الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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Medical Devices Field Safety Notice Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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

Contents

1. Definitions

Field safety notices (FSNs): are safety communications sent out by medical device manufacturers or their representatives in relation to actions that may be taken in relation to their Medical Device that is on the market.

Field Safety Corrective Action: (FSCA) is a corrective action recommended by the manufacturer to use the medical device in a safe way to reduce potential risk and protect patient's / user's health.

This may include:

- Software update
- New instruction for use.
- Spare part replacement.

Recall: it is a type of FSN where a manufacturer has to withdraw the defected medical device from the market due to a defect which cannot be resolved by a corrective action and can put patient/user under high risk.

2. Introduction

With reference to **Decision (48) 2020, Article (11) "**The Authority reviews and checks the communications received by its Medical Devices and Products reporting Center and takes the necessary measures to ensure the safety of public health, and when needed issues field safety notices to educate users of the medical device and product to the relevant patients, and also review the text and content of the alerts with the medical device and product manufacturer or authorized representative before issuing the alert." **And Article (12) "**The Authority withdraws or prohibits the use of any medical device and product when it appears that it may endanger the health or safety of patients and users**"**

Manufacturers or their representatives may sometimes need to undertake corrective or preventative action in relation to their medical devices. These include safety related field corrective actions taken by the manufacturer to reduce the risk of harm to patients, operators or others and/or to minimize the re-occurrence of the event.

When a Recall/ field safety notice is issued by a medical device manufacturer to the Kingdom of Bahrain market, NHRA seek confirmation from the authorized representative that the required action has been completed. Users of the affected medical devices should review the relevant information and follow the guidance provided.

This guideline is issued to all medical devices importers and healthcare facilities to clarify the requirements and procedures of handling field safety notices related to certain medical devices and require certain action to be taken to ensure the safety of patient and public health

3. General Rules

- All local Importers/Agents must comply with this guideline, failure to comply will be held responsible of legal actions.
- All involved stakeholders should be aware of the actions & requirements in this document.

4. Classification of Field Safety Notice

Recalls are classified into a numerical designation (I, II, or III) by the FDA to indicate the relative degree of health hazard presented by the product being recalled.

- Class I (Very High Risk): a situation in which there is a reasonable probability that the use of, or exposure to, a defected product will cause serious adverse health consequences or death.
- Class II (High Risk): a situation in which use of, or exposure to, a defected product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- Class III (Moderate Risk): a situation in which use of, or exposure to, a defected product is not likely to cause adverse health consequence.

5. Process

Applicant should submit the below required documents to NHRA by sending them at medical_device@nhra.bh once receiving FSN from either NHRA or directly from the manufacturer within the time frame set below in order to ensure that the required action has been implemented to prevent the use of defected medical device and protect patient / user health.

Required documents:

1. **FSN form (Annex 1)** and copy of the **FSN** issued by the manufacturer.
2. If the Bahrain market is not affected by the FSNs (i.e. affected medical device by the FSN is not marketed or distributed in Bahrain) then an **official letter from the manufacturer (Signed and Stamped)** should be provided to NHRA by the Authorized representative confirming that Bahrain market is not affected by the FSN.
3. If the Bahrain market was affected by the FSN (i.e. affected medical device by the FSN is marketed or distributed in Bahrain), Once the Authorized Representative receives the FSN issued from either the manufacturer or international regulatory authorities, **a copy of the notice must be provided to NHRA within**:

- **2 working** days in case of very high risk FSNs.
- **5 working** days in case of high risk FSNs.
- **10 working** days in case of moderate risk FSNs.

4. Applicant has **1 month** starting from the date of confirming / reporting to NHRA to provide the rest of the required documents:

- Acknowledgment.
- Evidence of action taken based on FSN.

to close FSN case and any delay in providing these documents may affect the public health and put patient/user under risk.

5. **Acknowledgment** which is a declaration from the end user stating that the action required has been implemented whether it is a corrective action or return the defected medical devices to the authorized representatives, this document should be signed and stamped the authorized person in healthcare facility.

In case of delay in providing the acknowledgment, an email from the end user including NHRA email in CC will be accepted.

6. In Case of a Recall; **an evidence of action taken** should be provided to NHRA which is either:
    - Invoice of destruction in Bahrain.
    - Air way bill in case of return the defected medical device to the manufacturer.

Authorized Representative should continuously follow up the adherence of the end users to the notice, when needed.

6.Sources of Field Safety Notices

There are international agencies publish on regular bases FSN related to medical devices worldwide such as:

- **US. FDA:** US Food and Drug Administration (United States of America).
- **MHRA:** Medicines and Healthcare products Regulatory Agency (United Kingdom).
- **GHC:** Gulf Health Council.
- **TGA:** Therapeutic Goods Administration (Australia).
- **Swissmedic:** Swiss agency for Therapeutic Products.
- **ECRI:** Emergency Care Research Institute (United States of America).
- **Health Canadians.**
- **NCMDR (SFDA):** National Center for Medical Devices Reporting.

7. Membership

Authorized Representative should be fully aware of international agencies alerts regarding FSN/Recall of their Medical Devices & will be legally responsible in case of violations.

In order to be updated with the latest adverse events and field safety notices worldwide, please visit the below link to have a membership to receive notifications:

FDA	https://www.fda.gov/about-fda/contact-fda/get-email-updates https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reportingprogram/subscribe-medwatch-safety-alerts
MHRA	https://www.gov.uk/drug-device-alerts/email-signup https://www.gov.uk/email/subscriptions/new?frequency=immediately&topic_id=medical-device-alertsand-field-safety-notice-2
SFDA	https://ncmdr.sfda.gov.sa/Login.aspx

8.Roles and Responsibilities

Handling field safety notices is a shared responsibility between manufacturer, supplier, end user and regulatory authority to ensure the safety of patients, users and public health.

Roles of manufacturer:

- Should have good communication system with their suppliers and authorized representative worldwide.
- Inform the suppliers in case of being aware of a defect in their medical device.
- Follow up with the suppliers to ensure the corrective action has been implemented.

Roles of Supplier/Authorized representative:

- Inform NHRA.
- Inform end user and follow up to ensure required action has been implemented,

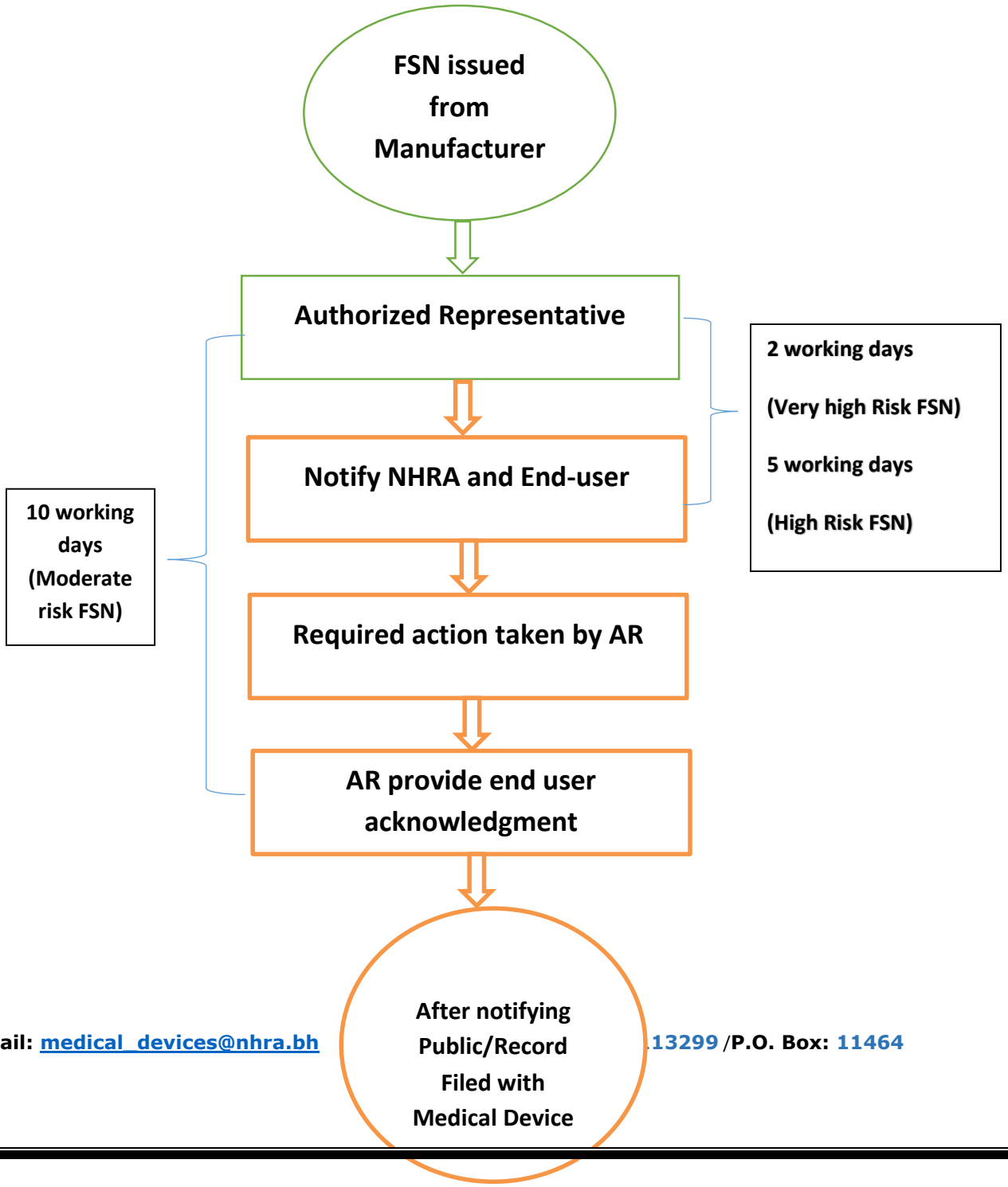
- Provide the required documents within the time frame set.
- Inform NHRA in case of any difficulties in providing required documents.

Roles of end user:

- Implement the required action recommended by the manufacturer.
- Quick response to the supplier to provide the acknowledgment within the time frame set.
- In case patients were affected by the defected medical device, then end-user must immediately report to NHRA complain sector to take necessary actions.

Roles of NHRA:

- Insure required documents has been provided by authorized representative.
- Issue a FSN circular to all healthcare facilities and importers.
- List all the recalls and FSCA on NHRA website.


FSN issued from Manufacturer
Authorized Representative
Notify NHRA and End-user
Required action taken by AR
AR provide end user acknowledgment
After notifying Public/Record Filed with Medical Device
2 working days
(Very high Risk FSN)
5 working days
(High Risk FSN)
10 working days
(Moderate risk FSN)

9.Annex

Please visit NHRA Website www.nhra.bh for more information about the checklist and FSN form.

1. **FSN Form**

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

2. **Check list**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/Checklists/MDR%20Checklist_Recall_FSN.pdf