ETHIOPIAN FOOD AND DRUG AUTHORITY (EFDA)

Guideline for Decommissioning and Disposal of Medical Devices

First Edition

March 2022

Addis Ababa, Ethiopia

Table of content

Acronyms

EFDA	Ethiopian Food and Drug Authority
MoH	Ministry of Health, Ethiopia
SAPHE	Sustaining and Accelerating Primary Health in Ethiopia
IVD	In vitro diagnostic
WHO	World Health Organization
EIA	Environment Impact Assessment
Ni-Cd	Nickel Cadmium
SSLA	Small Sealed Lead Acid
SuMD	Single use Medical device
IP	Internet Protocol
PVC	Polyvinyl Chloride

Acknowledgement

Ethiopian Food and Drug Authority is very grateful to those who have participated directly or indirectly in preparing this Guideline. The Authority would like to express its special thanks and appreciation to all members of the Medical device technical working group who have dedicated their time, energy and resource to contribute to develop this Guideline from its drafting until its approval.

Last but not least, it also thanks the technical advisors from SAPHE and others for their very important contribution for the development of this document.

1 Introduction

Medical devices are essential components of the health care system and are crucial in the prevention, diagnosis, and treatment of disease and in rehabilitation. However, medical devices that no longer meet specifications and inoperable (e.g., expired, contaminated, damaged, defective, etc.), or that are no longer needed due to obsolescence, or that have met a scheduled replacement milestone or that have been confiscated because of illegal trade should be decommissioned or disposed of properly. Medical devices decommissioning is usually the first physical process in the disposition process and includes proper identification, authorization for disposition, and sanitization of the equipment, as well as removal of patient health information or software, or both. Article 4 (4) and 4 (17) of proclamation 1112/2019 decree that the authority has the power to order the disposal of regulated product that is not in compliance with this proclamation or other law issued to implement this proclamation and to ensure proper disposal of the products in collaboration with appropriate bodies. The authority is also responsible for ensuring appropriate decommissioning or disposal of confiscated medical devices. The disposal method is dependent upon many factors based on the type of medical device to be disposed. Methods of decommissioning may include but not limited to disposal, incineration, return to product owner (radiation devices), reuse, refurbishment, donation, sale, etc.

Therefore, this guideline is intended to establish control system to ensure that the medical devices meant for decommissioning are properly handled and those for disposal are not made available for illegal resupply to the market, and they are decommissioned or disposed of in accordance with standardized procedures and in line with the manufacturer's instructions.

2 Scope

This guideline is applicable to all medical devices and all parties involved in the supply chain of medical devices including manufacturers, importers, wholesalers or retail outlets of medical devices, both public and private health institutions as well as responsible entities engaged in the medical devices decommissioning or disposal in Ethiopia. It is also applicable to decommissioning/disposal of medical devices confiscated by the custom and revenue authorities and police officers. This guideline is not applicable to management of other health care wastes (other than medical device wastes) generated by health institutions.

3 Objective

The objective of this guideline is to set out proper management procedures and requirements for medical device decommissioning/disposal to prevent use of unsafe, poor quality and/or ineffective medical device to ensure public health protection.

4 Definitions

Authority means Ethiopian Food and Drug Authority.

Controlled landfilling means operating practices and design improvements subjected to a permit system and technical control procedures in accordance with the Ethiopian Environmental Protection legislation to reduce the health and environmental impacts of waste disposal in landfills.

Decommissioning means removal of medical devices from their originally intended uses in a health care facility to an alternative use or disposal.

Decontamination means removal of soil and pathogenic microorganisms from objects to make them safe to handle, subject to further processing, use or discard.

Disposal means intentional burial, deposit, discharge, dumping, placing or release of any waste material into or on air, land or water without the intention of retrieval. In the context of radioactive waste management, disposal is the placement of waste in an approved, specified facility (e.g. near-surface or geological repository) or approved direct discharge into the environment.

Donation means giving an item or service free of charge.

Hazardous waste means a waste that is potentially harmful to human beings, property or the environment, such as used reagent strips contaminated with human blood, reagent solution containing sodium oxide and decommissioned instruments containing heavy metals, including waste that is inflammable, combustible, ignitable, corrosive, toxic, reactive, injurious or infectious.

Health institution means hospitals, health centers, health posts, clinics, diagnostic centers and other related facilities which involve in diagnosis and treatment of illnesses.

Health care waste means waste generated at health care facilities, such as hospitals, clinics, physicians' offices, dental practices, blood banks, and medical laboratories. Generally, such wastes may be contaminated by blood, body fluids or other potentially infectious materials.

Incineration means the high temperature burning (rapid oxidization) of wastes.

Media sanitization means a process that makes access to the data on media impossible.

Nonhazardous waste means a waste that does not pose a biological, chemical, radioactive or physical hazard.

Professional service means a service requiring specialized knowledge and skill usually of a mental or intellectual nature and usually requiring certification.

Radioactive waste means a waste containing radioactive substances.

Reassignment means the transfer of a medical device internally or externally to another unit or facility.

Recipient means a person or institution who receives donated medical devices.

Recycling means converting waste into a reusable material or returning materials to an earlier stage in a cyclic process. Note that recycling is distinct from reuse.

Refurbishing means reconditioning medical devices for safety and effectiveness with no significant change in their performance, safety specifications or service procedures as defined by the manufacturer and their original intended use.

Reprocessing means steps performed to decontaminate a reusable or single-use device for use in patients, including cleaning, functional testing, repackaging, re-labelling, disinfection or sterilization.

Responsible entity means public or private companies registered for reliable functions by the national laws and for this guideline that can execute or process the medical device disposal/decommissioning.

Risk assessment means the overall process of hazard identification, risk analysis and risk evaluation at health institution and institutions to identify those things, situation, processes, etc., that may cause harm, particularly to people and environment.

Sterilization means a validated process to render an object free from viable microorganisms, including viruses and bacterial spores.

Trade-in means a return of a medical device (sometimes partial) as payment for a replacement.

Vendor means an individual or company that supplies goods and services to businesses or customer.

5 General principles

1. Decommissioning of medical devices might include disposal, and reuse which offers manufacturers new opportunities.
2. The primacy of the medical devices' disposal method should be intended to protect patients, health care providers and the public who come into contact with the material being disposed of.
3. Health institutions may devise different strategies to dispose medical devices in the cases of unanticipated pressures resulting from the ongoing pandemic and the increasing amounts of medical devices waste they must dispose of.
4. Medical devices that are manufactured from high-quality materials, such as metals, plastics, and combinations of the two, would be better to reuse, recycle, or even refurbish rather than sending them to landfill or incinerating them so as to conserve natural resources and minimize the environmental impact of the waste.
5. The handling of used, infectiously or noninfectiously contaminated medical devices in health institutions should be in accordance with the national regulations that give priority to occupational public health protection and occupational health and safety.
6. If the vendor or provider no longer services a medical device, the owner of the device should appropriately assess the requirement for the safety and performance of the medical device and decommission it.
7. Outdated or obsolete packaging material or printed medical devices packaging material should be destroyed, and the disposal should be recorded.

6 Medical Devices decommissioning or Disposal methods

6.1 General requirement for disposal or decommissioning

1. All applications for decommissioning/disposal of medical devices should be submitted to the authority and be accompanied with lists of devices to be decommissioned/disposed (please refer annex 1). Applicants should state the device name, strength (where applicable), pack type and size, quantity, model/serial number, batch/lot number, expiry date (where applicable), manufacturer, supplier, country of origin, and product price.

2. The applicant should pay service fee for decommissioned/disposed medical device in accordance with the rate of service fee regulation.
3. Medical devices that no longer meet specifications, inoperable or unfit for use should be stored in segregated and secured area and they shall not be stored for more than one year.
4. Any entity that is engaged in the disposal/decommissioning of medical devices should get approval and authorization from responsible public agency to provide such services. The authority and/or an appropriate organ ensures the proper disposal/decommissioning of expired, unusable, unfit for use, and/or damaged medical devices by such authorized entities.
5. The appropriate option for decommissioning of medical devices should be selected by the owner of the device and verified by inspector or responsible representative from an appropriate organ (regional regulatory body, MOH, etc.).
6. For medical devices returning to its country of origin as a result of failure to meet national law and standards for quality, safety, and performance, the manufacturer or importer of a medical device is responsible for all processes and related costs.
7. For medical devices that are to be disposed by landfill or incineration, the disposal sites shall be environmental and society friendly and shall be approved by appropriate organ in accordance with Environment Impact Assessment (EIA).
8. When decommissioning or disposal is outsourced to a third party, the copy of decommissioning/disposal service request letter sent to a licensed decommissioning/disposal firm should be submitted to the authority or an appropriate organ by the applicant. In such instances, they should sign contractual agreement with licensed firms that have the capability and the resources for the devices to be decommissioned/disposed.
9. Any party that is engaged in the decommissioning/disposal of medical devices should ensure that security measures are in place at disposal sites and temporary storage areas to prevent scavenging of the disposed medical devices.
10. Medical device manufacturers, suppliers and health institutions who have their own disposal facilities or capabilities to carry out other decommissioning processes should get approval from the responsible public agency.

11. The disposal process of medical devices shall comply with this guideline and other relevant national and/or international laws to ensure occupational health and accident prevention as well as public health protection and infection control.
12. The applicant who initiated the decommissioning/disposal request should retain appropriate records and should seek a disposal certificate/approval for decommissioning from the authority (see annex II) or an appropriate authorizing organ after disposal/decommissioning of the medical device by a suitable method.
13. The authority and/or an appropriate authorizing organ should issue certificate for the proper disposal of medical devices and attach list of disposed items.

6.2 Prelusive requirements for disposal or decommissioning

The responsible entity should follow appropriate procedures and steps during decommissioning or disposing of medical devices depending on the type of medical device and the option chosen for decommissioning it. The options may be device disposal, donation, sale, refurbishing or reprocessing, cannibalization, trade-in, or internal reassignment. The firm preparing for decommissioning/disposal should ensure availability of the following resources and procedures:

- Personnel
- Infrastructure
- Risk analysis
- Removal of patient data
- Decontamination

6.2.1 Assigning Personnel

1. The firm should categorize personnel who should be responsible for assessing risks, as well as for ensuring proper and safe decommissioning/disposal of the devices. It should also provide guidance on decommissioning to these personnel. The members of the decommissioning/disposal committee should, as appropriate, include:
    - Firm managers and regulatory staff.
    - Safety officers, biomedical engineers, radiographers, laboratory technologists, medical doctors, pharmacists, and nurses.

- Storekeeper, finance personnel, waste handlers and drivers.

2. The firm should ensure that members of the decommissioning committee are qualified, trained, and competent in the processes and are relevant for the medical device to be decommissioned/disposed to guarantee safe decommissioning of the medical devices and minimize incidents that may harm them, the public and/or the environment.
3. Every firm should establish and implement standard procedures for disposal of used medical devices. Such procedures should include the roles and responsibilities of health care workers in waste management, and technical instructions on their application. When hazardous material is involved, the firm should provide appropriate personal protective equipment for all personnel engaged in the preparation for disposal.

6.2.2 Risk Assessment

Institutions should assess risks to determine the best course of action in relation to the personnel and infrastructure available. In addition, risk assessments done by the responsible entity in relation to medical devices decommissioning should take health and safety of the patients, the public, the environment, and the health care workers into consideration. A comprehensive plan should be outlined for the mitigation, transfer or monitoring of any risk. The procedures and steps taken should ensure that:

- the device is safe for handling and treatment or removal,
- it is cleaned and decontaminated (as appropriate) prior to disposal,
- all patient data are removed, and
- all consumable parts are disposed of (if relevant).

The institution should document and retain records of all the stages and the end status of the device in a report for future reference. After completing all the decommissioning steps, the firm should remove the device from the asset registry and retain a “decommissioning document”.

6.2.3 Identifying Infrastructure

The institution should identify the type of infrastructure required for decommissioning medical devices based on the size and nature of the device to be decommissioned/disposed. The infrastructure required for decommissioning of medical devices should be proportionate to the size and risk related to the device. The firm should ensure availability of essential infrastructure when decommissioning large devices such

as computed tomography scanners, linear accelerators, X-ray machines, magnetic resonance imaging scanners, steam sterilizers, etc. Appropriate individuals, such as a qualified contractor, department manager, facility manager or the original manufacturer, should be engaged to ensure safe removal of the device.

The firm should ensure availability and adequacy of special equipment and transports that may be required for decommissioning large and heavy medical devices. It should also devise appropriate mechanism to take out bulky equipment, including reenforcing of a passage or widening or destroying of walls. Components of large devices such as screens, cameras and other components must be considered in decommissioning the main device.

The time required to decommission a large device should also be taken into consideration and planned, consulted with the equipment planner in close collaboration with the staff of the unit. When necessary, the firm should foresee the need for protection and signalization for patients.

For medical devices containing hazardous material, emergency equipment must be functional, accessible, and available. The firm should, as appropriate, fulfil necessary equipment such as fire extinguishers, eye wash, emergency showers, ventilation, and spill kits. Consideration should also be given to potential escape of gases such as helium gas. Decommissioning of higher-risk medical devices should be undertaken by experienced contractors.

6.2.4 Removal of patient data

The institution should have a policy and/or procedure for protecting sensitive information and patient confidentiality. Removal of patient data and information stored in the medical devices should be carried out in accordance with the procedure and by assigned person responsible for erasing or removal of such information before a medical device is decommissioned (regardless of its end status).

If the device is identified for disposal, media sanitation may include destruction of confidential data and software registered to that device. Medical devices believed to contain data can be sent to a biomedical or clinical engineer who can use proven procedures to erase the data thoroughly.

If the device is configured to cloud storage, the Internet Protocol (IP) pathway connecting the device to the cloud needs to be deactivated. Additionally, the data stored on the cloud of the device needs to be either deleted or made part of the Electronic Record System such that access to such data including images captured by the device (now planned for decommissioning) is either preserved by another

pathway or deleted. The firm should ensure that such steps eliminate the probability of data loss or data misuse once the device has been decommissioned.

6.2.5 Decontamination of devices

Responsible entity should develop and implement procedures for decontaminating both single-use and reusable medical devices before decommissioning. All used or potentially used medical devices must be cleaned as per the instructions specific for the device or type of device. The firm should follow the basic steps and instructions during cleaning and disinfection as listed below, but not limited to:

6.2.5.1 Disassembling

The devices should be disassembled and sorted, as appropriate, before decommissioning. Any consumables and sharps must be removed and properly disposed of according to health care waste management procedures.

6.2.5.2 Cleaning

After disassembling and sorting**,** the device or its parts should be cleaned with a compatible and appropriate cleaning agent such as a detergent (alkaline or pH-neutral) or enzymatic solution. The cleaning method should ensure removal of air pockets and prevent aerosolized transmission of infection. Submerging in water and rubbing, scrubbing, or brushing or following other imperative instructions could be used to ensure the device cleaning. Once the device has been cleaned of debris, it should be thoroughly rinsed with detergent and inspected.

For grossly soiled devices, cleaning should be carried out manually before being processed in a mechanical washer.

If mechanical washers are used, the type of washer (disinfectors and ultrasonic washers) used to increase the effectiveness of cleaning should be designed to remove microorganisms by cleaning and rinsing thermally or chemically and/or cavitation.

6.2.5.3 Disinfecting

Devices that are not intended for immediate reuse (e.g. for relocation, trade-in, donation or disposal) should, at a minimum, be thoroughly disinfected thermally or pasteurized after thorough cleaning. Sterilization is recommended and preferred for complete removal of microorganisms.

6.2.6 Waste management

The firm should develop and implement a comprehensive health care waste management system that includes medical devices waste to ensure safety and to minimize effects on the health care workers, the population, and the environment. Such a comprehensive system should at least include:

- waste generation and minimization,
- separation and segregation of sources,
- identification and classification of wastes,
- handling and storage,
- packaging and labelling,
- transport on site and off site,
- treatment,
- disposal of residues (including emissions),
- consideration of occupational, public and environmental health and safety,
- stakeholder and community awareness and education, and
- use of improved technologies and environment-friendly practices.

6.3 Selection of appropriate decommissioning/disposal methods

Responsible entity should choose the best options for decommissioning based on the type of medical device, the risk assessment, volume of device to be decommissioned/disposed and related costs. Medical devices can be decommissioned/disposed by landfill, incineration, sewerage, return to the country of origin, or reuse.

6.3.1 Waste categorization, segregation, and treatment

Medical devices for decommissioning or disposal should be categorized as either hazardous or nonhazardous and the firm personnel must be trained in procedures for managing all types of such medical device.

Medical devices should be sorted according to treatment methods, the source of the waste (i.e. ward, operation theater, laboratory, bedside, etc.) and disposal requirements.

Medical devices must be treated to reduce potential health and environmental hazards prior to disposal. Selection of the treatment method should take the following into considerations:

1. type and quantity of medical devices for treatment and disposal,
2. capability of the health care facility to handle the quantity of medical device for disposal,
3. local availability of treatment options and technologies, skill in using the technology, installation requirements,
4. availability of space for equipment and infrastructure,
5. operation and maintenance requirements,
6. environmental and safety factors,
7. location and surroundings of the treatment site and disposal facility,
8. occupational health and safety,
9. public acceptability,
10. options for final disposal,
11. regulatory requirements, etc.

In view of these considerations, medical devices may need to undergo thermal, chemical, radiation, biological or mechanical treatment. Hazardous (infectious) medical device waste should be disinfected or sterilized to minimize potential disease transmission.

An appropriate option should be chosen from one of the following treatments for infectious waste:

1. steam treatment (autoclaving),
2. integrated steam treatment (hybrid autoclaves or advanced steam treatment),
3. microwave treatment,
4. dry heat treatment,
5. chemical treatment (internal shredding or chemical disinfectants), and
6. combustion, pyrolysis, or gasification.

These treatments can be supplemented by shredders, grinders, and compactors.

6.3.2 Disposal

1. The product owner or disposing firm should use details of the current techniques and processes applicable to dispose the device provided by the manufacturers.
2. All responsible entities engaged in the disposal of medical devices should establish and implement disposal procedure that includes the pre-stages of disassembling medical devices to be disposed. The procedure should guide how to choose the best method for disposal of medical devices, which may be undertaken by burial, deposit, discharge, dumping, placing or release of any waste material into or on air, land, or water.
3. Disposal of radioactive medical device wastes should be in accordance with the Radiation and Nuclear Protection Proclamation (Proclamation No. 1025/2017) and should get approval from the Ethiopian radiation protection authority.
4. All disposal procedures should ensure prevention of the intention of retrieval and untreated medical waste should not be disposed in municipal landfills.
5. Any health institution that carries out disposal of medical device waste on site should fulfil the necessary infrastructure at its facility and must possess trained personnel.

6.3.2.1 Controlled Landfills

1. Discarding of medical devices waste by landfills should be undertaken in controlled dumps to minimize scattered deposition of wastes that may lead to acute pollution, fires, high risks of disease transmission and open access to human and animal scavengers.
2. The disposing responsible entity should exercise controlled landfilling practices and improved design to reduce impacts on health and the environment.
3. As appropriate, in addition to treatment of medical device waste before disposal, there should be an improved engineering standards to ensure geological isolation of waste from the environment to:
    a. minimize contamination of soil, surface water and groundwater,
    b. limit atmospheric releases and odors,
    c. block access to waste by pests and vectors, and
    d. prevent contact of the public.

6.3.2.2 Burning in open containers/area

Medical device packaging materials, papers, leaflets, labels, and posters may be disposed of by burning in open containers/area. However, PVC materials shall not be disposed of by such methods.

6.3.2.3 Sewerage

Only medical device (chemical) wastes approved for drain disposal by the authority and/or Environmental Protection Agency may be disposed of down the drain. The list of medical device waste (chemicals) that may be disposed of by sewer as well as the permitted dilutions will be prepared by the authority and updated on a regular basis.

6.3.3 Incineration

1. For medical devices that are disposed of by incineration, the incinerator should guarantee that all potentially dangerous germs and other biogenic contaminants on medical device waste from health institutions are rendered harmless.
2. The firm involved in the disposal activity should ensure that the thermal treatment plant is adequate for the devices to be incinerated.
3. The firm should choose the method for incineration depending on the type and volume of medical device to be disposed. Sharps (injection cannulas, scalpels, curettes), e.g., are considered hazardous waste and, therefore, must be collected separately from other waste in special, type-tested containers. Provided that the containers remain securely closed, this waste can then be mixed with nonhazardous clinical waste, which can then be disposed of in waste-fed heating and power plants with no other special requirements.
4. The high-temperature incinerator used for incinerating medical device waste should be proportionate with the type of the device (800 to 1,200^{o}c).

6.3.4 Return to the country of origin

1. Return to the country of origin is the best recommended option for decommissioning/disposal of medical devices. This is especially applicable for special medical device wastes such as radioactive wastes, wastes containing certain metals (e.g. mercury above 3%), some batteries, wastes from coolants and all medical devices which cannot be disposed of/decommissioned locally.
2. For devices that must return to the country of origin, the responsible local entity should include returning the devices to the manufacturer’s country of origin during signing an initial agreement with

the manufacturer. The agreement should also include transportation and shipment modalities and periodic checks should be made with the manufacturer to ensure that the agreement is still valid.

3. Items returned to the manufacturer's premises or country of origin for disposal /decommissioning should be decontaminated beforehand.
4. When returning medical devices to the manufacturer for decommissioning at end of life, or due to some other reasons, the responsible entity should ensure that they are appropriately packaged and secured. Issues that should be addressed include strength of packing materials, protecting sharp edges, ensuring the device is not damaged in transit, etc., to minimize any risk to the shippers, public and the environment.

6.3.5 Reprocessing and reusing materials

1. Single-use medical devices shall not be reprocessed as they do not come with appropriate instructions for cleaning, disinfection or sterilization after use, and the manufacturer has not investigated whether their safety and performance deteriorate if they are reprocessed.
2. Medical device can be recycled, when:
    a. It is possible to separate the used medical devices materials and reuse the materials. E.g., steels in surgical instruments and explants would have to be melted down and recycled.
    b. The devices are made of a small number of different materials and their design allows them to be easily disassembled into their individual components.

6.3.6 Refurbishment

1. Refurbishment is one of the medical devices decommissioning option that is considered an effective way of preventing waste and saving resources.
2. Although medical devices refurbishment is a more economical alternative to purchasing a new one, not every medical device can be refurbished, and careful assessment and selection criteria must be used.
3. Removal of device for decommissioning should get a permit from the authority, and it should be labelled as such and meet all requirements stated in the proclamation 1112/2019 after refurbishment.
4. The device intended for refurbishment must fulfil the basic requirements and eligibility criteria stated in the authority's subsequent directive/guidelines and other national and international regulatory requirements and standards.

5. Devices intended for single use or designed as not eligible for refurbishment should not be refurbished.
6. The refurbishment process must ensure that the reprocessed medical device does not pose any risk of damage to health during subsequent use, particularly regarding infections, pyrogen-induced reactions, allergic reactions, toxic reactions or any altered technical or functional properties.
7. The refurbishing process undertaken for reconditioning used medical devices should not introduce undesirable changes in their performance, safety specifications or service procedures as defined by the manufacturer and its original intended use.
8. The entity responsible for refurbishing or the third party should meet the same regulatory requirements as applied to the original medical device. The refurbished medical devices should meet the same requirements of safety, quality, and performance as the new devices manufacturer's specification.
9. As for any medical device, the manufacturer's instructions for use should be followed. If there are no validated instructions, they should be obtained from the supplier or manufacturer. Copies of user and maintenance manuals should be available and accessible to personnel and updated as required.
10. If the medical device has been determined to be safe for refurbishment by the authority, it must be decontaminated, cleaned, dried, tested for functionality, repackaged, relabeled, disinfected, or sterilized before it is returned to service.
11. A medical device refurbishing entity should develop, validate and implement instructions for refurbishing and minimizing the risk of infection posed by the devices. E.g., "class II" risk devices should ideally be thoroughly cleaned and decontaminated and then sterilized, thermally disinfected or pasteurized, while "critical devices" should be thoroughly decontaminated, cleaned, dried, repackaged and relabeled before sterilization, including steam sterilization method.
12. Devices that cannot withstand heat can be sterilized chemically with hydrogen peroxide, ethylene oxide, peracetic acid or ozone or others as per the manufacturer's written instructions.
13. To minimize and prevent damage to devices, they should be handled in small lots. Items with sharp edges should be protected to prevent damage and harm to the user, while delicate items should be separated from heavy items and protected to prevent damage.
14. Firms that are engaged in the refurbishing of medical devices should fulfil the below (Figure 1) recommended five steps of medical devices refurbishing process.

Figure 1. Recommended steps for refurbishing process

6.3.7 Donation

"Donation" in this guideline refers to designating a medical device as an aid within the country, generally free of charge for the recipient.

1. Medical devices can be donated only when their safety and performance conditions can be met. E.g., a tertiary hospital may consider donating medical equipment directly to a primary hospital or to a health center, usually on agreement.
2. The donor will be responsible for preparing the equipment for reuse and assigning the device to a health facility that has sufficient capacity and means to use the device. Medical devices should be cleaned and disinfected before being donated.
3. There must be clear communication between the donor and the recipient before, during and after the donation by all means available to ensure active, responsible involvement of both parties and mutual benefit. The communication should ensure that needs are met, infrastructure is set up, and medical and biomedical human resources, material resources, financial resources and transport are coordinated.
4. The donor should provide the history and documentation of the device and all available information on its condition to guide the recipients in installing, using and maintaining the donated material, especially electrical and electronic medical equipment.
5. The recipients should be involved in all stages of donation including prioritizing donor offers according to their needs and capacity (e.g. access to water, stable electrical supply).
6. For donations made from abroad, which is out of the scope of this guideline, both donors and recipients should adhere to the national regulations for exporting and importing medical devices as well as the authority's directive for medical devices donation.

6.3.8 Sale

1. Any health institution that has an intent to decommission medical device by sale should submit device-specific application supported by justified reason for sale to the authority or regional regulatory body prior to transfer of the device.
2. Medical devices that are transferred or sold to another health care facility as a decommissioned device, within the country, should be done in accordance with this guideline and other relevant national regulations.
3. When a medical device is intended to be sold as a second-hand device to a health care facility in a lower-resource setting, the procurer should ensure that reuse, training, and maintenance of the device are compatible with its infrastructure and resources.
4. The person responsible for the sale of a second-hand medical device should provide medical device history file and a previous technical certificate that proves the medical device has been maintained regularly. This certificate should mention the indications necessary for identifying the medical device and the date of first commissioning or, if the device has never been used, the date of first acquisition.
5. Sold medical devices should be transported and delivered with all necessary accessories in a safe way.

6.3.9 Trade-in

1. Medical devices that are procured on a lease or on loan may be returned to its vendor at a predetermined value towards the purchase of a new device or upgrade.
2. This service may be used particularly for devices that require intensive maintenance or rapid technological upgrades.
3. The responsible entity should consider and calculate the cost-benefit of a trade-in service at the time of procurement.
4. The responsible entity engaged in such service should ensure that the benefits of establishing a trade-in plan with a medical device supplier includes:
    a. removal and decommissioning of the device by the supplier,
    b. provision of a new or upgraded device to better serve the user’s needs, and
    c. guarantee economic benefits.

5. Trade-in should ensure replacement of eligible device when it reaches the end of its useful working life, becomes obsolete or is damaged.
6. Responsible entity engaged in trade-in should set the service and warranty terms and conditions before contacting the device supplier. Often, a device can be traded in for an equivalent replacement or an upgrade with a revised lease agreement. Alternatively, an agreement may be established with another supplier who will take responsibility for removing and decommissioning the existing device after procurement of a new one.

6.4 Single-use vs. reusable medical devices

6.4.1 Single-use devices

1. Single-use medical devices (SUMDs) refer to disposable devices that are intended to be used on one patient during a single procedure and which shall not be reprocessed or used on another patient. Their labelling should include a characteristic symbol for single-use products and no instructions for reprocessing.
2. These devices should be disposed of in a way that ensures the highest standard of patient safety, and their disposal should ensure preventing intentional retrieval.

6.4.2 Reusable medical devices

1. Responsible entity should establish and implement procedure for appropriate means of decommissioning reusable medical devices that are designed to be used on more than one patient. This procedure should clearly specify the final fate of the decommissioning whether it is to be disposed, donated, sold, traded in, for internal reassignment, refurbished, or upgraded. It should also include both external or internal reassignment of a medical device within the health care system.
2. The relocating entity should ensure that the performance of the device is acceptable and reliable before relocation to another department that needs it.
3. Both the relocator and recipient of the device should ensure that the device qualifies for reuse based on a lower acuity application, availability of training, maintenance, and other resources. Examples of relocating or reassignment of medical devices are:
    a. relocating a patient monitor from an emergency department to a general ward,
    b. relocating devices to a biomedical department for reuse as substitutes or spares, and

c. recycling parts and modules that function properly and have a viable application in existing systems. This is sometimes termed “cannibalization” and is often done by biomedical technicians to ensure a source of spare parts and modules, which is valuable in locations where parts are difficult and expensive to procure.

4. In the case of relocating circuit boards, responsible entity should ensure compatibility of part numbers and software revision.
5. All reusable devices must be decontaminated before any of the decommissioning actions.

7 Special cases of medical devices decommissioning

Some medical devices such as sharps, devices containing mercury or radioactive sources, IVDs and laboratory devices, chemicals, implants, assistive devices and computer hardware and software require special care during decommissioning. Location of these devices should be subject to safety and security as well as access for disposal by others.

7.1 Sharps

1. Sharps or pointed objects and materials that can cause injury and/or infection are classified as single-use medical devices. Examples of medical device sharps include syringes, needles, lancets, pipettes, glassware, etc.
2. Health institutions should use sharps with safety devices when available. The safety device should be activated immediately after use, and the whole object should be discarded to prevent the risk of injuries.
3. All sharps require cautious waste management and should be decommissioned by disposal.
4. Appropriate procedure for management of all sharps should be established to minimize the risk of infection with communicable diseases. Examples could be sharps used on patients, in isolated wards and from laboratory waste.
5. All needles and syringes should be organized from collection point to destruction. They should be stored in a labelled, puncture-proof, leak-tight container after use and separated from other waste. Only trained personnel should have access to storage of these wastes. Alternatively, other practices such as use of needle cutters, pullers or destroyers to remove needles from syringes may be practiced. Personnel should not manually bend or break needles.

6. Leftover syringes should be placed in containers, and the containers with syringes can be transferred to a treatment facility or be destroyed before being released to the environment from an incinerator, if this service is available in the health care facility.
7. The following steps should be followed for treating sharps waste:
    a. Activate the safety device and/or separate needles from the syringes with a needle cutter or needle destroyer.
    b. Decontaminate and sterilize needles and syringes in an autoclave.
    c. Shred needles and syringes in an incinerator, if available.
    d. Bury sharps in sharps pits or concrete vaults.
    e. Melt the plastics for recycling.

7.2 Devices containing mercury

1. Mercury is a heavy metal that evaporates easily into the atmosphere, and people may be exposed by breathing air containing elemental mercury vapors. Inhaled elemental mercury vapor can have harmful effects on the nervous, digestive and immune systems, and lungs and kidneys. Mercury waste is a great concern globally since mercury released into the environment can be transformed by bacteria into methylmercury, which is toxic to the nervous system and a concern for developing fetuses.
2. Waste medical devices are one source of mercury in the atmosphere. Hence, responsible entity should ensure sound management of mercury-containing devices to address the health aspects of exposure to mercury and mercury compounds and to prevent its negative health impacts. Such devices include sphygmomanometers, thermometers, dental amalgams and batteries.
3. Care must be taken in all steps of handling devices that contain elemental mercury, from collecting and storing to transporting the devices and their disposal.
4. Any mercury spill from broken devices should be removed immediately by proper procedures to avoid inhalation by health facility staff. Responsible entity should provide kits and guidelines for cleaning up spills of mercury in a proper and safe way. The responsible users and personnel should be trained on use of these kits and the guidelines.
5. Mercury devices must not be placed in red (biohazard) medical waste containers or sharps containers but should be collected for hazardous waste disposal or for designated recycling. Health institutions

should determine an area dedicated to mercury waste where it is picked up for disposal. Mercury waste should be sent to authorized facilities or to the original suppliers (if applicable) or it should be sent to a disposal or storage site designated for hazardous industrial waste.

7.3 Radioactive sources

1. Radioactive sources are used in nuclear medicine, radiotherapy, medical research and diagnostic imaging, such as in cobalt therapy, single-proton emission computed tomography and positron emission tomography.
2. A prime example of radioactive waste is material contaminated with radionuclides, which may be present in solid, liquid and gaseous forms.
3. Short half-life radioactive materials can be classified as single-use devices, while long half-life radioactive materials are considered reusable devices and are usually used in radiotherapy, conditioned as a sealed source. The sealed source should be disinfected before reuse and stored in a container with a lead shield.
4. Decommissioning of radioactive sources should end with their return to the manufacturer.
5. The activity of radioactive materials should meet the clearance level before the waste is released from the health facility to be processed further. According to the International Atomic Energy Agency, the "clearance level" is the concentration and/or total activity at or below which a source of radiation may be released.
6. When the activity of radioactive material has reached the clearance level, it can be disposed of by the usual methods.
7. Disposal of various types of radioactive materials used in medical services should be in accordance with the methods that have been described by the International Atomic Energy Agency.
8. Until radioactive sources have met the clearance level, they should be stored within Health institutions, with proper handling, in a lead container or in a lead-shielded room to prevent transmission to the environment.
9. They should be placed in containers that prevent their dispersal before transport to a central facility to be disposed of or to the vendor. Plastic bags designated for radioactive material waste or lead boxes for storing radioactive waste, labelled with appropriate hazard symbols should be used. They should be clearly labelled, with information on the types and activity at a given date.

10. Radioactive sources in large devices, such as cobalt-60 used in teletherapy, should not be stored inside a hospital while being decommissioned. When such devices are designated for donation, trade-in, refurbishment or relocation, they should be transported carefully, especially when the radioactivity level is still high, and the responsible person should ensure that the device will not emit harmful radiation into the environment. Proper sealing, usually made of lead, should be used. Large radioactive sources might include housing; however, housing is not appropriate for transport or long storage of these devices. When radioactive sources are designated for disposal, they should be sent to an authorized institution or the manufacturer.

7.4 In vitro diagnostic devices

IVD medical devices, some of which are used at points of care may be decommissioned because of one of the following:

1. It is a single-use IVD that must be disposed of after use, such as a rapid diagnostic test.
2. It has unacceptable wear or damage or is unreliable.
3. Its expiration date has been reached.
4. It is under instruction for "field safety corrective action" issued by the manufacturer.
5. The technology is obsolete.
6. The necessary reagents or consumables are no longer commercially available.

Supplier and end users should ensure that, even after the sale of an IVD, the manufacturer is obliged to ensure that any risks related to its use throughout its life cycle (installation, use and disposal) are managed in their risk management framework. The agreement between suppliers and the manufacturer should indicate that the manufacturer is responsible for ensuring that their product can be disposed of safely.

Each manufacturer shall establish and maintain continuous risk management throughout the product's life cycle, from conception to decommissioning, identify the hazards associated with an IVD, estimate and evaluate any risks and control the risks and evaluate the effectiveness of implemented risk control measures. The program shall include risk analysis, assessment, control and risk monitoring.

Responsible entities are responsible for decommissioning of non-disposable IVDs, such as auxiliary equipment and analysers. E.g., in reagent rental or leasing, a clause should be present in the procurement contract to ensure that equipment to be decommissioned is decontaminated and removed safely by the manufacturer in a timely manner. When the device is procured as an outright purchase, the manufacturer

should assist the user in decontaminating and disposing of the equipment in the most environment-friendly way.

The safety considerations for disposal of an IVD should be proportionate with its risk category. Responsible entity should ensure biological safety by an appropriate means, such as disinfection (with antimicrobial agents other than antibiotics or antiseptics), sterilization (in an autoclave) and use of other biocides. Practically, single-use rapid diagnostic tests can be autoclaved before disposal or incinerated.

“Chemical safety”, “radiation safety” and “electrical safety” which refer, respectively, to measures taken to protect users, patients and the environment from any harmful effects of exposure to chemicals, radiation and electrical sources due to malfunction, damage or inadequate design should be ensured.

7.5 Chemicals used for diagnosis with devices

Chemical waste consists of discarded solid, liquid and gaseous chemicals generated during diagnosis with medical devices and during cleaning and disinfection may pose significant risks and can be harmful to public health and the environment.

1. Chemical wastes should be handled responsibly and disposed of after use.
2. Different types of chemicals must not be mixed to avoid unnecessary or dangerous reactions.
3. Chemical wastes cannot be disposed of by pouring down the sewer or burying or encapsulating them, unless recommended by the manufacturer and approved by a national authorized agency such as Environmental Protection Agency (EPA), as these methods can harm public health and the environment.
4. The best options for disposing of chemical waste, when applicable, is sending back to the original supplier, and this service should be included in purchasing agreements. Otherwise, suppliers and/or end users should send them to an authorized institution that has the capability and expertise to dispose of hazardous chemicals.
5. Photographic fixing and developing solutions used in X-ray departments contain chemicals that are considered hazardous wastes.
6. The steps in disposing of fixing and developing baths should be as follows:
    a. Personnel who neutralize and dispose of chemical waste should be trained in safe removal procedures; personal protective equipment and safety equipment should be provided.

b. X-ray chemical waste should be collected separately from other chemical waste. Waste from conventional X-ray machines for which a dark room is still used to process films must be handled separately.

c. Neutralized waste solution should be properly labelled in a secondary container and stored for not more than one day.

d. For chemical wastes that can be disposed of by sewerage, the wastes should be diluted 1:2 with water and poured slowly into a sewer and chemicals should not be mixed.

e. All chemicals should be clearly labelled, and safety data sheets should be available and made accessible in the case of accidental exposure or spill.

f. Containers and consumables should be labelled to ensure safety in the workplace.

g. A service log should be in place to track the dates, types of service performed, cartridge changes and volume of waste disposed of. Cartridges should be marked with the date of installation.

7.6 Implants

Implants are considered single-use devices and their end status should be disposal and should not be reused. Exceptional devices (e.g. pacemakers) may be reused provided that:

1. studies have demonstrated that reuse of the properly refurbished device is feasible and safe,
2. it is supported by the decision of the original owner,
3. the safety, quality and performance of the device is maintained,
4. supported by validated cleaning and sterilization procedures,
5. the liability of the reprocessor to respect the regulations of the original manufacturer is ensured, and
6. the liability associated with reprocessing SUMDs, as the obligation of the original SUMD manufacturer for regulation is transferred to the re-processor.

7.7 Computer software and hardware

1. All data and patient information should be removed from devices before decommissioning computer software and hardware before they reach their end status.
2. A biomedical or clinical engineer, if available, or the person responsible for use of the medical equipment should safely store and delete patient information from the software and/or the hardware

of equipment such as intensive care monitors, laboratory information systems, radiology information systems and any other device that holds patient information.

3. Concern about information privacy and security in information disposal and media sanitization is not about the media but about the recorded information. Media containing sensitive information, patient data and registered software include magnetic storage, optical storage, solid state storage and hard copy storage.
4. Methods for sanitizing a device to dispose of the media include degaussing, disintegration, incineration and shredding. Computer software or hardware may be taken back by the manufacturer to recycle and dispose of it properly. When this option is not available, a biomedical engineering department might be able to reuse computer software or hardware parts.
5. If reuse is not possible, computer waste should be sent to authorized facilities capable of depollution and dismantling waste of electronic and electrical equipment according to national or international standards. If there is no authorized facility in the country, computer waste must be handled by operators who are aware of and trained in the health and environmental toxicological impacts of e-waste. Otherwise, such waste should be sent to a disposal or storage site designated for hazardous waste after all the patient information and other confidential information are erased or destroyed.

7.8 Electronic/Electrical wastes of medical devices

Medical device electrical/electronic wastes are wastes of medical equipment which is dependent on electric currents or electromagnetic fields to work properly and equipment for the generation, transfer and measurement of such currents and fields.

1. For the decommissioning/disposal of medical device electronic/electrical wastes, the responsible entities are required to take appropriate measures to protect the environment and human health by preventing or reducing the adverse impacts of the wastes.
2. Medical devices electronic/electrical wastes containing electronic components and parts (e.g. batteries, printed circuit boards, embedded electronic parts, piezoelectric crystals) should be separately collected and should undergo appropriate treatment before decommissioning/disposal.
3. Single-use or rechargeable batteries such as lithium batteries are recommended to be recycled, and they should be disposed only if there is no access to recycling in the location.
4. Rechargeable Nickel Cadmium (Ni-Cd) and Small Sealed Lead Acid (SSLA) batteries contain cadmium and lead respectively, which can leak, be vaporized, and carried on the wind, or leach from

incinerator waste if they are disposed of improperly. Hence, during recycling, the heavy metals should be removed from the batteries so that the metals do not escape into the environment.

5. Before decommissioning batteries capable of storing large electric charge, it is mandatory to make sure that the batteries are discharged to the recommended level of discharging to avoid any damage caused during handling by the battery's electric current and without damaging the battery.
6. If reuse is not possible, medical electronic/electrical waste should be sent to authorized facilities capable of depollution and dismantling waste of electronic and electrical equipment according to applicable national or international standards.

8 Documentation and record keeping

1. Firm should document and retain records of all decommissioned medical devices and report to the authority or regional regulatory bodies and as appropriate to other relevant agencies.
2. The information to be included in the decommissioning report should contain as appropriate:
    a. device name,
    b. type of medical device, or device class (as appropriate),
    c. manufacturer/supplier, country of origin,
    d. package type and size, quantity, model, serial number or batch number, expiry date (as appropriate),
    e. original location (such as laboratory, general ward, intensive care unit, manufacturers, importer, wholesale warehouses),
    f. date and/or period of decommissioning,
    g. condition of the device before decommissioning,
    h. selected decommissioning option and reasons for decommissioning/disposal,
    i. decommissioning process,
    j. end status of the device,
    k. official transfer document for donated or sold devices,
    l. receipt for sold or traded in device, purchase value and other relevant information, and
    m. personnel involved in decommissioning.

3. All decommissioning/disposal report by a third party should include the name and address of the decommissioning/disposal firm, date of request, name, and address of the service requester.
4. Devices that have been disposed of, donated, sold or traded in should be removed from the list of the devices and from the inventory database or archived. In the case of internal reassignment or reprocessing, the inventory must be updated.

9 References

1. Decommissioning medical devices. Geneva: World Health Organization; 2019 (WHO medical device technical series).
2. Medicines Waste Management and Disposal Directive. Addis Ababa: EFDA; 2011.
3. Managing Medical Devices: Guidance for health and social care organisations. Medicine and Health Products Regulatory Agency; 2021.
4. Medical Devices Guidance: GN-33: Guidance on the Application of Singapore Standard Good Distribution Practice for Medical Devices.
5. Medical Device Guidance Document: Notification for obsolete and discontinued medical devices. Medical Devices Authority, Ministry of Health Malaysia, 2020.

10 Annex

ANNEX I

Medical Device Decommissioning/Disposal Application Form

To: _____

Subject: <u>Medical Device Decommissioning/Disposal request</u>

I/We (company name) _____ of (address _____ undertaking the business of (specify) _____ hereby apply for decommissioning/disposal of medical device.

Location of business: _____

Name of person in charge: _____

Reason for decommissioning/disposal: _____

Weight (in kg): _____

Value (in Birr): _____

Attached is the list of products to be decommissioned/disposed.

Declaration:

I certify that the information provided in the application form is true and correct.

Date of application _____ Signature of applicant _____ Stamp _____

Cc:

To appropriate organs

List of Medical Devices to be Decommissioned/Disposed

No.	Name of Medical Device (generic and brand name)	Unit type and size	Quantity	Batch/ lot/serial number	Manufacturing and/or expiry date	Selected decommissioning option (e.g. disposal, refurbishment, sale, donation, trade-in, etc.)	Reason for disposal/ decommission (expired, damaged, etc.)	Name of the manufacturer /supplier	Country of origin	Purchase value
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

ANNEX II

Decommissioning/Disposal Certificate Template

We hereby certify that the following listed items, imported/distributed by **[Name of the local importer]** have been **[selected decommissioning option]** under the direct supervision of inspectors of the authority on the date _____

S. no.	Name of medical device	Unit type	Quantity	Batch/lot/ serial number	Manufacturing and/or expiry date	Manufacturer name	Selected decommissioning option	Reason for decommissioning/ disposal	Country of origin	Decommissioning/ disposal site	Method of disposal
1											
2											
3											
4											
5											

Inspectors

Name	**Signature**	**Date**	**Name of Director**
1. _____	_____	_____	Signature _____
2. _____	_____	_____	Signature _____