Section 4

QCI – AIMED
Voluntary Initiative on Medical Devices

Indian Certification of Medical Devices ICMED (Scheme)

CERTIFICATION PROCESS FOR SYSTEMS CERTIFICATION

Copyright © 2020 by Quality Council of India. All rights reserved. No part of this publication shall be reproduced or distributed in any form or by any means, or stored in a data base or retrieval system, without the prior permission of the publisher. Issued on behalf of the QCI – AIMED Voluntary Initiative on Medical Devices Steering Committee.
CERTIFICATION PROCESS FOR SYSTEMS CERTIFICATION

0. Scopes

0.1 This document describes the certification process to be followed by the Certification Bodies approved under the Indian Certification for Medical Devices (ICMED) Scheme in processing applications received from medical devices manufacturers for certification as per criteria specified under the Scheme.

0.2 The certification process for ICMED Plus is based on tenets of QMS with an additionality of product certification based on ISO 17065: 2012, to come to a reliable certification decision w.r.t. establishing the product quality, safety etc.

0.3 This document thereby aims to reduce the level of subjectivity, promote uniformity in the operation of the Scheme and increase the implementation consistency between different CBs across different situations, desirous of operating the ICMED Scheme for certification.

0.4 This document specifies the requirements and procedures to be followed by the manufacturers in India seeking and thereafter maintaining certification of the ICMED and the Certification Bodies (CBs) to evaluate the medical devices (in case of ICMED Plus) in order to establish conformity to applicable certification requirements as per the Certification Criteria. The certification is granted only against the ICMED Certification Criteria defined under the Scheme.

0.5 The certification shall be carried out by the Certification Bodies (CBs) duly approved by the Scheme owner (SO) provisionally and eventually accredited for the certification scheme as per ISO/IEC 17021, 17065 etc. by NABCB.

1. Types of Certification -The following levels of certification shall be available:

i. ICMED 9000 Certification which is as per the requirements of ISO 9001 read with the additional requirements prescribed under the Scheme in ICMED 9000.

ii. ICMED 13485 which is as per the requirements of ISO 13485 read with the additional requirements prescribed under the Scheme in ICMED 13485

iii. ICMED 13485 Plus Certification of Medical Devices as per specifications, where available developed by the National Health Systems Resource Centre (NHSRC) of the Ministry of Health & Family Welfare in addition to the requirements of the ICMED 13485, in line with national and international standards like ISO, IEC, BIS etc.

iv. The certification shall be granted for each manufacturing facility/premises after due verification of compliance to the prescribed criteria.

NOTE: Plant, Unit, Manufacturing facility, Medical device manufacturing facility, Premises, Manufacturer are interchangeable and all these terms refer to an individual medical device manufacturing facility.

2. Application for Certification

2.1 Application Form

2.1.1 The manufacturer shall apply in the application form prescribed by the Certification Body.

2.1.2 The applicant shall clearly indicate the type of certification it is applying for.
2.1.3 The applicant shall provide information about each manufacturing facility to be certified.

2.1.4 The applicant shall clearly indicate if any of the activities covered under the criteria for certification are being carried out at any premises other than the main premises. This is to plan and facilitate covering the applicable criteria under the same audit. For example, Design or R &D or Testing or any outsourced processes.

2.1.5 The applicant shall specify/list all the activities to be audited and certified. It shall mention whether all the activities are covered at single or multiple locations/sites. For multiple sites, overlapping activities, if any shall also be mentioned.

2.1.6 Irrespective of the number of facilities of a manufacturer, to be covered under certification, each and every manufacturing facility shall be audited for compliance to the Criteria as applicable.

2.1.7 The applicant shall provide the list of medical devices to be covered under the scope of certification.

2.2 List of Documents

2.2.1 The applicant shall submit all necessary documents (as per applied criteria) to the Certification Body (CB) for document review.

2.2.2 In case of ICMED Plus following documents are required (that are indicative only)
   a) Documents confirming the Indian legal entity of the manufacturer.
   b) Documents relating to authorizations and permissions required as per regulations.
   c) Detailed specifications
   d) Design appraisal if required
   e) Analysis Reports and Test reports (as per scheme requirement)
   f) Device logbook/ manufacturers operating manual
   g) Maintenance manual
   h) Maintenance inspection schedule
   i) Other relevant reports

2.3 Any information considered essential for determining auditor competence and estimation of auditor man-days.

2.4 Regulatory body or suspension/cancellation/withdrawal of any relevant approvals/certifications under any Regulations or otherwise.

2.6 Information for Applicants

2.6.1 The information describing certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and geographical areas in which it operates shall be publicly available on certification body’s website and by other modes.

2.6.2 The other information available on certification bodies website and by other modes shall include:
   i. An Application form;
   ii. Reference to the Certification Criteria,
   iii. Procedure for obtaining certification under the ICMED Scheme, a detailed description of the initial and continuing certification activity, including the application, initial
evaluation, periodic surveillance, evaluations, and the process for granting, maintaining, reducing, extending, suspending, withdrawing certification and re-certification.

iv. List of documents required to be submitted along with the application.

v. Information about the fees for application, initial certification and continuing certification and policy for the fee

vi. Documents describing the rights and duties of applicants/ certified clients, and

vii. Information on procedures for handling complaints, feedbacks and appeals.

2.7 Registration of Application

2.7.1 The CB shall respond to all enquiries received from prospective applicant organisations for certification with complete information for facilitating registration of application, within 7 working days of receipt of the query.

2.7.2 The applicant for certification shall apply to any of the approved Certification Bodies on the Application format prescribed by the CB, and provide the information as mentioned in previous clauses and any other information the CB may consider relevant to the certification process.

2.7.3 The applicant shall declare (in the form of an undertaking in application) whether it has been an applicant / certified under this Scheme with or by any other certification body, and if yes then shall provide the previous evaluation reports to the new certification body. The certification body may verify the information provided by contacting the earlier certification body.

2.7.4 The prospective applicant for Medical device manufacturer shall along with the application declare any judicial proceedings relating to its operations, any proceedings by any Regulatory body or suspension / cancellation / withdrawal of any certification / approvals under any Regulations or otherwise. Such declaration shall be a part of the undertaking mentioned in 1.4.3 above.

2.7.5 Certification is granted only against the current relevant certification criteria. The certification body shall review all applications for the above and ensure the same.

2.7.6 All applications for certification shall be reviewed by the certification body for adequacy and deficiencies observed, if any, shall be informed to applicant within 7 working days of receipt of application. Review of applications shall be done by a competent person. Records of review shall be maintained.

2.7.7 Only complete applications supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. Registration shall be done within 7 days of receipt of application or information in response to the deficiencies communicated as per 1.4.6 above. In case the applicant discloses any proceedings, suspensions etc as per 1.4.3 above, the applicant shall not be entertained for a period of one year from the date of conviction, suspension, withdrawal, deregistration etc.

2.7.8 If the certification of any level under the Scheme has been suspended / cancelled by any approved CB, the application from such a manufacturer shall not be accepted till suspension is revoked by the concerned CB or for one year from the date cancellation
of certification. This will be applicable only for the manufacturing facility whose certification has been suspended/cancelled. However, this will not be applicable to other manufacturing facilities under same legal entity.

2.7.9 The certifications (ISO 9001 and/or ISO 13485) by CBs other than IAF MLA signatory accredited CBs shall not be accepted.

2.7.10 Where manufacturing facility is certified by Certification Bodies accredited by NABCB, audit related to scheme criteria shall be carried out.

2.7.11 Where the certification (for ISO 9001 and/or ISO 13485) is carried out by IAF MLA signatory accredited CBs other than NABCB, full audit as per scheme criteria requirements shall be carried out.

2.7.12 If ISO 9001 and/or ISO 13485 certification of the applicant is under suspension, application for certification shall not be entertained till the suspension of ISO 9001 and/or ISO 13485 certification is revoked. In case ISO 9001 and/or ISO 13485 certification of a manufacturing facility is cancelled by any CB, the application certification Under the Scheme may be carried out considering manufacturing facility as new client.

2.7.13 The antecedents of the applicants shall be checked in relation to the Scheme. Applications from manufacturers who have earlier either misused the Certification, or whose earlier certificate was cancelled because of violation of terms & conditions / misuse of certification or have been implicated / convicted by the court in relation to their manufacturing activities, shall not be entertained for a period of one year of conviction / strictures by the court / cancellation of the certificate by any CB.

2.7.14 Applications from manufacturer found to be misusing the certification while their application is being processed for grant of certification, shall not be processed any further, and rejected after a due notice of 15 days. Fresh applications from them shall be treated as per clause 1.4.13 given above.

2.7.15 Requests for grant of certification from previous applicants as per 1.4.16 (a), (b) & (c) / expired certificates shall be processed like fresh applications and the entire procedure for grant of certification shall be adhered to subject to clauses 1.4.8 to 1.4.12 above.

2.7.16 An application shall be rejected or closed under the following conditions;

i. if Initial Evaluation is not carried out within 3 months of registration of application

ii. if the entire certification process is not completed within 6 months of registration of application.

iii. If the applicant shows no progress towards completion of corrective actions within 3 months of Initial Evaluation and 6 months of Registration of application.

iv. Misuse of certification under the Scheme

v. Evidence of any malpractice

vi. Voluntary withdrawal of application.

2.7.17 The application fee, if charged by CB, shall be non-refundable.
3. Audit Programme

3.1 Considering the type of the certification sought, the following program shall be followed:

<table>
<thead>
<tr>
<th>Certification activity</th>
<th>ICMD 9000</th>
<th>ICMED 13485</th>
<th>ICMED 13485 PLUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certification Audit – Stage 1</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certification Audit – Stage 2</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surveillance – “Once in a year”, Second surveillance audit shall be a unannounced audit which shall be carried out within period of 9 to 12 months from previous surveillance audit.”</td>
<td>√</td>
<td>√</td>
<td>For ICMED PLUS, refer ICMED PLUS Certification Criteria for Product Certification.</td>
</tr>
</tbody>
</table>

For ICMED PLUS, refer ICMED PLUS Certification Criteria for Product Certification.

i. For ICMED 9000 and ICMED 13485 the audit cycle shall include
   a. Initial certification audit in two stages (Stage 1 and Stage 2) as per ISO 17021-1:2015 and
   b. Recertification audits (generally 3 months before the end of 3-year validity) – However Provision given in Clause 9.6.2.2.4 and 9.6.3.2.5 of ISO 17021-1: 2015 shall apply.

ii. for ICMED 13485 Plus
   a. Initial certification audit as per ISO 17065:2012 and
   b. Recertification audits (generally 3 months before the end of 3-year validity)

3.2 Sampling of Manufacturing Facility to be Audited.

The certification shall be granted for each manufacturing facility/premises after due verification of compliance to the prescribed criteria. If same products are manufactured at different sites, sampling can be considered based on risk assessment. The certification body shall record the justification for sampling the sites for audits (initial, surveillance or recertification)

3.3 Audit Man days

The man days required to conduct an effective audit shall be calculated in accordance with the following Table:

<table>
<thead>
<tr>
<th>Certification Activity</th>
<th>Audit Man-day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bifurcation of Stage – I (20%) and Stage - II (80%)</td>
</tr>
<tr>
<td></td>
<td>ICMED 9000</td>
</tr>
<tr>
<td>Certification Audit/ Surveillance/ Recertification</td>
<td>As per IAF MD 5 Plus</td>
</tr>
<tr>
<td></td>
<td>1 man day on Site</td>
</tr>
</tbody>
</table>

June 2021

Page 6 of 19
3.3.1 Time duration shall be calculated for each manufacturing facility and each manufacturing facility shall be individually audited by CBs.

3.3.2 The minimum audit time for each on site audit shall be at least one man-day (8 hrs. per day).

3.3.3 Document review, audit preparation and report preparation time shall be additional and shall be at least one man-day.

4. Pre Audit Requirements

4.1 Preliminary information to be provided to the CB

4.1.1 CBs shall inform client regarding documentation to be provided by manufacturing facility for “Document review” in compliance to scheme criteria requirements as applicable.

4.1.2 Before starting the application review, the applicant shall provide the Certification Body with the documentation in compliance to ICMED 9000 and ICMED 13485 requirements, as applicable.

4.1.3 Apart from information regarding the equipment and facilities of manufacturing facility particularly sterilization process, the applicant shall provide information regarding the plan and frequency of controls carried out on incoming material, production facilities and testing equipment in order to allow auditors to have a preliminary overview of the manufacturing facility.

4.1.4 The documentation to be provided shall include the following:

i. Quality Manual – Addressing all the requirements as per criteria document

ii. Procedures – (Procedures related to process and general area of operation such as purchase, H.R. etc)

iii. Quality Plan – Addressing controls applied & verification frequency of inspection of incoming material, Process controls and final Product(s) etc.

iv. Standard operation procedures/ Work instructions

v. Form and Formats.

4.2 Audit Team

4.2.1 The CB shall appoint an Audit Team having the necessary competences required to conduct the audit.

<table>
<thead>
<tr>
<th>Audit Type</th>
<th>Audit Team composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certification Audit / Surveillance / Recertification Audit</td>
<td>Team Leader + Auditor (If required) + Technical Expert (if Lead auditor or Auditor is not qualified for medical device sector)</td>
</tr>
</tbody>
</table>

4.3 Audit Plan
4.3.1 The CB shall ensure that the Audit is conducted during working days in which all manufacturing and support processes are functional.

4.3.2 No audit shall be planned in case the manufacturing facility is non-operational.

4.3.3 The Auditors, if more than one, may conduct part of the audit in parallel being focused on specific processes/areas.

4.3.4 All the activities as included in the scope of certification of manufacturing facility such as design, manufacture, construction, marketing, installation, servicing or supply of the medical device etc shall be audited irrespective of location.

4.3.5 The audit of the controlling/ head office shall be planned in case it is catering to multiple manufacturing facilities to verify all the functions of its activities.

5. Certification Audit (ICMED 9000 and ICMED 13485)

5.1 Stage 1 Audit

5.1.1 The stage 1 audit is performed to:

i. Audit the client’s management system documentation

ii. Evaluate the client’s location and specific conditions and to undertake discussions with the client’s personnel to determine the preparedness for the stage 2 audit;

iii. 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 including scheme requirements;

iv. Collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance (e.g. Quality, environmental, legal aspects of the client’s operation, associated risks, etc.);

v. Review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit;

vi. Provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client’s management system and site operations in the context of possible significant aspects;

vii. Evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.

viii. Auditors shall identify personal protective equipment which may be reasonably required during while auditing processes in stage – 2 audit and report in stage – 1 audit and ensure availability of the required personnel protective equipment during Stage – 2 audit.

ix. If manufacturing facility operating in shifts, Justification to be recorded if shifts are not to be audited. (Refer clause 9.1.3.5 of ISO 17021-1)
5.1.2 The Stage – I audit shall be carried out by a competent audit team on site to judge the adequacy of the system to meet requirements of applicable ICMED 9000 and ICMED 13485 criteria. It shall result in a formal report.

5.1.3 The stage 1 audit shall be carried out at the client's premises in order to achieve the objectives. The CB shall have a defined guideline for the same. (Also Ref IAF MD 2).

5.2 Stage 2 Audit

5.2.1 The Objectives of stage 2 audit shall be to verify compliance to the applicable certification criteria, regulatory requirements, verification of documents and records, and interviews with the personnel involved in various relevant activities. The stage 2 audit shall be conducted on site.

5.2.2 Competence of people at manufacturing facility shall be audited to verify the effective knowledge QA/QC and of internal procedures, applicable standards related to medical device being produced. The competency of the personnel shall be as per applicable regulation. The requirement is as follows.

“The manufacture & Quality Assurance will be conducted under the active direction and personal supervision of competent technical staff consisting of at least one person each for manufacturing & Quality Assurance who is a whole time employee and who is

i. a Graduate in Engineering or Pharmacy from a University recognized by the Central Government for such purposes and has had at least eighteen-month practical experience in the manufacturing or Quality Assurance of devices after his graduation; or

ii. a Graduate in Science, from a University recognized by the Central Government for such purposes and has had at least three years practical experience in the manufacturing or Quality Assurance of devices after his graduation; or

iii. a Diploma in Engineering or Pharmacy from a Board or Institute recognized by the Central Government or the State Government, as the case may be, for such purposes and has had at least four years practical experience in the manufacturing or Quality Assurance of devices after his diploma; or

iv. having a foreign qualification, the quality and content of training of which are comparable with those specified in clause (i), clause (ii) and clause (iii) above and is permitted to work as competent technical staff

6. Certification Audit (ICMED 9000 and ICMED 13485)

6.1 Initial Evaluation

6.1.1 Initial site evaluation - The site visit shall cover review of records (Stage 1) and onsite testing and laboratory testing (stage 2). If required, witnessing of testing shall be carried out, hence forth shall be called as on-site evaluation.

6.1.1.1 Initial evaluation shall be carried out by a competent evaluation team in two stages. Both the Stage 1 and Stage 2 evaluation shall be combined evaluation.
6.1.1.2 The information gathered during stage 1 evaluation shall be used for making adjustment in evaluation time and/or audit team competence for stage 2 evaluation, as necessary.

6.1.1.3 Timings and date of Initial site evaluation shall be fixed in consultation with the applicant ensuring that all the activities related to the applicable certification criteria are carried out.

6.1.1.4 The evaluation plan covering the relevant evaluation objectives shall be prepared and communicated to the applicant well in advance.

6.1.1.5 Stage 1 Evaluation - The Objectives of stage 1 evaluation shall be:
   i. To review the documents and records submitted by the applicant, for each of the device applied for compliance to the applicable requirements as per ICMED Plus Certification Criteria.
   ii. To review and revise, if required an evaluation plan for stage 2 evaluation.

6.1.1.5.1. Deficiencies (non-conformities) observed with respect to the certification criteria during the Stage 1 shall indicate non-compliance with respect to applicable requirements of the ICMED Plus certification criteria. No further categorisation of deficiencies/non-conformities is done.

6.1.1.5.2. In case of any non-compliance with respect to a particular device is observed, the certification body shall require from the applicant to submit a set of documents and records to indicate the compliance as per the applicable clause with fresh sample, as applicable for the relevant device.

6.1.1.5.3. The evaluation team shall prepare a report highlighting the level of compliance for each of the applicable requirements for every device as per the scope of certification including the deficiencies. As and when the deficiency is observed, a recommendation be made for holding the certification until a reasonable time so that the applicant may submit the compliant records, documents and equipment as may be the case. On completion of the stipulated time, a recommendation be made for the discontinuation of the certification process and closure of the certification.

6.1.1.6 Stage 2 Evaluation

6.1.1.6.1 The Stage 2 evaluation by certification body shall take place only when all the applicable requirements of the ICMED (13485 and Plus) certification criteria have been evaluated in stage 1 and compliance to requirements observed and no deficiencies (non-conformities) have been observed.

6.1.1.6.2 The objective of the stage 2 evaluation shall be:
   i. The stage 2 evaluation shall cover on-site testing and laboratory testing for each of the medical device(s) applied for in the scope of application. Witnessing of testing shall be carried out as part of the stage 2 evaluation.
   ii. Software and firmware shall be evaluated for safety and security requirements in an Government approved/NABL accredited laboratory for the scope. To enable this, necessary information relating to architecture, design and source code and other information to enable their evaluation shall be collected from the applicant. On the basis of the satisfactory reporting, the evaluation team shall validate the same on-site at the applicant’s site for compliance. When access to the Govt. approved lab/NABL labs are in ICMED Plus Certification Process a distant location, the testing being conducted by the applicant onsite shall be witnessed by the CB evaluation team.
6.1.1.6.3 Deficiencies (non-conformities) observed with respect to the certification criteria during the Stage 2 shall indicate non-compliance with respect to applicable requirements of the ICMED Plus certification criteria. As and when the deficiency is observed, a recommendation be made for holding the certification until a reasonable time so that the applicant may submit the compliant records, documents and equipment as may be the case. On completion of the stipulated time, a recommendation be made for the discontinuation of the certification process and closure of the certification.

6.1.1.6.4 In case of any non-compliance with respect to a particular device is observed, the certification body, a recommendation be made for holding the certification until a reasonable time so that the applicant may submit the compliant records, documents and equipment as may be the case. On completion of the stipulated time, a recommendation be made for the discontinuation of the certification process and closure of the certification.

6.1.1.7 The evaluation report – The evaluation reports for stage 1 and stage 2 shall clearly provide evidence and conclusions about the fulfilment of the evaluation objectives as described above and shall contain sufficient detailed information regarding conformity with all the relevant certification requirements, including the Certification Criteria for each device singularly. The Certification Body shall develop appropriate report format(s) and report writing guidance document to ensure that the report provides, adequate and complete details for ensuring appropriate, evaluation, review and decision in respect of grant of certification.

6.2 Independent testing of samples

6.2.1 Software and firmware shall be evaluated for safety and security requirements in an Government approved/NABL accredited laboratory for the scope. To enable this, necessary information relating to architecture, design and source code and other information to enable their evaluation shall be collected from the applicant. On the basis of the satisfactory reporting, the evaluation team shall validate the same on-site at the applicant’s site for compliance.

6.2.2 When the Government approved lab/NABL labs located at a distant location are difficult to access, the testing being conducted by the applicant onsite shall be witnessed by the CB evaluation team. Please see 4.1.1.6.2 b (above).

6.2.3 When the testing being conducted by the applicant onsite is witnessed by the CB evaluation team this would be considered as independent testing.

6.2.4 All test witnessed conducted by the applicant shall be considered as equivalent to independent testing of medical device.

6.2.5 The device submitted to lab by the manufacturer may not exceed 3. In case, the CB requires additional devices, the same may be requested with proper justification with adequate advance notice.

6.3 Final Evaluation

6.3.1 The purpose of this process step is to conduct an evaluation of all the information gathered through the process steps of Stage 1 and stage 2 evaluation and the results of independent testing:

i. to ascertain if all the process steps as described in the certification process leading to grant of certificate have been fulfilled,

ii. to confirm that the medical device applied for as per scope of application complies with requirements described in the relevant certification criteria.
6.3.2 The final evaluation shall ensure compliance to the certification requirement and any other requirements prescribed by the Certification Body, and no non-conformances observed.

6.3.3 Based on the evaluation as above, recommendations for proceeding to next step (independent review and decision making) shall be made. In case the evaluation indicates that some requirements of the certification criteria or the certification scheme have not been met and then these need to be completed and evaluated before proceeding to the next step.

6.3.4 The final evaluation shall be carried out by competent personnel, duly authorised for this function. The team leader designated for the conduct of Initial Evaluation may also be authorised for this activity.

6.3.5 Records of final evaluation along with all supporting documents and reports shall be retained at least for the period of two certification cycles i.e. 6 years or until the device is in service, whichever is later

6.4 Safety during Audits

6.4.1 The Audit at medical device manufacturing facility involves risks linked to work environment. The responsibility for risk analysis and the identification of the most suitable means of protection is shall be that of the manufacturer.

6.4.2 Auditors must have personal protective equipment which may be reasonably required to while auditing different manufacturing processes of manufacturing facility particularly sterilization.

6.5 Non-Conformities

6.5.1 Any non-conformities observed during audit, with respect to the certification criteria shall be informed in writing to the applicant for taking necessary action. The non-conformities shall be classified as Major or Minor depending on their severity.

   i. Major Non-conformity – A non-conformity that affects the capability of the management system to achieve the intended results. A number of minor NCs on the same aspect shall be clubbed together and raised as single major NC.

   ii. Minor Non-conformity – All other gaps and non-conformities shall be classified as Minor. These shall generally be related to other implementation issues which do not directly affect the capability of the management system to achieve the intended results.

6.5.2 In case of major and minor NCs the organization shall carry out root cause analysis and inform the same along with correction and corrective actions, within a period of one month or 3 months respectively. All non-conformities are required to be closed before initial certification and recertification through verification of adequacy of the correction and corrective actions. All Major non-conformities, shall invariably require an onsite follow-up audit.

6.6 Audit Report

6.6.1 The Certification Bodies shall send the Audit Report to the client within 7 working days from the date of the completion of the audit.

6.6.2 The audit reports for stage 1 and stage 2 shall clearly provide evidence and conclusions about the fulfilment of the audit objectives as described above and shall contain sufficient detailed information regarding conformity with all the relevant
certification requirements, including the Certification Criteria. The Certification Body shall develop appropriate report format(s) and report writing guidance document to ensure that the report provides, adequate and complete details for ensuring appropriate, evaluation, review and decision in respect of grant of certification. The Audit report shall have the following as minimum:

i. identification of the certification body;
ii. the name and address of the client and the client’s representative;
iii. the type of audit (e.g. initial, surveillance or recertification audit or special audits);
iv. the audit criteria;
v. the audit objectives;
vi. the audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit;
vii. any deviation from the audit plan and their reasons;
viii. any significant issues impacting on the audit programme;
ix. identification of the audit team leader, audit team members and any accompanying persons;
x. the dates and places where the audit activities (on site or offsite, permanent or temporary sites) were conducted;
xi. audit findings, reference to evidence and conclusions, consistent with the requirements of the type of audit;
xii. significant changes, if any, that affect the management system of the client since the last audit took place;
xiii. any unresolved issues, if identified;
xiv. where applicable, whether the audit is combined, joint or integrated;
xv. a disclaimer statement indicating that auditing is based on a sampling process of the available information;
xvi. recommendation from the audit team
xvii. the audited client is effectively controlling the use of the certification documents and marks, if applicable;
xviii. verification of effectiveness of taken corrective actions regarding previously identified non-conformities, if applicable.

NOTE: ISO 17022 may be referred to for further guidance on Audit reporting

7. Certification Decisions

7.1 Certification decision shall be the sole responsibility of the certification body and the decision shall be taken by its internal person(s) competent for the job provided they have not been involved in the process of audit of the organization. Impartiality and absence of conflict of interest shall be ensured before entrusting the task of certification decision making. Also refer 4.3.3 of “ICMED - Requirement of CB” document.

7.2 Conditions for Granting a Certificate:

7.2.1 The CB shall grant the certification when all the following conditions are met with:

a. The audit report with suitable recommendation is available
b. All NCs raised have been closed.
c. There are no other issues impacting grant of certification

There shall be no conditional grant of certification.

8. Certificate
8.1 The manufacturer may achieve one of the following certificates:

<table>
<thead>
<tr>
<th>Certificate</th>
<th>Object</th>
<th>Extension</th>
<th>Certificate Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Manufacturing facility</td>
<td>All the processes carried out</td>
<td>Single manufacturing facility</td>
<td>One certificate number</td>
</tr>
<tr>
<td>Multi-Site</td>
<td>Group of manufacturing facilities sharing common facilities or processes</td>
<td>Group of manufacturing facilities</td>
<td>One number (the certificate shall have an annexure with the list of certified Manufacturing facilities)</td>
</tr>
<tr>
<td>Company</td>
<td>Entire company</td>
<td>All manufacturing facilities</td>
<td>One number per company (the certificate shall have an annexure with the list of certified manufacturing facilities)</td>
</tr>
</tbody>
</table>

8.2 **Certification Documentation** - The certificate shall include the following information:

i. the name and geographical location of each certified client (or the geographical location of the headquarters and any sites within the scope of a multi-site certification);

ii. the effective date of granting, expanding or reducing the scope of certification, or renewing certification which shall not be before the date of the relevant certification decision;

**NOTE:** The certification body can keep the original certification date on the certificate when a certificate lapses for a period of time provided that:

a. the current certification cycle start and expiry date are clearly indicated;

b. the last certification cycle expiry date be indicated along with

c. the date of recertification audit.

iii. the expiry date or recertification due date consistent with the recertification cycle;

iv. a unique identification code i.e. Certificate number

v. Certification Scheme name/ the management system standard and/or other normative document, including indication of issue status (e.g. revision date or number) used for audit of the certified client;

vi. the scope of certification with respect to the type of activities, products and services as applicable at each site without being misleading or ambiguous;

vii. the name, address and certification mark of the certification body; other marks, Scheme logo, Accreditation Logo (applicable only, once accredited) etc. symbol, client’s logo) may be used provided they are not misleading or ambiguous;

viii. any other information required by the standard and/or other normative document used for certification

ix. in the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents.

x. Signature of the CBs authorized representative
xi. In case of company certification, the CB shall annex to the certificate the list of the certified manufacturing facilities.

8.3 Validity

8.3.1 The certificate shall be valid for 3 years from the date of issue.

9. Surveillance Audits

9.1 Surveillance audits, announced and unannounced shall be carried out on site at a frequency mentioned in clause 2.1, by a competent audit as per clause 3.2 above. The audit man-days for surveillance audits shall be as defined in clause 2.3.

9.2 Non-conformities observed during surveillance audit shall be categorized as major and minor as defined in clause 3.4.

10. Suspension

10.1 The certification body shall issue instructions to the certified organization for suspension of certification when

   i. the major NCs issued are not closed in timelines prescribed
   ii. repeated major NCs are raised in consecutive surveillance assessments there is failure to organize a surveillance audit within the specified time period
   iii. there is non-payment of outstanding dues
   iv. any major changes have taken place in the legal status, ownership, name etc without prior information to the CB
   v. any willful misuse of the logo of the Scheme is detected
   vi. any willful false declaration in the application form or otherwise is detected
   vii. excessive or serious complaints against the certified organization management system are received and are found to be valid
   viii. the certified organization voluntarily requests a suspension. Such request must be submitted in writing to the CB along with the reasons. The CB may decide to accept the request but may not allow the client to revoke suspension on its own.

10.2 The certification body shall issue due notice of at least one week for suspension of certification to the certified organization.

10.3 When certification is suspended, the certification body shall require that, during the period of suspension, the certified organization makes no misleading claims.

10.4 The certification body shall revoke suspension only when Corrective actions have been taken and verified by the certification body.

11. Renewal of Certification
11.1 The certification shall be renewed at the expiry of 3 years validity period. However, the renewal process and the renewal of certification decision shall be taken on or before the certificate expiration date. In order to achieve the same, the certification body shall send the Renewal notice to the certified units at least four months prior to expiry of certificate validity period. However, Provision given in Clause 9.6.2.2.4 and 9.6.3.2.5 of ISO 17021-1: 2015 shall apply.

11.2 The certified organization shall apply for renewal in the prescribed format along with fee, if any prescribed by the CB at least 3 months before expiry of the certification.

11.3 The onsite surveillance audit conducted towards the end of third year and before the expiration of the certificate shall be considered as the recertification audit (refer clause 2.3). The objectives of this audit will be a combination of stage 2 and surveillance audits, unless there have been any changes in product and process requirements, which would then also require assessment of the organization’s revised processes, controls and systems.

11.4 The certification body shall review the performance of the certified unit who has sought renewal of the Certificate, with respect to compliance to certification criteria during the entire certification cycle, prior to a decision on the renewal of the certificate. The review shall essentially be based on the following:

i. Surveillance and recertification audit reports for the audits carried out during the certification cycle. The NCs raised and the satisfactory resolution of the issues raised and their effectiveness.

ii. Any suspension of certificate during the previous validity period;

iii. corrective actions taken

iv. complaints if any received,

v. Adverse information from stakeholders and regulators, if any.

11.5 The review shall be conducted by competent person (s) designated for the job.

11.6 The decision for renewal of certificate shall be taken by the competent personnel authorised for the same, based on the satisfactory performance of the certified organization.

11.7 The certification body shall not renew certification with conditions for compliance to be verified subsequently. There shall be no conditional renewal of certification.

11.8 When performance of the certified unit is not satisfactory, the certification body shall withhold the renewal of the certificate clearly stating the reasons and give time for effecting corrective actions. The verification and decision on renewal should be taken within 3 months of the certification expiry date.

11.9 The corrective actions shall be verified generally on site unless the Certification Body can verify the same off site prior to considering for renewal of certificate. The justification for off-site review shall be recorded.

11.10 In case the manufacturing unit does not complete satisfactorily actions within three months, the certificate shall stand expired from the date of expiry of previous validity.
11.11 When a certificate is not renewed, it shall expire at the end of validity period.

12. **Withdrawal**

12.1 Certification body shall withdraw the certificate when

i. Certified organization contravenes the terms and conditions of certification and provisions of the ICMED scheme

ii. The certified organization is not conforming to the requirements of the Certification Criteria and the corrective actions taken are not ensuring compliance,

iii. the proposed plan for corrective actions will take a considerable time beyond 6 months for implementation;

12.2 Certification body shall withdraw the certificate at the request of the certified plant, if the operation(s) in the certified organization can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc., lock out declared by the management, or closure of business operations etc.

13. **Change of location/Ownership/Name**

13.1 The certified organization shall inform the CB of any change in the location of the manufacturing unit.

13.2 On receipt of such information, the certification body shall issue instructions to the certified organization for suspension of certification with immediate effect.

13.3 The manufacturing unit shall be subject to an onsite audit at the new site like an Initial audit of an applicant.

13.4 If the audit is satisfactory, the Certification Body shall transfer the Certificate to the new location.

13.5 The CB shall endorse the change of premises on the Certificate.

13.6 In the event of change of Ownership, the organization shall provide necessary documentary evidence. The new management of the organization shall submit its acceptance to the agreement with the Certification Body, and payment of fees. The same process shall be followed as and when an existing applicant undergoes a change in management. Such changes shall not call for a visit to the production site.

13.7 In case of change of Name, the manufacturer shall inform the change in the name to the CB supported with documentary evidence, and if satisfied the CB shall endorse the Certificate in the new name.

14. **Complaints and appeals**

14.1 The certification body shall have a documented procedure for handling of complaints and appeals.

14.2 The procedure for complaint handling shall include complaints from all stake holders, especially its certified organization as well as customers of its certified organizations.
14.3 The procedure for receipt and handling of complaints shall be made available to public on the CB’s website and shall also be easily accessible on the website.

14.4 Upon receipt of a complaint or appeal, the certification body shall confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, shall address it. The certification body shall acknowledge receipt of a formal complaint or appeal.

14.5 The certification body shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

14.6 The procedure shall include the process steps for receiving and recording, evaluating and establishing validity of the same, investigating and make decisions on complaints and appeals. The process step shall also include the activities of root cause analysis, correction and corrective actions.

14.7 If the complaint relates to a certified organization, then the examination and evaluation of the complaints shall take in to consideration the effectiveness and implementation of the certified organizations system.

14.8 The CB’s complaint handling process shall document the actions to be taken by the CB as well as the certified organization, some of these actions/conditions shall also be included in the CB’s legally enforceable contract with the certified organization.

14.9 The certification body shall record and track complaints and appeals, as well as actions undertaken to resolve them.

14.10 The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal. To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy for a certified organization, or been employed by the certified organization, shall not be used by the certification body to review or approve the resolution of a complaint or appeal for that certified organization within two years following the end of the consultancy or employment.

14.11 Whenever possible, the certification body shall give formal notice of the outcome and the end of the complaint process to the complainant.

14.12 In respect of appeals the CB shall ensure that the individual(s)/committee entrusted with handling of appeal and its resolution decision shall be independent of the persons involved in certification related recommendations and decision and their position in the CB shall be such that it shall not be possible to influence their decisions with respect to the subject of the appeal.

14.13 The procedure shall also have provision for giving a written statement to the appellant, of the appeal findings including the reasons for the decisions reached and also communicating to the appellant about the provision for giving an opportunity to formally present his case.

14.14 Based on the presentation made, the individual or a committee appointed for hearing the case shall take a final decision on the appeal and a formal notice of the outcome and the end of the appeal process shall be given to the appellant.
14.15 The certification body shall give formal notice of the outcome and the end of the appeal process to the appellant.

14.16 The certification body shall take any subsequent action needed to resolve the complaint or appeal.

15. Fee

15.1 A fee to be charged to the organization for various activities of the certification scheme, without any discrimination between manufacturing facilities, geographical location, size of the manufacturing facility.

15.2 The CBs fee structure shall be publicly accessible and also be provided on request. The fee structure shall provide break up of costs.

15.3 CB shall notify and obtain consent to its fee structure from the organizations prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all including applicants and the manufacturing facility certified under this scheme of certification for their acceptance.