Requirements for Quality, Safety and Effectiveness of Medical Devices at Healthcare Facilities

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Introduction

Purpose

The purpose of this document is to specify and clarify requirements to ensure and promote quality, safety and effectiveness of medical devices, and to minimize the risks associated with the usage, transportation and storage of medical devices at healthcare facilities.

Scope

These requirements applies to healthcare providers established within the KSA and third party service contractors.

Background

SFDA/MDS has issued these requirements in reference to Clause Two, Surveillance Responsibilities, Article Five of "The Law of Saudi Food and Drug Authority" issued by the Royal Decree No.(M/6) on 25/1/1428 H, which mandates SFDA to monitor compliance of healthcare providers with the international standards for safety related to the safe performance of medical devices.

Requirements

A. General

1. SFDA may conduct onsite visits on healthcare facilities and third party service contractors to ensure they apply the requirements of quality, safety and effectiveness of medical devices at healthcare facilities.
2. Healthcare providers shall ensure the safe use of relevant medical device to enhance the performance, effectiveness of medical devices in order to protect staff, patients, and public.

B. Healthcare Providers Responsibilities

Healthcare providers shall:

1. Ensure that all relevant medical devices are approved by SFDA (i.e. they have a medical devices marketing authorization (MDMA) and/or Medical Device National Listing Number).
2. Request SFDA approval for advertisement material (posters, lectures, and marketing media) on Medical Devices.
3. Ensure that all clinical studies related to medical devices that are carried out in the healthcare facilities have been registered with the SFDA and obtain "No Objection Letter".
4. Deal only with medical devices distributers licensed by SFDA.
5. Deal only with third party service contractors (establishments that have provide maintenance services for medical devices), if applicable, licensed by SFDA.
6. Report to SFDA any adverse event caused by medical devices.
7. Establish and maintain Biomedical Engineering Department responsible to either directly implement the requirements specified in this document or oversea and monitor a third party company licensed by SFDA to manage and maintain the Medical devices and equipment with the healthcare facilities.
8. Have Biomedical Engineers (BME)/Biomedical Technicians (BMT) with qualifications in biomedical or clinical engineering or any relevant specialty, and have training in relevant fields.
9. Ensure availability of well-equipped workshop(s) for the maintenance of medical devices.
10. Perform necessary commissioning tests including electrical, mechanical, chemical, functional, safety and other relevant tests to ensure the safety and efficacy of the devices.

11. Ensure the medical device supplied matches the specification of the device indicated in the Supplier's invitation to tender response, direct purchase, lease or Guaranteed Price per Reportable Result (**GPPRR).**
12. Ensure the medical device has been supplied with the appropriate original medical device manufacturer recommended accessories and consumables.
13. Ensure that all necessary information and documentation accompanying a medical device, including instructions for use, have been provided.
14. Ensure that manufacturers' transport and storage requirements are met.
15. Appoint a BME/BMT as a point of contact with SFDA during their onsite visit.
16. Appoint an officer to be point of contact to receive the recalls weekly report, then do the following:
    - Ensure that the healthcare provider remove the recalled medical device from use or implement the recommended action for any affected device/product mentioned in the FSNs/Recalls.
    - Communicate with the National Center Medical Devices Reporting Team and authorized representative of the manufacturer to ensure the implementation of the necessary corrective actions.
    - If the FSN requires the user to stop using the device, then the officer shall take the necessary actions to ensure that the affected device(s) are not in use until a corrective action is done.
17. Ensure the BMEs/BMTs and users of the medical devices are properly trained based on the manufacturer requirements before operating and maintaining the medical device.
18. Ensure that medical device is used according to the intend of use.
19. Keep a separate record for all disposed medical devices for two years.
20. Not re-use any medical device designed for single use only.
21. When transferring a device to be used in another location or department, a transfer form shall be filled. The form shall contain at least the device description and asset number, present location, new location, date of transfer.
22. A copy of the (transfer form) must be sent to the BME department to update the device's record in order to keep track of the device for the purpose of the device's maintenance, utilization, and future needs assessments.
23. In case the device needs to disassembled and reassembled in different locations, qualified engineer according to the manufacturer recommendations shall conduct this task. In case the device needs to be stored, it must be stored in accordance with the manufacturer's storage instructions such as the device's shelf life, storage room temperature and humidity requirements.

C. BME Department Responsibilities

BME department shall:

1. Ensure availability of test equipment, and ensure they are calibrated as per manufacturer requirements by an authorized lab.
2. Ensure availability of maintenance management system and inventory management system to collect, store, organize, analyze, and report medical device data for healthcare provider. The maintenance management system shall include record for each device, but not be limited to, the following information:
    a) Device general information
    b) Periodic Preventive Maintenance (PPM): frequency of PPM, Updated procedures of PPM, calibration requirements and spare parts used in PPM, date of each PPM, PPM kits and parts used, who completed the work, and time spent performing PPM.
    c) Corrective Maintenance (CM) history: date of failure, failure description, spare parts used, time duration of maintenance, and related FSNs/recalls.
    d) For new devices, the record shall be generated when they are ready for clinical operation (installed, tested, and tagged).
    e) Required test equipment.
3. Source appropriate and genuine spare parts for maintenance based on manufacturer service manuals and technical bulletins.
4. Provide mechanisms to avoid failures or breakdowns of the device during patient treatment, diagnosis or therapy.
5. Be proactive in the identification of possible points of failure of device related services and develop contingency plans before the catastrophic event or possible incident.
6. Plan, with the assistance of the device supplier, for appropriate inventories of spare parts to minimize downtime.

D. BME/BMT Responsibilities

BME/BMT shall:

1. Assure that the status of the device is matching the manufacturer specifications and comply with SFDA regulations.
2. Take into account the manufacturer instructions for CM and PPM.
3. Ensure and maintain the accuracy of the maintenance management system and inventory information.
4. Be responsible for the following phases of medical devices:
    a) Pre-procurements and pre-installation of medical device:
        - Develop the technical specifications of medical device.
        - Provide pre-installation requirements request.
        - Ensure that all relevant medical devices are approved by SFDA (i.e. they have a medical devices marketing authorization (MDMA) and/or Medical Device National Listing Number).
        - Ensure that all clinical studies related to medical devices that are carried out in the healthcare facilities have been registered with the SFDA and obtain "No Objection Letter".
        - Ensure that medical devices distributers dealing with are licensed by SFDA.
        - Ensure that third party service contractors dealing with (establishments that have provide maintenance services for medical devices), if applicable, are licensed by SFDA.
        - Review of published hazard and recalls data to identify any ongoing technology issues.
        - Ensure the availability of manuals (user, operation, instructions for use (IFU), service, spare part list, lists of tool and test equipment required, circuit diagram, planned preventive maintenance manual and checklist as per manufacturer's requirements).
        - Apply the evaluation criteria for all suppliers of medical devices.
        - Ensure the availability of the decontamination, cleaning, disinfection and sterilization procedures, ensuring the healthcare provider is able to reprocess in line with the manufacturer's instructions (e.g. by trained technicians). The infection control and CSSD team and shall be consulted.
        - Ensure the availability of disposal instructions
        - Any other requirements associated with the medical device (e.g. radiation safety, chemical, medical gases, central supply and sterilization/cleaning requirements).

- Any site preparation work before delivery and installation shall be completed.

b) Installation and commissioning of medical device:

- The device is configured in an appropriate manner.
- Installed according to the original medical devices manufacturer's recommendations and located where required with oversight of this process by the BME department.
- Delivery has been achieved with the technology/medical device in good condition and fully functional.
- Manufacturer's and regulatory authorities' Health & Safety requirements during the installation process are considered and met.
- If needed, the availability of disinfection and sterilization contract or competent personnel tools and spaces.
- Data has been captured and stored on the organizations CMMS for asset tracking purposes.
- Formal training needs according to the manufacturer requirements have been identified and implemented and data captured for inclusion in training databases for ongoing needs.
- In the case of reusable devices, maintenance requirements have been identified and scheduled.
- Information about proper storing and transporting.
- Involvement of BME and End-user departments during the installation and acceptance process. The entire process shall be coordinated by BME department, which shall liaise with other groups as required.
- Report signed from the responsible BME and end user explaining that the medical device is installed, in good condition and fully functional.
- Confirmation that all documentation has been delivered including local configurations, as-built drawings, and IT information for connected devices.
- A control number will be assigned and labelled, placed on the unit, along with any other appropriate labels (e.g. warranty expiration date, loaned device.)
- In case the delivered medical device failed to comply with healthcare provider's identified requirements in the tender, the BME department and other related department shall be responsible for liaising with the medical device supplier in the event of damaged or inappropriately delivered or unrepairable medical device.

c) Operation of medical device:

- PPMs, spare parts inventory and doing the electrical safety test. When performing PPM, the following points shall be considered:
    - The PPM frequency and procedures shall be in line with the manufacturer requirements.
    - The PPM frequency is usually indicated by time periods (interval-based), or as per device's operation hours (meter-based), or both.
    - Only trained personnel shall perform the PPM.
    - For some devices, the PPM procedure requires replacing some parts or PPM kits. In this case, an adequate number of PPM kits shall be kept in stock, and periodically re-stocked, depending on the number of devices used in the facility and frequency of PPMs.
    - Before performing PPM, the device shall be clean, decontaminated (if needed), and working in a good condition.
    - After performing PPM, a device's performance and function tests shall be carried out.
    - In all cases, this shall include a safety test and safety inspection as part of the PPM.
    - The PPM details (date, PPM kits, etc.) shall be recorded in the device's history in the CMMS. Data shall be filed for a minimum of five years.
    - All PPMs must be signed off by the end-user and BME/contractor performing the service. In addition, the device shall be tagged after PPM. The tag shall contain at least the date of last performed PPM, the due date for the next PPM, and responsible the BME/BMT.
    - The device shall be clean, decontaminated (if needed), and working in a good condition.
    - After performing PPM, a device's performance and function tests shall be carried out.
    - In all cases, this shall include a safety test and safety inspection as part of the PPM.

d) CM:

- For all electrical medical devices, a test/safety inspection shall be conducted as part of the CM.

- Function and calibration tests shall be conducted after installation, any major replacement and modification.
- If applicable, the device shall be calibrated after the CM, as per manufacturer requirements.
- If the CM procedure includes using test equipment for performance or calibration checks, the test equipment shall be tested and calibrated by the manufacturer or a certified body.

e) Calibration test, safety and performance inspection of medical devices:

- The healthcare provider shall conduct safety and performance inspection and calibration tests on devices at intervals based on manufacturer recommendation but not exceeding two years. These inspections and tests shall be conducted by a qualified BME/BMT with the proper tools and biomedical test equipment that is calibrated by an authorized lab in addition to the training and experience.
- BMED shall monitor all technical services provided during the warranty period for appropriate responses, quality and types of repairs and turnaround time. They must ensure that supplier performance is continuously assessed, and the related clinical department is informed. Supplier performance management and ratings are key indicators and shall be factored during future procurement activity.

f) Reprocessing of re-usable medical devices:

- Ensure the availability reprocessing method setting and infrastructure.
- Ensure the availability of the Reprocessing written procedure.
- Ensure the availability of proper Equipment, disinfectant and relevant supplies and consumables for the required reprocessing method.
- Ensure the availability of trained staff for the available reprocessing method.
- Ensure the commitment to required maintenance and calibration of all available reprocessing method.

g) Improve the awareness about the reporting adverse events to the SFDA:

- It is a moral responsibility for users, patients and all those using a medical device or accessory to report adverse events. There are multiple numbers of the same device being used by other patients in other healthcare providers and reporting the incident will save others from facing the same accident (reporting is saving).

E. Third Party Service Contractors Requirements

Third party service contractors shall:

1. Be registered and licensed by SFDA.
2. Have a BME/BMT with at least bachelor degree or any relevant specialty.
3. Receive training from manufacturers regard their system.
4. Declaration of scope of devices covered by the activity
5. Ensure availability of Test equipment: Appropriate test equipment for analyzing, performance and safety of medical devices shall be available.
6. Ensure availability of dedicated instruments, spaces, devices and other work equipment such as other measuring tools and testing equipment that is mandatory to conduct each activity properly and comprehensibly.
7. Ensure that all test equipment are procured and calibrated by an authorized lab as per manufacturer requirements.
8. Ensure availability of maintenance management system and inventory management system to collect, store, organize, analyze, and report medical device data for healthcare facility.
9. Take into account the manufacturer instructions for corrective and preventive maintenance.
10. Ensure and maintain the accuracy of the maintenance management system and inventory information and keep it updated.
11. Ensure availability of well-equipped workshops for maintenance of medical devices.
12. Report an adverse events caused by the medical devices to SFDA.
13. The establishment shall establish and submit to the SFDA periodic report about the performance of the medical devices covered by their maintenance activity.
14. have Quality Management System (QMS).
15. Establish documented procedures to ensure:
    h) All work orders are effectively completed and accomplished after client approval.
    i) Soliciting feedback from clients about his satisfaction of the quality of provided service, response time
16. Ensure the availability of Electrical Safety Analyzer that tests according IEC 60601 and IEC 62353.
17. Ensure the availability of proper storage area (as recommended by manufacturer) for medical devices and spare parts
18. Ensure the availability of Standard Operating Procedures (SOPs) and checklists for each medical device's maintenance activity.

19. Ensure the availability of effective documented method of communication with client to facilitate conducting maintenance activities punctually.
20. Ensure the availability of enough Saudi Biomedical Engineers hired to meet all client visit based on defined schedule of all maintenance activities visits taking in consideration time margin of the Engineers and technicians working hours for unexpected corrective maintenance.
21. Ensure the availability of PPM Tags with the establishment information.
22. Ensure the availability of defined scope of medical devices covered by the establishment's medical devices' maintenance activities.
23. Ensure the availability of effective spare parts stock availability management with list of all spare parts certified suppliers. The spare parts shall be provided to the client immediately and the delay is only acceptable when justified in case of corrective maintenance.
24. Ensure that the service or maintenance personnel:

    j) Have a qualification of bachelor in biomedical or clinical engineering, Biomedical Technology or any relevant engineering specialty.

    k) Receive training from manufacturer) s on their medical devices and systems compared to the scope of medical devices covered by the establishment's medical devices' maintenance activities..

    l) Assure that the status of the device is matching the manufacturer specifications and comply with SFDA regulations.

    m) Take into account the manufacturer instructions for corrective and preventive maintenance.

    n) Ensure and maintain the accuracy of the computerized maintenance management system CMMS and inventory information and keep it updated.

Annexes

Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
National Center for Medical Device Reporting (NCMDR)	an organization managing a database of information on safety and/or performance related aspects of medical devices and employing staff capable of taking appropriate action on any confirmed problems.
Healthcare provider	any party, governmental or private, provides healthcare services within KSA including health clinics.
Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: ○ Diagnosis, prevention, monitoring, treatment or alleviation of disease, ○ Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, ○ Investigation, replacement, modification, or support of the anatomy or of a physiological process, ○ Supporting or sustaining life, ○ Control of conception, ○ Disinfection of medical devices, ○ Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; And B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Clinical Investigation	Systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device.
Adverse Event (AE)	Means any malfunction or deterioration in the characteristics and/or performances of a medical device, including any inadequacy in its labelling or the instructions for use, or use error, which may compromise the health or safety of patients, users or third parties.

Calibration Test	Procedure for determining the accuracy of a medical device's performance by measuring the deviation of its output from standard measurements to ascertain necessary corrective adjustments.
Calibration	The corrective adjustments to medical devices required to maintain their performance accuracy according to a standard.
Biomedical Engineer/Technician	A professional who supports and advances patient care by applying engineering and managerial skills in healthcare technology. Note: The BME/BMT shall have an academic background in biomedical/medical engineering or biomedical technology (instrumentation).
Computerized Maintenance Management Systems (CMMSs)	Computer-based software systems that are used to automate issues related to the technical support of medical devices and provide support for medical device inventory management, corrective maintenance (CM), preventive maintenance (PM), and contract management and provide a wide range of real-time data reports on different issues related to the medical device lifecycle, such as downtime, lifecycle cost and inventory reports related to the device type, location or selected manufacturers.
Corrective Maintenance (CM)	A process used to restore the physical integrity, safety and/or performance of a device after a failure. CM and unscheduled maintenance are regarded as equivalent to the term repair. This document uses these terms interchangeably.
Biomedical Engineering	The cost-effective and effective clinical management of all issues related to the medical device lifecycle. This may consist of a framework of standard policies and procedures designed to address all different components and issues related to medical devices.
Periodic Preventive Maintenance (PPM)	PM involves maintenance performed to extend the life of the device and prevent failure. PM is usually scheduled at specific intervals and includes specific maintenance activities, such as the lubrication, cleaning (e.g., filters) or replacement of parts that are expected to wear (e.g., bearings) or have a finite lifetime (e.g., tubing). The procedures and intervals are usually established by the manufacturer. In exceptional cases, the user may change the frequency to accommodate local environmental conditions. PM is sometimes referred to as "planned maintenance" or "scheduled maintenance." This document uses these terms interchangeably.
Repair	A process used to restore the physical integrity, safety, and/or performance of a device after a failure. This term is used interchangeably with CM in this document.

Reuse	Repeated use or multiple uses of any medical device with reprocessing (e.g., cleaning, disinfection or sterilization) between uses.
Single-Use Medical Device	A medical device intended for one use on an individual patient for a single procedure. The device shall then be discarded.
Field Safety Corrective Action Recall	means an action taken by a manufacturer to reduce or remove a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.
Field Safety Notice (FSNs)	a notification from the SFDA to relevant medical device users in relation to a Field Safety Corrective Action.