Standards for Medical Equipment Management

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Health Policies and Standards Department

Health Regulation Sector (2023)

INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (14) of the year (2021) amending some clauses of law No. (6) of 2018 pertaining to the Dubai Health Authority (DHA), to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector;
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice;
- Managing patient complaints and assuring patient and physician rights are upheld;
- Governing the use of narcotics, controlled and semi-controlled medications;
- Strengthening health tourism and assuring ongoing growth; and
- Assuring management of health informatics, e-health and promoting innovation.

The Standard for Medical Equipment Management aims to fulfil the following overarching DHA Strategic Priorities (2022-2026):

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.

ACKNOWLEDGMENT

The Health Policy and Standards Department acknowledges subject matter experts and DHA licensed facilities for their input in the standards of management of medical equipment to ensure that all Healthcare Facilities are adequately and consistently evaluated for compliance with the standards provided within this document to improve patient safety and quality of care in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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EXECUTIVE SUMMARY

Medical equipment refers to devices, instruments, machines, or tools used by healthcare professionals to diagnose, monitor, treat or prevent medical conditions. They play a crucial role in healthcare delivery to support patient care, improve diagnostic and operational accuracy, and facilitate medical procedures. The World Health Organization (WHO) considers medical equipment as assets that directly affect human lives and subsequently their regulation and management is critical in the provision of safe and high quality of care.

The Dubai Health Authority (DHA) Standards for Medical Equipment Management sets out the minimum requirements of managing medical equipment at health facilities licensed by DHA. It aims ensure the continuous monitoring for medical equipment management to assure high quality patient care and safe environment is provided for the operator and patient. The standards cover key areas related to medical equipment management including but not limited to: maintenance plan, inventory management, risk management and quality monitoring.

DEFINITIONS

Corrective Maintenance (CM): A process used to restore the physical integrity, safety and/or performance of a device after a failure.

CE Marked: certifies that a product has met European Union health, safety, and environmental requirements, which ensure consumer safety.

Federal Authority for Nuclear Regulation (FANR): is the UAE federal regulatory body of nuclear and radiation related issues including the medical use of ionizing radiation. All the institution and units that are involved with ionizing radiation in UAE shall be licensed by FANR and abide by their regulations.

Health Facility: DHA licensed health facility that performs medical examinations on patients, diagnosing their diseases, treating or nursing them, admitting them for convalescence, or assuming any activity related to treatment or to rehabilitation after treatment, whether it is owned or managed by natural or juridical persons.

Healthcare professional: are healthcare personnel working in health facilities and required to be licensed as per the applicable laws in United Arab Emirates (UAE).

Medical Equipment: Means machinery designed to aid in the diagnosis and treatments of medical problems with rigorous safety standards.

Preventive Maintenance (PPM): Refers to all the scheduled activity necessary to ensure a piece of medical equipment is functioning correctly and is well maintained.

ABBREVIATIONS

CE Mark : The Conformité Européene

CM : Corrective maintenance

DHA : Dubai health authority

FANR : Federal Authority for Nuclear Regulation

FDA : Food and drug administration

KPI : Key performance indicator

MOHAP : Ministry of Health and Prevention

PPM : Planned Preventive maintenance

QC : Quality Control

QA : Quality Assurance

WHO : World Health Organization

1. BACKGROUND

Medical equipment refers to devices, instruments, machines, or tools used by healthcare professionals to diagnose, monitor, treat or prevent medical conditions. These devices play a crucial role in modern healthcare and are designed to enhance patient care, improve accuracy, and facilitate medical procedures. Medical equipment can vary greatly in complexity and purpose, ranging from simple devices like thermometers and blood pressure monitors to advanced equipment such as MRI machines, X-ray systems, ventilators and surgical robots. Each type of equipment serves specific function and is used across various medical specialties. Manufacturers of medical equipment must comply with strict regulations and safety standards to ensure the devices are safe and effective for patient use. Regular maintenance and calibration are necessary to ensure their proper functioning and accuracy. Advancements in technology continue to drive innovations in medical equipment, leading to improved patient outcomes and enhanced healthcare practices. As technology evolves, medical professionals have access to more sophisticated tools to diagnose and treat medical conditions with greater precision and efficiency. The DHA Standards for Medical Equipment Management sets out the minimum requirements of managing medical equipment at health facilities licensed by Dubai Health Authority. It aims ensure the continuous monitoring for medical equipment management to assure high quality patient care and safe environment is provided for the service provider and patient.

2. SCOPE

2.1. Applies to all health facilities licensed by DHA.

3. PURPOSE

3.1. Govern the management of medical equipment at all health facilities licensed by DHA.

3.2. Assure provision of the highest levels of safety and quality of medical equipment services complying with international healthcare standards.

3.3. Reduce the risks associated with medical equipment failures and ensure the function and reliability of medical equipment.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities using Medical Equipment.

5. STANDARD ONE: HEALTH FACILITIES DOCUMENTED PROGRAM/PLAN FOR MEDICAL EQUIPMENT

5.1. Health facilities shall cover the entire range of medical equipment installed at the facility as well as its affiliate services (such as homecare, ambulances etc.).

5.2. Health facilities shall provide internal policies and procedures for all stages of equipment lifecycle management (new medical equipment acquisition, installation, condemnation, breakdown maintenance, preventive maintenance, inventory, tagging and tracking, risk management and recalls) to align with DHA requirements listed in this document.

6. **STANDARD TWO:** NEW MEDICAL EQUIPMENT ARRIVES TO THE FACILITY (PURCHASED/ NON-FACILITY EQUIPMENT)

6.1. All medical equipment in the health facilities should be registered in Ministry of Health and Prevention (MOHAP).

6.2. All medical equipment acquisition at hospitals should ensure:

6.2.1. Availability of technical specifications, and purchase recommendations based on technical features, should have regulatory compliance (FDA/CE/Japanese) or any equivalent international quality certificate and after sale support.

6.2.2. Health facilities are encouraged to consider sustainable options during the acquisition of medical equipment.

6.2.3. Sustainable and an environmentally friendly feature of new medical equipment to be added as a point when evaluating new medical equipment (e.g.: less power consumption, recyclable materials).

6.3. For new purchase, all installation documents should be available with supply chain document to ensure the safety of the supply chain and therefore, protecting patients and staff from unstable, contaminated, defective, and counterfeit supplies. Documents include but are not limited to:

6.3.1. Purchase order.

6.3.2. Country of origin.

6.3.3. Installation report.

6.3.4. PPM schedule.

6.3.5. Warranty certificate.

6.3.6. Quality Certifications (FDA/CE/Japanese or any equivalent quality certification.

6.3.7. Delivery note.

6.3.8. Transport & Storage Certificate.

6.3.9. User training certificates or attendance sheet document.

6.3.10. Spare part list.

6.3.11. Cybersecurity Compliance Certificate (as applicable).

6.4. All accessories and consumables for critical equipment should be aligned with equipment functions and as per manufacturer's recommendations.

6.5. All medical equipment (purchased, demonstration, loaned etc.) should be tested as applicable for safety (electrical safety test, mechanical, radiation etc.), QC and calibration is done upon installation.

6.6. Availability of operating manual accessible by clinical staff of the department and service manuals should be available for all inhouse service equipment.

6.7. Training records for end users and engineers to be available.

6.8. To eliminate the use of extension cords.

6.9. For non-Facility medical equipment (DEMO/LOANED/PATIENT PROPERTY):

6.9.1. Should be tagged with DEMO/LOANED/PATIENT PROPERTY stickers.

6.9.2. A file containing all non-facility equipment details and checklist shall be checked and verified by Biomedical Engineering, insuring they are properly checked and are safe for all patients, staff, and visitors, prior to use in the health facility.

6.9.3. To insure non-facility medical equipment adheres to infection control standards and requirements.

6.10. For the radiology equipment with radiation, the facility must ensure that they have the required credentials and licenses from FANR for all equipment producing radiation and falling in the scope of FANR licensing. The facility and the supplier should adhere the following:

6.10.1. The facility shall notify FANR of their intention to use ionizing radiation by registering with FANR online E-licensing System to obtain the necessary FANR approvals at https://www.fanr.gov.ae/en/services/elicensing

6.10.2. Both supplier and the facility should be registered with FANR and has a license to import/install the unit in the facility.

6.10.3. Once equipment is purchased, the facility must update the ownership for the equipment in FANR system.

6.10.4. Any radiation equipment cannot be accepted or imported unless it matches FANR requirement.

6.10.5. Medical physics has to approve the imaging machine with radiation before the operation, radiation dose management systems and the dose features to be reviewed by the medical physicist.

7. **STANDARD THREE:** MEDICAL EQUIPMENT INVENTORY MANAGEMENT

7.1. Maintaining proper inventory through inventory system for all the medical equipment available and to be updated every time a new equipment arrives or removed from service.

7.2. Critical equipment is identified in the inventory, there is provision for back-up/ alternative for critical equipment during their failure or maintenance.

7.3. All medical equipment should be labelled and tagged with biomedical asset number.

7.4. All details of medical equipment (manufacturer/ model/ serial number/ local supplier/ date of purchase and location at the facility) should be available.

7.5. Capacity of medical equipment is appropriate to meet the service scope of the facility.

8. **STANDARD FOUR:** CORRECTIVE MAINTENANCE

8.1. Certified biomedical engineers should be responsible for the maintenance of medical equipment.

8.2. Staff (in-house, contracted, supplier) responsible for maintenance of medical equipment shall be qualified and trained on their repairing and testing.

8.3. Availability of biomedical workshop and biomedical engineer is mandatory at general hospitals.

8.4. All service records, test results, calibration and adjustment and QA/QC records should be documented and maintained for each piece of equipment.

8.5. Clear Procedures for Stock and Non-stock spare part.

8.6. Physical availability of calibrated test equipment and tools for all ranges of medical equipment should be available in the facility for inhouse serviced medical equipment.

8.7. The facility should tag and remove any defective equipment from use.

9. **STANDARD FIVE:** PLANNED PREVENTATIVE MAINTENANCE OF MEDICAL EQUIPMENT

9.1. PPM schedule is available for all medical equipment which needs PPM.

9.2. Facility to ensure that PPM is performed according to type, use and as per recommendations of their manufacturers. The PPM period should adhere at least the manufacturer recommendation or better.

9.3. All test equipment for all the range of available medical equipment in the facility to be available and calibrated with valid calibration date, the calibration is through an organization certified by a component national or international body.

9.4. PPM stickers should be available physically on the medical equipment and matching the PPM date on medical equipment management system in the facility and in the PPM check list.

10. STANDARD SIX: MEDICAL EQUIPMENT RISK MANAGEMENT

10.1. The facility should have a product/equipment recall system which is implemented through active monitoring of recalls, and hazard notices, to insure receiving and being notified about any incident involving serious injury or death of patients, visitors or staff, resulting from malfunction of medical equipment in addition to incidents on medical equipment due to mishandling/improper use of medical equipment.

10.2. Medical equipment risk assessment should be conducted and documented annually throughout the facility, and medical equipment risks are identified and prioritized from the risk assessment.

10.3. A standard medical device recall procedure should be used by the facility to identify and assist in the removal of potentially defective products throughout the facility.

10.4. Shall follow manufacturer specifications and procedures regarding any medical device recalls including the maintenance of all associated documentation related to recall notices.

10.5. Facility's process should follow the below steps to manage a medical device recall:

10.5.1. Verify the availability of the equipment in the facility.

10.5.2. Equipment recall record is to be prepared and updated properly.

10.5.3. Equipment to be removed from the use and informed to the supplier/manufacturer.

10.5.4. Reports are to be documented and kept in the equipment file.

10.5.5. Necessary repair/replacement should be done.

11. STANDARD SEVEN: MEDICAL EQUIPMENT PERFORMANCE EVALUATION (KPI'S)

11.1. The facility should monitor Key performance indicators (KPIs) related to medical equipment maintenance which include but not limited to:

11.1.1. Key performance indicators (KPI) related to medical equipment corrective maintenance.

11.1.2. Percentage of Planned preventive Maintenance (PPM) completed on or before PPM due date.

12. STANDARD EIGHT: MEDICAL EQUIPMENT DATA INFORMATION SECURITY COMPLIANCE

12.1. For all medical equipment connected to networks, the health facility should ensure that the purchased medical equipment is adhering to the information security standard requirement before purchasing the equipment.

12.2. The facility must ensure that patient data are secured and are not to be shared or stored out of the facility as per UAE Federal Law No. 2 of 2019 concerning the Use of Information and Communication Technology (ICT) in Health Fields.

12.3. The facility must ensure that all patient data are fully deleted before removing any medical equipment from service, if the medical equipment has any stored data on it and should be documented in the condemnation certificate upon removing the medical equipment.

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APPENDICES

APPENDIX 1: DHA PROPOSED MEDICAL EQUIPMENT CHECKLIST

Management Type	Ref No	Specification	Guidelines
Medical Equipment Management	EM001	The facility has a documented medical equipment, management program/plan to cover the entire range of medical equipment installed at the facility as well as its affiliate services (Such as homecare, ambulances etc.)	Review of Management plan and its reflection in maintaining medical equipment
Medical Equipment Management	EM002	Policies and procedures for all stages of equipment lifecycle management (from planning to disposal) are available.	Review of Management plan and its reflection in maintaining medical equipment
Medical Equipment Management	EM003	All incoming critical technologies/equipment (to be purchased, loaned and placed) are appraised , before acquisition, based on criteria including technical features, regulatory compliance (FDA and or CE etc.) and after sale support.	Check Policy and appraisal documentation
Medical Equipment Management	EM004	Medical equipment inventory is available, complete with all necessary information and is updated on regular basis.	Inventory list
Medical Equipment Management	EM005	Extent and capacity of medical equipment is appropriate to meet the service scope of the facility.	KPI, risk and Need assessment

Medical Equipment Management	EM006	Critical equipment are identified, listed and updated on regular basis. There is provision for back-up / alternative for critical equipment during their failure or maintenance.	Policy and appraisal documentation
Medical Equipment Management	EM007	Utilities, accessories and consumables for critical equipment are aligned with equipment functions and as per manufacturer's recommendations.	End user requisition request, Appraisal documentation, installation report
Medical Equipment Management	EM008	Planned preventive maintenance (PPM) schedule for medical equipment is available and implemented.	Check PPM Schedule
Medical Equipment Management	EM009	All medical equipment (purchased, demonstration, loaner etc.) are tested for safety (electrical, mechanical, radiation etc.) and QC and calibration is done upon installation, PPM and major repairs. PPM is performed according to type, use and as per recommendations of their manufacturers. labeled with PPM stickers with correct date matching the check list and the PPM recording system.	Check History files
Medical Equipment Management	EM010	All service records, test results, calibration and adjustment and QA/QC records are documented and maintained for each piece of equipment.	Check History files

Facility and Equipment Management	EM011	Staff (in-house, contracted, supplier) responsible for maintenance of medical equipment are qualified and trained on their repairing and testing.	Check History files, training forms and technical knowledge
Facility and Equipment Management	EM012	An ongoing end-user training program/plan is developed and implemented by the biomedical engineering department on operation, safety and user level maintenance of medical equipment.	Check Training schedule and policy (check if it is linked with incidents, risk and KPI)
Medical Equipment Management	EM013	The facility has test tools for the range of medical devices maintained in house. The facility ascertains that equipment under warranty, outsourced and loaned are serviced using appropriate test tools.	Check Inventory list, calibration report, installation reports, service contract
Medical Equipment Management	EM014	All test tools used for maintenance and testing of medical devices are calibrated through an organization certified by a component national or international body (DAC, ESMA etc.)	Check Inventory list, calibration report and service contract if applicable
Medical Equipment Management	EM015	The facility has developed a product/ equipment recall system, which is implemented through active monitoring of recalls, and hazard notices.	Check policy, Monthly reports and access to notices

Medical Equipment Management	EM016	Incidents involving medical devices are reported, investigated and mitigation mechanisms are devised based on the findings.	Check policy, Incidents Reports and Log
Medical Equipment Management	EM017	Key performance indicators (KPI) are developed and monitored for quality improvement of the medical equipment management system.	Check policy, Monthly reports and analysis and action plans