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## 1. Purpose

The purpose of the procedure is to detail the Certification process for Biomedical Equipment Maintenance Certification (BEMC) Scheme at KIHT Certification Services (KCS). This document lists and describes the activities that would be performed by KCS in the certification process at the client site.

## 2. Scope

KIHT Certification Services (KCS) is carrying out evaluations of "Biomedical equipment maintenance" at organization premises under the BEMC scheme which is based on ISO/IEC 17065:2012 standards.

## 3. Reference Documents/Standards

- ISO/IEC 17065 - Conformity assessment — Requirements for bodies certifying products, processes and services.
- Quality manual (KCS/QM/S/R00).
- BEMC Scheme Documents:

1. Technical Criteria document (AMTZ/BEMCS/TC/R00)
2. Annexures for Technical Criteria document (AMTZ/BEMCS/ATC/R00)
3. Certification Process document (AMTZ/BEMCS/CP/R00)
4. CB & AB Requirements document (AMTZ/BEMCS/CBABR/R00)
5. Provisional approval for CBs document (AMTZ/BEMCS/PAP/R00)
6. Rules for Use of Scheme Mark document (AMTZ/BEMCS/SM/R00)

## 4. Responsibilities

All certification processes will be conducted by a person designated by the Certification Manager and the Certification Manager will oversee the execution of this process.

## 5. Procedures

### 5.1 Pre-certification process

#### 5.1.1 Applicant Requirement

The application form, along with the application processing fee (as decided by KCS) needs to be submitted by the applicant organization. The application can be submitted either in person at the KCS office at Kalam Convention Centre or via email (kcs@kiht.in)

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

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

### 5.1.2 Application processing

Upon a written or oral request for Certification from an applicant organization, KCS will contact an authorized representative from the organization (via phone or email kcs@kiht.in).

The application form and the process of evaluation is publicly available by the KCS on its website (https://kalamcertification.in)..

The application form can be downloaded from the KCS website (https://kalamcertification.in).

Before accepting the application form, KCS is responding to all queries of the applicant organization
w.r.t application/evaluation process on this Scheme.

After completing and submitting the application form by the applicant organization it should be shared with the KCS with the application processing fee (as decided by KCS) along with the initial information required to commence the certification process.

The application which is received from the applicant organization is reviewed for its adequacy and availability of resources to perform the evaluation by a Client Manager.

The review shall specifically examine the following criteria:

- Availability of a properly documented Preventive Maintenance (PM) schedule covering a minimum period of one year.
- Possession or arrangement of adequate and calibrated test equipment required for conducting the evaluation.
- Evidence of implementation of the maintenance system for a minimum period of three months.

The review shall also take into consideration whether the organization is operating under:
Annual Maintenance Contract (AMC), or Comprehensive Maintenance Contract (CMC), or Direct association/support from the Original Equipment Manufacturer (OEM).
Applications that are complete in all respects — including all required supporting documents and the prescribed application fee — shall be accepted and processed further for the subsequent stages of evaluation.
Incomplete applications or applications that do not meet the defined adequacy criteria shall be communicated to the applicant with the reasons for non-acceptance and the requirements for resubmission, as per the documented procedure.

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

The certificate will be issued by KCS only against the current revision/issue of the Scheme criteria documents.

KCS may close or reject the applications under the following circumstances;

a) No actions are being taken from the applicant organization 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, will be rejected after a due notice of 15 days. Fresh applications may be considered from the same applicant organization after one year of cooling period.
c) Voluntary withdrawal of application. In such cases, the application fee paid is forfeited.

## 5.2 Evaluation Duration/ man-days

The KCS 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.

The KCS will maintain records with justification on time allocation/planning for each organization.

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

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

If required, KCS may 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 will meet the applicable requirements of ISO/IEC 17025 for testing and ISO/IEC 17020 for inspection, considering the applicable impartiality requirements.

## 5.3 On-site evaluation Process

KCS decided on a competent team, to perform the evaluation and review the relevant document.

Evaluation will be conducted in two stages.

Stage 1 to check the readiness of the applicant and fulfilling the legal obligations if any. The review includes, 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.

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

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 KCS. Corrective actions should be provided by the organization within 15 days for major NC or as agreed with KCS. Major nonconformities if any will result in onsite follow-up evaluation at the discretion of the KCS.

If there are multiple equipment to be covered in the Scheme based on the complexity of the maintenance process, KCS has a plan for evaluation activities to allow for the necessary arrangements to be managed.(Annex 1. KCS Sampling Criteria for BEMC Scheme).

KCS follows 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 KCS checklist for Medical Equipment (F12a).

KCS will 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.

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

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

KCS ensures the calculations and data transfer are subject to appropriate checks in a systematic manner, to avoid errors.

The evaluation report will be prepared and submitted to the client organization along with the findings.

Evaluation report includes:

i. Name of the organization

ii. Name 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.

KCS will seek feedback on the conduct of the evaluation from the client organization.

## 5.4 Review and Certification decision

The KCS assigned one person to review all information and results related to the evaluation. The review is carried out by person (s) who have not been involved in the evaluation process.

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

The Certification manager makes the certification decision based on all information related to the evaluation, its review, and any other relevant information. The certification decision will be carried out by a CM.

We have an agreement detailing the terms and conditions of certification between the KCS and Client organization. (Certification Agreement: F03)

The certificate is valid for 3 years from the date of issuance. (KCS Certificate Copy: F13a).

## 5.5 Surveillance

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

## 5.6 Termination, reduction, suspension or withdrawal of certification

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

a) Continuation of certification under conditions specified by the CB
b) Reduction in the scope of certification.
c) suspension of the certification pending remedial action by the organization.
d) Wthdrawal of the certification

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

If certification is terminated (by request of the organization), suspended or withdrawn, the KCS will 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.

If a scope of certification is reduced, the KCS will take actions which include 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.

If certification is suspended, the KCS will communicate the actions needed to end suspension and restore certification based on the certification decisions.

If certification is reinstated after suspension, the KCS will 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.

If a decision to reduce the scope of certification is made as a condition of reinstatement, the KCS will 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.

## 5.7 Records

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

The KCS keeps records confidential. Records are transported, transmitted and transferred in such a way that confidentiality is maintained. (Control of records :KCS/BEMC/PR06/R00)
If the Scheme involves complete re-evaluation of the process within a 3 year cycle, records will be retained at least for the current and the previous cycle.

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

**NOTE:** Records may include:
a) Raw data sheets
b) Evaluation reports
c) Checklists
d) Any relevant instructions

## 5.8 Complaints and appeals

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

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

The KCS will acknowledge receipt of a formal complaint or appeal.

The KCS is responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

The decision resolving the complaint or appeal is made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal.

Whenever possible, the KCS will give formal notice of the outcome and the end of the complaint process to the complainant.

The KCS will give formal notice of the outcome and the end of the appeal process to the appellant.

The KCS will take any subsequent action needed to resolve the complaint or appeal.

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

## 6.0 Records - Other Applicable Document

1) Application Form (F01a)
2) KCS Personnel Agreement (F02)
3) Certification Agreement (F03)
4) Technical Expert Mapping with Scheme Product Category for BEMC Scheme (F09a)
5) Audit Plan (F10)
6) Audit Report (F11)
7) Checklist for BEMC Scheme (Medical Equipment) (F12a)
8) Certificate for BEMC Scheme (F13a)
9) Non-Disclosure Agreement for Auditor/Technical Expert (F14)

10) Audit Attendance Sheet (F20)
11) Non-Conformity Report (F21)
12) Concern Report (F22)
13) Technical Review of Reports for Decision Making (F23)
14) Complaint Register (F24)
15) Appeal Register (F25)
16) Customer Feedback (F26)

# Annexure I

# KCS Sampling Criteria for BEMC Scheme

## 1. Hospitals

KCS get the following documents from the client but not limited to:

- List of equipments
- Planned Preventive maintenance Schedule
- List of testing equipment available with 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 fertilization (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 | Devices for extra-corporal circulation, infusion and hemapheresis | 10% of the total equipment in this Scheme Product Category |
| 13 | Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anesthesia | 10% of the total equipment in this Scheme Product Category |
| 14 | Devices for stimulation or inhibition | 2% of the total equipment in this Scheme Product Category |
| 15 | Active surgical devices | 5% of the total equipment in this Scheme Product Category |
| 16 | Active ophthalmologic devices | 2% of the total equipment in this Scheme Product Category |
| 17 | Active dental devices | 2% of the total equipment in this Scheme Product Category |
| 18 | Active devices for disinfection and sterilization | 2% of the total equipment in this Scheme Product Category |
| 19 | Active rehabilitation devices and active prostheses | 2% of the total equipment in this Scheme Product Category |
| 20 | Active devices for patient positioning and transport | 2% of the total equipment in this Scheme Product Category |
| 21 | Active devices for in vitro fertilization (IVF) and assisted reproductive technologies | 2% of the total equipment in this Scheme Product Category |

| | | |
|---|---|---|
| 22 | Medical gas supply systems and parts thereof | 1% of the total equipment in this Scheme Product Category |
| 23 | Devices utilizing ionizing radiation (devices for imaging) | 5% of the total equipment in this Scheme Product Category |
| 24 | Devices utilizing non-ionizing radiation (devices for imaging) | 5% of the total equipment in this Scheme Product Category |
| 25 | Monitoring devices of non-vital physiological parameters | 5% of the total equipment in this Scheme Product Category |
| 26 | Monitoring devices of vital physiological parameters | 5% of the total equipment in this Scheme Product Category |
| 27 | Devices utilizing ionizing radiation (Devices for therapy) | 4% of the total equipment in this Scheme Product Category |
| 28 | Devices utilizing non-ionizing radiation (Devices for therapy) | 4% of the total equipment in this Scheme Product Category |
| 29 | Devices for hyperthermia / hypothermia | 1% of the total equipment in this Scheme Product Category |
| 30 | Devices for (extracorporeal) shock-wave therapy (lithotripsy) | 1% of the total equipment in this Scheme Product Category |
| 31 | IVD Instruments | 10% of the total equipment in this Scheme Product Category |
| 32 | Ethylene oxide gas sterilization (EOG) | 1% of the total equipment in this Scheme Product Category |
| 33 | Moist heat | 1% of the total equipment in this Scheme Product Category |
| 34 | Thermic sterilization with dry heat | 1% of the total equipment in this Scheme Product Category |
| 35 | Sterilization with hydrogen peroxide | 1% of the total equipment in this Scheme Product Category |
| 36 | Radiation sterilization (e.g., gamma, x-ray, electron beam) | 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)** | | |

**Note:The following criteria are adopted for Witness activities during the site evaluation.**

**Witness of preventive maintenance:** A minimum of–**10%** of the equipment sampled above in Table 1 shall be physically verified for maintenance activities. However, the selection of equipment will be as follow (whichever is higher):

If Equipment number is ≤ 2 equipment: All equipment will be evaluated
If Equipment number is 3 to 10 equipment: **3** equipment will be evaluated
If Equipment number is 11 to 20 equipment: **4** equipment will be evaluated and
If Equipment number is 20 equipment then Minimum **10** (capped).

**Record Verification Sampling** A minimum of **25%** of the sampled equipment shall be verified onsite for documentation. However, the actual number of records to be verified shall follow:

- ≤ 2 equipment: All
- 3 to 30 equipment: **4**
- 30 equipment: **4** + **2** for every additional block of 10 equipment (or part thereof)

**Table 2: Number of Mandays**

| Sl.No | Total Equipment Considered (T) from Table 1 | Man-days (Stage-2) |
|---|---|---|
| 1 | Up to 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 |

- For both Stage-1 and Stage-2, KCS have a technical expert whose mandays are decided by the KCS.
- Stage-1 Man-days is less than Stage-2 Man-days.
- Stage-1 Man-days is decided by the CB after reviewing the application form from the respective client.
- KCS ensures 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.

## 2. AMC/CMC Service Provider and OEM

KCS get the following documents from the AMC/CMC service provider or OEM but not limited to:

- List of Hospital (for whom KCS provide service) with their location details
- Equipment list and preventive maintenance schedule for each hospital
- List of testing equipment available with calibration status
- KCS selects the 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
- In each auditing cycle, KCS selects different hospitals excluding the previous the selected highest and lowest number of equipment for the surveillance auditing and in the next cycle, excluding these two, next highest and lowest hospital number of equipment shall be selected and so on.

**Revision Status**

| Date of approval | Clause/Para under change | Reason of Change |
|---|---|---|
| 01.12.2025 | Annexure 1 | Update the KCS Sampling size 36 to 38<br>In Sampling Criteria Equipment Selection updated |
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|---|---|
| Revathi. K | K. Udayabhaskar |
| **Prepared By:** Quality Manager<br>**Date:** 01-12-2025 | **Reviewed & Approved By:** Certification Manager<br>**Date:** 01-12-2025 |