الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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Medical Devices Storing Facility Registration Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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1.0 Introduction:

With reference to **Decision (48) 2020, Article (6)** "Importers, distributors, manufacturers and authorized representatives of manufacturers engaged in the supply or distribution of medical devices and products must obtain a license from the Authority."

The main aim of this guideline is to highlight the characteristics of storing facilities of medical devices in addition to demonstrate the procedure of registering a storing facility.

2.0 General Rules:

1. If the authorized representative (AR) has a separate storing facility then the storing facility should be registered as an authorized storing facility in a separate application.
2. In case of outsourcing the maintenance staff, a contract agreement should be provided.
3. All the imported devices in the storing facility should be approved in OFOQ system before the importation, **Annex 1**.
4. Some medical devices (cold chain products, radioactive, etc...) needs for special storing and transportation conditions.
5. Storing facility should have a qualified staff (engineers/ technicians) with a medical devices background.

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6. Storing facility must have a tracing system to monitor:

- Importation
- Service maintenance
- Adverse Events
- Alerts & modifications
- Distribution
- Recalls
- Complains
- FSN

3.0 Storing facilities requirements:

1. Storing Area:

- Storing area should be isolated from high temperature, lights, moistures, etc... depending on the type of medical devices to be stored. (For more information about storing requirements for the devices read the product label, **Annex 4**).
- Some medical devices need a special storing conditions like radioactive products which require a separate storing facility instead of store it along with AR facility.
- There must be a warning and instruction signs in the facility.
- The facility should be always clean and remoted from pollution sources.
- Fire extinguisher must be always available and easy to access.
- Electronic equipment and system should always monitor the storing conditions like: temperature and moisture.
- Recalled items and devices under complaint should be stored in a separate section in the facility.
- In case of storing a medical device that need for special storing equipment like freezers, the facility should be allocated in an area with good electricity source and have a generator.

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2. Tracing System:

- Storing facility should have an integrated system that have the functionality of monitoring the distribution, annual maintenance, recalled devices, adverse events, Complains, devices Alerts & modifications, FSN and Importation in addition to monitor the expiry date of the items.
- The system should have the functionality of tracing the products location and quantity in the storage by its lot/batch/serial number.

3. Equipment & vehicles to be used in the facility:

- Appropriate vehicles should be equipped to move the products in the storing facility according to product manual.
- The vehicles should be equipped to protect the devices from moisture and temperature changes.
- In case the products have been falls or breaks the defected items should be recorded.

4. Staff competence:

- The employees working in the establishment should have a medical device background (e.g., engineer/ technician).
- The employees should aware of safety procedure in the facility.
- Staff in the facility should be capable to make the prober maintenance and calibration for the devices.

5. Polices & procedure:

- The establishment should have a clear/ strict polices with regards: products maintenance, complaint handling, adverse events, recalls, distribution and

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importation with taking into consideration informing NHRA in case of recall or alerts (Annex 5).

- For each category of medical devices there must be a written procedure for shoring condition according to manufacturer recommendations.

  (Remark: if the manufacturer does not publish any storing conditions then the storing conditions should be obtained from reference country entities for medical devices like FDA)

4.0 Registration procedure:

To apply for storing facility/AR registration an appointment should be booked on "Microsoft bookings" first for submitting the required documents, Then applicant should pay the fees for the application, a Notice to Pay will be issued and after completing the payment the submitted documents will be reviewed during **4-8 weeks.**

If the submitted documents does not fulfill the requirements, then the request will be rejected and a list of missing requirements will be sent for the applicant to reapply again and submit the missing requirements.

If the request is approved, an inspection visit will be scheduled in order to ensure compliance with NHRA requirements. If the inspection was successful, a NTP will be issued to pay the fees for obtaining the registration certificate.

(Remark: please note that no application will be reviewed if the applicant does not submit his application during the booked appointment)

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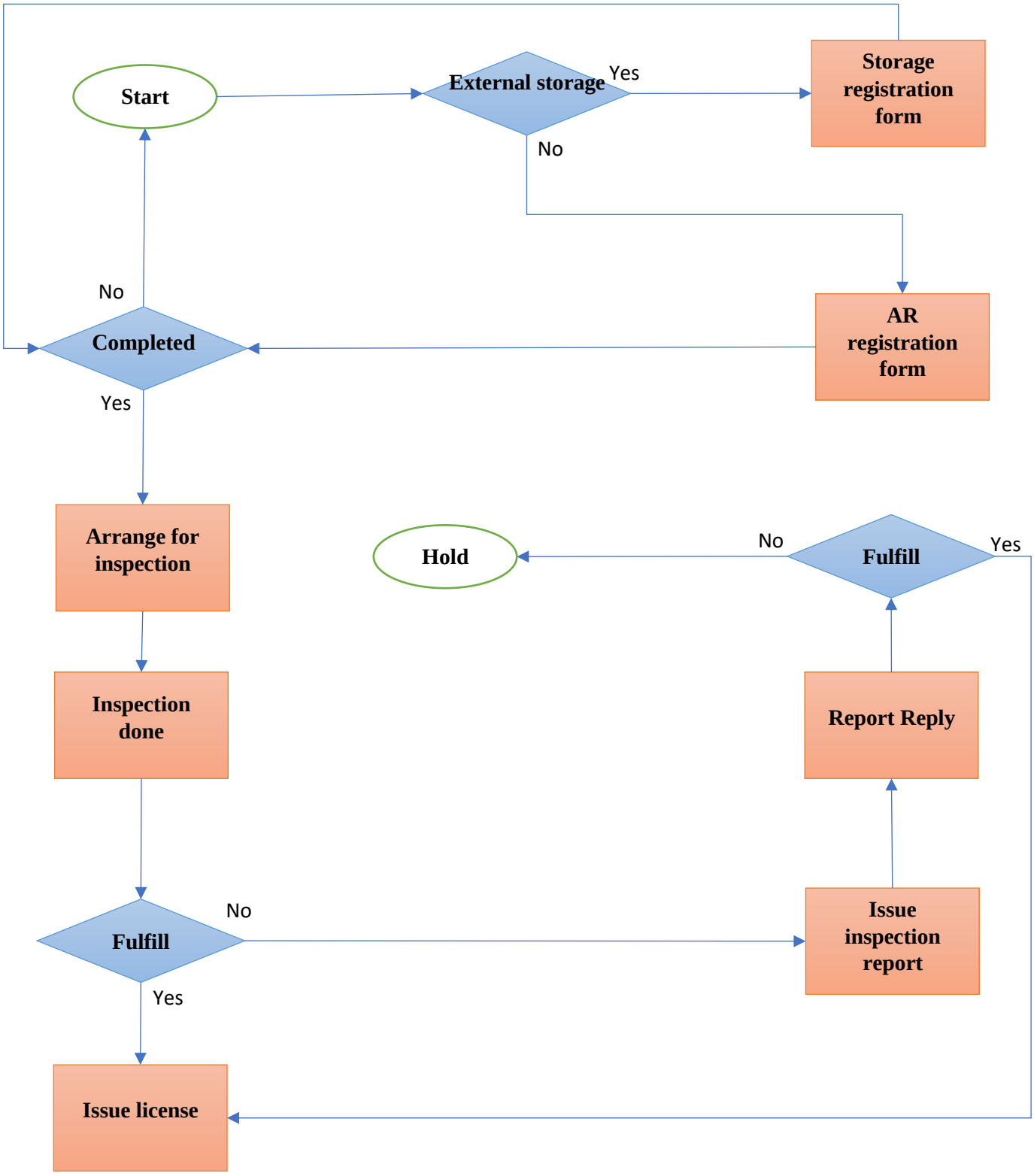
This flowchart demonstrates the registration procedure:



5.0 Annex:

1. **Importation guideline (OFOQ):**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/guidelines/Medical%20Device%20Importation%20OFOQ%20Guideline%20-Ver%208.1.pdf

2. **Medical device Storing facility application Form:**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Medical%20device%20Storing%20facility%20application%20Form.pdf

3. **Medical Devices Storing Facility Requirements Checklist:**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/Checklists/medical%20storage%20cheklist%201.pdf

4. **Medical Device Labeling guideline:**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/guidelines/MDR_Guideline_Medical%20Devices%20Labeling.pdf

5. **Polices and procedure guideline for medical devices authorized representative:**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/guidelines/Policies%20and%20Procedures%20Guideline%20

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for%20Medical%20Devices%20Authorized%20Representatives-%20Ver%202.2.pdf

6.0 Glossary:

No.	Terminology	Definition
1.	**Medical device**	'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.
2.	**IVD (in-vitro diagnostic)**	any Medical Device which is a reagent, reagent product, calibrator, control material, kit, instrument apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: • concerning a physiological or pathological state, or • concerning a congenital abnormality, or • to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures.

3.	**Combined medical device**	Medical devices combined with pharmaceutical and/or chemicals and/or Biological materials and does not achieve its action by pharmacological, immunological or metabolic means, used for prevention of illness.
4.	**Authorized representative (AR)**	Any legal entity exercises an activates related to medical devices/products like manufacturing, using, marketing, distributing or representing the manufacturer.
5.	**Manufacturer**	Means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
6.	**Adverse Event**	Any problem that can or caused an injury or death to the patient or the user.
7.	**Field safety notices (FSNs)**	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
8.	**Recall**	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

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