## 1.0 OBJECTIVE

- Define the requirements for Certification, Initial Stage I & Stage II certification audit of a client's MS, in accordance with the provisions of ISO/IEC 17021-1, ISO 20000-6, ISO 22003, ISO/IEC 27006-1:2024, IAF MD 9, ISO 50003
- 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: MR

## 4.0 Definition and Purpose

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| **4.1** | **Document Review** | Verify adequacy of the management system documents to the relevant contractual standard including any exclusion.<br>Document review will be conducted on site along with Stage I audit or off site |
| **4.2** | **Stage I audit**<br>**Identification: Stage I** | Verify the following<br>• Clients' management system documentations<br>• Evaluate client's location and site-specific condition<br>• Verify client's preparedness for Stage II audit<br>• Review client status and understanding regarding the requirements of the standard<br>• Collect information regarding scope, processes, statutory and regulatory requirements and exclusions claimed etc.<br>• Review the allocation of resources/ logistics for stage II audit<br>• Internal audit and Management Review are planned and performed<br>• Identify concerns if any in the planning of management system |
| **4.3** | **Stage II Audit**<br>**Identification: Stage II** | Verify the following:<br>• Compliance to contractual standards, documented system, statutory and regulatory requirements.<br>• Effective implementation of the planned management system<br>• Management commitment<br>• Awareness of the system across the organization<br>• Acceptance of the management system for Recommendation for issue of certificate of compliance with / without conditions or otherwise. |

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| **4.4** | **Follow up audit Identification: FA** | 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.<br><br>Verify the following<br>• Effectiveness of the Corrective action taken for the non-conformances identified during the base audit.<br>• Revision to the system documents if any |
| **4.5** | **(ISO/IEC 27006: 2015 Clause 9.4.2) - Specific elements of the ISMS audit** | RICL, represented by the audit team, shall:<br><br>(a) require the client to demonstrate that the audit of information security related risks is relevant and adequate for the ISMS operation within the ISMS scope;<br><br>(b) establish whether the client's procedures for the identification, examination and evaluation of information security related risks and the results of their implementation are consistent with the client's policy, objectives and targets.<br><br>RICL shall also establish whether the procedures employed in risk audit are sound and properly implemented. |
| **4.6** | **(ISO/IEC 27006: 2015 Clause 9.1.6.1)** | RICL may accept documentation that is combined (e.g., for information security, quality, health and safety and environment) as long as the ISMS can be clearly identified together with the appropriate interfaces to the other systems. |
| **4.7** | **(ISO/IEC 27006: 2015 Clause 9.1.6.2)** | The ISMS audit may be combined with audits of other management systems, provided that it can be demonstrated that the audit satisfies all requirements for certification of the ISMS. All the elements important to an ISMS shall appear clearly and be readily identifiable in the audit reports. The quality of the audit shall not be adversely affected by the combination of the audits. |
| **4.8** | **(ISO/IEC 27006:2015 Clause 9.2.1.1)** | The audit objectives shall include the determination of the effectiveness of the management system to ensure that the client, based on the risk audit, has implemented applicable controls and achieved the established information security objectives. |
| **4.9** | (ISO 20000-6:2017 Clause 8.2.1) | Scope definition – For ITSMS scope definition, RICL should use the guidance in ISO 20000-3 when defining the scope. |
| **4.10** | (ISO 20000-6:2017 Clause 9.1.6.1) | **Combining management system audits -** An SMS audit can be combined with audits of other management systems. A combined or integrated audit shall ensure that the audit evidence fulfils the requirements specified in ISO/IEC 20000-1 within the scope of the audit. All findings relating to ISO/IEC 20000-1 shall be easily identifiable in audit reports. |

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| | | The integrity of the ISO/IEC 20000-1 audit shall not be adversely affected by the combination of audits. |
| **4.11** | (ISO 20000-6:2017 Clause 9.1.6.2) | **Combining management system audits for ISO/IEC 20000-1 and ISO/IEC 27001 -** Where an audit is combined for ISO/IEC 27001 and ISO/IEC 20000-1, the information security management process in ISO/IEC 20000-1 shall be audited to ensure that:<br><br>a) the information security policy is relevant to the SMS and the services;<br>b) relevant information security risks are identified and information security controls are implemented to support the SMS and the services.<br><br>The auditor may find some supporting evidence from the information security management system (ISMS).<br><br>If the scope of the ISMS is outside of the scope of the SMS, then the information security management process in ISO/IEC 20000-1 shall be audited as a standalone process without the support of the ISMS.<br><br>The information security policy, risks and controls shall be audited to ensure that they are appropriate for the services within the scope of the client's SMS. |
| **4.12** | (ISO 20000-6:2017 Clause 9.2.1.1) | **Determining audit objectives -** The audit objectives shall include checking that interface at the boundaries of the SMS with other parties participating in the activities of the SMS, are identified and controlled. RICL body shall also ensure that the client is aware of and managing any risks to the SMS and the services arising from the interfaces. |
| **4.13** | (ISO 20000-6:2017 Clause 9.3.2) | **Integration of SMS documentation with that for other management systems –** RICL shall take into account that the client can integrate the documentation for the SMS with that for other management systems, e.g., a quality management system or information security management system.<br><br>If the documentation for multiple management systems is combined, the client's SMS shall be clearly identified. |
| **4.14** | (IAF MD9: 2022 Clause 9.3.1) | RICL shall undertake full audit as per requirements of ISO 13485, MD 9, RICL Procedure and applicable legal / statutory requirements. |

## 5.0 Audit Process

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| 5.1 | Initial audit shall be planned in two stages. Upon confirmation of the contract by the client and issue of contract number as per procedure, RICL shall develop a comprehensive 3-year audit programme specific to client and its scope of certification. The programme shall be shared with client and updated as and when required as per outcome of audits or any change in client's processes, systems, size, scope or location. |
| 5.2 | **Document Review** |
| | Document review shall be conducted by RICL 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:<br>• Adequacy of requirements of applied standard<br>• Statutory requirements for the product as applicable<br>• Manufacturing process<br>• Exclusion of with justification<br>• Justification for exclusion for any of the process (es) shall be reviewed considering following guidelines:<br>• Liability of the client for the specific clause for which exclusion has been claimed.<br>Ex.: Liability for design and development in 9001<br>• 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<br>• 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<br>• 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<br>• 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<br>• One time validation for setting of the dies shall be considered as process validation.<br>• 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.<br>• Manufacture of basic chemicals/ pharmaceuticals based upon known formulations can be considered for exclusion unless the manufacturer is not revising the formulations. Source of formulations shall be verified during the compliance audit to accept any justification for exclusion.<br>• In case of changes to the original specification taken from an outside source when claiming exclusion, acceptance of justification for the complete clause of |

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| | 8.3 of ISO 9001 shall be reviewed as only part of the clause of design changes may be applicable.<br><br>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.<br>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.<br><br>Document review comments shall be forwarded (in case it is conducted off site) to client indicating:<br>• Nature of the comments<br>• Request for response to document review comments<br>• Proposed date for stage I audit, if the comments are acceptable with/ without comments.<br><br>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.<br>If the document review is conducted on site, comments shall be recorded in the observation sheet of audit report and communicated to the client during stage I audit.<br>Corrective action for the document review comments shall be reviewed by the lead auditor prior to stage II audit. |
| **5.3** | **Audit team selection** |
| | Upon decision on the feasibility of the audit based upon the information provided by client in client information for certification and review by RICL, 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.<br>Following are the criteria for audit team selection of size and composition.<br>a. 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.<br>b. Combined or joint audit<br>c. 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 (RICL/PR/01).<br>d. Applicable statutory, regulatory, contractual and accreditation/ certification requirement.<br>e. Independence and conflict of interest of auditors/ Technical Experts.<br>f. Audit team ability to interact effectively with the auditee and work together.<br>g. Language of the audit, Auditee's social and cultural characteristics. Support of required external experts may be considered, if required.<br>h. Technical expert may be selected considering the criticality of the scope and audit criteria.<br>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.

j. **(ISO/IEC 27006:2015 Clause 9.2.2.1)** The audit team shall be formally appointed and provided with the appropriate working documents. The mandate given to the audit team shall be clearly defined and made known to the client.

An audit team may consist of one person provided that the person meets all the criteria set out in clause 7.1.2.1.

k. **(ISO/IEC 27006:2015 clause 9.2.2.2)** For surveillance and special audit activities, only those requirements which are relevant to the scheduled surveillance activity and special audit activity apply.

When selecting and managing the audit team to be appointed for a specific certification audit, RICL shall ensure that the competences brought to each assignment are appropriate.

The team shall:

(a) have appropriate technical knowledge of the specific activities within the scope of the ISMS for which certification is sought and, where relevant, with associated procedures and their potential information security risks (technical experts may fulfil this function);

(b) have understanding of the client sufficient to conduct a reliable certification audit of its ISMS given the ISMS' scope and context within the organization in managing the information security aspects of its activities, products and services

(c) have appropriate understanding of the legal and regulatory requirements applicable to the client's ISMS.

l. **(IAF MD 9:2022 Clause 9.2.2.1)** The audit team shall have the competence for the Technical Area (Annex A of MD 9 in conjunction with relevant knowledge and skills as defined in Annex B of MD 9) for the scope of audit.

If the audit is performed for an organization that only manufactures parts and offers services (see Table A.1.7 of MD 9), the audit team does not have to demonstrate technical competence at the same level as that for a manufacturer providing medical devices.

To include devices that are sterile or intended for end-user sterilization, the audit team shall be competent according to sterilization process detailed in

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| | Table 1.5 of Annex A of MD 9.<br><br>m. **(IAF MD 9:2022 Annexure A (b))** - RICL shall use the Technical Areas described in the tables A.1.1 – A.1.7 of annexure A of IAF MD 9 to identify if any technical qualification, including competence in sterilization processes of its auditors is necessary for that particular technical area<br><br>n. **(IAF MD 9:2022 Annexure A (c))** - RICL shall use the Technical Areas described in the tables A.1.1 – A.1.7 of annexure A of IAF MD 9 to select a suitably qualified audit team<br><br>o. **(IAF MD 9:2022 Annexure A)** - RICL shall use the Technical Areas described in the tables A.1.1 – A.1.7 of annexure A of IAF MD 9 for ISO 13485 certification. |
| **5.4** | Stage I audit shall be conducted provided:<br>• Client has implemented the system for a period of 3 months<br>• Conducted one internal audit and one management review covering scope of certification.<br>If the above criteria are not fulfilled, RICL shall not certify the management system. |
| **5.5** | **Initial Audit / Conducting Audits** |
| | **ISO 17021-1:2015 Clause 9.3.1.1** - The initial certification audit of a management system shall be conducted in two stages: stage 1and stage 2.<br><br>**ISO 17021-1:2015 Clause 9.4.1 Conducting Audits** RICL has a process for conducting on-site audits. This process includes an opening meeting at the start of the audit and a closing meeting at the conclusion of the audit.<br><br>Where any part of the audit is made by electronic means or where the site to be audited is virtual, RICL ensures that such activities are conducted by personnel with appropriate competence. The evidence obtained during such an audit shall be sufficient to enable the auditor to take an informed decision on the conformity of the requirement in question.<br><br>**ISO 50003:2021 Clause 9.4.1 During the EnMS audit,** energy performance improvement can be verified at the equipment, process, system or facility level.<br>During each EnMS audit within the audit programme, RICL shall confirm the suitability of the EnMS scope and boundary(ies) as defined by the client.<br><br>**9.4.2 Conducting the opening Meeting**<br>A formal opening meeting, shall be held with the client's management and, where appropriate, those responsible for the functions or processes to be audited. The purpose of the opening meeting, usually conducted by the audit team leader, is to provide a short explanation of how the audit activities will be undertaken.<br>The degree of detail shall be consistent with the familiarity of the client with the audit process and shall consider the following:<br><br>(a) Introduction of the participants, outlining 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 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 is responsible for the audit and shall 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:

**9.4.3 Communication during the audit**

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

9.4.3.2 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 shall report this to the client and, if possible, to RICL to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The audit team leader shall report the outcome of the action taken to RICL**.**

9.4.3.3 The audit team leader shall review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the CAB.

**9.4.4 Obtaining and verifying information**

9.4.4.1 During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and

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| | processes) shall be obtained by appropriate sampling and verified to become audit evidence.<br><br>9.4.4.2 Methods to obtain information shall include, but are not limited to:<br>(a) Interviews;<br>(b) Observation of processes and activities;<br>(c) Review of documentation and records.<br><br>**9.4.5 Identifying and recording audit findings**<br><br>**9.4.5.1** Audit findings summarizing conformity and detailing nonconformity shall be identified, classified and recorded to enable an informed certification decision to be made or the certification to be maintained.<br><br>**9.4.5.2** Opportunities for improvement may be identified and recorded, unless prohibited by the requirements of a management system certification scheme. Audit findings, however, which are nonconformities, shall not be recorded as opportunities for improvement.<br><br>**9.4.5.3** A finding of nonconformity shall be recorded against a specific requirement, and shall contain a clear statement of the nonconformity, identifying in detail the objective evidence on which the nonconformity is based. Nonconformities shall be discussed with the client to ensure that the evidence is accurate and that the nonconformities are understood. The auditor however shall refrain from suggesting the cause of nonconformities or their solution.<br><br>**9.4.5.4** The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, and unresolved points shall be recorded. |
| **5.6** | **Audit Plan for Stage I Audit & Audit Pack – Stage I** |
| | Upon confirmation of the audit schedule by the client and acceptance of the schedule subject to considerations in 5.4 above, audit plan is planned for stage I audit by lead auditor.<br>• Audit plan is completed and forwarded to client with copy to audit team.<br>• 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.<br>Audit pack comprising following documents shall be forwarded to the lead auditor.<br>I. Document Review Report<br>II. Audit report of Stage I audit<br>III. Observation report Stage audit<br>IV. Audit Programme<br>V. Opening Meeting Prompter<br>VI. Attendance Sheet<br>VII. Stage I Audit report<br>VIII. Closing Meeting Prompter<br>Logistics arrangements are coordinated by lead auditor and communicated to the |

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| | client vide audit programme |
| **5.7** | **Stage I audit:** |
| | **(ISO 17021-1:2015 Clause 9.3.1.2.1)** Planning shall ensure that the objectives of stage 1 can be met and the client shall be informed of any "on site" activities during stage 1.<br><br>**(ISO 17021-2:2015 Clause 9.3.1.2.2)** The objectives of stage 1 are to:<br>(a) Review the client's management system documented information;<br>(b) Evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2;<br>(c) Review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;<br>(d) Obtain necessary information regarding the scope of the management system, including:<br>• the client's site(s);<br>• processes and equipment used;<br>• levels of controls established (particularly in case of multisite clients);<br>• applicable statutory and regulatory requirements;<br>(e) Review the allocation of resources for stage 2 and agree the details of stage 2 with the client;<br>(f) provide a focus for planning stage 2 by gaining a sufficient understanding of the client's management system and site operations in the context of the management system standard or other normative document;<br>(g) Evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2.<br><br>**(ISO 17021-2:2015 Clause 9.3.1.2.3)** Documented conclusions with regard to fulfillment of the stage 1 objectives and the readiness for stage 2 shall be communicated to the client, including identification of any areas of concern that could be classified as a nonconformity during stage 2.<br><br>**(ISO 17021-2:2015 Clause 9.3.1.2.4)** In determining the interval between stage 1 and stage 2, consideration shall be given to the needs of the client to resolve areas of concern identified during stage 1. RICL may also need to revise its arrangements for stage 2. If any significant changes which would impact the management system occur, RICL shall consider the need to repeat all or part of stage 1. The client shall be informed that the results of stage 1 may lead to postponement or cancellation of stage 2. |
| **5.7.1** | Stage I audit is carried out by a competent auditor for a specific number of man day(s) to verify:<br>• Clients' management system documentations<br>• Evaluate client's location and site-specific condition<br>• Verify client's preparedness for Stage II audit<br>• Review client status and understanding regarding the requirements of the standard<br>• Collect information regarding scope, processes, statutory and regulatory |

requirements, and exclusions claimed etc.

- Review the allocation of resources for stage II audit
- Audit of top management, internal audit and Management Review are planned and performed.

Audit is carried out using the relevant MS standard & checklist.

I. Opening meeting is conducted by Lead Auditor and is held with the client representatives:
   - 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.
   - Attendance sheet is completed by all personnel present in the opening meeting.

II. Plant visit is completed along with audit team member(s) to:

a. Understand the locations of various functions and physical location.
b. Brief on the infrastructure and processes.
c. Assess changes to the audit programme, if required

III. Lead Auditor to have discussions with audit team members and technical expert if used.

Areas of concerns are recorded as observations and communicated to the client along with the audit report. Audit team shall complete the audit report (QMS for stage I). Lead Auditor shall complete the audit report in all respects as required providing complete description of the organization for Planning the resources / logistics for stage II audit.

- Lead auditor shall review the acceptance of the scope of certification. Scope of certification shall be confirmed with the client management.

- Recommendation shall be indicated in the audit report based on following consideration.

- Recommended for stage II Audit
  - When there is no Observations

- Recommended for stage II Audit subject to action on Observation
  - When Observations are recorded

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.

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 reaudit as applicable. Lead auditor to get concurrence of client representative for each observation and copy of all observations are given to the client

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| | organization. Lead auditor to keep the original copy of the observation.<br>Lead Auditor to sign the Stage I Audit report and get concurrence of the client representative. Original copy of the audit report is given to the client organization.<br><br>Client Feedback report on the audit is obtained. Action on all Observations shall be taken by client and submitted to RICL. 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.<br><br>Information gathered during the stage I is used for further audit planning. Lead Auditor shall review the audit pack for completeness and forward to RICL corporate office within 3 working days. |
| **5.7.2** | **(ISO 27001:2015) Clause 9.1.3.3** RICL shall ensure that a client makes all necessary arrangements for the access to internal audit reports and reports of independent reviews of information security. following information shall be provided by the client during stage 1 of the certification audit:<br><br>(a) general information concerning the ISMS and the activities it covers;<br><br>(b) a copy of the required ISMS documentation specified in ISO/IEC 27001 and, where required, associated documentation. |
| **5.7.3** | **(ISO/IEC 27006:2015) Clause 9.1.3.5** RICL's audit team shall audit the ISMS of the client covered by the defined scope against all applicable certification requirements. RICL shall confirm, in the scope of the client ISMS, that clients address the requirements stated in ISO 27001 clause 4.3.<br><br>RICL shall ensure that the client's information security risk audit and risk treatment properly reflect its activities and extends to the boundaries of its activities as defined in the scope of certification. RICL shall confirm that this is reflected in the client's scope of their ISMS and Statement of Applicability. The certification body shall verify that there is at least one Statement of Applicability per scope of certification.<br><br>RICL shall ensure that interfaces with services or activities that are not completely within the scope of the ISMS are addressed within the ISMS subject to certification and are included in the client's information security risk audit. An example of such a situation is the sharing of facilities (e.g., IT systems, databases and telecommunication systems or the outsourcing of a business function) with other organizations. |
| **5.7.4** | **(ISO/IEC 27006:2015 Clause 9.3.1.1)** In this stage of the audit, RICL shall obtain documentation on the design of the ISMS covering the documentation required in ISO/IEC 27001.<br><br>RICL shall obtain a sufficient understanding of the design of the ISMS in the context of the client's organization, risk audit and treatment (including the controls determined), information security policy and objectives and, in particular, of the client's preparedness for the audit. This allows planning for stage 2. |

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| | **(ISO/IEC 27006:2015 / AMD.1:2020)** RICL shall document the results of stage 1 in written report and shall review the stage 1 audit report before deciding on proceeding with stage 2 and shall confirm if the stage 2 audit team members have the necessary competence. This will be done by the auditor leading the team that conducted the stage 1 audit if deemed competent and appropriate.<br><br>RICL shall make the client aware of the further types of information and records that may be required for detailed examination during stage 2. |
| **5.7.5** | **(IAF MD 9:2022 Clause 9.3.1.2)** For ISO 13485 certification, Stage 1 audit shall be conducted on site. |
| **5.8** | **Audit Planning for Stage II audit**<br><br>While preparing Stage II audit plan, RICL 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 audit report may be revised as required. In case the audit team is different as that of stage I audit, reports such as audit 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.<br>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:<br>1. Organization name and audit site address<br>2. Size of the organization<br>3. Scope of certification.<br>4. Audit objective.<br>5. Results of previous audits if any<br>6. Proposed number of audit man days during contact review<br>7. Auditor wise details of the processes (functions / departments) to be audited during stage 2 (Input to be taken from stage 1 audit)<br>8. Assignment of auditor for each process based upon the competence of auditors and technical experts.<br>9. Size of the audit team shall be such that audit duration will not exceed a maximum of 5 working days.<br>10. Conflict of interest of the audit team<br>11. Copy of audit plan to be forwarded to client with copy to audit team.<br>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.<br>13. Plan for multisite certification audit shall be made as per provisions of IAF MD1:2018.<br>14. If the audit is being conducted remotely using ICT the RICL 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 optimize audit effectiveness and efficiency while maintaining |

the integrity of the audit process (Refer Audit Plan Form – F/30)

15. (ISO/IEC 27006-1:2024 Clause 9.1.3.3) RICL has defined procedures to determine the s level of remote audit activities ("remote audits") that can be applied to auditing a client's ISMS. The procedures shall include analysis of the risks related to the use of remote auditing for the client, which shall consider the following factors:
    a) available infrastructure of the certification body and the client;
    b) sector in which the client operates;
    c) type(s) of audit during the certification cycle from initial audit to recertification audit;
    d) competence of the persons of the certification body and the client, who are involved in the remote audit;
    e) previously demonstrated performance of remote audits for the client;
    f) scope of the certification.

    The analysis shall be performed prior to performing any remote audit. The analysis and the justification for use of remote audit during the certification cycle shall be documented.

    The audit plan and audit report shall include clear indications if remote audit activities have been performed.

    Remote audits shall not be used if the risk audit identifies unacceptable risks to the effectiveness of the audit process.

    The risk audit shall be reviewed during the certification cycle to ensure its continued suitability.

16. The audit plan shall identify the network-assisted auditing techniques that will be utilized during the audit, as appropriate.

    Network assisted auditing techniques may include, for example, teleconferencing, web meeting, interactive web-based communications and remote electronic access to the ISMS documentation or ISMS processes. The focus of such techniques should be to enhance audit effectiveness and efficiency and should support the integrity of the audit process.

17. RICL shall use Annex C of ISO/IEC 27006-1:2024 to determine audit time. RICL should agree with the organization to be audited the timing of the audit which will best demonstrate the full scope of the organization. The consideration could include season, month, day/dates and shift as appropriate.

18. (ISO/IEC 27006-1:2024 Clause 9.3.2.2) Based on the findings documented in the stage 1 audit report, RICL shall develop an audit plan for the conduct of stage 2. In addition to evaluating the effective implementation of the ISMS, the objective of stage 2 is to confirm that the client adheres to its own policies,

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| | objectives and procedures. To do this, the audit shall focus on the clients:<br>a) top management leadership and commitment to the information security objectives;<br>b) audit of information security related risks; the audit shall also ensure that the audits produce consistent, valid and comparable results, if repeated;<br>c) determination of controls based on the information security risk audit and risk treatment processes;<br>d) information security performance and the effectiveness of the ISMS, evaluating these against the information security objectives;<br>e) correspondence between the determined controls, the Statement of Applicability, the results of the information security risk audit, the risk treatment process and the information security policy and objectives;<br>f) implementation of controls (see Annex E for examples on auditing controls) taking into account the external and internal context and related risks, and the organization's monitoring, measurement and analysis of information security processes and controls, to determine whether controls declared as being implemented are actually implemented and effective as a whole;<br>g) programmes, processes, procedures, records, internal audits and reviews of the ISMS effectiveness to ensure that these are traceable to top management decisions and the information security policy and objectives |
| **5.9** | **Audit Pack – Stage II** |
| | Audit pack comprising following documents shall be forwarded to the lead auditor:<br>1. Audit report of Stage I audit<br>2. Observation report of stage I audit if any<br>3. Audit Programme<br>4. Opening Meeting prompter<br>5. Attendance sheet<br>6. Non-Conformance Report<br>7. Closing Meeting Prompter<br>8. Client Feed Back<br>9. Surveillance Audit Programme<br>10. Technical Expert Report, if applicable<br>Logistics arrangements are coordinated by client in communication with audit team. |
| **5.10** | **Stage 2 Audit** |
| | **(ISO 17021-2:2015 Clause 9.3.1.3)**<br>The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's management system. The stage 2 shall take place at the site(s) of the client. It shall include the auditing of at least the following:<br>(a) Information and evidence about conformity to all requirements of the applicable management system standard or other normative documents;<br>(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 document);<br>(c) The client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;<br>(d) Operational control of the client's processes; |

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| | (e) Internal auditing and management review;<br>(f) Management responsibility for the client's policies.<br><br>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<br>1. Information and evidence about conformity to all requirements to the applicable management standard and normative document.<br>2. Performance monitoring, measuring, reporting and reviewing against key performance objective and targets.<br>3. Client's management system and performance as regards to applicable legal compliance.<br>4. Operational control of the clients' processes.<br>5. Internal Auditing and Management Review.<br>6. Management responsibility for the client's policies.<br>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.<br>**Audit Steps**<br>➢ Stage II audit is conducted as per the audit programme<br>➢ Opening meeting is conducted by lead Auditor and is held with the client representatives:<br>o 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.<br>o Attendance sheet is completed by all personnel present in the opening meeting.<br>➢ Lead Auditor to have discussions with audit team members and technical expert if used.<br>➢ Technical expert shall accompany the auditor conducting audit of Design and Development and Product / Service provision & Inspection and testing if used. Other auditors can take assistance of technical expert for any clarification on the technical requirements<br>➢ Discuss the organization structure and document review comments<br>➢ Audits meeting schedule |
| **5.11** | **Audit Approach** |
| | 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:<br>a. Selecting sample for each of the product / services covered in the scope of audit<br>b. Selecting samples in each of the function considering the criticality, complexity and lot size<br>c. Interviewing personnel in each of the function to evaluate the awareness of the planned arrangements, policy, improvement areas and effectiveness of implementation.<br>d. Review records as referred in the planned management system documents<br>e. Verify exclusion of any clause to justify acceptance |

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.

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.
   - Function audited
   - Auditee representative name
   - Number of persons working in each function including repetitive nature of jobs
   - Reference of documents verified
   - Number of samples and their identification
   - Objective evidence to support any non-conformance like instrument number, purchase order number, etc.
   - 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.

h. Lead Auditor shall discuss with team members prior to the closing meeting to:
   - Understand the positive and negative observations of each auditor.
   - Scope of certificate and any revision, if required. Revision to the scope of certification shall be discussed with client management.
   - Classify non-conformances as major or minor.

i. (IAF MD22:2018 Clause G 9.4.4.2) For ISO 45001:2018 audits, the audit team shall interview the following personnel:
   i) the management with legal responsibility for OH&S,
   ii) employees' representative(s) with responsibility for OH&S,
   iii) personnel responsible for monitoring employees' health, for example, doctors and nurses. Justifications in case of interviews conducted remotely shall be recorded,
   iv) managers and permanent and temporary employees.

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

j. **ISO/IEC 27006-1:2024 Clause 9.4.2** Specific elements of the ISMS audit

   RICL audit team shall:
   a) require the client to demonstrate that the audit of information security related risks is relevant and adequate for the ISMS operation within the ISMS scope;
   b) establish whether the client's procedures for the identification, examination

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| | and evaluation of information security related risks and the results of their implementation are consistent with the client's policy, objectives and targets.<br><br>RICL shall also establish whether the procedures employed in risk audit are sound and properly implemented. |
| **5.12** | **Non-Conformance (NCR)** |
| | **ISO 17021-1:2015 Clause 9.4.6 Preparing audit conclusions**<br>Under the responsibility of the audit team leader and prior to the closing meeting, the audit team shall:<br>(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;<br>(b) Agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process;<br>(c) Agree any necessary follow-up actions;<br>(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).<br><br>**9.4.9** Cause analysis of nonconformities<br>RICL shall require the client to analyze the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities, within a defined time.<br><br>**9.4.10** Effectiveness of corrections and corrective actions<br>RICL shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. RICL shall verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities shall be recorded. The client shall be informed of the result of the review and verification. The client shall 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.<br><br>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 following criteria.<br><br>▸ **(A) Major Non-Conformance**<br>o Implementation not effective<br>o Not meeting statutory/ regulatory requirements<br>o Not taking corrective actions for the previous NCRs<br>o Respective minor non-conformances of similar nature across the organization/ across the sites sampled.<br>o Number of defective samples is more than 50% of total samples size.<br><br>▸ **(B) Minor Non-Conformance**<br>o Evidence of implementation observed except isolated cases |

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| | ○ Defective samples less than 50% of total sample size considered for audit.<br><br>▸ **(C) Identification of Non-Conformances**<br>▸ 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.<br>▸ 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.<br>▸ Client shall review the applicability of NCR to single site or multiple sites in case multi site organizations.<br><br>▸ **(D) (IAF MD22:2018 Clause G 9.4.5.3)** – If during the course of audit, RICL'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. |
| **5.12.1** | **(IAF MD 9:2022 Clause 9.4.5) Identifying and recording audit findings**<br><br>Examples of major nonconformities which require the acceptance and the verification of the effectiveness of correction and corrective actions are as follows:<br>a) failure to fully address applicable requirements and implement an entire process for quality management systems (e.g., failure to have a complaint handling or training system)<br>b) failure to implement applicable requirements for quality management systems<br>c) failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects<br>d) products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling<br>e) the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements<br>f) repeated nonconformities from previous audits |
| **5.13** | **Audit Report** |
| | **ISO 17021-1:2015 Clause 9.4.8 Audit Report**<br>**9.4.8.1** RICL shall provide a written report for each audit to the client. The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by RICL.<br><br>**9.4.8.2** The audit team leader shall ensure that the audit report is prepared and shall be responsible for its content. The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made and shall include or refer to the following: |

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| | (a) Identification of the CAB;<br>(b) The name and address of the client and the client's representative;<br>(c) The type of audit (e.g., initial, surveillance or recertification audit or special audits);<br>(d) The audit criteria;<br>(e) The audit objectives;<br>(f) The audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit;<br>(g) Any deviation from the audit plan and their reasons;<br>(h) Any significant issues impacting on the audit programme;<br>(i) Identification of the audit team leader, audit team members and any accompanying persons;<br>(j) The dates and places where the audit activities (on site or offsite, permanent or temporary sites) were conducted;<br>(k) Audit findings, reference to evidence and conclusions, consistent with the requirements of the type of audit;<br>(l) Significant changes, if any, that affects the system of the client since the last audit took place;<br>(m) Any unresolved issues, if identified;<br>(n) Where applicable, whether the audit is combined, joint or integrated;<br>(o) A disclaimer statement indicating that auditing is based on a sampling process of the available information;<br>(p) Recommendation from the audit team;<br>(q) The audited client is effectively controlling the use of the certification documents and marks, if applicable;<br>(r) Verification of effectiveness of taken corrective actions regarding previously identified nonconformities, if applicable.<br><br>9.4.8.3 The report shall also contain:<br>(a) A statement on the conformity and the effectiveness of the management system together with a summary of the evidence relating to:<br>• the capability of the management system to meet applicable requirements and expected outcomes;<br>• the internal audit and management review process;<br>(b) A conclusion on the appropriateness of the certification scope;<br>(c) Confirmation that the audit objectives have been fulfilled.<br><br>**9.4.8.4** (J.9.1.10.1) RICL shall ensure that audit OHSMS audit reports contain, where applicable:<br><br>(a) sufficient comments to demonstrate the means of determining conformity or nonconformity with the specified requirements for each of the sites within the scope of the audit;<br>(b) positive as well as negative comments relating to the effectiveness of the organization's OHS management system with clear statements of conformity or nonconformity;<br>(c) any useful comparison with the results of previous audits of the organization; and<br>(d) An explanation of any differences from the information presented to the |

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| | organization at the closing meeting. |
| **5.13.1** | Audit team shall complete the report for audit. Lead Auditor shall complete the 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. |
| **5.13.2** | Recommendation for certification shall be indicated in the report based on following guidelines:<br><br>Stage II Audit<br>▸ Recommended for certification in case of no NCR.<br>▸ 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.<br><br>a. If follow up audit is recommended, lead auditor to decide on the duration of the follow up audit. In case of major NCRs 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 RICL 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 RICL HO.<br><br>b. If follow up audit is not considered, client shall be requested to provide documentary evidence of corrective action within an agreed time frame. |
| **5.13.3** | Time period for submission of corrective action is 10 days and evidence of implementation of corrective action is 20 days for major nc and 30 days for minor nc from the date of closing meeting. Major nc to be closed within 20 days and minor in 30 days.<br><br>In case of OHSMS, 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 RICL 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 RICL.<br>▸ Not recommended for certification, if there is no evidence of effective |

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| | implementation, a complete reaudit shall be planned to evaluate compliance with planned arrangements. |
| **5.13.4** | 9.4.3.1 (ISO/IEC 27006-1:2024) The audit report shall provide the following information or a reference to it:<br>a) an account of the audit of the client's information security risk analysis;<br>b) any information security control sets used by the organization for comparison purposes as required by ISO/IEC 27001:2022, 6.1.3 c). |
| **5.13.5** | 9.4.3.2 (ISO/IEC 27006-1:2024) The audit report shall be sufficiently detailed to facilitate and support the certification decision. It shall contain:<br>a) the significant audit trails followed and audit methodologies utilized (see 9.1.1.2);<br><br>b) a reference to the version of the Statement of Applicability and, where applicable, any useful comparison with the results of previous certification audits of the client.<br><br>Completed questionnaires, checklists, observations, logs, or auditor notes may form an integral part of the audit report. If these methods are used, these documents shall be submitted to the certification body as evidence to support the certification decision. Information about the samples evaluated during the audit shall be included in the audit report, or in other certification documentation.<br><br>Where remote audit methods have been used, the report shall indicate the extent to which they have been used in carrying out the audit and their effectiveness in achieving the audit objectives.<br><br>Where the activities of the organization are not undertaken at a defined physical location and therefore all activities of the organization are conducted remotely, the audit report shall state that all activities of the organization are conducted remotely.<br><br>The report shall consider the adequacy of the internal organization and procedures adopted by the client to give confidence in the ISMS.<br><br>The report shall include a summary of the most important observations, positive as well as negative, regarding the implementation and effectiveness of the ISMS requirements and information security controls. |
| **5.13.6** | **9.4.8.1 (ISO 20000-6:2017)** The audit report shall be of sufficient detail to support the certification decision. It shall contain the certification scope definition with a reference to any changes in scope and descriptions of significant audit trails followed and audit methodologies used.<br><br>The report shall include the audit team's recommendation on certification of the client's SMS, with information to substantiate this recommendation. The substantiation |

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| | shall include a summary of nonconformities and opportunities for improvement regarding the implementation and effectiveness of the SMS. |
| **5.14** | **Closing Meeting** |
| | **ISO 17021-1:2015 Clause 9.4.7 Conducting the closing meeting**<br><br>**9.4.7.1** A formal closing meeting, where attendance shall be recorded, shall 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 nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.<br><br>**9.4.7.2** The closing meeting shall also include the following elements where the degree of detail shall be consistent with the familiarity of the client with the audit process:<br>(a) Advising the client that the audit evidence obtained was based on a sample of the information; thereby introducing an element of uncertainty;<br>(b) advising the client that RICL auditors conduct audits to a sufficient depth to gain a reasonable understanding of the level of systemic conformance to the specified requirements;<br>(c) The method and timeframe of reporting, including any grading of audit findings;<br>(d) RICL's process for handling nonconformities including any consequences relating to the status of the client's certification;<br>(e) The timeframe for the client to present a plan for correction and corrective action for any nonconformity identified during the audit;<br>(f) RICL's post audit activities;<br>(g) Information about the complaint and appeal handling processes.<br><br>**9.4.7.3** The client shall be given opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to RICL.<br><br>**5.14 A** - 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.<br><br>Lead Auditor shall chair the closing meeting and discuss all requirements of closing meeting prompter. Details of each NCR are discussed during the closing meting and clarify any clarification requested by client representatives. Attendance sheet is completed by all the personnel present in the closing meeting.<br><br>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 reaudit as applicable.<br><br>**5.14 B** - Lead auditor to get concurrence of client representative for each NCR and original of all NCRs are given to the client organization. Lead auditor to keep the copy |

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| | of the NCRs and request the organization to submit the corrective action in original.<br><br>**5.14 C** - Lead Auditor to sign the Audit report and get concurrence of the client representative. Original copy of the audit report is given to the client organization. Copy of the audit report with recommendation shall be submitted to RICL HO along with the audit pack.<br><br>**5.14 D** - Client Feedback report on the audit is obtained.<br><br>**5.14 E (IAF MD22:2018 Clause G 9.4.7.1)** - 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. |
| **5.15** | **Surveillance Audit Programme** |
| | Lead Auditor to complete the Surveillance audit programme for the complete period of certification based on:<br>▸ Criticality of the process in the organization<br>▸ Areas of improvement identified<br>▸ Audit all the process at least once during the certification period.<br>▸ Following processes are audited during each surveillance audit.<br>o Document and Data Control<br>o Control of records<br>o Internal audit<br>o Management Review<br>o Corrective and Preventive action<br>o Continual improvement<br>▸ Audit programme shall be reviewed at each subsequent audit for suitable. Surveillance program can be updated if any change is required for subsequent audit. |
| **5.16** | **Completed Audit Pack / Initial certification audit conclusions** |
| | **(ISO 17021-1:2015 Clause 9.3.1.4)** The audit team shall analyze all information and audit evidence gathered during stage 1 and stage 2 to review the audit findings and agree on the audit conclusions.<br><br>Lead Auditor shall review the audit pack for completeness and forward to RICL corporate office within 3 working days. |
| **5.17** | **Review of corrective action response** |
| | Client is responsible of forwarding corrective actions RICL within 10 days. Upon receipt of planned correction / corrective action, lead auditor shall review considering:<br>o Proper correction/ corrective action has been planned / taken by the client to address the identified non-conformances<br>o Necessary document as evidence has been submitted for review.<br>**or**<br>▸ If the follow up is recommended RICL shall coordinate with the client for the follow up audit. In case of multi-site, audit shall cover central office and affected |

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| | 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.<br><br>• Opening Meeting prompter<br>• Attendance Sheet<br>• Non- conformance Report + Non-conformance of the base audit<br>• Audit Report + Audit report of the base agreement<br>• Closing Meeting Prompter<br>• Client Feed Back<br><br>Logistics arrangement are coordinated by lead auditor and communicated.<br><br>Follow up audit is conducted to verify corrective action for the identified non-conformances of the base audit.<br>Audit pack reviewed and forwarded to RICL corporate office. |
| **5.18** | **Certificate Decision** |
| | **ISO 17021-1:2015 Clause 9.5.1 Certification Decision**<br><br>**9.5.1.1** RICL shall 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. The individual(s) appointed to conduct the certification decision shall have appropriate competence.<br><br>**9.5.1.2** The person(s) [excluding members of committees (see 6.1.4)] assigned by the RICL to make a certification decision shall be employed by, or shall be under legally enforceable arrangement with RICL or an entity under the organizational control of RICL. RICL's organizational control shall be one of the following:<br>(a) Whole or majority ownership of another entity by RICL;<br>(b) Majority participation by RICL on the board of directors of another entity;<br>(c) A documented authority by RICL over another entity in a network of legal entities (in which RICL resides), linked by ownership or board of director control.<br><br>**9.5.1.3** The persons employed by, or under contract with, entities under organizational control shall fulfil the same requirements of this part of ISO/IEC 17021 as persons employed by, or under contract with RICL.<br><br>**9.5.1.4** RICL shall record each certification decision including any additional information or clarification sought from the audit team or other sources.<br><br>**9.5.2** Actions prior to making a decision<br>RICL shall have a process to 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, including, that<br>(a) The information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification;<br>(b) For any major nonconformity, it has reviewed, accepted and verified the correction and corrective actions; |

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| | (c) For any minor nonconformity it has reviewed and accepted the client's plan for correction and corrective action.<br><br>**9.5.3** Information for granting initial certification<br>**9.5.3.1** The information provided by the audit team to RICL for the certification decision shall include, as a minimum:<br>(a) The audit report;<br>(b) Comments on the nonconformities and, where applicable, the correction and corrective actions taken by the client;<br>(c) Confirmation of the information provided to RICL used in the application review (see 9.1.2);<br>(d) Confirmation that the audit objectives have been achieved;<br>(e) A recommendation whether or not to grant certification, together with any conditions or observations.<br><br>**9.5.3.2** If RICL 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, RICL shall conduct another stage 2 prior to recommending certification.<br><br>**9.5.3.3** When a transfer of certification is envisaged from other CAB to RICL, RICL CAB shall have a process for obtaining sufficient information in order to take a decision on certification.<br><br>**9.5.4** Information for granting recertification - RICL shall make decisions on renewing certification based on the results of the recertification audit, as well as the results of the review of the system over the period of certification and complaints received from users of certification. |
| **5.18.1**<br><br>**5.18.2** | Audit pack forwarded by lead auditor (Both stage I & Stage II) is reviewed by report review committee (Technical Committee), 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:<br>• Audit has been conducted to cover the scope of certification.<br>• Audit has covered all the requirement of audit programme<br>• Audit check list has been completed with adequate details by each auditor.<br>• Do the auditors/ technical experts audit the respective processes based upon the competence as per the audit programme defined in 7.3.<br>• Audit conducted provides confidence in the justification for recommendation for certification.<br>• 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.<br>• Clients planned correction / corrective action along with adequate evidences for any other nonconformity is reviewed and accepted by the audit team.<br>• Any other relevant information<br>• Independence of audit team members<br><br>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. Technical review reports prepared in appropriate form. |

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| **5.18.3** | 9.5.1 (ISO/IEC 27006:2015) The certification decision shall be based, additionally to the requirements of ISO/IEC 17021-1, on the certification recommendation of the audit team as provided in their certification audit report (see 9.4.3).<br><br>RICL's technical committee that take the decision on granting certification should not normally overturn a negative recommendation of the audit team. If such a situation does arise, RICL shall document and justify the basis for the decision to overturn the recommendation.<br><br>Certification shall not be granted to the client until there is sufficient evidence to demonstrate that arrangements for management reviews and internal ISMS audits have been implemented, are effective and will be maintained. |
| **5.19** | **Certificate of compliance** |
| | Certificate of compliance is issued to give confidence in the product, process and services of the client organization. Certificate of compliance shall be issued with in a time frame of one month, unless a major concern is expressed by Technical Review.<br><br>Certificate of compliance shall consist of following information.<br>a. Reference number:<br>b. Scope of certificate<br>c. Physical location of the client organization only PO Box address shall not be accepted.<br>d. In case of multi site organization, the certificate shall contain the name address of 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.<br>e. A separate certificate for each site may be issued provided scope is same and include a clear reference to the main certificate.<br>f. Issue date is the date of certification decision by Technical Reviewer or after that<br>g. Expiry date, Certificate of compliance shall be valid for a period of 3 years from the certification decision date.<br>h. Last date, in case issue of revised Certificate.<br><br>Certificate is signed by M.D. or any of the directors.<br><br>The RICL 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.<br><br>Certificate is forwarded to the client along with the use of RICL and accreditation logo, and conditions of certification.<br><br>RICL maintains the Certified Organization Directory. Details of the certified organization shall be updated within 3 days of issue of Certificate. Certificate is valid subject to conducting surveillance audits to verify continued compliance of the client MS to the planned arrangements at agreed frequency from the date of Certificate as per certification agreement and conditions of certification. |

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| | Certificate may be withdrawn or kept under suspension or made inactive under specified conditions as described in Conditions for certification. |
| **5.20** | **Criteria for Certificate suspension and withdrawal** |
| | Procedure Suspension, Withdrawal, reducing scope of Certification shall be followed. (RICL/PR/23) |
| **5.21** | **Criteria for Refusing Certification** |
| | Client may be refused for issue of certification under following conditions:<br>• If Client does not comply with terms of certification during the certification process.<br>• If some information is discovered during certification process, deliberately hidden by client and poses unacceptable threat to impartiality.<br>• Client does not take timely action on non conformities.<br>• Default in timely payment of certification fees to RICL. |
| **5.22** | **9.6 Maintaining certification**<br>9.6.1 General - RICL shall maintain certification based on demonstration that the client continues to satisfy the requirements of the management system standard. It may maintain a client's certification based on a positive conclusion by the audit team leader without further independent review and decision, provided that:<br>(a) For any major nonconformity or other situation that may lead to suspension or withdrawal of certification, RICL has a system that requires the audit team leader to report to RICL the need to initiate a review by competent personnel (see 7. 2. 8), different from those who carried out the audit, to determine whether certification can be maintained;<br>(b) Competent personnel of RICL monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.<br><br>**ISO 50003:2021 Clause 9.6.1** - when conducting EnMS audits, RICL shall ensure that, across the certification cycle, evidence related to the whole of the EnMS, including energy performance and energy performance improvement, is collected, evaluated and recorded as evidence in the audit reports. |

**Amendment Record:**

26/12/2017 - Amended as per corrective action for NC no. 9 & 10 raised during reaccreditation audit by JAS-ANZ. (Point 7 & 8, Page 9 and Clause 5.17, Page 16) PR/04.04

21/03/2018 – Amended to refer to IAF MD1:2018 (for multisite certification) for transition.

07/09/2019 - Amended as per corrective action for NC 02 raised during 2nd UAF surveillance Audit. Clause 5.8, Page 9.

28/10/2019 – Amended as per requirements of IAF MD22:2018

01/07/2020 – Amended as per requirements of IAD MD4:2018

04/04/2022 – Amended as per requirements of ISO/IEC 27006:2015. Clause 4.5, 5.7.2 & 5.11 (j), 5.13.4, 5.13.5, 5.13.6, 5.18.3 added.

16/07/2022 – Requirements of ISO 17021-1:2015 added at different relevant clauses. Earlier these were addressed in quality manual. Clause 4.9, 4.10, 4.11, 4.12 & 4.13 added as per requirement of ISO 20000-6:2017.
01/08/2022 - Requirements of MD 9:2022 added at different relevant clauses. Clause 4.14, 5.3 (l, m, n, o), 5.7.5, 5.12.1 added.
01/12/2023 – Requirements of ISO 50001:2021 at clause 5.5 (ISO 50003:2021 Clause 9.4.1), clause 5.22 (ISO 50003:2021 Clause 9.6.1)
01/12/2025 – Amended as per requirements of ISO/IEC 27006-1:2024 (Clause 5.8, 5.11, 5.13)
01/06/2026 – Clause 5.1 amended to include requirement of client specific audit program.

Approved By

ROYAL IMPACT CERTIFICATION LTD. * RICL *

Prabhakar Pandey,
MD, RICL.