	<b>ASTRALEUS SERVICES PVT. LTD.</b>	<b>Doc. No.</b>	ASPL-QP-15
		<b>Rev. No.</b>	01
	<b>TITLE: CONDUCTING ONSITE AUDIT</b>	<b>Rev. Date</b>	10.03.2026


**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 ASPL.


**Responsibility:** Managing Director/ Quality Manager and ASPL ‘s Auditors.

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


Sec.	Description
<b>1</b>	Classification of Audit
<b>1</b>	<p>ASPL conducts only third-party certification audits. The Audit processes have been classified as per their intended objectives. Some of these are -</p> <ul style="list-style-type: none"> <li>- Initial certification audit (Stage-1 audit/ Pre audit review)</li> <li>- Initial certification audit (Stage-2 certification audit)</li> <li>- Re audit</li> <li>- Follow up audit</li> <li>- Special audit</li> <li>- Recertification audit</li> <li>- Joint audit (when two or more auditing organizations cooperate to audit a single client)</li> <li>- Combined audit (when the client is audited against two or more standards)</li> <li>- 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.</li> </ul>
<b>2</b>	<p><b>Client Enquiry and Application Review Process</b></p> <p>Whenever an enquiry is received from a client for certification services, ASPL provides an application (<b>ASPL-F01 Certification application form</b>) form to the client to collect all necessary information required for review. This information enables ASPL to understand the client’s scope, activities, and certification requirements, and to initiate the certification process.</p> <p>Based on the information received through the completed application form, ASPL conducts a formal review of the application (contract review) to ensure clarity of requirements, availability of resources, and feasibility of certification prior to proceeding further.</p> <p>Contract review carried out in <b>ASPL-F 02- Contract Review form</b>. Contract review will be carried out as <b>per Procedure ASPL-QP-03</b></p>
<b>3</b>	<p><b>Quotation and Audit Planning Process</b></p> <p>Following the successful completion of the contract review, ASPL provides the commercial terms to the client in the form of a quotation using the <b>ASPL-F-03 Quotation Form</b>.</p> <p>Upon confirmation and approval of the commercial terms by the client, ASPL proceeds with the planning of the audit. The client’s confirmation may be received through formal communication channels such as email or other documented means (e.g., WhatsApp), and where applicable, verbal confirmation may also be considered, provided it is subsequently recorded for reference.</p>
<b>4</b>	<b>Initial Audit: -</b>
<b>4.1</b>	Initial audit programming 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 or approved list of Application reviewer.
<b>4.2</b>	<p><b>SELECTION OF AUDIT TEAM</b></p> <p>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.</p>

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	<p>Audit assignment / Nomination is given to the selected stage-1 auditor only after getting declaration of impartiality from the concerned auditor. <b>(F-05 Auditor Nomination and Declaration for Confidentiality &amp; Impartiality)</b></p> <p>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.</p> <p><b>Team Leaders-</b> 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 ASPL procedures, is assigned the role of audit team leader.</p>
<b>5</b>	<b>Audit plan and Contractual agreement with client</b>
<b>5.1</b>	<b>Audit Objective;</b> -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. 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.
<b>5.2</b>	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.
<b>5.3</b>	Stage-1 audit intimation is provided to the client. Auditors' names contact no., detail of accompanying trainee auditors, observers are also forwarded and acceptance is taken from the client. The audit plan for Stage-1 audit is prepared and communicated to the client through <b>Form F-06 (Audit Plan – Stage-1)</b> , ensuring all relevant audit details, scope, objectives, and schedule are clearly defined prior to the audit. Prior to initiation of the audit, the client shall be legally bound to comply with the terms and conditions of certification as defined in <b>ASPL F-04 (Client Agreement Form)</b> . The signed agreement ensures formal acceptance of certification requirements and obligations by the client before commencement of audit activities.
<b>6</b>	<b>Stage 1 Audit</b>
<b>6.1</b>	<p><b>Stage-1 Opening Meeting</b></p> <p>The Stage-1 audit commences with the audit team (either a single auditor or a multi-member team) visiting the audit site as per the mutually agreed audit plan.</p> <p>The Audit Team Leader introduces himself/herself along with the audit team members. The client representatives are also requested to introduce themselves. The audit team confirms the audit site address and scope of the audit with the client.</p> <p>A brief explanation of the purpose, objectives, and methodology of the Stage-1 audit is provided to the client. The audit team also assures the client of maintaining strict confidentiality of all information obtained during the audit and informs them about the legally enforceable agreements and declarations of confidentiality applicable to the audit team.</p> <p>Signatures of all participants from both the audit team and the client side are obtained to confirm attendance and participation.</p> <p><b>Instruction:</b></p> <p>Guidelines for conducting opening and closing meetings are provided in <b>Form F-09 (Opening &amp; Closing Meeting Format cum Attendance Sheet)</b>. Attendance of all participants shall be recorded in the same format (F-09).</p>
<b>6.2</b>	<p><b>Conducting Stage-1 Audit</b></p> <p>The Stage-1 audit is initiated with an overview visit of the organization's physical facilities to understand the operational environment and scope of activities.</p> <p>The audit is conducted through a combination of document review, interviews with relevant personnel, and on-site observations. The primary objective of the Stage-1 audit is to assess the readiness of the client's Management System (MS) for the Stage-2 certification audit. During this process, potential gaps or issues that</p>

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	<p>could be raised as major non-conformities during the Stage-2 audit are identified.</p> <p>Audit findings are recorded by the auditor(s) in the audit checklist and/or audit reporting format, supported by notes maintained in the Auditor's Rough Sheet. Any inadequacies observed during the audit are communicated to the auditee in a clear and timely manner.</p> <p>Non-conformities and/or concerns identified during the Stage-1 audit are documented and communicated to the auditee through the Stage-1 Audit Report. A separate Non-Conformity (NC) format is not required at this stage.</p>
<b>6.3</b>	<p><b>Closing Meeting and Post Stage-1 Audit Activities</b></p> <p>During the closing meeting, the client is formally thanked for their cooperation, transparency, and hospitality extended to the audit team. The audit team communicates its conclusion regarding the recommendation or non-recommendation for proceeding to the Stage-2 (final certification) audit.</p> <p>Following the closure of the audit, all identified non-conformities (NCs) and/or inadequacies are finalized and documented. The client's authorized representative is requested to acknowledge these findings. The client is further advised to notify ASPL upon closure of the identified NCs, so that planning for the Stage-2 certification audit can be initiated.</p> <p>Signatures of all participants are obtained on the Audit Attendance Sheet, as per <b>Form F-09 (Opening &amp; Closing Meeting Format cum Attendance Sheet)</b>. Additionally, client feedback on the performance of the audit team is collected using <b>Form F-12 (Client Feedback Form)</b>.</p> <p>A copy of the Stage-1 Audit Report is provided to the client in format <b>F-43 Stage 1 Audit report format</b>, along with relevant management system Checklist. The Stage-2 audit process shall only be initiated upon receipt of confirmation from the client regarding closure of the identified gaps and areas of concern, which may otherwise be raised as non-conformities during the Stage-2 audit.</p> <p><b>Note:</b> Collection of auditor feedback is not mandatory for every audit; however, it shall be conducted on a random basis as per ASPL requirements.</p> <p>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 ASPL 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 ASPL office.</p>
<b>7</b>	<b>Stage- 2 Audit</b>
<b>7.1</b>	After receiving conformation from client about the closing of concen/ NC found during the stage one, ASPL Initiate the Stage -2 Audit.
<b>7.2</b>	<b>Stage II Audit objective:</b> Stage II audit is conducted to assess conformity of the client's MS to the audit standard (ISO 9001:2015 & ISO 13485:2016 or other MS). 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.
<b>7.3</b>	<p><b>Communication with Client (Stage-2 Audit Planning):-</b></p> <p>ASPL identifies and nominates authorized auditor(s) from the approved competency list based on the scope and requirements of the audit. The selected auditor(s) are formally nominated, and a declaration of impartiality and confidentiality is obtained using <b>Form F-05 (Auditor Nomination and Declaration for Confidentiality &amp; Impartiality)</b>.</p> <p>Subsequently, the Quality Manager/Auditor prepares the audit plan in <b>Form F-07 (Audit Plan – Stage-2)</b>. The client is informed about the proposed audit team at least 3–4 days prior to the scheduled audit date, allowing sufficient time for the client to raise any concerns or objections (assent or dissent) regarding the audit team composition.</p> <p>The availability of the nominated auditors is confirmed, and the audit plan is shared with the client organization for review and approval, particularly to confirm audit timings and ensure the availability of relevant personnel and resources.</p> <p>In the case of multi-site audits, a sampling plan is developed in accordance with the client's specific operational structure and applicable requirements. The audit is then planned accordingly.</p> <p>Upon receipt of formal acceptance of the audit plan from the client, the Stage-2 audit is scheduled and</p>

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	conducted.
<b>7.4</b>	<p><b>Opening Meeting:</b> - 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 &amp; declaration of confidentiality.</p> <p>Audit instructions are also available in the stage-2 audit reporting format. Opening and closing meeting instruction is given in “F-09 Opening &amp; Closing meeting Format cum Attendances sheet” Take opening meeting attendances in Format F-09.</p>
<b>7.5</b>	<p><b>Conducting Stage-II Audit</b> The Stage-II audit is conducted to evaluate the implementation and effectiveness of the client’s management system. It shall include, at a minimum, the following:</p> <ul style="list-style-type: none"> <li>• Verification of information and objective evidence demonstrating conformity to all requirements of the applicable management system standard or other normative documents.</li> <li>• Evaluation of performance monitoring, measurement, reporting, and review against key performance objectives and targets.</li> <li>• Assessment of the client’s compliance with applicable legal and other regulatory requirements.</li> <li>• Review of operational control procedures for key processes.</li> <li>• Evaluation of internal audit and management review processes.</li> <li>• Assessment of top management commitment, responsibilities, and alignment with organizational policies.</li> </ul> <p>The audit team shall use <b>Form F-44 (Stage-II Audit Report Format)</b> along with the <b>relevant Management System (MS) checklist</b> for conducting and recording the audit.</p> <p><b>Audit Sampling</b> During the Stage-II audit, the audit team shall select appropriate samples to obtain sufficient audit evidence covering all products, services, processes, and activities within the defined scope of the management system. The sampling shall ensure adequate coverage to determine conformity with the applicable standards and the client’s documented system.</p> <p><b>Audit Information Collection</b> Audit evidence is gathered through:</p> <ul style="list-style-type: none"> <li>• On-site observation of processes and activities</li> <li>• Interviews with relevant personnel</li> <li>• Review of applicable documents and records</li> </ul> <p>Where required, the audit team may also consider relevant information from external sources within the defined audit scope. All objective evidence of conformity and non-conformity shall be accurately recorded in audit notes/rough sheets. The audit team shall ensure that the evidence is sufficient, verifiable, and defensible.</p> <p><b>Communication within the Audit Team</b> The Audit Team Leader and team members shall maintain continuous communication to review audit progress and share audit findings. Based on emerging information, the Audit Team Leader may revise the audit plan and reassign responsibilities, while ensuring that the audit remains within the defined scope.</p> <p><b>Communication with the Client</b> During the audit, if the audit team determines that audit objectives cannot be achieved due to significant deficiencies in the management system or due to safety concerns, the Audit Team Leader shall inform the client in a professional manner. In such cases, the audit may be suspended or terminated, and the matter shall be reported to ASPL for further decision.</p>

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<b>7.6</b>	<p><b>Closing meeting</b></p> <p><b>Communication During Closing Meeting</b>  During the closing meeting, the Audit Team Leader shall:</p> <ul style="list-style-type: none"> <li>• Use form ASPL-F09 opening &amp; Closing meeting Format cum Attendances sheet” and discussed all point as per given in format and take attendance.</li> <li>• Present a summary of audit findings (NCs, observations, OFIs).</li> <li>• Clarify that the audit was conducted on a sampling basis.</li> <li>• Explain the types of non-conformities identified and agreed timelines for closure.</li> <li>• Describe the process for submission and verification of corrective actions.</li> <li>• Inform about the consequences of non-closure of NCs on certification decisions.</li> <li>• Explain the procedure for lodging complaints and appeals.</li> <li>• Outline post-audit activities, including verification of corrective actions, preparation of audit report, and review by technical committee/decision-makers.</li> <li>• In case of recommendation for certification, explain surveillance audits, certificate validity, and recertification requirements.</li> </ul> <p><b>Classification of non-conformities</b>  The Audit Team Leader, along with team members, classifies the identified non-conformities (NCs) and communicates the timelines for closure to the client:</p> <p><b>I. Major Non-Conformity</b></p> <ul style="list-style-type: none"> <li>• A serious non-compliance with significant impact on product/service quality or management system effectiveness.</li> <li>• Multiple minor NCs indicating systemic failure may be treated as a major NC.</li> <li>• Must be corrected and closed within 6 Months.</li> <li>• Verification is generally conducted through an on-site follow-up audit; however, legal non-compliances may be verified through documentary evidence.</li> <li>• Certification shall proceed only after satisfactory closure.</li> </ul> <p><b>II. Minor Non-Conformity</b></p> <ul style="list-style-type: none"> <li>• A less severe non-compliance not significantly affecting product/service quality.</li> <li>• To be closed within <b>60 days</b> through submission of corrective action evidence.</li> <li>• Verification may be carried out through document review or during subsequent surveillance audits, as applicable.</li> </ul> <p><b>III. Observation</b></p> <ul style="list-style-type: none"> <li>• An isolated lapse not indicating failure of the management system.</li> <li>• Requires submission of corrective action plan or evidence and should be addressed to prevent escalation into non-conformity.</li> </ul> <p><b>IV. Opportunity for Improvement (OFI)</b></p> <ul style="list-style-type: none"> <li>• Not a non-compliance.</li> <li>• Represents areas for potential improvement and value addition recommended by the audit team.</li> </ul> <p><b>Documentation and Communication of Findings</b>  All NCs, observations, and OFIs are documented, classified, and acknowledged by the client’s authorized representative during the closing meeting.  The findings are issued to the client in <b>Form F-10 (Audit Finding Action Report)</b> within <b>15 days</b> of completion of the audit.  In case of any disagreement regarding NCs or unresolved issues during the closing meeting, the Audit Team Leader shall record the same in the audit report and inform ASPL. Such cases shall be reviewed by ASPL along with an authorized auditor or technical expert, and the final decision shall be communicated to the client.  Certification shall not be granted until all non-conformities are satisfactorily closed. However, minor NCs requiring long-term verification may be reviewed during surveillance audits, subject to acceptance of corrective actions.  The client is also informed that a summary of the audit report, along with the documented audit results, will be shared after completion of the audit process.</p>
<b>8</b>	<p><b>Effectiveness of corrections and corrective actions:</b> - The certification body/ competent auditor reviews the</p>

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	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.
<b>9</b>	<p><b>Technical Review of Audit Report and Certification Decision</b></p> <p>The technical review of the audit report and certification decision shall be carried out using the prescribed format <b>F-11 Certificate Issue Checklist – Decision Making Sheet</b>.</p> <p>The Quality Manager shall identify and assign a competent report reviewer from the approved list of auditors, ensuring that the reviewer belongs to the same technical code/cluster. Where required, a reviewer from a different code may be assigned with the support of a qualified technical expert to ensure adequacy of technical evaluation.</p> <p>The designated reviewer shall conduct a comprehensive technical review of the audit report to verify:</p> <ul style="list-style-type: none"> <li>• Completeness and accuracy of audit findings</li> <li>• Adequacy of objective evidence</li> <li>• Correct classification of nonconformities</li> <li>• Compliance with applicable standards and certification requirements</li> </ul> <p>Upon successful completion of the technical review, the case shall be forwarded to the Certification Decision-Making Committee.</p> <p>The Certification Decision-Making Committee (Same cluster Auditor + QM + with or without MD) shall independently evaluate the audit report and review findings, and take the final decision regarding:</p> <ul style="list-style-type: none"> <li>• Granting of certification</li> <li>• Refusal of certification</li> <li>• Suspension of certification</li> <li>• Extension or reduction of scope of certification</li> </ul> <p>All certification decisions shall be made impartially and in accordance with established procedures and applicable accreditation requirements.</p>
<b>10</b>	<p><b>Issue of Certificate</b></p> <p>Based on the decision of the Certification Decision Committee, the Management System Certificate shall be issued to the client.</p> <p>The certificate shall be duly signed by the Managing Director and/or Quality Manager of ASPL.</p> <p>Acceptance of the use of the certification mark shall be obtained from the auditee at the time of certificate issuance.</p> <p>Furthermore, the issued certificate shall be uploaded on the IAF portal within 15 working days by the Quality Manager.</p>
<b>11</b>	<b>Submission of report:</b> Report in detail along with objective evidence is submitted to the Quality manager of ASPL, 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.
<b>12</b>	<b>Follow up audit:</b> In case where nonconformity 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.
<b>13</b>	<b>Extensions to scope:</b> ASPL 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.
<b>14</b>	<b>Surveillance Audit:</b> 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.

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<b>15</b>	<p><b>Re-Certification audit:</b> 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 recertification audit conformity to all clauses of the audit standard is verified.</p>
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<b>16</b>	<p><b>Unannounced Audit</b>  ASPL may conduct unannounced audits in cases where serious complaints or adverse information are received from the market, clients of the certified organization, or other credible sources. Such audits may also be initiated in the event of serious incidents/accidents, or as required by applicable management system standards or regulatory authorities.  Unannounced audits are carried out without prior notice to the client and are conducted in accordance with ASPL’s established procedures and applicable requirements.</p>
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<p><b>Reference:</b> Audit standard ISO 9001:2015 &amp; ISO 13485:2016 for Management System  <b>Note:</b> Where MS has written – It Means all the Management System Applied i.e. (QMS, MD QMS, FSMS, EMS, OH&amp;MS, EnMS, ISMS etc)  <b>Records:</b> Audit pack/Audit file forms</p>
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