Indian Certification for Medical Devices (ICMED) Scheme
ICMED 9000 / ICMED 13485 Schème information & Certification process

What's New ?

Scheme has been Launched with Two Levels of Certification

- ICMED 9000 Certification

Which is based on ISO 9001:2015 +Additional requirements (29)

- ICMED 13485 Certification

which is based on ISO 13485:2016 + (MDR 2017 + Additional Requirements)=270

Following Information from CB has to be publically available

a) Certification process for granting, maintaining, extending renewing, reducing, suspending or withdrawing the certificate and the geographical area of operation of CB.

b) Application form

c) Reference to the certification criteria

d) Detailed procedure of certification under scheme

e) List of documents required along application

f) Fees for application till continuous maintenance of certificate and the policy for Fee.

g) Information regarding rights, duties of applicants and certified clients and procedure of complaints/ Appeals

Application for Certification

Application form – prescribed by CB

- Applicant indicate type of certification
- Details of manufacturing facility – no of sites, activities to be audited, list of MD in scope
- Each and every Mfg. facility shall be audited

List of documents –

- As per the applied criteria for document review.
- Only complete applications supported with required documents shall be accepted.

Registration of Application

- Response to queries from applicant within 7 days.
- Applicant has to furnish all relevant information on the prescribed form

— if approved earlier for the same scheme with other CB. The CB now may verify and evaluate the previous reports.

— if any judicial proceedings are going which need to be verified.

- Certification is granted only against the current relevant certification criteria.
- Application review status to be informed to applicant within 7 days.
- Only complete application has to be accepted and registered with unique ID number

Registration of Application

- In case of declaration about any proceedings or suspension etc, the client application will not be entertained for a period of one year from the date of conviction, suspension, withdrawal or deregistration etc.
- In the certification of any level under the scheme suspended / cancelled by any approved CB, the application will not be accepted till suspension is revoked or one year from the date of action, however other facilities will not be affected under the same legal entity.
- In case ISO 9001/ 13485 certification is cancelled by any CB, after checking the antecedents carefully, the certification activity may be carried out considering the facility is new.
- The ISO certification by CB other than IAF MLA signatory accredited will not be accepted.
- Where facility is certified by NABCB accredited CB, audit for scheme criteria will be carried out only.

Rejection of Application

- Initial Evaluation is not carried out within 3 months of registration of application
- Entire certification process is not completed within 6 months of registration of application.
- Applicant shows no progress towards completion of corrective actions within 3 months of Initial Evaluation and 6 months of Registration of application.
- Misuse of certification under the Scheme Evidence of any malpractice

Request for grant of certification from applicant whose application rejected as above and /or certificate expired may be processed like a fresh application.

- Voluntary withdrawal of application
- The application fee if already charged is not refundable.

Audit Time Duration

- Stage 1 (20%) + Stage 2 (80 %)
- ICMED 9000 – As per IAF MD 5 + 1 Man Day on site
- ICMED 13485 –As per IAF MD 9 + 1 Man Day on site
- Time duration shall be calculated for each manufacturing facility and shall be audited individually.
- Min. 1 man-day (8 hrs) for each audit site
- Document Review, audit preparation and report preparation time shall be additional at least one man-day

Preliminary Information Provided to the CB

Relevant to the manufacturing facility for Document Review The documents shall include the following – QM, Procedures, Quality Plan, SOPs , WI, Forms and formats Audit Team.

Audit Plan –

- Audit has to be conducted while the plant is operational.
- The audit can be conducted in parts between the team members.
- All activities as per scope such as design, manufacture etc shall be audited irrespective of the location
- HO shall be audited if controlling multiple facilities /activities

Certification Audit

Stage 1

- At client's premises
- As per CB's guidelines (ref IAF MD 2-Transfer)
- To ensure the status of over all preparedness and understanding related to the standard and also adequacy of system.
- To collect the information regarding scope of system
- To review the allocation of resources for Stage 2 audit
- Evaluate IA/MRM, if conducted

Certification Audit

- **Gap Between Stage1 & Stage2 shall not exceed 90days.**

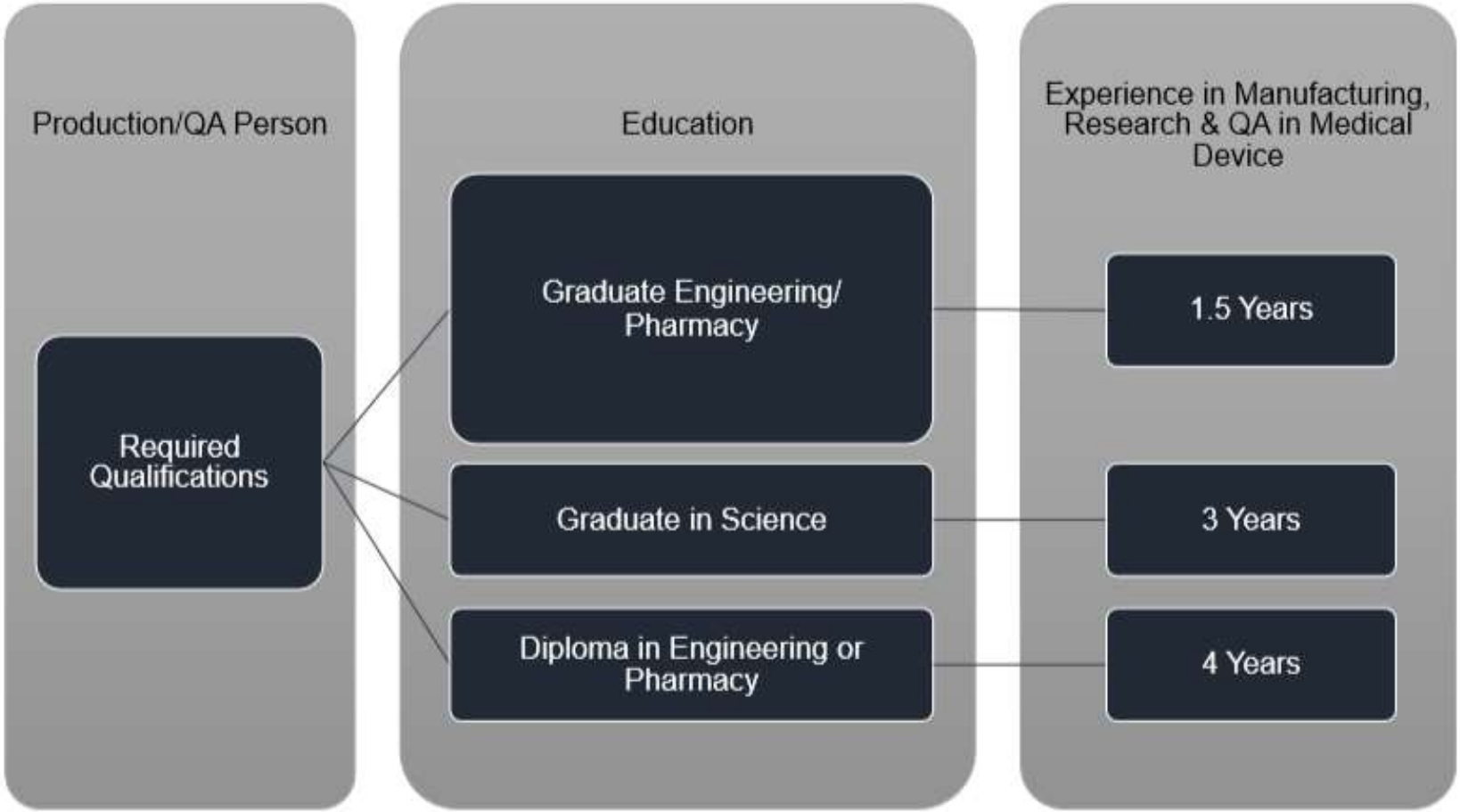
- **Stage 2 Audit – Shall be conducted on site to verify –**

- Compliance to the criteria
- Competence of people for different activities being held

Organization's Requirements –

- **At least one person at manufacturing and QA site who is at supervisory position and whole time employee having qualification.**

Qualification & Experience of Supervisory Position (Prod/QA)



Safety During Audits

- MD manufacturing may involve risks linked to work environment. To identify and analyse the risk and accordingly to provide prevention and protection is responsibility of Mfr.
- Auditors must have PPE which may be required while auditing different activities at manufacturing site.

Non-Conformities

- Need to be reported in writing with evidence to the client for taking necessary action in stipulated time (1 or 3 months).
- Shall be classified as Major and Minor according to the severity and also as per CBs guidelines.
- In case of Non conformities - root cause analysis and inform the same along with CAPA.
- Need to be closed before initial certification.

Audit Report

CB shall send the Audit Report within 7 working days after audit

Audit report for stage 1 and 2 shall clearly provide evidence and conclusions about the fulfillment of audit objective of the Criteria in the CBs report format as per their guidance document.

The decision in respect of granting certificate has to be based on proper evaluation and review.
The audit Report shall cover at least –

−Name, address of the client
−Scope of certification and Processes excluded by the scope of certification, if any
−Name of Audit team
−Date and time of audit
−Audit criteria
−Structure of audited Mfg facility
−Report on auditing covering“ Additional Requirements” with evidence of competence.
−Finding

Certification Decision

Certification decision shall be the sole responsibility of CB taken by the internal person who is competent and evaluated based on the requirement in Annex B of MD9

- has not been involved in the process of Audit of that organisation.
- Impartiality and absence of any COI shall be ensured before entrusting the task of certification decision making.

Conditions for Granting a Certificate – When following conditions are met

- Audit Report with suitable recommendations is available
- NCs if raised are closed
- No other issue open impacting grant of certification, There shall be no conditional grant for certification

The manufacturer may achieve one of the following Certificates

Certificate	Object	Extension	Certificate Number
Single mfg facility	All processes carried out	----	One Certificate
Mutisite mfg facility	Group of mfg facilities sharing common facility / process	Group of Mfg facilities	One certificate with annexure listing all mfg facilities
Company	Entire Company	All Manufacturing facilities	One certificate with annexure listing all

Certificate content

The Certificate shall include the following information –

−Certificate No.
−Certification scheme name
−Reference to Certification Criteria
−Mfr Name with locations
−Certified Mfg facility address
−Scope of Certification
−Scheme logo
−Logo/mark of the CB
−Accreditation symbol
−Date of Certification
−Expiry date
−Signature of CB's authorized representative

• In case of company or multisite facility, the CB shall annex to the certificate the list of the certified manufacturing facilities.
• The certification shall be valid for 3 years from date of issue.

Surveillance Audits

- 1st Surveillance audit within 12 months from certification
- 2nd unannounced between 9 to 12 months after 1st one
- shall be carried out on site as mentioned in the criteria
- The audit man-days also as described earlier IAF MD 5 / MD 9

Renewal of Certification

After the expiry of validity period that is 3 years normally.

- The notice by CB has to be sent prior to 4 months of expiry
- The organization has to apply in the prescribed form of CB along with fee at least 3 months before expiry of certificate.
- The objective of this audit will be a combination of SA + stage 2 audit if there is no change in product, process etc which will require revised assessment.
- CB shall review the performance of the organization during entire certification cycle, prior to a decision on renewal of certificate.

- The review shall be conducted by a competent person essentially has to be based on the following –

  a) SAs and RA reports b) Closure of NCs if raised c) Any suspension during previous validity period – status now d) Complaints if any received and their response – satisfactory e) Adverse information from stake holders / regulators – resolved

Renewal of Certification

- When performance of organization found unsatisfactory the CB will withhold the renewal giving time for effective CA.
- The CB shall not renew certificate with conditions for verifying compliance subsequently.
- The verification and decision making have to be completed within that 3 months of expiry period
- The corrective action shall be verified on site if not then justification for off site review has to be recorded.
- In case the manufacturing unit does not complete satisfactory actions within these 3 months, the certificate shall stand expired from the date of expiry of previous validity

Change of Location/ Name/Ownership

- Organization will inform CB if any change in location of the plant/ Manufacturing unit happens.
- On receipt of such information the CB will issue instructions to the organization for suspension of the certificate with immediate effect.
- An on-site audit will be required at new site like an initial one
- On satisfactory audit CB shall transfer Certificate to the new location endorsing the change of premises in certificate.
- In case of change in ownership, organisation shall provide necessary documentary evidence, acceptance of CB's terms by new management and payment of fees. These changes do not require any on site visit.
- In the event of change in Name, the manufacturer shall inform CB with all supported documents and on satisfaction CB can endorse the Certificate in new name.

Suspension

- The CB shall issue instructions to the Certified Organisation for suspension of certification when –
- Major NCs not closed within stipulated time;
- Repeated Major NCs raised in consecutive SA;
- Failure to organise SA within specified time frame;
- Non payment of dues;
- Major changes in legal status, ownership, name etc without prior information to CB;
- Any intentional misuse of logo of scheme is detected;
- Any willful false declaration in the application or otherwise is detected;
- Excessive or serious complaints against the management system are received and found to be valid;

Suspension

- Certified Organisation voluntarily requests a suspension in writing with quoting reasons but not allowed to revoke of its own
- CB shall issue notice at least one week before suspension
- During suspension client can not make misleading claims
- CB can revoke suspension when corrective actions done by organisation & verified by CB

Withdrawal

- CB will withdraw the certificate when
- Organisation contravenes the terms and conditions of certification & provisions of the ICMED Scheme.
- The corrective actions taken by organisation are not ensuring compliance
- The proposed plan for corrective actions will take longer time beyond 6 months for implementation.
- CB shall also withdraw certificate at the request of organisation, if the operations can no longer be carried out due to unavoidable circumstances, natural calamities, lock out declared or closure of business operations etc.

Complaints and Appeals

•CB shall have a documented procedure for handling complaints and appeals and need to be made available to the public on CB's website.
•Procedure for complaints handling shall include complaints from all stake holders, certified organisations and their customers.
•Upon receipt of complaint/ appeal, CB will acknowledge the same and shall verify whether it relates to certification activity, if so, CB has to address the same.
•CB shall gather and verify all possible relevant information to progress to a decision.
•The process step shall include the activities of root cause analysis, correction and corrective action.
•If the complaint relates to a certified organisation then the examination and evaluation of complaint shall take into consideration the effectiveness and implementation of their system.
•CB's process shall document the required action by CB as well as certified organisation. Some of these actions may be the part of CB's legal enforceable contract with the client

Complaints and Appeals

- The CB shall record and track such complaints and appeals and the actions being undertaken to resolve them.
- The decision resolving the Complaint or Appeal shall be made, reviewed and approved by person(s) not involved in the certification activities related to the complaint /appeal.
- Persons involved in consultancy or been employed by the organisation shall not be used by CB to review or to approve the resolution of complaint /appeals before 2 yrs after the end of contract.
- Wherever possible CB shall give formal notice of the outcome and end of the complaint process to the complainant
- In case of appeals CB shall ensure that individual(s)/ committee involved in appeal and its resolution decisions should not be in the position in CB to influence the decision.

Complaints and Appeals

- The CB procedure shall have provision for giving a written statement to the appellant about the findings and also to give him opportunity to formally present his case.
- Based on presentation made the individual or committee appointed for hearing shall take a final decision and formal notice of outcome and the end of appeal process shall be given to appellant.
- The CB then formally put a notice for the end of the process of appeal to the appellant
- The CB shall take any subsequent action needed to resolve the complaint or appeal

Fee Structure

- The CB's fee structure shall be provided on request.
- The fee structure shall provide break up of costs.
- A fee to be charged to the organisation for various activities of the scheme without any discrimination between manufacturing facilities, geographical locations, size of the manufacturing facility
- CB shall notify and obtain consent to its fee structure from the client prior to grant of certification.
- As and when fee undergoes a change all clients and applicants certified under this scheme shall be communicated for their acceptance

Logo of scheme

Thank you