Andhra Pradesh MedTech Zone Ltd (AMTZ)

Biomedical Equipment Maintenance Certification (BEMC) Scheme

(Certification Process)

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1.0 Scope

This document describes the requirements, the Certification body (CB) has to follow for carrying out evaluations of "Biomedical equipment maintenance" at organization premise under this Scheme. The BEMC Scheme is developed based on type 3 as per ISO/IEC 17067:2013 standards.

This document shall be read with the document titled "**Technical Criteria" (AMTZ/BEMCS/TC/R00)**.

2.0 Normative References

- ISO/IEC 17065:2012: Conformity assessment — Requirements for the operation of various types of bodies performing certifying products, processes and services
- ISO/IEC 17067:2013: Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes
- ISO/IEC TR 17032:2019: Conformity assessment — Guidelines and example of a scheme for the certification of processes
- Technical Criteria documents (AMTZ/BEMCS/TC/R00 and AMTZ/BEMCS/ATC/R00)

3.0 Terms and definitions

3.1 Appeal

request by the provider of the item of evaluation to the Certification body (CB) for reconsideration by that body of a decision it has made relating to that item

NOTE Adapted from ISO/IEC 17000:2004, definition 6.4.

3.2 Complaint

expression of dissatisfaction, other than appeal, by any person or organization to an certification body (CB), relating to the activities of that body, where a response is expected

NOTE Adapted from ISO/IEC 17000:2004, definition 6.5.

3.3 Evaluation

combination of the selection and determination functions of conformity assessment activities

NOTE The selection and determination functions are specified in ISO/IEC 17000:2004, Clauses A.2 and A.3.

3.4 Certification requirement

specified requirement, including product requirements, that is fulfilled by the client as a condition of establishing or maintaining certification

3.5 Client

organization or person responsible to a certification body for ensuring that certification requirements including product requirements are fulfilled

NOTE Whenever the term "client" is used in this document, it applies to both the "applicant" and the "client", unless otherwise specified.

3.6 Organization

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

NOTE 1 In the context of scheme, the organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private related to the maintenance of medical equipment as defined above.

For example, this can be a AMC/CMC service provider, hospital, an individual clinic or Original Equipment Manufacturers (OEM) etc.

NOTE 2 This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

[SOURCE: ISO/IEC TS 17021-4:2013, 3.7]

4.0 Pre-Certification process:

4.1. Requirements for the applicant

4.1.1 The applicant organization shall complete the prescribed application with detailed information in the application form and submit to CB along with the prescribed fee.

4.1.2 If any activities of maintenance are carried out by the applicant other than main address, those additional premises are to be mentioned in the application along with the equipment details/activities.

4.1.3 The applicant shall declare at the time of application submission regarding any legal proceedings relating to its operation by any regulatory body.

4.2. Application Processing

4.2.1 The application form and the process of evaluation shall be made publicly available by the approved CB.

4.2.2 CB shall respond to all queries of applicant w.r.t application/evaluation process on this Scheme before accepting the application.

4.2.3 The application received must be reviewed for its adequacy and availability of resources to perform the evaluation by a competent person of the CB.

4.2.4 The applications received with complete details along with the required application fee shall be processed further for evaluation.

4.2.5 Based on the scope of certification, the CB shall constitute an evaluation team (if required, more than one evaluator) to carry out the evaluation. If required, CB may include technical expert in the team to make the team competent enough to conduct onsite evaluation based on the scope of certification. In such case, the details of the expert shall be informed to applicant/organization sufficient in advance.

4.2.6 The certificate shall be issued by CB only against the current revision/issue of the Scheme criteria documents.

4.2.7 CB may close or reject the applications under the following circumstances.

a) No actions are being taken from applicant on identified issues during the evaluation within 3 months-time.
b) The applicant organization if, found to be misusing the Scheme logo while their application is being processed shall be rejected after a due notice of 15 days. Fresh application may be considered from the same applicant after one year of cooling period.
c) Voluntary withdrawal of application. In such cases, the application fee paid is forfeited.

5.0 Evaluation duration/man-days

5.1 The CB shall have a defined process to allocate sufficient time for the evaluation considering the factors like type, no of equipment, multi-location/sites etc based on risk assessment (Annexure-1: Sampling Criteria for BEMC Scheme).

5.2 The CB shall maintain records with justification on time allocation/planning for each organization.

5.3 The evaluation duration planned, shall be informed to organization sufficiently in advance along with evaluation team composition and their CVs to identify any conflict-of-interest (CoI) issues.

5.4 When a CB performs evaluation activities, either with its internal resources or with other resources under its direct control, it shall meet the applicable requirements of the relevant International Standards and, as specified in the Scheme. Where appropriate, it shall meet the applicable requirements of ISO/IEC 17025 for testing and ISO/IEC 17020 for inspection, considering the applicable impartiality requirements.

5.5 The CB shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and, as specified in the Scheme. Where

appropriate, it shall meet the applicable requirements of ISO/IEC 17025 for testing and ISO/IEC 17020 for inspection, considering the applicable impartiality requirements.

6.0 On-site Evaluation process

6.1 CB shall decide a competent team, to perform the evaluation and review the relevant document.

6.2 Evaluation shall be conducted in two stages.

6.2.1 Stage 1 to check the readiness of the applicant and fulfilling the legal obligations if any. The review shall include, but is not limited to the following:

a) Verification of the facts/details submitted in the application form

b) Review of the competencies of the personnel involved in maintenance process

c) Review of the applicable procedures established for the maintenance process.

6.2.2 Subject to satisfactory completion of stage 1, the CB shall conduct the stage 2 (witnessing the maintenance process) within 3 months from the said date.

6.2.3 In case, there are non-conformities (major and minor), the applicant organization is given 30 days to resolve minor NC and provide evidence to the CB. Corrective actions shall be provided by organization within 15 days for major NC or as agreed with CB. Major nonconformities if any shall result in onsite follow-up evaluation at the discretion of the CB.

6.2.4 Where there are multiple equipments to be covered in the Scheme based on the complexity of the maintenance process, the CB shall have a plan for evaluation activities to allow for the necessary arrangements to be managed.

6.3 CB shall follow evaluation methods and procedures as documented under clause 5.0 of the CB and AB requirement document (AMTZ/BEMCS/CBAB/R00) of the Scheme along with the checklist provided in Annexure IV of the document "Annexures for Technical Criteria" (AMTZ/BEMCS/ATC/R00) based on scope of certification.

6.4 CB shall uniquely identify the medical equipment (item), offered by the organization for witnessing the maintenance process. In case of any abnormalities in the suitability of the item, the organization has to be documented and suitably informed.

6.5 The CB shall conduct the evaluation in a manner to ensure all the compliance applicable to health and safety are followed as per the local regulations.

6.6 Equipment submitted by the organization for maintenance shall be safeguarded during the process in such a manner to avoid any damage or deterioration affecting its maintenance integrity.

6.7 CB shall ensure the calculations and data transfer are subject to appropriate checks in a systematic manner, to avoid errors.

6.8 The evaluation report shall be prepared and submitted to organization along with the findings.

6.9 Evaluation report shall include at least the following:

i. identification of the organization
ii. identification of the issuing body (CB)
iii. unique identification of report and date of issue
iv. date(s) of evaluation
v. identification of the equipment (s) inspected/evaluated
vi. signature or other indication of approval, by authorized personnel
vii. a statement of conformity where applicable
viii. name and calibration status of the instruments used during the evaluation.

7.0 Review and Certification decision

7.1 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.

7.2 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

7.3 The CB shall assign at least one person to make the certification decision based on all information related to the evaluation, its review, and any other relevant information. The certification decision shall be carried out by a person or group of persons [e.g., a committee] that has not been involved in the process for evaluation.

7.4 It is desirable to have an agreement detailing the terms and conditions of certification between the CB and organization.

7.5 Certificate shall include at least the following:

i. Identification of the organization providing the maintenance service
ii. Identification of the issuing body (CB)
iii. Reference to the maintenance Scheme doc of the organization
iv. Scope of certification
v. Scheme name and version
vi. Logo of AB and Scheme, as applicable
vii. Certificate number
viii. Date of certification
ix. expiry date

x. signature, by authorized personnel

7.6 The certificate shall be valid for 3 years from the date of issuance.

8.0 Surveillance

8.1 The first surveillance evaluation shall take place within 9 months from the date of issuance of certificate. The second surveillance shall be unannounced and shall take place within 4 to 6 months prior to the date of expiry of certificate.

9.0 Termination, reduction, suspension or withdrawal of certification

9.1 When a non-conformity with certification requirements is substantiated, either as a result of surveillance or otherwise, the CB shall consider and decide upon the appropriate action which can include the following:

a) continuation of certification under conditions specified by the CB (e.g., increase in the frequency of the surveillances);
b) reduction in the scope of certification;
c) suspension of the certification pending remedial action by the organization;
d) withdrawal of the certification

9.2 When the appropriate action includes evaluation, review or a certification decision, the requirements in evaluation, review or certification decision, respectively, shall be fulfilled.

9.3 If certification is terminated (by request of the organization), suspended or withdrawn, the CB shall take actions which include modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the maintenance process continues to be certified in the organization.

9.4 If a scope of certification is reduced, the CB shall take actions which includes modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the organization and clearly specified in certification documentation and public information.

9.5 If certification is suspended, the CB shall communicate the actions needed to end suspension and restore certification based on the certification decisions.

9.6 If certification is reinstated after suspension, the CB shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications exist that the process continues to be certified.

9.7 If a decision to reduce the scope of certification is made as a condition of reinstatement, the CB shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the organization and clearly specified in certification documentation and public information.

10.0 Records

10.1 The CB shall retain records to demonstrate that all certification process requirements (those in ISO/IEC 17065 Standard and those of the BEMC Scheme) have been effectively fulfilled.

10.2 The CB shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained.

10.3 If the Scheme involves complete re-evaluation of the process within a 3 years cycle, records shall be retained at least for the current and the previous cycle.

10.4 All the records related to evaluation and testing shall be maintained to establish traceability and appropriately safeguarded.

NOTE: Records may include but are not limited to:

a) Raw data sheets
b) Evaluation reports
c) Checklists
d) Any relevant instructions

11.0 Complaints and appeals

11.1 The CB shall have a documented process to receive, evaluate and make decisions on complaints and appeals. The CB shall record and track complaints and appeals, as well as actions undertaken to resolve them.

11.2 Upon receipt of a complaint or appeal, the CB shall confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, shall address it.

11.3 The CB shall acknowledge receipt of a formal complaint or appeal.

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

11.5 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.

11.6 Whenever possible, the CB shall give formal notice of the outcome and the end of the complaint process to the complainant.

11.7 The CB shall give formal notice of the outcome and the end of the appeal process to the appellant.

11.8 The CB shall take any subsequent action needed to resolve the complaint or appeal.

11.9 The complaints regarding the activity carried out by the certified organization, the CB shall review the complaints received and shall evaluate the complaints by doing a short visit to the certified organization, if required and report the findings to the organization and the complainant.

12.0 Application Fee

12.1 A fee to be charged to the organization for various activities of the certification under the Scheme, should be based upon units, geographical location, scope of certification etc.

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

12.3 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 certified organization under this Scheme of certification for their acceptance.

13. Annexure-1

Sampling Criteria for BEMC Scheme

13.1 Hospitals

13.1.1 Certification body shall get the following documents from the client but not limited to:

a. List of equipments
b. Planned Preventive maintenance Schedule
c. List of testing equipment available with their calibration status

Table 1 Sampling Percentage Calculation

S.No	Product Categories Covered by the Technical Areas as per IAF (Scheme Product Category)	Sampling Percentage for the equipment to be considered
1	Non-active devices for anesthesia, emergency, and intensive care	2% of the total equipment in this Scheme Product Category
2	Non-active devices for injection, infusion, transfusion and dialysis	2% of the total equipment in this Scheme Product Category
3	Non-active orthopedic and rehabilitation devices	2% of the total equipment in this Scheme Product Category
4	Non-active medical devices with measuring function	2% of the total equipment in this Scheme Product Category
5	Non-active ophthalmologic devices	1% of the total equipment in this Scheme Product Category
6	Non-active instruments	1% of the total equipment in this Scheme Product Category
7	Contraceptive medical devices	1% of the total equipment in this Scheme Product Category
8	Non-active medical devices for disinfecting, cleaning, rinsing	1% of the total equipment in this Scheme Product Category
9	Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies	1% of the total equipment in this Scheme Product Category
10	Non-active medical devices for ingestion	1% of the total equipment in this Scheme Product Category
11	Non-active dental devices/equipment and instruments	1% of the total equipment in this Scheme Product Category
12	Non-active medical devices other than specified above	1% of the total equipment in this Scheme Product Category

13	Devices for extra-corporal circulation, infusion and haemopheresis	10% of the total equipment in this Scheme Product Category
14	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	10% of the total equipment in this Scheme Product Category
15	Devices for stimulation or inhibition	2% of the total equipment in this Scheme Product Category
16	Active surgical devices	5% of the total equipment in this Scheme Product Category
17	Active ophthalmologic devices	2% of the total equipment in this Scheme Product Category
18	Active dental devices	2% of the total equipment in this Scheme Product Category
19	Active devices for disinfection and sterilization	2% of the total equipment in this Scheme Product Category
20	Active rehabilitation devices and active prostheses	2% of the total equipment in this Scheme Product Category
21	Active devices for patient positioning and transport	2% of the total equipment in this Scheme Product Category
22	Active devices for in vitro fertilization (IVF) and assisted reproductive technologies	2% of the total equipment in this Scheme Product Category
23	Medical gas supply systems and parts thereof	1% of the total equipment in this Scheme Product Category
24	Devices utilizing ionizing radiation (devices for imaging)	5% of the total equipment in this Scheme Product Category
25	Devices utilizing non-ionizing radiation (devices for imaging)	5% of the total equipment in this Scheme Product Category
26	Monitoring devices of non-vital physiological parameters	4% of the total equipment in this Scheme Product Category
27	Monitoring devices of vital physiological parameters	5% of the total equipment in this Scheme Product Category
28	Devices utilising ionizing radiation (Devices for therapy)	4% of the total equipment in this Scheme Product Category
29	Devices utilising non-ionizing radiation (Devices for therapy)	4% of the total equipment in this Scheme Product Category
30	Devices for hyperthermia / hypothermia	1% of the total equipment in this Scheme Product Category
31	Devices for (extracorporeal) shock-wave therapy (lithotripsy)	1% of the total equipment in this Scheme Product Category

32	Active (non-implantable) medical devices other than specified above	1% of the total equipment in this Scheme Product Category
33	IVD Instruments	9% of the total equipment in this Scheme Product Category
34	Ethylene oxide gas sterilization (EOG)	1% of the total equipment in this Scheme Product Category
35	Moist heat	1% of the total equipment in this Scheme Product Category
36	Thermic sterilization with dry heat	1% of the total equipment in this Scheme Product Category
37	Sterilization with hydrogen peroxide	1% of the total equipment in this Scheme Product Category
38	Radiation sterilization (e.g., gamma, x-ray, electron beam)	1% of the total equipment in this Scheme Product Category
Total Equipment Considered (T)		

Table 2: Number of Mandays

Sl.No	**Total Equipment Considered (T) from Table 1**	**Man-days (Stage-2)**
1	Upto 50	1.5
2	51-100	2.0
3	101-200	2.5
4	201-300	3.0
5	301-400	3.5
6	401-500	4.0
7	501-750	5.0
8	751-1000	6.0
9	> 1000	7.0

13.1.2 For both Stage-1 and Stage-2, Certification body (CB) shall have a technical expert whose mandays can be decided by the CB itself.

13.1.3 Stage-1 Man-days shall be less than Stage-2 Man-days.

13.1.4 Stage-1 Man-days shall be decided by the CB after reviewing the application form from the respective client.

13.1.5 CB shall ensure that all the maintenance records of the total equipment list considered are checked and also verify the process of planned preventive maintenance which are scheduled in the same month for the equipment list considered for the stage-2 audit.

13.2 Hospital with Multiple sites, AMC/CMC Service Provider and Original Equipment Manufacturer (OEM)

13.2.1 CB shall get the following documents from the Hospital with Multiple sites, AMC/CMC service provider or OEM but not limited to:

a. List of Hospitals with their location details.
b. Equipment list and preventive maintenance schedule for each hospital
c. List of testing equipment available with their calibration status

13.2.2 The CB shall select the hospital site with the highest and lowest number of equipment for auditing and follow the same methodology as mentioned in Table 1 and Table 2 while deciding the mandays.

13.2.3 In each auditing cycle (surveillance audit), CB shall select different hospital excluding the previously selected hospital sites and can use the same methodology mentioned in 13.2.2.