QCI – AIMED Voluntary Initiative on Medical Devices

Indian Certification of Medical Devices
ICMED (Scheme)

Certification Process for Systems Certification

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0 **Scope**

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

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

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

c) **Certification of medical devices** as per specifications developed by the National Health Systems Resource Centre (NHSRC) of the Ministry of Health & Family Welfare in addition to the requirements of the above levels – this level is still under development.

0.3 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.

1. **Application for Certification**

1.1 **Application Form**

1.1.1 The manufacturer shall apply in the application from prescribed by the Certification Body.

1.1.2 The applicant shall clearly indicate the type of certification it is applying for.

1.1.3 The applicant shall provide information about each manufacturing facility to be certified.

1.1.4 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.
1.1.5 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.

1.1.6 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.

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

1.2 *List of Documents*

1.2.1 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 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. The information shall include:*

a) An Application form;

b) Reference to the Certification Criteria,

c) 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 .

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 rights and duties 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 certification with complete information for facilitating registration of application, within 7 working days of receipt of the query.

1.4.2 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.

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 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.

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 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.

1.4.8 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.

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

1.4.11 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.

1.4.12 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.

1.4.13 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.

1.4.14 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.

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 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.

1.4.16 An application shall be rejected or closed 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 certification under the Scheme

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>
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<tbody>
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<td>Certification Audit – Stage 1</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Certification Audit – Stage 2</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Surveillance –“Once in a year”, Second surveillance audit should be an unannounced audit which shall be carried out within period of 9 to 12 months from previous surveillance audit.”</td>
<td>√</td>
<td>√</td>
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a) For ICMED 9000 and ICMED 13485 the audit cycle shall include

- Initial certification audit in two stages (Stage 1 and Stage 2) as per ISO 17021-1:2015; and
- Recertification audits (generally 3 months before the end of 3 year validity)

2.2 Sampling of manufacturing facility to be Audited

2.3 Audit Mandays

2.3.1 The mandays required to conduct an effective audit shall be calculated in accordance with the following Table:
### 2.3.2 Time duration shall be calculated for each manufacturing facility and each manufacturing facility shall be individually audited by CBs

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

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

### 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 and ICMED 13485 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 auditors to have a preliminary overview of the manufacturing facility.

#### 3.1.4 The documentation to be provided shall include the following:

a) Quality Manual – Addressing all the requirements as per criteria document

b) Procedures – (Procedures related to process and general area of operation such as purchase, H.R. etc)
c) Quality Plan – Addressing controls applied & verification frequency of inspection of incoming material, Process controls and and final Product(s) etc.

d) Standard operation procedures/ Work instructions

e) Form and Formats.

3.2 Audit Team

3.2.1 The CB shall appoint an Audit Team having the necessary competences and skills 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 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.

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 Stage 1 Audit

4.1.1 The stage 1 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 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.

4.1.2 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

4.1.3 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).

4.2 Stage 2 Audit

4.2.1 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 personnel involved in various relevant activities. The stage 2 audit shall be conducted on site.
4.2.2 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.

4.2.3 Safety during audits

4.2.3.1 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.

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

4.3 Non conformities

4.3.1 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.

a) **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.
b) **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.

4.3.2 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 through verification of adequacy of the correction and corrective actions. All Major non-conformities, shall invariably require a follow-up audit.

4.4 **Audit Report**

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

4.4.2 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:

a) Scope of the Certification,

b) Name and address of manufacturing facility (ies) audited

c) Name(s) of auditor/membbers of the team

d) Date & time of audit

e) Audit Criteria

f) Structure of the audited manufacturing facility

g) Report on auditing including that for all “Additional Requirements” with evidence of compliance

h) Nonconformities, if any

i) Processes excluded by the Scope of the certification, if any,

**NOTE:** ISO 17022 may be referred to for further guidance on Audit reporting
5. **Certification Decisions**

5.1 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.

5.2 **Conditions for granting a certificate:**

5.2.1 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.

6. **Certificate**

6.1 The manufacturer may achieve one of the following certificates:

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

a) Certificate number  
b) Certification scheme name  
c) Reference to certification criteria  
d) Manufacturer’s name (that of the 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**

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

7. **Surveillance audits**

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

7.2 Non conformities observed during surveillance audit shall be categorized as major and minor as defined in clause 3.4.
8. **Suspension:**

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

a) the major NCs issued are not closed in timelines prescribed

b) repeated major NCs are raised in consecutive surveillance assessments

c) there is failure to organize a surveillance audit within the specified time period

d) there is non payment of outstanding dues

e) any major changes have taken place in the legal status, ownership, name etc without prior information to the CB

f) any wilful misuse of the logo of the Scheme is detected

g) any wilful false declaration in the application form or otherwise is detected

h) excessive or serious complaints against the certified organization management system are received and are found to be valid

i) 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.

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

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

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

9. **Renewal of certification**

9.1 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.
9.2 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.

9.3 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 has been any changes in product and process requirements, which would then also require assessment of the organization’s revised processes, controls and systems.

9.4 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:

a) 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.

b) Any suspension of certificate during the previous validity period;

c) corrective actions taken

d) complaints if any received,

e) Adverse information from stakeholders and regulators, if any.

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

9.6 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.

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

9.8 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.

9.9 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.
9.10 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.

9.11 When a certificate is not renewed, it shall expire at the end of validity period.

10. **Withdrawal**

10.1 Certification body shall withdraw the certificate when

a) Certified organization contravenes the terms and conditions of certification and provisions of the ICMED scheme

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

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

10.2 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.

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

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

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

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

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

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

11.6 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.
11.7 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.

12. **Complaints and appeals**

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

12.2 The procedure for complaint handling shall include complaints from all stake holders, especially its certified organization as well as customers of its certified organizations.

12.3 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.

12.4 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.

12.5 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.

12.6 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.

12.7 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.

12.8 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.

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

12.10 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.

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

12.12 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.

12.13 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.

12.14 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.

12.15 The certification body shall give formal notice of the outcome and the end of the appeal process to the appellant.

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

13. **Fee**

13.1 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.

13.2 The CBs fee structure shall be provided on request. The fee structure shall provide break up of costs.

13.3 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.