الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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Medical Devices Reporting Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Contents

1. Introduction

With reference to **Decision (48) 2020, Article (16) "**The Chief Executive Officer of the Authority issues the requirements, controls, procedures, standards and decisions necessary to implement the provisions of this decision**"**

This guideline is intended to guide and encourage all healthcare facilities, importers, patients and professionals to the importance of reporting problems associated with medical devices. It focuses on the area of adverse events and complaints, defining what are they and outlines the different roles and responsibilities, which users, distributors and manufacturers have in the handling of such situations.

The aim of medical devices reporting is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of problem being repeated in different places at different times.

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:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease,
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
3. Investigation, replacement, modification, or support of the anatomy or of a physiological process,
4. Supporting or sustaining life,
5. Control of conception,
6. Disinfection of medical devices,
7. Providing information by means of in vitro examination of specimens derived from the human body;
8. 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.

- **An adverse event:** is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons.

- **Serious injury**
  An injury which meets any of the criteria:

  - Life threatening illness or injury has occurred or is likely to have occurred.
  - Permanent impairment of a body function or permanent damage to a body structure.
  - An unexpected condition requiring medical or surgical intervention to prevent permanent damage of a body function or structure.

- **Minor injury**
  An injury which does not meet the criteria of serious as defined above occurred or is likely to have occurred.

- **Malfunction**

means the failure of a **device** to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the **device**.

3. Adverse events Reporting types

Anyone can report an adverse event associated with a medical device to NHRA. Patients, users, healthcare professionals and suppliers are all encouraged to report an adverse event has occurred and there is a concern about the safety of the device or its use.

- **Reportable Adverse Events:**

Adverse event caused by any malfunction or deterioration in the characteristics and/or performance of a medical device, as well as any inadequacy in the labelling or the instructions for use should be reported to NHRA to take the necessary action, for example:

- A patient, user, or professional is injured (Serious / Minor injury) as a result of a medical device failure or its misuse.
- A patient's treatment is interrupted or compromised by a medical device failure.
- A misdiagnosis due to a medical device failure leads to inappropriate treatment.
- A patient's health deteriorates due to medical device failure.
- User error (or "use error") which means a device-related error or mistake made by the person using the device. The error could be the main cause of an adverse event or just a contributing factor. Such errors often reflect problems with device labeling, the user interface, or other aspects of device design.

Also, may include design; poor user instructions or training; inappropriate modifications; inadequate maintenance; and unsuitable storage and use conditions.

- **Non-Reportable Adverse Events:**

The following events are **not** considered to be reportable events and need not be reported to NHRA. For example:

- Deficiency of a new device found by the user prior to its use. The deficiency being one that would always be detected by the user, where no injury has occurred, and it is not likely that a serious injury could occur due to the deficiency.
- Adverse event caused by patient conditions, where the root cause of the event is due to a patient condition.
- Service life or shelf life of the medical device. When the only cause for the adverse event was that the device exceeded its service life or shelf life as specified by the manufacturer and the failure mode is not unusual.
- Malfunction protection operated correctly (i.e. fail-safe). Adverse events which did not lead to serious injury or death, because a design feature protected against a malfunction becoming a hazard.
- Adverse events described in a recall, recall for product correction or hazard alert.
- Issues arising due improper use or maintenance of the device, or due to damage to the device.
- Expected and predictable events, which are fully described in the instructions for use.

4. NHRA Process

Adverse events and Complaints are being reported to NHRA by submitting **"Medical Devices Reporting form"** **(Annex 1)**, then being reviewed, evaluated and starting to investigate the relationship between the device and the problem may be carried out.

NHRA should ensure that both manufacturer and its authorized representative in Kingdom of Bahrain are immediately and fully informed of the **adverse event/Complaint**.

As part of these reviews further information may be requested from the reporter and/or the device supplier. If necessary, NHRA may also contact international regulatory authorities to check whether they have received similar reports about the device and may issue an alert or Field safety notice.

The manufacturer should investigate the causes of medical device problem and recommend a corrective action plan which should be implemented by its authorized representative in Kingdom of Bahrain.

NHRA ensure that the corrective action is implemented and ensure its effectiveness to prevent such an event from occurring again.

5. Adverse Event Roles and Responsibilities

All users of medical devices should be aware of their responsibilities with regard to adverse event reporting.

- **Roles of the Reporter:**

Staff involved in any adverse event associated with a medical device should be aware of the procedures that they need to follow:

- All staff understand what is an adverse event is and what they should do on discovery of it.
- All adverse events are promptly acted upon.
- The manufacturer / distributor is promptly informed of the adverse event.
- Appropriate local action is taken to ensure the safety of patient, user and other person that was involved in the adverse event.
- When it has been identified that the adverse event is one that needs to be reported to NHRA, then it must be promptly informed by submitting "**Medical Devices Reporting form"** including all details and information related to it.
- All details relating to adverse event are recorded accurately; including date, time, and the medical device name, model, serial / lot number.
- The devices involved in the adverse event should be kept in quarantine, where practicable, until all involved parties, including NHRA, have been consulted and the investigation is completed.

- **Roles of Authorized Representative:**

All authorized representatives, distributers and importers of medical devices should be aware of how to handle adverse event that are reported to them.

The authorized representatives and the manufacturer should have an agreed practice outlining:

- How the investigation or evaluation of adverse event, if appropriate, should be conducted by the distributor on behalf of the manufacturer.
- How and what information should be recorded.
- How the different parties should be advised of the adverse event, including NHRA.
- What testing / evaluation needs to be conducted and where.

- **Roles of the manufacturer:**
- The manufacturer must ensure that all adverse events are examined and investigated in a timely and appropriate manner
- The manufacturer must ensure that he establishes an effective communication system with all parties involved, the user, the distributor and NHRA.
- The manufacturer must ensure that his distributor knows what to do on the receipt of an adverse event report and understands his role in the investigation process.
- The manufacturer must ensure that he carries out a detailed investigation.
- The manufacturer must ensure that he informs users of any associated risks with their products. He must organize and coordinate any identified field safety corrective action in a timely manner. He must organize and coordinate the device recall if it is identified as necessary.
- In carrying out the above, the manufacturer must ensure that his distributor knows his role in the completion of corrective actions and recalls.

6. Reporting Time Frame

According to the severity of the adverse event, NHRA should be informed during the time frame set below:

Reporter	Type of problem	Report to whom	Time frame
Manufacturer	Death / Serious injury	NHRA	10 working days.
	Other Problems not associated with high risk or injury.	NHRA	30 working days.
AR / Supplier	Death / Serious injury	Manufacturer / NHRA	10 working days.
	Other Problems not associated with high risk or injury.	Manufacturer / NHRA	30 working days.
Healthcare Facilities	Death / Serious injury	Supplier / Manufacturer / NHRA	10 working days.
	Other Problems not associated with high risk or injury.	Supplier / Manufacturer / NHRA	30 working days.

7. Complaints

Complaints are defined as any written, electronic, or oral communication that declares insufficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device after it is released for distribution.

NHRA receives complaints directly by sending **"Complaint Form" (Annex 2)** at medical_devices@nhra.bh , or through **tawasul program** where the complaint is being

received by complaints department in NHRA and transferred to MDR Dept to review, evaluate and investigate.

NHRA perform a root cause analysis by communicating with all involved parties (patient, HCF, Supplier and manufacturer) to find out causes of the problem and ensure that the corrective action has be implemented by the concerned party to prevent the recurrence of the complaint.

8. Reporting Requirements during Pandemic

NHRA plays a critical role in protecting Kingdom of Bahrain from threats such as emerging infectious diseases, including the COVID-19 pandemic.

During a pandemic, normal adverse evenst/complaints reporting processes should be maintained to the maximum extent possible. All data should be handled using usual standard operating procedures, and regulatory and statutory requirements for medical devices reporting should be met to the maximum extent possible.

Therefore, NHRA encourages all Authorized Representatives, Healthcare facilities and users to plan for these circumstances to maintain the highest possible level of medical devices monitoring and reporting throughout the pandemic period.

9. Annex

1. Medical Devices Reporting Form.

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/MDR_Form_Medical%20Devices%20Report.pdf

2. Medical Devices Complaint Form.

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/MDR_Form_Medical%20Devices%20Complaint.pdf