الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Ref. 2022-MDGUD-Q1-004

Medical Device Management Guideline

National Health Regulatory Authority (NHRA)

Kingdom Of Bahrain

Feb 2022

Version 1.3

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Introduction

Medical Devices provides many valuable services to support and enhance patient care, however there are several risks limiting its use. While appreciating the benefits that medical devices can provide, healthcare providers and staff also should remain aware of potential safety issues.

Medical Device management strategies can help healthcare personnel to proactively manage medical devices. When device is properly selected, evaluated, used, and maintained, it is more likely to work properly, which can help avoid delays in care, reduce the risk of patient and staff injuries, and optimize patient outcomes.

With reference to Decision (48), Article (2) "This decision aims to protect public health in the Kingdom by implementing procedures and requirements that ensure the protection of the health and safety of patients, the public, and users of the medical device and product, in order to ensure the safety of medical devices and products during the stages of their manufacture, marketing and use by taking measures and determining the responsibilities necessary to ensure the conformity of the medical devices and products offered in the Kingdom for all standards and requirements of this decision**"**

and Article (4) "The Authority monitors the use of medical devices and products in the Kingdom and takes the necessary and appropriate measures to ensure the safety of their use and maintenance in order to ensure the safety of patients, the public and users of the medical device and product, and the authority shall notify patients or users once it is confirmed that the medical device or product is/are not complying with the of the provisions of this decision.**"**

This guideline is intended to guide all Healthcare facilities licensed by NHRA to manage Medical Devices during its life cycle including purchasing, installing, maintenance, calibration and decommissioning.

Purchasing

The selection of medical devices should be based on adequate decisions according to the requirements set by the end-user. The biomedical department in the healthcare facility is responsible to understand the required specifications of the medical device and contact the procurement department internally with full details of the required medical device including features and technical requirements.

If the facility don't have a bio-medical department in place due to the small amount of medical devices in the facility, the procurement department should follow the same selection parameters. The selection will be based on the compliance range with the technical details and it should not be limited to price.

Medical Device Selection Parameters

It is the responsibility of the biomedical department to set the technical parameters that match with the requirements set by the end-user. The selection of the medical device should be based on the below parameters:

1. The purchased medical device should have a **validated Quality Assurance Certificate** to ensure good manufacturing as per international standards and has no recalls or adverse events.

2. The medical device should be purchased from a well-known reputable NHRA registered authorized representative to ensure:
   - Patient safety and public health.
   - Repairing, Preventive maintenance, post market surveillance and availability of spare parts.
   - The purchased devices are not substandard, counterfeit, used, or have passed their expiry dates.
   - Ensure all purchased medical devices are manufactured as per international standards approved and cleared as per NHRA regulations.

3. High-risk purchased medical devices must be quoted with continues end-user training by certified trainer.

4. **Ensure the devices powered by electrical mains are compatible with the electricity supply in Bahrain. (3 pin adapter should be included) based on GSO recognized standards. Click here**

5. Low Running cost; Cost of repair or spare parts should not overweigh (exceed) certain percentage of the medical device price.
6. Make sure the medical device has the features and functions to do the required work and cost significantly less.
7. Pre-installation requirements complies with the designated location in the healthcare facility.
8. Medical devices should be well-designed, safe and usable to avoid the risk of injuries and misuse and user-friendly.
9. Warranty of medical device should be provided by the supplier to avoid device failure and ensure Implementation of device upgrades and modifications, if needed.
10. End-user in house training by qualified trainer.

11. Purchased medical devices should be compatible, integratable with existing devices or system and user-friendly.

12. Its technical features should be in correspondence to end-user requirements.

Once the selection of certain medical device is finalized, **NHRA approval for use** should be granted before purchasing to ensure the compatibility of the purchased device with the specialization of healthcare facility. Please refer to **NHRA Approval for Use guideline.**

Commissioning and Evaluation

Once the medical device is delivered and installed by a qualified engineer under the supervision of biomedical engineering department in the healthcare facility, it is necessary to check:

- Physical inspection to ensure that the device is free of damage and that there has been no damage during transportation.
- Enquire the supplier about the maintenance arrangement and after sale service, including warranty period, contract terms, technical manual, maintenance plan and training.
- Labeling the device with next PPM after filling the commission form.
- Shelf life duration.

At the time of receiving the medical device, a form (Commissioning Form) should be filled with full device's details and description, testing and evaluation results, signed by healthcare facility and supplier.

The healthcare facility should keep records of the local purchase order (LPOs) and the delivery inspection report, the individual device or batch identifier and any safety or functional tests.

Documentation

It is an essential step in order to build a data base (Management System) including full details about all the medical devices owned by the facility, the most common information to be included are:

- Unique identification number of each medical device linked to GMDN.
- Medical device name.
- The manufacturer details.
- Model number and serial number.
- Description of the medical device similar to GMDN code.
- Location of the device (for devices generally kept in a fixed location).
- Medical device preventive maintenance (device name, model, calibration date…).
- Staff training record and plan as per manufacturer recommendation.

Recording the Medical devices or batch details on a validated and secure database means it can subsequently be traced for maintenance or for a manufacturer's recall/field correction, if necessary.

Education and Training

Before the medical device is formally introduced into clinical use, training of users on safety aspects and usage issues is an essential step as medical device failures leading to increased risk to patients can often be linked to use errors rather than technology failures. The training should be:

- Done by certified trainer and it should be clinical training on how to use the medical device. **(Clinical training is not allowed to be done on patient unless it is approved by Clinical Trial Department in NHRA).**
- How to report a medical device that is not functioning properly, which can include visual clues like smoking, sparking, or display errors.
- How to remove the medical device from service, tag-out the device, and notify the appropriate repair service or biomedical engineering contractor for repairs.
- Train appropriate staff on how to properly setup, use, calibrate, and clean medical device.
- Document all medical device training and competency for both providers and staff in each individual's personnel file.

If a staff person has not been trained, or is not appropriately licensed/certified, he or she should not be allowed to use the medical device.

Appropriate training of engineers by the manufacturers' representatives would ensure that all these activities are carried out correctly, thus resulting in the medical device remaining safe throughout its life cycle.

- **The importance of effective instructions**

Good clear instructions for use have a crucial role in the safe and effective use of device. The supplier is responsible for providing appropriate instructions to healthcare facility, taking into account the knowledge and training of the intended user(s).

Clear responsibilities should exist for ensuring that the manufacturer's instructions are passed on to all users. The manufacturer's instructions may need to be supplemented with training.

When manufacturers update their information, healthcare facility should have a protocol for keeping track of all sets of instructions they hold or have issued to users to enable replacement of existing instructions with revised versions. Consideration should be made to updating the content of relevant training.

Maintenance

Once the medical device is put into routine clinical use, trained Bio-medical Engineers need to carry out periodic performance checks (Calibration) and preventive maintenance as per the manufacturer's recommendations and safety testing as per the national and international standard.

Preventive maintenance (PPM) refers to scheduled activities performed to extend the life of a device and prevent failure (i.e. by calibration, part replacement, lubrication, cleaning, etc.). Inspection can be conducted as a stand-alone activity and in conjunction with PM to ensure functionality; this is important as PM can be fairly invasive in that components are removed, cleaned or replaced.

Each Medical Device should be labeled with a sticker containing last and next date of calibration.

Reporting

1. **Adverse Event.**

An adverse event is an unexpected consequence associated with the use of a medical device or with an implanted medical device. Such events may be indicative of a quality or safety issue that needs to be investigated and reported to **NHRA.**

All categories of staff can make a report using this form. These are examples of staff that can make a report:

- Staff involves in the incident.
- Staff who witness the incident.
- Staff who detect an "error" or "miss use".

All adverse incidents, safety or quality issues regarding medical devices that caused or might cause one or all of the following should be reported:

- Death
- Serious injury
- Need for hospitalization, surgical or medical intervention
- Uncertainty of results

For more information about how to report an adverse event to NHRA, please refer to "Medical Devices Reporting Guideline" on NHRA website.

2. Recall

Once the heath care facility receives a Field Safety Notice from the supplier concerning affected medical device to be checked, adjusted, fixed or removed, an acknowledgment should be provided to the supplier stating that the corrective action has been implemented to be submitted to NHRA as per the time frame set in NHRA Guidelines.

For more information about how to report FSN to NHRA, please refer to "Medical Devices Field Safety Notice Guideline" on NHRA website.

Decommission and disposal on Medical Devices

This Guideline provides guidance on the procedure to be followed to decommission and dispose medical devices at the end of life cycle in healthcare facilities to ensure proper and safe medical device management.

Before going into deep details, there are some definitions should be recognized to understand the process:

- **Condemnation:** the process of conducting an evaluation to determine whether or not the medical device should be removed from service. This includes clinical and technical testing of the device to assess whether or not the medical device is functioning under manufacturer standards and parameters.

- **Decommission:** the process of planned shut down or removal of the medical device from operation and storage in a secure and safe location until disposal.

- **Depreciation:** an accounting method of allocating the cost of the medical device over its useful life.

- **Disposal:** the process to remove medical device from accounting records and to take action to remove it from the healthcare facility. This may include: donation, sale or destruction.

- **Life span / Shelf life:** the number of years expected for the medical device to remain functional and in service and **this being determined by the manufacturer.**

Decommissioning

It is when the medical device has to be removed from service, this done if one of the following conditions exits:

- **Unserviceable:** damaged beyond economical repair, damaged by contamination, absence of manufacturer/supplier technical support, or non-availability of spare parts or consumables.
- **Obsolete:** passed its life span, clinically or technically obsolete, or changes in local policy for device use.
- **Unsafe:** doesn't comply with safety requirements from the manufacturer.
- **Ineffective:** unable to provide accurate results.
- **Costly:** not economical to use
- **Surplus:** without a useful purpose for healthcare facility, but maybe transferred or donated.

Decommissioning includes (notification, removal from service, informing NHRA):

A. Notification:

When a user or service engineer or technician identifies that a medical device is no longer safe or not functioning well, a notification form should be sent to healthcare facility management to inspect, evaluate, and take necessary action to remove the medical device from service.

B. Removal from Service:

Removal from service includes the following steps:

- **Communicate to users:** the engineer/technician is responsible for informing the users that the medical device will be removed from service.
- **Erase confidential patient information:** the user is responsible for erasing all confidential patient information from the medical device if needed.
- **Remove Software:** the engineer/technician is responsible for removing software from medical device to avoid breaching software licensing rules, if needed.
- **Safely remove from service:** the engineer/technician is responsible for disconnecting electrical and water connections and any other accessories from device.
- **Transfer to safe and secure storage:** the engineer/technician is responsible for ensuring that the medical device is appropriately packaged, labelled and transferred to storage. The storage must be secured, organized, and environmentally safe (dry and well-ventilated).
- **Documentation:** all details of the removed medical device should be documented including (device name, model, quantity, date of removal...).

C. Informing NHRA

After implementing all the above steps, a report should be provided to NHRA including all the details of the unwanted medical device and the necessary action taken.

Disposing

Disposal of Medical Device should be undertaken at minimum financial cost and minimum risk to public health and the environment. The healthcare facility is responsible to decide an appropriate disposal method either by:

A. **Destruction:** this process is done properly according to manufacturer instructions and as per international standards by Bahrain Medical waste. And an evidence should be submitted to **NHRA**.

B. **Return to the manufacturer:** healthcare facility is responsible for returning unfit and unusable medical device to the manufacturer for safe disposal.

   This decision is taken when the disposal method cannot be done properly in the Kingdom of Bahrain. An airway bill should be submitted to **NHRA** as an evidence for returning.

The Financial expenses of medical devices disposal will be covered by device owner.

Special Circumstances

Hazardous or potentially hazardous medical device will require additional actions to be taken for removal from service and storage to ensure the individuals don't expose to potential hazards. For example:

1. Heavy metals, such as Mercury.
2. Oil wastes.
3. Radioactive waste.
4. Electronic waste.