

<b>RAPL</b>	<b>ROYAL ASSESSMENTS PVT. LTD.</b>	PR/04.01
	<b>Procedure for Certification &amp; Audits (Stage I &amp; II)</b>	04/02/2021

## 1.0 OBJECTIVE

- Define the requirements for Certification, Stage I & Stage II audit
- Process steps and reporting
- Criteria for issue of certificate of compliance and conditions
- Maintain records
- Multisite Auditing (As per IAF MD1:2018)
- Remote auditing (As per IAF MD4:2018)

## 2.0 SCOPE

Certification Audits for client certification as per applicable international standard.

## 3.0 RESPONSIBILITY: Director (Technical) / MR

## 4.0 Definition and Purpose

<b>Document Review</b>	Verify adequacy of the management system documents to the relevant contractual standard including any exclusion. Document review will be conducted on site along with Stage I audit or off site
<b>Stage I audit Identification: Stage I</b>	Verify the following <ul style="list-style-type: none"> <li>• Clients' management system documentations</li> <li>• Evaluate client's location and site-specific condition</li> <li>• Verify client's preparedness for Stage II audit</li> <li>• Review client status and understanding regarding the requirements of the standard</li> <li>• Collect information regarding scope, processes, statutory and regulatory requirements and exclusions claimed etc.</li> <li>• Review the allocation of resources/ logistics for stage II audit</li> <li>• Internal audit and Management Review are planned and performed</li> <li>• Identify concerns if any in the planning of management system</li> </ul>
<b>Stage II Audit Identification: Stage II</b>	Verify the following: <ul style="list-style-type: none"> <li>• Compliance to contractual standards, documented system, statutory and regulatory requirements.</li> <li>• Effective implementation of the planned management system</li> <li>• Management commitment</li> <li>• Awareness of the system across the organization</li> <li>• Acceptance of the management system for Recommendation for issue of certificate of compliance with / without conditions or otherwise.</li> </ul>
<b>Follow up audit Identification: FA</b>	Follow up audit is recommended when it is considered that a site verification is required to verify the corrective actions for the non-conformances recorded during any audit.  Verify the following

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	<ul style="list-style-type: none"> <li>• Effectiveness of the Corrective action taken for the non-conformances identified during the base assessment.</li> <li>• Revision to the system documents if any</li> </ul>
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## 5.0 Assessment Process

Sl.	Process Step
5.1	<p>Initial audit shall be planned in two stages.</p> <p>Upon confirmation of the contract by the client and issue of contract number as per procedure RAPL coordinate for the proposed date for conducting stage I audit. In case it is deemed necessary for offsite document review, coordinate for submission of the following documents for the adequacy audit.</p> <ul style="list-style-type: none"> <li>• Quality Manual</li> </ul> <p>Documents should be submitted at least two weeks prior to the planned stage I audit.</p>
5.2	<p><b>Document Review</b></p> <p>Document review shall be conducted by RAPL qualified lead Auditor during stage I audit/ offsite document review. Assistance of technical expert and / or technical guidance notes may be taken, if required. Submitted management system documents are reviewed with respected to:</p> <ul style="list-style-type: none"> <li>• Adequacy of requirements of applied standard</li> <li>• Statutory requirements for the product as applicable</li> <li>• Manufacturing process</li> <li>• Exclusion of with justification</li> <li>• Justification for exclusion for any of the process (es) shall be reviewed considering following guidelines: <ul style="list-style-type: none"> <li>• Liability of the client for the specific clause for which exclusion has been claimed.</li> <li>• Providing design drawings, specifications, standards or other working documents essential for the manufacture of the product under the scope of certification by the customer without any liability for the design and development</li> <li>• Production as per the applicable product catalogue / national/ international standards provided there is no further requirement for design and development essential for the delivery of product / services</li> <li>• If there is any additional requirement for application of design and development concepts for provision of delivery of product/ services like selection of suitable pump and / or motor model for a specific application, no exclusion shall be accepted</li> <li>• Exclusion for process validation shall not be accepted unless otherwise there is a detailed description of the process and subsequent capability to inspect the products. Exclusion for process validation for processes like welding, heat treatment, chemical processes shall not be accepted</li> <li>• One time validation for setting of the dies shall be considered as process validation.</li> <li>• Fabrication of equipments like pressure vessels to a specific standard like American Society for Mechanical Engineers shall not be considered for exclusion as design competence for a specific configuration required.</li> <li>• Manufacture of basic chemicals/ pharmaceuticals based upon known formulations can be considered for exclusion unless the manufacturer is not</li> </ul> </li> </ul>

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	<p>revising the formulations. Source of formulations shall be verified during the compliance audit to accept any justification for exclusion.</p> <ul style="list-style-type: none"> <li>In case of changes to the original specification taken from an outside source when claiming exclusion, acceptance of justification for the complete clause of 8.3 of ISO 9001 shall be reviewed as only part of the clause of design changes may be applicable.</li> </ul> <p>Above considerations shall be reviewed by the audit team prior to acceptance of the exclusion. If there is evidence that a particular clause is applicable to the maximum extent, exclusion shall not be granted.</p> <p>Exclusion for any clause shall be verified during every surveillance and excluded clause is being implemented in any of the contracts, same shall not be accepted unless included in the QMS and implementation verified.</p> <p>Document review comments shall be forwarded (in case it is conducted off site) to client indicating:</p> <ul style="list-style-type: none"> <li>Nature of the comments</li> <li>Request for response to document review comments</li> <li>Proposed date for stage I audit, if the comments are acceptable with/ without comments.</li> </ul> <p>If the submitted documents are not acceptable for any reason, same shall be informed to the client and request for resubmission after making necessary revision to the documents.</p> <p>If the document review is conducted on site, comments shall be recorded in the observation sheet of assessment report and communicated to the client during stage I audit.</p> <p>Corrective action for the document review comments shall be reviewed by the lead auditor prior to stage II audit.</p>
<b>5.3</b>	<b>Audit team selection</b>
	<p>Upon decision on the feasibility of the audit based upon the information provided by client in client information for certification and review by RAPL, audit team comprising team leader and audit team members is assigned for each assignment. If the audit team consists of one auditor, all responsibilities including the lead auditor responsibilities shall be taken by the nominated auditor.</p> <p>Following are the criteria for audit team selection of size and composition.</p> <ol style="list-style-type: none"> <li>Audit objectives, scope, criteria and estimated duration of the audit. Number of audit team members depending upon the number of audit man days. Total number of audit man days not exceed 5 working days.</li> <li>Combined or joint audit</li> <li>Overall competence of the audit team needed to achieve the objectives of the audit. Audit team members shall be competent as per procedure audit team competency (PR/01).</li> <li>Applicable statutory, regulatory, contractual and accreditation/ certification requirement.</li> <li>Independence and conflict of interest of auditors/ Technical Experts.</li> </ol>

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	<p>f. Audit team ability to interact effectively with the auditee and work together.</p> <p>g. Language of the audit, Auditee's social and cultural characteristics. Support of required external experts may be considered, if required.</p> <p>h. Technical expert may be selected considering the criticality of the scope and audit criteria.</p> <p>i. Knowledge and skill to achieve the objective of the audit and ensuring the total competence of audit team including provision for technical expert, if required. Technical experts shall not participate in the audit and work under the guidelines of the auditor. Client may request for replacement of any audit team member and/ or technical expert for a specific cause and sound evidence. MD shall review such request from client and take appropriate action.</p>
<b>5.4</b>	<p>Stage I audit shall be conducted provided:</p> <ol style="list-style-type: none"> <li>I. Client has implemented the system for a period of 3 months</li> <li>II. Conducted one internal audit and one management review.</li> </ol>
<b>5.5</b>	<b>Audit Program for Stage I Audit</b>
	<p>Upon confirmation of the audit schedule by the client and acceptance of the schedule subject to considerations in 5.4 above audit programme is planned for stage I audit by Lead Auditor.</p> <ol style="list-style-type: none"> <li>I. Audit programme, is completed and forwarded to client with copy to audit team.</li> <li>II. If any of the auditor / technical expert has conflict of interest with the organization, client is given an opportunity to request for a change in the audit team composition.</li> </ol>
<b>5.6</b>	<b>Audit Pack – Stage I</b>
	<p>Audit pack comprising following documents shall be forwarded to the lead auditor.</p> <ol style="list-style-type: none"> <li>I. Document Review Report</li> <li>II. Assessment report of Stage I audit</li> <li>III. Observation report Stage audit</li> <li>IV. Audit Programme</li> <li>V. Opening Meeting Prompter</li> <li>VI. Attendance Sheet</li> <li>VII. Stage I Audit report</li> <li>VIII. Closing Meeting Prompter</li> </ol> <p>Logistics arrangements are coordinated by lead auditor and communicated to the client vide audit programme</p>
<b>5.7</b>	<b>Stage I audit:</b>
	<p>Stage I audit is carried out by a competent auditor for a specific number of man day(s) to verify:</p> <ul style="list-style-type: none"> <li>• Clients’ management system documentations</li> <li>• Evaluate client’s location and site-specific condition</li> <li>• Verify client’s preparedness for Stage II audit</li> <li>• Review client status and understanding regarding the requirements of the standard</li> <li>• Collect information regarding scope, processes, statutory and regulatory requirements, and exclusions claimed etc.</li> <li>• Review the allocation of resources for stage II audit</li> <li>• Audit of top management, internal audit and Management Review are planned and performed.</li> </ul>

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	<p>Audit is carried out using the ISO 9001: 2008 standard &amp; Check schedule.</p> <ol style="list-style-type: none"> <li>I. Opening meeting is conducted by Lead Auditor and is held with the client representatives: <ul style="list-style-type: none"> <li>▶ Discuss each of the point as per opening meeting prompter to enable the client to understand the audit process and reporting method. Lead auditor shall clarify any issues raised by client representatives.</li> <li>▶ Attendance sheet is completed by all personnel present in the opening meeting.</li> </ul> </li> <li>II. Plant visit is completed along with audit team member(s) to: <ol style="list-style-type: none"> <li>a. Understand the locations of various functions and physical location.</li> <li>b. Brief on the infrastructure and processes.</li> <li>c. Assess changes to the audit programme, if required</li> </ol> </li> <li>III. Lead Auditor to have discussions with audit team members and technical expert if used.</li> </ol> <p>Area's of concerns are recorded as observations and communicated to the client along with the assessment report. Audit team shall complete the assessment report (QMS for stage I). Lead Auditor shall complete the assessment report in all respects as required providing complete description of the organization for Planning the resources / logistics for stage II audit.</p> <ul style="list-style-type: none"> <li>▶ Lead auditor shall review the acceptance of the scope of certification. Scope of certification shall be confirmed with the client management.</li> <li>▶ Recommendation shall be indicated in the assessment report based on following consideration. <ul style="list-style-type: none"> <li>▶ Recommended for stage II Audit <ul style="list-style-type: none"> <li>• When there is no Observations</li> </ul> </li> <li>▶ Recommended for stage II Audit subject to action on Observation <ul style="list-style-type: none"> <li>• When Observations are recorded</li> </ul> </li> </ul> </li> </ul> <p>Closing meeting is conducted to communicate to the client on the audit team observations. Lead Auditor shall chair the closing meeting and discuss all requirements of closing meeting prompter.</p> <p>Details of each observation are discussed during the closing meeting and clarify any clarification requested by client representatives. Attendance sheet is completed by all the personnel present in the closing meeting. Lead auditor shall give recommendations as agreed in the audit team meeting and agree on a time frame for corrective action or follow up audit or reassessment as applicable. Lead auditor to get concurrence of client representative for each observation and copy of all observations are given to the client organization. Lead auditor to keep the original copy of the observation.</p> <p>Lead Auditor to sign the Stage I Assessment report and get concurrence of the client representative. Original copy of the assessment report is given to the client organization.</p>
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	<p>Client Feed back report on the assessment is obtained. Action on all Observations shall be taken by client and submitted to RAPL. Stage II audit shall be planned only after satisfactory completion of actions. Client is informed that any ineffective action on the observations may lead to non- conformities during stage II audit.</p> <p>Information gathered during the stage I is used for further audit planning. Lead Auditor shall review the audit pack for completeness and forward to RAPL corporate office within 3 working days.</p>
<b>5.8</b>	<b>Audit Planning for Stage II audit</b>
	<p>While preparing Stage II audit plan, RAPL secretariat shall take advice from Stage I assessor in order to adequately address all processes / functions and applicable clauses. Plan shall be prepared after closure of stage I finding. Time interval between stage I and stage II depend upon the nature of observation and time frame required by the client to resolve all the identified observation during stage I audit. Proposed stage II audit schedule indicated in the stage I assessment report may be revised as required. <u>In case the audit team is different as that of stage I audit, reports such as assessment report, non conformities recorded if any and checklist of stage I audit is provided to lead auditor for the review and follow up in stage II audit.</u></p> <p>Stage II audit shall be scheduled upon confirmation of the audit by client. Audit plan shall be forwarded to client with following details and consent obtained:</p> <ol style="list-style-type: none"> <li>1. Organization name and audit site address</li> <li>2. Size of the organization</li> <li>3. Scope of certification.</li> <li>4. Audit objective.</li> <li>5. Results of previous audits if any</li> <li>6. Proposed number of audit man days during contact review</li> <li>7. Auditor wise details of the processes (functions / departments) to be audited during stage 2 (Input to be taken from stage 1 audit)</li> <li>8. Assignment of auditor for each process based upon the competence of auditors and technical experts.</li> <li>9. Size of the audit team shall be such that audit duration will not exceed a maximum of 5 working days.</li> <li>10. Conflict of interest of the audit team</li> <li>11. Copy of audit plan to be forwarded to client with copy to audit team.</li> <li>12. If any of the auditor/ technical expert has conflict of interest with the organization, client is given an opportunity to request for a change in the audit team composition.</li> <li>13. Plan for multisite certification assessment shall be made as per provisions of IAF MD1:2018.</li> <li>14. If the audit is being conducted remotely using ICT the RAPL shall document in plan about how and to what extent ICT will be used with consideration given to the risks and opportunities. Audit plan shall address process wise use of ICT methodology to optimise audit effectiveness and efficiency while maintaining the integrity of the audit process (Refer Audit Plan Form – F/30)</li> </ol>
<b>5.9</b>	<b>Audit Pack – Stage II</b>
	<p>Audit pack comprising following documents shall be forwarded to the lead auditor:</p> <ol style="list-style-type: none"> <li>1. Audit report of Stage I audit</li> </ol>

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	<ol style="list-style-type: none"> <li>2. Observation report of stage I audit if any</li> <li>3. Audit Programme</li> <li>4. Opening Meeting prompter</li> <li>5. Attendance sheet</li> <li>6. Non-Conformance Report</li> <li>7. Closing Meeting Prompter</li> <li>8. Client Feed Back</li> <li>9. Surveillance Audit Programme</li> <li>10. Technical Expert Report, if applicable</li> </ol> <p>Logistics arrangements are coordinated by client in communication with audit team.</p>
<b>5.10</b>	<b>Stage II Audit</b>
	<p>Stage II audit is conducted <u>onsite</u> to evaluate the implementation, including, effectiveness, of the client's management system and shall cover the following as minimum</p> <ol style="list-style-type: none"> <li>1. Information and evidence about conformity to all requirements to the applicable management standard and normative document.</li> <li>2. Performance monitoring, measuring, reporting and reviewing against key performance objective and targets.</li> <li>3. Client's management system and performance as regards to applicable legal compliance.</li> <li>4. Operational control of the client's processes.</li> <li>5. Internal Auditing and Management Review.</li> <li>6. Management responsibility for the client's policies.</li> <li>7. Links between the normative documents, policy, performance objectives and targets, any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusion.</li> </ol> <p><b>Audit Steps</b></p> <ul style="list-style-type: none"> <li>➤ Stage II audit is conducted as per the audit programme</li> <li>➤ Opening meeting is conducted by lead Auditor and is held with the client representatives: <ul style="list-style-type: none"> <li>○ Discuss each of the point as per opening meeting prompter to enable the client to understand the audit process and reporting method. Lead auditor shall clarify any issues raised by client representatives.</li> <li>○ Attendance sheet is completed by all personnel present in the opening meeting.</li> </ul> </li> <li>➤ Lead Auditor to have discussions with audit team members and technical expert if used.</li> <li>➤ Technical expert shall accompany the auditor conducting audit of Design and Development and Product / Service provision &amp; Inspection and testing if used. Other auditors can take assistance of technical expert for any clarification on the technical requirements</li> <li>➤ Discuss the organization structure and document review comments</li> <li>➤ Audits meeting schedule</li> </ul>
<b>5.11</b>	<b>Audit Approach</b>
	<p>Stage II audit is carried out as per the audit programme and using the compliance audit check list. Process approach audit shall be conducted with focus on:</p>

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	<p>a. Selecting sample for each of the product / services covered in the scope of assessment</p> <p>b. Selecting samples in each of the function considering the criticality, complexity and lot size</p> <p>c. Interviewing personnel in each of the function to evaluate the awareness of the planned arrangements, policy, improvement areas and effectiveness of implementation.</p> <p>d. Review records as referred in the planned management system documents</p> <p>e. Verify exclusion of any clause to justify acceptance</p> <p>f. Lead Auditor shall brief the client organization at the end of every day on any major observation, adherence to audit programme and any other issues of importance.</p> <p>g. Make audit notes in the check list providing adequate following minimum details to enable certification decision committee to get an understanding of the implementation and depth of audit and accept the audit team recommendations.</p> <ul style="list-style-type: none"> <li>○ Function audited</li> <li>○ Auditee representative name</li> <li>○ Number of persons working in each function including repetitive nature of jobs</li> <li>○ Reference of documents verified</li> <li>○ Number of samples and their identification</li> <li>○ Objective evidence to support any non-conformance like instrument number, purchase order number, etc.</li> <li>○ Non-conformance from the planned arrangement and classification of the non-conformance as major/ minor with justification. Number the non-conformances as per the non-conformance report for easy traceability.</li> </ul> <p>h. Lead Auditor shall discuss with team members prior to the closing meeting to :</p> <ul style="list-style-type: none"> <li>▶ Understand the positive and negative observations of each auditor.</li> <li>▶ Scope of certificate and any revision, if required. Revision to the scope of certification shall be discussed with client management.</li> <li>▶ Classify non-conformances as major or minor.</li> </ul> <p>i. (IAF MD22:2018 Clause G 9.4.4.2) For ISO 45001:2018 audits, the audit team shall interview the following personnel:</p> <ul style="list-style-type: none"> <li>i) the management with legal responsibility for OH&amp;S,</li> <li>ii) employees' representative(s) with responsibility for OH&amp;S,</li> <li>iii) personnel responsible for monitoring employees' health, for example, doctors and nurses. Justifications in case of interviews conducted remotely shall be recorded,</li> <li>iv) managers and permanent and temporary employees.</li> </ul> <p>Other personnel that should be considered for interview are:</p> <ul style="list-style-type: none"> <li>i) managers and employees performing activities related to the prevention of Occupational Health and Safety risks, and</li> <li>ii) contractors' management and employees.</li> </ul>
<b>5.12</b>	<b>Non-Conformance (NCR)</b>
	Product, Process and system not meeting the planned arrangements are considered as non-conformances. Non-conformances are classified as major or minor based on the



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	<p>following criteria.</p> <ul style="list-style-type: none"> <li>▶ <b>(A) Major Non-Conformance</b> <ul style="list-style-type: none"> <li>○ Implementation not effective</li> <li>○ Not meeting statutory/ regulatory requirements</li> <li>○ Not taking corrective actions for the previous NCRs</li> <li>○ Respective minor non-conformances of similar nature across the organization/ across the sites sampled.</li> <li>○ Number of defective samples is more than 50% of total samples size.</li> </ul> </li> <li>▶ <b>(B) Minor Non-Conformance</b> <ul style="list-style-type: none"> <li>○ Evidence of implementation observed except isolated cases</li> <li>○ Defective samples less than 50% of total sample size considered for audit.</li> </ul> </li> <li>▶ <b>(C) Identification of Non-Conformances</b> <ul style="list-style-type: none"> <li>▶ One NCR shall be raised for each clause of standard where non confirming situation is observed. If there are similar NCRs in different functions, one combined NCR may be raised providing objective evidence from each function.</li> <li>▶ Audit team shall compile the observations of each audit team member and their findings from different functions. NCRs are recorded in Non-conformance Report Respective auditors shall sign the NCRs recorded by them and initialed by lead auditor.</li> <li>▶ Client shall review the applicability of NCR to single site or multiple sites in case multi site organizations.</li> </ul> </li> <li>▶ <b>(D) (IAF MD22:2018 Clause G 9.4.5.3)</b> – If during the course of audit, RAPL’s audit team discovers a non-compliance with relevant regulatory requirements, it shall be classified as major non-conformity. The same shall be immediately communicated to the organization being audited.</li> </ul>
<b>5.13</b>	<b>Assessment Report</b>
	<p>Audit team shall complete the assessment report for stage II audit. Lead Auditor shall complete the assessment report in all respects as required providing complete description and justification for the recommendation adequate for the certification decision committee to decide on the acceptance of the report and issue of certificate of compliance. While making the recommendation, lead auditor shall also consider stage I audit outcome/ findings and its satisfactory closing.</p> <ul style="list-style-type: none"> <li>▶ Recommendation for certification shall be indicated in the assessment report based on following guidelines.</li> </ul> <p>Stage II Audit</p> <ul style="list-style-type: none"> <li>▶ Recommended for certification in case of no NCR.</li> <li>▶ Recommended for certification with corrective action, corrective action plan, if any non-conformances are recorded. Lead auditor shall review whether corrective actions for the recorded NCRs can be verified by review of documents or follow up audit.</li> </ul> <p>a. If follow up audit is recommended, lead auditor to decide on the duration of</p>

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	<p>the follow up audit. In case of major NCR's in other functions, requirement for follow up audit is decided by the lead auditor with justification. Follow up audit shall be conducted within 90 working days to verify corrective actions for effectiveness for the NCR raised during the audit which prompted follow up audit, if the follow up audit is not conducted within 90 working days, unless otherwise agreed by RAPL HO, a complete audit shall be conducted. Additional samples may be taken to ensure the effectiveness of corrective action. For conducting follow up audit, lead auditor shall coordinate with the client and agree for the audit date with information to RAPL HO.</p> <p>b. If follow up audit is not considered, client shall be requested to provide documentary evidence of corrective action within an agreed time frame.</p> <p>Normally, time period for submission of corrective action is 10 days and evidence of implementation of corrective action is 20 days from the date of closing meeting.</p> <p>In case of OHSAS, if a member of the audit team, in their professional judgment, discovers a breach of an Act of Parliament or a contravention of a regulatory requirement it should be treated as an immediate threat to OHS. Any breach or contravention shall be recognized as nonconformity as soon as predicted and shall be communicated to client. Further, if above situation or any other nonconformity poses an immediate threat to OHS, then RAPL shall suspend the audit until the risk is removed or significantly reduced. In such cases the time allowed shall be promptly and independently reviewed by the RAPL.</p> <ul style="list-style-type: none"> <li>▶ Not recommended for certification, if there is no evidence of effective implementation, a complete reassessment shall be planned to evaluate compliance with planned arrangements.</li> </ul>
<b>5.14</b>	<b>Closing Meeting</b>
	<p><b>5.14 A</b> - Closing meeting is conducted to communicate to the client on the audit team observations and evidence of implementation and areas of non-compliance with planned arrangements.</p> <p>Lead Auditor shall chair the closing meeting and discuss all requirements of closing meeting prompter. Details of each NCR are discussed during the closing meeting and clarify any clarification requested by client representatives. Attendance sheet is completed by all the personnel present in the closing meeting.</p> <p>Lead auditor shall give recommendations as agreed in the audit team meeting and agree on a time frame for corrective action or follow up audit or reassessment as applicable.</p> <p><b>5.14 B</b> - Lead auditor to get concurrence of client representative for each NCR and original of all NCRs are given to the client organization. <u>Lead auditor to keep the copy of the NCRs and request the organization to submit the corrective action in original.</u></p> <p><b>5.14 C</b> - Lead Auditor to sign the Audit report and get concurrence of the client representative. Original copy of the assessment report is given to the client organization. <u>Copy of the assessment report with recommendation shall be submitted to RAPL HO</u></p>

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	<p><u>along with the audit pack.</u></p> <p><b>5.14 D</b> - Client Feedback report on the assessment is obtained.</p> <p><b>5.14 E (IAF MD22:2018 Clause G 9.4.7.1)</b> - The organization representative shall be requested to invite the management legally responsible for occupational health and safety, personnel responsible for monitoring employees' health and the employees' representative(s) with responsibility for occupational health and safety to attend the closing meeting. Justification in case of absence shall be recorded.</p>
<b>5.15</b>	<b>Surveillance Audit Programme</b>
	<p>Lead Auditor to complete the Surveillance audit programme for the complete period of certification based on :</p> <ul style="list-style-type: none"> <li>▶ Criticality of the process in the organization</li> <li>▶ Areas of improvement identified</li> <li>▶ Audit all the process at least once during the certification period.</li> <li>▶ Following processes are audited during each surveillance audit. <ul style="list-style-type: none"> <li>○ Document and Data Control</li> <li>○ Control of records</li> <li>○ Internal audit</li> <li>○ Management Review</li> <li>○ Corrective and Preventive action</li> <li>○ Continual improvement</li> </ul> </li> <li>▶ Audit programme shall be reviewed at each subsequent audit for suitable. Surveillance program can be updated if any change is required for subsequent audit.</li> </ul>
<b>5.16</b>	<b>Completed Audit Pack:</b>
	Lead Auditor shall review the audit pack for completeness and forward to RAPL corporate office within 3 working days.
<b>5.17</b>	<b>Review of corrective action response</b>
	<p>Client is responsible of forwarding corrective actions RAPL within 10 days. Upon receipt of planned correction / corrective action, lead auditor shall review considering:</p> <ul style="list-style-type: none"> <li>○ Proper correction/ corrective action has been planned / taken by the client to address the identified non-conformances</li> <li>○ Necessary document as evidence has been submitted for review.</li> </ul> <p style="text-align: center;"><b>or</b></p> <ul style="list-style-type: none"> <li>▶ If the follow up is recommended RAPL shall coordinate with the client for the follow up audit. In case of multi site, audit shall cover central office and affected sites as minimum. Audit pack comprising the following documents shall be forwarded to the Lead Auditor. Lead Auditor for the follow up audit shall be the same auditor who was the lead auditor for the base audit unless otherwise required because of any exigencies. <ul style="list-style-type: none"> <li>● Opening Meeting prompter</li> <li>● Attendance Sheet</li> <li>● Non- conformance Report + Non-conformance of the base assessment</li> <li>● Assessment Report + Assessment report of the base agreement</li> <li>● Closing Meeting Prompter</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>Client Feed Back</li> </ul> <p>Logistics arrangement are coordinated by lead auditor and communicated.</p> <p>Follow up audit is conducted to verify corrective action for the identified non-conformances of the base audit.</p> <p>Audit pack reviewed and forwarded to RAPL corporate office.</p>
<b>5.18</b>	<b>Certificate Decision Committee/ Technical Review of audit pack:</b>
	<p>Audit pack forwarded by lead auditor (Both stage I &amp; Stage II) is reviewed by Technical Review, who is an independent, competent authority and qualified auditor who are not member of audit team. Technical review the audit pack along with contract review records to ensure that:</p> <ul style="list-style-type: none"> <li>Assessment has been conducted to cover the scope of certification.</li> <li>Assessment has covered all the requirement of audit programme</li> <li>Audit check list has been completed with adequate details by each auditor.</li> <li>Do the auditors/ technical experts audit the respective processes based upon the competence as per the audit programme defined in 7.3.</li> <li>Assessment conducted provides confidence in the justification for recommendation for certification.</li> <li>Audit team has reviewed, accepted and verified the effectiveness of correction and corrective action along with evidences, for all non conformities which represent, (a) Failure to fulfill one or more requirements of the management system standard of (b) A situation that raises significant doubt about the ability of the client's management system of achieve its intended outputs.</li> <li>Clients planned correction / corrective action along with adequate evidences for any other nonconformity is reviewed and accepted by the audit team.</li> <li>Any other relevant information</li> <li>Independence of audit team members</li> </ul> <p>Technical Reviewer may ask for any clarification from the lead auditor, if required Assistance from a technical expert other review shall be considered, if technical reviewer does not have competency in the product sector.</p> <p>Technical review reports prepared in appropriate form.</p>
<b>5.19</b>	<b>Certificate of compliance</b>
	<p><u>Certificate of compliance is issued to give confidence in the product, process and services of the client organization.</u></p> <p><u>Certificate of compliance shall be issued with in a time frame of one month, unless a major concern is expressed by Technical Review.</u></p> <p><u>Certificate of compliance shall consist of following information.</u></p> <ol style="list-style-type: none"> <li><u>Reference number:</u></li> <li><u>Scope of certificate</u></li> <li><u>Physical location of the client organization only PO Box address shall not be accepted.</u></li> <li><u>In case of multi site organization, the certificate shall contain the name address of</u></li> </ol>

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	<p><u>the central office and a list of all sites. If temporary sites are included in the scope, such sites shall be identified as temporary in certification document.</u></p> <p>e. <u>A separate certificate for each site may be issued provided scope is same and include a clear reference to the main certificate.</u></p> <p>f. <u>Issue date is the date of certification decision by Technical Reviewer or after that</u></p> <p>g. <u>Expiry date, Certificate of compliance shall be valid for a period of 3 years from the certification decision date.</u></p> <p>h. <u>Last date, in case issue of revised Certificate.</u></p> <p><u>Certificate is signed by M.D. or any of the directors.</u></p> <p><u>The RAPL logo and applicable Accreditation logo is printed on all the accredited certificate of compliance. Accreditation number / registration number of the concerned accreditation is marked for the traceability purpose.</u></p> <p>Certificate is forwarded to the client along with the use of RAPL and accreditation logo, and conditions of certification. RAPL maintains the Certified Organization Directory. Details of the certified organization shall be updated within 3 days of issue of Certificate.</p> <p>Certificate is valid subject to conducting surveillance audits to verify continued compliance of the client QMS to the planned arrangements at agreed frequency from the date of Certificate as per certification agreement and conditions of certification.</p> <p>Certificate may be withdrawn or kept under suspension or made inactive under specified conditions as described in Conditions for certification.</p>
<b>5.20</b>	<b>Criteria for Certificate suspension and withdrawal</b>
	<u>Procedure Suspension, Withdrawal, reducing scope of certification shall be followed (PR/23)</u>
<b>5.21</b>	<b>Criteria for Refusing Certification</b>
	<p>Client may be refused for issue of certification under following conditions:</p> <ul style="list-style-type: none"> <li>• If Client does not comply with terms of certification during the certification process.</li> <li>• If some information is discovered during certification process, deliberately hidden by client and poses unacceptable threat to impartiality.</li> <li>• Client does not take timely action on non conformities.</li> <li>• Default in timely payment of certification fees to RAPL.</li> </ul>

**Amendment Record:**

04/02/2021 – Amended as result of change in CB name.