FOOD AND DRUGS AUTHORITY

GUIDELINE FOR THE REGISTRATION OF USED AND REFURBISHED MEDICAL EQUIPMENT

Document No. : FDA/MCH/MDD/GL-RMD/2021/01
Date of First Adoption :
Date of Issue :
Version No. :

Table of Contents

ACKNOWLEDGMENT

In the development of this guidance document, the following resources were referenced:

a. The Common Submission Dossier Template (CSDT) of the Asian Harmonization Working Party (AHWP).
b. Medical Device Regulations of the Malaysia, Canada and Australia
c. Principles of Medical Device Classification: GHTF/SG1/N77:2012
d. The European Standards (Medical Devices)
e. MDA (Malaysia Medical Device Authority) Good Refurbishment Practice of Medical Device (GPRMD)
f. Principles of Conformity Assessment of Medical Devices: GHTF/SG1/N78:2012
g. The Medical Devices Regulations – Global overview and guiding principles of WHO

EXECUTIVE SUMMARY

The guideline aims to provide stakeholders with the regulatory framework for refurbished and used medical equipment in Ghana. Refurbished and used medical equipment market provides the avenue for cheaper access to healthcare delivery and reduces cost in developing countries where these equipment are donated or purchased for use.

The the relevant stakeholders include parts/components suppliers, original equipment manufacturers, industry associations, standard bodies, service providers, distributors and marketers.

The high cost of new medical equipment makes it almost imposible for healthcare facilities to procure highly sensitive medical equipment for diagnostics and effective healthcare delivery. As a result, healthcare facilities involved in diagnostics and treatment in developing countries rely on refurbished or used medical equipment for the diagnosis and treatment of patients.

To ensure safety, quality and performance standards of a refurbished or used medical equipment, regulatory oversight is important to ensure compliance with this criteria because most of these medical equipments are sold for use or donated to recipients who may not have adequate knowledge in the operation and performance of the medical equipment.

1.0 INTRODUCTION

Medical equipment constitute essential components in the delivery of effective health care. Thus, in a regulatory framework, the safety, quality and performance of medical equipment are important. Experts have estimated that new versions of medical equipment are introduced to the market periodically between 18 to 24 months following which they are sold as used, disposed or refurbished within or after the life cycle of the medical equipment.

To ensure the safety, quality and performance standards of refurbished or used medical equipment, regulatory oversight is important because most of these medical equipment are sold for use or donated to recipients in developing countries.

In pursuance of Section 148 of the Public Health Act, 2012, Act 851, this Guideline is hereby promulgated for information, guidance and strict compliance by all stakeholders on the procedure and requirements for the registration of refurbished medical equipment in Ghana. This guideline is applicable but not limited to medical imaging equipment and in-vitro diagnostic equipment. This guideline excludes medical equipment which are critical for life support.

This guideline must be read and used in conjunction with the enabling legislation, the Public Health Act, 2012, Act 851, Part 7, the current version of the FDA Guideline for Registration of Medical Equipment, and the FDA Guideline for Donation of Medical Equipment and other relevant Guidelines and Regulations issued by the Food and Drugs Authority.

2.0 SCOPE

This guidance document specifies the requirements for the registration of refurbished and used medical equipment intended for distribution in Ghana. Single use medical devices and equipment which are critical for life support are not covered under this guideline.

3.0 LEGAL BASIS

The core mandate of the FDA to maintain Public Health and Safety is enshrined in the Public Health Act, 2012 (Act 851) Sections 118, 122, 123 and 148;

Section 118 (1) 'A person shall not manufacture, prepare, import, export, distribute, sell, supply or exhibit for sale a food, drugs, herbal medicines, cosmetics, medical devices or household chemical substances unless the article has been registered by the Authority'

Section 122 (1) 'A person who has not been issued with a licence or permit under this Part, shall not import a food, drugs, herbal medicines, cosmetics, medical devices or household chemical substances'

Section 123 (1) 'A person shall not manufacture, import, export, supply, possess or offer for sale a counterfeit food, drugs, herbal medicines, cosmetics, medical devices or household chemical substances'

Section 148 (1) The Authority may issue guidelines and codes of practice in connection with food and drugs and any other products or devices regulated by the Authority to persons in the food and drugs industry and the persons shall comply with the guidelines and codes of practice

Section 148 (2) 'Without limiting subsection (1) the Authority may issue guidelines in respect of the following:

(c) for the regulation of importation or exportation of food, drugs, herbal medicines, cosmetics, medical devices or household chemical substances in order to ensure compliance with this Part.

4.0 GLOSSARY

In these Guidelines, unless the context otherwise requires, the following terms have the assigned meanings:

Authority: The Food and Drugs Authority, Ghana.

Manufacture: Includes all operations involved in the production, preparation, processing, filling, refining, transformation, packing, packaging, re-packaging and labelling of medical equipments.

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

Applicant: The product owner or licence holder. Representatives of licence holders may not hold themselves as applicants unless they own the product.

Authorised Local Representative (local agent): Every applicant who is not resident in Ghana shall appoint one local representative who must be a company incorporated in Ghana and authorized by FDA to import medical equipment.

Used Medical Device: medical equipments which are already on the market and have been 'pre-owned' and used, and subsequently 'sold on' or donated for the same continued use.

Refurbishing: a systematic restoration that ensures safety and effectiveness of the medical equipment without significantly changing the equipment's or system's safety, quality, performance, and/or changing intended use or its original specification". The restoration includes actions such as repair, rework, software/hardware updates, and the replacement worn out of new parts.

Refurbisher: a person/company that restores an equipment to a condition of safety and effectiveness that is comparable to a new medical equipment. This includes reconditioning, repair, installation of certain software/hardware updates that do not change the intended use of the equipment, and replacement of worn out parts.

Single-use Medical Equipment: Also referred to as a “disposable device”, intended to be used on one patient during a single procedure. It is not intended to be reprocessed/refurbished (cleaned, disinfected or sterilized) or used on another patient. Labelling should identify the device as single use or disposable and does not include instructions for reprocessing/refurbishing.

Medical Device or Devices: Refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is:

(a) Recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;

(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;

(c) Intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes

ACRONYMS

***GSA*:** Ghana Standards Authority

***IEC* :** International Electrotechnical Commission

***SUD*:** Single Use Devices

***ME* :** Medical Equipment

5.0 REQUIREMENTS

5.1 General

5.1.1 Principles of Good Refurbishment Practice

Medical Equipment intended for single use or designed as not eligible for refurbishment and does not meet, or cannot be refurbished to meet, the manufacturers initial specification shall not be refurbished.

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 comparable to the manufacturer's original standard.

The following criteria are considered important when considering the refurbishment of a used medical equipment:

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

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

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

ACTIVITY	INFORMATION AND RESOURCES REQUIRED (*Examples*)
Evaluate type, age and configuration of the medical equipment	Product service history, data of the Installed Medical equipment Database
Evaluating the condition of a medical equipment	Service records of the relevant equipment; site and incoming check instructions; service instructions by the manufacturer; equipment condition requirements that have to meet the refurbishment criteria
Evaluating upgradeability of software and hardware status	Device upgradeability documentation of the equipment manufacturer/availability of software update
Evaluating availability of spare parts and service	Spare parts and service availability

5.1.2. REFURBISHMENT PROCESS: DISMANTLING/DISASSEMBLY, PACKAGING AND SHIPMENT

5.1.2.1 Dismantling/disassembly

a) Dismantling/disassembly of fixed medical equipment shall be done in accordance with manufacturer instructions or by competent technical personnel.

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

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

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

5.1.2.2 Packaging and transportation

a) The refurbisher is responsible for developing instructions to make sure that refurbished medical equipment are not damaged during packaging or shipment. The purpose of this process step is to ensure that any medical equipment 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 packaging and transportation

ACTIVITY	INFORMATION AND RESOURCES REQUIRED (EXAMPLES)
Packaging of the used medical equipment	Manufacturer product instructions for packaging, including specified tools, packing material e.g. frames, etc.
Transportation to the refurbishment facility	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: Refurbishment

5.1.3.1 Decontamination and sterilisation

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

b. A used medical equipment can become contaminated when used in a clinical environment. The purpose of this process step is to make sure that any medical equipment 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 sterilisation.

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

ACTIVITY	**INFORMATION AND RESOURCES REQUIRED** (*Examples*)
Decontamination / disinfection / sterilisation	Instructions/Requirements for decontamination/ disinfection/ sterilisation as part of validated refurbishing process

5.1.3.2 Refurbishment planning

a. This process step depends on the medical equipment to be refurbished. The medical equipment configuration shall be defined either by the refurbisher or according to customer requirements. The final configuration of the refurbished medical equipment shall be within the scope of the manufacturers specification.

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 Medical Equipment History Record (MEHR) shall be continuously updated.

c. 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 of the medical equipment which can pose a potential risk. Due to the critical nature of the refurbishment process,

the refurbisher shall have reliable controls for this process step and have it defined in detail in the quality management system of the medical equipment.

d. A refurbished medical equipment that does not have the same intended use and specification after restoration shall be treated as a new medical equipment. The refurbishment of a medical equipment shall not compromise on safety, quality 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 equipment will be refurbished according to original manufacturer product specifications.	• Original manufacturer product specifications. • 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 equipment.
• Planning cosmetic, mechanical and electrical refurbishment as well as medical equipment configuration.	• Original manufacturer product specifications and documentation; e.g. medical equipment configuration documentation.
• Planning of medical equipment testing.	• Original manufacturer product specifications and documentation.
• Preparation of GRP declaration.	• Technical documentation for the respective medical equipment.
• 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

Cosmetic refurbishment is the process of improvement by cleaning, decorating and re-equipping. In general, refurbishment can encompass such works as 'cosmetic' renovations (such as painting and decorating).

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 specification of the original manufacturer regarding biocompatibility.

5.1.3.4. Mechanical and electrical refurbishment and medical equipment configuration

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

Table 7. Activities, information and resources needed on mechanical and electrical refurbishment and medical equipment 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 specification. • 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 MEHR to show evidence that the medical equipment was refurbished according to the specification of the equipment.	• MEHR of the relevant medical equipment regarding refurbishment.
• Appropriate actions to avoid violation of privacy rules concerning patient data stored on the relevant medical equipment.	• Dedicated tool and validated process.

5.1.3.5 Medical Equipment Testing

Medical device testing includes an end-to-end analysis, assessment, and evaluation of any medical device to certify that it performs as intended, does not provide faulty information, and is fit for practical usage.

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

Table 8. Activities, information and resources needed on medical equipment 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 equipment and system check procedure.
• Updating the MEHR to show evidence that the medical equipment was refurbishedaccordingtothe specification of the equipment.	• Equipment History Record of the relevant medical equipment 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 (DoC) that the refurbished medical equipment is safe and effective as the original medical equipment. 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) • Refer to Clause 8.
• Updating the MEHR to show evidence that the equipment was refurbished according to the specification of the equipment.	• Installed Medical equipment Database for tracking the medical equipment and ensuring optimised maintenance.
• Preparing the DoC.	• DoC.
• Updating the MEHR to show evidence that the equipment was refurbished according to the specification of the equipment.	• Equipment 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 equipment the advantage of a medical equipment that has the same quality, performance, safety and intended use as the initial specifications. 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 equipments. 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 equipment.	• 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: Reinstallation of refurbished medical equipment

Medical equipment refurbished according to Good Refurbishment Practice of Medical Devices (GRPMD) is intended to meet original quality, performance and safety standards based on ISO 13485 (Quality Management System), 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 equipment.

Table 11. Activities, information and resources needed on reinstallation of refurbished medical equipment

ACTIVITY	INFORMATION AND RESOURCES REQUIRED (Examples)
• Professional installation	• All involved employees shall be trained according to original manufacturer requirements.
• Start-up and repeated check-up of the medical equipment'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 MEHR to show evidence that the equipment was refurbished according to the original manufacturer product specifications	• Equipment History Record of the relevant medical equipment.

5.1.5. Refurbishing process: Professional services

The refurbisher shall provide after-sale services and support, identical to what is provided for new medical equipments. It is, thus, ensured that the user of the refurbished medical equipment will have the full necessary support of after sales services and spare parts available over the planned lifetime of the equipment. Table 12 indicates examples of activities required for professional services.

Table 12. Activities required for professional services

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

5.1.6 General Quality

- The applicant shall ensure that the used or refurbished medical equipment is fully operational at all levels, and that all essential accessories and supplies are available.

Documentation

- A checklist completed by the applicant to ensure that all parts, components, accessories, supplies (for initial operations) etc are included. Checklists are often found in operating manuals produced by the manufacturer or refurbisher.

- Operating and service manuals with part lists are critical to the usability of the used or refurbished equipment and should accompany the equipment in question.

5.1.7 Safety, Specifications and Standards

- Equipment should meet or exceed existing safety and performance specifications provided by the manufacturer, and where applicable, they should meet standards promulgated by international bodies such as International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and standards approved by Ghana Standards Authority (GSA).

- Equipment that has not been approved by the appropriate regulatory agency in the country of origin may not be accepted for registration.
- Equipment that is the subject of manufacturer recalls or hazard alerts shall be updated to the new requirements or not be accepted.

5.1.8 Registration

Where the refurbished equipment has been registered in Ghana by the FDA, the importer will be required to monitor the quality, safety and performance of the equipment and update the appropriate agency with the performance of the equipment.

5.1.9 Fees

All fees are specified in the current FDA Fee Schedule.

5.1.10 Sampling

Equipment would be verified on site and smaller equipments shall be in conformity with the FDA's samples schedule.

5.1.11 Letter

All applications for processing of medical equipment donations shall be made by submitting a letter addressed to:

The Chief Executive Officer, Food and Drugs Authority, P. O. Box CT 2783, Cantonments, Accra

5.1.12 Importer

An application for processing of medical equipment can be made by a manufacturer, a donor, or by an importer of the medical equipment. The personnel submitting this application would be responsible for the product and all issues relating to the equipment, including any information accompanying the equipment.

A non-resident personnel importing such equipment would be required to appoint a local agent with the requisite mandate to represent the said applicant. The agent would be required to produce the relevant documentation, or any other documentation, affirming his/her appointment as an agent for the equipment.

5.1.13 Local Agent

A local agent is a natural person resident in Ghana or a corporate body registered in Ghana, with the relevant mandate, to act on the non-resident applicant's behalf as regards matters relating to the registration of a medical equipment in Ghana. The Local Agent would, among other things:

5.1.13.1 Monitor the equipment and appropriately inform the Authority of any relevant issue relating to the equipment, including any serious manufacturing defects with the potential to endanger the safety and/or health of the patient, operator or any other person, or public health.

5.1.13.2 Facilitate communication between the non-resident applicant and the Authority on matters relating to the equipment.

5.1.13.3 Handle equipment recalls.

5.1.13.4 Provide technical support and services to users of the equipment(s).

5.2 SPECIFIC REQUIREMENTS

5.2.1 Refurbished Equipment

Refurbishers of medical equipment are responsible for restoring equipment to its original working condition, and are therefore subject to general principles of liability. Refurbishers are required to follow the Good Refurbishment Practice (GRP) established by their national authorities for manufacturers of medical equipment.

Such equipment are expected to be restored to the manufacturer's specifications.

‘Fully refurbished’ is considered to mean that an equipment has been completely rebuilt / made as new from used equipment and is assigned a new ‘useful life’. It would also be considered as a new equipment if a new intended purpose was assigned.

5.2.2. Requirements for Refurbished Equipment

- Document the source of all purchased equipment.
- Provide the requisite certificate of analysis (performance and safety test).
- Attach the Good Refurbishment practice (GRP) certificate of the refurbisher.
- Label the equipment with the refurbishers name and indicate that the equipment has been refurbished.
- Verify and document the operation of the equipment and the performance standards used to calibrate it (Operational and user manual).
- The refurbisher’s manufacturing license and a Certificate of Free Sale.
- Refurbishment plan
- Installation of performance update (if applicable)
- GRP Declaration (release)

5.2.3 Used Equipment

Normally these are medical equipment removed from service in hospitals in well-resourced environment, and donated to hospitals in less-resourced environment. Most of these never become operational. Where they are operational, however, most of these never work for any significant length of time. Again, in situations where they work, they can rarely be supported without adequate local arrangements for the necessary training, maintenance, spare parts, and user's and service manuals.

5.2.4 Requirements for Used Equipment

Document the source of all purchased equipment.

Document the components that were replaced in, and the repair services that were performed on the equipment. (Maintenance and service history of the medical equipment)

Submit and include the following:

- User Manual (Service and Maintenance)
- Installation manual
- Spare parts
- Training Manual
- Consumables
- Accessories
- Decommissioning report
- Maintain a customer complaint file and document the actions that were taken to resolve customer complaints.
- An Engineer's Report stating the status of the equipment, the reason for decommissioning the equipment and the functional status.

Damaged medical equipments which are imported for the intension of repairs locally for use are not acceptable.

5.2.5 On-site Verification and Validation

The precision and accuracy of medical devices including refurbished equipments are of utmost importance for the health and safety of patients. The effective use of refurbished medical equipment prevents dire consequences for patients. Optimum operating conditions are difficult to control in clinical settings, which affects the function of clinical equipment. Verification and validation is, therefore, necessary to determine a equipment's optimum operating conditions, safety, and efficiency.

The following documents are required for on-site verification and validation:

- Operational Manual
- Installation Qualification report
- Performance Qualification report
- Operational Qualification report
- Calibration Procedure (where applicable)
- Calibration Records (where applicable)
- Standards for Calibration (where applicable)

5.2.6 Radiation Emmiting (Radiological) Equipment

Due to the harmful effects associated with the use of radiation emitting medical equipment including refurbished equipment, the Nuclear Regulatory Authority (NRA) Act , 2015 (Act 895) mandates the NRA to ensure the protection and safety of humans and the environment from exposure to ionizing radiation from these equipment.

In order to ensure efficient regulation of radiological refurbished equipment in compliance with the Public Health Act, 2012 (Act 851) and the NRA Act, 2015 (Act 895), the FDA collaborates with the Nuclear Regulatory Authority, the National Authority mandated to certify the setting up and operation of diagnostic radiology facilities in Ghana.

As part of the requirements for the registration of refurbished radiological equipment, a radiation safety report from the NRA is thus, required to be submitted for evaluation by the FDA to demonstrate compliance of the equipment to the Public Health Act, 2012 (Act 851).

5.2.7 Disposal of Medical Equipment

a) Equipment contaminated with biological, chemical or other hazardous materials. Disposal of such equipment must comply with environmental laws that govern the discharge of contaminants into the natural environment.

b) Equipment associated with workplace hazards. Disposal of such equipment must comply with occupational health and safety laws that govern workplace safety.

c) Equipment with stored patients' personal health information. Disposal of such equipment must comply with health privacy laws.

d) Equipment associated with radioactive components. Disposal of such equipment must comply with the unique legislative regime governing such equipments (Ghana Atomic Energy Regulation)

6.0 TIMELINES

A minimum period of 3 (three) months is to be allowed for the completion of the process.

7.0 SANCTIONS

A person who contravenes these Guidelines or sections thereof is liable to regulatory sanctions per Sections 119 and 132, Part 7, Act 851, the Public Health Act, 2012 which

shall be imposed by the Authority. These sanctions may include, but not limited to, any of the following:

7.1 Suspension of the processing of a pending application for donation.

7.2 Suspension of the processing of a pending import license application.

7.3 Cancelation of an import license

7.4 Payment of administrative charges as per the current Fees and Charges (Amendment) Instrument.

8.0 PENALTIES

In line with the provisions of Section 129, Part 7, Act 851, the Public Health Act, 2012, a person who contravenes these Guidelines commits an offence and is liable on summary conviction to a fine of

8.1 not less than seven thousand five hundred (7,500) penalty units and not more than Fifteen thousand penalty units (15,000), or

8.2 to a term of imprisonment of not less than fifteen years and not more than twenty-five years, or

8.3 to both.