ETHIOPIAN FOOD AND DRUG AUTHORITY

Guidelines for Medical Devices Refurbishment

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ABBREVIATIONS

DHR	Device History Record
DoC	Declaration of Conformity
EFDA	Ethiopian Food and Drug Authority
eRIS	Electronic Regulatory Information System
GRP	Good refurbishment Practice
GRPMD	Good refurbishment Practice of Medical Device
QMS	Quality Management System
IVD	In Vitro Diagnostic

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1. INTRODUCTION

The Food and medicine administration proclamation No 1112/2019 gives the power to the Ethiopian Food and Drug Authority (EFDA) to ensure the safety, quality, and effectiveness of medical devices. Article 40 of this proclamation stipulates requirements for refurbished medical devices. It restricts the use of refurbished medical devices without getting approval from the Authority.

Refurbishment is where a used medical device is subjected to a systematic process to restore to original functions and ensure its safety and effectiveness without significantly changing medical device's performance, safety specifications and its original intended use. A refurbished medical device that has been taken out of service and specially processed to meet the original manufacturer's specifications and qualified to be used can be made accessible to users.

Compared to a new device, used medical devices may bear additional risks (e.g. contamination, worn parts and misalignment) to the patient, user, third parties and the environment if not adequately maintained. Hence, the refurbishment process should be carefully carried out to avoid such and other related risks.

This guideline describes the set of procedures and quality requirements to be followed by the refurbisher of the device to fulfil regulatory requirements so as to ensure that a refurbished medical device is safe and effective.

Section five of this guideline describe the requirements for good refurbishment practice of medical device (GRPMD) while in section six, application requirements for refurbished medical device are indicated. It should be noted that the detail requirements and organization of dossier for submission of medical device including refurbished devices are provided in the Authority's G*uidelines for Registration Requirements for Non-IVD* Medical Devices and G*uideline for Registration Requirements of IVD* Medical Devices. In this guideline, the additional requirements for refurbished medical device are indicated and hence, applicants are advised to consider the mentioned requirements when organizing dossier for submission in need of marketing authorization of refurbished medical devices.

2. DEFINITIONS

Device history record (DHR): History records for refurbished medical device representing individual devices or lots of devices for all finished devices that were processed. The history record for refurbished medical devices should reflect that all operations, processes, etc., described in the validated refurbishment plan have been accomplished

Maintenance is consist 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.

Manufacturer: A person or party responsible for designing, manufacturing, packaging and labelling a medical device before placing it on the market; also responsible for providing documentation, instructions and recommendations for the installation, use and maintenance of the device to ensure its performance, as well as the safety of patients and health workers.

Refurbishment: To restore a used 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.

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

a) Manufacturer; or

b) Third party refurbisher.

Remanufacturing: Actions taken, such as processing, conditioning, renovating, repackaging, etc. on a used medical device or System, that significantly changes the device's or devices system performance, safety specifications, or intended use. This guideline does not cover remanufacturing of medical devices.

Repair and maintenance: The restoration of a medical device or system by a service provider to its original function, in response to the failure of the device or system. The repair process may also include servicing, reconditioning, modification and refurbishment.

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, it is considered a manufacturer as defined in proclamation #1112/19

Second hand medical device: A medical device that has been in service, taken out of service and is put back into service usually at another location without any processing.

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

Refurbished medical device is

a medical device whose service year is yet to expire or has already expired and undergone the appropriate renovation and effectiveness testing for use in medical purpose. It may refer to devices that have been wholly or partially rebuilt in order to be used for the original purpose as determined by the original manufacturer.

3. SCOPE

This guideline is applicable to all refurbished medical devices intended to be used in the Ethiopian market and all parties involved in the refurbishment activities.

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

4. OBJECTIVE

The objective of this guideline is to provide guidance on refurbishment procedures and safety and performance requirement of refurbished medical devices.

5. REQUIREMENTS FOR GOOD REFURBISHMENT PRACTICE

5.1. General

During the refurbishment process, there shall be no compromises on quality or safety on any level. Therefore, the refurbisher should ensure that the medical device is refurbished in accordance with the Good Refurbishment Practices for Medical Devices (GRPMD).

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

The five refurbishment process steps described in this section should be carried out by qualified people and by using appropriate tools, instructions, files/records/documents, test device, parts, packing material, etc.

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

The refurbisher and the importer shall be held liable for the refurbished medical devices. If it is refurbished in Ethiopia, the refurbisher shall be liable for any health consequences, if any.

5.2. Refurbishment process

5.2.1. Step 1: Selection of medical devices for refurbishment

Generally, the selection of medical device 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 refurbishment phase in the life cycle of a medical device is generally determined 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 (Example)**
Evaluate type, age and configuration of the medical device	Product service history, data of the Installed medical devices database
Evaluating condition of medical device	Service records of the relevant device; site and incoming check instructions; service instructions by the manufacturer; device condition requirements that have to meet the refurbishment criteria
Evaluating upgradeability of software and hardware status	Device upgradeability documentation of the original manufacturer
Evaluating availability of spare parts and service compatible for the device	Manufacturer spare parts and service availability compatible for the device

5.2.2. Step 2: Dismantling, packaging and shipment

5.2.2.1. Dismantling

For refurbishment activities that require dismantling:

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

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

Table 2: Activities, information and resources needed on dismantling

Activity	Information and resources needed (Example)
Medical device check at customer's site	Instructions of the manufacturer for system check, tools needed for system check as specified by the original manufacturer
Preliminary Decontamination/Disinfection	Preliminary Decontamination Instructions
Professional Disassembly	Original manufacturer instructions for system disassembly, appropriate tools needed for system disassembly as specified by the original manufacturer, appropriate tools for transportation lock, trained personnel performing the disassembly

5.2.2.2. Packaging and transportation

a) For identification purpose, the device to be refurbished should bear appropriate labeling showing the device is to be refurbished.

b) The instructions should ensure that any medical device that is destined for refurbishment will be packed and shipped in such a manner that prevents damage during transportation.

c) 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 packaging and transportation

Activity	Information and resources needed (Example)
Packaging of the used medical devices	Original manufacturer product instructions for packaging, including specified tools, packaging material e.g. frames
Transportation to the refurbishment facility	Original manufacturer device instructions for transportation, including specified tools for monitoring

	transportation e.g. shock indicators
Incoming inspection	Validated incoming inspection instructions, specified tools

5.2.3. Step 3: Refurbishment

5.2.3.1. 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 device configuration 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. 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. Table 4 indicates examples of activities, information and resources needed on refurbishment planning.

Table 4: Activities, information and resources needed on refurbishment planning

Activity	**Information and resources needed (Example)**
Check for relevant technical documentation for detailed planning to ensure that the device will be refurbished according to original manufacturer product	• Original manufacturer product specifications • Technical documentation for the planning of the refurbishment

specifications	
• Check for necessary field updates regarding safety, reliability, performance etc. • Planning appropriate updates	• Original manufacturer product specifications The PMS and vigilance reports of the same device
Planning cosmetic, mechanical and electrical refurbishment as well as system configuration	Original manufacturer product specifications and documentation; e.g. medical device configuration documentation
Planning medical device testing	Original manufacturer product specifications and documentation.
Preparing of GRP declaration	Technical documentation for the respective medical device.
Planning packing & shipment	Original manufacturer product specifications and documentation.
Planning reinstallation and start-up check at the customer's site	Original manufacturer product specifications and documentation.

5.2.3.2. Decontamination and sterilization

a. 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.

b. The refurbisher shall establish, implement, document and maintain requirements for decontamination of refurbished devices and its components, which may include cleaning, disinfection and sterilization where applicable.

c. Effectiveness of disinfectant and sterilization method used shall be validated and documented.

d. 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.

If the refurbishment activities involve cleaning or disinfection/ sterilization/ decontamination, the refurbisher should use the validated methods and processes for these activities.

5.2.3.3. Cosmetic refurbishment

Cosmetic refurbishment is the process of improvement by cleaning, decorating and re-equipping.

If the refurbishment activities involve surface treatment, (e.g painting), the refurbisher may follow refurbishment plan instructions and biocompatibility test report of the painting used by its manufacturer.

5.2.3.4. Mechanical and electrical refurbishment and medical device configuration

The refurbisher is required to take appropriate actions to avoid violation of privacy rules concerning patient data stored on certain medical device. Table 5 indicates examples of activities, information and resources needed on mechanical and electrical refurbishment and medical device configuration.

Table 5: Activities, information and resources needed on mechanical and electrical refurbishment and medical device configuration

Activity	**Information and resources needed (Example)**
Replacing worn parts	Instructions according to the refurbishment plan Compatible spare parts
Performing the planned applicable updates Customizing through options and accessories within the scope of device Adding new and complete original manufacturer user documentation in the English language	Instructions according to the refurbishment plan Original manufacturer parts, components and accessories, original manufacturer user documentation in the English language or verified translation
Updating the Device History Record (DHR)	DHR of the relevant medical device regarding

to show evidence that the medical device was refurbished according to the specification of the device	refurbishment
Appropriate actions to avoid violation of privacy rules concerning patient data stored on the relevant medical device	Dedicated tool and validated process

5.2.3.5. Refurbished Medical device testing

Refurbished medical device testing includes an end-to-end analysis, assessment, and evaluation of the medical device to certify that it performs as intended, does not provide faulty information, and is fit for practical usage. Table 6 indicates examples of activities, information and resources needed on medical device testing.

Table 6: Activities, information and resources needed on medical device testing

Activity	**Information and resources needed (Example)**
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 device was refurbished according to the specification of the device	Device History Record of the device regarding refurbishment

5.2.3.6. Declaration of Conformity

When all necessary actions for refurbishment have been successfully completed, the refurbisher declares in the Declaration of Conformity (DoC) that the refurbished medical device is safe and effective as the original medical device. Table 7 indicates examples of activities, information and resources needed on declaration of conformity.

Table 7 Activities, information and resources needed on declaration of conformity

Activity	**Information and resources required**
Labelling- adding date of refurbishment	GRP Labelling tool for controlled labelling

and GRP-Label to the genuine labelling	according the labeling requirement stated in this guideline (Control refurbishment label design)
Updating the DHR to show evidence that the device was refurbished according to the specification of the device	Installed Medical device Database for tracking the medical device and ensuring optimized maintenance DHR of the device regarding refurbishment
Preparing the DoC	DoC

5.2.3.7. Labelling

Refurbishers of medical devices are required to indicate that the medical device contain, on its labelling, the word "refurbished". In addition, the label of refurbished medical device should contain:

- Name and address of refurbisher
- Date of refurbishment
- Validity date [the length of its prior use]
- Any upgrade, changed parameters, warnings/ precautions , limitations and methods from the original device should be indicated on instruction for use /user manual

It shall also comply with other labelling requirements as per the Guidelines for Medical Device Labeling and other relevant regulatory documents of the Authority.

5.2.3.8. Packaging and shipment of the Refurbished Device

The packaging and transportation of the refurbished medical device shall be according to instructions recommended the original manufacturer. Table 8 indicates examples of activities, information and resources needed on packaging and transportation.

Table 8: Activities, information and resource needed on packaging and transportation

Activity	**Information and resources needed (Example)**
Packaging of the refurbished	• Original manufacturer instructions for packaging

medical device	• Original manufacturer specified tools needed for packaging • Original packaging material of the manufacturer e.g. frames • Legal documents and medical device packaging and labeling of EFDA
Transportation to customer's site	• Original manufacturer instructions for transportation • Original manufacturer specified tools for monitoring transportation, e.g. shock and temperature indicators

5.2.4. Step 4: Installation of Refurbished Medical Device

Medical device refurbished according to GRPMD (indicated in this guideline) is intended to meet original quality, performance and safety standards. Hence, it is essential to follow the original manufacturer's installation procedures including site planning and preparation works. Table 9 indicates examples of activities, information and resources needed on reinstallation of refurbished medical device.

Table 9: Activities, information and resources needed on installation of refurbished medical device

Activity	**Information and resources needed (Example)**
Professional installation	All involved employees must be trained according to original manufacturer requirements
Start-up and repeated check-up of the system's performance	
Application training as contracted between customer and the refurbisher	
Hand-over of required user documentation and GRP Declaration	User documentation and GRP Declaration

Updating the DHR to show evidence that the device was refurbished according to the original manufacturer product specifications	DHR of the relevant medical device

5.2.5. 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. The below list are examples of activities required for professional services.

- Warranty
- Original 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 OF REFURBISHED MEDICAL DEVICES

When the refurbished medical device is to be placed in the market, the refurbisher shall ensure that the refurbished medical device complies with the Food and Medicine Administration Proclamation No 1112/2019 and subsequent regulation, directives and guidelines that are applicable to medical device.

7. TESTING, COMMISSIONING AND MAINTENANCE

Testing, commissioning and maintenance of refurbished medical devices shall comply with the manufacturers' instruction as per the original device manufacturer and other relevant national requirements applicable to installation, testing & commissioning and acceptance criteria of medical device.

8. APPLICATION REQUIREMENTS FOR REFURBISHED MEDICAL DEVICES

Submission of application for authorization of refurbished medical devices should follow the same procedure for new medical devices. An application shall be submitted by an applicant appointed by refurbisher or refurbisher itself to the Authority via eRIS. An applicant should submit applications of refurbished medical devices as per the requirements set in the guideline for registration Non IVD medical device and guideline for registration IVD medical device based on the category of refurbished medical device. The application submission should follow other relevant documents including guideline on grouping of medical devices of the Authority.

The application shall contain all elements required by the Authority, including, but not limited to:

1. Name and complete address of refurbisher
2. Name and address of original device manufacturer
3. Roles of the original medical device manufacturer
4. Establishment license of refurbisher issued by competent body
5. Names 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 the 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 5.2.3.5 of this guideline,
10. Declaration of Conformity from refurbisher
11. User documentation and Good Refurbishment Practice (GRP) Declaration

12. Local third party refurbisher who wishes to carry out refurbishment activities shall obtain establishment license as Manufacturer and shall be responsible for registration of the medical device through eRIS.
13. Third party refurbisher shall not use the brand name of the original manufacturer.

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

- Service instructions by the original manufacturer
- Device upgradeability documentation of the original manufacturer
- Original manufacturer instructions for system disassembly
- Original manufacturer product instructions for packaging
- Original manufacturer device instructions for transportation, including specified tools for monitoring transportation e.g. shock and temperature indicators
- Validated incoming inspection instructions, specified tools
- Original manufacturer product specifications including medical device configuration documentation
- Technical documentation for the planning of the refurbishment
- The PMS and vigilance reports of the refurbished medical device
- Technical documentation for the respective medical device.
- Requirements for cleaning and disinfection /sterilization/ decontamination as part of a validated refurbishing process
- Original manufacturer parts, components and accessories, original manufacturer user documentation in the English language or verified translation
- Updated DHR of the medical device regarding refurbishment
- Instructions per original manufacturer test specifications
- Test medical device and system check procedure

9. REFERENCE

1. Food and Medicine Administration Proclamation No 1112/2019; House of Peoples Representatives of FDRE, Federal Negarit Gazette, Addis Ababa, Ethiopia, February 2019.
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4. Guidelines for Medical Device Labelling, First Edition, Ethiopian Food and Drug Authority, Addis Ababa, Ethiopia April 2022.