

Purpose: To establish and describe the procedure for conducting audit of the client's management system against the agreed MS standard, as per the requirements of ISO 17021-1:2015.

Scope: This procedure is applicable over all type of MS audits undertaken by HYM.

Responsibility: Managing Director/ Quality Manager and HYM 's Auditors.

Authority: This procedure has been authorized by the Managing Director and can be amended only by him.

Sec.	Sub Sec.	Description
1		HYM conducts only third-party certification audits. The Audit processes have been classified as per their intended objectives. Some of these are - - Initial certification audit (Stage-1 audit/ Pre audit review) - Initial certification audit (Stage-2 certification audit) - Re audit - Follow up audit - Special audit - Recertification audit - Joint audit (when two or more auditing organizations cooperate to audit a single client) - Combined audit (when the client is audited against two or more standards) - Integrated audit (when a client has integrated the application of requirements of two or more management systems standards into a single management system and is being audited against more than one standard. HYM does not outsource auditing activity to any other organization.
2	2.1	Initial Audit Planning:- Initial audit planning is done by a competent Application reviewer (or by any approved auditor with the help of a competent Technical expert). This is done on the basis of information provided by the client as per Application form. The Application reviewer is selected by the Quality manager, from among the available pool of auditors {HYM-F-15-16 }. The audit program includes plan for stage-1 audit and a tentative plan for stage-2 audit and tentative plans of 2 surveillance audits and then recertification audit. For audits involving specialized academic, technical or professional disciplines, consideration shall be given to inclusion of personnel possessing relevant sector knowledge and experience. The justification for inclusion or non-inclusion of a Technical Expert shall be documented as part of the audit planning process.
	2.2	SELECTION OF AUDIT TEAM Selection of audit team for stage-1 audit or for stage-2 audit is done by the application reviewer and audit programmer. This is done in consultation with the Quality manager, but the overall responsibility lies with the Application reviewer. Audit assignment is given to the selected stage-1 auditor only after getting declaration of impartiality from the concerned auditor. A Competent audit team is selected/ appointed to carry out initial certification audit of the client. Suitable auditor/ audit team is picked from the list of auditors approved for each type of industry. It is ensured that the auditor/ audit team as whole, possess the required competency. In case competent auditor is not available, any available auditor (competent for any industry of similar or higher complexity) is assigned the task of audit to be carried out with the help of a competent technical expert, approved as per the list of Auditors.

		Team Leaders- Where the audit team contains only one auditor, the auditor becomes the leader of the one-member audit team. Where the audit team is constituted by more than one auditor, the auditor having greater expertise in the audit standard and HYM procedures, is assigned the role of audit team leader. Prior to audit team appointment, HYM shall evaluate the technical complexity of the client's activities, processes, products and services. Where the audit scope involves specialized sectors such as educational institutions, healthcare, pharmaceutical education, engineering, medical sciences or other discipline-specific activities, the need for inclusion of a Technical Expert or Subject Matter Expert (SME) shall be evaluated and documented. The Audit Team Leader shall ensure that the combined competence of the audit team is sufficient to achieve the audit objectives.
3		Audit Objective
	3.1	Stage 1 audit is conducted to assess the adequacy of the MS documented system and readiness of the client to organize stage-2 certification audit. The same will be clearly documented in the Audit objective. During audit, information supplied by the client as per its application is also verified. Further information is gathered to, develop a good audit plan. In view of new information, initial audit program developed by the Application reviewer may be revised and improved with mutual consultation.
	3.2	While conducting audit in remote locations, some part of the document audit may be conducted off site, provided the onsite audit duration (stage-1 and stage-2) is not reduced to less than 80% of the total planned audit duration.
4		Communication with the client Stage-1 audit intimation is provided to the client. Auditors name contact no., detail of accompanying trainee auditors, observers is also forwarded and acceptance is taken from the client.
5	5.1	Stage I opening meeting: The audit team (one member or multi member team) visits the audit site as per mutually agreed audit plan. The audit team leader introduces him/her and the audit team members. Client's introduction is received and after confirming address and scope of this audit, brief explanation of the purpose of the stage-1 audit, and its methodology is provided by the audit team. The audit team assures the client about maintaining full confidentiality and informs about audit team's legally enforceable contract & declaration of confidentiality. Signature of the participants from both the sides is taken. Instruction for auditors has been provided in the stage-1 audit reporting format. Ref: HYM-F-08 - Opening / Closing Meeting Attendance Sheet
	5.2	Conducting stage-1 audit: Audit function is started with taking a round of the physical facilities of the organization. Audit is conducted by perusal of documents, interview and observation. Readiness of the clients MS for successful certification audit is assessed, and issues that may be flagged as major non conformity during the stage-2 audit, are identified. Audit findings are noted by the auditor/s in their audit checklist/ audit reporting format in Auditor Rough Sheet. Inadequacies identified during the audit are communicated to the auditee, in order to allow them sufficient time to close the nonconformities, on the same day, wherever possible. Corrective Action request regarding non conformities/ inadequacies identified during the audit is made in the Stage-01 Audit Report {EMS, EOMS, EnMS}
	5.3	Closing Meeting: During the closing meeting the client is thanked about their transparency and hospitality. Audit team's conclusion about recommendation / no recommendation regarding approval for stage-2 final audit is communicated to the Client. After audit closure pending non conformities / inadequacies are finalized, documented and the client's representative is asked to acknowledge it. The client is further asked to inform the HYM after closing the NC, in order to plan for Stage-2 certification audit. Signature of the participants is taken in the audit attendance sheet in Form HYM-F-08 Attendance Sheet Client's feedback about performance of the audit team is taken in form HYM-F-14 Client Feedback Form. The client is provided a copy of the stage-1 audit report. Stage-2 audit process is initiated only after getting confirmation from the client about closure of the identified gaps/ areas of concerns (that might be flagged as non-conformity during stage-2 audit)

5.4	Stage II Audit objective: Stage II audit is conducted to assess conformity of the client's MS to the audit standard (ISO 14001:2015, ISO 50001:2018, ISO 21001:2018). Client's capability to achieve planned product quality and quality objectives is also assessed. In addition to this OFI, to further strengthen the client's MS, is also identified.
5.5	Communication with client: The client is informed about the stage-2 audit team at least 3-4 days before audit date to enable him/ her to submit assent or dissent. Audit plan in form HYM-F-06(a) Audit Plan is prepared by the Quality Manager with the help of stage-2 audit team leader as per inputs received from the Stage I audit team leader. Availability of the Stage-2 auditors is confirmed, and the audit plan is submitted to the Client organization for approval of timings and to ensure availability of required officers. For multi-site audit, sampling plan is developed as per each client's individual situation and accordingly audit is planned. After receipt of acceptance of the audit plan from the client, the stage II audit conducted. Stage-2 audit is assigned to the auditors/ technical experts, only after they submit a declaration of confidentiality and no conflict of interest to the HYM office. <i>In case during stage-1 audit gross deficiency in documentation is found and audit objective is unattainable, the audit team leader should advise to the client to prepare all the documents and re-invite the audit team for stage-1 audit and inform to HYM office. If the audit team leader feels that the client is not co-operating with the audit the Team Leader should warn the client's representative about the termination of the audit, if even after this the client does not co-operate the team leader should talk with organizations head and warn him/her that if the client does not co-operate the audit will be abandoned. Even after this the client does not co-operate the audit team leader should abandon the audit and inform the HYM office.</i>
5.6	Opening Meeting: - The audit team (one member or multi member team) visits the audit site as per mutually agreed audit plan. The audit team leader introduces him/her and the audit team members. Client's introduction is received and after confirming address and scope of this audit, brief explanation of the purpose of the stage-2 audit, and categories of findings, is provided by the audit team. The audit team assures the client about maintaining full confidentiality and informs about audit team's legally enforceable contract & declaration of confidentiality. Audit instructions are also available in the stage-2 audit reporting format.
5.7	Conduct Stage-II Audit Stage 2 audit shall include at least the following: - Information and evidence about conformity to all requirements of the applicable management system standard or other normative document - Performance monitoring, measuring, reporting and reviewing against key, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document). - The client's management system and performance as regards to legal and other requirements - Operational control procedures of the client's processes. - Internal auditing and management review - Management commitment and responsibility for the client's policies <u>Audit Sample-</u> <i>During Stage-2 audit the audit team must pick appropriate samples to gather audit evidences regarding each product, services, aspects or activities, described in the scope of the MS. The audit team should gather information about the various aspects described in the scope and should evaluate whether this conforms to the Related MS audit standards and clients MS documentation, or not.</i> <u>Audit Information-</u>

Audit Information is gathered by observation of the processes and activities by interviewing personnel involved in activities described in the scope and review of related documents and records. In addition to these methods the audit team may investigate as per audit scope related information gathered from external sources.

After verification objective Evidences of conformity and non-conformity should be recorded in audit note/rough sheets. The audit team should be confident of defending audit evidence if challenged.

Communication within the Audit Team-

During the audit process the audit team leader and the audit team members should communicate with each other to assess the audit progress. They should make each other aware of existing audit leads. The audit team leader should deviate from the audit plan and reassign work to the audit team members, in accordance with the new information gathered in course of audit. However, the audit team should always remain within the scope of the audit.

Updating the Client-

The audit team should inform the client about minor non-conformities which may be easily eliminated before the end of the audit.

In course of the audit if the audit team feels that available audit evidence show that the audit objectives are unattainable due to deficiency in the MS or due to safety risk to the audit team, the audit team leader should inform the client tactfully and should terminate the audit and inform HYM office.

5.8

Closing Meeting: -

After audit closure, audit findings are reconciled and finalized by the audit team. In case of conflict between the audit team members, decision of the audit team leader prevails.

Audit non-conformities are classified as major non-conformity and minor non-conformity

Major Non-Conformance

Major NC is a non-compliance of a serious nature that may have a significant and direct adverse impact on the quality of the product / services provided by the client. Multiple minor non-compliance may also be flagged as major Non conformity, because this shows a lack of knowledge or lack of commitment. Major non conformities must be responded to, corrected and formally closed-out, preferably within 90 days. These are re-verified by the auditors, mostly by revisiting the audit site. Only after satisfactory closure of major non conformities the certification and registration can proceed. Major non-conformity related to legal non-compliance may be closed by perusal of documentary evidence submitted to the HYM without any re-visit at the audit site.

Minor Non-Conformance

Minor NC is a non-compliance of less serious nature that does not cause significant adverse impact over the goods or services provided by the client. These Minor non conformities are closed-out by the auditors by reviewing evidences of corrective action, which the client must submit to the HYM office within the agreed time, preferably within 30 days. Some minor non-conformities where corrective action may be initiated within 30 days but full closure can be verified only after months of implementation-are verified during subsequent surveillance audit.

Observation is an isolated non compliance that does not show collapse of MS process. It is not mandatory to submit corrective action plan or corrective action evidence. However, observations should be treated as

potential non conformities, which should be closed in order to stop its conversion into actual non conformities.

Opportunity for Improvement (OFI) is not a non-compliance. These are areas where scope of further improvement is available. These are recommendation and value addition by the audit team. Compliance is not mandatory.

No conformities are documented and classified and the client's representative is asked to acknowledge it. During the closing meeting the client is thanked about their transparency and hospitality. Positive and negative issues are shared and the Client is asked to submit corrective action plans against each individual non conformities recorded in form NCR Report within one week along with the NC Closure Format- HYM-F-10.

As per audit findings, the audit team leader declares the audit result/ conclusion/ recommendation regarding grant, refusal, hold up, suspension, scope extension, scope reduction, continuation or withdrawal of the certificate.

The client is asked to close minor NC within one month, and major NC within 3 months. Mode of verification of effectiveness of the corrective action is also explained and documented by the audit team leader, which varies depending upon the nature of the non-conformities. Some non-conformities corrective action may be verified by submission of documentary evidence of corrective action.

In case of some major non conformity and in case of multiple minor non conformities follow up audit is declared to verify corrective action at the audit site.

Certificate of conformity is not issued unless all non-conformities are closed by HYM auditors.

However, Corrective action verification of some minor non conformities where evidence of initiating corrective action is submitted within one month, but due to nature of non-conformity the actual closure requires many months (not affecting product conformity and/ or customer satisfaction, not amounting to collapse of key element of MS) may be deferred up to next surveillance audit, and in this case the client may be recommended for grant of certification, without verifying closure of such minor NC.

Summary of non-conformities, observations for improvement and decision about recommendation/non recommendation is communicated to the Client organization by the Audit team leader, during the Closing meeting. Audit summary report is also submitted in hard and soft copy to the client within two weeks.

During closing meeting brief narration of audit findings is done. It is explained that the audit was conducted on sampling basis. Type of non-conformities detected and time frame and method of submitting corrective action plan and corrective action evidence for verifying Closure of non-conformities and its time frame is also explained. Information about method of lodging complaints and appeal and its handling is also explained. Consequences of closure or non-closure of non-conformities and its impact on certification decision is also explained to the client. Post audit activities of the HYM like, verification of corrective action plan and corrective actions (where required), preparation of audit report and its subsequent review by the decision makers is also explained. If the client is recommended for certification, the process of surveillance, validity of certificate and recertification process is also explained. The client is informed that a summary of audit report would be submitted to the client along with documented audit result.

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Effectiveness of corrections and corrective actions: - The certification body/ competent auditor reviews the statement of corrections, root cause of non-conformity and corrective actions, submitted by the client to determine if these are acceptable. The certification body verifies the effectiveness of the correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities is recorded. The client is informed about the result of the review and verification.



7		Submission of report: Report in detail along with objective evidence is submitted to the Quality manager of HYM, within 10 days after the day of stage-2 audit. The Quality manager submits the audit report to the competent report reviewer for appropriate decision.
8		Follow up audit: In case where non conformity leading to system failure is noted and on-site verification of elimination of non-conformity is required for recommendation, follow up audit is conducted to verify the same.
9		Extensions to scope: HYM reviews application for extension to the scope of a certification already granted, and plans audit activities necessary to decide whether or not the extension may be granted.
10		Surveillance Audit: Surveillance audit is organized within one year from the last day of stage-2 audit. However as per auditor's recommendation, based on business volume, its complexity, and stability of the organization's management system, it can be conducted even earlier. It is necessarily conducted within one year from the last day of stage-2 audit. This is done to maintain confidence that the certified client continues to maintain conformity with the audit criteria during the validity of the certificate.
11		Recertification audit: After 3-year audit cycle, before the expiry of the certificate, and within one year of the last day of the last surveillance audit, recertification audit is conducted. During the Re-certification audit conformity to all clauses of the audit standard is verified.

Reference: Audit standards ISO 14001:2015, ISO 50001:2018, ISO 21001:2018 for Management System

Note: Where MS has written – It Means all the Management System Applied i.e. (EMS, EOMS, EnMS).

Records: Audit pack/Audit file forms