National Agency for Food and Drug Administration & Control (NAFDAC)

Vaccines, Biologics and Medical Devices - Registration and Regulatory Affairs (VBM-R&RA) Directorate

Guidelines for Good Refurbishment Practice of Medical Devices (NGRPMD)

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1. Introduction

The NAFDAC Guidelines for Good Refurbishment Practice of Medical Device(NGRPMD) describes the process by which the industry refurbishes medical devices. Refurbishment is where a device is subjected to a systematic process to ensure safety and effectiveness of the medical device without significantly changing the device' s or medical device' s performance, safety specifications and/or changing intended use as in its original registration. Any upgrade processed during GRPMD refurbishment shall be performed in a manner consistent with the original product specifications and service procedures defined by the manufacturer for that device or medical device. This guideline on Good Refurbishment Practice for Medical Device (GRPMD) is to fulfil regulatory requirements for safe and effective refurbished medical devices.

Conserving assets is a fundamental principle of ecological thinking in a recycling economy. The replacement of a medical device with high residual value generates a cascading effect in trade – which means that after refurbishment, the replaced device provides additional value to a new user. Refurbishment addresses the high demand for affordable and reliable products. Customers of refurbished medical devices are not only small hospitals with limited budgets but also leading medical institutes. Refurbishment is a well-established element of the global healthcare economy.

If a used medical device is not maintained according to requirements defined by the original manufacturer, it may result in an additional risk for patients and operators. Consequently, to protect public health and healthcare provider interests, some countries have imposed bans on the import of used medical equipment. These bans usually fail to distinguish between high-quality refurbishment to the original manufacturer' s specifications and second-hand

equipment of undefined quality, with the effect that patients may be denied access to the safe and economical medical device they need.

2. Objective

Good refurbishment practice comprises of a set of standard operating procedures and dedicated quality requirements that ensure a refurbished medical device is as safe and effective as when it was new.

A refurbished medical device is one that has been taken out of service and specially processed to be reused. Compared to a new device, a used one may bear additional risks (e.g. contamination, worn parts and misalignment) to the patient, user, third parties and the environment if not adequately maintained. The point behind the refurbishment process is to restore used devices to its original registration conditions, making them fit to be returned to service.

It is important that the disparities between refurbishment from service/maintenance or repair of medical devices be understood clearly as it will not be covered in this topic. As such, from this point forward, the focal point of this document will be on the process of refurbishing used medical devices to ensure that they adhere to the stipulated safety and effectiveness standards.

This guideline aims to assist the industry in ensuring the safety and performance of refurbished medical devices and address the liabilities associated with a refurbished device.

3. Scope

This guideline specifies the requirements of Good Refurbishment Practice of medical devices (GRPMD) excluding in vitro diagnostics.

Reprocessing of single-use devices and the remanufacture of used medical devices are out of the scope of this guideline.

4. Terms and definitions

For the purposes of this guideline, the terms and definitions in Act 737, the regulations under it and the following requirements apply:

4.1. Device history record (DHR)

History records of one or many refurbished medical devices reflecting operations, processes, etc., that are described in the validated refurbishment process.

4.2. Manufacturer

As defined under Part V, Miscellaneous of the NAFDAC Medical Devices, In vitro Diagnostics and Related Products (Registration, Labelling and Advertisement) Regulations 2024

4.3. Refurbishment

To restore a used medical device or medical device to manufacturer defined safety and performance standards, which include actions such as repair, recondition, rework, software updates, replacement of worn parts with original parts. All actions shall be performed in a manner consistent with product specifications and service procedures defined by the manufacturer without changing its intended use.

4.4. Refurbisher

A person who refurbishes a medical device. There are two categories of refurbisher:

a) manufacturer; or
b) third party refurbisher.

4.5. Remanufacturing

Actions taken, such as processing, conditioning, renovating, repackaging, etc. on a used medical device or medical device, that significantly changes the

device' s or medical device' s performance, safety specifications, or intended use. Remanufacturing of medical devices is not covered by this guideline.

4.6. Maintenance

Maintenance consists of schedule maintenance and unscheduled maintenance. Scheduled maintenance is planned maintenance program to ensure an optimum performance, safe operation, minimum downtime, and maximum useful life from each medical device. Unscheduled maintenance involves those actions necessary to restore normal function, safety, performance, and reliability to malfunctioning medical devices.

4.7. Third party refurbisher

Any person who is authorised by the manufacturer to refurbish a medical device.

If a third party refurbisher places a refurbished medical device in the market under its own name, the Agency may consider such party as a manufacturer.

4.8. Used medical device

A medical device that has been in service, taken out of service and is put back into service usually at another location.

4.9. Validation

Confirmation by examination and provision of objective evidence that a particular requirement for a specific intended use can be consistently fulfilled.

5. Refurbishment process

During the refurbishment process, there shall be no compromises on quality or safety on any level. Therefore, the purpose of the following process steps is to ensure that any medical device that is refurbished according to GRPMD will have the same quality, performance, safety, and intended use - including warranty and service requirements - as when it was new.

The manufacturer shall ensure test validation protocol and validation reports of refurbishment processes are established and maintained.

5.1. Five-step refurbishing process

Each refurbishment process step incorporates certain dedicated activities and certain necessary resources. These resources could be qualified people, tools, instructions, files/records/documents, test equipment, parts, packing material, etc.

As with the manufacturing process of a new medical device, the refurbishing process shall meet critical specifications (e.g. environmental conditions such as facility temperature and humidity) as defined by the original manufacturer.

5.1.1. **Refurbishing process Step 1**: Selection of medical devices for refurbishment

Generally, the selection of equipment to be refurbished, is based on the principle that when completed, it will have the same quality, performance, safety and intended use as when it was new. The following criteria are important when considering to refurbish a used medical device:

a) Type, configuration and condition of a used medical device as well as age, upgradeability and the phase in the life cycle.

b) The phase in the life cycle of a medical device is generally defined by the availability of spare parts. The lack of spare parts will limit a medical device' s serviceability. Table 1 indicates examples of activities, information and resources needed on selection of medical devices for refurbishment.

Table 1. Activities, information and resources needed on selection of medical devices for refurbishment.

ACTIVITY	INFORMATION AND RESOURCES NEEDED (*Examples*)
Evaluate type, age and configuration of the medical device	Product service history, data of the Installed Medical devices Database
Evaluating the condition of a medical device	Service records of the relevant equipment; site and incoming check instructions; service instructions by the manufacturer; equipment condition requirements that have to meet therefurbishment criteria
Evaluating upgradeability of software andhardware status	Device upgradeability documentation of theoriginal manufacturer
Evaluating availability of original spare partsand service	Original manufacturer spare parts and serviceavailability

5.1.2. Refurbishment process Step 2: Dismantling, packaging, andshipment

5.1.2.1. Dismantling

a. Dismantling of fixed medical device shall be done in accordance with manufacturer instructions or by competent technical personnel.

b. If a medical device has been used in a special environment (e.g. emergencyroom, operating room) it might be necessary to first perform a decontamination/disinfection process at the place of disassembly, to limit therisk of exposure to pathogens. Table 2 indicates examples of activities, information and resources needed on dismantling, packaging and transportation.

Table 2. Activities, information, and resources needed on dismantling,packaging and transportation.

ACTIVITY	**INFORMATION AND RESOURCES NEEDED (*Examples*)**
Medical device check at customer'ssite	Instructions of the manufacturer for medical device check and the tools needed as specified by the original manufacturer.
Preliminary decontamination/disinfection	Preliminary decontamination instructions.
Professional disassembly	Original manufacturer instructions for medical device disassembly, appropriate tools needed for medical device disassembly as specified by the original manufacturer, appropriate tools for transportation lock, trained personnel performing the disassembly.

5.1.2.2. Packaging and transportation

The refurbisher is responsible for developing instructions to make sure that refurbished medical devices are not damaged during packaging or shipment. Therefore, the purpose of this process step is to ensure sure that any medical device that is destined for refurbishment will be packed and shipped in such a manner that prevents damage during transportation. All instructions shall be validated. Table 3 indicates examples of activities, information and resources needed on packaging and transportation.

Table 3. Activities, information and resources needed on packagingand transportation

ACTIVITY	**Information and resources needed** (*Examples*)
Packaging of the used medical device	Original manufacturer product instructions for packaging, including specified tools, packing material e.g. frames, etc.
Transportation to the refurbishment facility	Original manufacturer product instructions for transportation, including specified tools for monitoring transportation e.g. shock indicators.
Incoming inspection	Validated incoming inspection instructions, specified tools.

5.1.3. Refurbishing process Step 3: Refurbishment

5.1.3.1. Decontamination and sterilization

a. The refurbisher shall establish, document, and maintain requirements for decontamination of refurbished products, which may include cleaning, disinfection and sterilization where applicable.

b. For sterile refurbished medical devices, the refurbisher shall subject the medical devices to a validated sterilization process and record all the control parameters of the sterilization process.

c. A used medical device can sometimes become contaminated by its use in a clinical environment. The purpose of this process step is to make sure that any medical device that is to be refurbished will bear no risks of infection to any person during or after the refurbishment process. Table 4 indicates examples of activities, information and resources needed on decontamination and sterilization.

Table 4. Activities, information and resources needed on decontamination and sterilization.

ACTIVITY	**INFORMATION AND RESOURCES NEEDED (*Examples*)**
Decontamination / disinfection / sterilization	Requirements for decontamination/ disinfection / sterilization as part of a validated refurbishing process.

5.1.3.2. Refurbishment planning

a. This process step depends on the medical device to be refurbished. The medical device configuration shall be defined either by the refurbisher itself or according to customer requirements. The final configuration of the refurbished medical device shall be within the scope of the original product registration from the manufacturer when it was new.

b. The refurbishment planning process is a critical phase for refurbishment because all necessary actions shall be thoroughly assessed and determined. Throughout the refurbishing process, the Device History Record (DHR) shall be continuously updated. The refurbisher planning the necessary refurbishment actions shall be skilled to ensure that the required actions do

not represent a modification that might impair the original identity and approved configuration, meaning that regulatory implications might arise. Due to the criticality of the refurbishment planning process, the refurbisher shall have reliable controls for this process step and have it defined in detail in its quality management of medical device.

c. A refurbished medical device that does not have the same intended use and specifications shall be treated as a new medical device. The refurbishment of medical devices shall not compromise on safety and performance. Table 5 indicates examples of activities, information and resources needed on refurbishment planning.

Table 5. Activities, information and resources needed on refurbishment planning.

ACTIVITY	**INFORMATION AND RESOURCES NEEDED (*Examples*)**
• Check for relevant technical documentation for detailed planning to ensure that the medical device will be refurbished according to original manufacturer product specifications.	• Original manufacturer productspecifications. • Technical documentation for the planning of refurbishment.
• Check for necessary field updates regarding safety, reliability, performance etc. • Planning appropriate updates	• Original manufacturer product specifications. • The results of product surveillance of the relevant medical device.

• Planning cosmetic, mechanical and electrical refurbishment as well as medical device configuration	• Original manufacturer product specifications and documentation; e.g. medical device configuration documentation
• Planning of medical device testing.	• Original manufacturer product specifications and documentation.
• Preparation of GRP declaration.	• Technical documentation for the respective medical device.
• Planning of packaging & shipment	• Original manufacturer product specifications and documentation.
• Planning of reinstallation and start-up check at the customer' s site.	• Original manufacturer product specifications and documentation.

5.1.3.3 Cosmetic refurbishment

Table 6 indicates examples of activities, information and resources needed on cosmetic refurbishment.

ACTIVITY	INFORMATION AND RESOURCES NEEDED (*Examples*)
• Surface treatment, painting as needed	• Instructions according to the refurbishment plan. • Original paint tested and approved by the original manufacturer regarding biocompatibility.

5.1.3.4. Mechanical and electrical refurbishment and medical device configuration

The refurbisher is also required to take appropriate actions to avoid violation of privacy rules concerning patient data stored on certain medical device. Table 7 indicates examples of activities, information and resources needed on mechanical and electrical refurbishment and medical device configuration.

Table 7. Activities, information and resources needed on mechanical and electrical refurbishment and medical device configuration.

ACTIVITY	INFORMATION AND RESOURCES NEEDED (*Examples*)
• Replacing worn parts	• Instructions according to the

	refurbishment plan
• Performing the planned applicable updates. • Customising through options and accessories within the scope of product registration. Adding new and complete original manufacturer user documentation in the required language.	• Instructions according to the refurbishment plan. • Original manufacturer user documentation in the required language or verified translation.
• Updating the DHR to show evidence that the medical device was refurbished according to the specification of the device.	• DHR of the relevant medical device regarding refurbishment.
• Appropriate actions to avoid violation of privacy rules concerning patient data stored on the relevant medical device.	• Dedicated tool and validated process.

5.1.3.5. Medical device testing

Table 8 indicates examples of activities, information and resources needed on medical device testing.

Table 8. Activities, information and resources needed on medical device testing

ACTIVITY	**INFORMATION AND RESOURCES NEEDED** (*Examples*)
• Performing a system check • Thorough checking of components and subsystems	• Instructions per original manufacturer test specifications. • Test medical device and system check procedure.
• Updating the DHR to show evidence that the medical devicewas re furbished according to the specification of the device.	Device History Record of the relevant medical device regarding refurbishment.

5.1.3.6. Declaration of Conformity

When all necessary actions for refurbishment have been successfully completed, the refurbisher declares in the Declaration of Conformity of the essential principle of safety and performance (DoC) that the refurbished medical device is safe and performs effectively as the original medical device. Table 9 indicates examples of activities, information and resources needed on declaration of conformity.

Table 9. Activities, information and resources needed on declaration of conformity

ACTIVITY	**INFORMATION AND RESOURCES NEEDED** (*Examples*)
• Labelling – adding date of refurbishment and GRP-Label to the genuine labelling.	• GRP Labelling tool for controlled labelling (Control refurbishment label design)
• Updating the DHR to show evidence that the equipment was refurbished according to the specification of the equipment.	• Installed Medical device Database for tracking the medical device and ensuring optimised maintenance. • Device History Record of the relevant equipment regarding refurbishment

5.1.3.7. Packaging and shipment

The overall objective of refurbishment is to provide the new user of the refurbished medical device the advantage of a medical device that has the same quality, performance, safety and intended use as original registration conditions Following this objective the process steps after refurbishment itself such as packaging and transportation shall be identical or equivalent to the process steps for new medical devices. Table 10 indicates examples of activities, information and resources needed on packaging and transportation.

Table 10. Activities, information and resources needed on packaging and transportation

ACTIVITY	**INFORMATION AND RESOURCES NEEDED (*Examples*)**
• Packaging of the refurbished medical device.	•Original manufacturer instructions for packaging. •Original manufacturer specified tools needed for packaging. •Original packaging material of the manufacturer e.g. frames. • Regulation regarding packaging material.
• Transportation to customer's site.	•Original manufacturer instructions for transportation. •Original manufacturer specified tools for monitoring transportation, e.g. shock and temperature indicators.

5.1.4. Refurbishing process Step 4: Reinstallation of refurbished medical device

Medical device refurbished according to GRPMD is intended to meet original quality, performance and safety standards based on ISO 13485, hence it is essential to follow the original manufacturer' s installation procedures including site planning and preparation works. Table 11 indicates examples of activities, information and resources needed on reinstallation of refurbished medical device.

Table 11. Activities, information and resources needed for reinstallation of refurbished medical **device**

ACTIVITY	**INFORMATION AND RESOURCES NEEDED** **(*Examples*)**
• Professional installation	•All involved employees shall be trained according to original manufacturer requirements.
• Start-up and repeated check-up of the medical device' s performance	•All involved employees shall be trained according to original manufacturer requirements.
• Application training as contracted between customer and the refurbisher	•All involved employees shall be trained according to original manufacturer requirements.
Hand-over of required user documentation.	•User documentation.
Updating the DHR to show evidence that the equipment was refurbished according to the original manufacturer product specifications	•Device History Record of the relevant medical device.

5.1.5. Refurbishing process Step 5: Professional services

The refurbisher shall provide after-sale services and support, identical to what is provided for new medical devices. It is, thus, ensured that the user of the refurbished medical device will have the full necessary support of after sales

services and spare parts available over the planned lifetime of the device. Table 12 indicates examples of activities required for professional services.

Table 12. Activities required for professional services

ACTIVITY
• Warranty equivalent to a new medical device
• Spare parts availability
• Maintenance contracts
• Manufacturer update management
• Application training
• Financing solutions and service contracts
• Qualified contact partners for product support when needed

6. Safety and performance

6.1 Safety and performance requirements for refurbished medical devices

When the refurbished medical device is to be placed in the market, the refurbisher shall ensure the refurbished medical device complies with the Medical Device Act 2012 (Act 737) and Medical Device Regulations 2012.

7. Testing, commissioning and maintenance

Testing and commissioning of refurbished medical devices shall comply with the manufacturers' instruction as per the original device.

For the maintenance of refurbished non-active medical device, reference shall be made to the original device maintenance instruction**.**

8. Labelling

8.1 Refurbishers of medical devices are required to indicate that the medical device is a refurbished medical device. The refurbishment date shall also be indicated. Other labelling requirements are as prescribed by the Agency.

9. Liability issues

The refurbisher shall be held liable for the refurbished medical devices.

REQUIREMENTS FOR GRANTING APPROVAL FOR REFURBISHED MEDICAL DEVICES

An application for authorization for refurbished medical devices should be made to the Director-General (NAFDAC), attention: The Director, Vaccines, Biologics and Medical Devices Registration and Regulatory Affairs Directorate (VBM-R&RA) for approval of refurbished medical devices. The application should be submitted by an applicant either an authorized representative of the refurbisher or refurbisher itself to NAFDAC.

The requirements in the NAFDAC guideline for registration of medical devices and other relevant NAFDAC guidelines including the guideline on grouping of medical devices based on the category of the refurbished medical devices.

The application submission should contain all elements required by the Agency, including, but not limited to:

1. Name and complete address of the refurbisher

2. Name and address of the original device manufacturer

3. Roles of the original medical device manufacturer

4. Establishment license of the refurbisher issued by a competent body

5. Name of the device and the brand as indicated in the labeling,

6. Intended use of the device as initially defined by the manufacturer,

7. New lot/batch number assigned to the device by the entity performing the

refurbishment,

8. Catalogs or other printed materials containing information regarding the initial

intended purpose of the device, and also the general description of the device itself

and the way it operates,

9. The label of the device indicating that it has been refurbished, the refurbishment date and other information as indicated in section 8.1 of this guideline,

10. Declaration of Conformity from the refurbisher

11. User documentation and Good Refurbishment Practice (GRP) Declaration

12. Local third party refurbishers who wish to carry out refurbishment activities must have been evaluated by NAFDAC' s Drug Evaluation and Research (DER). Directorate

13. The tariff for registration of medical devices will apply

Furthermore, the following information should be part of the submission for refurbished medical devices:

1. Service instructions by the original manufacturer
2. Device upgradeability documentation of the original manufacturer

3. Original manufacturer instructions for system disassembly
4. Original manufacturer product instructions for packaging
5. Original device manufacturer instructions for transportation, including specified tools for monitoring transportation e.g. shock and temperature indicators
6. Validated incoming inspection instructions, specified tools
7. Original manufacturer' s product specifications including medical device configuration documentation
8. Technical documentation for the planning of the refurbishment
9. The PMS and vigilance plan of the refurbished medical device
10. Requirements for cleaning and disinfection /sterilization/ decontamination (as applicable) as part of a validated refurbishing process
11. Original manufacturer parts, components and accessories, original manufacturer user documentation in the English language or verified translation
12. Updated DHR of the medical device regarding refurbishment
13. Instructions per original manufacturer test specifications
14. Test medical device and system check procedure