INDIAN CERTIFICATION FOR MEDICAL DEVICES (ICMED) CERTIFICATION SCHEME

Certification Process
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Scope</td>
<td>3</td>
</tr>
<tr>
<td>1 Application for Certification</td>
<td>3</td>
</tr>
<tr>
<td>2 Audit Programme</td>
<td>7</td>
</tr>
<tr>
<td>3 Certification Audit Planning</td>
<td>8</td>
</tr>
<tr>
<td>4 Certification Audit</td>
<td>9</td>
</tr>
<tr>
<td>5 Certification Decision</td>
<td>13</td>
</tr>
<tr>
<td>6 Surveillance</td>
<td>13</td>
</tr>
<tr>
<td>7 Complaints</td>
<td>13</td>
</tr>
<tr>
<td>6 Certificate</td>
<td>13</td>
</tr>
<tr>
<td>9 Suspension and Withdrawal of Certificate</td>
<td>16</td>
</tr>
<tr>
<td>10 Change of Location / Ownership / Name</td>
<td>17</td>
</tr>
<tr>
<td>7 Fee</td>
<td>17</td>
</tr>
</tbody>
</table>
0. SCOPE

0.1 This document describes the certification process to be followed by the Certification Bodies approved under the Medical devices manufacturer facility Certification Scheme operated by the Quality Council of India for ICMED 9000, ICMED 13485 and ICMED 13485 Plus (Product specification as per MoHFW’s Technical specifications) as per criteria specified for each type of scheme.

0.2 Types of Certification
The following certification schemes shall be available:

i. ICMED 9000, An ISO 9001 requirements Plus additional requirement

ii. ICMED 13485, An ISO 13485 requirements Plus additional requirements

iii. ICMED 13485 Plus (Product specification as per MoHFW's Technical specifications)

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

0.4 This document should be read with the document titled “Indian certification for medical devices Certification Criteria ICMED 9000, ICMED 13485 and ICMED 13485 Plus” published by the QCI – AIMED in support of the QCI AIMED Voluntary initiative for medical devices.

1. Application for Certification

1.1 Application Form
1.1.1 The applicant shall clearly indicate the type of certification being applied for.

1.1.2 The application form shall include the information about each manufacturing facility to be certified.
1.1.3 The Application form shall clearly indicate if any of the activities covered under the criteria for certification are being carried out at any other premises other than the main location. This is to plan & facilitate covering the applicable criteria under the same audit. Example Deign or R &D, Testing and any outsource processes etc.

1.1.4 The applicant shall specify/enlist 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 overlap activities, if any shall also be mentioned.

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

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

1.3 Information for Applicants
1.3.1 The certification body shall maintain and make publicly available (on its web site and by other modes) accurate information describing its certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and geographical areas in which it operates. The information shall include:

a) An Application form;
b) Reference to the Certification Criteria,
c) Procedure for obtaining Medical devices manufacturing Certification, 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 .
d) List of documents required to be submitted along with the application.
e) Information about the fees for application, initial certification and continuing certification and policy for the fee
f) Documents describing the obligation of applicants/ certified clients, and
g) Information on procedures for handling complaints, feedbacks and appeals

1.4 Registration of Application
1.4.1 The CB shall respond to all enquiries received from prospective applicant organisations for Medical device manufacture scheme Certification with complete information for facilitating a registration of an applicant, within 7 working days of receipt of the query.
1.4.2 The applicant 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.

1.4.3 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.

1.4.4 The applicant 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.

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

1.4.6 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.

1.4.7 Complete application 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 working 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.

1.4.8 If the Medical device manufacture scheme Certification of either type has been suspended / cancelled by any approved CB, the application from such an manufacturer facility shall not be accepted till suspension is lifted 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 have been suspended. However this will not be applicable to other manufacturing facilities under same legal entity.
1.4.9 The certifications (ISO 9001 and/ or ISO 13485) by CBs other than IAF MLA signatory accredited CBs shall not be accepted.

1.4.10 Where the certification activities (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.

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

1.4.12 If ISO 9001 and/or ISO 13485 certification of the applicant is under suspension, application for Medical device manufacture scheme 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 for Medical device manufacture scheme Certification can be carried out considering manufacturing facility as new client.

1.4.13 The antecedents of the applicants shall be checked in relation to the Scheme. Applications from Medical device manufacture scheme Certification facilities 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, shall not be entertained for a period of 1 year of conviction / strictures by the court / cancellation of the certificate by any CB.

1.4.14 Applications from manufacturing facility found to be misusing the Medical device manufacture scheme Certification while their application is being processed for grant of certificate, 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.

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

1.4.16 Certification Bodies shall reject or close an application under the following conditions;  
a) if Initial Evaluation is not carried out within 3 months of registration of application  
b) if the entire certification process is not completed within 6 months of registration of application.  
c) If the applicant shows no progress towards completion of corrective actions within 3 months of Initial Evaluation and 6 months of Registration of application.  
d) Misuse of Medical device manufacture scheme Certification  
e) Evidence of any malpractice  
f) Voluntary withdrawal of application.

1.4.17 The application fee, if charged by CB, shall be non refundable.
2. Audit Programme

2.1 Audit Programme

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

<table>
<thead>
<tr>
<th>Certification activity</th>
<th>ICMD 9001</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 surprise audit and shall be carried out within period of 9 to 12 months from previous surveillance audit.</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
</tbody>
</table>

a) For ICMED 9000, ICMED 13485 and ICMED 13485 Plus the audit cycle shall include:
- Initial certification audit in two stages (Stage 1 and Stage 2) as per ISO 17021:2011 for ICMED 9000 and ICMED 13485
- Initial certification audit in two stages (Stage 1 and Stage 2) as per ISO 17021:2011 and ISO 17065:2012 for ICMED Plus
- Recertification audits (before end of 3 year validity)

2.2 Sampling of manufacturing facility to be Audited

2.2.1 Each manufacturing facility applying for certification shall be audited for ICMED 9000, ICMED 13485 and ICMED 13485 Plus as applied for.

2.2.2 The ISO 9001 and ISO 13485 audits may be carried out on sampling basis as allowed under ISO 9001 and ISO 13485 certification. (Ref IAF MD 1)

2.3 Audit Mandays

The mandays 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-days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICMED 9000</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Certification Audit/ Surveillance/ Recertification</td>
<td>As per IAF MD 5 Plus 1 man day on Site</td>
</tr>
</tbody>
</table>

2.3.1 Time duration shall be calculated for each manufacturing facility and each manufacturing facility shall be individually audited by CBs.

2.3.2 The audit time shall be at least one man-day (8 hrs. per day) on-site audit.

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

2.3.4 CBs shall audit all the requirements as audit criteria as applicable, witness all the tests/ requirements as required in the MoHFW’s Technical specifications of the product in manufacturer premises and review of reports in case of outside lab.

2.3.5 Time required for auditing as per clause 2.3.4 above shall be additional. For Product specification assessment audit as per MoHFW product specifications.

2.3.5.1 Justification is to be recorded in audit report of stage – 1 or document review as the case may be, for the time spent for product audit as for simple device like Thermometer it may not take more than 2 hours where in as for MRI machine it may take two days.

2.3.5.2 Time spent for product audit is min. 2 Hours in addition to the time spent for ICMED 13485

3. **Certification Audit Planning**

3.1 Preliminary information to be provided to the CB

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

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

3.1.3 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 auditor to have a preliminary overview on the manufacturing facility.

3.1.4 The documentation to be provided is 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.

3.2 Audit Team
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</td>
<td>Auditor + Technical Expert (if Auditor is not qualified for medical device sector)</td>
</tr>
<tr>
<td>Surveillance</td>
<td>same as above</td>
</tr>
</tbody>
</table>

3.3 Audit Plan

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

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

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

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

3.3.5 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.

4. Certification Audit

4.1 Certification Audit

4.1.1 ICMED 9000, ICMED 13485 and ICMED 13485 Plus based Certification

4.1.1.1 The Initial certification audit is performed to:
a) Audit the client's management system documentation;
b) 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;
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 including scheme requirements;
d) 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.);
e) Review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit;
f) 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;
g) 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.
h) Auditors must 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.

4.1.1.2 The Stage – I shall be carried out and judge the adequacy of the system to meet requirements of applicable ICMED 9000, ICMED 13485 and ICMED 13485 Plus criteria. It shall result in a formal report and will include justifications for auditing/ not auditing shift and time to be spent for product audit in case of ICMED 13485 Plus.

4.1.1.3 The stage 1 audit during the initial certification 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)

4.1.2 Certification Audit

Audit at manufacturing facility

Objective: Verifying the effective implementation of the Criteria ICMED 9000, ICMED 13485 and ICMED 13485 Plus as applicable.
The audit plan shall be modified accordingly.
During the opening meeting, the Team leader shall collect information on the situation and on changes concerning manufacturing facility, equipment, raw materials and anything else relevant.

4.1.3 Scheme certification only

The audit shall be conducted for “Additional requirements” of the Criteria document. The auditor shall audit the entire area related to particular requirement with remarks giving objective evidence of compliance/non-compliance in the manufacturing facility itself and in audit report.

The “Scheme only” audit report used by CBs shall be verified by the Accreditation Body to ensure the compliance with the “Additional Requirements” of ICMED 9000, ICMED 13485 and ICMED 13485 Plus criteria documents, as applicable.


4.1.4 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 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

4.1.5 Safety during audits

4.1.5.1 The Audit involves risks linked to work environments. Responsibility for risk analysis and the identification of the most suitable means of protection is shall be of the manufacturer.
4.1.5.2 Auditors must have personal protective equipment which may be reasonably required to while auditing different manufacturing processes of manufacturing facility particularly sterilization.

4.2 Non conformities

Certification bodies shall have a procedure, for identification, grading of findings, corrective action acceptance and closure time of any audit findings graded as nonconformities.

4.3 Audit Report

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

4.3.2 The Audit report shall have the following as minimum:

a) Scope of the Certification,
b) Name and address of manufacturing facility
c) Name of auditor and date & time of audit
d) Criteria of audit
e) Describe the structure of the audited manufacturing facility
f) Report on auditing all “Additional Requirements”
g) Report on Non-conformance, if any
h) The processes excluded by the Scope of the certification, if any,

NOTE: ISO 17022: 2012 can be referred for further guidance on Audit reporting

5. Certification Decision

5.1 Criteria for granting a certificate

The purpose of this section is to minimize the variation among CBs in taking the decision of granting a certificate.

5.2 Conditions for granting a certificate:

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

a) All NCs raised are closed
b) Payment of outstanding dues
c) Certification decision is taken
6. Certificate

6.1 Certificate

The organization 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>

6.2 Information

The certificate shall include the following information:

(a) Certificate number
(b) Certification scheme name (or logo)
(c) Reference to certification criteria
(d) Company name (should be a legal entity) with all locations in the schedule
(e) Certified Manufacturing facility address
(f) Scope of certification
(g) Scheme logo
(h) Logo of the CB
(i) Accreditation number with logo
(j) Date of certification
(k) Expiry date
(l) Signature of the CB’s authorized representative

In case of company certification, the CB shall annex to the certificate the list of the certified manufacturing facilities.

6.3 Validity

The certificate shall be valid for 3 years from the date of issuance.
7. **Fee**

7.1 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.

7.2 The CBs fee structure shall be publicly accessible and also be provided on request.

7.3 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.