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THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR HANDLING UNFIT MEDICAL DEVICES AND DIAGNOSTICS

First Edition

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TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P.O. Box 1253,
Dodoma – Tanzania, Tel: +255 (26) 2961989/2061990, Email: info@tmda.go.tz,
Website: www.tmda.go.tz, Toll free: 08001100834

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Abbreviations

AE/AI	-	Adverse Events/Adverse Incident
CAPA	-	Corrective Actions and Preventive Actions
CROs	-	Clinical Research Organisations
DMD	-	Director, Medical Devices and Diagnostics
DMO	-	District Medical Officer
IVDs	-	In Vitro Diagnostics
LGAs	-	Local Government Authorities
LTR	-	Local Technical Representative
MAH	-	Marketing Authorization Holder
MSD	-	Medical Stores Department
NEMC	-	National Environmental Management Council
NGOs	-	Non Governmental Organisations
PMS	-	Post Market Surveillance
RCA	-	Root Cause Analysis
RMO	-	Regional Medical Officer
SUMDs	-	Single-use medical devices
TMDA	-	Tanzania Medicines and Medical Devices Authority

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Kissa W. Mwamwitwa
DIRECTOR, MEDICAL DEVICES AND DIAGNOSTICS

Foreword

Tanzania Medicines and Medical Devices Authority (TMDA) was established under the Tanzania Medicines and Medical Devices Act, Cap 219 to regulate among others, the quality, safety and performance of medical devices and diagnostics manufactured locally, imported and distributed for use by the general public. To attain this function, various measures and strategies were introduced to detect and remove from the market unfit medical devices and diagnostics so as to protect public health.

These guidelines have been prepared to provide guidance on conducting withdraw and recall of unfit medical devices and diagnostics based on relative health risks and adverse events or adverse incident that may occur to patients or users respectively. These guidelines have also emphasized the need for appropriate handling and disposal of unfit medical devices and diagnostics which includes those recalled from the market. The guidelines intend to elaborate step by step procedures for enforcing the provisions stipulated under the Act and TMDA *Control of Medical Devices Regulations, 2015.*

Generally, improper recall and or unsafe disposal of unfit medical devices and diagnostics could present serious health risks to the general public or to the environment. For example, falsified medical devices and diagnostics may come into hands of unscrupulous dealers and diverted to the market for resale and cause health risks. Also, improper disposal may be hazardous to individual if it leads to contamination of the environment. Furthermore, burning of medical devices and diagnostics at low temperatures or in open containers could result in release of toxic pollutants into the air and affects both the environment and human being.

Therefore, these guidelines sets out vital procedures and actions which should be adhered by the entire community and other players or stakeholders such as manufacturers, medical devices and diagnostics dealers, public and private health facilities, LGAs, NGOs and inspectors during implementation of recalls at different levels. Handling or managing of recalled products during safe disposal have also been highlited so as to protect the public from harmful medical devices or diagnostics.

It is anticipated that, our esteemed stakeholders will acquaint and make use of these guidelines to meet the overall objective of protecting the public and the environment. TMDA will make use of its zone offices and other staff to create awareness to stakeholders regarding requirements of these guidelines so as to enhance smooth implementation. Any comments or inputs that will improve this document in future are highly welcomed.

Adam M. Fimbo
DIRECTOR GENERAL

Definition of terms
For the purpose of these guidelines the following terms are defined as follows:

Act
Means Tanzania Medicines and Medical Devices Act, Cap 219;

Authority
Means Tanzania Medicines and Medical Devices Authority or its acronym “TMDA”;

Decommissioning
Removal of medical devices from their originally intended uses in a health care facility to an alternative use or disposal. A medical device can be decommissioned when it has been deemed to be unfit or when the user/healthcare facility has determined that it no longer wishes to use the device for reasons that are not related to the quality, safety and performance of the device.

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.

Environmental Inspector
Means an inspector appointed under or designated pursuant to the section 82 of the Environmental Management Act, Cap 191;

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 facilities
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.

Inspector
Means TMDA inspector appointed, authorized, or recognized under section 105 of the Act;

Importer
Means person or institutions authorized under the Act to import medical devices and diagnostics in the Country;

In Vitro Diagnostic Medical Device
Means a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Marketing Authorization Holder (MAH)
Means a person resident or domicile to Tanzania or a foreigner who holds authorization to place a medical device or diagnostic product in the country and is responsible for that product;

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

Medical Device or Devices
Means an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part of 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 functions 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 depended upon being metabolized for the achievement of any of its principle intended purposes

Mock Recall
Means an exercise carried out by the manufacturer to challenge the effectiveness of the defined medical device or diagnostic product recall procedures;

Non-hazardous 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

Recall
Means the removal of specific batch or batches or lot or lots of a medical device or diagnostics from the market for reasons related to deficiencies in the quality, safety, or performance;

Recall implementing agents
Means manufacturers, market authorization holders, local technical representatives or any other authorized importer.

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 facilities 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.

Unfit Medical device or diagnostic product
Means products that have expired, improperly sealed, damaged, unexpired but improperly stored, improperly labeled, substandard, falsified, prohibited or unauthorized.

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

Withdraw
Means total removal of medicinal device or diagnostic from the market;

1. INTRODUCTION

Medical devices and diagnostics play a major role in saving lives and alleviating suffering, while at the same time when these products are regarded unfit may present serious hazardous effects on public health and environment especially if their quality, safety and performance have been compromised, hence have to be recalled from the market.

To reinforce effective and efficient recall operations and guarantee safe disposal of unfit medical devices and diagnostics, the Authority has established its guidelines by clearly outlining procedures for executing the recall, which have taken on board the levels of recall, roles and responsibilities of key actors. To ensure public and environmental safety a detailed guidance on safe handling of medical devices and diagnostics has been provided.

These guidelines are divided into three (3) major parts which are recall of unfit medical devices and diagnostics, handling of unfit medical devices and diagnostics and disposal of unfit medical devices and diagnostics.
The Authority expect that good implementation of these guidelines will help to prevent unnecessary accumulation and protect the public from unfit medical devices and diagnostics marketed in Tanzania.

With regards to decommissioning health care decision-makers are obliged to use their resources rationally and efficiently and to base their actions on well-determined factors in order to avoid unnecessary investments that may be a significant economic burden on their organizations.

2. RECALL OF UNFIT MEDICAL DEVICES AND DIAGNOSTICS

2.1. Initiation of recall

Recall of unfit medical devices and diagnostics may be initiated by the following agents or firms:

a. Authority;
b. Marketing Authorization Holder (MAH);
c. Manufacturer; or
d. Any other authorized importers.

Where the recall has been initiated by MAH, manufacturer or any other authorized importer the Authority should be informed in writing prior to execution of the recall.

2.2. Main causes for initiation of recall

The following factors may trigger the Authority, MAH, manufacturers or authorized importer to initiate recall of any Medical Device or Invitro Diagnostic Device(MD or IVD):

a. Complaints from users or general public;
b. Reports of Adverse Events (AEs) and Adverse Incidents (AI);
c. Results of Post Market Surveillance (PMS);
d. Incorrect labeling of the MD or IVD;
e. Proof that a MD or IVD has caused or is about to cause injury to the health or safety of patients or other users; or
f. Proof that a MD or IVD does not meet specifications;
g. Any other defect related to quality, safety and performance of the MD or IVD.

The costs associated with recall shall be borne by either MAH, Manufacturer, or Local Technical Representative (LTR).

2.3. Recall Procedures

2.3.1. Information to be submitted to the Authority

Prior to implementation of recall; Manufacturer or MAH or LTR or authorized importer should submit to the Authority the following information of the MD(s) or IVD(s) to be recalled:-

a. Proprietary name and common name;
b. Batch or lot number;
c. Pack size;
d. Name and address of the manufacturer;

e. Manufacturing and expiry date;
f. Reason(s) for the recall;
g. Nature of the defectiveness or possible defectiveness;
h. Date on and circumstances under which the defects or possible defects were discovered;
i. Total quantity of the product to be recalled originally in possession of the manufacturer, MAH or importer;
j. Date on which distribution of the product began;
k. Total quantity of the product to be recalled that had been distributed up to the time of the recall;
l. Area of distribution of the product;
m. List of customers to whom medical device or diagnostic product was distributed; and
n. Quantity of the product still in possession of the manufacturer, registrant or importer'

The received information shall be evaluated or assessed by the Authority followed by issuance of official directive to carry out the recall.

2.3.2. Submission of weekly progress and final recall reports

After start of the recall process as directed by the Authority, the recall implementing agents should submit weekly progress reports to the Authority and upon completion of the recall, the recalling agent shall submit the following to the Authority:-

a. Final report which includes reconciliation between distributed and recovered quantities of the product.
b. A thorough investigation report detailing causes of the defect and Corrective Actions and Preventive Actions (CAPA) undertaken.

2.4. Recall classification and recall timelines

There shall be three (3) classes of recalls based on relative health risks or adverse events or adverse incidencies to patients or users as described below;

a. Class I refers to recall of defective, dangerous or potentially life-threatening medical devices and diagnostics that predictably or probably could result into serious health risk or adverse events/adverse incident or death;

b. Class II refers to recall of medical devices and diagnostics that possibly could cause temporary or medically reversible adverse health problem or mistreatment; and

c. Class III refers to recall of medical devices and diagnostics which are defective and are unlikely to cause any adverse events/adverse incident or which do not comply with the requirements of the Act, in terms of the

requirements of printed packaging material, product specification or labeling.

The maximum time for recall shall be fourteen days for Class I, twenty-one days for Class II and thirty days for Class III from the date of instruction. The Authority shall have the final decision on the maximum time for recalling of any medical device or invitro diagnostic device.

2.5. Levels of Recall

For purpose of ensuring that the general public is protected from consuming unfit medical devices or invitro diagnostics, there shall be three (3) levels of recall based on recall classes stipulated in 2.4

a. Level A

Level A refers to recall designed to reach all suppliers of medical devices and diagnostics throughout the supply chain (i.e., all public and private medical devices and diagnostics outlets and healthcare facilities) and individual customers or patients through media release such as radio, television and websites. Communication to inform facilities and individuals or customers under this level shall be made urgently via media release and issuance of letters at the same time.

b. Level B

Level B refers to recall designed to reach public and private medical devices and diagnostics outlets and health facilities. Communication to inform facilities (wholesalers and retailers) under this level shall be made urgently by sending letters.

c. Level C

Level C refers to recall designed to reach wholesaler and retailer levels. Communication to inform the concerned outlets could be achieved by means of a representative calling on wholesalers and/or retail outlets. If it is known where the product in question had been distributed; specific telephone calls or recalls letters requesting for the return of the product could be made.

2.6. Roles and responsibilities of key stakeholders in the recall process

During implementation of recall there shall be involvement of different players with the following roles and responsibilities:

2.6.1. The Authority

a. Receive, evaluate and assess information related to unfit MDs or IVDs present in the market.
b. Instruct recall of unfit MDs or IVDs depending on classification of recall and levels.
c. Monitor recall progress on weekly basis until completion of the recall.
d. Document recalled MDs or IVDs in the 'DMD Quality and Safety Issues Register'.
e. Issue public notice where applicable.
f. Assess the CAPA submitted from the Manufacturer or MAH.
g. Provide timely feedback to individuals who reported incidents related to quality, safety and performance of medical devices and diagnostics.
h. Official closure of the recall process.

2.6.2. Manufacturer/MAH/Authorized importer

a. Take the prime responsibility for implementing recall processes;
b. Voluntarily initiate recall after detection of any problem related to quality, safety and performance of a MDs or IVDs;
c. Handle product recall according to TMDA established medical device and diagnostic recall procedures.
d. Maintain records and establish procedures for conducting recall;
e. Have in place a documented procedure for conducting mock recall;
f. Conduct Root Cause Analysis (RCA) on the identified defect;
g. Timely submission of CAPA to the Authority for assessment and
h. Submit to the Authority, recall progress and final reports.

2.6.3 Consumers

a. Report to the Authority, health facilities or any other law enforcing agencies issues related to quality, safety and performance of MDs or IVDs;
b. Remain vigilant during purchase and use of MDs or IVDs; and
c. Provide cooperation with Authority and other law enforcing agencies

2.6.4 Inspectors

a. Make prompt follow up to the MAH, manufacturer and any other authorized importers regarding recall progress;
b. Close monitoring the effectiveness of recall progress and intervene by conducting inspection whenever necessary;
c. Prepare and submit recall report to supervisors; and
d. Foster cooperation with LGAs and other law enforcing agencies on behalf of TMDA.

2.6.5 Local Government Authorities (LGAs)

a. Report incidents of presence of unfit medical devices and diagnostics

b. Cooperate with the Authority in implementing recalls.
c. Conduct inspection on the market to remove unfit medical devices and diagnostics as instructed by the Authority.
d. Submit recall report to the Authority

3. DECOMMISSIONING

Decommissioning is the removal of a medical device from service in a health care facility after a decision to disinvest in the device itself or in a service in which it is used. The Authority recommends that when the facility procures the MDs or IVDs the clause which indicates how the equipment will be safely decommissioned is included in the procurement contract by the manufacturer.

There are two main pathways for decommissioning a MD or IVD and determining its final disposition after decontamination are:
a. Permanent elimination (Disposal) and
b. Re-use (i.e., donated, sold, refurbished, reprocessed, traded-in or reassigned internally to another location)

Factors that determine the pathway to be followed are as categorized below;

a. **Device intrinsic factors**:

   i. Single-use designation,
   ii. Inadequate disinfection or sterilization,
   iii. Unresolved performance issues,
   iv. Unresolved safety issues,
   v. Continuous unreliability or history of serious failure,
   vi. High cost of repair making the device cost-effective or financially unviable, and
   vii. End of life

b. **Infrastructure related factors (decision to be made by local health care workers) are:**

   i. Re-organization, closure or relocation of the health care facility;
   ii. Shortage of local technical support, spare parts, accessories or consumables
   iii. Infrastructure incompatibility (e.g., The device must be connected to a network in order to provide electronic health records or for another purpose, but this is not technically or financially feasible);
   iv. Serious concern about unreliable cybersecurity (for networked devices); and
   v. A catastrophic event (such as an accident, emergency or disaster) that may compromise the functioning of the device.

c. **Administrative or policy-level decisions factors**:

i. High maintenance costs,
ii. Regulatory withdrawal of a medical device from the market,
iii. Availability of new or clinically effective technology,
iv. Standardization (limiting the number of models of a particular device) and
v. Clinical or technical obsolescence

If the medical device or diagnostic device has to be disposed or re-used, the procedures stipulated in section 3.1 of these guidelines are applicable.

3.1. Procedures for decommissioning of medical devices

3.1.1. Role of the owner of the device including importer, wholesaler or healthcare facility

a. Identification of medical devices that require decommissioning;
b. Segregate the medical devices that are to be decommissioned from the medical devices that are in use. Unfit medical devices should be clearly labelled. If a medical device is not unfit but the facility wishes to decommission it, it should be stored in the manner that does not impact its quality, safety and performance and as prescribed by the manufacturer;
c. Ensure that the device is safe for handling and treatment or removal, by cleaning and decontaminating it, removing data, disposing of consumable parts and (if relevant) withdrawing or removing its listing from the paper-based or computerized inventory;
d. Attain approval from the Accountant General (for Government and Public Private Partneship Healthcare facilities);
e. Apply for disposal/decommissioning of the devices through TMDA Online Traders Portal. The documentation requirements for applications are outlined in section 4 of this guideline;
f. After inspection by TMDA, receive TMDA verification report and submit to NEMC or any other institution as applicable;
g. Contact TMDA once all applicable approvals and permits are in place to schedule the disposal date; and
h. Document and keep records of all decommissioned/disposed medical devices. Details on documentation and record keeping are available in section 5 of this guideline.

3.1.2. Role of TMDA

a. Receive applications for disposal/decommissioning of medical devices and review the documents submitted;
b. Conduct physical verification of the medical devices to confirm that they have been adequately segregated, decontaminated, all data has been removed and that the devices are safe for handling;

c. Assess risk of the device and approve the method of disposal or direct another means;
d. Depending on the method proposed, direct the facility to other institutions that require to be involved; and
e. Supervise the disposal/decommission process and issue a disposal/decommission certificate to the healthcare facility.

3.2. Types of decommissioning

3.2.1. Permanent disposal

The product owner or disposing firm shall use details provided by the manufacturers, relevant techniques available and processes applicable to propose the disposal method that shall be approved by the Authority dispose the device provided by the manufacturers.

All disposal methods shall adhere to the national policy and conducted in a manner that shall align with other related national regulations.

The recommended methods for disposal of unfit medical devices and diagnostics are;

a. Incineration
b. Controlled landfills
c. Burning in open containers/area
d. Sewerage
e. Return to the country of origin

3.2.2. Reprocessing and reusing of medical devices

The following are the reprocessing methods that can be applied to MDs or IVDs for re-use:

a. Recycling

Medical device can be recycled, when:

i. It is possible to separate the used medical devices and reuse the materials. E.g., steels in surgical instruments and explants would have to be melted down and recycled.

ii. The devices are made of a small number of different materials and their design allows them to be easily disassembled into their individual components.

b. Refurbishment

i. Refurbishment is one of the medical devices decommissioning option that is considered an effective way of preventing waste and saving resources. 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. Removal of device for decommissioning should get a permit from the authority, and it should be labelled as such.

ii. Devices intended for single use or designed as not eligible for refurbishment should not be refurbished.

iii. The refurbished medical devices should meet the same requirements of quality, safety and performance as the new device manufacturer's specification.

iv. 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.

c. Donation

i. Medical devices can be donated only when their safety and performance conditions can be met. 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.

ii. 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.

iii. 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 device.

iv. 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).

v. 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.

d. Sale

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. Sold medical devices should be transported and delivered with all necessary accessories in a safe way.

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.

Note:
Single-use medical devices (SUMDs) shall not be reprocessed or used on another individual since they are intended to be used on one individual only during a single procedure. Their labelling should include a characteristic symbol for single-use products and no instructions for reprocessing. 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.

3.3. Special cases of medical devices decommissioning or disposal

Some medical devices such as sharps, devices containing mercury or radioactive material, 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.

3.3.1. Sharps

a. Sharps or pointed objects and materials that can cause injury and/or infection are classified as SUMDs. Examples of medical device sharps include syringes, needles, lancets, pipettes,glassware, etc.
b. Health facilities 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.

c. All sharps require cautious waste management and should be decommissioned by disposal.

d. 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.

e. Appropriate procedures for disposal of all sharps should be established by the health facility to minimize the risk of infection with communicable diseases.

3.3.2. Devices containing mercury

a. Medical devices containing mercury such as sphygmomanometers, thermometers and dental amalgams must be handled with care in order to avoid harmful effects of elemental mercury on humans and environment.

b. Institutions should have procedures for handling mercury spillages that may result from broken devices to avoid inhalation by the nearby individuals.

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

3.3.3. Devices containing radioactive substances

Decommissioning of radioactive devices should end with their return to the manufacturer. All disposal methods shall adhere to the Atomic Energy Act, 2002 and the Atomic Energy (Protection from Ionization Radiation) Regulations as well as other applicable regulations as issued by The Tanzania Atomic Energy Commission (TAEC).

3.3.4. 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:

a. It is a single-use IVD that must be disposed of after use, such as a rapid diagnostic test.

b. It has unacceptable wear or damage or is unreliable.

c. Its expiration date has been reached.

d. It is under instruction for “field safety corrective action” issued by the manufacturer.

e. The technology is obsolete.

f. 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.

3.3.5. Chemicals used during use of medical devices

Unused reagents and other chemical wastes generated during the use with medical devices and during cleaning and disinfection may pose significant risks and can be harmful to public health and the environment.

Chemical wastes should be handled responsibly and disposed of after use. Different types of chemicals must not be mixed to avoid unnecessary or dangerous reactions. 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.

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.

3.3.6. Implants

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

a. Studies have demonstrated that reuse of the properly refurbished device is feasible and safe,

b. It is supported by the decision of the original owner,

c. The safety, quality and performance of the device is maintained,

d. Supported by validated cleaning and sterilization procedures,

e. The liability of the reprocessor to respect the regulations of the original manufacturer is ensured, and

f. The liability associated with reprocessing SUMDs, as the obligation of the original SUMDmanufacturer for regulation is transferred to the re-processor.

3.3.7. Computer Software and Hardware

All data and patient information should be removed from devices before decommissioning of computer software and hardware. The decommissioning method to be used after removal of all the patient information and other confidential information can be any of the decommission methods stated under these guidelines.

4. REQUIREMENT FOR DECOMMISSIONING

4.1. General Requirements

a. Decommissioning shall be carried out under the supervision of Authority and the certificate for decommissioning shall be issued by the Authority upon completion.

b. When decommissioning is out sourced to a third party, the copy of decommissioning service request letter sent to a licensed decommissioning 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.

c. Any Institution that is engaged in the decommissioning 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.

d. Medical device manufacturers, suppliers and health facilities who have their own disposal facilities or capabilities to carry out other decommissioning processes should get approval from the Authority.

e. The disposal process of medical devices shall comply with these guidelines and other relevant national laws to ensure occupational health and accident prevention as well as public health protection and infection control.

f The applicant who initiated the decommissioning request should retain appropriate records.

4.2. Documentation requirements

Any institution that wishes to dispose of or decommission a medical device should submit the following information through the TMDA online traders portal:

a. List of medical devices for disposal or decommissioning;
b. Details of each medical device including trade and common name, name and address of the manufacturer of the device, date of manufacturing, batch/lot/serial number, quantities/volume of the device, date of procurement and value of device;
c. Reasons for disposal/decommissioning of each device;

d. Proposal of the method of decommissioning; and
e. Approval from the Accountant General (if applicable).

5. DOCUMENTATION AND RECORD KEEPING

Institution shall document and retain records of all decommissioned medical devices, the information to be included in the decommissioning report should contain:

a. device name;

b. type of medical device, or device class;

c. manufacturer/supplier, country of origin;

d. package type and size, quantity, model, serial number or batch number, expiry date (asappropriate);

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;

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.

Devices that have been decommissioned 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.

6. REFERENCES

a. NEMC, (2004).,*The Environment Management Act Cap 191,* National Environment Management Council, Government Printer, Dar es Salaam,

Tanzania.

b. WHO, (2019)., Decommissioning of Medical Devices, World Health Organization, Geneva, Switzerland.

c. TMDA, (2003)., *TheTanzania Medicines and Medical Devices Act Cap 219*, Tanzania Medicines and Medical Devices Authority, Government Printer, Dar es Salaam, Tanzania.

d. TMDA, (2015).,*The Tanzania Food, Drugs and Cosmetics (Recall, Handling and Disposal of Medical devices and diagnostics and Cosmetics) Regulations, GN 312*, Tanzania Medicines and Medical Devices Authority, Government Printer, Dar es Salaam, Tanzania.

e. MHRA, (2021)., Managing Medical Devices ,Guidance for health and social care organisations, London United Kingdom.

f. EFDA, (2022)., Ethiopian Food and Drug Authority, Guideline for Decommissioning and Disposal of Medical Devices First Edition, Addis Ababa Ethiopia.

g. TMDA, (2021)., *The Tanzania Medicines and Medical Devices (Fees and Charges) Regulations, GN 686,* Tanzania Medicines and Medical Devices Authority, Government Printer, Dar es Salaam, Tanzania.