MEDICAL EQUIPMENT MANAGEMENT

GUIDELINE

Department: Quality Improvement

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GUIDELINE – Medical Equipment Management

INTRODUCTION

This guideline specifies the process to be observed within the associated guidelines regarding the management of medical equipment in a clinical environment. In addition, all relevant rules, codes, regulations instructions or other legislation, adopted by the guideline are identified.

This guideline has been developed to ensure that all Healthcare Facilites are adequately and consistently evaluated for compliance with the standards provided within this guideline.

1. PURPOSE	
1.1	To govern the management of medical equipment in healthcare facilities licensed by DHCA.
1.2	To comply with the statutory authorities and associated guidelines described herein, all healthcare facilities should have at least reliability and redundancy in the provision of essential medical equipment. Without such provisions, proprietors risk their duty of care to patient safety associated with operating health facilities.
1.3	To select and acquire safe medical equipment; reduce the risks associated with equipment failures; and ensure the function and reliability of medical equipment. These goals are consistent with the healthcare facility mission in providing quality services to all

2. SCOPE OF APPLICATION	
2.1	This guideline applies to all healthcare facilities licensed by DHCA.

3. GUIDELINE	
3.1	Healthcare facilities should have a plan for maintaining and managing medical equipment
3.2	This plan should include the management of the following: 3.2.1 Medical Equipment Management 3.2.2 Equipment Acquisition 3.2.3 Equipment Tagging 3.2.4 Breakdown Maintenance 3.2.5 Preventative Maintenance 3.2.6 Medical Device Recall 3.2.7 Safety Testing 3.2.8 Management of Compressed Gas
3.3	Healthcare facilities are responsible for managing the Medical Equipment Management Program.
3.4	The facility is responsible for orienting new staff members to the capabilities, limitations, special applications of equipment, basic operating and safety procedures, emergency procedures if failure

	occurs, maintenance responsibilities, and the reporting procedures for equipment problems, failures and user errors.
3.5	**Medical Equipment Plan**
3.5.1	The scope of the Medical Equipment Management Plan defines the processes which healthcare facilities adopt for the safe and proper use of medical equipment used in the patient care setting.
3.5.2	The plan should be designed to protect patients, staff, and equipment, by promoting the safe and reliable operation of medical equipment. The primary objectives of the plan are: 3.5.2.1 Ensuring compliance with applicable regulatory requirements, standards and guidelines, and manufacturer recommendations. 3.5.2.2 Selecting and acquiring safe medical equipment. 3.5.2.3 Carrying out an effective preventive maintenance program. 3.5.2.4 Providing user training and post training evaluations. 3.5.2.5 Monitoring hazard notices and recalls and providing related information to equipment users.
3.5.3	The Selection and Acquisition of Medical Equipment: A needs assessment will be completed by each facility for replacement or new equipment to determine if the equipment meets appropriate space requirements, load and phase requirements, minimum safety standards of 3 wire AC line cord with grade 3 pin plugs, appropriate warranties and manufacturer's reliability prior to purchase. If the equipment does not meet the above specifications and any additional facility requirements, it should not be ordered and an alternative piece of equipment should be selected.
3.5.4	Inventory Management: 3.5.4.1 All Medical Equipment should be registered and documented properly and an inventory of all the equipment will be updated every time a new piece of equipment arrives. 3.5.4.2 All new equipment should be inventoried and inspected prior to use. 3.5.4.3 Equipment that fails electrical safety tests should not be approved for use until the deficiencies have been corrected. 3.5.4.4 There should be a current inventory of all equipment included in the equipment management program. 3.5.4.5 An up-to-date inventory with all “In Use” medical equipment only should be maintained in the clinic 3.5.4.6 No medical equipment which is not in use, or not maintained should be stored in the clinic

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3.5.5	Hazards Notices & Recalls: 3.5.5.1 All electrical patient care equipment should be evaluated based on function and physical risks associated with patient use. 3.5.5.2 All product safety alerts, hazard notices, and/ or recalls will be directed to the facility management. 3.5.5.3 In the event equipment must be removed from service, the equipment should be replaced with a safe and effective substitute. 3.5.5.4 The facility should tag and remove any defective equipment from use due to any recall notices until it can be rendered safe.
3.5.6	Performance Evaluation: Healthcare facilities should keep records of equipment performance and identify quality indicators that cove preventive & breakdown maintenance, incidents etc.
3.6	**Medical Equipment Acquisition**
3.6.1	All medical equipment and devices, including the replacement or purchase of new equipment, should be based on a needs assessment completed by the facility. For purchasing, importing, trading of medical equipment's in UAE and their registration please follow Ministry of Health and Prevention (MOHAP) guidelines and regulation. For more information visit https://www.mohap.gov.ae/
3.6.2	Each facility should have a needs assessment program regarding medical equipment. This program should be evaluated by the facility management considering patient and staff safety, infection control, clinical effectiveness, compliance with manufacturer's specification and codes standard, compatibility with existing equipment/system, ergonomic & operational factors and maintenance & operating cost throughout equipment's life.
3.6.2.1	The facility should review the equipment prior to purchase to ensure it meets a minimum of the following requirements: 3.6.2.1.1 Appropriate Space requirement 3.6.2.1.2 Load & phase requirement 3.6.2.1.3 Underwriter laboratory requirement 3.6.2.1.4 Minimum safety standards of 3 wire AC line cord with Grade 3 plug. 3.6.2.1.5 Appropriate warranties and manufacturer's reliability.
3.6.2.2	The clinical staff should receive specific orientation and training prior to the use of any device or piece of equipment. All training should be documented and kept on record. These trainings should be on-going to maintain knowledge and skills.

3.6.2.3	A copy of the manufacturer's operating manuals and instructions must be made accessible to staff to review at the location of the equipment.
3.7	**Medical Equipment Tagging system**
3.7.1	The healthcare facility should have a policy stated that no biomedical equipment within the facility is to be used unless it has a valid *Bio-Medical Engineering* label attached. This applies to all new purchases as well.
3.7.2	The facility should follow the below general principle: 3.7.2.1 No biomedical equipment within the facility is to be used unless it has a label attached. This applies to all new purchases as well. 3.7.2.2 All medical equipment that is included in the equipment inventory will be permanently tagged with a Control Number Tag.
3.8	**Breakdown Maintenance**
3.8.1	A process should be in place within each facility to ensure that immediate and necessary action is taken to rectify equipment issues, including documentation of the identification of the issue, as well as notification and rectification processes.
3.8.2	Healthcare facilities should have a policy to cover the management of breakdown maintenance of all biomedical equipment.
3.9	**Preventive Maintenance**
3.9.1	Healthcare facilities should have a policy to cover the preventive maintenance of a biomedical equipment.
3.9.2	Facilities are to ensure that preventive maintenance has been carried out as per manufacturer suggested schedule to reduce the breakdown and to ensure that the unit is performing as per manufacturer specification and meeting necessary safety requirements.
3.10	**Medical Device Recall**
3.10.1	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.
3.10.2	The facility should follow manufacturer specifications and procedures regarding any medical device recalls including the maintenance of all associated documentation related to recall notices.
3.10.3	The facility's process should follow the below steps to manage a medical device recall: 3.10.3.1 Verify the availability of the equipment in the facility. 3.10.3.2 Equipment recall record is to be prepared and updated properly.

	3.10.3.3 Equipment is to be removed from the use and informed to the supplier/manufacturer. 3.10.3.4 Reports are to be documented and kept in the equipment file. 3.10.3.5 Necessary repair/replacement is to be done and equipment returned to the user department.
3.11	**Electrical Safety Testing of Medical Equipment**
3.11.1	Facilities are to ensure that all medical equipment is checked for their performance as per manufacturer's specifications, schedule, safety and statutory requirements. Electrical Safety Testing of Medical Equipment should be performed annually, and a detailed report and record of the electrical safety test performed on the equipment's must be maintained for quality assessment surveys.
3.11.2	The facility should have policy which covers the electrical safety test of all equipment based on IEC 60601 Standard policy. (IEC60601 is the series of technical standards for the safety and effectiveness of medical electrical equipment published by the International Electrotechnical Commission).
3.12	**Handling of Compressed Gas**
3.12.1	The facility should have a policy concerning the safe handling and use of compressed gas & cylinders. Compressed gases are unique in that pose both physical and chemical hazards. The gases contained in these cylinders vary in chemical properties, ranging from inert and harmless to toxic and explosives. The high pressure of the gases constitutes a serious hazard in the event that the cylinders sustain physical damage and /or are exposed to high temperature.
3.12.2	The facility should have a policy to ensure safety in the storage, use and transport of compressed gas. The following should be considered when dealing with compressed gases: 3.12.2.1 All compressed gas cylinders received should be identified by the color and tagged with the name of its content. 3.12.2.2 Empty cylinders should be stored apart from full cylinders while awaiting to be removed. 3.12.2.3 Gas cylinders should be handled by only experience and properly trained and authorized personnel. 3.12.2.4 The user responsible for the cylinder and its installation should check the identity of the gas before use. If the cylinder content is not identified, if the test date is past due date, or if the cylinder Is in any way damaged, the supplier should be called to collect and replace the cylinder. 3.12.2.5 Cylinders should not expose to excessive dampness, or to corrosive chemicals or fumes. 3.12.2.6 Cylinders should be securely capped and then fastened to prevent them from falling

	or being knocked over. Suitable racks, straps, chains or stands or other devices should be required to support cylinders. 3.12.2.7 Cylinders should not be exposed to temperature extremes nor stored in the vicinity of combustible substances. 3.12.2.8 MRI compatible cylinders should be placed in the MRI area and no other cylinder should be around the area. 3.12.2.9 Never use a cylinder without a regulator. Always use the correct pressure regulator. After attaching the regulator and before the cylinder is opened, check the adjusting screw of the regulator to see that it is released. Never permit the gas to enter the regulator suddenly. 3.12.2.10 Never strike an electric arc on a cylinder. Never use a damaged cylinder. Never force a cap or regulator. 3.12.2.11 Avoid dropping and striking cylinders together. Avoid dragging, sliding or rolling cylinders and always use trolleys for transportation. A sign should be displayed on doors stating "No Smoking". Storage rooms should be dry, cool, and well ventilated. 3.12.2.12 Limited cylinders should be stored in patient care areas. When small-sized cylinders are in use; they should be attached to cylinder stand. An individual cylinder placed in patient room for immediate use by a patient should not be required to be stored in an enclosure but in cylinder trolley with lock. Cylinders should not be chained to portable or movable apparatus. Cylinders should not be stored near elevators, or in corridors. Cylinders should be protected from tampering by unauthorized persons and will be kept capped at all times. Free standing cylinders should be properly chained or supported in a proper cylinder stand or cart. 3.12.2.13 In the event of the leak or suspected leak of a toxic or flammable gas, evacuate from the building or the area. Activate the fire alarm by pulling the nearest break glass unit (B.G.U) and immediately call health &safety department to initiate the proper code. The event is to be reported to DHCR HSE Department in addition to Security for oversight and investigation (where appropriate). 3.12.2.14 "No Smoking" signs should be placed near flammable gas cylinders. Fire-suppression equipment using carbon dioxide or dry chemicals should be available. 3.12.2.15 "No Smoking" signs should be placed near flammable gas cylinders. Fire-suppression equipment using carbon dioxide or dry chemicals should be available.

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3 DEFINITIONS	
3.1	References to Licensed Healthcare Professionals means those Healthcare Professionals licensed or certified under the Healthcare Professionals Regulations.
3.2	"Accreditation body" or "body" means an entity that has been approved by FDA to accredit mammography facilities.
3.3	"Commissioning Tests" means all commissioning test described in this guideline below, commissioning tests recommended by the manufacturer of any part of the Equipment.
3.4	"DHCR" means Dubai Healthcare Authority, its nominees, successors or permitted assigns or such other division or divisions within DHCR authorized to process, administer and/or oversee the functions of DHCR as described in these Regulations.
3.5	"DHCC" means the Dubai Healthcare City free zone established by Dubai Law No. 9 of 2003.
3.6	"DHCA" means the Dubai Healthcare City Authority established under Article (4) of the Law No.9 of 2011.
3.7	"Director" means a person on the governing body of an Entity, by whatever name called, and any person in accordance with whose directions or instructions (but not advice given in a professional capacity) the Directors of an Entity are accustomed to act.
3.8	"FDA" means Food and Drug Administration" is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
3.9	"Healthcare Operator" (HCO) means a hospital, clinic, laboratory, pharmacy or other Entity providing healthcare that would be subject to the Healthcare Operators Regulations and the applicable Rules there under if it intends to engage in one or more Clinical Activities in the DHCC but that has not received a Clinical Operating License pursuant to those Regulations and the applicable Rules.
3.10	"Healthcare Professional" means a natural person engaged in a healthcare profession who would be subject to the Healthcare Professionals Regulations and the applicable Rules there under if he intends to engage in Professional Practice in the DHCC but who is not licensed or certified pursuant to those Regulations and the applicable.
3.11	"Hospital" means a hospital licensed by DHCR.
3.12	"Licensed Healthcare Operator" or "Licensee" means a Healthcare Operator holding a Clinical Operating License duly issued by the Licensing department in accordance with these Regulations and the applicable Rules.
3.13	"Manuals" means all manuals to be prepared by Project Company pursuant to this document including all policy and procedure manuals.
3.14	"Maintenance" means the performance of those adjustments or procedures by the user to keep equipment in its intended operating condition. Maintenance does not include operation or service as defined in this section.

3.15	"Manager" means the person who performs those functions with respect to a Healthcare Operator that are described for a Manager in the DHCC Healthcare Operator Regulations.
3.16	"Medical Equipment" means machinery designed to aid in the diagnosis and treatments of medical problems with rigorous safety standards.
3.17	"Operation" means the performance of tasks required for the equipment to perform its intended functions. It does not include maintenance or service tasks as defined in this section.
3.18	"Operator" is an individual, group of individuals, partnership, firm, corporation, or association conducting the business or activities carried on within a MRI installation.
3.19	"Person" means any individual, corporation, limited liability company, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof and any legal successor, representative, agent or agency of the foregoing.
3.20	"Personal Protective Equipment" means specialized clothing or equipment worn by employees for protection against health and safety hazards. Personal protective equipment is designed to protect many parts of the body, i.e., eyes, head, face, hands, feet, and ears.
3.21	"Service" means the performance of adjustments, repairs or procedures required to return equipment to its intended state. These adjustments and procedures usually require specialized training and/or tools. Service does not include operation or maintenance as defined in this section.
3.22	"Phantom image" means a radiographic image of phantom.

4 APPENDICES	
4.1	Appendix 1- SOP for Medical Gas Outlets

5 REFERENCE	
5.1	Health Technical Memoranda (Institute of Electrical and Electronics Engineers (IEEE)
5.2	Medical Equipment Management Manual by (AAMI)
5.3	International Electro Technical Commission (IEC)

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Appendix 1

SOP for Medical Gas Outlets

This is inclusive of Medical Compressed Air, Nitrogen, Nitrous oxide, Oxygen, Carbon Dioxide and other gases if piped.

1. Examine the condition of the outlet.

2. Check that each outlet is properly labeled with the name of the dispensed gas and that its cover plate is securely fastened. Ensure that color coding is consistent for the standards for the gas supplied to each outlet (e. g. green for oxygen, yellow for medical compressed air)

3. Make sure that the adapter specific for the gas dispensed locks securely into the outlet, that the outlet does not leak with the adapter installed, that the adapter is easily removed, and that the valve closes when the adapter is removed. Listen for leaks before and after inserting adapters.

4. Attach the oxygen analyzer, a pressure measuring device and a flow meter or pneumatic analyzer to the outlet; measure and record the flow and pressure of that flow on part 8 of the Medical Gas/Vacuum inspection form, NFPA 99 requires that the piping systems be able to deliver flows at the pressures as listed below.

Recommended Pressures and Flows

Medical Gas	Pressure in psig	Flow l/min
Oxygen	50-55	> or = 100
Nitrous Oxide	50-55	> or = 100
Medical Air	50-55	> or = 100
Carbon Dioxide	50-55	> or = 100
Nitrogen	> or = 160	> or = 145

5. Open the flow control valve until a flow of 100 l/min is seen. Pressure at the outlet should not dip below 50 psig for all gases except Nitrogen, which should not drop below 160 psig at a flow of at least 145 l/min. However, if the pressure drops to below 80% of the listed values in the older systems or below the required values in the new systems, corrective action is required, Unacceptable pressure or flow may indicate a blockage in either the distribution piping or the outlet check valves.

6. If the above issues are not resolved, the outlet may have to be replaced or depending on the severity of the restriction, a portion of the system may have to be modified. Please also consider whether simultaneous use of multiple outlets will further degrade performance.

7. In some hospitals, hoses extend from ceiling connectors to outlets that are suspended at a lower more accessible height. Although the ceiling connector and suspended outlets may have proper labels and unique fittings for each gas to prevent incorrect connections, the end connections of the hoses and the pipelines to the gas fittings may be identical. Thus it may be possible to attach an outlet or connector to the wring hose. If you have such an installation, please make sure that the ceiling connector and outlet linked by a given hose have the same gas label. The problem may arise if your use extension hoses to connect equipment to a wall or ceiling outlet.

8. Gas hoses should have appropriate connectors for attachment to equipment. Avoid using special adaptors for connecting hoses to minimize problems such as gas leaks at the connectors. Color coded hoses are recommended for this application to reduce risk or misconnection.