الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS – G49

Guidance for Medical Devices Maintenance Facilities

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Introduction

Purpose

The purpose of this guidance is to clarify the Saudi Food & Drug Authority (SFDA) requirements on the maintenance services of medical devices and supplies in health facilities to ensure the performance of the medical device according to its intended purposes by applying calibration, planned preventative maintenance (PPM) and corrective maintenance (CM) during the usage of the medical device.

Scope

This guidance document applies to all medical devices maintenance facilities in the Kingdom of Saudi Arabia (KSA).

Background

In accordance with “The Law of Saudi Food and Drug Authority” issued by the Royal Decree No. (M/6) dated on 25/1/1428 H, which states that SFDA undertakes the responsibility of monitoring the compliance of healthcare provider with the international standards related to the safety performance of medical devices/supplies. As well as Saudi Health Council Resolution No. 84/4, which includes obligating health sectors to direct all their health facilities to manage and calibrate the measurements, quality and specifications of the operation and maintenance of medical devices or a third party licensed by the Food and Drug General Authority.

Medical Devices Maintenance Facilities Requirements

The Medical Devices Maintenance Facilities that are responsible for providing maintenance services of medical devices must:

1. Clarify the scope of medical devices used in every maintenance operation.
2. Provide suitable test equipment to check the function, safety and performance of the medical device taking into consideration that this equipment must be calibrated in an approved laboratory in the KSA or in a factory.
3. Provide tools, spaces, specialized devices and other work equipment in maintenance process such as measurement tools and test equipment.
4. Provide maintenance management system and stock management system to collect, store, organize, analyze and record medical device data as well as the spare parts needed. In addition to a list of all spare parts distributors, which are certified by manufacturer that supply spare parts.
5. Grant the person/sector requesting maintenance service with the original spare parts immediately. Bearing in mind, that delaying is not acceptable except in the case of CM.
6. Apply the CM and calibration instructions issued by the manufactory. If the instruction was not existed, refer and comply with the standard (SFDA.MD/IEC 62353).
7. Report to the SFDA for any medical devices/products incidents, in addition to the incidents that happen during the maintenance operation which affects the safety and performance of the device.
8. Achieve the quality goals and policies by applying a system that documents the operations, procedures and responsibilities.
9. Implement documented procedures to ensure the following:
    a) Perform all work requests after getting the approval of person/sector requesting maintenance service within healthcare facility.
    b) Attain the feedback from the person/sector requesting the maintenance services within healthcare facilities regarding the level of satisfaction about the quality of services provided and the response time through specific performance indications.
    c) Provide the Standard Operating Procedures (SOPs) and forms for every maintenance process of medical devices/supplies.
10. Provide a proper space for storing medical devices and spare parts as specified by the manufacturer.
11. Provide an efficient and coherent communication with the person/sector requesting maintenance service within healthcare facilities to ensure that the maintenance request is responded on time.

12. Provide PPM label, which includes information of the facility that offers the maintenance services.
13. Provide Biomedical Engineers/Technicians in maintenance according to the following criteria:
    a) Carrying Technical certifications and qualifications in either Biomedical Engineering, Biomedical Technology, clinical Engineering or any other related Engineering major.
    b) Obtaining continuous and specialist trainings on the medical devices that are covered by class (B), (C) and (D) depending on level of risk or any equivalent.

Annexes

Annex (1): Definitions & Abbreviations

Biomedical Engineering	The department responsible to all medical device – related issues in terms of usage. This includes the procedures and policies designed to treat different matters of medical devices.
Calibration	The required correction adjustments to medical devices to maintain its performance accuracy according to standard.
Calibration Test	Procedures of determination of the accuracy of medical devices performance, by measuring the deviation of its output and measurement from a standard, to ascertain necessary correction adjustment.
Clinical Engineer/ Specialist	A professional who supports and advances patient care by applying engineering and managerial skills in healthcare technology. Note: the clinical engineer shall be personnel with an academic background in biomedical/ medical engineering or biomedical technology (Instrument).
Corrective Maintenance (CM)	A process used to restore the physical integrity, safety and/or performance of a device after a failure. Corrective maintenance and unscheduled maintenance are regarded as equivalent to the term repair. This document uses these terms interchangeably.
Healthcare Provider	Any party, governmental or private, provides healthcare services with KSA including health clinics.
Incidents	Events involving* medical devices that have resulted in, or could have resulted in (i.e. near misses), harm to a patient, health professional or other person. Other issues involving* medical devices that have not led to harm, but affect quality, timeliness and cost-effectiveness of health care delivery and may, if it happens often enough, lead to harm. * "Involving" in this means associated with the use, or misuse, of a medical device – either caused or partially attributable to a device
KSA	Kingdom of Saudi Arabia
MDS	Medical Devices Sector
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.
Medical Devices Maintenance Facilities	Any side or party that fixes, repairs or performs calibration tests to a medical device after distribution with the purpose of restoring it to a higher quality and performance. In addition to, applying the safety procedures of the factory.
National Center for Medical Device Reporting (NCMDR)	Is an organization managing a database of information on safety and performance related aspects of medical devices and capable of taking appropriate action on any confirmed problems.
PPM	Planned preventive maintenance
Preventive Maintenance (PM)	PM involves maintenance performed to extend the life of the device and prevent failure. The PM is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, cleaning (e.g. filters) or replacing parts that are expected to wear (e.g. bearings) or which have a finite life (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. Preventive maintenance 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. Used interchangeably with corrective maintenance.
SFDA	Saudi Food and Drug Authority
SOPs	Standard Operating Procedures