Medical Devices Shelf Life Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Contents

1. Introduction

The service life or shelf-life must be specified by the device MANUFACTURER and included in the technical file and, where appropriate, the instructions for use (IFU) or labelling, respectively.

Service life or shelf-life can include e.g.: the time or usage that a device is intended to remain functional after it is manufactured, put into service, and maintained as specified. Reporting assessment shall be based on the information in the master record or in the IFU.

2. Definitions

- **Shelf life**

Shelf life is the period of time, from the date of manufacture, that a product is expected to 208 remain within its approved product specification while handled and stored under defined 209 conditions.

- **Expected Service Life**

Expected Service Life is a manufacturer defined term for how long the product will continue to be in compliance with the requirements of the standard.

In another words, includes the time of use that a device is intended to remain functional after it has been manufactured, put into service, and maintained as specified.

- **lifetime (life span)**

The lifetime (life span) of a medical device refers to the time interval from design and development of the device to the decommissioning (proper disposal) of the MEE. The lifetime of the device could be how long the MEE is expected to be functional (i.e., fulfill its intended use) and remain safe (i.e., free from unacceptable risk)

- **life cycle**

Represents all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.

3. Factors affecting Shelf Life of Medical Devices

In some cases the life of a medical device may be longer or shorter depending on a number of factors, including the:

- Frequency of use
- Nature of use
- Environment of use
- Experience and knowledge of the user
- Care and attention paid to use and operator maintenance
- Existence, capability and cost of maintenance support
- Management of scheduled and unscheduled maintenance
- Availability and cost of consumables and spare parts
- Availability and cost of replacement devices
- Relative efficacy and effectiveness of the alternative methods and devices
- Funding availability

4. Variables to be Considered

There are many things that can influence the determination of shelf life of a medical device, categories of factors that should be considered. These include:

- **Storage Conditions:**

This includes the impact of temperature, humidity, air pressure, air-born contamination, visible light and radiation.

- **Intended Use:**

Some medical devices use materials that degrade over time because the intended use of the device justifies their selection.

- **Components:**

Some devices contain components that may have unique expiration features, such as batteries.

- **Method of Manufacture:**

Manufacturing processes may introduce variables that impact the shelf life of the device.

- **Packaging:**

Some devices are affected by contact with its packaging and different packaging concepts may impact devices differently.

- **Transportation:**

Shipping stresses including shock, vibration, and temperature.

- **Sterilization:**

The effect of the sterilization method on both the package and the device.