الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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Medical Devices Violations Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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1. Introduction

Medical devices importation and marketing in the kingdom of Bahrain is regulated by NHRA who set rules and regulations to monitor Medical Devices in the 3 stages pre-market, on-market and post market to ensure patient safety and public health.

With reference to **Decision (48) 2020, Article (15)** "The Authority shall take all necessary legal measures when violating any of the provisions of this decision." All importers, healthcare facilities and medical devices users have to comply with NHRA regulation and any non-compliance will consider a violation and NHRA has the right to take the proper action.

2. Types of Violations

Non-compliance to NHRA Regulation below points can be considered as a reference but it is not limited to these examples:

Field	Violations
Importation	1. Submitting falsified documents / invalid documents. 2. Providing Misleading information. 3. Changing (CoO, HS code, invoice) after submission. 4. Shipped items details are not matching with approved request details. 5. Multiple requests for similar invoice. 6. Intentional ignorance of previous rejection reasons by resubmitting the same documents.
Marketing	1. Using advertisement materials not approved by NHRA. 2. Miss branding, Misleading information. 3. Marketing falsified medical devices, providing false details to users. 4. Marketing a banded or recalled medical devices.

Field	Violations
Post Market Surveillance	1. Not taking actions on PMS during assigned period. 2. Lack of responding with regards to Medical Devices Post Market Surveillance. 3. Not reporting an incident.
Registration	1. Submitting falsified documents. 2. Providing Misleading information. 3. Forging NHRA registration certificate
Permit to Use	1. Using medical device in unlicensed healthcare facility. 2. Using medical device that is not approved by NHRA. 3. Using a medical device that is not matching with healthcare facility specialty.
Storage	1. Storing expired items mixed with new items. 2. Storing conditions is not as per manufacturer recommendations. 3. No Record for cold rooms. 4. Disposing of active medical devices without reporting to NHRA.
Transportation	1. Transportation vehicle is not licensed by NHRA. 2. Medical devices are not transported as per manufacturer recommendation.

3. What are the actions taken by NHRA

Violations are being evaluated by NHRA in order to take the proper action. In case of not complying with NHRA regulation for the First and second time, **a warning letter will be issued** to the authorized representative and **1 week** will be given to provide a justification letter and a **grace period of one month** to take the necessary measures and corrective action to avoid repeating the violation.

Third time violation, the authorized representative will be listed in **restricted list** in customs (where every single shipment will be physically inspected and it will have a major impact in importation flow) **and a violation will be added in CR.**

In case of repeating violation, CR will be canceled.

4. Confiscated Medical Devices

In case of confiscating medical devices by NHRA in a violative healthcare facility due to many reasons including:

- Using medical device in unlicensed healthcare facility.
- Using medical device that is not approved by NHRA
- Using a medical device that is not matching with healthcare facility specialty

The financial expenses of confiscated medical devices will be covered by the device owner.

5. Removal of Violation

During the grace period (1 month) CAPA (Corrective Action and Preventive Action) should be provided by the authorized representative to NHRA in order to be evaluated and ensure that it is effectively implemented.

Once CAPA is approved, authorized representative will be closely **monitored for 3 months** after that violation will be removed automatically from Sijilat given that no other violation was recorded during the grace period.

But in case a violation was done during grace period, the violation will remain for **1 year** on Sijilat and if the AR continuously violated NHRA regulation, then either:

- The **CR will be terminated** as this will have an impact on users and patient safety.
- Or an official letter will be sent to all international manufacturers including all details of the violation.