Recall and Field Safety Notice Guideline

National Health Regulatory Authority (NHRA)

Kingdom Of Bahrain

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1. Definition

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 an action taken by a manufacturer to reduce potential risk in the state of health associated with the use of a medical device.

This may include:

- The return of a medical device to the manufacturer or its representative.
- Device modification.
- Device exchange.
- Device destruction.
- Advice given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants).

Recall: it is a type of FSN where a manufacturer takes a correction or removal action to address a problem with a medical device, Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

2. Introduction

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 local agent that the required action has been completed. Users of the affected medical devices should review the relevant information and follow the guidance provided.

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

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 violative product will cause serious adverse health consequences or death.
- Class II (High Risk): a situation in which use of, or exposure to, a violative 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 violative product is not likely to cause adverse health consequence

5. Process

- 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 should be provided to NHRA by the local agent confirming that Bahrain market is not affected by the FSN.

- 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 local agent receives a FSN issued from either the manufacturer or international regulatory authorities, a copy of the notice must be provided to the end-users by the agent 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.

- An evidence of the end user adherence must be documented after taking necessary action if any. Where they must declare that the action has been taken based on the notice and that no patient were affected, incase patients were affected then end-user must immediately report to NHRA complain sector to take necessary actions.
- Local Agent should be fully aware of international agencies alerts regarding FSN/Recall of their Medical Devices & will be legally responsible in case of violations.
- Local agent should submit the above documents (End-users Acknowledgment and Recall/FSN) to NHRA within the timeframe set above from the date of receiving the notification using the filled form through sending it to **Medical_Device@nhra.bh** and if there are convincing reasons that could cause

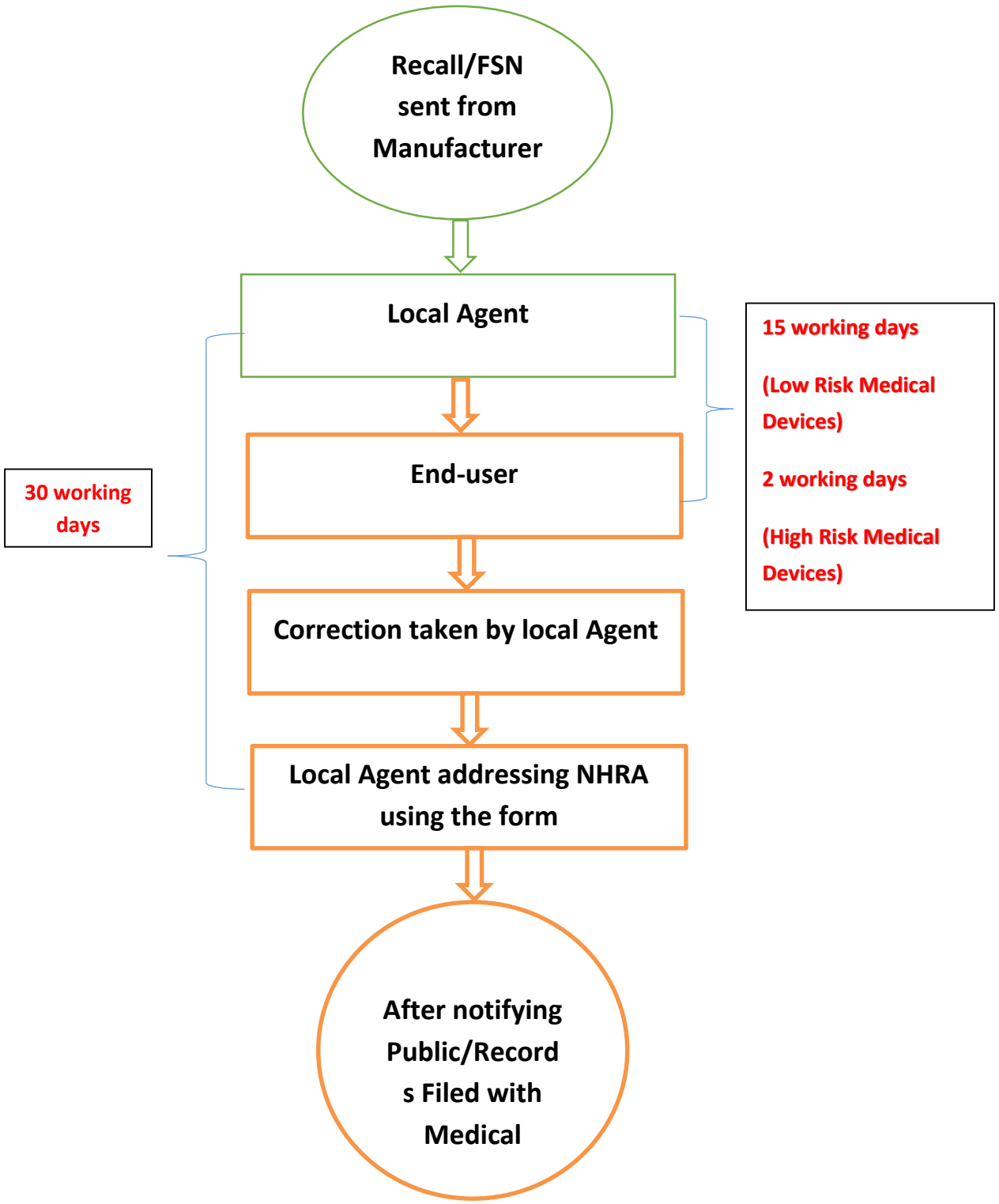
delay in submission, such delay have to be justified otherwise legal actions will be applied on the local agent.

- In Case of a Recall; an evidence should be provided to NHRA either from Bahrain Medical Waste or an Airway Bill stating that the device has been returned to the manufacturer.
- Local agent should continuously follow up the adherence of the end users to the notice, when needed.
- NHRA shall maintain the notice in the Medical devices records after notifying the public.

6. Sources of Field Safety Notice

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).
- **BfArM:** Federal Institute for Drugs and Medical Devices (Germany).
- **TGA:** Therapeutic Goods Administration (Australia).
- **Swissmedic:** Swiss agency for Therapeutic Products.
- **ECRI:** Emergency Care Research Institute (United States of America).
- **Health Canadians.**
- **NCMDR:** National Center for Medical Devices Reporting.


Recall/FSN sent from Manufacturer
Local Agent
End-user
Correction taken by local Agent
Local Agent addressing NHRA using the form
After notifying Public/Records Filed with Medical
30 working days
15 working days
(Low Risk Medical Devices)
2 working days
(High Risk Medical Devices)

7. Annex

- **Recall Form**
  http://www.nhra.bh/files/files/2018/MD%20doc/Forms/Medical%20Device%20%20Recall%20form.pdf

- **FSN Form**
  http://www.nhra.bh/files/files/2018/MD%20doc/Forms/Medical%20Device%20%20FSN%20Form.pdf