UMS CERTIFICATIONS PRIVATE LIMITED
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AUDITOR GUIDE

AUDITOR GUIDELINES

GUIDELINES FOR AUDITING OF MANAGEMENT SYSTEMS

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REVISION HISTORY

Revision Date	Description	Clause Affected	Revised By	Approved By

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1. INTRODUCTION

This document is intended to provide guidance to the UMS personnel conducting management systems audits of its clients for certification to Quality Management Systems (QMS) ISO 9001:2015 Standard / Environmental Management Systems (EMS) ISO14001:2015 Standard / Food Safety Management Systems (FSMS) ISO 22000:2005 Standard / Occupational Health & Safety Management System (OHSMS) ISO 45001:2018 Standard, and Educational Organization Management System (EOMS) 21001:2018 as applicable to the client.

2. SCOPE

This document provides guidance for personnel responsible for planning, carrying out, and documenting audits of clients' management systems e.g., quality, environmental, occupational health & safety, and food safety management systems. The document covers the following areas and other related requirements on the follow-up of corrections, corrective, preventive, or improvement actions, as applicable. In addition, it describes the competence criteria that the audit team should meet.

a) The Certification Process
b) Code of Conduct
c) Auditors' Responsibilities
d) Initial Certification Audit i.e., Stage-1 and Stage-2 Audit
e) Conduct of Surveillance & Recertification Audit
f) Procedures for Reporting

3. PURPOSE

The purpose of this document is to:

Harmonize and to provide guidance on auditing management systems of clients' organization;
Help the UMS develop their auditing procedures;
Assist auditors and auditees in preparing for, facilitating and responding to audits.

4. REFERENCES

4.1. ISO 19011:2011: Guidelines for Auditing Management Systems

4.2. ISO/IEC 17021-1:2015: Conformity assessment —Requirements for bodies providing audit and certification of management systems: — Part 1: Requirements

4.3. ISO/IEC TS 17021-2: Conformity assessment —Requirements for bodies providing audit and certification of management systems: — Part 2: Competence requirements for auditing and certification of environmental management systems

4.4. ISO/IEC TS 17021-3: Conformity assessment —Requirements for bodies providing audit and certification of management systems: Part 3: Competence requirements for auditing and certification of quality management systems

4.5. ISO/IEC TS 17021-10:2018 – Competence requirements for auditing and certification of Occupational Health and Safety Management Systems

4.6. ISO/TS 22003:2013: Food safety management systems –Requirements for bodies providing audit and certification of food safety management systems

4.7. ISO/IEC 27006:2015 – Information technology — Security techniques — Requirements for bodies providing audit and certification of information security management systems

5. THE CERTIFICATION PROCESS

5.1. The Certification process consists of the following key stages:

a) Receipt of Enquiries,
b) Preparation of Quotations,
c) Client's Application for Certification,
d) Initial Certification Audit i.e., Stage-1 and Stage-2 Audit,
e) Surveillance Audit, and
f) Recertification Audits

5.2. Enquiries are received in several forms, by telephone, letter or facsimile. If they fall within UMS scope of accreditation by IAS or others – 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.

5.3. Upon acceptance of the fee quotation, the client completes and submit the "Application Form for Certification" 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 Application/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.

5.4. Initial Certification Audit

The initial certification audit of a management system is normally conducted in two stages: Stage-1 and Stage-2 audit.

5.4.1. Stage-1 Audit

5.4.1.1. The Stage-I audit is performed to:

a) Review the client's management system documented information against the requirements of the relevant ISO 9001/ISO 14001/ISO 22000/ISO 45001/ISO 21001/ISO 27001 Standard;
b) Evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage-2 audit;
c) Review the client's status and understanding regarding requirements of the relevant standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;
d) Obtain necessary information regarding the scope of the relevant management system, including:
   - The client's site(s);
   - Processes and equipment used;
   - Levels of controls established (particularly in case of multisite clients);
   - Applicable statutory and regulatory requirements;
e) Review the allocation of resources for stage 2 audit and agree the details of stage 2 audit with the client;
f) Provide a focus for planning Stage -2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of the relevant management system standard or other normative document;
g) Evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the relevant management system substantiates that the client is ready for stage 2 audit.

5.4.1.2. A report on the documentation of the relevant management system with regard to fulfilment of the Stage-1 requirements and the readiness for Stage-2 audit will be communicated to the client, including identification of any areas of concern that could be classified as nonconformity during stage 2 audit.

5.4.1.3. It is expected that the relevant management system has been in place for at least about three months before the Stage-1 audit is considered.

5.4.1.4. A period of two to three weeks is normally recommended between Stage-1 and Stage-2 visits but the certification audit is to be scheduled on a mutually convenient date upon client's intimation of readiness and the number of days required to resolve the areas of concern identified during Stage-1 audit.

5.4.2. Stage-2 Audit

5.4.2.1. Planning for Stage-2 audit

5.4.2.1.1. Stage-2 audit is only undertaken on effective closure by the client's areas of the concerns raised during the Stage-1 audit. In some cases, depending on the outcome of the Stage-1 audit, there may be needed to amend the previously done application/contract review.

Planning for Stage-2 audit normally includes:
a) Dates for audit/assessment;
b) Required number of audit man-days;
c) Constitution of audit/assessment team, including Technical Expert, if required;
d) Location(s)/site(s) of audit

5.4.2.1.2. Stage-2 audits are scheduled on dates agreed with the client during the Stage-1 audit. Client is advised of the above details in advance for his confirmation and acceptance including the audit team members.

5.4.2.1.3. A detailed Audit Plan, giving the allocation(s) of the audit, name of audit team members, Technical Expert (if required) and the time schedules for various audit activities/departments/processes is forwarded to the client in advance together with the agreed traveling arrangements.

5.4.2.1.4. The audit Team Leader is responsible for the detailed planning, organizing and execution of the audit plan. The audit plan is based upon the competence of the audit team members and audit man-days requirements after the application/contract review and as per the outcome of Stage-1 review and is designed to verify the relevant clauses/requirements of the applicable standard and give the appreciate areas of the client's organization.

5.4.2.2. Purpose of Stage-2 Audit

The purpose of the Stage-2 is to evaluate the implementation, including effectiveness, of the client's management system relevant to applicable ISO 9001/ISO 14001/ISO 22000/OHSAS 18001/ISO 45001/EOMS 21001 standard or any other management system. The Stage-2 audit is normally take place at the site(s) of the client. The Stage-2 audit includes the auditing of at-least of the following:

a) Information and evidence about conformity to all requirements of the applicable management system standard or other normative documents;
b) Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative documents)
c) The client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;
d) Operational control of the client's processes;
e) Internal auditing and management review;
f) Management responsibility for the client's policies;
g) Scope of activities is also to be verified for various products items, processes covered and verified for the implementation with records references as required.

5.4.3. Initial Certification Audit Conclusion

5.4.3.1. After conducting Stage-1 and Stage-2 audit, the audit team is required to analyse all information and audit evidence gathered during Stage-1 and Stage-2 audit to review the audit findings and agree on the audit conclusions.

5.4.3.2. All the objective evidence of compliance and any non-compliance identified with the requirements of the relevant management system standard are required to be brought to the attention of the auditee and noted on the report format by

the auditors. At the end of assessment, these are to be discussed along with the improvement suggestions (if any) and the client's management representative is asked to sign the report acknowledging that he understands and accepts the findings.

5.4.3.3. The assessment is concluded with a "Closing Meeting" in which the Team Leader presents the findings and makes recommendations, either for certification to the applicable management system standard or otherwise with a requirement for a verification audit in case of non-conformances having been identified.

5.4.3.4. In case non-conformances are identified during the audit, UMS will provide a detailed report to the client and request the client to complete the correction and corrective action plan (CAP) in detail, including proposed time frame for effective implementation of the corrective actions. The client must submit the completed correction and corrective action plan within 21 days of completion of the audit visit. The organisation has a maximum of 30 days from the last day of the audit to provide evidence of effective correction and corrective action. Verification may require an on-site visit or a desktop review of documents, depending on the seriousness of the Non-conformance. During initial certification, failure to effectively close a non-conformance may trigger a repeat of the Stage-2 audit. For any existing certification, failure to close a non-conformance may result in the withdrawal of the organisation's certification approval.

5.4.3.5. Each certified client 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 client's organization management system with the relevant certification standard is verified by auditing selected elements of the applicable management system at each visit besides verification of the effective action for the suggested improvement during the previous audit.

5.4.3.6. Auditors are required to complete the audit reports in a precise and accurate manner. The justification for non-inclusion of any element as per the management system standard e.g., Design & Development etc. (e.g., ISO-9001) should be carefully verified and recorded in the audit report.

6. CODE OF CONDUCT

6.1. Auditors should understand that they are visiting the client's organization as representatives of UMS 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 UMS documents and formats;

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 client's organization. Auditors are not expected to:

a) Correspond directly with the client unless authorized by UMS Certifications Pvt. Ltd.;
b) Offer advice that may be interpreted as consultancy to the client's organization being assessed.

7. AUDITORS' RESPONSIBILITY

7.1. For each assessment a Team Leader (TL) is nominated who is responsible for the management of the audit and observes the performance and conduct of each of the auditor and/or Observers/Technical Expert present on behalf of UMS.

7.2. The Team Leader is responsible for planning and conduct of the audit. Team Leader is also responsible for ensuring that all relevant information concerning the assessment is reported.

7.3. Team Leader shall allocate tasks to each member of the audit team and Team Leader shall ensure that the members of the team are fully prepared and capable of undertaking the auditing functions professionally and effectively. Assessment recommendations are arrived at by the audit team at the pre-closing meeting where the Team Leader will debrief all the auditors. The final report & recommendation, however, shall be decided by the Team Leader himself.

7.4. During the planning phase of the auditing process, the Team Leader and other members may prepare individual audit check lists for evaluating the relevant management 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 client's applicable management systems.

7.5. The Team Leader should ensure that the completed check lists and rough notes of each auditor are attached to the audit reports before forwarding the same to UMS.

8. AUDIT PLANNING/PREPARATION

8.1. Audit Plan Matrix

The team has to prepare in advance a matrix of the elements of the relevant management system standard against the departments/functions to be audited. Matrix should have judicious cross reference to the auditees' activities.

8.2. Audit Programme

8.2.1. After ascertaining the geographical location of various departments and functions of the client's organization and their quantum of work, 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 with the Audit Team members and the Technical Experts, during Audit Team briefing before the commencement of the Audit.

8.2.2. Audit Plan and composition of Audit Team details are advised to the client's management and its representative in advance for their acceptance and the same is explained in details at the time of opening meeting.

8.3. Check list/Recording of Observations/Use of UMS Audit Report Documents & Formats

The Team Leader should advise the team members to prepare their individual check lists relating to their assigned audit areas/functions. This check list should be based on the type of industry/NACE Codes and the Scope of Management System Certification. Further, it may also be based upon the criticality of the function/product/process and it's bearing on the relevant management systems e.g., Quality/Environment/Occupational Health & Safety/Food Safety.

Assessment checklists for all the schemes of certification viz. ISO 9001:2015, ISO 14001:2015, OHSAS 18001:2007/ISO 45001:2018, ISO 22000:2005 and EOMS 21001:2018 standards are provided with these guidelines for the guidance of the auditing personnel.

8.4. Guidance Documents

8.4.1. Audit team members should study sector/technical area specific guidance materials well before the audit. Based on this, clauses/requirements of the applicable management system standard which become critical because of the peculiar requirements of the sector specific industry should also be identified.

8.4.2. UMS normally arranges, where necessary, sector or technical area specific guidance including checklists or briefing notes relevant to the auditing of industry scope/sectors as per IAF Code Classification with the assistance of the technical experts or from any other sources e.g., internet, in that field. UMS has maintained adequate database of technological information, applicable legal requirements, processes, environmental aspects and impacts and occupational, health & safety information in respect of various sectors and technical areas for the assistance and guidance for its personnel involved in certification activities.

8.5. Audit Scope

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

8.5.2. The Team Leader should confirm 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 client, the Team Leader should seek instructions from UMS office before proceeding for the assessment, 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 assessment and reported, accordingly.

9. AUDIT EXECUTION

9.1. Time Management

Good planning by preparation of Audit Plan Matrix, UMS Programme sheet and check lists 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 UMS for each audit giving tentative time schedule, covering clauses/requirements of the relevant management system 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/requirements may be suitably clubbed under a single auditor to avoid duplication of effort.

9.2. Check on Interface Activities

Good planning and thorough preparation by detailed study of the various functions/departments of the client's organization will ensure that its interface activities are covered. While conducting audit in one department/function, do not see it in isolation, but 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.

9.3. In-depth Probing/Questioning

Auditors should seek objective evidence of compliance of each audit function with the relevant management system standards and scope of certification 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. 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 management system standard in order to arrive at Non-conformities (NCs). This should be agreed to by the auditee during the execution of Audit. In case of ISO 9001 Quality Management Systems certification audit, any clause/requirement being considered not applicable to the client's operations, a suitable explanation is required to justify the exclusion of the clause/requirement of the standard from the audit in the audit report.

9.4. Audit Trail

Audit plan for each auditee function relevant to the clauses of the required certification standard should provide for audit to be conducted in a logical sequence, consistent with the flow of work rather than leap forging. For example, in case of ISO 9001 standard, auditors nominated for production areas may cover in one sequence planning, issue of material, preparation of material, machine shop, fabrication, assembly and final inspection. When auditing Q.C./Inspection/Testing department, verify the calibration status of the monitoring and measuring equipment from the Calibration Department.

10. CONDUCTING AUDITS

10.1. General

The Team Leader and other audit team members will ensure that due caution are exercised in complying with the following requirements when conducting management systems audits. The following process for conducting on-site audits has been established by UMS. The process normally includes an opening meeting at the start of the audit and a closing meeting at the conclusion of the audit.

Where any part of the audit is to be made by electronic means or where the site to be audited is virtual, such activities will be conducted by a competent auditor deputed by UMS. The auditor is required to ensure that the evidence obtained during such an audit is sufficient to take an informed decision on the conformity of the requirement in question.

NOTE: *"On-site" audits can include remote access to electronic site(s) that contain(s) information that is relevant to the audit of the applicable management system. Consideration can also be given to the use of electronic means for conducting audits.*

10.2. Conducting of Opening Meeting

A formal Opening Meeting will be conducted by the Audit Team Leader with the client's management and, where appropriate, those responsible for the functions or processes to be audited. The purpose of the opening meeting is to provide a short explanation of how the audit activities will be undertaken. The detail of explanation during the opening meeting should be consistent with the familiarity of the client with the audit process and the following points are required to be addressed:

a) Introduction of participants, including an outline of their roles;
b) Confirmation of the scope of certification;
c) Confirmation of the audit plan including type and scope of audit, objectives and criteria, any changes and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management;
d) Confirmation of formal communication channels between the audit team and the client;
e) Confirmation that the resources and facilities needed by the audit team such as room, transport, tea, lunch, etc. are available;
f) Confirmation of matters relating to confidentiality;
g) Confirmation of relevant work safety, emergency and security procedures for the audit team;
h) Confirmation of the availability, roles and identities of any guides and Observers;
i) The method of reporting, including any grading of audit findings;
j) Information about the conditions under which the audit may be prematurely terminated;
k) Confirmation that the audit team leader and audit team representing the certification body (UMS) is responsible for the audit and will be in control of executing the audit plan including audit activities and audit trails;
l) Confirmation of the status of findings of the previous review or audit, if applicable;
m) Methods and procedures to be used to conduct the audit based on sampling;
n) Confirmation of the language to be used during the audit;
o) Confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;
p) Opportunity for the client to ask questions.

10.3. Auditing Process

10.3.1. The audit of the management system is to be conducted against the requirements of the applicable management system standard (ISO 9001/ISO 14001/ISO 22000/ISO 27001/ISO 45001/ISO 21001 etc.) on a sampling basis by covering all the clauses/requirements of the relevant management system standard and other normative requirements. The assessment is concerned with establishing that the client's documented Management System is well established and implemented in accordance with the requirements of the applicable management system standard i.e., ISO 9001/ISO 14001/ISO 22000/ISO 27001/ISO 45001/ISO 21001 etc. The audit should also include a verification of the legal/statutory requirements applicable to the client's products and/or services and its compliance in the client's organization.

10.3.2. The Audit team accompanied by the company's representative shall start their audit in the designated areas/processes/functions at random by selecting a feature relevant to the appropriate requirement of the applicable management system standard against which the client's organization is to be audited, and proceed according to the audit programme ensuring that the audit takes account of all requirements of applicable management system standard(s) and any other applicable normative document. The team members shall keep in mind the possibility that some elements may overlap over more than one department's functions.

10.4. Communication during the audit

10.4.1. During the audit, the audit team is required to periodically assess audit progress and exchange information. The audit team leader may reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client's management representative.

10.4.2. Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g., safety), the audit team leader is required to report this to the client's management representative and, if possible, to the CEO of UMS 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 is required to report the outcome of the action taken to the CEO of UMS.

10.4.3. The audit team leader is required to review with the client's management representative any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the CEO of UMS.

10.5. Obtaining and verifying information

10.5.1. During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) is required to be obtained by appropriate sampling and verified to become audit evidence.

10.5.2. The following methods are required to be used to obtain information, but may not be limited to:

a) Interviews;
b) Observation of processes and activities;
c) Review of documentation and records.

10.6. Identifying and recording audit findings

10.6.1. Audit findings summarizing conformity and detailing nonconformity are required to be identified, classified and recorded to enable an informed certification decision to be made or the certification to be maintained.

10.6.2. Opportunities for improvement may be identified and recorded, unless prohibited by the requirements of the applicable management system certification scheme. Audit findings, however, which are nonconformities, are not required to be recorded as opportunities for improvement.

10.6.3. A finding of nonconformity is required to be recorded against a specific requirement, and it must contain a clear statement of the nonconformity, identifying in detail the objective evidence on which the nonconformity is based. Nonconformities are required to be discussed with the client's management to ensure that the evidence is accurate and that the nonconformities are understood. The auditor however is required to refrain from suggesting the cause of nonconformities or their solution.

10.6.4. The audit team leader is required to attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, and unresolved points shall be recorded.

10.7. Preparing audit conclusions

Under the responsibility of the audit team leader and prior to the closing meeting, the audit team is required to:

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

10.8. Conducting the closing meeting

10.8.1. A formal closing meeting, where attendance is to be recorded, to be held with the client's management and, where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting, usually conducted by the audit team leader, is to present the audit conclusions, including the recommendation regarding certification. Any nonconformity observed during the audit is to be presented in such a manner that they are understood, and the timeframe for responding is to be agreed.

NOTE *"Understood" does not necessarily mean that the nonconformities have been accepted by the client.*

10.8.2. The following elements are also to be included in the closing meeting:

a) Advising the client that the audit evidence obtained was based on a sample of the information; thereby introducing an element of uncertainty;
b) The method and timeframe of reporting, including any grading of audit findings;
c) The certification body's process for handling nonconformities including any consequences relating to the status of the client's certification;
d) The timeframe for the client to present a corrective action plan (CAP) for correction and corrective action for any nonconformities identified during the audit;
e) The certification body's post audit activities;
f) Information about the complaint and appeal handling processes.

10.8.3. The client is to be given opportunity for questions. Any diverging opinions' regarding the audit findings or conclusions between the audit team and the client is required to be discussed and resolved where possible. Any diverging opinions that are not resolved are to be recorded and referred to UMS, the certification body.

10.9. Audit report

10.9.1. UMS, the certification body will provide a written report for each audit to the client. The audit team may identify opportunities for improvement but will not recommend any specific solutions. The ownership of the audit report lies with UMS, the certification body.

10.9.2. The audit team leader is required to ensure that the audit report is prepared and is responsible for its content. The audit report must provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made and it must include the following:

a) Identification of the certification body;
b) The name and address of the client and the client's representative;
c) The type of audit (e.g., initial, surveillance or recertification audit or special audits);
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) Any deviation from the audit plan and their reasons;
h) Any significant issues impacting on the audit programme;
i) Identification of the audit team leader, audit team members and any accompanying persons;
j) The dates and places where the audit activities (on site or offsite, permanent or temporary sites) were conducted;
k) After stage-1 Audit findings (ISO9001/EMS14001/ISO 27001/ISO 45001/ISO 22000) (see 10.6), reference to evidence and conclusions, consistent with the requirements of the type of audit;
l) Significant changes, if any, those affect the management system of the client since the last audit took place;
m) Any unresolved issues, if identified;
n) Where applicable, whether the audit is combined, joint or integrated;
o) A disclaimer statement indicating that auditing is based on a sampling process of the available information;
p) Recommendation from the audit team
q) The audited client is effectively controlling the use of the certification documents and marks, if applicable;
r) Verification of effectiveness of taken corrective actions regarding previously identified nonconformities, if applicable;
s) A statement on the conformity and the effectiveness of the management system together with a summary of the evidence relating to:
   i. The capability of the management system to meet applicable requirements and expected outcomes;
   ii. The internal audit and management review process;
t) A conclusion on the appropriateness of the certification scope;
u) Confirmation that the audit objectives have been fulfilled.

10.10. Cause analysis of nonconformities

The client is required to analyse the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities and submit a Corrective Action Plan (CAP), within a defined time, which is normally within 2 weeks.

10.11. Effectiveness of corrections and corrective actions

10.11.1. The certification body will review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The certification body will verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities will be recorded. The client will be informed of the result of the review and verification. The client will be informed if an additional full audit, an additional limited audit, or documented evidence (to be confirmed during future audits) will be needed to verify effective correction and corrective actions.

10.11.2. Verification of effectiveness of correction and corrective action can be carried out based on a review of documented information provided by the client, or where necessary, through verification on-site. Usually, this activity is done by a member of the audit team.

10.12. Recommendation by Audit Team

10.12.1. Non-grant of Certification: In the event of there being non-conformities which are considered to render the management system deficient and inoperable, a recommendation for certification should not be made. Depending upon the extent and nature of deficiencies, a recommendation for a supplementary audit for verification of corrective actions or reassessment may be made. A client **will not be recommended for grant of certification unless it has demonstrated effective implementation** of the requirements of the applicable management system standard particularly an Internal Audit programme and the Management Review process. The audit team leader is required to ensure that non-compliances and matters of concern are recorded in the Executive Summary of the audit report and the non-conformities are reported in the non-conformance format. These should be recorded objectively and precisely.

10.12.2. Where recommendation for certification to the applicable management system standard was not being granted, the audit team leader will discuss further action with the client. Such action is left to the audit team leader's discretion and may be anything from a "follow-up action" in areas of non-compliance to a total re-assessment depending on the severity of the deficiencies.

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

10.12.4. Right to Appeal against Non-granting of Certification

In case when the audit team's recommendation is for non-grant of certification, the client must be advised of their "RIGHT TO APPEAL" and availability of information about the complaint handling and appeal processes on the UMS web sites. The client is required to submit its appeal within 14 days in writing to the CEO of UMS, the certification body. The CEO will refer the appeal to the Expert Committee which will constitute a separate Appeals Panel. The Appeals Panel decision will be final.

10.12.5. Recommendations for Certification

10.12.5.1. In the event of nonconformities being identified in respect of the implementation of any clause/requirement of the applicable management system standard, a recommendation for certification is to be made subject to a Corrective Action Plan (CAP) being submitted within 2 weeks and corrective actions being verified onsite and closed out through a special visit within 30 days of the audit date, or as decided by CEO of the certification body.

10.12.5.2. In case when "opportunities for improvement" have been raised and recorded during the certification audit, the actions, as applicable, are verified for the effectiveness at the subsequent audit visit.

11. CERTIFICATION DECISION

11.1. UMS, the certification bodies always ensure that the persons or committees that make the decisions for granting or refusing certification, expanding or reducing the scope of certification, suspending or restoring certification, withdrawing certification or renewing certification are different from those who carried out the audits. UMS also ensure that the individual(s) appointed to conduct the certification decision have appropriate competence.

11.2. The person(s) assigned by UMS to make a certification decision are either employed by, or are under legally enforceable arrangement with these certification bodies. These persons have to fulfil the same requirements as persons employed by, or under contract with these certification bodies.

11.3. UMS maintain record of each certification decision including any additional information or clarification sought from the audit team or other sources.

11.4. Actions Prior to Making a Decision

UMS conduct an effective review prior to making a decision for granting certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification, on the basis of:

a) The information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification;
b) Any major nonconformities, it has reviewed, accepted and verified the correction and corrective actions;
c) Any minor nonconformities it has reviewed and accepted the client's plan for correction and corrective action.

11.5. Information for granting initial certification

11.5.1. The information provided by the audit team to UMS, for the certification decision must include, as a minimum:

a) The audit report;
b) Comments on the nonconformities and, where applicable, the correction and corrective actions taken by the client;
c) Confirmation of the information provided by the client to UMS which was used in the application (contract) review;
d) Confirmation that the audit objectives have been achieved;
e) A recommendation whether or not to grant certification, together with any conditions or observations.

11.5.2. If UMS is not able to verify the implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of Stage-2, the certification body will conduct another Stage-2 prior to recommending certification.

11.6. Information for granting recertification

UMS make decisions on renewing certification based on the results of the recertification audit, as well as the results of the review of the applicable management system over the period of certification and complaints received from users of certification.

12. MAINTAINING CERTIFICATION

12.1. UMS maintain client's certification based on demonstration that the client continues to satisfy the requirements of the applicable management system standard. Client's certification is maintained on the basis of a positive conclusion by the audit team leader without further independent review and decision, provided that:

There is no any major nonconformity or other situation that may lead to suspension or withdrawal of certification and need to initiate a review by competent personnel, different from those who carried out the audit, to determine whether certification can be maintained; Competent personnel of the certification body monitor its surveillance activities'; including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

12.2. Surveillance Activities

12.2.1. UMS conduct its surveillance activities so that representative areas and functions covered by the client's scope of the applicable management system certification scheme are monitored on a regular basis, and take into account changes to its certified client and its management system.

12.2.2. Surveillance activities normally include on-site auditing of the certified client's management system's fulfilment of specified requirements with respect to the applicable standard to which the certification is granted. Other surveillance activities may include:

a) Enquiries from the certification body to the certified client on aspects of certification;
b) Reviewing any certified client's statements with respect to its operations (e.g. Promotional material, website);
c) Requests to the certified client to provide documented information (on paper or electronic media);
d) Other means of monitoring the certified client's performance.

12.3. Surveillance Audit

Surveillance audits are on-site audits, but are not necessarily full system audits, and are normally planned together with the other surveillance activities so that the certification body can maintain confidence that the client's certified management system continues to fulfil requirements between recertification audits. Each surveillance audit for the relevant management system standard normally includes:

a) Internal audits and management review;
b) A review of actions taken on nonconformities identified during the previous audit;
c) Complaint's handling;
d) Effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);
e) Progress of planned activities aimed at continual improvement;
f) Continuing operational control;
g) Review of any changes;
h) Use of certification marks and/or any other reference to certification.

12.4. Recertification

12.4.1. Recertification audit planning

12.4.1.1. The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification. A recertification audit is planned and conducted to evaluate the continued fulfilment of all of the requirements of the relevant management system standard/scheme or other normative document. This is being planned and conducted in due time to enable for timely renewal before the certificate expiry date.

12.4.1.2. The recertification activity normally includes the review of previous surveillance audit reports and considers the performance of the management system over the most recent certification cycle.

12.4.1.3. Recertification audit activities may need to have a Stage-1 in situations where there have been significant changes to the client's management system, the organization, or the context in which the management system is operating (e.g. changes to legislation).

NOTE: *Such changes can occur at any time during the certification cycle and the certification body might need to perform a special audit, which might or might not be a two-stage audit.*

12.4.2. Recertification Audit

12.4.2.1. The recertification audit includes an on-site audit that addresses 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) The effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system(s).

12.4.2.2. For any major nonconformity, the client is required to submit Corrective Action Plan (CAP) within 2 weeks and corrective actions being verified onsite and closed out through a special visit within 30 days of the audit date, or as decided by CEO of the certification body. These actions are required to be implemented and verified prior to the expiration of certification.

12.4.2.3. When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate will be on or after the recertification decision.

12.4.2.4. In case UMS could not complete the recertification audit or the is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification will not be recommended and the validity of the certification will not be extended. The client will be informed and the consequences will also be explained.

12.4.2.5. Following expiration of certification, UMS can restore certification within 6months provided that the outstanding recertification activities are completed, otherwise at least a Stage-2 will be conducted. The effective date on the certificate will be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

12.4.3. Special Audits

12.4.3.1. Expanding scope

UMS, in response to an application from the certified client for expanding the scope of a certification already granted, will undertake a review of the application and determine if any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit.

12.4.3.2. Short-Notice Audits

If in case it is necessary for the UMS to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes, or as follow up on suspended clients, then in such cases UMS:

a) Will describe and make known in advance to the certified clients the conditions under which such audits will be conducted; and
b) Will exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

12.4.4. Suspending, withdrawing or reducing the scope of certification

12.4.4.1. UMS normally suspends certification in cases when, for example:

a) The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system;
b) The certified client does not allow surveillance or recertification audits to be conducted at the required frequencies;
c) The certified client has voluntarily requested a suspension.

12.4.4.2. Under suspension, the client's management system certification is temporarily invalid.

12.4.4.3. UMS restores the suspended certification if the issue that has resulted in the suspension has been resolved. Failure to resolve the issues that have resulted in the suspension in a time established by the certification body will result in withdrawal or reduction of the scope of certification.

NOTE: *In most cases, the suspension would not exceed six months.*

12.4.4.4. UMS can reduce the scope of certification to exclude the parts not meeting the requirements, when the certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification. Any such reduction will be in line with the requirements of the applicable standard used for certification.

13. PERFORMANCE EVALUATION

13.1. Performance Evaluation of Audit Team Members

The Audit Team Leader will evaluate each member/observer as per the need/guidance from UMS office of his team against the various parameters. The performance reports should be forwarded separately to the CEO of UMS and these will be treated confidentially. The Reporting Auditor may suggest any training need, where necessary.

13.2. Performance Evaluation of Auditor / Leaders

The performance of Team Leaders will be verified through Witness Audits independently by Senior Lead Auditors nominated by CEO of UMS, who will report on the Auditor's performance. Each Auditor's performance is normally verified once a year, and that of Lead Auditor once in 3 years.

13.3. Performance Evaluation of Trainee Auditors

a) All auditors who are qualified as an approved Lead Auditor/Assessor for ISO 9001/ISO 14001/ISO 22000/ISO 27001/ISO 45001/ISO 21001 and fulfilled the other qualification and knowledge & skills criteria for empanelment of external auditors are required to obtain auditing experience for 20 audit man-days before qualifying them for assignment as an audit team member for that management system in which he/she qualified as Lead Auditor/Assessor on behalf of UMS.
b) The requisite audit experience is obtained through attachment with audit teams for conduct of third-party audits of management systems including documentation review, certification and surveillance audits.
c) Trainee 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 Trainee Auditor is guided and trained in the methodology and practical conduct of all aspects of auditing of a management system as per ISO 9001/ISO 14001/ISO 22000/ISO 27001/ISO 45001/ISO 21001 standards.
e) The Team Leader is required to assess the understanding and performance of the 'Trainee Auditor' under his supervision and report on his compliance with the various attributes and skills as per UMS Performance Report including recommendation for desirable corrective actions, training and improvement.
f) The performance report is required to be forwarded for each audit by the Team Leader in respect of each Trainee Auditor for review by the UMS office and record. The Trainee Auditor will be advised of any deficiencies and requirement of training in specific area for improvement in his performance.
g) Upon completion of the requisite man-days of auditing, overall performance of the 'Trainee Auditor' is evaluated to confirm his up gradation to the Audit Team Member's grade or recommend further training, if necessary.
h) The up gradation of 'Trainee Auditor' will be duly recorded and his name entered in the UMS list of Approved Auditors.

14. Technical Experts

Technical Experts (TE) are selected for a specific technical area/sector and assigned as and when required. Their appointment as Technical Expert is based on their Technical/Professional Qualification, Industry experience, knowledge& skills and expertise in that specific technical area. Their expertise is also verified during the audit in that technical area.

Annex. 1

Annex. 1 - Assessment Checklist for Quality Management Systems - ISO 9001:2015

Context of the organization

- Has the organization determined the external and internal issues that are relevant to the organization's purpose and the achievement of customer satisfaction and the organization's strategic direction?
- Does the organization have a way of reviewing and monitoring these on a regular basis?
- Has the organization determined the needs and expectations of interested parties that are relevant to the Quality Management System (QMS)?
- Has the scope of the QMS been determined taking into account the external and internal issues, interested parties and the organization's products and services?
- Has the organization QMS been established including the processes needed and their sequence and interaction?
- Have the criteria for managing these been established together with responsibilities, methods, measurements and related performance indicators needed to ensure the effective operation and control?

Leadership

- Has the organization's top management taken accountability for the effectiveness of the QMS?
- Have the policy and objectives for the QMS, which are compatible with the strategic direction of the organization, been established and communicated?
- Have the objectives been established at relevant departmental and individual levels with the business?
- Have the requirements for the QMS been integrated into the business processes and have management promoted awareness of the process approach?
- Have customer requirements and applicable statutory and regulatory requirements been determined, met and communicated throughout the organization?
- Have the risks and opportunities that are relevant to the QMS been established?
- Has the organization established and communicated the responsibilities and authorities for the effective operation of the QMS?

Planning

- Have the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended result(s) been established?
- Has the organization planned actions to address these risks and opportunities and integrated them into the system processes?
- Is there a defined process for determining the need for changes to the QMS and managing their implementation?

Support

- Has the organization determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS (including people, environmental and infrastructure requirements)?
- If monitoring or measuring is used for evidence of conformity of products and services to specified requirements, has the organization determined the resources needed to ensure valid and reliable monitoring and measuring of results?
- Has the organization determined the knowledge necessary for the operation of its processes and achievement of conformity of products and services and implemented a lesson learnt process?
- Has the organization ensured that those persons who can affect the performance of the QMS are competent on the basis of appropriate education, training, or experience or taken action to ensure that those persons can acquire the necessary competence?
- Has the documented information required by the standard and necessary for the effective implementation and operation of the QMS been established?

Operation

- Is there a defined process for the provision of products and services that meet requirements defined by the customer?
- When changes are planned are they carried out in a controlled way and actions taken to mitigate any adverse effects?
- Are any outsourced processes managed and controlled?
- Is there a defined process for reviewing and communicating with customers in relation to information relating to products and services, enquiries, contracts or order handling?
- Is there review conducted prior to the organization's commitment to supply products and services?
- If the organization design and develop products or services, are these processes established and implemented in line with the requirements of the standard?
- Does the organization ensure that externally provided processes, products, and services conform to specified requirements?
- Does the organization have criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?
- Is the provision of products and services carried out in controlled conditions? which include:
- The availability of documented information that defines the characteristics of the products and services?
- The availability of documented information that defines the activities to be performed and the results to be achieved?
- Monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met?
- The people carrying out the tasks are competent?
- Does the organization have effective methods of ensuring traceability during the operation process?
- Where property belonging to customers or external providers is used in the provision of the product or service, is this controlled effectively?
- If there is a requirement for post-delivery activities associated with the products and services such as warranty, maintenance services, recycling or final disposal, are these defined and managed?
- Are any nonconforming process outputs managed so as to prevent their unintended use?

Performance evaluation

- Has the organization determined:
- What needs to be monitored and measured and
- The methods for monitoring, measurement, analysis and evaluation, to ensure valid results?
- Has it established when the results from monitoring and measurement shall be analysed and evaluated?
- Have methods of monitoring customer perceptions of the provision of products and services been established?
- Has it determined the need or opportunities for improvements within the QMS and how these will be fed into management reviews?
- Has the organization established a process for an internal audit of the QMS?
- Has an approach to perform management reviews been established and implemented?

Improvement

- Has the organization determined and selected opportunities for improvement and implemented the necessary actions to meet customer requirements and enhance customer satisfaction?
- Has the organization determined appropriate processes for managing nonconformities and the related corrective actions?
- Has the organization decided on how it will address the requirement to continually improve the suitability, adequacy, and effectiveness of the QMS?

Annex. 2

Annex.2 - Assessment Checklist for Environmental Management Systems - ISO 14001:2015

Context of the organization

- Has the organization undertaken a review to determine fully the external and internal issues that are relevant to establishing the context of the organization?
- Has the organization undertaken a review to identify interested parties, to understand their needs and expectation and which of these, if any, they will adopt as a compliance obligation?
- Has the organization determined the boundaries and applicability of the Environmental Management System (EMS)?
- Has the organization established an environmental management system?

Leadership

- Has top management demonstrated its commitment to establishing an EMS and effective leadership in the continual improvement of the system?
- Has the organization established an environmental policy?
- Has the organization assigned responsibilities and authorities in respect of the EMS?

Planning

- Does the organization follow a process that determines risks and opportunities?
- Have the risks and opportunities been considered with regard to the context of the organization and the needs and expectations of interested parties?
- Has the organization identified and evaluated its environmental aspects and impacts, and identified the risks and opportunities associated with adverse and beneficial impacts?
- Has the organization determined and have access to its compliance obligations and determined how these apply?
- Has the organization established an action plan to address the identified risks and opportunities and determined how these specifically apply to the organization?
- Does the organization have plans in place to achieve environmental objectives?

Support

- Has the organization provided adequate resources (including human, technological and financial) for the establishment, implementation, maintenance and continual improvement of the EMS?
- Has the organization taken the necessary steps to determine the competence of persons, undertaking work under its control, which can affect EMS performance?
- Has the organization promoted awareness of environmental management; so that all those working under the organization's control are aware of the requirements as associated with their work0 and have they determined their competence requirements?
- Has the organization planned, implemented and maintained a communication process operating internally and externally taking into account compliance obligations and ensuring consistency with information generated by the EMS?
- Has the organization established, maintained and sufficiently controlled documented information as required by the standard and as determined necessary by the organization?

Operation

- Has the organization determined planned and implemented control of the processes to meet the requirements of the EMS?
- Has the organization considered the life cycle perspective where appropriate when procuring products and services, designing its products and services, communications with contractors and end users?

- Has the organization established and implemented a process specifying how it will respond to a potential environmental emergency situation?

Performance evaluation

- Has the organization determined details, methods and frequency of areas of operation that need to be monitored, measured, analysed and evaluated in order to establish the performance and effectiveness of the EMS?
- Has the organization established and implemented a process to evaluate the organization's level of conformances with its compliance obligations, recording the results?
- Has the organization established, implemented and maintained an EMS internal audit program and documented evidence of the results?
- Has the organization undertaken management reviews of the EMS, does the output of the review include opportunities to improve the integration of the EMS in to other business processes if needed?

Improvement

- Does the organization react effectively to any nonconformity identified within its EMS and maintain documented information where appropriate?
- Does the organization continually improve its EMS to enhance its environmental performance?

Annex. 3

Annex. 3 - Assessment Checklist for Occupational Health & Safety Management Systems - ISO 45001:2018

Context of the organization

- Has the organization undertaken a review to determine fully the external and internal issues that are relevant to establishing the context of the organization?
- Has the organization undertaken a review to identify interested parties, to understand their needs and expectation and which of these, if any, they will adopt as a compliance obligation?
- Has the organization determined the boundaries and applicability of the Occupational Health & Safety Management System (OH&SMS)?
- Has the organization established an Occupational Health & Safety Management System?

Leadership

- Has top management demonstrated its commitment to establishing an OH&SMS and effective leadership in the continual improvement of the system?
- Has the organization established an OH&SMS policy?
- Has the organization assigned responsibilities and authorities in respect of the OH&SMS?

Planning

- Does the organization follow a process that determines risks and opportunities?
- Have the risks and opportunities been considered with regard to the context of the organization and the needs and expectations of interested parties?
- Is a comprehensive risk assessment programme following a hierarchy of control measures and covering all activities in place?
- Is a risk control action plan in place to deal with those risks not judged to be acceptable?
- Are legal and other requirements which apply to all activities identified and the relevant documents are held?
- Are overall plans and objectives in place for achieving OH&SMS policy?
- Are arrangements in place for ensuring that there are sufficient knowledge, skills and experience available to manage OH&SMS issues effectively?
- Are operational plans for implementing risk controls in place?
- Are operational plans for implementing legal and other requirements in place?
- Are operational control activities in place for ensuring that OH&SMS policy is implemented and effectively managed?
- Are arrangements in place for measuring, auditing and reviewing OH&SMS performance to identify any shortfalls and implementing necessary corrective and preventive actions?
- Are arrangements in place for implementing, monitoring and reviewing corrective and preventive actions?

Support

- Has the organization provided adequate resources (including human, technological and financial) for the establishment, implementation, maintenance and continual improvement of the OH&SMS?
- Has the organization taken the necessary steps to determine the competence of persons, undertaking work under its control, which can affect OH&SMS performance?
- Has the organization promoted awareness of OH&SMS management; so that all those working under the organization's control are aware of the requirements as associated with their work and have they determined their competence requirements?
- Has the organization planned, implemented and maintained a communication process operating internally and externally taking into account compliance obligations and ensuring consistency with information generated by the OH&SMS?
- Has the organization established, maintained and sufficiently controlled documented information as required by the standard and as determined necessary by the organization?

Operation

- Has the organization determined planned and implemented control of the processes to meet the requirements of the OH&SMS?
- Has the organization considered the life cycle perspective where appropriate when procuring products and services, designing its products and services, communications with contractors and end users?
- Is a top manager allocated with full responsibility for OH&S throughout the organization?
- Is there clear responsibility in the management structure?
- Is there clear accountability in the management structure?
- Is there clear delegation of authority in the management structure?
- Are any necessary resources allocated?
- Are all personnel working for, or on behalf of, the organization aware of their individual responsibilities?
- Are all personnel working for, or on behalf of, the organization aware of their responsibility to others who may be affected by the activities they control?
- Are all personnel working for, or on behalf of, the organization aware of the consequences of their action or inaction?
- Are a training, awareness and competence assessment programme in place for personnel working under its control?
- Is a retraining and refresher training programme in place?
- Is a system for effective, open two-way communication of OH&SMS information in place with all interested parties?
- Are specialist (in-house or external) advice/services made available, where appropriate?
- Workers (including contractors) and external interested parties are fully involved and consulted
- Is an adequate documentation system in place?
- Is a system in place for ensuring documents are kept up to date and relevant?
- Are contingency plans in place for emergencies, including arrangements for evacuating the site, liaison with the emergency services and start-up following an emergency?
- Is emergency response takes into account the needs of relevant interested parties and is periodically tested?

Performance evaluation

- Has the organization determined details, methods and frequency of areas of operation that need to be monitored, measured, analysed and evaluated in order to establish the performance and effectiveness of the OH&SMS?
- Has the organization established and implemented a process to evaluate the organization's level of conformances with its compliance obligations, recording the results?
- Has the organization established, implemented and maintained an OH&SMS internal audit program and documented evidence of the results?
- Has the organization undertaken management reviews of the OH&SMS, does the output of the review include opportunities to improve the integration of the OH&SMS in to other business processes if needed?

Improvement

- Does the organization react effectively to any nonconformity identified within its EMS and maintain documented information where appropriate?
- Does the organization continually improve its OH&SMS to enhance its Occupational health & safety performance?

Annex. 4

Annex. 4 - Assessment Checklist for Food Safety Management Systems - ISO 22000:2018

Food Safety Management System

General requirements

- Has the organization established, documented and implemented an effective food safety management system requirement of ISO 22000:2005 Standard?
- Is the FSMS maintained and updated?
- Is the scope of the FSMS defined?
- Are the products or product categories, processes and production sites that are addressed by the food safety management system specified by scope?
- Are the food safety hazards that may be reasonably expected to occur in relation to products within the scope of the system identified, evaluated and controlled in such a manner that the products of the organization do not, directly or indirectly, harm the consumer?
- Are the appropriate information regarding safety issues related to the products communicated throughout the food chain?
- Are the information concerning development, implementation and updating of the FSMS throughout the organization communicated to the extent necessary to ensure the food safety required by the ISO 22000 standard?
- Does the organization periodically evaluate FSMS (and update when necessary) to ensure that the system reflects the organization's activities and incorporates the most recent information on the food safety hazards subject to control?
- Has the organization ensured control over the outsourced processes that may affect end product conformity?
- Is the control of such outsourced processes identified and documented within the FSMS?

Documentation Requirements

- Does the FSMS documentation include:
- Documented statements of a food safety policy and related objectives?
- Documented procedures and records required by ISO 22000 standard?
- Documents needed by the organization to ensure the effective development, implementation and updating of the food safety management system?
- Are the documents - which are required by the food safety management system - controlled?
- Do the established controls ensure that all proposed changes are reviewed prior to implementation to determine their effects on food safety and their impact on the food safety management system?
- Does a documented procedure exist to define the controls needed
- To approve documents for adequacy prior to issue?
- To review and update as necessary and reapprove documents?
- To ensure that changes and the current revision status of documents are identified?
- To ensure that relevant versions of applicable documents are available at points of use?
- To ensure that documents remain legible and readily identifiable?
- To ensure that relevant documents of external origin are identified and their distribution controlled?
- To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?
- Are required records established and maintained in order to provide evidence of conformity to requirements and evidence of the effective operation of the food safety management system?
- Do records remain legible, readily identifiable and retrievable?
- Does a documented procedure exist in order to define the controls needed for the correction, identification, storage, protection, retrieval, retention time and disposition of records?

Management Responsibility

Management Commitment

- Is top management able to provide evidence of its commitment to the development and implementation of the food safety management system?
- Is top management able to provide evidence that the effectiveness of the food safety management system is continually improved by:
- Showing food safety is supported by the business objectives of the organization?
- Communicating to the organization the importance of meeting the requirements of ISO 22000 standard, any relevant statutory and regulatory requirements, as well as customer requirements relating to food safety?
- Establishing the food safety policy?
- Conducting management reviews, and
- Ensuring the availability of resources?

Food safety policy

- Has top management defined, documented and communicated its food safety policy?
- Does top management ensure that food safety policy:
- Is appropriate to the role of the organization in the food chain
- Conforms with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers,
- Is communicated, implemented and maintained at all levels of the organization,
- Is reviewed for continued suitability,
- Adequately addresses communication, and
- Is supported by measurable objectives.

Food safety management system planning

- Does top management ensure that:
- The planning of the food safety management system is carried out to meet the requirements in clause 4.1, as well as the objectives of the organization that support food safety?
- The integrity of the food safety management system is maintained when changes to the food safety management system are planned and implemented?

Responsibility and authority

- Does top management ensure that the responsibilities, authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the food safety management system?
- Is the responsibility assigned to all personnel to report the problems with the food safety management to identified person(s)?
- Are there designated personnel with defined responsibility and authority to initiate and record actions?

Food Safety Team Leader

- Has top management appointed a food safety team leader who, irrespective of other responsibilities, shall have responsibility and authority:
- To manage a food safety team and organize its work?
- To ensure relevant training and education of the food safety team member?
- To ensure that the food safety management system is established, implemented, maintained and updated?
- To report to the organization's top management on the effectiveness and suitability of the food safety management system?

Communication

External communication

- Has the organization established, implemented and maintained effective arrangements for communicating with Suppliers and contractors?

- Customers or consumers, in particular in relation to product information (including instructions regarding intended use, specific storage requirements and, as appropriate, shelf life), enquiries, contracts or order handling including amendments, and customer feedback including customer complaints?
- Statutory and regulatory authorities?
- Other organizations that have an impact on, or will be affected by, the effectiveness or updating of the food safety management system?
- Does such communication provide information on food safety aspects (specially to known food safety hazards that need to be controlled by other organizations in the food chain) of the organization's products that may be relevant to other organizations in the food chain?
- Are records of communications maintained?
- Are the food safety requirements - from statutory and regulatory authorities and customers – available?
- Are there designated personnel with defined responsibility and authority to communicate externally any information concerning food safety?
- Is information obtained through external communication included as input to system updating and management review?

Internal communication

- Has the organization established, implemented and maintained effective arrangements for communicating with personnel on issues having an impact on food safety?
- Has the organization ensured that the food safety team is informed in a timely manner of changes, including but not limited to the following:
- Products or new products;
- Raw materials, ingredients and services;
- Production systems and equipment;
- Production premises, location of equipment, surrounding environment;
- Cleaning and sanitation programmes;
- Packaging, storage and distribution systems;
- Personnel qualification levels and/or allocation of responsibilities and authorizations;
- Statutory and regulatory requirements;
- Knowledge regarding food safety hazards and control measures;
- Customer, sector and other requirements that the organization observes;
- Relevant enquiries from external interested parties;
- Complaints indicating food safety hazards associated with the product;
- Other conditions that have an impact on food safety.
- Does the food safety team ensure that above mentioned information is included in the updating of the food safety management system?
- Does top management ensure that relevant information is included as input to the management review?

Emergency preparedness and response

- Has top management established, implemented and maintained procedures to manage potential emergency situations and accidents that can impact food safety and which are relevant to the role of the organization in the food chain?

Management review

General

- Does top management review the organization’s food safety management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?
- Does this review include assessing opportunities for improvement and the need for changes to the food safety management system, including the food safety policy?
- Are records from management reviews maintained?

Review input

- Does the input to management review include information about:

- Follow-up actions from previous management reviews?
- Analysis of results of verification activities?
- Changing circumstances that can affect food safety?
- Emergency situations, accidents and withdrawals?
- Reviewing results of system-updating activities?
- Review of communication activities, including customer feed-back?
- External audits or inspections?
- Are the data presented in a manner that enables top management to relate the information to stated objectives of the food safety management system?

Review output

- Does the output from the management review include any decisions and actions related to:
- Assurance of food safety?
- Improvement of the effectiveness of the food safety management system?
- Resource needs?
- Revisions of the organization's food safety policy and related objectives?

Resource Management

Provision of resources

- Does the organization provide adequate resources for the establishment, implementation, maintenance and updating of the food safety management system?

Human resources

General

- Are the food safety team and the other personnel carrying out activities having an impact on food safety, competent on the basis of appropriate education, training, skills and experience?
- Are there available records of agreement or contracts defining the responsibility and authority of external experts, where the assistance of external experts is required for the development, implementation, operation or assessment of the food safety management system?

Competence, awareness and training

- Does the organization:
- Identify the necessary competencies for personnel whose activities have an impact on food safety?
- Provide training or take other action to ensure personnel have the necessary competencies?
- Ensure that personnel responsible for monitoring, corrections and corrective actions of the food safety management system are trained?
- Evaluate the implementation and the effectiveness of the actions taken in a), b) and c)?
- Ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to food safety,
- Ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on food safety?
- Maintain appropriate records of training and actions described in b) and c)?

Infrastructure

- Does the organization provide the resources for the establishment and maintenance of the infrastructure needed to implement the requirements of ISO 22000 standard?

Work Environment

— Does the organization provide the resources for the establishment, management and maintenance of the work environment needed to implement the requirements of ISO 22000 standard?

Planning and Realization of Safe Products

General

— Does the organization plan and develop the processes needed for the realization of safe products?
— Does the organization implement, operate and ensure the effectiveness of the planned activities and any changes to those activities.

Prerequisite Programmes (PRPs)

— Has the organization established, implemented and maintained PRP(s) to assist in controlling:
— The likelihood of introducing food safety hazards to the product through the work environment?
— Biological, chemical and physical contamination of the product(s), including cross contamination between products?
— Food safety hazard levels in the product and product processing environment?
— Are the PRP(s):
— Appropriate to the organizational needs with regard to food safety?
— Appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled?
— Implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or operational line?
— Approved by the food safety team.
— Does the organization identify statutory and regulatory requirements related to the above?
— Does the organization consider and utilize appropriate information, when selecting and/or establishing PRP(s)?
— Does the organization consider the following (when establishing PRP(s)):
— Construction and lay-out of buildings and associated utilities;
— Lay-out of premises, including workspace and employee facilities;
— Supplies of air, water, energy and other utilities;
— Supporting services, including waste and sewage disposal;
— The suitability of equipment and its accessibility for cleaning, maintenance and preventative maintenance;
— Management of purchased materials (e.g. Raw materials, ingredients, chemicals and packaging), supplies (e.g. Water, air, steam and ice), disposals (e.g. Waste and sewage) and handling of products (e.g. Storage and transportation);
— Measures for the prevention of cross contamination;
— Cleaning and sanitizing;
— Pest control;
— Personnel hygiene;
— Other aspects as appropriate.
— Is verification of PRP(s) planned?
— Are PRP(s) modified as necessary?
— Are records of verifications and modifications maintained?
— Do documents specify how activities included in the PRP(s) are managed?

Preliminary Steps to Enable Hazard Analysis

General

— Are all relevant information - needed to conduct the hazard analysis - collected, maintained, updated and documented?
— Are the records related to hazard analysis maintained?

Food Safety Team

— Has a food safety team been appointed?

- Do the members of the food safety team provide a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system?
- Are records - that demonstrate that the food safety team has the required knowledge and experience - maintained?

Product Characteristics

Raw material, ingredients and product- contacted material

- Are all raw materials, ingredients and product contact materials described in documents to the extent needed to conduct the hazard analysis, including the following, as appropriate:
- Biological, chemical and physical characteristics;
- Composition of formulated ingredients, including additives and processing aids;
- Origin;
- Method of production;
- Packaging and delivery methods;
- Storage conditions and shelf life;
- Preparation and/or handling before use or processing;
- Food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses.
- Does the organization identify statutory and regulatory food safety requirements related to the raw materials, ingredients and product-contact materials?
- Are the descriptions kept up-to-date including, when required?

Characteristics of End Products

- Are the characteristics of end products described in documents to the extent needed to conduct the hazard analysis, including information on the following, as appropriate:
- Product name or similar identification;
- Composition;
- Biological, chemical and physical characteristics relevant for food safety;
- Intended shelf life and storage conditions;
- Packaging;
- Labelling relating to food safety and/or instructions for handling, preparation and usage;
- Method(s) of distribution.
- Does the organization identify statutory and regulatory food safety requirements related to the characteristics of end products?
- Are the descriptions kept up-to-date including, when required?

Intended Use

- Are the intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product considered and described in documents to the extent needed to conduct the hazard analysis?
- Are groups of users and, where appropriate, groups of consumers identified for each product, and consumer groups known to be especially vulnerable to specific food safety hazards considered?
- Are the descriptions kept up-to-date including, when required?

Flow diagrams, process steps and control measures

Flow diagrams

- Are flow diagrams prepared for the products or process categories covered by the food safety management system?
- Do flow diagrams provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards?
- Are flow diagrams clear, accurate and sufficiently detailed?
- Do flow diagrams, as appropriate, include the following:

- The sequence and interaction of all steps in the operation;
- Any outsourced processes and subcontracted work;
- Where raw materials, ingredients and intermediate products enter the flow;
- Where reworking and recycling take place;
- Where end products, intermediate products, by-products and waste are released or removed.
- Does the food safety team verify the accuracy of the flow diagrams by on-site checking?
- Are verified flow diagrams maintained as records?

Description of process steps and control measures

- Are the existing control measures process parameters and/or the rigorousness with which they are applied, or the procedures that may influence food safety, described to the extent needed to conduct the hazard analysis?
- Are external requirements (e.g. regulatory authorities or customers) that may impact the choice or rigorousness of the control measures described and updated?

Hazard analysis

General

- Does the food safety team conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required?

Hazard identification and determination of acceptable levels

- Are all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities identified and recorded?
- Is the identification based on
- The preliminary information and data collected in preliminary steps to enable hazard analysis,
- Experience,
- External information including, to the extent possible, epidemiological and other historical data, and
- Information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products and the food at consumption.
- Are the step(s) (from raw materials, processing and distribution) - at which each food safety hazard may be introduced – indicated?
- Is the consideration - when identifying the hazards - given to
- The steps preceding and following the specified operation,
- The process equipment, utilities/services and surroundings, and
- The preceding and following links in the food chain.
- Are the acceptable level of the food safety hazard in the end product determined (whenever possible) for each of the food safety hazards identified?
- Does the determined level take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data?
- Are the justification for, and the result of, the determination of the acceptable level of the food safety hazard recorded?

Hazard Assessment

- Is a hazard assessment conducted to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met?
- Is each food safety hazard evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence?
- Is the methodology used for hazard described?
- Are the results of the food safety hazard assessment recorded?

Selection and assessment of control measures

- Is an appropriate combination of control measures selected (based on the hazard assessment), which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels?
- Is each of the selected control measures reviewed with respect to its effectiveness against the identified food safety hazards?
- Is each selected control measure categorized as to whether it needs to be managed through operational PRP(s) or by the HACCP plan, using a logical approach that includes assessments with regard to the following:
- Its effect on identified food safety hazards relative to the strictness applied;
- Its feasibility for monitoring (e.g. Ability to be monitored in a timely manner to enable immediate corrective actions);
- Its place within the system relative to other control measures;
- The likelihood of failure in the functioning of a control measure or significant processing variability;
- The severity of the consequence(s) in the case of failure in its functioning;
- Whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s);
- Synergistic effects (i.e. Interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects).
- Are control measures - categorized as belonging to the HACCP plan – implemented?
- Are other control measures implemented as operational PRPs?
- Are the methodology and parameters - used for this categorization - described in documents?
- Are the results of the assessment recorded?

Establishing the operational prerequisite programmes (PRPs)

- Are the operational PRPs documented?
- Are the operational PRPs included the following information for each programme:
- Food safety hazard(s) to be controlled by the programme?
- Control measure(s)?
- Monitoring procedures that demonstrate that the operational PRPS are in place?
- Corrections and corrective actions to be taken if monitoring shows that the operational PRPS are not in control?
- Responsibilities and authorities?
- Record(s) of monitoring?

Establishing the HACCP Plan

HACCP Plan

- Is the HACCP plan documented?
- Is the HACCP plan included the following information for each identified critical control point (CCP):
- Food safety hazard(s) to be controlled at the CCP?
- Control measure(s)?
- Critical limit(s)?
- Monitoring procedure(s)?
- Corrections and corrective action(s) to be taken if critical limits are exceeded?
- Responsibilities and authorities?
- Record of monitoring?

Identification of critical control points

Are CCP(s) identified for the control measures identified, for each hazard that is to be controlled by the HACCP plan?

Determination of critical limits for CCP(s)

- Are critical limits determined for the monitoring established for each CCP?

- Are critical limits established on such way to ensure that the identified acceptable level of the food safety hazard in the end product is not exceeded?
- Are critical limits measurable?
- Are the rationales for the chosen critical limits documented?
- Are critical limits - based on subjective data (such as visual inspection of product, process, handling, etc.) - supported by instructions or specifications and/or education and training?

System for the monitoring of critical control points

- Is a monitoring system established for each CCP to demonstrate that the CCP is in control?
- Are all scheduled measurements or observations - relative to the critical limit(s) - included in the monitoring system?
- Does the monitoring system consist of relevant procedures, instructions and records that cover the following:
- Measurements or observations that provide results within an adequate time frame?
- Monitoring devices used?
- Applicable calibration methods?
- Monitoring frequency?
- Responsibility and authority related to monitoring and evaluation of monitoring results?
- Record requirements and methods?
- Are the monitoring methods and frequency capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed?

Actions when monitoring results exceed critical limits

- Are planned corrections and corrective actions - to be taken when critical limits are exceeded - specified in the HACCP plan?
- Do the actions ensure that:
- The cause of nonconformity is identified?
- The parameter(s) controlled at the CCP is (are) brought back under control?
- Recurrence is prevented?
- Are documented procedures established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated?

Updating of Preliminary Information and Documents Specifying the PRPs and the HACCP Plan

- Does the organization update the following information in operational PRP(s) and/or the HACCP plan, if necessary:
- Product characteristics?
- Intended use?
- Flow diagrams?
- Process steps?
- Control measures?
- Are the HACCP plan and the procedures and instructions specifying the PRP(s) amended, if necessary?

Verification Planning

- Does verification planning define the purpose, methods, frequencies and responsibilities for the verification activities?
- Do the verification activities confirm that:
- The PRP(s) are implemented?
- Input to the hazard analysis is continually updated?
- The operational PRP(s) and the elements within the HACCP plan are implemented and effective,
- Hazard levels are within identified acceptable levels?
- Other procedures required by the organization are implemented and effective?
- Is the output of verification planning in a form suitable for the organization's method of operations?
- Are verification results recorded and communicated to the food safety team?

- Are verification results provided on such way to enable the analysis of the results of the verification activities?
- Are the affected lots of product handled as potentially unsafe, if system verification is based on testing of end product samples, and where such test samples show lack of conformity with the acceptable level of the food safety hazard?

Traceability System

- Has the organization established and does it apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records?
- Is the traceability system able to identify incoming material from the immediate suppliers and the initial distribution route of the end product?
- Are traceability records maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal?
- Are records in accordance with statutory and regulatory requirements and customer requirements?

Control of Nonconformity

Corrections

- Does the organization ensure that when critical limits for CCP(s) are exceeded or there is a loss of control of operational PRP(s), the end products affected are identified and controlled with regard to their use and release?
- Is a documented procedure established and maintained defining:
- The identification and assessment of affected end products to determine their proper handling?
- A review of the corrections carried out?
- Are potentially unsafe products - manufactured under conditions where critical limits have been exceeded - handled in accordance with clause 7.10.3.?
- Are products - manufactured under conditions where operational PRP(s) have not been conformed with - evaluated with respect to the cause(s) of the nonconformity and to the consequences thereof in terms of food safety?
- Are these products, where necessary, handled in accordance with 7.10.3.?
- Is the evaluation recorded?
- Are all corrections approved by the responsible person(s), and recorded together with information on the nature of the nonconformity, its cause(s) and consequence(s), including information needed for traceability purposes related to the nonconforming lots.

Corrective Actions

- Are data - derived from the monitoring of operational PRPs and CCPs - evaluated by designated person(s) with sufficient knowledge and authority to initiate corrective actions?
- Are corrective actions initiated when critical limits are exceeded or when there is a lack of conformity with operational PRP(s)?
- Has the organization established and does it maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to bring the process or system back into control after nonconformity is encountered?
- Are corrective actions recorded?

Handling of Potentially Unsafe Products

General

- Does the organization handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain unless it is possible to ensure that:
- The food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels,
- The food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering into the food chain, or
- The product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity?

- Are all lots of product - that may have been affected by a nonconforming situation - held under control of the organization until they have been evaluated?
- Does the organization notify relevant interested parties and initiate a withdrawal, if products that have left the control of the organization are subsequently determined to be unsafe?
- Are the controls and related responses and authorization for dealing with potentially unsafe products documented?

Evaluation for Release

- Is each lot of product affected by the nonconformity released as safe only when any of the following conditions apply:
- Evidence other than the monitoring system demonstrates that the control measures have been effective;
- Evidence shows that the combined effect of the control measures for that particular product complies with the performance intended;
- The results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned?

Disposition of Nonconforming Products

- Is the lot of product - which is not acceptable for release - handled (after evaluation) by one of the following activities:
- Reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels;
- Destruction and/or disposal as waste.

Withdrawals

- To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe:
- Has top management appointed personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal?
- Has the organization established and does it maintain a documented procedure for:
- Notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
- Handling of withdrawn products as well as affected lots of the products still in stock, and
- The sequence of actions to be taken?
- Are withdrawn products secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe?
- Are the cause, extent and result of a withdrawal recorded and reported to top management as input to the management review?
- Does the organization verify and record the effectiveness of the withdrawal programme through the use of appropriate techniques (e.g. challenge testing, mock withdrawal or practice withdrawal)?

Validation, verification and improvement of the FSMS

General

- Does the food safety team plan and implement the processes needed to validate control measures and/or control measure combinations, and to verify and improve the food safety management system?

Validation of control measure combinations

- Does the organization validate (prior to implementation of control measures to be included in operational PRP(s) and the HACCP plan and after any change therein) that:
- The selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated?
- The control measures are effective and capable of, in combination, ensuring control of the identified food safety hazard(s) to obtain end products that meet the defined acceptable levels?
- Are the control measure and/or combinations thereof modified and re-assessed when the result of the validation shows that one or both of the above elements cannot be confirmed?

Control of monitoring and measuring

- Are there evidences that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures?
- Are the measuring equipment and methods used:
- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards?
- Is the basis used for calibration or verification recorded, where no such standards exist?
- Adjusted or re-adjusted as necessary?
- Identified to enable the calibration status to be determined?
- Safeguarded from adjustments that would invalidate the measurement results?
- Protected from damage and deterioration?
- Are records of the results of calibration and verification maintained?
- Does the organization assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements?
- Does the organization take action appropriate for the equipment and any product affected, if the measuring equipment is nonconforming?
- Are records of such assessment and resulting actions maintained?
- Is the ability of computer software confirmed to satisfy the intended application when used in the monitoring and measurement of specified requirements?
- Is the confirmation of computer software undertaken prior to initial use and reconfirmed as necessary?

FSMS Verification

Internal Audit

- Does the organization conduct internal audits at planned intervals to determine whether the food safety management system:
- Conforms to the planned arrangements, to the food safety management system requirements established by the organization, and to the requirements of this International Standard?
- Is effectively implemented and updated?
- Is an audit programme planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits?
- Are the audit criteria, scope, frequency and methods defined?
- Do the selection of auditors and the conduct of audits ensure objectivity and impartiality of the audit process?
- Is it ensured that auditors do not audit their own work?
- Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records defined in documented procedure?
- Does the management responsible for the area being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes?
- Do follow-up activities include the verification of the actions taken and the reporting of verification results?

Evaluation of Individual Verification Results

- Does the food safety team systematically evaluate the individual results of planned verification?
- Does the organization take action to achieve the required conformity, when verification does not demonstrate conformity with the planned arrangements?
- Does action – taken for achieving the required conformity – include (but is not limited to), review of:
- Existing procedures and communication channels?
- The conclusions of the hazard analysis, the established operational PRP(s) and the HACCP plan?
- The PRP(s)?
- The effectiveness of human resource management and of training activities?

Analysis of Results of Verification Activities

- Does the food safety team analyse the results of verification activities, including the results of the internal audits and external audits?
- Is the analysis carried out in order:
- To confirm that the overall performance of the system meets the planned arrangements and the food safety management system requirements established by the organization?
- To identify the need for updating or improving the food safety management system?
- To identify trends which indicate a higher incidence of potentially unsafe products?
- To establish information for planning of the internal audit programme concerning the status and importance of areas to be audited?
- To provide evidence that any corrections and corrective actions that have been taken are effective?
- Are the results of the analysis and the resulting activities recorded and reported, in an appropriate manner, to top management as input to the management review?
- Are the results of the analysis and the resulting activities used as an input for updating the food safety management system?

Improvement

Continual Improvement

- Does top management ensure that the organization continually improves the effectiveness of the food safety management system through the use of:
- Communication,
- Management review,
- Internal audit,
- Evaluation of individual verification results,
- Analysis of results of verification activities,
- Validation of control measure combinations,
- Corrective actions, and
- Food safety management system updating?

Updating the Food Safety Management System

- Does top management ensure that the food safety management system is continually updated?
- Does the food safety team evaluate the food safety management system at planned intervals in order to achieve that FSMS is continually updated?
- Does the team consider whether it is necessary to review the hazard analysis, the established operational PRP(s) and the HACCP plan?
- Are the evaluation and updating activities based on:
- Input from communication, external as well as internal?
- Input from other information concerning the suitability, adequacy and effectiveness of the food safety management system?
- Output from the analysis of results of verification activities?
- Output from management review?
- Are system updating activities recorded and reported, in an appropriate manner, as input to the management review?

Annex. 5

Annex. 5 - Assessment Checklist for Information Security Management Systems - ISO 27001:2013

4 Context of the organization

- **4.1 Understanding the needs and expectations of interested parties**
  - Determine external and internal issues relevant to the information security management system

- **4.2 Understanding the needs and expectations of interested parties**
  - Determine interested parties
  - Requirements of the parties

- **4.3 Determining the scope of the information security management system**
  - Determine boundaries and applicability of the ISMS
  - Be available as documented information
  - The Organisation shall consider; external and internal issues, requirements of interested parties, interface and dependencies between activities performed by the Organisation and those performed by other organizations

  The Scope is required Documented Information.

- **4.4 Information security management system**
  - The Organisation shall establish, implement, maintain and continually improve the ISMS

5 Leadership

- **5.1 Leadership and commitment**
  - Establish policy and objectives in line with strategic direction
  - Ensure integration with organizations processes
  - Ensure resources
  - Communicate importance of management and conformity
  - Ensure ISMS achieves intended outcomes
  - Directing and supporting persons involved in the ISMS
  - Promoting continual improvement
  - Supporting other relevant managers

- **5.2 Policy**
  - Is appropriate to the purpose of the Organisation
  - Includes information security objectives or provides the framework for setting information security objectives
  - Includes a commitment to satisfy applicable requirements related to information security
  - Includes a commitment to continual improvement of the information security management system
  - Is available as documented information
  - Be communicated within the Organisation
  - Be available to interested parties

  The Policy is required Documented Information.

- **5.3 Organizational roles, responsibilities and authorities**
  - Roles and authorities are assigned and communicated
  - Top management shall assign responsibilities for; ensuring the ISMS conforms to the standard, reporting on the performance to top management (and within the Organisation)

6 Planning

- **6.1 Actions to address risks and opportunities**

  - **6.1.1 General**
    - The organizations shall consider; context of the Organisation, needs and expectations of interested parties.
    - Determine the risks and opportunities that need to be addressed; ISMS achieves intended outcomes, prevents or reduces undesired effects and achieves continual improvement
    - The Organisation shall plan; actions to address risks and opportunities and how to; integrate and implement actions into its ISMS and evaluate the effectiveness

  - **6.1.2 Information security risk assessments**
    - The Organisation shall define and apply a risk assessment approach that; establishes and maintains risk acceptance criteria and criteria for performing risk assessments
    - Ensures repeatability producing consistent, valid and comparable results
    - That identifies security risks associated with loss of Confidentiality, Integrity and Availability and identifies Risk Owners
    - Analyses risks; potential consequences, realistic likelihood, levels of risk
    - Evaluates risks; compares and priorities

    The organizations shall retain documented information
    Information on the Risk Assessment Process is required Documented Information.

  - **6.1.3 Information security risk treatment**
    - The Organisation shall define and apply Information security risk treatment process to; select treatment options
    - Determine controls “from any source”
    - Compare controls with Annex A
    - Produce a Statement of Applicability
    - Formulate a treatment plan
    - Obtain owners approval of treatments and residual risks
    - Retain documented information

    Information on the Risk Treatment Process is required Documented Information.
    The Statement of Applicability must be documented.

- **6.2 Information security objectives and planning to achieve them**
  - The Organisation shall establish objectives “at relevant functions and levels”.
  - They shall be; consistent, measurable (where practicable), take into account requirements, assessment and treatments, communicated, updated
  - The Organisation shall retain documented information; what will be done, what resources will be required, who will be responsible, when it will be completed and how results will be evaluated

  The Objectives are required Documented Information.

7 Support

- **7.1 Resources**
  - The Organisation shall provide resources

- **7.2 Competence**
  - The organizations shall; determine the necessary competence, ensure it, take actions to acquire, retain documentation Evidence of competence is required Documented Information

- **7.3 Awareness**
  - Persons shall be aware of; the ISMS policy, their contributions to the ISMS, consequence of not Conforming

- **7.4 Communication**

— The Organisation shall determine the need for internal and external communication

- **7.5 Documented information**
  - **7.5.1 General**
    — The organizations ISMS shall include documented information required by the standard
    — Information deemed by the Organisation as required
    Information Necessary for the effectiveness of the ISMS is required Documented Information.

  - **7.5.2 Creating and updating**
    — When creating documented information, the Organisation shall ensure appropriate; identification and description, format, review and approval

  - **7.5.3 Control of documented information**
    — Documented information shall be controlled to ensure; availability and suitability, protection
    — The Organisation shall address; distribution, access retrieval and use, storage and preservation, change control, retention and disposition
    — External documents
    Documented Information of External Origin shall be controlled as other Documented Information.

8 Operation

- **8.1 Operational planning and control**
  — The Organisation shall plan, implement and control processes
  — The Organisation shall implement plans to achieve objectives
  — The Organisation shall control planned changes and review consequences of unplanned changes
  — The Organisation shall ensure outsourced processes are determined and controlled
  Information necessary to have confidence that processes are being carried out as planned are required Documented Information.

- **8.2 Information security risk assessments**
  — The Organisation shall perform risk assessments at planned intervals or significant changes
  — The Organisation shall retain documented information
  Information on Risk Assessments is required Documented Information.

- **8.3 Information security risk treatment**
  — The Organisation shall implement risk treatment plan and retain documentation
  Results of Risk Treatment is required Documented Information.

9 Performance evaluation

- **9.1 Monitoring, measurement, analysis and evaluation**
  — The Organisation shall evaluate the ISMS performance and effectiveness
  Evidence of Monitoring and Measuring is required Documented Information.

- **9.2 Internal audit**
  — The Organisation shall conduct internal audits.
  Auditors shall be selected and conduct audits "that ensure the objectivity and impartiality of the audit process" however the statement "auditors shall not audit their own work" is omitted.
  The Audit Programme and Results are required Documented Information.

- **9.3 Management review**
  — Top management shall review the ISMS this shall include;
    - *Status of actions from previous meetings*
    - *External and internal changes*
    - *Feedback on performance*

- *Non-conformities and corrective actions*
- *Monitoring and measurement*
- *Audit results*
- *Fulfilment of objectives*
- *Feedback from interested parties*
- *Results of risk assessments and treatment plans*
- *Opportunities for continuous improvement*

The results of Management Review are required Documented Information.

10 Improvements

- **10.1 Nonconformity and corrective actions**

  — The Organisation shall react to nonconformities, evaluate the need for actions, implement actions

  Information on Non-conformances and actions are required Documented Information.

- **10.2 Continual improvement**

  — The organizational shall continually improve the ISMS