



Andhra Pradesh MedTech Zone Ltd (AMTZ)

Biomedical Equipment Maintenance Certification (BEMC) Scheme (Provisional Approval Process for CBs)



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0. Introduction

- 0.1 The Certification Body (CB), in order to operate under the Provisional approval-Biomedical Equipment Maintenance Certification (BEMC) Scheme hereafter referred to as the Scheme, shall need to primarily comply with the following requirements specified in ISO 17065 and the additional requirements prescribed by AMTZ, as the scheme owner.
- 0.2 CB would not get a client unless they are approved under the Scheme and would not be able to offer an audit/evaluation for witnessing and get the relevant scope added in their accreditation.
- 0.3 Therefore, it is necessary to establish a procedure for provisional approval of CB under the Scheme by AMTZ till such time they can get the scope added in their accreditation or get formally accredited from accreditation body (AB) to be formally approved.
- 0.4 This document sets out the requirements to be fulfilled by CB desirous of operating under the Scheme pending formal accreditation and approval.
- 0.5 In order to be formally accredited by the AB as above, the CB, even if already accredited by International Accreditation Forum (IAF) Multi-lateral Arrangement (MLA) signatory, would need to undergo a short assessment by Witnessing of an actual Certification under the Scheme.

1. Scope

- a. This document defines the process for CB to obtain provisional approval to operate under the BEMC Scheme pending formal accreditation for the Scheme by the AB as per the prescribed international standard(s) ISO/IEC 17065.
- b. This approval shall be valid for a period of one year within which the approved CB shall have to obtain formal accreditation from IAF MLA signatory AB.



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2. Criteria for Approval

2.1. The CB desirous of operating Certification of Biomedical Equipment Maintenance Process under this Scheme shall meet the criteria as prescribed in clauses 3 and 4 of this document.

3. General Requirements

3.1. Legal Entity

The CB shall be a legal entity, or shall be a defined part of a legal entity, such that it can be held legally responsible for all its Certification activities. A governmental CB is deemed to be a legal entity on the basis of its governmental status. A CB, that is part of an organization involved in functions other than Certification, shall be separate and identifiable within that organization.

3.2 Impartiality

3.2.1. The CB shall be impartial.

3.2.2 The CB shall be so structured and managed as to safeguard impartiality.

3.2.3 The CB and its personnel/staff shall not engage in any activities that may conflict with their Impartiality.

3.2.4 The CB shall require personnel involved in the Certification process to sign a contract or other document by which they commit themselves to declare any prior and/or present association on their own part, or on the part of their employer.

3.2.5 The CB and any part of the same legal entity and entities under its organizational control shall not

a) be the designer, manufacturer, installer, distributor, or maintainer of the certified Biomedical equipment maintenance process (es).



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b) offer or provide product or process consultancy or internal auditing to its clients under same scheme.

3.2.6 The CB shall ensure that activities of separate legal entities, with which the CB or the legal entity of which it forms a part has relationships, do not compromise the impartiality of its Certification activities.

3.2.7 When the separate legal entity in 3.2.6 offers/provides consultancy for the certified process, the CB's management personnel and personnel in the review and certification decision making process shall not be involved in the activities of the separate legal entity. The personnel of the separate legal entity shall not be involved in the management of the CB, the review, or the certification decision.

3.2.8 The CB shall act impartially in relation to its applicants and organizations certified.

3.2.9 The CB shall have a process to identify, analyze, evaluate, monitor, and document the threats to impartiality arising from its activities including any conflicts arising from its relationships, or from the relationships of its personnel on an ongoing basis.

NOTE Sources of threats to impartiality of the CB can be based on ownership, governance, management, personnel, shared resources, finances, contracts, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

3.2.10 The CB shall not certify system / product / process / personnel on which they have provided consultancy, carried out internal audits or provided specific training with problem solving, for a minimum of two years following the completion of consultancy/internal audits/training.

3.2.11 The CB personnel shall not perform any Certification activities in relation to their previous involvements. The period shall be long enough to ensure that the threats to impartiality are minimized or eliminated. The period shall be at least two years subject to review by the CB.

3.2.12 The CB shall not have any relationship with its clients other than third party conformity assessment.



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3.3 Liability and financing

The CB shall evaluate the financial resources and ensure adequate provision for liability insurance. The CB shall be free from any commercial/financial and other pressures which compromise with its impartiality. This shall be applicable at all the operating locations of the CB.

3.4 Organizational Structure

The CB shall define and document the duties, responsibilities and reporting structure of its personnel and its place within the organization. When the CB is a defined part of a legal entity, documentation of the organizational structure shall include the line of authority and the relationship to other parts within the same legal entity.

3.5 Publicly Available Information

3.5.1 The CB shall maintain a website for providing information about the Scheme and its Certification activities under the Scheme.

3.5.2 The CB shall maintain and make publicly available information describing its processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification and about the certification activities and its operational locations.

3.5.3 The CB shall make available information about applications registered and certifications granted, suspended or withdrawn on request.

3.5.4 The CB shall make publicly available its process for handling appeals and complaints.

3.6 Confidentiality and Integrity

3.6.1 The CB shall ensure confidentiality of information obtained in the course of its Certification activities by having a suitable system.

3.6.2 The CB and its personnel shall maintain integrity at all times. The CB shall implement adequate measures to ensure integrity.

3.7 Certification agreement



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The CB shall have a legally enforceable agreement for the provision of Certification activities to its client. In addition, the CB shall ensure its Certification agreement requires that the client comply at least, with the specific requirements as prescribed in the relevant accreditation standards (ISO/IEC 17065) and the updated Scheme document.

3.8 Responsibility for decision on Certification

The CB shall be responsible for all its work and shall not delegate its decisions relating to certification including the granting, maintaining, recertifying, expanding and reducing the scope of the certification, and suspending or withdrawing the certification.

4. Technical Requirements

4.1 Personnel

4.1.1 The CB shall have, as part of its own organization, personnel, either employed or on contract, having sufficient competence for managing the Certification process of the Scheme.

4.1.2 The CB shall have defined processes for selecting, training, and formally authorizing and monitoring their performance its personnel involved in carrying out the various Certification activities and for selecting technical experts, if needed.

4.1.3 Competence

4.1.3.1 The CB shall define the competence of the personnel involved in the scheme (Annexure-I of the document “CB and AB requirements” (AMTZ/BEMCS/CBABR/R00)). The entire CB competence process shall be subject to verification by the AB.

4.1.3.2 The CB may use personnel who do not have the requisite qualifications as prescribed in the scheme document provided they are supported by technical experts (TEs) who meet the qualifications as described in Annexure-I of the document “CB and AB requirements” (AMTZ/BEMCS/CBABR/R00). The time spent by the TE on an audit shall not be counted in determining the audit time as prescribed under the ‘Certification Process’ which the CB is expected to spend.



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4.1.4 Personnel records

The CB shall maintain up-to-date personnel records, as per requirements of the Scheme document, of each member of its personnel involved in its Certification activities.

4.2 Certification Procedure

4.2.1 The CB shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process.

4.2.2 Recommendations for a Certification decision based on the review shall be documented unless the review and the certification decision are completed concurrently by the same person.

4.2.3 The CB shall manage the process of Certification as per the documented 'Certification Process' prescribed under the Scheme.

4.2.4 The CB shall maintain records to demonstrate that the Certification process is effectively fulfilled.

4.2.5 The CB shall ensure the requirements of the Scheme are met with at any point of time.

4.2.6 The CB shall certify the organization as per the Scheme and shall use the logo of the Scheme in the certificates issued to the certified organization as per Rules for use of Scheme Mark document (AMTZ/BEMCS/SM/R00).

4.2.7 The CB shall have a written agreement with the certified organization on the use of the certification and the Scheme logo, subject to approval by AMTZ.

4.2.8 The CB shall have a process to handle appeals by the clients against any of certification Body decision.

4.2.9 The CB shall have a process to handle complaints from the users of the services of the CB or any other stakeholder.



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5.0 Provisional Approval Process

5.1 Application

5.1.1 Any organization interested in approval as a CB for the purpose of this Scheme may apply to AMTZ in the prescribed application format along with the prescribed application fee. The applicant shall also enclose the required information and documents as specified in the application form (AMTZ/BEMCS/APPLICATION FORM).

5.1.2 The filled in application form for approval shall be duly signed by the CEO/authorized representative/s of the organization seeking approval.

5.1.3 On receipt of the application form along with required documents, it will be scrutinized by the secretariat at AMTZ and those found complete in all respects will be processed further.

5.2 Assessment process

5.2.1 On satisfactory review (document review off-site) of the application, a suitable date at mutual convenience, shall be fixed up for the assessment of the applicant. The assessment of the Head office shall be normally for a period of two man-days (inclusive of half man-day for Technical expert if required). In case, the CB is already accredited to ISO/IEC 17065, the duration may be reduced.

5.2.2 The names of the members of the assessment team along with their CVs shall be communicated to the applicant CB giving adequate time to raise any objection against the appointment of any of the team members, which will be dealt with by AMTZ on merits. All auditors/experts nominated by AMTZ have signed undertakings regarding confidentiality and conflict of interest.

5.2.3 If necessary, AMTZ may decide based on the report of office assessment or otherwise, to undertake witness assessment(s) of actual evaluation or any part of the certification process by the applicant.

5.2.4 An assessment plan shall be provided by the assessment team leader in advance.



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5.2.5 The date(s) of assessment shall be mutually agreed to between the applicant CB and AMTZ/assessment team.

5.2.6 The Office assessment shall begin with an opening meeting for explaining the purpose and scope of assessment and the methodology of the assessment. The actual assessment process shall cover review of the documented system of the organization to assess its adequacy in line with the assessment criteria as specified. It is an assessment for the verification of the implementation of the system including scrutiny of the records of personnel competence and other relevant records and demonstration of personnel competence through means like interviews, etc. In short, it shall be an assessment for verifying technical competence of the applicant for operating under the Scheme.

5.2.7 At the end of the Office assessment, through a formal closing meeting, all the non-conformities and concerns observed in the applicant's system as per the assessment criteria and the assessment team's recommendation to AMTZ, shall be conveyed to the applicant.

5.2.8 Based on the report of assessment, and the action taken by the applicant CB on the non-conformities/concerns, if any, AMTZ shall take a decision on whether to:

- a) Undertake further witness assessments(s) or any part of the Certification process by the applicant prior to granting of provisional approval. In such case the same man-days will be charged to CB as that of their evaluation man-day at organization's site.
- b) Granting provisional approval to the applicant as CB under the Scheme.

6.0 Validity of Approval

6.1 The approval shall be valid for a period of one year.

6.2 During the validity of approval, AMTZ shall undertake at least one witness assessment to confirm the CB's competence. This may be waived of if the organization is able to provide a witness assessment report from AB.

6.3 The CB shall obtain formal accreditation as per ISO 17065 from IAF MLA signatory AB within one year of provisional approval by AMTZ.



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6.4 Based on the request of the CB and review of previous performance, it may be decided to extend the period of validity; in such a case, the CB shall be assessed covering either office or witnessing on site or both, as decided by AMTZ, prior to such an extension.

6.5 The approval shall be subject to suspension/withdrawal with due notice of 15 days in the event of any noncompliance to the requirements of the Scheme.

6.6 The approved CB shall inform AMTZ without delay about any changes relevant to its approval, in any aspect of its status or operation relating to;

- a) Its legal, commercial, ownership or organizational status,
- b) The organization, top management and key personnel,
- c) Main policies, resources, premises and scope of approval, and
- d) Other such matters that may affect the ability of the CB to fulfill requirements for approval.

6.7 AMTZ shall examine such information and decide on the issue on merits with or without an on-site verification.

7.0 Fee

7.1 The following fee structure shall apply:

- a) Application fee: INR 25000/-
- b) Man-day charges (Assessor/TE) INR per man-day: 15000/-
- c) Travel/stay on actuals

7.2 AMTZ at its discretion may revise/levy any other fee necessary with due notice to the CB



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Amendment Sheet

The history of changes is as below:

Sl. No	Date of Amendment	Page No./Clause No.	Amendment details