prepared by TNV for each audit giving tentative time schedule, covering clauses of the concerned standard and name of the auditor for guidance of audit team and auditee. This will be issued 7 to 10 days in advance. In case of integrated management system audit common clauses may be suitably clubbed under a single auditor to avoid duplication of effort.

3.2 Check of Interface Activities

Good planning and thorough preparation by detailed study of the various functions/departments of the company will ensure that its interface activities are covered. While conducting audit in one department/function, do not see it in isolation. See with which other functions, it is inter-related/ inter-dependent/interacting. It is essential that we look into these areas/interfaces during our audits.

3.3 In-depth Probing/Questioning

Auditors should seek objective evidence of compliance of each audit function with the standards and scope of registration by in-depth verification of the related documents, operations and processes (e.g. note an instrument in production area with calibration sticker duly affixed and check its calibration status in Calibration Laboratory. Again note down particulars of an operator who is not performing as per work instructions and look for his training records in HRD) and seek objective evidence. This should be compared with the relevant clause of the standard in order to arrive at Non Conformities. This should be agreed to by the auditee during the execution of Audit. In case of any element of applicable ISO standard being considered not applicable to the auditees operations, a suitable explanation is required to justify the exclusion of the element from the audit on page 1 of Report.

3.4 Audit Trail

Audit plan for each auditee function relevant to the clauses of the standard should provide for audit to be conducted in a logical sequence, consistent with the flow of work rather than leap forging. Auditors nominated for production areas may cover in one sequence planning, issue of material, preparation of material, machine shop, fabrication, assembly and final inspection. Auditors while auditing

inspection/testing, verify the calibration status while going forward or backwards in your visit to Calibration Department. In the Food sector verify the calibration certificate of the master equipment by which calibration is carried out i.e., traceability certificate.

3.5 Organizational Situations:

The auditors skills need to include the following

- organizational size, structure, functions and relationships
- general business processes and related terminology
- cultural and social customs of the auditee

The Methods to collect information shall include, but are not limited to:

a) Interviews;

b) Observation of processes and activities;

c) Review of documentation and records.

d) Customer Satisfaction

e) Data Analysis

3.6 Communication during audit:

The Lead Auditor need to adopt following steps of communication during any audit;

i) During the audit the audit team shall periodically assess audit progress and exchange information. The audit team leader shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.

ii) 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, strike, non-cooperation, threatening), the audit team leader shall report this to the client and, if possible, to the TNV CEO/ED 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 audit team leader shall report the outcome of the action taken to TNV CEO/ED.

iii) 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 TNV CEO/ED.

iv) If during the auditor identifies any breach of an Act of Parliament, or a contravention of a regulatory requirement Non-Conformity is issued immediately and communicated to the Top Management.

3.7 Audit Conclusion:

Before commencing the closing meeting, the audit team shall do the audit conclusion which must cover the following:

a) review the audit findings, and any other appropriate information collected during the audit, against the audit objectives;

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

c) identify any necessary follow-up actions;

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

e) An explanation need to be given in case of any differences from the information presented to the organisation at the closing meeting during OHSMS audit.

3.8 Audit Evidence:

The Lead Auditor must ensure that he collects sufficient objective evidences for conformity towards the audit objectives, scope of the certification, the processes including verification for conformity towards the standards requirement and organizations laid down requirement which is collected by appropriate sampling and verified.

Method of collecting information shall include but not limited to following:

a) Interviews;

b) Observation of processes and activities;

c) Review of documentation and records.

4. Performance Evaluation

4.1 Performance Evaluation of Audit Team Members

The Audit Team Leader will evaluate each member/observer as per the need /guidance from TNV office of his team against the various parameters listed in No. (TNV- F-020).The performance reports should be forwarded separately to the CEO OF **TNV** and these will be treated confidentially. The Reporting Auditor may suggest any training need where necessary.

4.2 Performance Evaluation of Auditor / Team Leaders

The performance of the Team Leaders will be verified through witness Audits independently by TNV qualified Lead Auditors who will report on the Auditor's performance as per (TNV- F-019). Each Auditor's/ performance will be verified once a year/and lead Auditor and once in 3 years.

4.3 Performance Evaluation of Observer Auditors – Training & Assignment Of "Observer Auditors"

a. All auditors who have qualified at an approved QMS/EMS/OHSMS/FSMS Lead Auditors Course and fulfilled the other qualification criteria for empanelment of external auditors are required to obtain auditing experience for 20 audit man-days as per the requirements of ISO 19011:2011 before qualifying for assignment as an audit team member for Management System audits on behalf of TNV

b. The requisite audit experience is obtained through attachment with audit teams for conduct of third party audits of quality management systems including Documentation Review, Pre-Audits, Certification and Surveillance Audits.

c. Observer Auditors are assigned for working strictly under the direction and supervision of the assigned Team Leader and do not undertake any audit function, independently, during training.

d. The Team Leader is responsible for ensuring that the Observer Auditor is guided and trained in the methodology and practical conduct of all aspects of auditing of a management system as per the ISO standards (ISO 9001/14001/45001/27001/22301/37001)

e. The Team Leader is required to assess the understanding and performance of the 'Observer Auditor' under his supervision and report on his compliance with the various attributes and skills as per TNV Performance Report (TNV) including recommendation for desirable corrective actions and improvement.

f. The Performance Report is required to be forwarded for each audit by the Team Leader in respect of each Observer Auditor for review by the AM and record. The Observer Auditor will be advised of any deficiencies and improvement required in his performance.

g. Upon completion of the requisite man-days of auditing as an 'Observer Auditor', the AM will assess his overall performance on the basis of the performance reports and confirm his up gradation to the Audit Team Member's grade or recommend further training, where necessary.

h. The up gradation of an 'Observer Auditor' will be duly recorded and his name entered in the TNV List of Approved Auditors.

4.4 Technical Experts

Technical expertise are selected for a specific scope sector and assigned as and when required. Before their appointment the Qualification, Industry experience and current technical knowledge are verified for any particular audit. Also their performance is reported by the team leader and evaluated by Quality Manager.

4.5 Translator & Interpreters

Translators & Interpreters appointed to the audit team shall work under the direction of Audit team or individual auditor. The translator and interpreters are selected in a manner that they do not unduly influence the audit and the same must ensured by the Audit team.

4.6 Auditor in Training

In case of any auditor in training included in the team as participant, the Lead Auditor/Evaluator has the final responsibility for the activities and findings of the trainee auditor.

Section A6 Audit Trail (Questioning Mechanism)

1. **How do you contribute to achieving your organization's objectives?**
   Closely related questions include:
   a. How are objectives determined?
   b. How are employees trained on objectives?
   c. How is progress against objectives communicated to the organization?
   d. What processes and/or tools are in place to help achieve objectives?
   e. Is there evidence of progress?
2. **What happens if your product, materials, or supplies are nonconforming? *During an audit, find some examples of nonconforming products—if any exist—and follow-up with these questions:***
   a. How are nonconforming products identified?
   b. Where are they located?
   c. What are the responsibilities and authorities related to dealing with nonconforming products?
   d. How do dispositions get determined and implemented?
   e. What are the records of nonconforming products and actions taken on them?
   f. What are the trends in nonconforming products?
   g. How is the procedure linked to the corrective action process?
3. **How do you access product requirements?**

Specific points of inquiry related to product requirements include:

a. Are product requirements complete?
b. How does the organization ensure that correct versions are available?
c. How are requirements reviewed prior to acceptance?
d. How do you ensure that product meets the stated requirements?
e. What happens when changes are made to product requirements?

4. **How are problems prevented?**

Additional points of inquiry related to preventive action include:

a. How do data trends get analyzed?
b. How do employees communicate their improvement ideas?
c. How do preventive actions get recorded?
d. Are statistical techniques used?
e. How are customer perceptions captured on a proactive basis?

5. **How do you use data on customer perceptions?**

Here are some related audit questions:

a. How are data on customer satisfaction analyzed?
b. How are opportunities identified and prioritized?
c. What's the connection to the corrective and preventive action systems?
d. What are the organization's long-term trends in customer satisfaction?
e. How are resources for customer satisfaction identified and provided?
f. What connections exist between customer satisfaction and the organization's objectives?

6. **How are customer complaints handled?**

Here are some related questions:

a. What's the largest complaint category?
b. What's being done about it?
c. Has the amount of complaints changed over time?
d. How are personnel trained in their roles in preventing complaints?
e. How are customers made aware of actions on their complaints?
f. What tools are used to identify the causes of complaints?

7. **How does top management review the organization's performance?**

Here are some related questions:

a. Who's involved in reviewing the organization's performance?
b. What actions have resulted from these reviews?
c. How are records of the reviews generated?
d. Are all required inputs and outputs addressed by records?
e. How does the rest of the organization learn of actions and decisions that are determined during reviews?

8. **What evidence can you provide of continual improvement?**

These are some related lines of inquiry:

a. Who's involved in improvement efforts?

b. What tools are used to pursue continual improvement?
c. How are personnel trained to use improvement tools?
d. How are improvement ideas prioritized?
e. How are employees made aware of improvement efforts and successes?

9. **How are training needs determined?**

Here are some related questions:

a. What kind of orientation training is provided when employees are hired?
b. How are personnel made aware of the organization's mission, values, and measurable objectives?
c. How is the effectiveness of training evaluated?
d. What happens when training is determined to have been ineffective?
e. What records of training are maintained?

10. **What's the most important thing about your job?**

Consider these related questions:

a. What's the hardest thing about your job?
b. What are some things you'd like to change about your job?
c. What resource would help you be more effective?
d. What should your manager know that he or she currently doesn't know?
e. If you were the manager here, what would you do differently?

Section A7) Pre-Audits (Document Review):

TNV consider onsite Document Review pre-audits on systems as an optional part of the certification process. TNV performs pre-audits on site on request.

A complete pre-audit program consists of the following elements:
Review of the system documentation,
Pre audit at the premises of the organisation during a number of days, Preparation of a detailed pre-audit report,
Presentation of the results of the pre-audit.
The organisation is free to decide about the pre-audit program.

For the performance of a pre-audit, the TC assigns an auditor (LA or AD). The auditor contacts the organisation and makes further arrangements.

The auditor performs the pre-audit in a similar way as a certification audit, with exception of: Only the activities agreed with the organisation shall be audited.

No corrective action shall be requested for the non-conformities presented at the exit meeting. Pre-audit man-days shall not exceed the stage 2 man-days and auditors involved in a pre-audit should preferably not be involved in the certification audit of the same organization.

There are no specific rules concerning the format of a pre-audit report. Format and content should be agreed with the customer.

Section A8 Certification Audit Visits (Stage 1 & Stage 2):

1. DEFINITION OF SCOPE

The Scope of certification of a client company is defined to cover the type and range of the company's products or/and services to which the management system is applicable
(ISO 9001/14001/45001/27001/22301/37001) and is to be assessed.

2. Stage -1

Stage 1 Audits are a review of a client company's readiness for Audit against the following objectives:

a) To audit the clients management system documentation.

a) To review the clients location and site-specific conditions and to undertake discussions with the clients personnel to determine the preparedness for the stage-2 audit.

b) To review the client's status and understanding regarding requirement of the standard, in particular with respect to the identification of key performance or significant aspects, processes objectives and operation of the management system.

c) To collect necessary information regarding the scope of the management system, processes and locations of the client's, and related statutory and regulatory aspects and complex (e.g. quality environmental, legal aspects of the client's operation, associated risks, etc.)

d) To review the allocation of resources for stage-2 audit and agree with client on the details of the stage-2 audit.

e) To provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects.

f) To evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.

g) The OHSMS management system includes adequate processes to identify the organizations OHS hazards and determine their significances as well.

h) The OHS management system provides an adequate description of the organization and its on-site processes.

i) An overview of the applicable regulations, agreement with approving authorities has been included in the OHSMS management system, also if there is any OHS license requirement in application the relevant activities of the organization are in place.

j) The OHSMS management system is designed to achieve the organization's OHS policy.

k) To verify that at least one cycle of Internal Audit & Management Review has been conducted and the OHSMS management system programme is implemented properly and the preparedness for the conduction of Stage 2 audit. To collect necessary information for on-site audit of temporary sites considering the sites as per the complexity category.

l) To verify that the information derived from the Contract Review is complete and appropriate in all the terms for the OHS management system.

m) To collect necessary information and identify the issues which will need special attention during the stage 2 audit.

n) The organization has identified PRPs appropriate to the business (e.g. regulatory and statutory requirements), Auditor need to verify that When client organisation selecting and/or establishing PRP(s), have they considered and utilize appropriate information [e.g. statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimentarius Commission (Codex) principles and codes of practices, national, international or sector standards**]. Reference while checking international standards, reference of the following should be taken:**

- **i ISO/TS 22002-1 Prerequisite programmes for food safety – Part 1: Food manufacturing**
- **ii ISO/TS 22002-2 Prerequisite programmes for food safety – Part 2: Catering**
- **iii ISO/TS 22002-3 Prerequisite programmes for food safety – Part 3: Farming**

iv **ISO/TS 22002-4 Prerequisite programmes for food safety – Part 4: Food packaging manufacturing.**

v **ISO/TS 22002-5 Prerequisite programmes for food safety – Part 5: Transport and storage**

vi **ISO/TS 22002-6 Prerequisite programmes on food safety - Part 6: Feed and animal food production**

o) 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)

p) Food safety legislation is in place for the relevant sector(s) of the organization

q) Food safety legislation is in place for the relevant sector(s) of the organization

r) FSMS implementation programme justifies proceeding to the Stage 2 audit

s) The validation, verification and improvement programmes conform to the requirements of the FSMS standard

t) The FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties

u) Additional documentation needs to be reviewed and/or what knowledge needs to be obtained in advance.

v) Where an organization has implemented an externally developed combination of control measures, the stage 1 audit shall review the documentation included in the FSMS to determine if the combination of control measures is suitable for the organization, was developed in compliance with the requirements of ISO 22000, and is kept up to date. The availability of relevant authorizations should be checked when collecting information regarding the compliance to regulatory aspects.

3. REVIEW OF MANAGEMENT SYSTEMS DOCUMENTATION

Before an Audit of a company can be undertaken, TNV must ensure that the company can be undertaken; TNV must ensure that the company has a documented Management system complying with the relevant part of **ISO 9001/14001/45001/27001/22301/37001**. Management system documentation will normally take the form of a Policy Manual, a Procedures Manual, work instructions and formats. In some cases, particularly with small companies, it may be practicable for all the documented system companies; it may be practicable for all of documented system to be included in a single manual. However, in many instances, detailed documented procedures will be contained in supplementary manuals which are referenced by the Documented Management System Manual (Guidance of Documented Management System structure and content can be found in Section A13, Section A14 & Section 15). It is obviously not possible to carry out an exhaustive examination of the clients' system documentation. However, the Auditor must ensure that each relevant clause of the Standard is addressed, and that written procedures or records are included as per mandatory requirement.

If the Auditor feels that the requirements of the Standard are not addressed in the documentation, he will note them for discussion with the client. Instances where it is agreed that a requirement of the Standard is not addressed by the documentation will be recorded in the report as a non-conformance.

4. (STAGE- I)

After a review of the complete Management System documentation, the Auditor will record his findings in the Stage 1 Report identifying the non-conformities agreed with the client after discussing observations of deficiencies in the addressal of the requirements of the applicable standard.

If the Auditor is satisfied that the company's Management System documentation will comply with the requirement after necessary corrective actions in respect of the reported concerns have been completed by the

client, he recommends that the company may proceed with the stage-II of the Audit, as agreed.

In the event that Management System documentation is found to be seriously deficient in addressal of the stipulated requirements, the Auditor may recommend a fresh Stage 1 audit which will be detailed in the Report. **TNV** will advise the client of the additional fees chargeable as applicable and the proposed dates for supplementary review of Management System documentation.

A copy of the Stage 1 Report is handed over to the client and it is incumbent upon the company to take necessary actions against the reported concerns and submit a corrective action plan within the stipulated period of approx 2 weeks days to TNV Head office. The company is entitled to clarify the nature of concerns with the Auditors who should be helpful in explaining as appropriate, but he/she should not put himself/herself in the position of acting as consultant.

5. Time Plan for Stage-II audit.

While planning in the interval between **stage-I and stage-II** audit consideration is toward the need of the client to resolve the areas of concerns identified in stage-I audit. If during the stage 1 audit there is some mismatch from the initial details which affect the audit man-days and auditor competency, the contract review needs to be reviewed again for the conduction of the Stage 2 audit.

6. GUIDANCE DOCUMENTS

QM will arrange where necessary for generation of sector specific Guidance Documents including Checklist and Briefing Notes relevant to the auditing of industry scope sectors as per **Technical Area as defined by TNV** Classification with the assistance of the Experts in each field. The documents will be approved by the Impartiality Committee.

The purpose of these documents is to advise the auditors with the type of applicable Management System Standard against which the audit is to be conducted. Further, the aim of these guidelines is to provide sector specific expertise in Technological Processes and associated Regulatory requirements in respect of the Management Systems applicable to the products or services.

The Auditors should make use of these documents to audit critical areas, relevant to the specific Auditee activity in depth so that the critical production processes affecting the quality of the final product are properly identified and audited.

The draft guidance notes are prepared with the assistance of Expert Panel Members representing specific industry sectors and other specialists competent in that industry and are required to be approved by the Expert Committee before being released for circulation to the audit personnel, as necessary.

7. Audit Planning (Stage-II) Activities: -

The audit plan should ensure the following

a) the audit objectives;
b) the audit criteria and any reference documents
c) the audit scope, including identification of the organizational and functional units and processes to be audited
d) the dates and places where the on-site audit activities are to be conducted.
e) the expected time and duration of on-site audit activities, including meeting with the auditee's management and audit team meetings
f) the role and responsibilities of the audit team members and accompanying persons

g) the allocation of appropriate resources to critical areas of the audit.

The audit schedule is communicated to the client via TNV- F-005.

The Certification audits ***Stage-II*** are scheduled on dates agreed with the client who is advised of the above details in advance for his confirmation and acceptance including the audit team members.

A detailed audit plan giving the allocation of the audit team members and the time schedules for various auditing functions / depts. etc is forwarded to the Auditee Company in advance together with the agreed traveling arrangements.

The Lead Auditor is responsible for the detailed planning and organization of the audit plan. This plan is based upon the competence and audit Manday requirements of the contract review and is designed to verify the relevant clauses of the standard and give the appreciate areas of the company's establishment.

The purpose of the stage-II audit is to evaluate the implementation including, effectiveness, of the clients management system and documentation at site.

a) Stage –II shall include conformity to applicable management system and evidence of implementation
b) Review of objective and targets and check the performance on monitoring, measurement and reporting.
c) Management System performance for legal compliance.
d) Monitoring of process control
e) Verification of internal auditing and management Review process
f) Verification of management responsibility of its commitment towards policies.
g) Verify the 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) Various mandatory records to ensure that the management system is operational
i) Evidence of the monitoring of customer satisfaction
j) The organisation adheres to its own OHSMS policies, objectives and procedures
k) The OHS management system conforms to all the requirements of the OHS standard and is achieving the organization's policy objectives for providing a safe and healthy working environment.
l) Verify effective implementation of OHS including temporary sites.

CONTROL OF EXTERNALLY PROVIDED FUNCTIONS OR PROCESSES (OUTSOURCING):

- If client organisation outsources part of its functions or processes, Auditor need to obtain evidence that the organization has effectively determined the type and extent of controls to be applied in order to ensure that the externally provided functions or processes do not adversely affect the effectiveness of the MS, including the organization's ability to consistently deliver conforming products and services to its customers or to control its environmental aspects and commitments to compliance with legal requirements.
- The TNV's Auditor will audit and evaluate the effectiveness of the client's management system in managing any supplied activity and the risk this poses to the delivery of objectives, customer and conformity requirements. This may include gathering feedback on the level of effectiveness from suppliers. However auditing the supplier's management system is not required, considering that it is included in the scope of the organization's management system only the control of the supplied activity, and not the performance of the activity itself. From this understanding of risk any additional audit time shall be determined.

Section A9) Surveillance & Renewal Audit:

1. Surveillance Audits:

The conduct of a Surveillance visit is similar to that of an initial audit in that it consists of an opening meeting, Audit and closing meeting. However, it is undertaken on a selected sample of the company's activities. The Team Leader shall check if the company's quality system has been amended since the last visit and to record the latest issue of the Management System documentation on the front page of the report. The effectiveness of the changes indicated will be verified by the Team Leader.

The corrective action against the non-conformities identifies during the previous visits shall be verified to ensure that corrective actions have been effectively implemented, as per the agreed corrective action plan and the NC is closed out.

If the surveillance audit plan requires a visit to an operational site, this will be planned by the Team Leader, when arranging the date of the visit with the company.

It is a fundamental requirement that the following elements are checked at each visit and details entered into the Surveillance Audit report of the respective management system standard:

1. The verification and closing out of the corrective action of previously raised non-compliances.
2. The company's own system review procedure, including internal audits.
3. Management Responsibility including review of the analysis of data and improvement Plans.
4. Preventive and Corrective Actions.
5. Management Review.
6. Changes required to Scope of Registration if any.
7. Use/miss-use of logo with certificate number, the relevant part of ISO **(9001/14001/45001/27001/22301/37001)** as applicable) and supplementary Audit criteria where applicable.
8. Achievement of the measurable targets and objectives.
9. Number of employees in the company
10. Treatment of Complaints
11. New Customers Orders, new developments in the organisation, organisational structural changes etc.
12. The continuing conformity with regulatory requirements applicable to the OHS hazards, and is fully implemented
13. Regulatory Compliance has been evaluated and the action has been taken in cases of nonconformity with relevant regulations
14. Check records of employee safety committees and other relevant bodies
15. Check Appeals
16. Complaints and disputes brought before TNV, where any nonconformity or failure to meet the requirements of certification is revealed, that the organization has investigated its own systems and procedures and taken appropriate corrective action.

Other requirements of applicable ISO Standard shall be sampled over the programme period. The areas covered at previous visits will be taken into consideration when deciding which areas to audit. It is intended that the implementation of the whole of the company's documents Management system is verified by use of surveillance visits over a period of 3 years, after initial Audit. At each visit an entry onto the surveillance audit record will be made and clauses needed for next audit verification are indicated. Corrective Action Plans arising from a surveillance visit must be returned, to the TNV. office, by the company within 2 weeks from the date of Audit.

17. Verify the OHS for the respective objectives and targets
18. Hazard Identification & Assessment Controls
19. Compliance towards Legal & Other requirement including customer requirements
20. Verify the OHS management systems at the temporary site
21. Verify the OHS management at the Multisite based on the Audit Program

The audit team shall interview the following personnel: the management with legal responsibility for Occupational Health and Safety, employees' representative(s) with responsibility for Occupational Health and Safety, personnel responsible for monitoring employees' health, for example, doctors and nurses. Justifications in case of interviews conducted remotely shall be recorded, managers and permanent and temporary employees. Other personnel that should be considered for interview are: managers and employees performing activities related to the prevention of Occupational Health and Safety risks, and contractors' management and employees.

2. Renewal Audit:

2.1 The process of recertification would include a re Audit of the organization's documented quality management system including a review of the Management System documentation, where necessary, to be conducted before the expiry of three years term of validity.

2.2 Renewal Audit is a requirement of ISO 17021-1-2015 and is intended to verify overall continuing effectiveness of the organization's applicable management systems in its totality.

2.2.1 Renewal Audit provides a review of the past performance of the management system over the period of previous certification, including examination of the documents/records relating to the internal audits, management review and effectiveness of corrective and preventive actions, etc.

2.2.2 The above Renewal Audit may replace or extend regular surveillance audits, as considered appropriate.

2.2.3 In the case of multiple site or certification to multiple management system standards being provided by TNV, the planning for the audit ensures adequate on site audit coverage to provide confidence in the certification.

2.2.4 The re-certification audit shall include on site audit covering the followings:

a) Verification of management systems effectiveness w.r.t. change (internal and external) and applicability to the scope of certification

b) Verification of the management commitment for overall performance improvement.

c) Verification of the achievement of policies and objectives.

2.2.5 In case of non-conformities observed during re-certification audit time limits are fixed for corrective action before the expiry date of certification.

2.2.6 TNV takes the decision based on

a) Complaints received from users of certification

b) Performance of system over period of certification.

c) Results of the re-certification audit.

2.5.7 The recertification audit will include an on-site audit that addresses at least the following:

a) The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;

b) Demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;

c) Whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives.

d) Effective handling of customer complaints, corrective and preventive system implementation throughout the organization.

e) Overall effectiveness of the system in its entirety in the light of changes in operations

f) Demonstrated commitment to maintain the effectiveness of the system

g) Summary of Previous Audit Reports

h) Whether all areas/ processes/ clauses have been audited at least once in the last three year cycle

i) Any concentration of non-conformities against particular clauses/areas and effectiveness of corrective actions taken on nonconformities identified by TNV shall be closed within 15 days of recertification audit

j) Objectives and Continual Improvement

k) Whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives

l) In the case of multiple sites or certification for multiple management system standards being provided by the TNV, the planning for the audit ensure adequate on-site audit coverage to provide confidence in the certification
m) Verify the OHS for the respective objectives and targets
n) Hazard Identification & Assessment Controls
o) Compliance towards Legal & Other requirement including customer requirements
p) Verify the OHS management systems at the temporary site
q) Verify the OHS management at the Multisite based on the Audit Program

Section A10) Reporting:

1. Audit Report Responsibility:

The responsibility of report preparation and submission to the organization as well as TNV lies with the lead Auditor and the LA is responsible for the contents of the report.

The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made and shall include or refer to the following:
a) Identification of the TNV logo
b) The name and address of the client and the client's management representative;
c) The type of audit (e.g. initial, surveillance or recertification audit);
d) The audit criteria;
e) The audit objectives;
f) The audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit;
g) Identification of the audit team leader, audit team members and any accompanying persons;
h) The dates and places where the audit activities (on site or offsite) were conducted;
i) Audit findings, evidence and conclusions, consistent with the requirements of the type of audit;
j) Any unresolved issues, if identified.

2. REPORTING:

The Stage1 Audit, Stage 2 Audit and Surveillance Audit visits will be reported on TNV Audit Report Forms. The Audit Report is based upon the Reporting Formats as per TNV requirements & Guidelines on compiling of Reports on Management System Audits. The Auditor's attention is drawn to following specific requirements.

(a) Page 1 of the Audit Report is the cover sheet. It contains details regarding names of the Auditors and Auditee and provides space for signature of the company representative. Format No. as follows
QMS: St 1: TNV-F-014Q, St2: TNV-F-015Q, Surveillance: TNV-F-065Q EMS: St 1: TNV-F-014E, St2: TNV-F-015E, Surveillance: TNV-F-065E OHSMS: St 1: TNV-F-014O, St2: TNV-F-015O, Surveillance: TNV-F-065O FSMS: St 1: TNV-F-014F, St2: TNV-F-015F, Surveillance: TNV-F-065F

(b) Audit Activity Summary, Non-Compliance/Observations, Audit Summary and Corrective Action Plans are described in the underlying paragraphs.

c) Places for entering name of the Auditing Organization, the auditee and the places where the representatives of TNV and the Company sign are indicated in these formats.

d) Besides, the Team Leader should initial at the left bottom of each page where there is no place for signature of the Auditor.

(e) Where a technical expert is required to be included in the team, his clarifications and guidance, where obtained may also be suitably recorded.

f) Audit matrix must contain details of documentation and/or items examined during the audit. Also the auditors are required to verify and record the following:

1. Customer Complaint Procedures
2. Use of TNV Logo
3. Applicable exclusion.

3.0 Non-Compliance/Observation

Observation shall be recorded in the audit report. Non-compliances shall be reported on the TNV-F-011. A non-compliance or observation as issued by the auditor shall be explained to the auditee as soon as possible and discussed with the company's representative(s). This will allow the company's representative(s) to accept agreement of the facts by signing the Non-compliance/Observation report, thus evoking later defensive arguments when detailed evidence may not be readily available.

Each Non-compliance/Observation, in addition to the information required at the head of the form shall refer, as appropriate, to the following:

a) The requirement of ISO 9001/14001/45001/27001/22301/37001 standard against which the non-compliance is listed.

b) The documents verified including precise observation/evidence.

c) The observed non-compliance against the company's documented procedure.

Non-compliances and Observations may be recorded on the same report page. In fact, if non-compliance and observation are recorded against the same clause, these shall be grouped together.

The Non-compliance/Observation shall be factual in stating what does not comply with the requirements, using as far as possible the same language as the requirement itself.

Objective Evidence: It is essential that each Auditor prepares individual audit notes of his findings, observations and comments on the areas of activity audited by him. These notes which should be attached to the Audit Report by the Team Leader before submission to TNV, should report on the positive and negative aspects of the company's documented Quality/Environment/OHSMS/Food Safety system and the records/documents verified to indicate the depth of audit carried out Team Leader is also required to comment on the effectiveness of the MRM and the IQA in the audit summary.

4.0 Categories of Non-Conformities

All non-conformities, identified, during an audit should be distinctly classified under the following categories: -

Major Non-Conformity (Category 'A'): A major non-compliance relates to the absence of a required procedure or the total breakdown in the implementation of a procedure. A number of minor non-compliances listed against the same clause of ISO 9001/14001/45001/27001/37001, 22301 represents a total breakdown of a system and thus collectively constitute a major non-compliance.

Where any nonconformity poses an immediate threat to OHS, LA shall demand Corrective Action Plan immediately and communicate to the client that the audit is suspended till the concern is either removed or mitigated. In any case the time for closure of Non-Conformity shall not be more than 3 months. In any such cases the time allowed for the closure will be reviewed by CEO.

Minor Non-Conformity (Category 'B'): A minor non-compliance relates to a single observed lapse in the effective implementation of a documented procedure/work instruction which indicates a deficiency requiring a corrective action.

Observation (Category 'C'): An observation is a matter about which the Auditor is concerned but which cannot be clearly stated as non-compliance. Observations also indicate trends which may cause problems in the future and need to be considered for corrective action by the company but does not justify verification by the auditor.

Major non-compliances will be clearly identified in 'Comments' section of the Report in addition to the Non-

Compliance.

Non-conformities/Observations shall never be worded in such a way as to advise the company of action which should be taken in order to comply with the requirements. However, it must be emphasized that any concerns the Auditor may have, and particularly the specific reasons for non-certification must be detailed in the comments sectioned as major non-compliances. The Auditor is also encouraged to make positive comments regarding the Audit here.

The auditors are required to specifically report on the status as well as the degree of reliability that can be placed on the implementation of client's internal audit and the management review procedures Recommendations for certification are not to be made where the effectiveness of the Internal Audits and management Review has not been established.

5.0 Recommendation

A clear and unambiguous recommendation must be made with defined time scales for corrective action.

Follow up Action

Again, a clear and unambiguous statement of the next step must be made. This is particularly important in the case of non-certification, where the period before Re-Audit can be conducted must be stipulated.

Distribution of the Report

Copy shall be retained by the Auditor for forwarding to TNV office for inclusion in the client file. The copy of the report shall be handed to the company's representative at the closing meeting. Ownership of the audit report shall be maintained by the certification body.

6.0 Effectiveness of Corrections and Corrective Actions

The auditor must verify the corrective action taken by the organization based on the Corrective action submitted and the effectiveness of the corrective action must be verified in the next audit. The corrective action submitted must include sufficient evidence for closing the Non-Conformity.

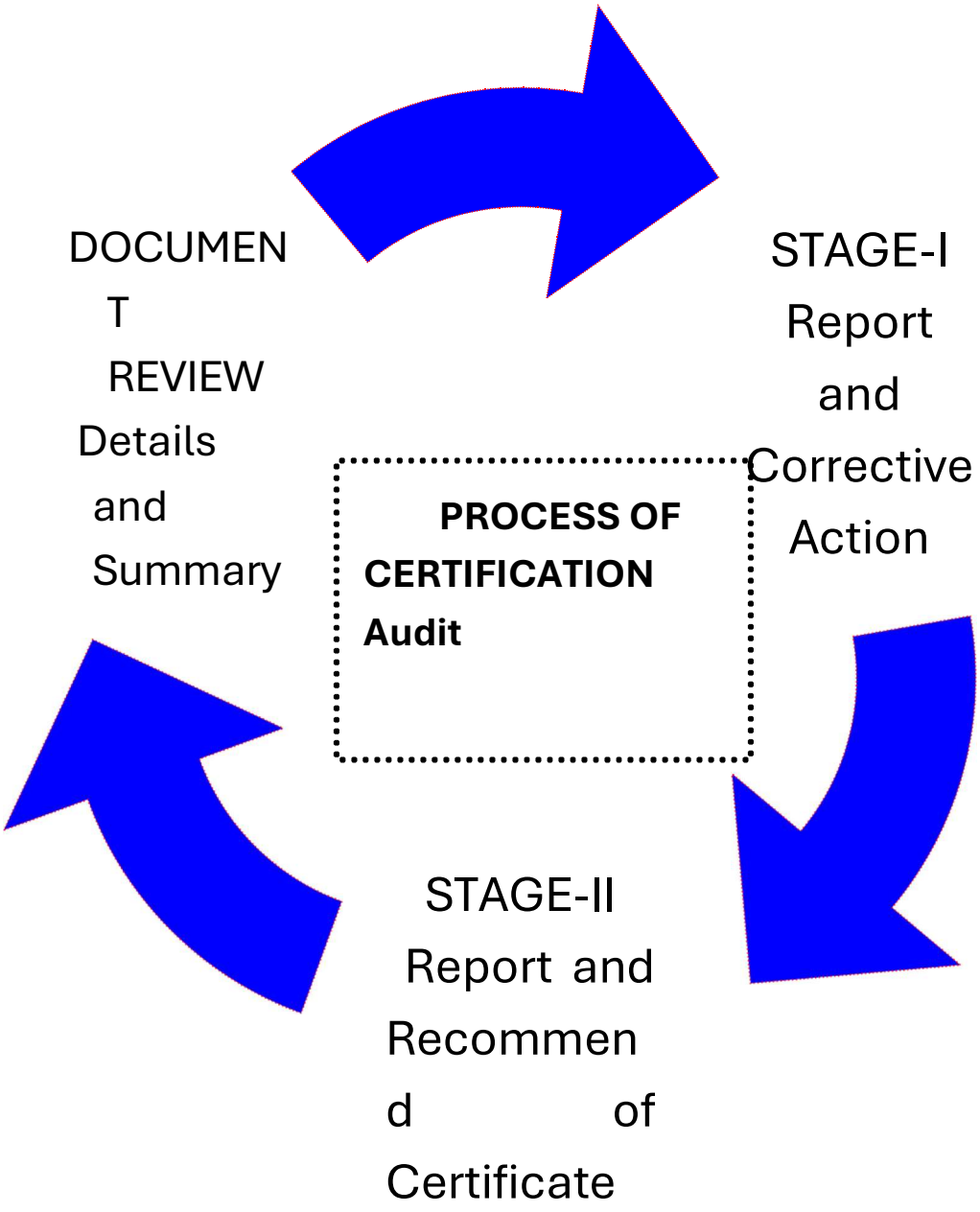
The auditor needs to communicate the client about the acceptance or denial of the Corrective Action submitted by the client.

Corrective Action Plan

The Company shall be advised to address both Non-conformities and observations raised by completing a Corrective Action Plan on the sheets provided by the Auditor and return the same to TNV office within 2 weeks of the audit. The AFAR pages are appended to the relevant report and MUST therefore carry the Company Name. The Auditor must write the report number on each CAP sheet before handing it to the company. The CAP is closed out by the Auditor after verification of the effective implementation of the corrective actions against each non-conformity before issue of certification or at a subsequent surveillance visit. Corrective Actions against **A** categories of nonconformities require to be closed out through verification at site and against Category 'B' nonconformities through verification at site or provision of objective evidence of the implication of corrective actions. Observations (Category C) need to be verified for closing out at the at the first or subsequent surveillance visits.

The closed-out status is endorsed after recording the reference of the objective evidence provided by the Auditee in each case. All the stage –I and Stage-II findings are considered before making the decision.

The Audit Report shall be forwarded to the TNV office by the Lead Auditor within one week of the completion of audit together with AFAR if any, Auditors Rough Notes by each audit team member and other documents relating to the Audit.


DOCUMENT REVIEW Details and Summary
STAGE-I Report and Corrective Action
PROCESS OF CERTIFICATION
Audit
STAGE-II Report and Recommend of Certificate

Section A11. ISO 45001:2018

A) Verification Needed during the assessment.

i. If the client provides services at another organization's premises, the CAB shall verify that the client's OH&SMS covers these offsite activities (notwithstanding the OH&SMS obligations of the other organization). In determining the time to be spent on auditing, the CAB shall consider auditing periodically any organization site where these employees work. Whether all sites shall be audited will depend on various factors such as OH&S risks associated with the activities therein performed, contract agreements, being certified by another accredited CAB, internal audit system, statistics on accidents and near misses. The justification for such a decision shall be recorded.

B) Multi-site sampling

i. In the case of OH&SMS operated over multiple sites it is necessary to establish if sampling is permitted or not based on the evaluation of the level of OH&S risks associated to the nature of activities and processes carried out in each site included in the scope of certification. The rationale of such decisions, the calculation of the audit time and the frequency of visiting each site shall be consistent with the requirements of clause B.10 in Appendix B, and shall be documented for each client.

ii. Where there are multiple sites not covering the same activities, processes and OH&S risks, sampling is not appropriate.

iii. Although a site performs similar processes or manufactures similar products to other sites, the CAB shall take account of the differences between the operations of each site (technology, equipment, quantities of hazardous materials used and stored, working environment, premises etc.).

iv. When sampling is permitted the TNV shall ensure that the sample of sites to be audited is representative of processes, activities and OH&S risks that exist in the organization to be audited and auditor shall confirm adherence of the same during the audit.

v. Temporary sites covered by the organization's OH&SMS are subject to audit on a sample basis to provide evidence of the operation and effectiveness of the management system (see clause B.9 of Appendix B).

C) Planning activities

i. For the determination of the ability of the management system to ensure the client meets applicable statutory, regulatory and contractual requirements, the approach described in Appendix C shall be applied

ii. The OH&SMS shall include activities, products and services within the organization's control or influence that can impact the organization's OH&SMS performance.

iii. Temporary sites, for example, construction sites, shall be covered by the OH&SMS of the organization that has control of these sites, irrespective of where they are located.

D) Conducting the opening meeting

i. The audit team shall interview the following personnel:

ii. the management with legal responsibility for Occupational Health and Safety,

iii. employees' representative(s) with responsibility for Occupational Health and Safety,

iv. personnel responsible for monitoring employees' health, for example, doctors and nurses. Justifications in case of interviews conducted remotely shall be recorded

v. managers and permanent and temporary employees

vi. Other personnel that should be considered for interview are: managers and employees performing activities related to the prevention of Occupational Health and Safety risks, and contractors' management and employees

E) Identifying and recording audit findings

i. Auditor shall follow reporting of finding method in the event that it discovers a non-compliance with relevant regulatory requirements. Please refer procedure TNV-F-01 which explain any such non- compliances are immediately communicated to the organization being audited.

TNV conduct audit under the New version of ISO 9001-2015 and in future when any changes in the standards comes, auditor / client need to make transition plan for the new version:

Section A 12. Opening & Closing Meeting

Management System Assessment Visits (Stage- 1/ Stage 2/ Surveillance/Re-certification) Basic Elements of an Audit

The Audit shall comprise of the following elements:

a) An "Opening Meeting" between the Audit Team and the Company's Representatives.

b) Auditing

c) A "Closing Meeting" at which the findings of the Audit Team are given to the company.

d) A checklist for opening and closing meetings is attached for guidance Aide Memory for all company visits

For OHSAS: The organization representative shall be requested to invite the management legally responsible for occupational health and safety, personnel responsible for monitoring employees' health and the employees' representative(s) with responsibility for occupational health and safety to attend the closing meeting. Justification in case of absence shall be recorded.

1. OPENING MEETING

The purpose of the opening meeting is communicating the methodology of the audit activities. The Opening Meeting is held on arrival and immediately before the commencement of the Certification Audit/surveillance. The meeting record shall be recorded on TNV- F-009.

The meeting is chaired by the Lead Auditor and addresses the following elements:

Sl. No.	Topic	Particular	Covered
1	Thanks	Give an expression of thanks to the auditee for Choosing TNV.	
2	Attendance	Request attendees to record their attendance	
3	Introduction	• Remind timeline to close opening meeting in 15-30 minutes.	

Sl. No.	Topic	Particular	Covered
		• Request to give brief introduction with brief roles (participants, observers, guides & Translators)	
4	Scope / Summery	Confirmation of the audit objectives (Assessment for ISO 9001:2015), scope and criteria;	
5	Changes	Changes in documents/Fact to the Application/Stage-1 Audit.	
6	Plan	Confirmation of the audit plan and other relevant arrangements with the auditee, such as the date and time for the closing meeting, any interim meetings between the audit team and the auditee's management, and any late changes;	
7	Method	Methods of Audit: Review of Documents & Records, Interview, Physical evidence…	
8	Sampling	Advise auditee that the audit is sample basis and findings will be based on a sample of the information selected;	
9	Communication Channel	Confirmation of formal communication channels between the audit team and the auditee; identify the facilitators.	
10	Language	Confirmation of the language to be used during the audit;	
11	Development	Confirmation that, during the audit, the auditee will be kept informed of audit progress;	
12	Resource	Confirmation that the resources and facilities (needed by the audit team are available;) like Guide, Interpreters, Observer, Facility etc.. (roles and identities)	
13	Confidentiality	Confirmation of matters relating to confidentiality and information security;	
14	Safeguard	Confirmation of relevant health and safety, emergency and security procedures for the audit team;	
15	Reporting of Findings	• NC may be against a clause of the standard i.e. ISO 9001, it's not against any person or department.	
		• Method of reporting audit findings & grading (Major, Minor & Observation)	
		• Time-span for corrective action (Minor-, Major-)	
		• Report time: Finding will be discussed at closing meeting and report will be given within 2 working days.	
16	Termination	Information about conditions under which the audit may be terminated;	
17	Audit Declaration	verify that all members of the organization know what is happening;	
18	Union/Problem	Ascertain union relations or any potential problems;	
19	Confidentiality	Remind the auditees that the audit is confidential.	
20	Closing Meeting	Timing of closing meeting; Participation of the Top Management & where appropriate, those responsible for the functions or processes which have been audited in the closing meeting.	
21	Appeals / Complaint	information about any system for feedback from the auditee on the findings or conclusions of the audit, including complaints or appeals	

2.0 AUDIT

The Audit of the management system against the Standards requirements is undertaken on a sampling basis of that system but not a sampling of the clauses of I.M.S. The Audit is concerned with establishing that the company's documented quality system is well established and operable in accordance with the requirements of the applicable standard ISO 9001/14001/45001/27001/22301/37001. The Audit should also include a verification of the legal/statutory requirements applicable to the company's products/services and compliance with the

same requirements applicable to the company's products/services and compliance with the same.

The Audit team member(s) accompanied by the company's representative(s) shall start their audit in a chosen area by selecting at random a feature relevant to the appropriate part of the ISO 9001/14001/45001/27001/22301/37001 as applicable against which the company is to be audited and proceed according to the audit programme ensuring that the audit takes account of all requirements of applicable ISO Standards and any applicable documents. The team member(s) shall keep in mind the possibility that some elements may overlap over more than one department's functions.

For example, procedures for documentation and change control may be required in design office, production department, inspection department, dispatch department etc. Remembering our third party responsibility, it is emphasized that during the audit the auditor shall satisfy himself/herself that the company has adequately demonstrated that its Management system provides evidence that its finished product or service complies with the specification either stipulated by the customer or offered by the company. Specific attention requires to be focused to ensure that the company's Policy statement addresses its commitment to provide customer satisfaction and to continual improvement in the effectiveness of its quality/Environment/Food safety/ OHS management system. While there should be sufficient evidence to demonstrate the reliability of the company's internal auditing procedures and the effectiveness of the management review, the implementation of a process based approach using "PDCA" cycle should be verified.

The audit team shall compile and analyze the results of both stage-I and stage-II audit and discuss with the client and finalize the conclusions.

3. CLOSING MEETING

The objective of the closing meeting is to enable the Team Leader to present the summary of the result of the audit to the client company and the team's recommendations. The closing meeting could also be used to arrive at mutual agreement on the corrective actions and their completion dates. Lead Auditor shall held a formal closing meeting with the clients management systems including the personals who will be audited for process verification and the attendance of the participants in the closing meeting is recorded on TNV- F-009. The purpose of the closing meeting, which shall normally to be conducted by the audit team leader, is to present the audit conclusions, including the recommendation regarding certification. Any nonconformity shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed. During the closing meeting the lead auditor shall ensure the written acceptance for the nonconformities identified in the audit and the Corrective Action plan.

The closing meeting shall be chaired by the TL and address the following:

Sl.	Topics	Particular	Verified
1	Introduction	Particularly if anybody not present at the opening meeting	
2	Thank to company	Thanks to your Team for cooperation during the audit and arrangements for the Audit.	
3	Reaffirmation of Scope	Reconfirm scope of activities assessed **and explanation of any differences from the information presented to the organisation at the closing meeting.**	
4	Confirm confidentially	Reassure the confidentiality for any information assessed during the audit.	
5	Appreciation	Comment on good points within the organisation	

6	Disclaimer	This was audit on sample basis, and it should not mean, that other deficiencies do not exist.	
7	*Audit Team Comment*	*Summary of individual findings from each auditor (if audit team consist more then 1)*	
8	*Decision*	• *Significance of categories of non-compliance and summary of findings,* • *Summary of overall findings and recommendation/Decision*	
9	*Acknowledgment*	*Assure that client acknowledge the NCs.*	
10	*Future Plan*	*If any NC is identified, Submitting plan for corrective action together with the objective evidence*	
11	*Follow-up action*	*Where do we go from here? emphasizing that the final decision regarding certification will be taken by TNV Certification*	
12	*Surveillance Audit*	*An explanation of the continual Audit (surveillance) procedure and other future actions*	
13	**Compliance with IAF MD 22**	**Confirm that personnel responsible for occupational health and safety, including those monitoring employees' health, were invited to the closing meeting and present. Record justifications for any absences.**	
14	**Attendance Verification**	**Present and confirm attendance records of the closing meeting, including occupational health and safety representatives.**	
15	**Documentation Protocol**	**Assure the organization that attendance and justifications for absences have been documented and will be reviewed systematically.**	
16	Appeal	Explain the Appeal & Complaint option available to the client against any decision of the Audit team.	
17	Invite questions	Invite questions, clarification from company (But no Consultancy)	
18	Signature	Obtain company representative's signature on report to acknowledge receipt.	

At the conclusion of the closing meeting the Team Leader shall leave with the company the copy of the Audit Report and take the acceptance of the Nonconformities identified in the audit.

Non-grant of Certification

In the event of there being major non-conformities which are considered to render the management system deficient and inoperable, a recommendation for certification cannot be made must be given. Depending upon the extent and nature of deficiencies, a recommendation for a supplementary audit for verification of corrective actions or Re-Audit may be made. In any case, a company will not be considered for grant of certification unless it has demonstrated effective implementation of the procedures for internal audits and the conduct of Management Review.

Non-certification implies that, although the company claims that its documented management system meets the requirements of the applicable ISO 9001/14001/45001/27001/22301/37001, the audit has revealed major non-

compliance/s or minor non-compliances which cumulatively amount to a major non-compliance necessitating major alterations to the company's documented procedures and implementation. The Team Leader shall ensure that all major non-compliances and matters of concern are recorded on the final page of the Audit report in the "Comments" section. The major non conformities should be reported on the Audit Report & Summary Section. These should be recorded objectively and precisely. Comments or concerns should be compatible and cross referenced with the Non-conformities / observations entered in the Audit report.

5.0 Action follows Non-Certification

Where an audit results in certification not being granted, the Team Leader will discuss further action with the company. Such action is left to the Team Leader discretion and may be anything from a 'follow up' action in areas of non-compliance to a total Re-Audit depending on the severity of the deficiencies.

In the case of a 'follow-up' action (limited re-Audit), the Team Leader will agree on a re-visit date with the company and be responsible for drafting the Re-Audit plan, based on the non-compliances raised. The Team Leader MUST state the duration of the limited Re-Audit i.e. 1 man-day, 2 man days in his recommendation and the maximum time limit will be approx 60 days for the conduct of audit.

6.0 Right to Appeal against Non-certification

When the recommendation made at the closing meeting is for non-certification, the company must be advised of their **RIGHT TO APPEAL.** The company should submit its appeal within 14 days in writing to the Technical Coordinator. The Quality Manager will refer the appeal to the CEO/ED for further investigation. CEO will then make an appeals panel for the review of the appeal, the Appeals Panel decision will be final. The Appeals Procedure is fully defined in the Procedures Manual and can be lodged as available on http://tnvgroup.org.

7.0 Recommendations for Certification

a) In the event of major non conformities being identified (Category 'A') in respect of the implementation of any element of the quality system or several minor non-conformities being recorded against any one element which renders the system deficient but operable, a recommendation for certification is made subject to a CAP being submitted within 2 weeks and corrective actions being verified onsite and closed out through a special visit within 60 days of the Audit date, before certification is granted or as decided by CEO.

b) Where the audit has revealed only minor non conformities (Category 'B') which need to be addressed through corrective actions, the certification may be recommended subject to the **CAP (Corrective Action Plan)** being submitted by the company within 2 weeks together with objective evidences of the corrective actions taken. The corrective actions plan is required to be closed out upon physical verification of the satisfactory implementation at the first subsequent audit.

c) In the case of where "opportunities for improvement: (Category 'C') having been recorded during the certification audit, the actions, as applicable, are observed for effectiveness at the subsequent audit visit.

8.0 INTRODUCTION OF THE OBSERVER:

Any person can be authorized by TNV (either representing Accreditation board or from TNV), to be present and observe the auditor and audit process with objective to determine the competence of the auditor and TNV's process with objective to verify effectiveness of the audit process may act as observer. This clause defines the situation and Roles during the audit (mainly in witness audit by accreditation board and TNV representative).

8.1 Definition of Observer:

- Individual who accompanies the audit team (3.14) but does not act as an auditor (3.15).
- Observer: An individual specifically authorized by the TNV to observe an audit.
  An observer does not actively participate (i.e., perform auditor functions) or interfere with ongoing audit activities.
- *Observers* accompany auditors and witness audit activities. However, they're not audit team members and therefore do not perform audit functions. They may not influence or interfere with the audit. *Observers* can represent Certification Body, Accreditation Board, auditee organizations, regulators, or any other interested party.

8.2 Roles of Audit Team Leader towards Observer

Roles of Audit Team Leader towards Observer	
Plan	Name of observer must be mentioned in Audit Plan
Informed	Audit Team Leader must inform any specific requirement related to check in system / requirements to auditee, PPE requirement, Safety Guidance etc in advance. Introduce
Welcome and introduce	Audit Team Leader shall welcome and introduce Observer in opening Meeting. Representation
Representation	Audit Team Leader must introduce observer with background and representation (i.e. TNV or Accreditation Board or any other as applicable)
Remain Neutral	Audit Team must do their natural audit.

8.3 Role and Responsibility of Observer

- Observer doesn't audit the client but review the performance of the audit team mainly audit team leader.
- Observer discuss the finding of the audit with audit team after the closing meeting, but observer have right to ask for discussion of development in between the audit without affecting audit schedule.
- Observer may review client documents/records if needed to verify if auditor are appropriately auditing or not.
- Observation report of the observation is basis for competence of the auditor.

8.4 Importance of Finding of the observer

- Finding given by observer shall be discussed during the closing meeting and reported to TNV head office.
- Any major lack in auditing process (if reported) may be basis for the training or limitation of the auditing or further evaluation.
- Observer must give due respect and seek if observer want to review any document during the development of the audit.
- Team Leader must ensure Safety and convenience of the observer during the audit.
- Team Lead shall ensure refreshment & travel requirements etc for the observer if needed.

8.5 FAQ related to Observer

- The auditee should be notified of a presence of the observer in advance. There are times where this may not be allowed depending on the type of the audit.
- The Observer sign a confidentiality agreement (with Accreditation board or CAB) on not disclosing any information outside the audit process. The rules should be established as part of this confidentiality agreement.
- An observer may not engage in any part of the audit.
- The observer may not interfere in any aspect of the audit (may not inject, provide opinions, argue a finding, speak for or against a finding, use the audit information for a future punitive measure).
- If questioned during the audit, the observer should explain the role as observer. Ideally this should be brought to the attention of the auditor in advance.
- These basic rules ensure that the audit is not affected in any way (positive or negative) and the customer's request to witness the audit is conducted in a professional manner.

8.6 Rules of Observer Role:

1. **The Audit Observer shall:**
   a. Remember at all times that the role is purely observational.
   b. Maintain confidentiality throughout the audit process from the entrance notice to the final report.
   c. Maintain confidentiality of the names of the individuals interviewed and the content of the interviews, even after the audit report is issued.
2. **The Audit Observer may:**
   a. Take notes during an interview.
   b. Express concerns about the audit process to the Lead Auditor only and in private. At his or her discretion, the Lead Auditor may invite the audit team into these discussions.
3. **The Audit Observer shall not:**
   a. Talk during any interview or walkthrough
   b. Take any active part in the audit program. This includes asking questions of interviewees, participating in audit team discussions unless invited to do so by the Lead Auditor, etc.
   c. Separately, on their own, further review or assess any aspect of the program or area being audited prior to the issuance of the final audit report.
4. **Responsibilities of Lead Audit With Respect to the Observer**
   a. Include the Audit Observer in the distribution of the audit notification.

b. Provide the Audit Observer with a copy of the audit checklist prior to the start of the audit.

c. Invite Audit Observer to the entrance meeting, audit interviews or walk-throughs, team meetings, and the exit meeting (if held). The Audit Observer should recognize that team discussions may, unintentionally but necessarily, be impromptu.

d. Include the Audit Observer in the distribution of draft and final audit reports.

Section A 13. Confidentiality Agreement

Confidentiality (including conflict of interest) Statement for all Personnel Internal or External of (TNV)

I, _____, S/D/W of _____

resident of _____

I am working as a _____(Employee/Technical Expert/Empaneled Auditor) engaged under a contract of service with TNV System Certification Pvt. Ltd. I undertake not to disclose/divulge any confidential information relating to business of TNV or any of its clients, which I may obtain because of or during the course of such association/ employment.

2. I shall take all reasonable steps to prevent any other person from gaining access to and use of the confidential information, during and after my association/employment with TNV.

3. I agree to take good care of (any equipment or) documents which may from time to time to within my custody or control during the course of my engagement and shall not, except in the proper course of my duties, show or disclose or communicate the construction or contents thereof to anyone.

4. In the event of my being assigned any audit which includes an organization, where I have any commercial and other interest or to which I have provided consultancy services, including but not limited to conduct of on-site training and internal audits, within the last two years (prior to the planned audit date) I shall immediately inform TNV management of this who can take appropriate action on the same.

5. upon termination my engagement (for whatever reason) and at any other time at your request I shall, without retaining any copies or records thereof, immediately return all such (equipment and) documents or extracts of such documents and all other notes, memoranda, photographs, drawings, records or other material made or procured to be made by me or issued to me during my engagement relating to the business of TNV or any of its clients. For the purpose of this undertaking I acknowledge that Confidential Information means all technical and business information of TNV System Certification Pvt. Ltd. and its clients which are of a confidential, trade secret and/ or proprietary nature.

6. I shall reveal any situation known to me that may pose threat to impartiality or any conflict of interest arising on the assignment to TNV from time to time

7. Further, I undertake that I shall not indulge into any activity which might influence the impartiality of certification process.

As part of such Agreement, I am obligated to execute this Confidential Information and No Conflict of Interest Agreement for each client for which I perform Certification Activities.

8) This section shall be confirmed by each audit team member

8.1) I confirm that I have not provided any consulting or other services to or on behalf of Client during the 24 months period prior to the date hereof directly or indirectly.

YES/ NO

8.2) I confirm that I will not during the 12 months period succeeding the last day on which I provide Registration Activities with respect to Client pursuant to the Agreement or any future agreement between TNV and me, directly or indirectly provide any consulting or other services (including, but not limited to Registration Activities) to or on behalf of Client.

YES/ NO

8.3) I shall keep Confidential Information secret and confidential, and not disclose such Confidential Information to any person or entity except for TNV and, if applicable, a Contracted Registrar providing services to Client.

YES/ NO

8.4) I shall deliver to TNV, or at TNV' direction to Client all materials and reports (including all copies) in my possession (including quality manuals, reports, computerized data contained in any form) upon receipt of a written letter from Client or TNV instructing me to return such materials.

YES/ NO

I understand that my obligations under this Confidential Information and No Conflict of Interest Agreement shall survive till the termination of "Contractual Agreement ".

I hereby execute this Confidential Information and No Conflict of Interest Agreement with respect to above Client and declare that I have no conflict of interest with the client.

Signature:_____

Date: _____

Name: _____

Designation_____

GUIDELINES FOR AUDITING OF QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

Stage-1 Audit: Documentation Review and Readiness Assessment

Objective

The Stage-1 audit assesses whether the organization's QMS is adequately documented and prepared for the Stage-2 audit. It identifies gaps and areas needing improvement before advancing to the certification phase.

Detailed Activities

1. Review of Documented Information

- **Quality Policy and Objectives**:
  - Confirm that the quality policy aligns with the strategic direction of the organization and includes commitments to:
    - Satisfying applicable requirements.
    - Driving continual improvement.
  - Verify that quality objectives are measurable, monitored, and aligned with customer requirements.
- **Scope of the QMS**:
  - Evaluate the organization's defined scope (Clause 4.3), ensuring it reflects all relevant processes, products, and services.
  - Verify the justification for any exclusions.
- **Process Identification**:
  - Ensure all processes relevant to the QMS are identified, their interactions defined, and criteria for control established (Clause 4.4).
- **Risk-Based Thinking**:
  - Assess the documented approach to identifying risks and opportunities (Clause 6.1).
  - Review records of risk assessments, mitigation plans, and actions.
- **Internal Audit and Management Review Records**:
  - Verify the organization has conducted at least one cycle of internal audits and management reviews, as per Clauses 9.2 and 9.3.
  - Ensure records demonstrate the organization's ability to identify and resolve issues.

2. Understanding the Context of the Organization

- **Internal and External Issues (Clause 4.1)**:
  - Review how the organization identifies and monitors external and internal issues that impact its QMS.
- **Interested Parties (Clause 4.2)**:
  - Assess the identification and consideration of interested parties, such as customers, suppliers, regulators, and employees, in the QMS design.

3. Review of Additional Documents

- Customer-related processes (Clause 8.2), including methods for capturing and reviewing requirements.
- Control over externally provided processes and services (Clause 8.4).
- Monitoring and measuring resource calibration and maintenance records (Clause 7.1.5).

4. Site Visit (Optional)

- Inspect physical infrastructure and evaluate work environment suitability (Clause 7.1.3).
- Conduct preliminary discussions with key personnel to assess their understanding of QMS responsibilities.

5. Gap Analysis and Preliminary Findings

- Identify areas of non-conformity, partial conformity, and strengths.
- Highlight potential risks that may impact the Stage-2 audit.

Outputs

1. **Stage-1 Audit Report**:
    - Summarize documentation review results, including conformity, observations, and gaps.
    - Include recommendations for addressing gaps before Stage-2.
2. **Readiness Decision**:
    - Advise whether the organization is prepared for Stage-2 or requires corrective action.

Stage-2 Audit: Implementation and Effectiveness Assessment

Objective

The Stage-2 audit evaluates the implementation, effectiveness, and alignment of the QMS with ISO 9001:2015 requirements. It confirms that the QMS is operational and achieving intended results.

Detailed Activities

1. Opening Meeting

- Confirm audit objectives, criteria, and scope.
- Outline the audit methodology, including sampling and evidence collection techniques.
- Reaffirm confidentiality, impartiality, and the roles of audit team members.

2. Clause-by-Clause Assessment

Clause 4: Context of the Organization

- Verify the implementation of processes to monitor and review external and internal issues.
- Assess the integration of interested parties' needs and expectations into QMS processes.

Clause 5: Leadership

- **Leadership and Commitment (Clause 5.1)**:
    - Evaluate top management's active role in promoting the QMS, customer satisfaction,

and continual improvement.

- **Quality Policy (Clause 5.2)**:
  - Verify its communication and understanding across all levels of the organization.
- **Roles and Responsibilities (Clause 5.3)**:
  - Ensure responsibilities and authorities are assigned and understood.

Clause 6: Planning

- Review the effectiveness of risk and opportunity management processes.
- Verify that quality objectives are aligned with strategic goals and supported by actionable plans.
- Assess planning processes for maintaining QMS integrity during changes.

Clause 7: Support

- **Resources (Clause 7.1)**:
  - Evaluate infrastructure, equipment, and environmental conditions.
  - Verify that monitoring and measuring resources are calibrated and maintained.
- **Competence and Awareness (Clauses 7.2 and 7.3)**:
  - Review training records and confirm personnel understand their roles and the quality policy.
- **Documented Information (Clause 7.5)**:
  - Assess the creation, control, and retention of documented information.

Clause 8: Operation

- **Operational Planning and Control (Clause 8.1)**:
  - Ensure operational controls are effective in achieving planned results.
- **Customer Requirements (Clause 8.2)**:
  - Verify processes for determining, reviewing, and communicating customer requirements.
- **Production and Service Provision (Clause 8.5)**:
  - Assess work instructions, traceability, and preservation of products.
- **Non-Conforming Outputs (Clause 8.7)**:
  - Review processes for handling non-conforming products, including corrective actions.

Clause 9: Performance Evaluation

- **Monitoring and Measurement (Clause 9.1)**:
  - Verify data collection, analysis, and use in decision-making.
  - Review customer satisfaction and complaint-handling mechanisms.
- **Internal Audits (Clause 9.2)**:
  - Evaluate the effectiveness of the internal audit program.
- **Management Review (Clause 9.3)**:
  - Confirm that management reviews cover inputs, such as audit results, customer

feedback, risks, and objectives.

Clause 10: Improvement

- **Corrective Actions (Clause 10.2)**:
  - Review records of corrective actions and confirm that root causes are addressed.
- **Continual Improvement (Clause 10.3)**:
  - Assess evidence of initiatives taken to enhance QMS effectiveness.

3. Evidence Collection

- Conduct interviews with personnel across departments to evaluate their understanding of roles and processes.
- Observe operations and collect records, such as:
  - Inspection and test reports.
  - Supplier evaluations.
  - Customer feedback logs.
  - Training records.

4. Non-Conformities and Observations

- Classify findings into:
  - **Major Non-Conformities**: Significant gaps that affect QMS performance.
  - **Minor Non-Conformities**: Isolated lapses that do not affect overall performance.
  - **Observations**: Opportunities for improvement or potential risks.

5. Closing Meeting

- Present audit findings and classifications.
- Confirm understanding of non-conformities and agree on timelines for corrective actions.
- Provide preliminary recommendations for certification or further actions.

Outputs

1. **Stage-2 Audit Report**:
   - Comprehensive documentation of findings for each clause, supported by objective evidence.
   - Summary of non-conformities, observations, and strengths.
2. **Corrective Action Requirements**:
   - Include timelines and responsibilities for addressing non-conformities.
3. **Certification Decision**:
   - Recommend certification or additional corrective actions based on findings.

Key Audit Principles

- **Process-Based Auditing**:

- Focus on process interactions and their impact on overall QMS performance.

- **Risk-Based Thinking**:
  - Ensure risks are proactively identified, assessed, and managed.
- **Customer Focus**:
  - Evaluate processes for enhancing customer satisfaction and addressing feedback.

Section A 15. Stage 1 & Stage 2 Auditing Methodology EMS

Stage-1 Audit: Documentation Review and Readiness Assessment
Objective
The Stage-1 audit assesses the adequacy of the organization's documented EMS and its preparedness for the Stage-2 audit. It identifies gaps and areas requiring corrective action before certification.

Detailed Activities
1. Review of Documented Information

- **Environmental Policy**:
  - Verify the policy aligns with ISO 14001:2015 requirements (Clause 5.2).
  - Ensure it includes commitments to:
    - Protection of the environment.
    - Fulfillment of compliance obligations.
    - Continual improvement of the EMS.
- **Scope of the EMS**:
  - Confirm the organization has clearly defined its EMS scope, reflecting boundaries and applicability (Clause 4.3).
  - Validate the inclusion of all activities, products, and services with significant environmental aspects.
- **Environmental Aspects and Impacts**:
  - Review the methodology for identifying environmental aspects and impacts (Clause 6.1.2).
  - Assess if significant environmental aspects have been documented and evaluated.
- **Compliance Obligations**:
  - Confirm the organization has identified applicable legal and regulatory requirements (Clause 6.1.3).
  - Verify documented compliance obligations and evidence of evaluations.
- **Operational Controls**:
  - Review procedures for controlling significant environmental aspects and minimizing impacts (Clause 8.1).

2. Understanding the Context of the Organization

- **Internal and External Issues (Clause 4.1)**:
  - Assess how the organization identifies and monitors factors affecting its EMS.
- **Interested Parties (Clause 4.2)**:
  - Review how the needs and expectations of stakeholders (e.g., regulators, customers, community) are identified and integrated.

3. EMS Planning

- **Risk and Opportunity Identification (Clause 6.1.1)**:
  - Evaluate the organization's processes for addressing risks and opportunities related to environmental management.
- **Environmental Objectives**:
  - Confirm objectives are aligned with the policy, measurable, and include plans for achievement (Clause 6.2).

4. Site Visit (Optional)

- Review infrastructure, operational processes, and environmental conditions.
- Identify site-specific environmental aspects and impacts.

5. Gap Analysis and Preliminary Findings

- Highlight gaps in documentation or preparedness for Stage-2.
- Recommend corrective actions to address identified issues.

Outputs

1. **Stage-1 Audit Report**:
   - Summary of conformity, gaps, and recommendations.
   - Evaluation of EMS documentation against ISO 14001:2015 requirements.
2. **Readiness Decision**:
   - Confirm whether the organization is prepared to proceed to Stage-2 or requires corrective actions.

Stage-2 Audit: Implementation and Effectiveness Assessment

Objective

The Stage-2 audit evaluates the implementation and operational effectiveness of the EMS, ensuring it complies with ISO 14001:2015 requirements and achieves intended outcomes.

Detailed Activities

1. Opening Meeting

- Confirm audit objectives, scope, and methodology.
- Outline the audit schedule and areas of focus.
- Reiterate confidentiality, impartiality, and the audit team's roles.

2. Clause-by-Clause Assessment

Clause 4: Context of the Organization

- Verify how the organization monitors internal and external issues and integrates them into its EMS.
- Assess the inclusion of stakeholder expectations in planning processes.

Clause 5: Leadership

- **Leadership and Commitment (Clause 5.1)**:
  - Evaluate top management's involvement in promoting environmental management.
  - Confirm commitment to environmental protection and continual improvement.
- **Environmental Policy (Clause 5.2)**:
  - Ensure the policy is communicated, understood, and implemented across the organization.
- **Roles and Responsibilities (Clause 5.3)**:

- Review the assignment of responsibilities for maintaining the EMS.

Clause 6: Planning

- **Risk and Opportunity Management (Clause 6.1.1)**:
  - Verify the organization identifies risks and opportunities for improving its EMS and achieving environmental objectives.
- **Environmental Aspects (Clause 6.1.2)**:
  - Assess the identification, evaluation, and prioritization of environmental aspects and impacts.
  - Confirm controls for significant aspects are in place.
- **Compliance Obligations (Clause 6.1.3)**:
  - Verify processes for identifying and evaluating legal and regulatory requirements.
  - Review evidence of compliance evaluations.
- **Environmental Objectives (Clause 6.2)**:
  - Evaluate objectives and ensure they are specific, measurable, and monitored.

Clause 7: Support

- **Resources (Clause 7.1)**:
  - Confirm sufficient resources are allocated for implementing and maintaining the EMS.
- **Competence and Awareness (Clauses 7.2 and 7.3)**:
  - Review training records and ensure personnel understand their environmental responsibilities.
- **Documented Information (Clause 7.5)**:
  - Assess the control of documented information related to the EMS.

Clause 8: Operation

- **Operational Planning and Control (Clause 8.1)**:
  - Verify operational controls are implemented for significant environmental aspects.
  - Assess emergency preparedness and response plans (Clause 8.2).
- **Outsourced Processes**:
  - Evaluate controls for contractors and suppliers to ensure environmental requirements are met.

Clause 9: Performance Evaluation

- **Monitoring and Measurement (Clause 9.1.1)**:
  - Confirm processes for monitoring environmental performance, including key performance indicators (KPIs).
  - Review methods for evaluating compliance with legal and regulatory requirements (Clause 9.1.2).
- **Internal Audits (Clause 9.2)**:
  - Assess the effectiveness of internal audits in identifying and resolving EMS deficiencies.
- **Management Review (Clause 9.3)**:
  - Review evidence that management reviews include inputs such as performance data, risks, and opportunities.

Clause 10: Improvement

- **Nonconformity and Corrective Action (Clause 10.2)**:
  - Review processes for addressing nonconformities and implementing corrective actions.
- **Continual Improvement (Clause 10.3)**:
  - Assess evidence of initiatives to improve environmental performance and EMS effectiveness.

3. Evidence Collection

- Conduct interviews with personnel across departments.
- Observe operations and environmental controls.
- Review records such as:
  - Monitoring and measurement data.
  - Incident logs and corrective action records.
  - Environmental training records.
  - Compliance evaluation reports.

4. Non-Conformities and Observations

- **Major Non-Conformities**:
  - Significant gaps affecting the EMS's ability to achieve its intended outcomes.
- **Minor Non-Conformities**:
  - Isolated issues not affecting overall EMS performance.
- **Observations**:
  - Opportunities for improvement or risks needing attention.

5. Closing Meeting

- Present audit findings, including non-conformities and observations.
- Confirm timelines for corrective actions.
- Provide a preliminary recommendation for certification or further actions.

Outputs

1. **Stage-2 Audit Report**:
   - Comprehensive findings for each clause, supported by evidence.
   - Summary of non-conformities, observations, and strengths.
2. **Corrective Action Plan**:
   - Timelines and responsibilities for addressing non-conformities.
3. **Certification Recommendation**:
   - Decision on certification readiness based on audit findings.

Key Focus Areas for Auditors

1. **Environmental Aspects and Impacts**:
   - Ensure all significant aspects are controlled and monitored.
2. **Compliance Obligations**:
   - Verify adherence to legal and regulatory requirements.
3. **Risk-Based Thinking**:
   - Assess how risks and opportunities are integrated into EMS processes.
4. **Continual Improvement**:
   - Evaluate initiatives for enhancing environmental performance.

Section A 16. Stage 1 & Stage 2 Auditing Methodology OHSMS

Stage-1 Audit: Documentation Review and Readiness Assessment

Objective

The Stage-1 audit determines if the organization's documented OHSMS complies with ISO 45001:2018 and is ready for a Stage-2 audit. This includes assessing whether the system is designed to meet the standard's requirements, manage occupational health and safety risks, and achieve intended outcomes.

Detailed Activities

1. Review of Documented Information

- **OH&S Policy (Clause 5.2):**
  - Ensure the policy reflects the organization's commitment to:
    - Preventing work-related injury and ill health.
    - Fulfilling legal and other obligations.
    - Continual improvement in OH&S performance.
  - Confirm the policy is documented, communicated, and aligned with the organization's strategic direction.
- **Scope of the OHSMS (Clause 4.3):**
  - Verify the scope includes all relevant activities, products, and services that influence OH&S performance.
  - Assess the justification for any exclusions and ensure they do not affect the OHSMS's effectiveness.
- **Hazard Identification and Risk Assessment (Clause 6.1.2):**
  - Review the documented process for identifying hazards and assessing risks and opportunities.
  - Ensure that significant risks are prioritized and addressed with controls.
- **Compliance Obligations (Clause 6.1.3):**
  - Confirm legal and other requirements have been identified, documented, and integrated into operational processes.
- **OH&S Objectives and Planning (Clause 6.2):**
  - Assess the establishment of measurable OH&S objectives.
  - Verify documented plans to achieve these objectives include timelines, responsibilities, and resources.

2. Understanding Context and Stakeholders

- **Internal and External Issues (Clause 4.1):**
  - Evaluate how the organization identifies external and internal factors that affect its OHSMS.
  - Verify monitoring and review mechanisms for these factors.
- **Interested Parties (Clause 4.2):**

- Assess the identification and consideration of the needs and expectations of workers, contractors, customers, and regulators.

3. Roles, Responsibilities, and Worker Participation

- **Roles and Responsibilities (Clause 5.3):**
  - Verify that roles and responsibilities for implementing the OHSMS are clearly defined and communicated.
  - Ensure that top management demonstrates accountability for OH&S performance.
- **Consultation and Participation of Workers (Clause 5.4):**
  - Confirm there are mechanisms for worker engagement in hazard identification, risk management, and decision-making processes.

4. Emergency Preparedness and Response

- Review emergency preparedness plans (Clause 8.2), ensuring they cover:
  - Potential emergency scenarios.
  - Roles and responsibilities for emergency responses.
  - Testing and updating of emergency procedures.

5. Evaluation of Operational Planning

- Assess whether controls for significant risks are adequately planned and documented.
- Confirm processes for outsourced work and contractor management align with the OHSMS.

6. Preliminary On-Site Visit (if applicable)

- Inspect key operational areas to verify the identification of site-specific hazards.
- Observe infrastructure, equipment, and workplace conditions that influence OH&S performance.

Outputs

1. **Stage-1 Audit Report:**
   - Summary of document review findings, including conformity, gaps, and observations.
   - Recommendations for addressing non-conformities before Stage-2.
2. **Decision on Readiness:**
   - Advise on readiness for Stage-2 or identify areas requiring corrective actions.

Stage-2 Audit: Implementation and Effectiveness Assessment

Objective

The Stage-2 audit evaluates the implementation and effectiveness of the OHSMS in managing OH&S risks, complying with ISO 45001:2018, and achieving continual improvement.

Detailed Activities

1. Opening Meeting

- Confirm the audit objectives, scope, and criteria.
- Outline the audit schedule and explain evidence collection techniques.
- Emphasize confidentiality and impartiality.
- Discuss key focus areas, including compliance obligations, hazard controls, and worker participation.

2. Clause-by-Clause Assessment

Clause 4: Context of the Organization

- Verify how external and internal issues impacting the OHSMS are identified, monitored, and reviewed.
- Assess integration of the needs and expectations of interested parties into OH&S planning.

Clause 5: Leadership and Worker Participation

- **Leadership and Commitment (Clause 5.1):**
  - Evaluate top management's involvement in promoting the OHSMS.
  - Ensure leadership takes accountability for OH&S performance.
- **OH&S Policy (Clause 5.2):**
  - Confirm the policy is implemented across all levels and communicated effectively.
- **Consultation and Worker Participation (Clause 5.4):**
  - Verify the effectiveness of worker engagement in hazard identification and OH&S decision-making.

Clause 6: Planning

- **Risk and Opportunity Management (Clause 6.1):**
  - Assess processes for identifying risks and opportunities, particularly for significant hazards.
  - Evaluate controls based on the hierarchy of controls.
- **Compliance Obligations (Clause 6.1.3):**
  - Confirm processes for ensuring compliance with legal and regulatory requirements.
  - Review evidence of compliance evaluations.
- **OH&S Objectives (Clause 6.2):**
  - Verify objectives are measurable, achievable, and monitored for progress.

Clause 7: Support

- **Resources (Clause 7.1):**
  - Assess allocation of adequate resources for the implementation and maintenance of the OHSMS.
- **Competence and Awareness (Clauses 7.2 and 7.3):**

- Verify that workers are trained, competent, and aware of their OH&S responsibilities.

- **Communication (Clause 7.4):**
  - Evaluate processes for internal and external communication regarding OH&S matters.
- **Documented Information (Clause 7.5):**
  - Assess how documented information is maintained, controlled, and accessible.

Clause 8: Operation

- **Operational Planning and Control (Clause 8.1):**
  - Confirm implementation of controls for significant risks, including contractor management and outsourcing.
- **Emergency Preparedness and Response (Clause 8.2):**
  - Evaluate the effectiveness of emergency response plans through records, drills, and worker awareness.

Clause 9: Performance Evaluation

- **Monitoring, Measurement, and Evaluation (Clause 9.1):**
  - Verify data collection and analysis methods for tracking OH&S performance.
  - Review incident records and ensure trends are analyzed.
- **Internal Audits (Clause 9.2):**
  - Assess the internal audit process for identifying system gaps.
- **Management Review (Clause 9.3):**
  - Confirm management reviews address OH&S performance, risks, and opportunities.

Clause 10: Improvement

- **Nonconformity and Corrective Action (Clause 10.2):**
  - Review the organization's processes for investigating incidents, identifying root causes, and implementing corrective actions.
- **Continual Improvement (Clause 10.3):**
  - Evaluate evidence of initiatives for enhancing OH&S performance.

3. Evidence Collection

- Conduct interviews with workers, supervisors, and management to assess understanding of the OHSMS.
- Observe workplace activities and verify that hazard controls are implemented.
- Review records such as:
  - Risk assessments and incident reports.
  - Compliance evaluation reports.
  - Worker training and participation logs.

4. Non-Conformities and Observations

- **Major Non-Conformities:**

- Systemic failures impacting the effectiveness of the OHSMS.

- **Minor Non-Conformities:**
  - Isolated lapses that do not significantly impact OH&S performance.
- **Observations:**
  - Opportunities for improvement or risks requiring attention.

5. Closing Meeting

- Present findings, including non-conformities and recommendations.
- Discuss timelines for corrective actions and next steps for certification.
- Highlight strengths and opportunities for improvement.

Outputs

1. **Stage-2 Audit Report:**
   - Comprehensive findings for each clause, supported by evidence.
   - Summary of non-conformities, observations, and strengths.
2. **Corrective Action Plan:**
   - Timelines and responsibilities for addressing non-conformities.
3. **Certification Recommendation:**
   - Decision on certification readiness based on findings.

Key Focus Areas for Auditors

1. **Hazard Identification and Risk Control:**
   - Ensure robust processes for identifying and controlling workplace hazards.
2. **Legal Compliance:**
   - Confirm adherence to applicable legal and other requirements.
3. **Worker Participation:**
   - Assess worker engagement in hazard management and decision-making.
4. **Continual Improvement:**

Verify that the organization actively seeks to improve OH&S performance.

Section A 17. Stage 1 & Stage 2 Auditing QMS/EMS/FSMS/OHS

1. An audit of a Management System consists of following activities/planning:

- Audit Plan Stage 1 & Stage 2,
- Opening meeting
- Performing the audit,
- Auditors meeting
- Closing meeting
- Acceptance for the NC identified
- Verification of the Corrective Action and subsequent evidences

2. Stage 1 Audit:

The purpose of stage 1 is to obtain the optimal preparation of the certification audit (stage 2). In principle the Lead Auditor takes care of the preliminary contact, but he may delegate this task to an other auditor of the team. Stage 1 shall normally have the form of a visit. It may exceptionally be executed by phone calls, faxes or mail.

a) A member of the audit team shall review the system documentation (usually the quality manual, supported by organisational procedures) before or during the site visit.
b) The stage 1 site visit mainly involves the Applicant's Management representative.
c) During stage 1, arrangements shall be made about:
d) Identifying date, site location and site specific conditions,
e) Collecting necessary information regarding the scope of the management system, areas, processes, compliance to related statutory and regulatory aspects and the responsible persons to be audited. Aspect & Impact Analysis/Hazard Analysis/PRP/HACCP Plan/CCP whether suitable or not as per the nature of work.
f) Confirming that internal audits and management review have been planned and performed.
g) Gathering reasonable knowledge about the client's management system and site operations in order to plan the stage 2 audit.
h) Review of client's status and understanding regarding the requirements of the standard and readiness for Stage 2 audit.
i) Review the allocation of resources for Stage 2 audit and to aware the client about the requirements of Stage 2 audit.
j) In case, during Stage 1 Audit, auditor finds the information provided by the client before submission of quote is incorrect, he shall immediately inform the Technical Coordinator / Assessment Manger / Quality Manager. Quality Manager / CEO shall ensure that the quote is reviewed and contract review is done to address the changes.
k) After the completion of Stage 1 audit, the lead auditor shall write and send the stage 1 audit report together with the stage 2 audit schedule to the organization.

The audit plan should cover following points

- Audit of the management system processes.
- Time required to audit those processes and its activities
- Audit team allocation
- Safety arrangement required

The minimum time gap between Stage 1 and Stage 2 should be reasonably one week, but could be reduced based on the customer requirements.

In case of any major area of concern during the Stage 1 audit, the lead auditor can postpone the date of Stage 2 audit (not over 90 days) so that the organization get the time for doing the improvements and inform the same to Administration.

3. Stage 2 Audit

The essential objective of an audit team is to verify:

- the existence of a Management System in the organization that meets all applicable requirements of the reference standard,
- the effective implementation of the Management System,
- the suitability of the elements of the Management System (such as, organizational structure, responsibilities, procedures, processes, technical documentation and resources), to meet the expectations of the customer and to respect statutory requirements. Necessary arrangements to meet the Impacts/Hazards/CCP, communication channel for any emergency situation/suppliers/staff/ regulatory bodies, emergency arrangements and records of mock situation, pest control and other safety conditions as identified

by the organization and required for the nature of job.

4. Audit Process:

During the performance of the audit, the audit team verifies the following essential elements of a Quality/Environment/OHSMS/FS Management System:

- the availability of a system to identify without ambiguity the contractual requirements and the applicable codes, standards and statutory requirements,
- the suitability of the system to consider all identified requirements at the various stages of the process (engineering, procurement, production, inspection, installation, service, etc.),
- the availability of adequate resources, to achieve the desired results. This includes also the training aspects of the concerned personnel.

Therefore, the audit team examines during the audit, practical examples of running or terminated orders, with the purpose to verify that both upstream as well as downstream of the process indicators of the Quality / Environment / OHSMS/FS Management System and that the product or service meets the expectations of the customer.

This verification covers subjects that are directly related to the quality of the product or service (such as; key performance objectives, legal compliance, specifications, quality plan, work instructions, documents indicating the inspection and test status, inspection procedures and quality records) and during this verification the processes, aspects of completeness and coherence are reviewed.

In combination with the verification of the effectiveness of complementary aspects (such as; management review, document control, control of non-conforming products, internal audits, etc.), the audit team is able to make a judgement about the Quality/Environment/OHSMS/FS Management System of the organisation and particular about the essential elements of the system.

The audit team shall inform the organization regularly regarding the audit progress and results. In case of unreasonable accumulation of non-conformities indicating total breakdown of the system, the lead auditor shall have the authority to stop the audit.

5. Auditors Meeting:

After performance of the audit and prior to the exit meeting, the audit team joints together with the purpose to:

- discuss the results of the audit,
- define formally the detected non-conformities, if applicable,
- write the Non-Conformity report, if applicable,
- Prepare the final meeting.

Non-conformities disclosed during an audit are divided into major and minor.

Major non-conformities

i) Lack of essential documentation or lack of implementation of an applicable criterion of the Quality Management System.

ii) Lack or inadequacy of a quality plan or lack of resources to assure the quality of the related products and/or services.

iii) High number of minor non-conformities

Minor non-conformities

i) Incomplete documentation on the condition that the missing documentation is not essential for the operation, or incomplete implementation of applicable criteria of the reference standard.

ii) Individual non conformities which does not impair the operability of the management system.

iii) Lack of evidence demonstration the conformity with a criterion of the reference standard.

A complete re-audit shall be requested under following circumstances:

i) high number of major non-conformities or total breakdown of system, or

ii) high number of customer complaints and no clear evidence of action taken towards customer satisfaction.

6. Closing Meeting:

Communicating the outcome of audit Recommended/not recommended for Certification/Next phase of audit, surveillance communication , scope confirmation, NC Acceptance & Communication about corrective action, opportunities for improvement, copy of report to organization

7. FOOD SAFETY RELATED REQUIREMENTS NEED TO BE CONSIDERED DURING THE AUDITING:

❖ CONDUCT OPENING MEETING

- Confirm certification scope
- Review audit criteria/methodology and explain outcome (e.g. audit as sampling, process approach)
- Establish communication channels
- Identify guides/escorts
- Confirm reporting method
- Identify food safety and security requirements
- Confirm audit plan
- Reaffirm time of closing meeting
- Complete meeting records

❖ CONDUCT DOCUMENT REVIEW (Stage-1)

- Obtain program documentation
- Review documentation against requirements
- Verify the organization's management system
- Determine if organization's documents meet requirements or identify non-conformities.
- Establish investigative lines for Stage 2 audit.
- Confirm readiness for Stage 2 audit

❖ PLANNING AUDIT ACTIVITIES

- Verify the scope of the audit
- Review history of facility to be audited
- Confirm resource needs
- Confirm travel plans
- Develop or confirm audit strategy and methodology
- Assign audit team roles, responsibilities and activities
- Develop audit plan, including sampling plan
- Review audit logistics

- Consider results of any previous audits and corrective actions
- Consider any regulatory requirements
- Plan audit team meetings

❖ **COLLECTING AND VERIFYING INFORMATION:**

- Verify process flow chart
- Assess effectiveness of implementation of control measures and processes
- Verify effectiveness of corrective actions of previous non-conformities/deficiencies
- Perform process approach audit

❖ **Preparation for closing meeting:**

- Hold audit team preparatory meeting (if required)
- Analyze audit findings and compare to requirements
- Confirm completion of audit plan
- Categorize, review and finalize any non-conformities and opportunities for improvement and relate them to the process and the system

❖ **Conduct closing meeting.**

- Present and review audit findings (non-conformities and/or opportunities for improvement)
- Confirm objectives of audit have been met
- Provide positive feedback
- Explain next steps (e.g. appeals, post-audit processes, certification decision-making timeline)
- Obtain written acknowledgement of non-conformities
- Complete meeting records

❖ **FINALIZE AUDIT REPORT**

- Describe findings against certification standard 's requirements (e.g. non-conformities, opportunities for improvement)
- Incorporate comments of competence and conformity**.**
- Describe final audit conclusions
- Judge effectiveness of corrective actions (when required)
- Finalize audit report

❖ **CONDUCTING POST-AUDIT ACTIVITIES**

- Conducting post-audit activities
- Deliver audit report
- Communicate information regarding nonconformity resolution timing
- Report any unusual circumstances that occurred during the audit
- Review corrective actions for appropriateness
- Determine requirements for verification of corrective actions
- Verify effectiveness of implementation of corrective actions
- Report any necessary adjustment of audit programme, as appropriate

Section A 18 Work instruction on Report Writing

During the report review / internal audit / external audit, we have been reported that there has been some un-common mistake in the report writing which indicate that audit team is not seriously preparing the report.

Please be informed that report is fundamental and basis for certification decision and if report is submitted in which is vague or contain misleading information, this indicate that either audit was not effective or report writing have been taken casually, kindly note that your auditing time and remuneration of the same include Report writing, therefore submitting information in the report

which is insufficient / inadequate raise a doubt that audit process is getting compromised and this does not help the organisation to achieve audit objective.

We have identified and putting this into your knowledge that we have identified following uncommon mistake in few reports:

Problem Identified:

Sl	Problem Identified	Cause	Warning	Guidance
. 1	Report does not cover relevant point	**Competence**	If report does not provide adequate evidence of all the requirement, recommendation of the auditor for issuance of the certificate be doubtful.	Please note that auditor can recommend / not recommend to CAB in their report, but this is not a discretionary power, all the decision of the Audit team is reviewed by the Certification committee and they need adequate evidence to agree with the decision of the Audit team, therefore auditor must address all the clauses and must submit evidence in support of their recommendation.

2	Verification of Control in separate sheet in case of ISMS	**Ignorance**	We have experienced that auditor do address all the requirement of the ISO 27001 but failed to address the control as required in Annexure A. Report format have been changed and a annexure have been added to confirm the compliance of the requirement of the control in the organisation.	Auditor need to verify and confirm the effectiveness of the control in the Annexure (Audit note) of the ISMS report.

Sl.	Problem Identified	Cause	Warning	Guidance
3	Mistake in considering the Non-Applicability of clauses ISO 9001	**Exclusion are accepted as claimed**	Client may take exclusion / non-applicability of the clauses, but auditor must check if its applicable or not.	Please ask the client if any clause is not applicable, who is doing the same, suppose in case of Design, verify if client is not responsible for design, who is design responsible? Please provide proper justification for non-applicability of any clause, writing not applicable is not enough. Despite if any non-applicability is claimed in the inquiry form and application review have been done based on that, Auditor have right to discuss and verify the non-applicability and in case it is found otherwise, Auditor may recommend increase of the Man-Days for the stage-2 audit. Man-days of the audit have been scheduled based on information submitted to the TNV in inquiry form, auditor must verify the information of the inquiry form in the stage-1 audit as effective audit of Stage-2 can be planned only if all information is verified.

Sl.	Problem Identified	Cause	Warning	Guidance
4	Mistake in report	Use of Old Report	If you use old report to write the report, please note that there is huge possibility that you may miss something, and content of the report may goes in wrong direction.	Auditor are advised not to use old report but always blank report and ask TNV to provide latest format of the report, do not use old report which is in your record. Please note that report format is not fixed, and it changes, therefore you are expected to use only current version and blank report. Please note that we have modified in the report system and not you will be getting a excel sheet which shall have all the information; therefore, you shall not be able to use old report. If you sue old report, report shall be rejected, and this would waste your time.

Sl	Problem Identified	Cause	Warning	Guidance
.5	Confirm the site audited and include the location only which have been audited	Mistake or use of old report	We have witnessed that sometime address at the different place differ and data submitted don't match within report, which raise a doubt on the effectiveness of the auditing.	Please verify the audit location and double check the address which you are auditing, don't just believe on inquiry form, verify the physical address with some evidence like Legal document, Utility Bill or any other document which support that auditable site is properly evident. Please don't add any additional address which you are not auditing, details of the temporary site shall be given in the relevant clause only, you don't need to mention in the main address as additional site. Additional site and temporary site is different, please refer clause 6.1.4 Additional Sites of IAF MD 1 and 2.3 Temporary Site of same document. Please refer auditor guide or feel free to write to us for any clarification.
6	Mistake in audit team constitution at different place in the report	Mistake or use of old report	We have witnessed that audit team details specially in case where audit team is constituted with large number of the auditor, we have noticed mistake in the name of the auditor, Every audit team member is responsible to verify if their name is correctly mentioned in the audit report.	Each auditor need to check if their name is correctly mentioned in the audit report, any deviation in the auditor name may held them personally responsible for careless or negligence. Please double check all the point before sending final report to the TNV for certification decision.

Sl	Problem Identified	Cause	Warning	Guidance
.7	Closure of the NCs is not effective	Not applying requisite format.	We have received few audit report with the finding and auditor have closed the NCs and attached the evidence, AFAR form was not used and how auditor have responded to the response of the client on finding is not evident and this is violation of the requirement of the TNV	Please note that in stage-1 you may give finding and client may submit the evidence and you may close the Finding; auditor need to respond to all the finding. For Stage-2, you need to be extra careful and please note that all the finding must be given at the closure of the audit, you must submit all the finding to the client in AFAR format i.e. TNV-F-011. Please ask client to submit Root cause analys, Correction and Corrective action, if you accept the plan, thereafter client may submit evidence for the closure of the finding. Never share Findings in general format but provide finding in the specified form only. Please note that AFAR is a structured document and help client and auditor to respond to the findings and easy to understand the response of the client on findings. Please use different format for each finding, never use one AFAR for several finding as this may be misleading and client may be confused to understand the finding. Better discuss the finding and get consent of the finding before the closing meetings.

Conclusion: Audit report demonstrates effectiveness of the audit and your evaluation is done based on the quality of report you submit to TNV. Further Certification team decide based on the information / evidence submitted by you, therefore please be clear and submit detailed audit report and double check your report before submitting to TNV.

Pragyesh Singh
Managing
Director
TNV System Certification Pvt. Ltd.

Section A 19. Stage 1 & Stage 2 Auditing ABMS

Stage-1 Audit: Documentation Review and Readiness Assessment

Objective

The Stage-1 audit assesses whether the organization's documented ABMS complies with the requirements of ISO 37001:2016 and is ready for a Stage-2 audit. It identifies gaps in documentation and design that could impede implementation.

Detailed Activities

1. Review of Documented Information

- **Anti-Bribery Policy (Clause 5.2):**
    - Verify the policy demonstrates a clear commitment to:
        - Prohibiting bribery in all forms.
        - Fulfilling applicable anti-bribery laws and regulations.
        - Continual improvement of the ABMS.
    - Ensure the policy is documented, communicated, and aligned with the organization's objectives.
- **Scope of the ABMS (Clause 4.3):**
    - Confirm the defined scope includes all relevant activities, geographies, and entities exposed to bribery risks.
    - Assess justification for any exclusions.

- **Risk Assessment and Due Diligence (Clause 4.5, Clause 8.2):**
    - Review the documented process for identifying bribery risks and performing due diligence on business associates and transactions.
- **Compliance Function (Clause 5.3):**
    - Verify the establishment of an independent anti-bribery compliance function with defined roles and responsibilities.
- **Objectives and Planning (Clause 6.2):**
    - Ensure anti-bribery objectives are specific, measurable, and supported by implementation plans.

2. Understanding Context and Stakeholders

- **Internal and External Issues (Clause 4.1):**
    - Assess how the organization identifies and monitors internal (e.g., processes) and external (e.g., regulatory) factors influencing bribery risks.
- **Stakeholder Needs and Expectations (Clause 4.2):**
    - Confirm that relevant interested parties, such as employees, business associates, regulators, and communities, have been identified and their needs addressed in the ABMS design.

3. Review of Key Processes

- **Bribery Risk Management (Clause 6.1):**
    - Review the organization's approach to identifying and mitigating bribery risks.
- **Financial and Non-Financial Controls (Clause 8.4):**
    - Ensure documented procedures are in place for managing gifts, hospitality, donations, and other non-financial advantages.
- **Due Diligence (Clause 8.2):**
    - Confirm processes for assessing the bribery risk of business associates, suppliers, and third parties.

4. Preliminary On-Site Visit (if applicable)

- Evaluate workplace conditions and internal controls supporting anti-bribery efforts.
- Conduct interviews with key personnel to assess understanding of roles in the ABMS.

Outputs

1. **Stage-1 Audit Report:**
    - Findings from the documentation review.
    - Observations and recommendations for addressing gaps before Stage-2.
2. **Readiness Decision:**
    - Determine readiness for the Stage-2 audit or identify areas requiring corrective actions.

Stage-2 Audit: Implementation and Effectiveness Assessment

Objective

The Stage-2 audit evaluates the implementation, effectiveness, and operational compliance of the ABMS with ISO 37001:2016 requirements. It ensures the system is functional and capable of preventing, detecting, and addressing bribery risks.

Detailed Activities

1. Opening Meeting

- Confirm audit objectives, scope, and criteria.
- Discuss the audit schedule and evidence collection techniques.
- Highlight key focus areas, including bribery risk management, due diligence, and internal controls.
- Reiterate confidentiality and impartiality.

2. Clause-by-Clause Assessment

Clause 4: Context of the Organization

- Verify how internal and external factors impacting bribery risks are identified and monitored.
- Assess the integration of stakeholder needs into the ABMS framework.

Clause 5: Leadership

- **Leadership and Commitment (Clause 5.1):**
  - Evaluate top management's involvement in promoting an anti-bribery culture.
  - Confirm accountability for anti-bribery compliance at the highest levels.
- **Anti-Bribery Policy (Clause 5.2):**
  - Ensure the policy is effectively communicated and understood across all levels.
- **Roles, Responsibilities, and Authorities (Clause 5.3):**
  - Verify that the compliance function operates independently and is empowered to address bribery risks.

Clause 6: Planning

- **Bribery Risk Assessment (Clause 6.1):**
  - Assess the risk assessment process for identifying, prioritizing, and mitigating bribery risks.
  - Review records of risk analysis and the adequacy of identified controls.
- **Objectives and Plans (Clause 6.2):**
  - Verify objectives are aligned with the anti-bribery policy and are monitored for effectiveness.

Clause 7: Support

- **Resources (Clause 7.1):**
  - Confirm the organization allocates sufficient resources to maintain and

improve the ABMS.

- **Competence and Awareness (Clauses 7.2 and 7.3):**
    - Review training records and ensure personnel are aware of their roles in anti-bribery compliance.
- **Communication (Clause 7.4):**
    - Verify processes for internal and external communication of anti-bribery policies and expectations.
- **Documented Information (Clause 7.5):**
    - Assess the management and control of ABMS-related documents and records.

Clause 8: Operation

- **Due Diligence (Clause 8.2):**
    - Verify the implementation of due diligence processes for assessing business associates and transactions.
- **Financial Controls (Clause 8.4):**
    - Assess controls over financial transactions to prevent and detect bribery.
- **Non-Financial Controls:**
    - Evaluate procedures for managing gifts, hospitality, and charitable donations.
- **Investigation and Reporting (Clause 8.9):**
    - Review procedures for reporting suspected bribery incidents and conducting investigations.

Clause 9: Performance Evaluation

- **Monitoring, Measurement, and Analysis (Clause 9.1):**
    - Verify processes for monitoring the effectiveness of the ABMS.
    - Review reports on bribery risk trends and incident analysis.

- **Internal Audits (Clause 9.2):**
    - Assess the internal audit process for identifying and addressing ABMS gaps.
- **Management Review (Clause 9.3):**
    - Confirm that management reviews address bribery risks, compliance performance, and opportunities for improvement.

Clause 10: Improvement

- **Nonconformity and Corrective Action (Clause 10.2):**
    - Review processes for investigating nonconformities and implementing corrective actions.
    - Verify that lessons learned are integrated into risk management.
- **Continual Improvement (Clause 10.3):**
    - Assess initiatives to enhance anti-bribery performance and the effectiveness of the ABMS.

3. Evidence Collection

- Conduct interviews with employees, compliance officers, and key stakeholders to evaluate awareness of anti-bribery processes.
- Observe operations and review controls in high-risk areas.
- Examine records such as:
    - Risk assessments.
    - Training logs.
    - Incident reports and investigations.
    - Financial and non-financial transaction records.

4. Non-Conformities and Observations

- **Major Non-Conformities:**

- Systemic failures in the ABMS that expose the organization to significant bribery risks.

- **Minor Non-Conformities:**
  - Isolated lapses in implementation or documentation.

- **Observations:**
  - Opportunities for improvement or potential risks requiring attention.

5. Closing Meeting

- Present audit findings, including non-conformities, observations, and strengths.
- Confirm timelines for corrective actions and the certification decision.
- Highlight areas of excellence and opportunities for further improvement.

Outputs

1. **Stage-2 Audit Report:**
   - Comprehensive findings for each clause, supported by evidence.
   - Summary of non-conformities, observations, and strengths.
2. **Corrective Action Plan:**
   - Timelines and responsibilities for addressing non-conformities.
3. **Certification Recommendation:**
   - Decision on certification readiness based on audit findings.

Key Focus Areas for Auditors

1. **Bribery Risk Management:**
   - Assess the organization's ability to identify, mitigate, and monitor bribery risks.
2. **Compliance Culture:**

- Evaluate the commitment of leadership and employees to anti-bribery practices.

3. **Due Diligence:**
    - Verify the effectiveness of risk-based due diligence on business associates and transactions.
4. **Continual Improvement:**
    - Confirm the organization actively enhances ABMS's effectiveness.

Section A 20. Stage 1 & Stage 2 Auditing ISMS

Stage-1 Audit: Documentation Review and Readiness Assessment

Objective

The Stage-1 audit evaluates the adequacy of the ISMS documentation, ensuring alignment with ISO 27001:2022 requirements. It verifies the ISMS's readiness for Stage-2 and assesses foundational activities like the **Internal Audit** and **Management Review Meeting (MRM)**.

Detailed Activities

1. Review of Documented Information

- **ISMS Policy (Clause 5.2):**
    - Ensure the policy demonstrates commitment to protecting information confidentiality, integrity, and availability.
    - Confirm alignment with organizational objectives and compliance with applicable laws and regulations.
    - Verify the policy is documented, communicated, and accessible.
- **Scope of the ISMS (Clause 4.3):**
    - Review the scope to ensure it covers all relevant processes, assets, and systems influenced by information security risks.
    - Verify that exclusions are justified and do not affect the ISMS's effectiveness.

- **Risk Assessment and Risk Treatment (Clause 6.1.2 and 6.1.3):**
    - Evaluate the methodology for identifying, analyzing, and mitigating information security risks.
    - Assess the Statement of Applicability (SoA) to ensure appropriate Annex A controls are selected and justified.
- **Information Security Objectives (Clause 6.2):**
    - Confirm objectives are specific, measurable, achievable, relevant, and time-bound (SMART).
    - Verify documented plans support these objectives with assigned responsibilities and resources.

2. Internal Audit (Clause 9.2)

- **Objective:**
    - Verify that an internal audit program is in place and effectively implemented.
- **What to Assess:**

1. **Internal Audit Program:**
    - Ensure it defines the scope, frequency, criteria, and methods of the audit.
    - Verify it covers all clauses of ISO 27001:2022 and applicable Annex A controls.
2. **Audit Findings and Actions:**
    - Review non-conformities and observations identified in the internal audit.
    - Confirm corrective actions are documented, assigned, and tracked to closure.
3. **Effectiveness of Audits:**
    - Verify that internal audits identify gaps in the ISMS and provide inputs for

improvement.

3. Management Review Meeting (MRM) (Clause 9.3)

- **Objective:**
    - Assess whether top management reviews the ISMS to ensure its effectiveness and alignment with strategic objectives.
- **What to Assess:**

1. **MRM Inputs:**
    - Results of internal audits.
    - Risk assessment updates and treatment plans.
    - ISMS performance data, including incidents, corrective actions, and feedback from interested parties.
    - Opportunities for improvement.
2. **MRM Outputs:**
    - Decisions on ISMS improvements and resource needs.
    - Changes in ISMS policies or objectives.
    - Assigned responsibilities for improvement actions.

4. Compliance Obligations

- Verify the identification of legal, regulatory, and contractual requirements.
- Assess how these obligations are integrated into the ISMS processes.

5. Review of Additional Key Documents

- ISMS policy, SoA, risk treatment plans, internal audit reports, and MRM records.
- Evidence of training and awareness programs for information security.

Outputs

1. **Stage-1 Audit Report:**
    - Findings from the documentation review, including gaps and observations.
    - Recommendations for corrective actions.
2. **Readiness Decision:**
    - Confirm readiness for Stage-2 or identify areas requiring improvement.

Stage-2 Audit: Implementation and Effectiveness Assessment

Objective

The Stage-2 audit evaluates the implementation, effectiveness, and compliance of the ISMS with ISO 27001:2022 requirements. It ensures that the ISMS is operational, aligned with the organization's objectives, and effectively mitigating information security risks.

Detailed Activities

1. Opening Meeting

- Confirm audit objectives, scope, and criteria.
- Outline the audit schedule and focus areas, emphasizing confidentiality and impartiality.

2. Clause-by-Clause Assessment

Clause 4: Context of the Organization

- Verify the identification and monitoring of internal and external issues affecting the ISMS.
- Assess the integration of stakeholder requirements into ISMS objectives and processes.

Clause 5: Leadership

- **Leadership and Commitment (Clause 5.1):**
    - Confirm management's active role in supporting the ISMS and ensuring its integration with business processes.

- **Roles and Responsibilities (Clause 5.3):**
    - Verify responsibilities for ISMS performance are clearly assigned and understood.

Clause 6: Planning

- **Risk Assessment and Risk Treatment:**
    - Assess risk management practices, including the identification, analysis, and mitigation of risks.
- **Information Security Objectives:**
    - Verify that objectives are monitored and periodically reviewed for progress.

Clause 7: Support

- **Resources (Clause 7.1):**
    - Confirm adequate allocation of resources to maintain and improve the ISMS.
- **Competence and Awareness (Clauses 7.2 and 7.3):**
    - Review training records and assess staff understanding of ISMS responsibilities.
- **Communication (Clause 7.4):**
    - Assess the effectiveness of internal and external communication related to information security.

Clause 8: Operation

- **Operational Planning and Control (Clause 8.1):**
    - Verify processes are implemented as planned to achieve ISMS objectives.
- **Risk Treatment Plans (Clause 8.3):**
    - Confirm the selected Annex A controls are implemented and monitored for effectiveness.

Clause 9: Performance Evaluation

- **Monitoring and Measurement (Clause 9.1):**
    - Evaluate methods for assessing ISMS performance and effectiveness.
- **Internal Audit (Clause 9.2):**
    - Review internal audit findings and verify the resolution of identified gaps.
- **Management Review (Clause 9.3):**
    - Assess whether management reviews address ISMS performance, risks, and opportunities for improvement.

Clause 10: Improvement

- **Corrective Actions (Clause 10.2):**
    - Verify the organization has processes for identifying, investigating, and resolving non-conformities.
- **Continual Improvement (Clause 10.3):**
    - Assess initiatives to enhance ISMS effectiveness and adapt to changing risks.

3. Annex A Control Categories

Assess the implementation and effectiveness of controls across these categories:

- **A.5 Organizational Controls:**

5.1 Policies for Information Security

- **Audit Focus**: Confirm that policies are documented, approved, communicated, and periodically reviewed.
- **Evidence**: Policy documents, approval records, communication plans.

5.2 Information Security Roles and Responsibilities

- **Audit Focus**: Ensure all security responsibilities are clearly defined and assigned.
- **Evidence**: Role descriptions, organizational charts.

5.3 Segregation of Duties

- **Audit Focus**: Verify that conflicting duties are separated to reduce risks of unauthorized actions.
- **Evidence**: Role mappings, access reviews.

5.4 Management Responsibilities

- **Audit Focus**: Assess management's engagement in supporting the ISMS.
- **Evidence**: Meeting minutes, resource allocation records.

5.5 Contact with Authorities

- **Audit Focus**: Verify the existence of protocols for communicating with legal/regulatory authorities during incidents.
- **Evidence**: Incident logs, communication records.

5.6 Contact with Special Interest Groups

- **Audit Focus**: Evaluate partnerships with industry groups for knowledge sharing.
- **Evidence**: Membership records, meeting attendance.

5.7 Threat Intelligence

- **Audit Focus**: Ensure processes exist to monitor and respond to emerging threats.
- **Evidence**: Threat reports, response plans.

5.8 Information Security in Project Management

- **Audit Focus**: Verify security integration in project planning.
- **Evidence**: Project risk assessments, approval records.

5.9 Inventory of Information and Assets

- **Audit Focus**: Ensure a complete inventory of assets, including ownership details.
- **Evidence**: Asset registers.

5.10 Acceptable Use of Assets

- **Audit Focus**: Assess acceptable use policies for organizational assets.
- **Evidence**: Policy documents, training records.

5.11 Return of Assets

- **Audit Focus**: Verify asset retrieval procedures for terminated employees or contractors.
- **Evidence**: Asset logs.

5.12 Classification of Information

- **Audit Focus**: Ensure information is classified based on sensitivity and risk.
- **Evidence**: Classification schemes, asset labels.

5.13 Handling of Information

- **Audit Focus**: Evaluate guidelines for handling sensitive information.
- **Evidence**: Handling policies, user training.

5.14 Access Control Policy

- **Audit Focus**: Confirm an access control policy is in place and enforced.
- **Evidence**: Policy documents, access logs.

5.15 Access Control Principles

- **Audit Focus**: Ensure principles like least privilege and need-to-know are implemented.
- **Evidence**: Access request forms, privilege reviews.

5.16 Access Management

- **Audit Focus**: Evaluate procedures for granting and revoking access.
- **Evidence**: User access logs, approval workflows.

5.17 Identity Management

- **Audit Focus**: Assess identity authentication and lifecycle management processes.

- **Evidence**: Identity verification procedures.

5.18 Supplier Management

- **Audit Focus**: Ensure supplier relationships are risk-managed.
- **Evidence**: Contracts, risk assessments.

5.19 Security in Supply Chain

- **Audit Focus**: Verify that supply chain risks are identified and mitigated.
- **Evidence**: Vendor audits, security clauses in contracts.

5.20 Management of Technical Vulnerabilities

- **Audit Focus**: Confirm vulnerability scanning and patch management are conducted.
- **Evidence**: Scanning reports, patch logs.

5.21 Change Management

- **Audit Focus**: Assess the management of changes to IT infrastructure and applications.
- **Evidence**: Change requests, impact analyses.

5.22 Incident Response Planning

- **Audit Focus**: Ensure an incident response plan is in place and regularly tested.
- **Evidence**: Incident records, test reports.

5.23 Business Continuity

- **Audit Focus**: Evaluate business continuity plans for critical processes.
- **Evidence**: BCPs, recovery test results.

5.24 Disaster Recovery

- **Audit Focus**: Ensure IT systems have documented disaster recovery plans.
- **Evidence**: DR plans, backup test logs.

5.25 Monitoring and Measurement

- **Audit Focus**: Verify the use of metrics to monitor ISMS performance.
- **Evidence**: Metrics reports, management review records.

5.26 Secure Disposal of Assets

- **Audit Focus**: Confirm secure disposal of obsolete information assets.
- **Evidence**: Disposal records, certificates of destruction.

5.27 Compliance Monitoring

- **Audit Focus**: Ensure processes exist to monitor compliance with legal and contractual obligations.
- **Evidence**: Compliance audit reports, legal reviews.

5.28 Audit Logging

- **Audit Focus**: Assess the logging of critical security events.
- **Evidence**: Log files, retention policies.

5.29 Secure Development Practices

- **Audit Focus**: Verify secure coding practices in application development.
- **Evidence**: Code reviews, testing records.

5.30 Supplier Service Delivery

- **Audit Focus**: Evaluate monitoring of supplier services against agreed SLAs.
- **Evidence**: Service reports, vendor meetings.

5.31 Managing Supplier Security Risks

- **Audit Focus**: Assess processes for monitoring and managing supplier security risks.
- **Evidence**: Risk assessments, third-party audit records, and monitoring logs.

5.32 Supplier Service Delivery Management

- **Audit Focus**: Ensure supplier services align with agreed security terms and SLAs.

- **Evidence**: Service reviews, meeting minutes, and non-conformance records.

5.33 Handling of Information Security Incidents

- **Audit Focus**: Evaluate the organization's ability to detect, report, and respond to security incidents.
- **Evidence**: Incident management policies, logs, and post-incident reviews.

5.34 Ensuring Consistency During Disruptions

- **Audit Focus**: Confirm measures to maintain information security during business disruptions.
- **Evidence**: Continuity plans, incident response tests, and recovery logs.

5.35 Regular Security Audits

- **Audit Focus**: Verify regular internal and external audits of the ISMS.
- **Evidence**: Audit schedules, reports, and corrective action plans.

5.36 Third-Party Compliance Monitoring

- **Audit Focus**: Ensure compliance monitoring mechanisms for third-party service providers.
- **Evidence**: Vendor compliance logs, audit findings, and contract reviews.

5.37 Security Requirements for Software Development

- **Audit Focus**: Verify that security requirements are integrated into the software development lifecycle.
- **Evidence**: Development guidelines, code review records, and test results.

A.6 People Controls:

6.1 Screening

- **Audit Focus**: Assess background verification for employees and contractors.
- **Evidence**: Screening records, HR policies.

6.2 Terms and Conditions of Employment

- **Audit Focus**: Review employment terms requiring compliance with ISMS.
- **Evidence**: Employment contracts, confidentiality agreements.

6.3 Awareness, Education, and Training

- **Audit Focus**: Verify that all staff receive ISMS training.
- **Evidence**: Training logs, feedback forms.

6.4 Disciplinary Process

- **Audit Focus**: Ensure a process is defined for violations of security policies.
- **Evidence**: Disciplinary records, policy documents.

6.5 Responsibilities After Termination

- **Audit Focus**: Verify removal of access and return of assets post-employment.
- **Evidence**: Termination checklists, access logs.

6.6 Confidentiality Agreements

- **Audit Focus**: Ensure all employees sign NDAs for sensitive information.
- **Evidence**: Signed NDAs, policy reviews.

6.7 Remote Working

- **Audit Focus**: Assess security for remote workers.
- **Evidence**: VPN logs, remote access policies.

6.8 Information Security Event Reporting

- **Audit Focus**: Confirm mechanisms for reporting events.
- **Evidence**: Incident logs, escalation policies.

A.7 Physical Controls:

7.1 Security Perimeters

- **Audit Focus**: Assess secure boundaries.
- **Evidence**: Access control lists, physical inspections.

7.2 Entry Controls

- **Audit Focus**: Verify restrictions on physical access.
- **Evidence**: Surveillance logs.

7.3 Securing Offices, Rooms, and Facilities

- **Audit Focus**: Evaluate security measures for offices and facilities, such as locking mechanisms and alarms.
- **Evidence**: Physical security inspection reports, maintenance logs, and site diagrams.

7.4 Protecting Against External and Environmental Threats

- **Audit Focus**: Verify controls against natural disasters, power failures, and other external threats.
- **Evidence**: Risk assessments, power backup systems, fire protection equipment.

7.5 Working in Secure Areas

- **Audit Focus**: Ensure guidelines for working within secure areas, such as limiting access and monitoring activities.
- **Evidence**: Secure area policies, access logs, and CCTV footage.

7.6 Clear Desk and Clear Screen Policy

- **Audit Focus**: Confirm compliance with policies to ensure sensitive data is not exposed when unattended.
- **Evidence**: Policy documents, site inspections, and employee reminders.

7.7 Equipment Security

- **Audit Focus**: Evaluate physical protections for IT equipment against unauthorized access, damage, or theft.
- **Evidence**: Equipment logs, storage policies, and asset tracking systems.

7.8 Secure Disposal or Reuse of Equipment

- **Audit Focus**: Verify secure disposal methods to prevent unauthorized recovery of sensitive information.
- **Evidence**: Certificates of destruction, asset disposal records, and decommissioning processes.

7.9 Cabling Security

- **Audit Focus**: Assess protections for power and telecommunication cabling from interception and damage.
- **Evidence**: Physical inspections, cable routing diagrams, and maintenance records.

7.10 Equipment Maintenance

- **Audit Focus**: Ensure equipment is maintained according to manufacturer recommendations to ensure reliability and security.
- **Evidence**: Maintenance logs, contracts with service providers, and operational reports.

7.11 Removal of Assets

- **Audit Focus**: Verify controls over the removal of equipment or information from premises.
- **Evidence**: Approval workflows, asset registers, and audit trails.

7.12 Security During Equipment Transport

- **Audit Focus**: Ensure sensitive equipment is protected during transit to prevent loss or unauthorized access.
- **Evidence**: Transport logs, asset transfer policies, and vendor agreements.

7.13 Delivery and Loading Areas

- **Audit Focus**: Review controls in delivery and loading zones to prevent unauthorized access to secure areas.
- **Evidence**: Access controls, monitoring systems, and inspection records.

7.14 Secure Disposal of Media

- **Audit Focus**: Confirm the organization securely destroys or wipes media before disposal.
- **Evidence**: Data destruction logs, certificates of destruction, and policy documents.

A.8 Technological Controls:

8.1 User Endpoint Devices

- **Audit Focus**: Ensure endpoint devices such as laptops and mobile phones are securely configured and maintained.
- **Evidence**: Endpoint security software logs, configuration policies, and monitoring systems.

8.2 Privileged Access Rights

- **Audit Focus**: Verify controls for granting, reviewing, and monitoring elevated access privileges.
- **Evidence**: Access control lists, role reviews, and audit trails.

8.3 Information Access Restriction

- **Audit Focus**: Assess whether access to sensitive information is limited to authorized personnel based on the principle of least privilege.
- **Evidence**: User access records, permissions audits, and approval workflows.

8.4 Access to Source Code

- **Audit Focus**: Verify security measures for managing and restricting access to source code repositories.
- **Evidence**: Repository access logs, multi-factor authentication, and role-based permissions.

8.5 Secure Disposal of Data

- **Audit Focus**: Ensure that sensitive data is securely erased or destroyed when no longer needed.

- **Evidence**: Data wiping tools, destruction certificates, and compliance logs.

8.6 Capacity Management

- **Audit Focus**: Evaluate resource planning and capacity management processes to ensure systems can handle workloads.
- **Evidence**: Capacity monitoring reports, scaling plans, and incident logs.

8.7 Protection Against Malware

- **Audit Focus**: Verify deployment and effectiveness of anti-malware tools across systems.
- **Evidence**: Malware logs, endpoint protection policies, and threat detection tools.

8.8 Management of Technical Vulnerabilities

- **Audit Focus**: Ensure vulnerabilities are identified, assessed, and mitigated.
- **Evidence**: Vulnerability scanning reports, patch management schedules, and risk assessments.

8.9 Information Backup

- **Audit Focus**: Review backup strategies and test recovery processes.
- **Evidence**: Backup logs, restoration test results, and incident recovery reports.

8.10 Network Security

- **Audit Focus**: Ensure robust protection for internal and external networks.
- **Evidence**: Firewall rules, intrusion detection/prevention logs, and encryption policies.

8.11 Logging and Monitoring

- **Audit Focus**: Assess mechanisms for logging and monitoring security-related events.
- **Evidence**: Log files, SIEM (Security Information and Event Management) tool outputs, and audit trails.

8.12 Control of Technical Changes

- **Audit Focus**: Verify that technical changes are planned, approved, and documented to prevent disruptions or security risks.
- **Evidence**: Change requests, impact assessments, and configuration management records.

8.13 Security of Cloud Services

- **Audit Focus**: Evaluate controls for data stored and processed in cloud environments.
- **Evidence**: Service agreements, encryption protocols, and third-party audit reports.

8.14 Incident Detection and Response

- **Audit Focus**: Verify mechanisms for detecting, reporting, and responding to incidents.
- **Evidence**: Incident logs, escalation workflows, and response metrics.

8.15 Cryptographic Controls

- **Audit Focus**: Confirm cryptographic methods and key management practices are secure.
- **Evidence**: Encryption standards, key rotation policies, and compliance audits.

8.16 Monitoring System Use

- **Audit Focus**: Assess whether tools are in place to track and monitor user activity.
- **Evidence**: User activity logs, anomaly detection alerts, and monitoring dashboards.

8.17 Secure Development Practices

- **Audit Focus**: Verify that software development processes integrate security practices, such as secure coding and vulnerability testing.
- **Evidence**: Development lifecycle policies, testing logs, and code review records.

8.18 Security of Network Services

- **Audit Focus**: Ensure network services are secure and monitored for unauthorized access.
- **Evidence**: Network architecture diagrams, vulnerability test reports, and monitoring

logs.

8.19 Resilience of Information Processing Facilities

- **Audit Focus**: Assess whether systems have sufficient resilience to handle interruptions.
- **Evidence**: High-availability architecture, redundancy testing, and incident response plans.

8.20 Use of Cryptographic Techniques

- **Audit Focus**: Evaluate the use of encryption for sensitive data at rest and in transit.
- **Evidence**: Encryption standards, certificates, and key management procedures.

8.21 Secure Authentication

- **Audit Focus**: Verify authentication mechanisms, including multi-factor authentication (MFA).
- **Evidence**: Configuration logs, user access policies, and login records.

8.22 Remote Access Security

- **Audit Focus**: Assess the security measures for remote connections.
- **Evidence**: VPN configurations, access logs, and remote working policies.

8.23 Software Integrity

- **Audit Focus**: Ensure the integrity of software applications through version control and secure delivery mechanisms.
- **Evidence**: Code repositories, hash validation logs, and testing results.

8.24 Application Security

- **Audit Focus**: Verify the organization employs security controls during application development and deployment.
- **Evidence**: Secure coding guidelines, penetration testing reports, and OWASP compliance checks.

8.25 Backup Security

- **Audit Focus**: Ensure backups are encrypted and access-controlled.
- **Evidence**: Backup configuration settings, encryption logs, and restoration test results.

8.26 Secure Development Environment

- **Audit Focus**: Assess the security of environments used for software development and testing.
- **Evidence**: Environment configurations, access controls, and activity logs.

8.27 Outsourced Development

- **Audit Focus**: Ensure outsourced development follows secure practices and contractual obligations.
- **Evidence**: Contracts, compliance checks, and vendor audits.

8.28 Change Management in Development

- **Audit Focus**: Evaluate the control of changes in software during development phases.
- **Evidence**: Change requests, approval workflows, and version control logs.

8.29 System Acceptance Testing

- **Audit Focus**: Verify that systems undergo rigorous acceptance testing before deployment.
- **Evidence**: Test plans, results, and sign-off records.

8.30 System Redundancy

- **Audit Focus**: Assess whether redundancy measures are implemented for critical systems to ensure availability.
- **Evidence**: Redundancy designs, failover test results, and monitoring logs.

8.31 Protection of Test Data

- **Audit Focus**: Ensure test data is protected against unauthorized access or misuse.

- **Evidence**: Data anonymization logs, access policies, and test environment configurations.

8.32 Information Transfer

- **Audit Focus**: Assess mechanisms for securely transferring information, both internally and externally.
- **Evidence**: Encryption protocols, transfer logs, and user guidelines.

8.33 Monitoring of Information Transfer

- **Audit Focus**: Verify continuous monitoring of information transfer for unauthorized access or leaks.
- **Evidence**: Monitoring tools, alerts, and investigation reports.

8.34 Compliance with Cryptographic Regulations

- **Audit Focus**: Confirm the organization complies with legal and regulatory requirements for cryptographic controls.
- **Evidence**: Cryptography usage policies, compliance audit results, and certificates.

4. Evidence Collection

- Conduct interviews with key personnel to assess awareness and roles.
- Observe the implementation of physical and technological controls.
- Review documents such as risk assessments, incident logs, and training records.

5. Non-Conformities and Observations

- **Major Non-Conformities:**
    - Failures that compromise ISMS effectiveness.
- **Minor Non-Conformities:**
    - Isolated issues without significant impact.
- **Observations:**

- Opportunities for improvement or risks requiring attention.

6. Closing Meeting

- Present findings, including non-conformities and observations.
- Agree on corrective action timelines and responsibilities.
- Provide a recommendation for certification or further actions.

Outputs

1. **Audit Report:**
    - Detailed findings for each clause and control category.
2. **Corrective Action Plan:**
    - Responsibilities and timelines for resolving non-conformities.
3. **Certification Decision:**

Recommend certification or identify additional steps for compliance.

Section A 21. Stage 1 & Stage 2 Auditing BCMS

Stage-1 Audit: Documentation Review and Readiness Assessment

Objective The Stage-1 audit assesses whether the organization's documented BCMS complies with the requirements of ISO 22301:2019 and is ready for a Stage-2 audit. It identifies gaps in documentation and design that could impede implementation.

Detailed Activities

1. **Review of Documented Information**
    - **Business Continuity Policy (Clause 5.2):**

- Verify the policy demonstrates:
    - Commitment to ensuring continuity of critical processes.
    - Alignment with applicable legal requirements (e.g., local laws on emergency preparedness), regulatory frameworks (e.g., health and safety, data protection), and

contractual obligations (e.g., SLAs with clients or third-party agreements).

- Continual improvement of BCMS.

- Ensure the policy is documented, communicated, and aligned with the organization's objectives.
- Confirm the policy is periodically reviewed to incorporate changes in legal, regulatory, and business requirements.
  - Verify the policy demonstrates:
    - Commitment to ensuring continuity of critical processes.
    - Alignment with applicable legal, regulatory, and contractual requirements.
    - Continual improvement of BCMS.
  - Ensure the policy is documented, communicated, and aligned with the organization's objectives.
  - **Scope of the BCMS (Clause 4.3):**
    - Confirm the defined scope includes all relevant activities, locations, and processes critical to business continuity.
    - Assess justification for any exclusions.
  - **Business Impact Analysis (BIA) and Risk Assessment (Clause 8.2):**
- Review documented processes for identifying critical activities, risks, impacts, and recovery requirements.
- Examples of risks include supply chain disruptions, IT system failures, natural disasters, cyber-attacks, and critical resource shortages. Impacts may include financial losses, operational downtime, reputational damage, and non-compliance with legal or regulatory obligations.
- Ensure the risk assessment identifies maximum tolerable periods of disruption (MTPD), recovery time objectives (RTOs), and prioritized recovery strategies.
  - Review documented processes for identifying critical activities, risks, impacts, and recovery requirements.
  - **Roles and Responsibilities (Clause 5.3):**

- Verify defined responsibilities for business continuity management, including top management support.

- **Objectives and Planning (Clause 6.2):**
  - Ensure business continuity objectives are specific, measurable, and supported by implementation plans.

2. **Understanding Context and Stakeholders**
   - **Internal and External Issues (Clause 4.1):**
     - Assess how the organization identifies and monitors internal (e.g., resources, operations) and external (e.g., supply chain, regulatory) factors influencing continuity risks.
   - **Stakeholder Needs and Expectations (Clause 4.2):**
     - Confirm relevant interested parties (e.g., employees, customers, regulators) and their expectations have been addressed in the BCMS.
3. **Review of Key Processes**
   - **Business Continuity Risk Management (Clause 6.1):**
     - Review the approach to identifying, analyzing, and managing business continuity risks.
   - **Business Impact Analysis (Clause 8.2):**
     - Verify documented BIA for identifying critical functions, recovery time objectives (RTOs), and maximum tolerable periods of disruption (MTPD).
   - **Business Continuity Plans (BCPs) (Clause 8.4):**
     - Ensure documented plans include procedures for response, recovery, and resumption of critical activities.
4. **Preliminary On-Site Visit (if applicable)**
   - Evaluate the organization's preparedness, including facilities, controls, and communication systems.
   - Conduct interviews with key personnel to assess awareness of their roles in the BCMS.

Outputs

1. **Stage-1 Audit Report:**
    - Findings from the documentation review.
    - Observations and recommendations for addressing gaps before Stage-2.
2. **Readiness Decision:**
    - Determine readiness for the Stage-2 audit or identify areas requiring corrective actions.

Stage-2 Audit: Implementation and Effectiveness Assessment

Objective The Stage-2 audit evaluates the implementation, effectiveness, and operational compliance of the BCMS with ISO 22301:2019 requirements. It ensures the system is functional and capable of maintaining critical activities during disruptions.

Detailed Activities

1. **Opening Meeting**
    - Confirm audit objectives, scope, and criteria.
    - Discuss the audit schedule and evidence collection techniques.
    - Highlight key focus areas, including BIA, risk assessment, and business continuity plans.
    - Reiterate confidentiality and impartiality.
2. **Clause-by-Clause Assessment**
    - **Clause 4: Context of the Organization**
        - Verify how internal and external factors impacting business continuity are identified and monitored.
        - Assess the integration of stakeholder needs into the BCMS.
    - **Clause 5: Leadership**
        - **Leadership and Commitment (Clause 5.1):**

- Evaluate top management's involvement in promoting a continuity culture.
- Confirm accountability for BCMS at the highest levels.

- **Business Continuity Policy (Clause 5.2):**
  - Ensure the policy is effectively communicated and understood across all levels.
- **Roles, Responsibilities, and Authorities (Clause 5.3):**
  - Verify roles and responsibilities are clearly defined and communicated.

- **Clause 6: Planning**
  - **Business Continuity Objectives (Clause 6.2):**
    - Verify objectives align with the BCMS policy and are regularly monitored.
  - **Risk Management (Clause 6.1):**
    - Assess risk identification, analysis, and treatment processes.
- **Clause 7: Support**
  - **Resources (Clause 7.1):**
    - Confirm the allocation of resources for maintaining and improving the BCMS.
  - **Competence and Awareness (Clauses 7.2 and 7.3):**
    - Review training records and ensure personnel are aware of their roles.
  - **Communication (Clause 7.4):**
    - Verify internal and external communication processes regarding BCMS.
  - **Documented Information (Clause 7.5):**
    - Assess the management and control of BCMS-related documents and records.

- **Clause 8: Operation**
  - **Business Impact Analysis (Clause 8.2):**
    - Verify the implementation of BIA for critical activities and recovery requirements.
  - **Business Continuity Plans (Clause 8.4):**
    - Assess documented plans for response, recovery, and resumption of operations.
  - **Exercises and Testing (Clause 8.5):**

- Review records of testing and exercises to validate BCMS effectiveness.
- Verify the types of exercises conducted, such as:
  - **Tabletop Exercises:** Simulated discussions and scenario walkthroughs to validate response strategies and decision-making processes.
  - **Functional Exercises:** Testing specific components of business continuity plans in a controlled environment.
  - **Full-Scale Simulations:** Comprehensive testing involving real-time activation of recovery plans and coordination across teams and stakeholders.
- Confirm exercises are based on realistic scenarios, involve relevant stakeholders, and include post-exercise reviews to identify areas for improvement. - Review records of testing and exercises to validate BCMS effectiveness.
  - **Clause 9: Performance Evaluation**
    - **Monitoring, Measurement, and Analysis (Clause 9.1):**
      - Verify processes for measuring BCMS performance.
    - **Internal Audits (Clause 9.2):**
      - Assess internal audit processes for identifying BCMS gaps.
    - **Management Review (Clause 9.3):**
      - Confirm management reviews address continuity performance and opportunities for improvement.

- **Clause 10: Improvement**
    - **Nonconformity and Corrective Action (Clause 10.2):**
        - Review processes for addressing nonconformities and implementing corrective actions.
    - **Continual Improvement (Clause 10.3):**

- Assess initiatives to enhance BCMS effectiveness.
- Examples of continual improvement initiatives include:
    - Regular updates to business continuity plans based on lessons learned from incidents or exercises.
    - Implementing feedback mechanisms to capture insights from stakeholders.
    - Adopting new technologies or tools to streamline recovery processes.
    - Conducting periodic risk assessments to identify evolving threats and opportunities.
    - Benchmarking BCMS performance against industry best practices to identify gaps and opportunities for innovation.
        - Assess initiatives to enhance BCMS effectiveness.

3. **Evidence Collection**
    - Conduct interviews with employees, management, and key stakeholders to evaluate awareness of business continuity processes.
    - Observe operations and review preparedness in critical areas.
    - Examine records such as:
        - Business Impact Analysis (BIA).
        - Risk assessment results.
        - Test and exercise reports.
        - Incident reports and recovery documentation.
4. **Non-Conformities and Observations**

- **Major Non-Conformities:**
    - Systemic failures in the BCMS that could compromise continuity and require immediate corrective actions. These are prioritized based on the severity of their impact on critical operations.
- **Minor Non-Conformities:**
    - Isolated lapses in implementation or documentation that do not immediately compromise continuity but need to be addressed to prevent escalation.
- **Prioritization Process:**
    - Non-conformities are prioritized based on their impact, likelihood, and criticality to business continuity.
- **Corrective Actions:**
    - Major non-conformities require urgent corrective actions with clearly defined timelines and responsibilities.
    - Minor non-conformities are addressed through planned improvements and monitored for resolution.
- **Observations:**
    - Opportunities for improvement or potential risks requiring attention are documented and provided as recommendations to enhance BCMS.
    - **Major non-conformities:**
        - Systemic failures in the BCMS that could compromise continuity.
    - **Minor non-conformities:**
        - Isolated lapses in implementation or documentation.
    - **Observations:**
        - Opportunities for improvement or potential risks requiring attention.

5. **Closing Meeting**
    - Present audit findings, including non-conformities, observations, and strengths.
    - Confirm timelines for corrective actions and the certification decision.

- Highlight areas of excellence and opportunities for further improvement.

Outputs

1. **Stage-2 Audit Report:**
   - Comprehensive findings for each clause, supported by evidence.
   - Summary of non-conformities, observations, and strengths.
2. **Corrective Action Plan:**
   - Timelines and responsibilities for addressing non-conformities.
3. **Certification Recommendation:**
   - Decision on certification readiness based on audit findings.

Key Focus Areas for Auditors

1. **Business Impact Analysis (BIA):**
   - Assess the identification of critical activities, dependencies, and recovery priorities.
2. **Risk Management:**
   - Verify the organization's ability to analyze and mitigate continuity risks.
3. **Business Continuity Plans:**
   - Evaluate the effectiveness of documented plans and recovery strategies.
4. **Continual Improvement:**
   - Confirm the organization actively enhances the BCMS's effectiveness.

Section A 22 Common Mistake from Audit Team while conducting audit:

Waste Management:
The purpose of the criteria for an audit of waste issues is to enable the auditor to establish whether the entity has conducted an activity, which has an impact on the environment, in compliance with all applicable obligations defined in the waste laws and rules.

a) Sources of criteria could include:

- **National laws:** Acts of the legislature and any regulations, rules, orders etc., made under an Act and having the force of law. Those relating to waste are The Hazardous Wastes (Management, Handling and Transboundary Movement) Rules,2008, The Batteries (Management and Handling) Rules, 2001, The Municipal Solid Wastes (Management and Handling) Rules, 2000, The Recycled Plastics Manufacture and Usage Rules, 1999, The Recycled Plastics Manufacture and Usage (Amendment) Rules, 2003 ,The Bio-Medical Waste (Management and Handling) Rules, 1998 and BioMedical Waste (Management and Handling) (Amendment) Rules, 2003
- **International agreements**: such as treaties with other jurisdictions and United Nations Conventions like Agenda 21 document of the World Commission on Sustainable Development of the United Nations Conference on Environment and Development, held in Rio in June 1992 and United Nations Environment Programme (UNEP)
- **Guidelines:** Binding standards (including techniques, procedures, and qualitative criteria) issued by environmental monitoring/ regulatory agencies like CPCB/SPCB, Contracts.

b) Major compliance audit issues in management of waste

Compliance audit is a major part of any audit exercise and can form the first step in evaluating whether the acts/rules framed by the government are being adequately complied with. The areas listed below could be checked during compliance audit:

- Contracts, if any, awarded for waste management, the usual audit checks on contracts may be performed.
- Targets in the inspection of waste management facilities as per law/rule and whether shortfalls in inspection exist.
- Gaps in requirement of manpower and men in position to implement waste laws.
- Regulations for the issuance of licenses for the various establishments, checklist of conditions to be satisfied before issue of these licenses and cases of omissions and lapses in compliance.
- Strategy for the funding of waste management programs, the sources, conditions, sanctions, releases, payments, expenditure, maintenance of accounts etc.
- Role played by the pollution control boards, local bodies, state Governments, Non-Governmental Organizations (NGOs) in dealing with waste management as defined in the law/act.
- System of imposing punishments for the failures and non-adherence of the rules/ regulations. Imposition, collection, crediting and adequacy of penalties.
- Extent of dues for recovery, efficiency of the system of imposition and recovery of penalty.
- Inspection/checking of established infrastructure for waste management, facilities established for prevention of pollution.

c) Main Question for verifying management of waste

- Has an assessment of quantum of each kind of waste been made at the macro as well as micro level according to waste sources (like industries, households, hospitals etc.,) amounts and types (municipal solid waste, bio-medical waste, hazardous waste, e waste etc.,) to get an accurate picture of the waste being generated in the country and states.
- Has an identification and analysis of the expected parameters of significance for waste generation like increase in waste due to increase in population, due to greater

economic growth, due to increase in demand for consumer goods, due to changes in manufacturing methods etc., and the composition of waste been done at central and state level.

- Has an assessment been made about the current capacity to handle waste and whether more capacity needs to be created based on the quantity of waste being generated.
- Has any entity/government identified the risks to environment as a result of improper management of waste and waste accumulation
- Has the government identified risks to human health as a result of improper management of waste
- Does the legislation on protection of environment recognize waste as one of the threats to the environment in the country
- Do planning documents recognize the management of waste as a priority area for sustainable development of the country.
- Has the government enacted a separate policy for waste management and does the waste policy define the hierarchy governing waste management
- Has the government prepared an action plan for the reduction of each kind of waste
- Has the government put in place waste prevention, reduction, reuse and recycle strategies which will reduce the waste being generated in the country
- Has the government taken any action on consumer information and education to promote waste minimization, specifically reduction, reuse and recycling.
- Does an environment labelling program exist and has it succeeded in its objective in promoting the use of environmental friendly products
- Does legislation /rules exist in the country for the disposal of all types of waste.
- Do all the rules/ legislation for the management of waste exist in a framework in one place for easy understanding and implementation
- Whether the law/rules incorporate responsibility and penalty for violation (polluter pays principle) of waste laws
- Has a nodal agency regarding waste management issues been identified at central and state level.
- Have policy making bodies for each kind of waste been created
- Have bodies for implementation of waste laws and rules been created
- Have bodies been created and entrusted responsibility for monitoring the implementation of laws/ rules on waste
- Have regulatory bodies been set up to fix standards for emissions and effluents generated by waste
- Is there a body to assess the pollution being caused by the different types of waste
- Are the municipal authorities managing and handling solid waste in accordance with the compliance criteria and procedure laid down in law
- Is municipal solid waste being collected as envisaged under law.
- Is segregation of municipal waste taking place as envisaged under law
- Have municipal authorities established and maintained storage facilities in such a manner as they do not create unhygienic and unsanitary conditions around it
- Is the transportation of municipal solid waste taking place as envisaged under the law
- Is the processing of municipal solid waste done as envisaged under the law.

- Is the disposal of municipal solid waste being done as envisaged in the law
- Is the management of biomedical waste being done in accordance with the law.
- Has the segregation and labelling of biomedical waste prior to storage, transportation, treatment and disposal been done as per the law
- Is the disposal of plastic waste being done as per the law
- Is the disposal of industrial waste being done as per the law.
- Is the disposal of hazardous waste being done as per the law.
- Is the disposal of any other kind of waste for which laws have been enacted, disposed as per the laws
- Whether monitoring mechanism was effective in checking non-compliance with the provisions of waste laws
- Have any evaluation studies been carried out regarding implementation of these laws.
- Have the recommendations made by independent evaluation agencies been incorporated in the Acts/rules.
- Are funds being provided for implementation of waste management laws/rules.
- Is the funding adequate for waste management activities.
- Whether need assessment for technically qualified manpower to implement and monitor waste management has been made and have these been deployed effectively
- Whether facilities to monitor pollution and environmental degradation as a result of waste exists with the pollution monitoring agency.