Andhra Pradesh MedTech Zone Ltd (AMTZ)

Biomedical Equipment Maintenance Certification (BEMC) Scheme

(Technical Criteria)

Effective date:15 October 2022

Content List

0. 0 Foreword

This scheme is a voluntary scheme which applies to maintenance process certification including testing and verification of MEDICAL EQUIPMENT and SYSTEM (combination of medical equipment), or parts of such equipment or systems, which need maintenance on a periodic basis. The Scheme addresses the minimum requirements for verification after any such maintenance or repairs to ensure that the device is safe and functionally complies with these specified requirements. While the majority of such devices come under the electro-medical category, the scheme also addresses some of the non-active equipment and parts that may require maintenance. As the number of devices is vast and ever-growing the scheme has taken the reference of IAF MD 9, the international classification for medical devices for making the scheme internationally acceptable.

The manufacturer may have defined necessary measurement settings and methods including performance assurance tests in the instructions for use or other accompanying documents. This voluntary scheme provides consistent test procedures and lists of few generic checkpoints to ensure safety and functionality. The list precludes any other checks as may be required for the device to function. This guidance would come from the manufacturer or user or regulator.

To establish international equivalence, all the tests and checkpoints referred are from ISO/IEC standards. The scheme was prepared by the constituted multi-stakeholder committee (such as medical device industry associations, certification, inspection, testing laboratories/agencies, regulators, accreditation bodies, association of hospitals, and standards body) and details of the committees and the composition is provided in Annexure-VI of the document “Annexures for Technical Criteria” (AMTZ/BEMCS/ATC/R00). This voluntary scheme can be implemented by the hospital through biomedical maintenance department, biomedical maintenance by the manufacturer and third-party maintenance provider. This voluntary scheme shall not cover implantable medical devices, single-use or disposable medical devices and medical equipment which does not require preventive maintenance as per the manufacturer.

1. Introduction

1.1. Proper maintenance and proper use of medical equipment ensures maximum efficiency and increased availability of equipment, at optimal costs and under satisfactory conditions of quality, safety and environmental protection. Within large and modern hospitals, an increasingly common problem is the efficient management of the maintenance of the medical equipment, the quality of the same causing concerns about the subsequent functionality.

1.2. There are many countries that do not have a national health technology policy ensuring the effective use of resources through proper planning, assessment, acquisition and management of medical

equipment. Maintenance thus presents a challenge for many countries, especially those with low technical resources- both human and infrastructural. This scheme is a guidance document to address such scenarios.

In this voluntary scheme, the following verbal forms are used:

- "shall" indicates a requirement;

- "should" indicates a recommendation;

- "may" indicates a permission;

- "can" indicates a possibility or a capability.

2. Scope

The purpose of the scheme is to determine the efficacy of maintenance of medical equipment's function after Installation, Servicing, and Repair are done by the organization in accordance with the applicable standards, regulatory and manufacturer's requirements. However, maintenance service provider (AMC, CMC, Hospitals, Clinics, OEM etc) is responsible for the implementation of the scheme requirements on an ongoing basis. The implementation of the scheme requirements is verified/inspected by a third-party agency (certification body) to ensure its effectiveness and compliance. Also, the competence of such personnel performing the above function, including training on the subject, knowledge, experience and acquaintance with the relevant technologies, design standards and local regulatory requirements has been defined in this scheme. This voluntary scheme is applicable to medical equipment and IVD instrument as defined in Annexure-II of the document "Annexures for Technical Criteria" (AMTZ/BEMCS/ATC/R00).

The document also covers the competence requirements of the scheme users (For e.g. CB, AB etc.).

3. Terms and definitions

3.1 Accreditation

third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities

3.2 Competence

ability to apply knowledge and skills to achieve intended results

3.3 Conformity assessment

demonstration that specified requirements are fulfilled

NOTE 1 The process of conformity assessment as described in the functional approach in Annex A of ISO/IEC 17020:2020 can have a negative outcome, i.e., demonstrating that the specified requirements are not fulfilled.

NOTE 2 Conformity assessment includes activities defined elsewhere in this document, such as but not limited to testing, inspection, validation, verification, certification, and accreditation.

NOTE 3 Conformity assessment is explained in Annex A of ISO/IEC 17000:2020 as a series of functions. Activities contributing to any of these functions can be described as conformity assessment activities.

NOTE 4 This document does not include a definition of “conformity”. “Conformity” does not feature in the definition of “conformity assessment”. Nor does this document address the concept of compliance.

[SOURCE: ISO/IEC 17000:2020, 4.1]

3.4 Impartiality

presence of objectivity

NOTE 1 Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the inspection body.

NOTE 2 Other terms that are useful in conveying the element of impartiality are: independence, freedom from conflict of interests, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, balance.

[SOURCE: ISO/IEC 17020:2012, 3.1]

3.5 Certification body

third-party conformity assessment body operating certification schemes

NOTE A certification body can be non-governmental or governmental (with or without regulatory authority).

[SOURCE: ISO/IEC 17065:2012, 3.12]

3.6 Maintenance

combination of all technical and administrative means, including supervisory ones, to keep MEDICAL EQUIPMENT or a SYSTEM in a normal working condition or restored to normal working condition

NOTE Maintenance at times may also involve repairing.

3.7 Medical Equipment

are defined as medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers and is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment

3.7.1 Active Medical Equipment

means a medical device, the operation of which depends on a source of electrical energy or any other source of energy other than the energy generated by the human or animal body or gravity

3.7.2 Non-Active Medical Equipment

means a medical device, the operation of which does not depend on a source of electrical energy or any source of power other than that directly generated by the human or animal body or gravity

3.7.3 In vitro Diagnostic (IVD) Instrument

equipment or apparatus intended by a manufacturer to be used as an IVD medical device

3.7.4 In vitro Diagnostic (IVD) medical device

reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae

[SOURCE:21CFR809.3 of the US Federal Food, Drug and Cosmetic Act]

NOTE Medical equipment excludes implantable, disposable or single-use medical devices.

3.8 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, or 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]

3.9 Repair

means for restoring to a safe, functional, NORMAL CONDITION

3.10 Servicing

combination of all means for maintaining the MEDICAL EQUIPMENT or SYSTEM within requirements of the MANUFACTURER

3.11 System

means a combination of equipment interconnected or combined to achieve the intended medical purpose

4.0 Normative References

4.1 ISO/IEC 17000 - Conformity assessment — Vocabulary and general principles

4.2 IEC 62353 - Medical device - Recurrent Test and Test After Repair of Medical device

4.3 ISO/IEC 17020 - Conformity assessment — Requirements for the operation of various types of bodies performing inspection

4.4 ISO/IEC 17065 - Conformity assessment — Requirements for the operation of various types of bodies performing certifying products, processes and services

4.5 IAF MD 9 - Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

For all undated references, the latest version of standard shall be used.

5.0 Overview

5.1 Scheme is applicable for the technical areas of all the MEDICAL EQUIPMENT or SYSTEM, specified in Annexure-I of the document "Annexures for Technical Criteria" (AMTZ/BEMCS/ATC/R00) as well as similar equipment as may be decided by the CB.

5.1.1 The scheme implementation will involve the activities performed at different levels as indicated below:

a) The maintenance conducted at the site of installation of the device by the organization.

b) Maintenance conducted at the site by the outsourced service provider under ORGANIZATION.

c) Evaluation by a certification body as per applicable requirements of regulatory requirements/ISO/IEC 17065, this document and any other documents on functionality or checks as provided by the manufacturer of the equipment.

d) Accreditation to such certification bodies (CBs) by accreditation bodies (IAF MLA signatories) as per ISO/IEC 17065.

5.2 The entire process will be based on ensuring the competence of operator, evaluator and assessor along with the other scheme requirements. Further, it is essential to ensure that impartiality requirements are fulfilled across the implementation of schemes at all levels.

6.0 Requirements

6.1 Requirements for Organization (Maintenance service provider)

6.1.1 The organization shall maintain a list of all equipment with the authorized staff details dealing with maintenance.

6.1.2 All relevant and approved documents related to the maintenance of the equipment shall be available at the site.

6.1.3 For a multi-site organization, the above may be maintained at a centralized place and readily accessible to all stakeholders and all the applicable sites.

6.1.4 The details will be initially reviewed by the certification body who in turn will develop an audit programme to ensure that the entire process is adequately covered without compromising on the time concept.

6.1.5 The staff maintaining the device shall be competent as per the Annexure-V of the document "Annexures for Technical Criteria" (AMTZ/BEMCS/ATC/R00).

6.1.6 The organization shall provide complete access to the certification body in a transparent manner.

6.1.7 The organization shall ensure the documentation available shall contain at least the following

- Maintenance Schedule

- Meteorological Traceability where applicable

- Devices required for maintenance and post-maintenance checks

- Required Environmental conditions

- Devices taken out of the premises and returned after service/on site examination.

6.1.8 The flow-chart for the medical equipment maintenance process is provided in Annexure-III of the document "Annexures for Technical Criteria" (AMTZ/BEMCS/ATC/R00).

6.2. Requirements for Independent organizations providing servicing and maintenance of medical devices under ORGANIZATION/ OEM, Hospitals, Clinics etc (hereinafter known as organization)

6.2.1 Organization applying for certification under this scheme shall be a legal entity.

6.2.2 The competence requirements of the staff undertaking the maintenance work are required to have the same competency as outlined for the organization (Annexure-V of the document "Annexures for Technical Criteria" (AMTZ/BEMCS/ATC/R00)).

6.2.3 The organization shall provide all the documents regarding work done to the CB as and when required.

6.2.4 The checklist for medical equipment maintenance is provided in Annexure-IV of the document "Annexures for Technical Criteria" (AMTZ/BEMCS/ATC/R00).

Abbreviations used

AB- Accreditation body which is an IAF MLA Signatory

AMC- Annual Maintenance Contract

CAB- Conformity Assessment Body

CMC- Comprehensive Maintenance Contract

CB- Certification Body

Amendment Sheet

The history of changes are as below.

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