Disposal of Medical Devices Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

Sept 2021

Ver 1.0

E-Mail: medical_devices@nhra.bh **Website:** www.nhra.bh **Tel.:** 17113299 **/P.O. Box:** 11464

Contents

1. Introduction

Medical devices are essential components of the health care system and are crucial in the prevention, diagnosis and treatment of disease and in rehabilitation. Health technology is an indispensable component of effective health care. Of these technologies, medical devices provide the foundation for prevention, diagnosis and treatment of illness and disease and rehabilitation.

The process of medical devices disposal rest with **NHRA** in corporation with the **Supreme Council of Environment (SCE)** which will foresee that the disposal of medical devices is done as per the guidelines, laws and regulations of the Kingdom of Bahrain to ensure the safety of public health and the environment.

With reference to **Decision (48) 2020, Article (7)** The device and medical product must be used in healthcare facilities licensed by the Authority, and it is not permissible to manufacture or introduce any medical device and product to the Kingdom or put it in its markets or use it, except after registering with the Authority and obtaining written permission to market from Authority, and it is not permissible to transfer, resell, dispose of or export any medical device and product without the written approval of the Authority.

And Article (13) all facilities must dispose of medical devices and products in accordance with the requirements and medical devices and products may not be used beyond their shelf life.

The objective of this Guideline on Disposing of Medical Devices Management is to guide all healthcare facilities and authorized representatives on how to dispose of used, expired, obsolete and disposing of medical devices safely without harmful consequences to the public health and the environment.

Improper disposal of medical devices could lead the staff involved (patients, employees, healthcare providers etc.) to risk of exposure of hazardous medical waste including:

- Trauma
- Infection
- Chemical
- Fire or explosion
- Radioactivity
- Environmental pollution and Contamination

2. Definitions

Medical device: means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury.
- 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 by means of in vitro examination of specimens derived from the human body.

And does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Decommissioning: which is removal of medical devices from their originally intended use in a health care facility to an alternative use or disposal.

The two main pathways for decommissioning a medical device and determining its final disposition after decontamination are:

1. Permanent elimination (e.g. recycling, disposal or incineration).
2. Re-use (i.e. donated, sold, refurbished, reprocessed, traded-in or re-assigned internally to another location)

Sterilization: is a validated process to render an object free from viable microorganisms, including viruses and bacterial spores.

3. General Rules

- Decommissioning and disposal of medical devices should be done as per manufacturer's instructions.
- Ensure compliance with the national and international regulations and guidelines relating to the specific medical device disposal.
- Ensure that personal health information is removed or deleted from the device. Healthcare Facility (HCF) should contact the manufacturer or supplier on how to ensure that all personal health information and other patient or HCF related data is removed or deleted from the equipment.
- Some devices might be contaminated with biological, chemical or other hazardous materials. Disposal of such devices must comply with the environmental laws that govern the discharge of contaminants into the natural environment.
- Some devices can be considered as workplace hazards. Disposal of such devices must comply with the occupational health and safety laws that govern workplace safety.
- Some devices might have radioactive components or can generate radioactivity, disposal of such devices must comply with the local and international regulations

4. Labeling

The disposing of decommissioned medical devices should be labeled with a suitable size of a stable, water-resistant ink before transporting to the temporary storage site within the health facility or treatment unit.

These labels should at minimum include the following information:

1. Name of the healthcare facility / Authorized Representative.
2. Type / purpose of medical equipment.
3. Date of decommissioning of medical device.
4. expiry date of the medical device.

5. Storage of Disposing of Medical Devices

A storage location for disposing of medical equipment and devices should be designated inside the healthcare facility.

- **Recommendation for medical equipment storage:**

- The storage area should have an impermeable, hard-standing floor with good drainage. It should be easy to clean and disinfect.
- The storage area should have easy access for staff in charge of handling the waste and disposing of equipment.
- The storage area needs to have a proper access system to avoid entry by unauthorized persons.
- In case of any equipment with radiation, the international logo of radioactive waste equipment should be inserted /affixed on the disposing of equipment.

6. Medical Devices Disposal

It is the responsibility of the facility to ensure that there is a planned program for the replacement and disposing of unused, used and disposing of medical devices. The main reasons of disposing of this equipment are that they may be but not limited to:

- Damaged.
- Inaccurate.
- Defected (Recalled).
- Clinically or technically obsolete.
- Spare parts of the machine/ equipment no longer available.
- Absence of manufacturer/supplier support.
- Closure of manufacturer facility.
- Completed the life of the medical device.
- Availability of new equipment/ technologies and / or technological obsolescence.

Disposing of medical devices is done as per manufacturer recommendation by either:

- Return back to the manufacturer. (provide an Airway bill).
- Destruction in Bahrain through licensed medical waste companies.
- Donation.

7. Submission and Process

In case of destruction in Bahrain, applicant should provide the following required documents by email at medical_devices@nhra.bh :

1. Medical devices destruction supervision form.
2. In case of more than one medical device, a list of medical devices to be destructed with same required information in section (2) in the form.
3. Valid CR.
4. Supreme Council of Environment Approval in case of medical devices containing (mercury, radioactive materials, hazardous chemicals…).
5. Official letter issued by the manufacturer recommending destruction in Bahrain.(if needed).
6. When completing the destruction, invoice / certificate of destruction should be provided to NHRA.

After submitting the required documents, applicant will receive a NTP ***(please refer to Fees guideline)*** and after ensuring payment is done, destruction request will be reviewed.

If approved, Applicant will schedule an appointment with the destruction company and inform NHRA 3 days before to arrange for attending the destruction to ensure compliance with submitted documents.

For medical devices requiring SCE approval, SCE should be informed and involved in the destruction process as per their regulation.

8. Annex

- **Medical Devices Destruction Supervision Form.**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Medical%20Devices%20Destruction%20Form%209%20JUNE.pdf