THE UNITED REPUBLIC OF TANZANIA
NATIONAL AUDIT OFFICE

ISO 9001:2015 Certified

PERFORMANCE AUDIT REPORT ON THE REGULATION OF MEDICAL EQUIPMENT IN THE PUBLIC HEALTH FACILITIES

CONTROLLER AND AUDITOR GENERAL
MARCH 2024

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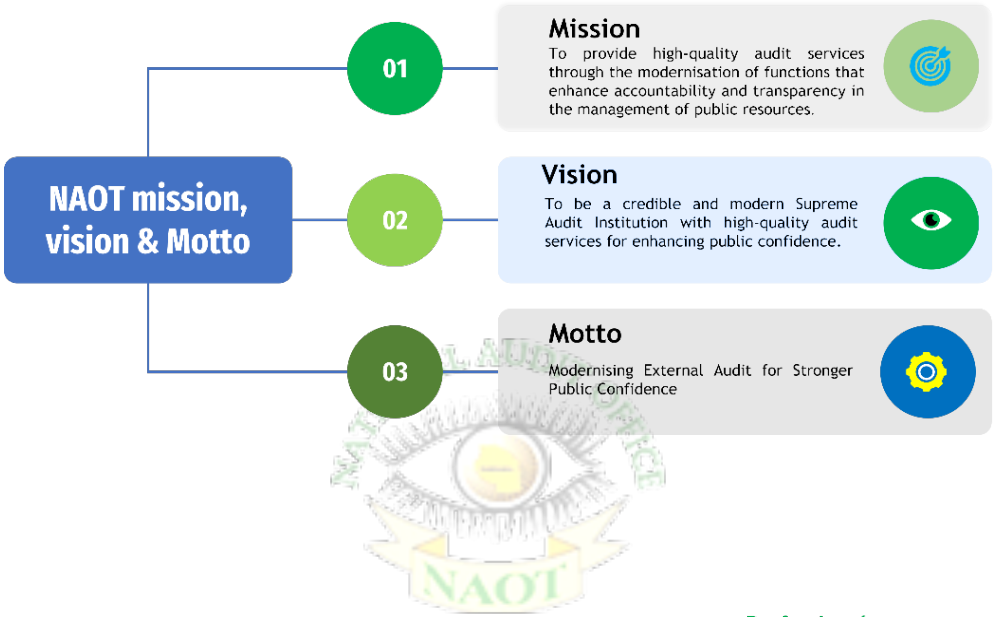

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PREFACE

Section 28 of the Public Audit Act, CAP 418 [R.E. 2021] gives a mandate to the Controller and Auditor General to carry out Performance Audit (Value-for-Money Audit) to establish the economy, efficiency, and effectiveness of any expenditure or use of resources in the Ministries, Departments and Agencies (MDAs), Local Government Authorities (LGAs) and Public Authorities and Other Bodies which involves enquiring, examining, investigating and reporting, as deemed necessary under the circumstances.

I have the honour to submit to Her Excellency, the President of the United Republic of Tanzania, Hon. Dr. Samia Suluhu Hassan, and through her, to the Parliament of the United Republic of Tanzania, the Performance Audit Report on the Regulation of Medical Equipment in the Public Health Facilities.

The report contains findings, conclusions, and recommendations directed to the Ministry of Health and the Tanzania Medicines and Medical Devices Authority.

The Ministry of Health and the Tanzania Medicines and Medical Devices Authority had the opportunity to scrutinise the factual contents of the report and comment on it. I wish to acknowledge that, the discussions with the Ministry of Health and the Tanzania Medicines and Medical Devices Authority have been useful and constructive.

My Office will conduct a follow-up audit at an appropriate time regarding actions taken by the Ministry of Health and the Tanzania Medicines and Medical Devices Authority to implement the recommendations of this report.

I would like to express my heartfelt gratitude to my staff for their commitment to preparing this report. I also acknowledge the audited entities for their cooperation with my Office, which facilitated the timely completion of the audit.

Charles E. Kichere
Controller and Auditor General
The United Republic of Tanzania
March, 2024

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LIST OF ABBREVIATIONS AND ACRONYMS

CC	:	City Council
CHOP	:	Comprehensive Hospital Operational Plan
CM	:	Corrective Maintenance
CT	:	Computerized Tomography
DC	:	District Council
DLS	:	Directorate of Laboratory Services
DMC	:	Directorate of Medical Product Control
ECG	:	Electrocardiography
EEG	:	Electroencephalogram
GCLP	:	Good Clinical Laboratory Practice
GMP	:	Good Manufacturing Practice
HC	:	Health Centre
HFR	:	Health Facility Registry
HFs	:	Health Facilities
HQ	:	Headquarters
HSSP	:	Health Sector Strategic Plan
HSSP	:	Health Sector Strategic Plan
ICT	:	Information, Communication and Technology
IMIS	:	Integrated Management Information System
INTOSAI	:	International Organisation of Supreme Audit Institutions
ISO	:	International Organization for Standardisation
ISSAIs	:	International Standards of Supreme Audit Institutions
KPIs	:	Key Performance Indicators
LGAs	:	Local Government Authorities
LINAC	:	Linear Accelerator
MAT	:	Medical Association of Tanzania
MDAs	:	Ministries, Departments and Agencies
MEIMIS:	:	Medical Equipment and Infrastructure Management Information System
MNH	:	Muhimbili National Hospital
MoH	:	Ministry of Health
MRI	:	Magnetic Resonance Imaging
MSD	:	Medical Stores Department
NAOT	:	National Audit Office of Tanzania

NEMC	:	National Environment Management Council
NGO's	:	Non-Governmental Organisations
ORCI	:	Ocean Road Cancer Institute
PA	:	Performance Audit
PMS	:	Post Market Surveillance
PO-RALG	:	President's Office - Regional Administration and Local Government
PPM	:	Planned Preventive Maintenance
PV	:	Pharmacovigilance
PQMS	:	Pharmaceutical Quality Management System
RHMT	:	Regional Health Management Teams
RIMS	:	Regulatory Information Management System
RS	:	Regional Secretariat
RSs	:	Regional Secretariats
SADC	:	Southern African Development Community
SDGs	:	Sustainable Development Goals
SMRIEG	:	Standard Medical Radiology and Imaging Equipment Guidelines
SOPs	:	Standard Operating Procedures
TAEC	:	Tanzania Atomic Energy Commission
TBS	:	Tanzania Bureau of Standards
TFDA	:	Tanzania Food and Drugs Authority
TMDA	:	Tanzania Medicines and Medical Devices Authority
TZS	:	Tanzanian Shillings
UN	:	United Nations
WHO	:	World Health Organisation

DEFINITION OF TERMS

Adverse Event / Effect	:	A problem that can or does result in permanent impairment, injury, or death to the patient or the user of the Medical Equipment (Medical Device Regulations Global Overview and Guiding Principles, 2003).
Calibration	:	This refers to periodically checking the medical equipment whereby the energy levels are to be measured and adjusted to see if there is any discrepancy (Medical Equipment Maintenance Programme Overview, WHO Medical Device Technical Series, 2011).
Certification of Medical Equipment	:	Refers to issuance or amendment of Registration Certificate whereby the Tanzania Medicines and Medical Devices Authority (TMDA) determines that a Medical Equipment/Device meets the safety and performance requirements (The Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015).
Corrective Maintenance	:	A process used to restore the physical integrity, safety, and performance of a Medical Equipment after a failure. (Medical Equipment Maintenance Programme Overview, World Health Organization (WHO) Medical Device Technical Series, 2011).
Defective/Unfit Medical Equipment	:	This means Medical Equipment that is expired, improperly sealed, damaged, improperly stored, wrongly labelled, counterfeit, substandard and prohibited or unauthorised (The Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015).
Diagnostic Services	:	It refers to detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity through medical equipment (The Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015).
Disposal	:	This means the discharge deposit, injection, dumping, spilling, leaking, emitting, or placing of any solid wastes or hazardous wastes into or on any land or ground or surface water or into the air such that it is rendered harmless (The Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015).
Efficacy	:	Means effectiveness under an ideal controlled setting (Medical Device Regulations Global Overview and Guiding Principles, 2003).
Failure	:	The condition of the Medical Equipment does not meet the intended performance or safety requirements and is a breach of physical integrity. (Medical Equipment Maintenance Programme Overview, World Health Organization Medical Device Technical Series, 2011).
Health	:	A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (Constitution of the World Health Organization).

Inspection	:	Refers to scheduled activities necessary to ensure a piece of Medical Equipment is functioning correctly. (Medical Equipment Maintenance Programme Overview, World Health Organization Medical Device Technical Series, 2011)
Medical Device	:	This means an instrument, apparatus, implement, Medical Equipment, Machines, Contrivance, implant, in vitro reagent, or another similar or related article, including any component, part or accessory which is recognised in the Official National Formulary, or Pharmacopoeia or any supplement to them. (Guideline for Developing Annual Health Centre and Dispensary Plans, 2016). Also, it can be defined as an article, instrument, apparatus or machine used in the prevention, diagnosis or treatment of illness or disease or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means (Medical Equipment Maintenance Programme Overview, World Health Organization Medical Device Technical Series, 2011).
Medical Equipment	:	Device used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices. Medical Equipment includes Ultrasound, Magnetic Resonance Imaging (MRI) machines and CT scanners (Guideline for Developing Annual Health Centre and Dispensary Plans, 2016). Also, it can be defined as Medical Equipment/Devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical Equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used alone or in combination with any accessory, consumable, or other medical equipment. Medical Equipment excludes implantable, disposable or single-use medical devices (Medical Equipment Maintenance Programme Overview, WHO Medical Device Technical Series, 2011).

Planned Preventive Maintenance (PPM)	:	Regular safety and performance inspection of physical assets (medical equipment) is used to evaluate risk and reduce failure to enhance safety, efficiency, and reliability. It involves cleaning, checking regular function/safety tests and ensuring any problems are picked up before they cause a breakdown (Guideline for Developing Comprehensive Hospital Operational Plan (CHOP) for Regional Referral Hospitals).
Post Market Surveillance	:	It is a term that covers all monitoring activities, including the vigilance system for Medical Equipment/Devices in use (Medical Device Regulations Global Overview and Guiding Principles, 2003).
Preventive Maintenance	:	Involves maintenance performed to extend the life of the device and prevent failure, usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, cleaning (e.g. filters) or replacing parts that are expected to wear (e.g. bearings) or which have a finite life (e.g. tubing). The manufacturer usually establishes the procedures and intervals. In special cases, the user may change the frequency to accommodate local environmental conditions (Medical Equipment Maintenance Programme Overview, WHO Medical Device Technical Series, 2011).
Registration of Medical Equipment	:	Refers to when a device is found to have complied with all the prescribed registration requirements, and the applicant is informed to that effect. A certificate of registration and such conditions as the TMDA may determine is issued. Registration of a device is site-specific. (Tanzania Food, Drugs and Cosmetics Act, 2003 as amended by section 24 of the Finance Act, 2019).

EXECUTIVE SUMMARY

Background Information

According to the World Health Organization (WHO) Regulation of Medical Devices: A step-by-step guide of 2016, medical equipment regulation covers activities to ensure that the equipment is of quality, safe, and efficacious. It is composed of processes that start from manufacturing, procuring, installing, operating, maintaining, and disposing/ recycling equipment that is no longer suitable for use. Similarly, proper regulation of medical equipment helps the management of health facilities develop and monitor their equipment, ensuring its safety and performance.

National Healthcare Policy of 2017 emphasised the adoption of equipment that utilises modern technology in diagnostic services. These are digital X-rays, magnetic resonance imaging (MRI), and computerised tomography (CT) scans. In this regard, the use of Equipment that utilises modern technology is associated with challenges such as high acquisition and operational costs, low utilisation capacity, and shortage of qualified personnel with the required competence to service the equipment.

Based on these facts, the main objective of the audit was to assess whether the Ministry of Health (MoH) and Tanzania Medicines and Medical Devices Authority (TMDA) effectively regulate the management of medical equipment to safeguard public safety and improve the quality of healthcare services provided by public health facilities in the Country.

In this regard, the audit focused on class D medical equipment, which is high-risk equipment that requires close monitoring and regulation to assess how it is regulated and managed throughout its life cycle, including purchase, maintenance, performance monitoring, and the disposal of unfunctional medical equipment.

Audit Findings

Despite several efforts by the Ministry of Health and TMDA to enhance the regulation of medical equipment in the country, the audit noted the following areas for further improvement:

The Existence of Unfunctional Medical Equipment in the Country

The presence of unfunctional medical equipment in Tanzania is contrary to the goals outlined in the TMDA Strategic Plan for 2016/17-2020/21. This plan mandated the Tanzania Medicines and Medical Devices Authority (TMDA) to enhance oversight and ensure the quality, safety, and efficacy of

medical equipment and diagnostic tools through more rigorous regulatory measures.

However, referring to the data collected for medical equipment obtained from the Directorate of Radiology and Imaging Services at the Ministry of Health, it was found that 14% of the selected medical equipment under the audit was found unfunctional. Similarly, observation through the audit verification in the public health facilities found that, 135 out of 492, equivalent to 27% of medical equipment, were unfuctional. The largest percentage of unfit medical equipment was noted in the Central zone, with 37 unfunctional Medical Equipment out of 115, equivalent to 32%.

Inadequate Procedures for the Registration of Medical Equipment

TMDA is mandated to register medical equipment manufactured within and outside the country before use. Based on this, the audit noted the following inadequacies regarding the procedures for registration of medical equipment:

Inadequate record-keeping on the procedures for the registration of medical equipment

In the financial year 2019/20 to 2022/23, there were 150 out of 209 registered medical equipment, equivalent to 56%, which TMDA inadequately recorded. The equipment records on the specified date of application for registration or the issuance of the certificates were not found in the TMDA's Register of Medical Equipment. This led to an inability to determine the certificate's expiration date on registration for the medical equipment.

Delayed processed application for the registration of Medical Equipment

In the period of the financial year 2019/20 to 2022/23, only 5 out of 59 selected medical equipment with both information for application for registration and certificate release were registered within 90 days, while the remaining 54 out of 59 medical equipment equivalents to 91% the processes for their registration were completed beyond 90 working days. This is contrary to the TMDA Clients' Service Charter, 2020 requirement, which indicates that the registration of medical equipment shall take 45 and 90 working days. Therefore, this poses a risk of delays to the intended health services from using medical equipment.

The registrants' ineffective payment of annual retention fees for the registered Medical Equipment

The audit noted that 51% of medical equipment registrants did not pay annual retention fees. Regardless of registrants not paying their retention fees, TMDA neither suspended nor cancelled their registration for a period of four (4) financial years, that is, 2019/20 to 2022/23. This is contrary to Regulation 17(2) & 18(g) of Tanzania Food, Drugs and Cosmetic Regulation on the Control of Medical Devices, 2015. This implies that TMDA did not collect revenue amounting to TZS 241,040,000. On the other hand, TMDA did not ensure whether the defaulted registrant from payment of annual retention fees for registered medical equipment in use still complies with other registration requirements to safeguard people's health and the public in general while using such medical equipment.

Ineffective Regulation on Medical Equipment Imported by the Public Health Facilities

The audit noted that the inspection reports and certificates for the importation of Medical Equipment did not have details regarding the inspection conducted on the medical equipment at the port of entry for the past four (4) years, 2019/20 to 2022/23. This was contrary to the requirement of Regulation 56 (1) of the Tanzania Food, Drugs and Cosmetic Regulation on the Control of Medical Devices, 2015. In turn, the medical equipment in the public health facilities was imported and installed without prior verification by TMDA on their safety, quality and efficiency.

Similarly, TMDA had not effectively established and maintained files of international standards and regulatory requirements for reference of each medical equipment and family. An interview with officials from TMDA revealed that ISO charges for the subscription of its standards. This implies that TMDA had to pay a subscription fee to access the service. Based on these facts, TMDA lacks a code for traceability and transparency in tracking conformity to standards and regulations based on the respective standards for medical equipment.

The Ministry of Health did not ensure that the Public Health Facilities Maintained Medical Equipment.

The audit noted that the Ministry of Health did not have a functional system to ensure medical equipment maintenance in public health facilities for the period under the audit. This was contrary to the requirement of paraph 7.2 of the Standard Medical Radiology and Imaging Equipment Guidelines (SMRIEG), 2018, which requires medical equipment maintenance to keep

them in operation as intended. Due to the lack of a functional system for the maintenance of medical equipment, the audit observation through physical verification in 17 visited health facilities noted that 76% of the health facilities had functional medical equipment.

Audit Conclusion

The audit concludes that the Ministry of Health (MoH), through TMDA, has ineffectively regulated medical equipment regarding efficiency, quality, and safety. This is due to the fact that they have not sufficiently ensured adequate registration of medical equipment, maintenance of medical equipment, quality of imported medical equipment, performance of medical equipment in health facilities, proper disposal of unfunctional medical equipment, and cooperation with other actors involved in medical equipment. This implies that, they were not in a position to enhance the provision of healthcare services and safeguard the environment and citizens in the country through adequate regulation of medical equipment used in the health facilities.

Similarly, through TMDA, MoH did not ensure that medical equipment were effectively regulated. This is due to a lack of effective functioning registration of medical equipment, adequate Monitoring of the performance of medical equipment in health facilities, proper disposal, and cooperation with stakeholders responsible for medical equipment. This was manifested by the delay in registering medical equipment and unfunctional medical equipment in health facilities.

This was attributed to inadequate control of medical equipment by TMDA, inadequate inspection of imported medical equipment during importation and post-market surveillance. It was further attributed to the inadequate allocation of human, physical and financial resources for maintaining and conducting post-market surveillance.

On the other hand, the capacity of TMDA's laboratory is low. This is because it does not suffice to perform necessary tests for medical equipment such as mammography units, differential counters, ultrasound machines, haematology analysers, and X-ray machines.

Audit Recommendations

Recommendations to the Ministry of Health

The Management of the Ministry of Health is urged to:

(a) Ensure an operable and functional system for the Inventory and Maintenance of medical equipment in public health facilities; and

(b) Enhance preparation and integration of information on nonfunctional medical equipment in health facilities, which are shared with TMDA for verification and suggestions on appropriate modes of disposal.

Recommendations to Tanzania Medicines and Medical Devices Authority

The Management of Tanzania Medicines and Medical Devices Authority is urged to:

(a) Enhance registration procedures for medical equipment by taking into account sample collection and timelines for each step involved;

(b) Devise mechanisms for post-market surveillance to cover medical equipment in health facilities and issue advice on proper maintenance and use. This should include effective planning and development of tools to track key performance aspects of medical equipment; and

(c) Enhance regulation of unfunctional medical equipment by TMDA, which involves initialling disposal, examination of disposal requests and ordering disposal of unfunctional medical equipment.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Medical equipment comprises instruments, apparatus, machines, appliances, implants, software, materials, or other related articles used for one or more specific medical purpose(s). Medical equipment are used in Health Facilities for diagnosis, investigation, prevention, monitoring and treatment of people in need of healthcare services[1].

According to the WHO Regulation of Medical Devices: A step-by-step guide of 2016, the regulation of medical equipment encompasses activities to ensure that the equipment is of quality, safe, and efficacious. It is composed of processes that start from manufacturing, procuring, installing, operating, maintaining, and disposing/ recycling equipment that is no longer suitable for use. Similarly, proper regulation of medical equipment helps the management of health facilities develop and monitor their equipment, ensuring its safety and performance.

National Healthcare Policy of 2017 emphasised the adoption of equipment that utilises modern technology in diagnostic services. These are digital X-rays, Magnetic Resonance Imaging (MRI), and Computerised Tomography (CT) scans. The equipment that utilises modern technology is associated with challenges such as high acquisition and operational costs, low utilisation capacity, and shortage of qualified personnel with the required competence to service the equipment[2].

In this respect, in the year 2020, the Government of Tanzania, through the Ministry of Health, spent an amount of TZS 68.706 billion to procure medical equipment for health facilities located in 22 Local Government Authorities throughout the country to implement the National Healthcare Policy of 2017. Based on this fact, it is essential to properly regulate medical equipment to achieve value for money while ensuring the delivery of healthcare services at the intended quality.

[1] https://www.who.int/health-topics/medical-devices#tab=tab_1 (accessed on June, 2021).
[2] The National Health Policy 2017, 6th Draft Version

1.2 Motivation for the Audit

The effective functioning of medical equipment is crucial to ensure the delivery of quality healthcare services. In this respect, the decision to audit the regulation of medical equipment was motivated by its importance and the reported weaknesses while providing healthcare services in public health facilities. Regardless of the significant amount of funds spent on procuring medical equipment and various improvements made by the government in the health sector. Therefore, the motivation behind the audit is detailed as follows:

(a) Promote achievement of sustainable development goals and national health policy objectives

This audit area is linked to one of the 17 Sustainable Development Goals of the United Nations. Specifically, it supports target 3.8 of SDG Goal 3, which aims to provide access to affordable, safe, and quality essential healthcare services. This implies that the improvement in regulating medical equipment directly supports and promotes this Sustainable Development Goal of ensuring health and well-being for all ages.

In this respect, the regulation of medical equipment facilitates the achievement of the National Health Policy of 2003, as amended in 2017, to improve public health in the country. This means that effective regulation of medical equipment can improve timely access to healthcare, contributing to national development and a healthier society.

The importance of safeguarding people's health

Effective regulation of medical equipment is key to effective and up-to-date diagnostic services. Supporting a functional health facilities system for providing healthcare services is also essential. This is because all health facilities need diagnostic capacity appropriate to their respective levels of care (laboratory, radiology, and medical imaging). This facilitates the provision of quality healthcare services based on the requirements of the essential package of the respective level. This is essentially for safeguarding people's health and ensuring that there is socio-economic development as well.

(b) Presence of unfunctional Medical Equipment in the Health Facilities

Based on the Regional Health Management Teams' Annual Plans Report for the Financial Year 2019/20 of the Mbeya and Mtwara Regions, it is indicated

that medical equipment was not functioning as expected. In the case of Mbeya, it was indicated that 50%, 15%, and 25% of medical equipment in Mbarali DC, Mbeya CC, and Mbeya DC were unfunctional.

Unfunctional medical equipment was linked to inadequate maintenance, shortage of spare parts, and absence of qualified personnel to operate the equipment. This resulted in most patients being forced to travel long distances to access healthcare services. This situation is a clear manifestation of weaknesses in the regulation of medical equipment.

(c) Increased budget allocated for the procurement of Medical Equipment

On 1st March 2021, the Minister for Health reported that the Government increased its budget for procuring Medicines and medical equipment from TZS 31 billion in 2015/16 to TZS 270 billion in 2020/21. In this regard, proper regulation of medical equipment is critical to ensure that the value of money spent on procuring medical equipment is realised[3].

1.3 The Design of the Audit

The audit process was guided by both general and specific objectives as follows:

1.3.1 General audit objective

The general objective of the audit was to assess the effectiveness of the Ministry of Health (MoH) and the Tanzania Medicines and Medical Devices Authority (TMDA) in regulating medical equipment to ensure the safety and quality of healthcare services delivered by public health facilities in the country.

Specific audit objectives

The audit process was guided by six (6) specific objectives, which focused on assessing whether the:

a) Procedures for registration of medical equipment are adequately functioning;

[3] https://www.thecitizen.co.tz/tanzania/news/-heads-to-roll-at-the-health-ministry-as-report-reveals-loss-of-sh27billion-in-drug-scam-3309006, Visisted on 16th June 2023.

b) Procured medical equipment by health facilities meets standards;
c) Maintenance of medical equipment in public health facilities is adequately done;
d) Performance of medical equipment in health facilities is effectively monitored;
e) Disposal of functional medical equipment is effectively done; and
f) Coordination between Ministries (MoH and PO-RALG), TMDA, and health facilities in regulating medical equipment is effectively done.

The specific audit and sub-audit questions were prepared to operationalise the audit objectives clearly, as presented in **Appendix 2.**

1.3.2 The scope of the audit

The main audited entities were the Ministry of Health (MoH) and the Tanzania Medicines and Medical Devices Authority (TMDA). In this respect, the Ministry of Health is responsible for formulating healthcare policies and ensuring their implementation, conducting inspections of healthcare services provided in the country, and managing medical equipment.

Similarly, the Ministry receives technical advice on the safety, quality, and effectiveness of medical equipment from TMDA. On the other hand, TMDA is an executive agency under the MoH responsible for controlling and regulating medical equipment quality, safety, and efficacy before and after use in the country.

In this respect, the audit assessed how Medical Equipment was regulated and managed throughout its life cycle, including pre-marketing authorisation, during marketing, maintenance, performance monitoring, and the disposal of unfunctional medical equipment. It further assessed the effectiveness of coordination between Ministries (MoH & PO-RALG), TMDA, and healthcare providers in regulating medical equipment.

Based on procedures for registration of medical equipment, the audit assessed the timeliness of TMDA in processing applications for registration of medical equipment that ought to be imported, already imported, and that is in use in health facilities; assess whether TMDA ensures the effective renewal of medical equipment certificate of registration; assessed on whether TMDA effectively collects and test samples of medical equipment applied for registration; and on whether TMDA effectively ensures that, registrants timely pay annual fee for the registered medical equipment.

Regarding the procurement of medical equipment in public health facilities that meet the required standards, the audit assessed the effectiveness of TMDA in verifying and inspecting imported medical equipment before its utilisation in public health facilities. Also, the audit assessed whether TMDA ensures that import permits are given to registered medical centres. Also, the assessment considered whether TMDA effectively established and maintained files demonstrating compliance with International Standards and regulatory requirements for each model of medical device. On the other hand, the audit assessed whether TMDA ensures procured Medical Equipment is accompanied by a user manual with detailed information on maintenance and troubleshooting and whether TMDA effectively enforces non-compliance issues with the procured medical equipment.

Moreover, the audit assessed the effectiveness of TMDA in planning and executing monitoring activities to track the performance of medical equipment in health facilities. This included evaluating whether TMDA effectively ensured registrants submitted biennial post-market surveillance reports, including any adverse occurrences.

Furthermore, the audit assessed the extent to which TMDA ensures healthcare providers report on the performance of medical equipment and the measures which TMDA has undertaken to address the reported challenges. Also, the audit assessed the extent of follow-ups conducted by TMDA on the implementation of the submitted recommendations by healthcare providers.

Regarding the disposal of non-functional medical equipment, the audit assessed the availability of a functional system to ensure non-functional medical equipment was properly disposed of. This included assessing the adequacy of TMDA in verifying information for the equipment to be disposed of. Additionally, the audit assessed the effectiveness of coordination between MoH and TMDA with other stakeholders responsible for medical equipment management. In this respect, it assessed whether the coordination effectively improves the functionality of medical equipment in providing healthcare services. Also, the audit assessed whether health facilities were provided with guidelines and training on properly using and maintaining the procured medical equipment.

To achieve the objectives of the audit, the audit team mainly focused on class D medical equipment, which was high-risk equipment that required

close monitoring and regulation from TMDA to safeguard users and patients from having adverse effects that could evolve from the use of such equipment. This, in turn, minimises the adverse effects on users and patients as well.

Therefore, the audit covered the period of four fiscal years, that is, 2019/20 to 2022/23. The rationale for the coverage of this period is that it enabled the audit team to analyse the performance trends of MoH and TMDA in regulating medical equipment and finally draw sound conclusions and recommendations. Also, during this period, the government supplied the required medical equipment in most of the country's health facilities. Meanwhile, in 2022/23, the government, through the Ministry of Health, spent more than TZS 270.2 billion on medical devices for 120 health facilities.

The assessment criteria

In order to assess the performance of MoH and TMDA in regulating medical equipment, the assessment criteria were drawn from different sources such as policies, legislations, guidelines, standards, good practices, and strategic plans from TMDA.

The following are the assessment criteria which were used for each specific audit objective:

(a) Adequately functioning procedures for the registration of Medical Equipment

Regulation 7(2)(b) of the Tanzania, Food, Drugs and Cosmetics (Control of medical devices) Regulations, 2015 requires every application for registration of medical equipment shall be accompanied by samples of the medical device and, or artwork as the case may be at the time of application.

Paraph 1.10 of the Guidelines on Submission of Documentation for Registration of Medical Devices, 2020 states that, once an application has been accepted and evaluation fees paid, the Processing of the application for registration of medical equipment class A will take 45 working days, and for class B, C and D will take 90 working days. Similarly, Paraph 8.1 (Service Standards) of the Tanzania Medicines and Medical Devices Authority Clients' Service Charter, 2020 requires that, the standard time for registration of domestic Medical Equipment class B, C, and D should be within 45 days and that of imported medical devices should be 90 days.

Moreover, Regulations 17(2) and 18(g) of the Tanzania Food, Drugs and Cosmetics (Control of medical devices) Regulations, 2015 require that every registrant shall, in addition to the fees related to registration of each medical device, pay annual retention fees before 31st January of each calendar year. In this respect, the Authority may suspend or cancel the registration of medical devices if it has reasonable grounds to believe that, the registrant of a respective medical device fails to pay the prescribed retention fee, which is in force within the stipulated time.

Furthermore, Regulation 17 (4 & 5) of the Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices), 2015 & Paraph 1.6 (Applications for renewal of registration) of the Guidelines on submission of documentation for Registration of medical devices, 2020 require the application for renewal of registration to be made to the Authority at least 90 days before its expiry. Further, it provides that, a grace period for renewal should extend to 90 days after the specified expiry date.

(b) Procured Medical Equipment in Health Facilities meets the required standards

Regulation 56(1) of the Tanzania, Food, Drugs and Cosmetics (Control of medical devices) Regulations, 2015 requires that, no imported medical equipment be cleared at the port of entry or any other place before it is inspected by the inspector and released.

On the other hand, Section 22(1) a &b, 22(2) c of the Tanzania Food, Drugs and Cosmetics Act, 2003, as amended by section 24 of the Finance Act, 2019 2003, notwithstanding the provisions of this Act or any other written laws, no person shall, on or after the appointed day, manufacture for sale, sell, offer, supply or import any product regulated under this Act unless the product is registered as per the provisions of this Act; the person holds the appropriate licence or permit required and issued by the Authority. Similarly, no person shall, in the course of any business carried on by him, sell, supply, import, or export any product by way of wholesale dealing or retail except in accordance with the licence or permit granted by the Authority.

Regulation 45 of the Tanzania Food, Drugs and Cosmetics (Control of medical devices) Regulations, 2015 stipulates that, no Person shall import a medical device regulated under this regulation unless he/she holds a valid permit issued by the Authority.

(c) Monitoring the performance of Medical Equipment in the Health Facilities

According to TMDA's Strategic Plan for the year 2016/17-2020/21, TMDA is required to improve the quality, safety, and effectiveness of medical equipment by improving the regulation of medical equipment and diagnostics.

Similarly, the International Organisation for Standardisation (**ISO 14971:2000)** emphasises that manufacturers must have a framework for monitoring the performance of medical equipment after the sale.

On the other hand, the Medical Device Regulations Global Overview and Guiding Principles (page 43), 2003 emphasises that, there must be monitoring of medical equipment through post-market surveillance to check the training of users before the use of medical equipment; regular maintenance of medical equipment in accordance with operation and service manuals; the presence of user networks and medical vigilance system to facilitate alert notification and adequate management and proper disposal of discarded devices.

In addition, Section 4.5 of the TMDA's Strategic Plan of the year (2017/18-2020/21) requires TMDA to conduct monitoring through post-market surveillance of medical equipment, testing and analysing medical equipment. Also, TMDA is required to produce quarterly reports of post-market surveillance.

(d) The disposal of unfunctional Medical Devices

Based on Regulation 62 (3, 4) Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 states that, after the verification exercise, TMDA is required to inform the applicant to liaise with the National Environment Management Council (NEMC) or any other Institution responsible for environment management on the proposed mode of destruction and issuance of disposal permit. It also requires the applicant to liaise with the Local Government Authority regarding the disposal site, cost, and destruction date of unfunctional medical devices.

Moreover, TMDA is required to ensure that the approval of the request to dispose of unfunctional medical devices is accompanied by a list of medical equipment to be disposed of. This list has to clearly state the trade name, generic name, strength, dosage form (where applicable), type of packaging

material, pack size, quantity, manufacturer, batch or lot number, and market value of each product.

Likewise, Regulations 62 (1), (2), (3), (4) and (5) c of Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 states that approval of the request to dispose unfunctional medical devices from Government Institutions is required to be accompanied by an approval from the Accountant General. The approval has to declare that, the products have been written off in the Books of Account and that, they are subject to disposal as required by the Public Finance Act and its Regulations in force for the time being. It is further required to state that, TMDA can condemn and order the destruction or disposal of any Medical device/equipment found unsuitable for its intended use.

(e) The coordination in the management of Medical Equipment

According to Sections 5(1) (e), (2) (a) of the Tanzania Food, Drugs and Cosmetics Act, 2003 as amended by section 24 of the Finance Act, 2019, TMDA is required to foster co-operation with LGAs, health facilities, TAEC and NEMC and maintain a system of consultation and cooperation with TAEC.

Also, Section 121 of the Tanzania Food, Drugs and Cosmetics Act, 2003, as amended by section 24 of the Finance Act, 2019states that, the Minister for Health, upon consultation with TMDA, when he considers appropriate and proper by order published in the Gazette, delegate to any other person, institution or body of persons some of the functions or powers of the Authority conferred upon it by Tanzania Food, Drugs and Cosmetics Act, 2003 as amended by section 24 of the Finance Act, 2019. On the other hand, Section 57(2) of the Local Government (Urban Authorities) Act, 1982, mandates TMDA to delegate some of its functions to LGAs in the country.

Similarly, Article 27 of the Protocol on Health in the Southern African Development Community (SADC), 1999, emphasises that, State parties are required to co-operate in the development and formulation of coherent, comparable, harmonised and standard policies and strategies on health technology and medical equipment, shall co-operate in the control of the procurement and maintenance of medical equipment.

Likewise, GN No.144, published on 22 April 2016, requires the MoH to coordinate international and local NGOs managing medical equipment.

1.4 Sampling Techniques, Data Collection and Analysis Methods

Various techniques for sampling and methods for data collection and analysis were used by the Audit Team, presented as follows:

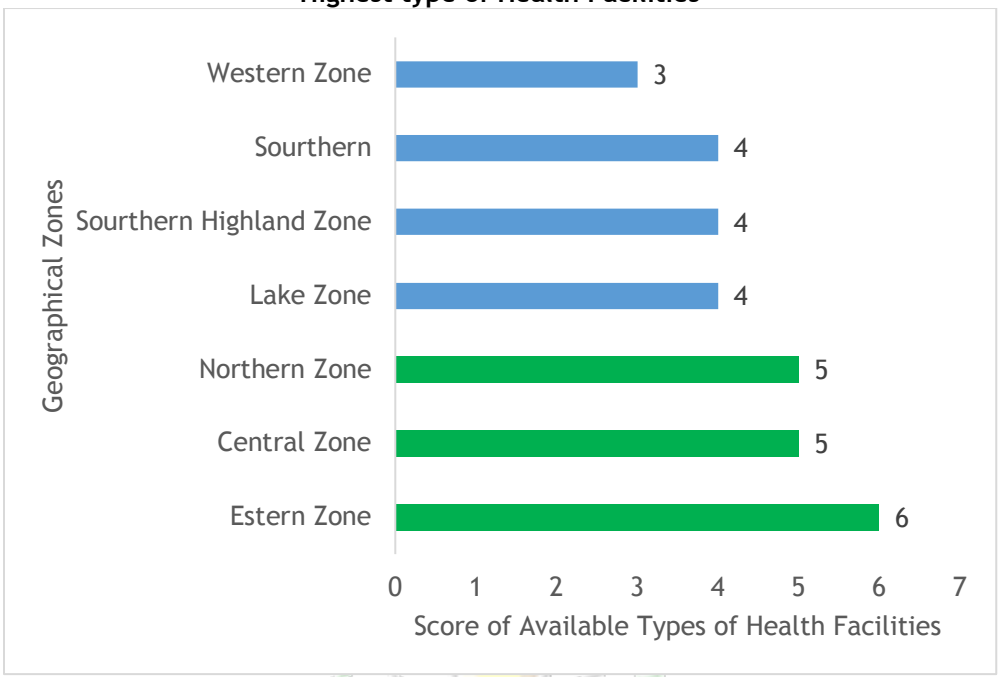
1.4.1 Sampling techniques used in the audit

A purposeful sampling technique was employed to select TMDA's Zonal Offices to be covered, health facilities and types of medical equipment to be assessed by the Audit Team. The rationale for using purposeful sampling was to ensure that, the selected entities by the audit team enable the collection of information to respond to the audit objectives as follows:

The sampling of TMDA's zonal offices

The Audit Team considered seven (7) geographical zones in sampling. In this regard, seven (7) geographical zones were ranked based on the types of health facilities available in the respective zones. The types of health facilities used for ranking were health centres, District Hospitals, Regional Referral Hospitals, Zonal Referral Hospitals, National Hospitals and National super-specialised Hospitals. The availability of each type of health facility in a zone was considered to score 1, whereas the maximum score was 6. The details of selected Geographical Zones are indicated in **Figure 1.1**:

Figure 1. 1: Ranking of the Zones for the Selection Based on the available Highest type of Health Facilities



Source: *Auditors' Analysis of the Health Facility Registry (HFR) Portal[4] (2023)*

Key information

Indicator	:	Available Type of Health Facility
1	:	Health Centres
2	:	Health Centres, District Hospitals
3	:	Health Centres, District Hospitals and Regional Referral Hospitals
4	:	Health Centres, District Hospitals, Regional Referral Hospitals, and Zonal Hospital
5	:	Health Centres, District Hospitals, Regional Referral Hospitals, Zonal Hospital and National Super Specialized Hospitals
6	:	Health Centres, District Hospitals, Regional Referral Hospitals, Zonal Hospital, National Hospital and National Super Specialised Hospitals

From **Figure 1.1,** the audit visited public health facilities in the eastern, central, and northern zones. These zones scored 5 to 6 on the list of available types of health facilities. The western zone was not selected because it had the least high-level health facilities, with its highest level at

[4] https://hfrs.moh.go.tz/web/index.php?r=portal%2Findex, Accessed on 6th June, 2023.

a Regional Referral Hospital. The audit team decided to select a zone with the largest number of health facilities. In this regard, the highest level of facilities is the zonal referral hospital, as indicated in **Table 1.1**.

Table 1. 1: The selected zone based on the number of Health Facilities in a zone

Geographical Zones	Type of Health Facilities	Number of Facilities in Zone	Status
Lake Zone	4	228	Selected
Southern Highland Zone	4	154	Not Selected
Southern	4	110	Not Selected

Source: *Auditors' analysis from the Health Facility Registry (HFR) Portal*[5] *(2023)*

Table 1.1 indicates that, the lake zone was selected and covered under this audit in a group of Zones that scored 4 points. This was due to the fact that, this zone had the highest number of health facilities.

The Sampling of Regions

The sampling of regions was purposeful based on four (4) selected geographical zones: eastern zone, central zone, northern zone, and lake zone. Also, the sampling was done based on the type of health facilities available in the region. The region with a large number of higher types of healthcare facilities than the rest within a zone was prioritised. This was due to the fact that, audit objectives mainly focused on healthcare facilities. The selection of regions is detailed in **Table 1.2.**

[5] https://hfrs.moh.go.tz/web/index.php?r=portal%2Findex, Accessed on 6th June, 2023.

Table 1.2: The Sampled Regions Covered

Zones	Regions	Highest type Facility	Selection Status
Central Zone	Dodoma	Super Specialised Hospital	Selected
	Singida	Regional Hospital	Not Selected
	Morogoro	Regional Hospital	Not Selected
Lake Zone	Geita	Zonal Hospital	Selected
	Kagera	Regional Hospital	Not Selected
	Mara	Regional Hospital	Not Selected
	Mwanza	Regional Hospital	Not Selected
	Simiyu	Regional Hospital	Not Selected
	Shinyanga	Regional Hospital	Not Selected
Northern Zone Office	Arusha	Zonal Hospital	Not Selected
	Kilimanjaro	Super Specialised Hospital	Selected
	Manyara	Regional Hospital	Not Selected
	Tanga	Regional Hospital	Not Selected
Eastern Zone	Dar Es Salaam	National Hospital	Selected
	Pwani	Regional Hospital	Not Selected

Source: Auditors' Analysis of HFR (2023)

From **Table 1.2**, the four (4) regions covered, namely, Dar es Salaam with a National Hospital, Dodoma with a National Super Specialised hospital, Kilimanjaro with a National Super Specialised Hospital, and Geita with a Zonal Hospital.

The Sampling of Health Facilities

The audit considered all levels of health facilities, including health centres, district hospitals, regional referral hospitals, zonal hospitals, and super-specialised national referral hospitals. The rationale was to assess the performance of MoH and TMDA in managing medical equipment at different levels to ensure adequate provision of quality healthcare services. Also, to assess proper management of medical equipment at basic and hospital levels (Health centres and District Hospitals). This would facilitate the provision of quality healthcare services to a larger number of citizens who mainly depend on the healthcare services offered at this level.

Therefore, in each of the selected zonal offices, the audit team visited 4 to 6 health facilities (one health centre, one district hospital, one regional referral hospital, one zonal referral hospital, one national super specialised

hospital and a national hospital). In this regard, only four (4) health facilities were covered in zones that do not have national referral hospitals and national super-specialised hospitals. This means six (6) health facilities were audited in Dar es Salaam Region, while five (5) were audited in Dodoma. On the other hand, Kilimanjaro and Geita regions each had four (4) audited facilities. **Table 1.3** shows the sampled health facilities in the respective regions.

Table 1. 3: The selected Health Facilities visited

Region	LGAs in which (1 Health Centre and 1 District Hospital) visited	Facility at the Regional Level & Zonal	Facility at the National Level	Total Health Facilities	Rationale fo the selection of health centre (HC)
Dar es Salaam	Ilala City Council	Amana Regional Hospital Lugalo Military Referral Zonal Office	1) Muhimbili National Hospital 2) Ocean Road Cancer Institute (ORCI)	6	1HC and 1 District Hospital were randomly Selected
Dodoma	Dodoma City Council	General Hospital Benjamin Zonal Referral Hospital	Mirembe Mental Hospital	5	1 HC and 1 District Hospital were randomly Selected
Geita	Geita Town Council	Geita Regional Hospital Chato Zonal Referral Hospital	Nil	4	1 HC and 1 District Hospital were randomly Selected

Region	LGAs in which (1 Health Centre and 1 District Hospital) visited	Facility at the Regional Level & Zonal	Facility at the National Level	Total Health Facilities	Rationale fo the selection of health centre (HC)
Kilimanjaro	Hai District Council	Mawenzi Regional Referral Hospital	Kibong'oto Super Specialised Hospital	4	1 HC and 1 District Hospital were randomly Selected

Source: *Auditors' Analysis of the National Distribution of Health Facilities (2023)*

From **Table 1.3**, the audit team visited 19 health facilities representing all levels of health facilities. The categories of health facilities covered comprised health centres, district hospitals, regional referrals, zonal referral hospitals, and national referral hospitals.

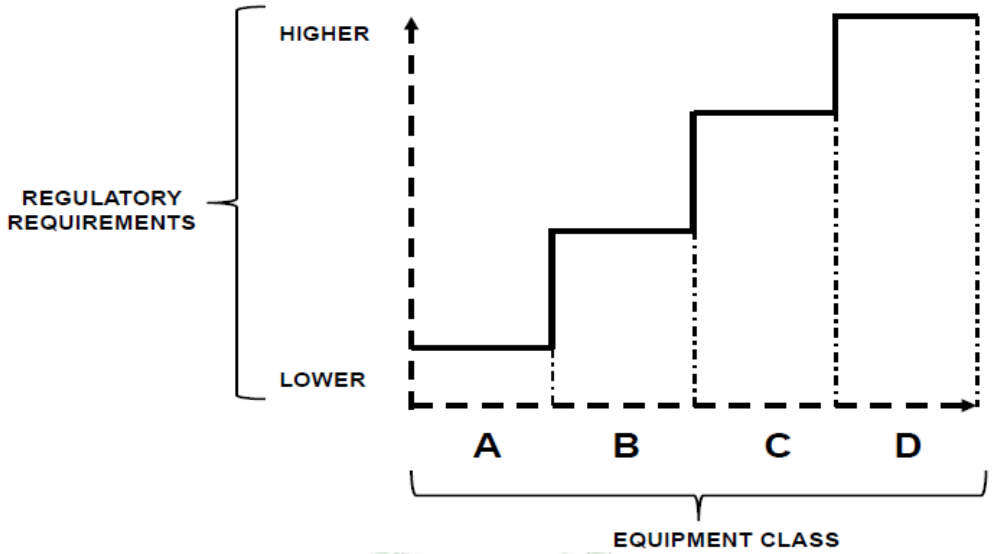
The sampling of Medical Equipment assessed

Medical equipment covered during the audit was purposefully selected by considering a combination of factors discussed as follows:

Category of Medical Equipment: Medical equipment is classified into four categories based on its level of risk. The classification rules depend on the equipment's features, such as:

- *Is life-supporting or sustaining*
- *Is invasive, and if so, to what extent and for how long*
- *Is an active medical device*
- *Could modify blood or other body fluids*
- *Incorporates medicinal products*
- *Incorporates human or animal tissues or cells*
- *Delivers medicinal products, energy or radiation*
- *Is used in combination with another medical device*

Figure 1.2: The Impact of Medical Equipment Classification on the Regulatory Scrutiny



Source: *WHO Global Model Regulatory Framework for Medical Devices, including in Vitro Diagnostic Medical Devices (2017)*

Table 1.4: Examples of Medical Devices by Risk Class[6]

Class	Risk	Examples
A	Low	Syringes, examination gloves, patient hoists, stethoscopes, wheelchairs, IVD instruments, microbiological culture media
B	Low – moderate	Surgical gloves, infusion sets, pregnancy tests
C	Moderate – high	Condoms (unless with spermicide (class D), infusion pumps, neonatal incubators, therapeutic and diagnostic X-rays, lung ventilators, haemodialysers, anaesthesia equipment, self-test glucose strips, IVDs for the diagnosis of Neisseria gonorrhoea
D	High	Implantable cardioverter defibrillators, pacemakers, breast implants, angioplasty balloon catheters, spinal needles, IVDs for the diagnosis of HIV, hepatitis C or hepatitis B

Source: *WHO Global Model Regulatory Framework for Medical Devices, including in Vitro Diagnostic Medical Devices (2017)*

Based on the description of classification above with examples indicated in **Table 1.4**, the category of medical equipment to be covered was selected

[6] The actual classification of each device depends on the claims made by the manufacturer for its intended use and the technology or technologies it utilizes. As an aid to interpreting the purpose of each rule, illustrative examples of medical devices that should conform to the rule have been provided in the table above. However, it must be emphasised that a manufacturer of such a device should not rely on it appearing as an example but should instead make an independent decision on classification taking account of its design and intended use.

by considering medical equipment that constituted a high risk for health and the ones with a high acquisition cost. Therefore, among the four (4) risk categories[7] of medical equipment, i.e., Class A, B, C and D, the focus was on class D medical equipment since they require close monitoring and regulation from TMDA to protect operators and patients from having adverse effects during and after the use.

The financial value/purchasing cost: The market value of medical equipment was rated as Very low, Low, Medium and High, as shown as follows.

Table 1.5: Cost of medical equipment

	Financial Value/Purchasing Cost of Medical Equipment		Categories based on Value
1.	Above TZS 20,000,000	:	High Market Value
2.	Between TZS 5,000,000 and TZS 20,000,000	:	Medium Market Value
3.	Between TZS 1,000,000 and TZS 5,000,000	:	Low Market Value
4.	Below TZS 1,000,000	:	Very Low Market Value

Source*: WHO Global Model Regulatory Framework for Medical Devices, including in Vitro Diagnostic Medical Devices (2017)*

The audit focused on the medical equipment under class D, with a high market value above an amount of TZS 20 million. This factor was considered because if the management of high-value medical equipment was not effectively done, it would pose a high risk for the community not realising the value of money in services rendered. A detailed analysis of the factors of the price being assumed low, medium, and high is indicated in **Table 1.5.**

The Technology and skills required: The audit prioritised the medical equipment requiring specialised or more sophisticated skills to enable the Audit Team to assess the capacity of TMDA to manage different kinds of medical equipment from the acquisition to the point of application. In this regard, the audit team was able to determine TMDA's capacity for conducting effective verifications and inspections of such kinds of medical equipment and the capacity of health facilities to perform maintenance as expected.

The Medical Equipment authorised for use in the Health Facilities: The focus was also on medical equipment designated by the Ministry of Health

[7] Class A represents medical equipment with low risks such as surgical retractors and tongue depressors; class B represent a low-moderate risk such as hypodermic needles and suction equipment and class C is for Moderate-high risk under this class examples are lung ventilator and bone fixation plate. Also, class D represents high risk medical equipment such as implantable defibrillator.

for use in the sampled health facilities[8]. Medical equipment at one level may differ from other Health Facilities, which enabled the audit team to avoid selecting medical equipment that was not designated for that health facility. A summarized list of selected medical equipment is presented in **Table 1.6**:

Table 1.6: The selected class D Medical Equipment

Name of the Medical Equipment	Level of the Health Facilities
MRI	Regional and National Referral Hospitals,
CT scan	Regional and National Referral Hospitals
Complete X-ray Unit	Health Centres, District, Regional and National Referral Hospitals
Mobile X-ray	Regional and National Referral Hospitals
Mammography Unit	Regional and National Referral Hospitals
Chemistry Analyzer	Health Centres, District, Regional and National Referral Hospitals
Ultrasound Machine	District, Regional and National Referral Hospitals
Major Operating Light 1	Health Centres, District, Regional and National Referral Hospitals
X-ray machine for dental diagnosis	Regional and National Referral Hospitals
Haematology Analyser	District, Regional and National Referral Hospitals
Differential counter	Health Centre and District Hospital
Ventilator	Health Centres, District, Regional and National Referral Hospitals
Diathermy Machine	Super Specialised Hospitals and National Level
Electrocardiography (ECG) Machine	Super Specialised Hospitals and National Level
Linear Accelerator (LINAC)	Super Specialised Hospitals and National Level
Electroencephalogram (EEG)	Super Specialised Hospitals and National Level

Source*: Auditors' Analysis of Medical Equipment for Health Centres (HC), District and Regional and National Referral Hospitals (2021)*

1.4.2 The Methods for Data Collection

The audit team gathered reliable and sufficient data through a triangulation of various data collection methods to address the audit questions and achieve the audit objective. These methods comprised documentary reviews, interviews, and observation through physical verification.

Documentary review

Different documents were reviewed to obtain comprehensive, relevant, and reliable information about the performance of the Ministry of Health through TMDA in regulating medical equipment in the Country. The other reason for conducting a documentary review was to corroborate information from interviews and observations done through physical verification. The

[8] Basic Standards for Health Facilities, Volume 1, 2, 3 and 4.

main categories of reviewed documents included short and long-term plans, performance and progress reports, and monitoring and evaluation reports. The specific list of documents reviewed and the reasons for their review is presented in **Appendix 3.**

Interviews

Interviews were conducted to obtain more information and further clarification on the information obtained through documentary review and observation. Also, the interviews were conducted to obtain comprehensive, relevant, and reliable information regarding the performance of the Ministry of Health through the TMDA in regulating medical equipment in the country. The list of officials who were interviewed is presented in **Appendix 4**.

Observation through physical verification

The audit team used the observation method by verifying the state of medical equipment in the selected public health facilities, assessing their condition, reviewing medical equipment records in the asset register, and determining the presence of scheduled maintenance of medical equipment and proper storage.

However, observation through physical verification was guided by an operational manual and guidelines forms for managing medical equipment. This guide enabled the audit team to assess whether medical equipment were effectively regulated.

1.4.3 Methods for data analysis

Quantitative data collected through documentary review were analysed using an excel spreadsheet. Quantitative data were analysed by organising, summarising, and compiling them using descriptive statistics. Then, the analysed data were presented in tables and graphs.

Qualitative data collected through interviews were described, compared, and categorised to generate findings based on the audit objectives. The analysis takes into account categories of issues such as events, descriptions, consistencies, or differences in the evidence provided to draw valid conclusions based on the audit objectives.

1.5 Data Validation Process

The Ministry of Health and TMDA were given the opportunity to go through the draft report and comment on the information and figures presented. MoH and TMDA confirmed the accuracy of the information and figures presented in this audit report. The information was also crosschecked and discussed with experts in the field of regulation of medical equipment to confirm the validity of the information and facts presented in the audit report.

1.6 The Standards Used for the Audit

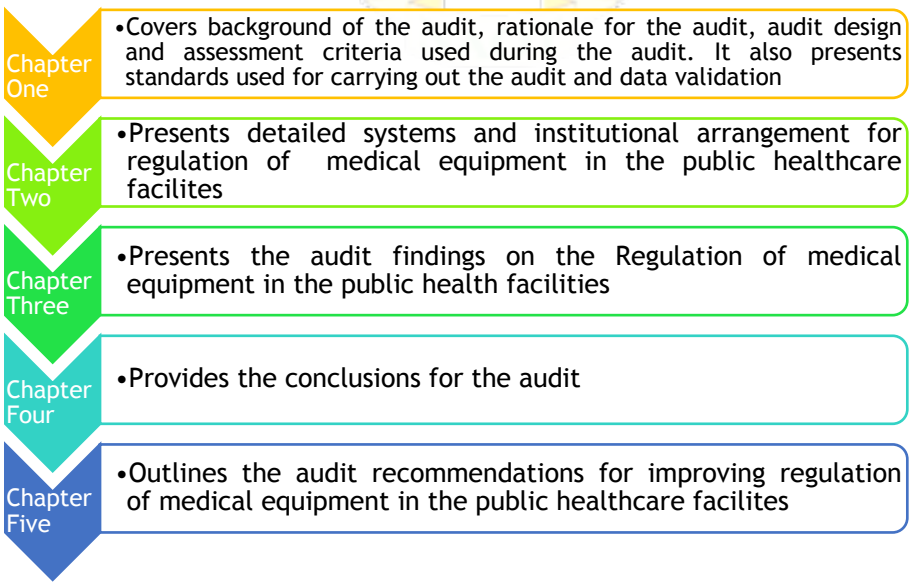
The audit was done in accordance with the International Standards of Supreme Audit Institutions (ISSAIs) on performance audit issued by the International Organisation of Supreme Audit Institutions (INTOSAI).

These standards require that, an audit is planned and performed to obtain sufficient and appropriate audit evidence to provide a reasonable basis for the findings and conclusion based on audit objectives.

1.7 The Structure of the Audit Report

Chapters of this report cover the following, as presented in **Figure 1.3**:

Figure 1.3: The Structure of the Audit Report



CHAPTER TWO

THE SYSTEMS FOR THE REGULATION OF MEDICAL EQUIPMENT

2.1 Introduction

This chapter describes the country's system for regulating medical equipment. It presents policies and legislations, strategies and plans governing the regulation of medical equipment. It also presents the roles and responsibilities of key stakeholders, funding arrangements, and the processes for regulating medical equipment in the country.

2.2 The Governing Policy and Legislation

2.2.1 The Governing Policy

The National Health Policy, 2007

The specific objective of the National Health Policy is to reduce communicable diseases. In this regard, para 5.5.2 emphasises that the government should strengthen the supply and distribution of medical equipment to ensure the prevention and care of communicable diseases.

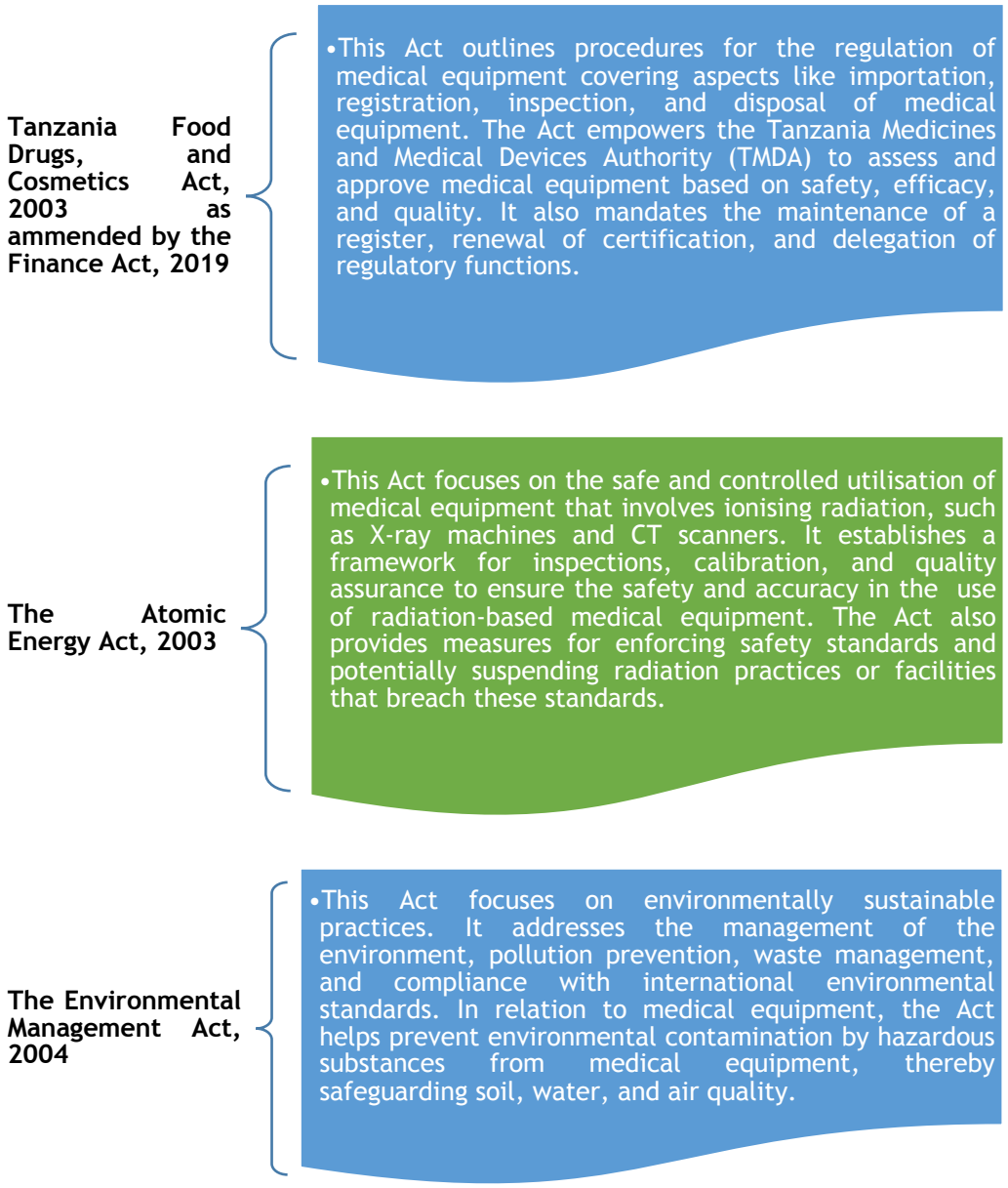
Likewise, para 5.10.2 of the policy requires the Government to improve rehabilitation services for persons with disabilities by strengthening the national support systems for assistive Medical Equipment.

2.2.2 The Governing Legislation

(i) The Governing Acts

The main acts governing the regulation of medical equipment in the country are described in **Figure 2.1**.

Figure 2.1: The Acts Governing the Regulation of Medical Equipment in the Country

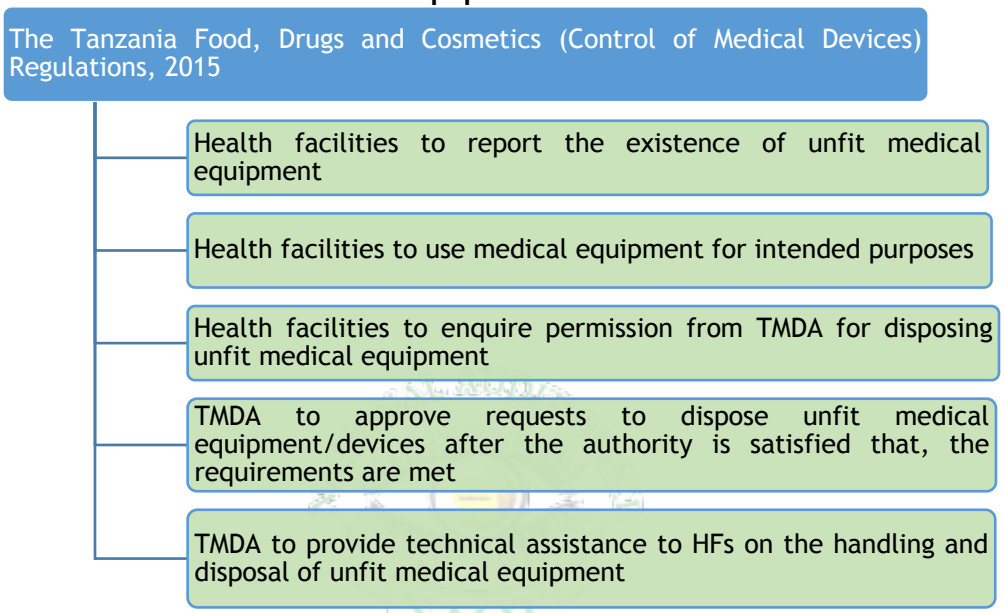


Source: *Auditors' Analysis of the Governing Acts for Regulation of Medical Equipment (2023)*

(ii) The Governing Regulations and Guidelines

Governing regulations specify different stakeholders' responsibilities in the regulation of the medical equipment process, as detailed in **Figure 2.2.**

Figure 2. 2: The Governing Regulations for the Regulation of Medical Equipment



Source: *Auditors' Analysis of Regulations (2023)*

(iii) The Guideline for the Regulation of Medical Equipment

The guidelines for the regulation of medical Equipment with specified responsible stakeholders are detailed in **Table 2.1**.

Table 2.1: The Guidelines for the Regulation of Medical Equipment

Guideline	Responsible Entity	Responsibilities/ Requirement
TMDA Guidelines for Importation and Exportation of Medical Devices, including in Virteo Diagnostics and Laboratory Equipment, 2020	Health Facilities	Ensure medical equipment has a user's manual with detailed maintenance, troubleshooting, and precaution information.
	TMDA	Ensure that HFs and licensed medical equipment dealers liaise with the requirement of medical equipment that has a user's manual.
Guidelines for Preventive Maintenance	Health Facilities	Conduct maintenance to medical equipment

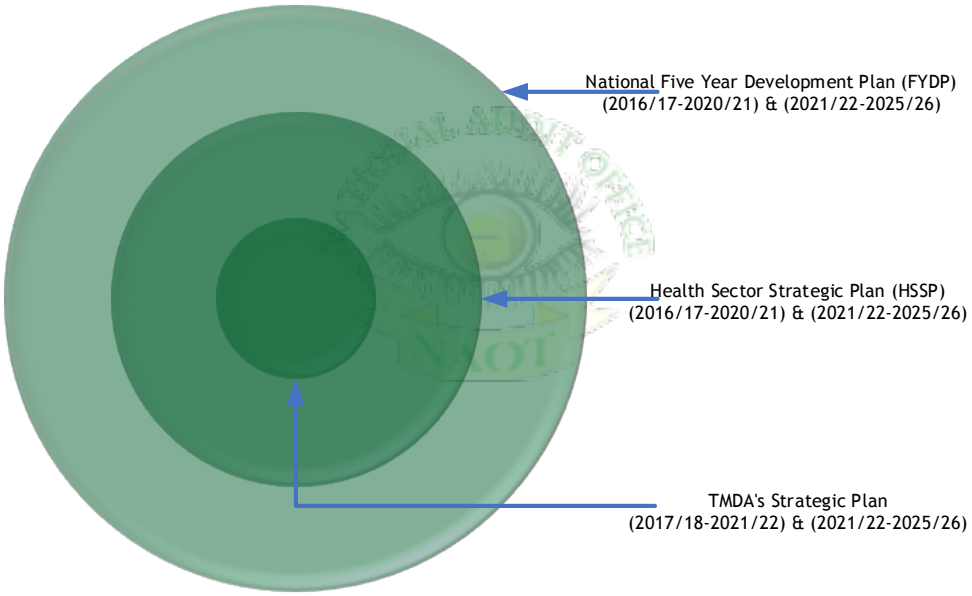
Guideline	Responsible Entity	Responsibilities/ Requirement
of Medical Equipment Volume 1, 2017 The Basic Standards for Hospitals at Level III & IV and Super Specialised Clinics at Level III		Plan for procurement of medical equipment and spare parts Propose service contracts with suppliers and funding where possible Ensure the availability of small workshops and maintenance stores at all facilities.

Source: *Auditors' Analysis of Regulations and Guidelines (2023)*

2.2.3 The Plans and Strategies

Figure 2.3 shows the relationship between key strategies/plans for regulating medical equipment in the country.

Figure 2. 3: The relationship between different strategies on the regulation of Medical Equipment



Source: *Auditors' Analysis of FYDP, HSSP, and TMDA Institutional Strategic Plans (2023)*

The National Five-Year Development Plan of 2016/17-2020/21

The National Five-Year Development Plan (2016/17 – 2020/21) aimed to enhance the accessibility of specialised healthcare services by enhancing diagnostic capabilities within the country. This objective was pursued by acquiring and maintaining medical equipment for regional and district hospitals. The plan also entailed organising short-term and long-term training programmes for healthcare personnel in referral, specialised, and national hospitals. Generally, the plan aimed to equip these hospitals with modern medical equipment.

The Health Sector Strategic Plan (HSSP) July 2021 to June 2026

In the strategic outcome, the focus is on quality of care which is geared towards ensuring the availability of high-quality essential healthcare services and interventions. The government's strategy involves bolstering the standardised procurement system and enhancing preventive maintenance and repair procedures for medical equipment. This responsibility is delegated to regional and zonal maintenance centres.

This implies that, implementing managed equipment services is intended to maintain the continuous functionality of medical equipment, encompassing laboratory, radiology, and medical imaging equipment, all in a cost-effective manner.

Similarly, within the health sector, the primary goal is to secure access to affordable, safe, and high-quality medical equipment to meet the nation's service delivery needs across all levels of care. To achieve this, the government has established a centralised committee responsible for quantifying all commodities and supplies at the national level. This committee also standardises equipment and maintenance protocols for all essential medical equipment.

MoH Medium Term Strategic Plan of 2016/17 -2020/21

MoH Strategic Plan 2016/17 aimed to improve the provision of curative services through diagnostic services and the quality of health services in all health facilities.

This was to be attained through strengthened laboratory management, planned preventive maintenance of medical equipment facilitated at all levels of health facilities, quality radiology services maintained at all levels, and operationalised inventory of medical equipment at all health facilities. The outcomes would be the improved quality of health laboratory and radiology services, the achievement of lifetime usability of medical equipment, and reduced downtime of medical equipment.

TMDA's Strategic Plan 2017/18-2021/22

Objective D on Paraph 3.2.4 of the TMDA - Strategic Plan 2017/18 – 2021/22 was to ensure medical equipment's quality, effectiveness, and safety.

To attain that, the targets below were set as indicated as follows:

(i) Marketing surveillance and vigilance of medicines, medical devices, and diagnostics would be conducted by June 2022 through Post Market Surveillance (PMS) for medical equipment and stakeholder meetings on pharmacovigilance and PMS.

(ii) Products (medicines, medical devices, and diagnostics) registered by June 2022 through evaluating applications for promotional adverts; evaluating applications for clinical trials; evaluating applications for registration of medical equipment; reviewing and implementing different guidelines for registration of medical equipment; review regulations for registration of medical equipment; participate in local conferences and workshops in respect to medical equipment; participate in regional and international conferences and workshops in respect to regulation of medical equipment.

TMDA sets the Key Performance Indicators (KPIs), which gauge the effectiveness and impact of the set targets, which comprise both output and outcome indicators. Output indicators include metrics such as the percentage of processed applications for registering premises, inspections of registered outlets, assessment of product registration applications, collection of planned post-marketing surveillance samples, evaluation of clinical trial authorisations, and inspection of approved clinical trials, among others.

Moreover, outcome indicators provide a holistic perspective on TMDA achievements. They comprise metrics such as the percentage of timely approvals or rejections of registration applications for medical equipment, compliance of selected post-marketing surveillance of medical equipment with quality standards, the effectiveness of recalls for non-compliant products, adherence of domestic manufacturing facilities to good manufacturing practices (GMP) and Quality System requirements, compliance of clinical trials with good clinical laboratory practices (GCLP) standards, and overall compliance of selling outlets and registered health laboratories. These outcome indicators reflect our dedication to ensuring the safety, quality, and efficacy of medical products in the market.

2.3 The Roles and Responsibilities of Key Stakeholders in the Regulation of Medical Equipment

2.3.1 The key stakeholders

The Ministry of Health (MoH) and its Authority, TMDA, are the key stakeholders responsible for managing medical equipment in the country. The roles of key stakeholders are briefly explained as follows:

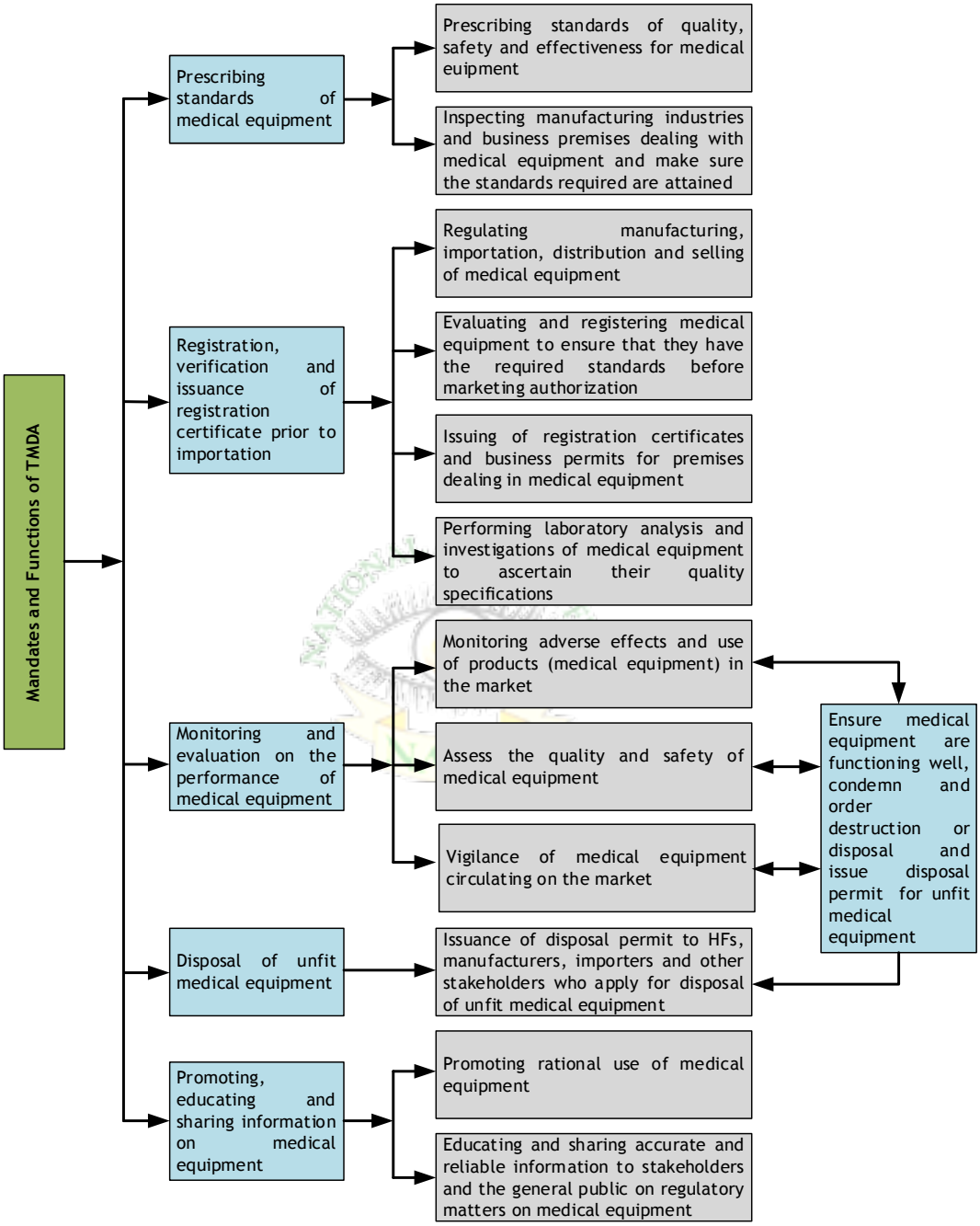
The Ministry of Health

As one of the key stakeholders, the MoH is responsible for formulating health-related policies, monitoring the implementation of policies, and inspecting healthcare services provided in the country. Also, the Ministry has the role of monitoring the performance of TMDA regarding the regulation of medical equipment through the Monitoring and Evaluation Section, which is under the Policy and Planning Department. It is also responsible for coordinating NGOs and International Organisations in the health sector.

The Tanzania Medicine and Medical Devices Authority (TMDA - Directorate of Medical Products Control)

As one of the key stakeholders, TMDA is an executive agency within the framework of the Executive Agency Act No.30 of 1997. Its mandates are derived under the Tanzania Food, Drugs and Cosmetics Act, 2003, as amended by section 24 of the Finance Act, 2019, including the functions presented in **Figure 2.4.**

Figure 2. 4: The mandates and the functions of TMDA in the regulation of Medical Equipment

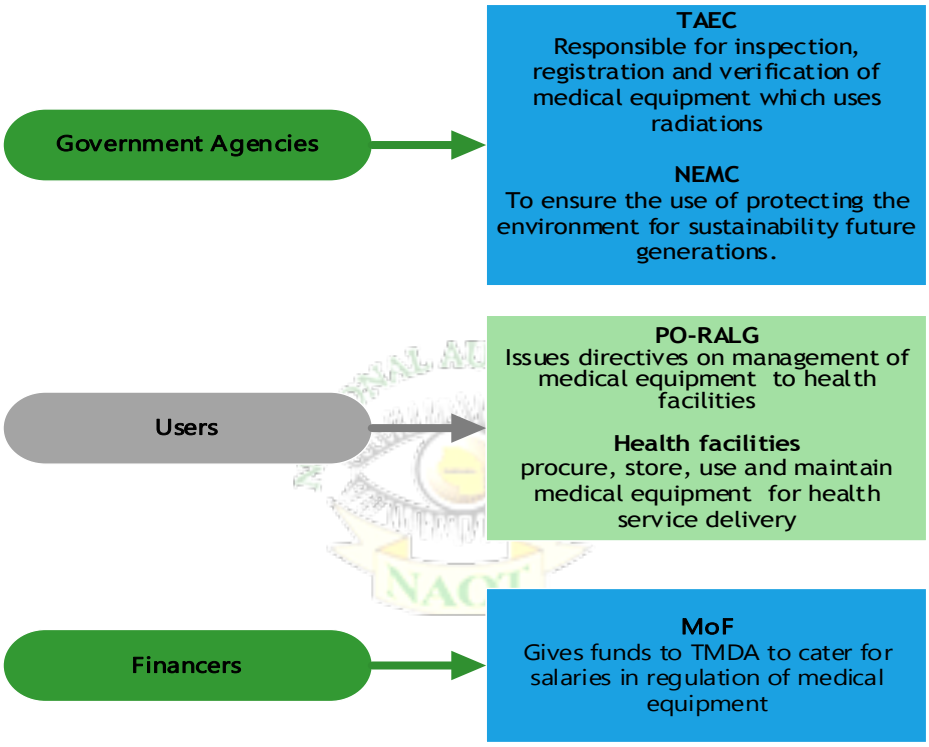


Source*: Auditors' Analysis of Information from the TFDA Act, 2003, as amended in the Finance Act, 2019*

2.3.2 Other Stakeholders

The regulation of medical equipment involves other stakeholders such as ministries, government agencies, departments (MDAs), and local government authorities. The roles and their responsibilities are described in **Figure 2.5** as follows.

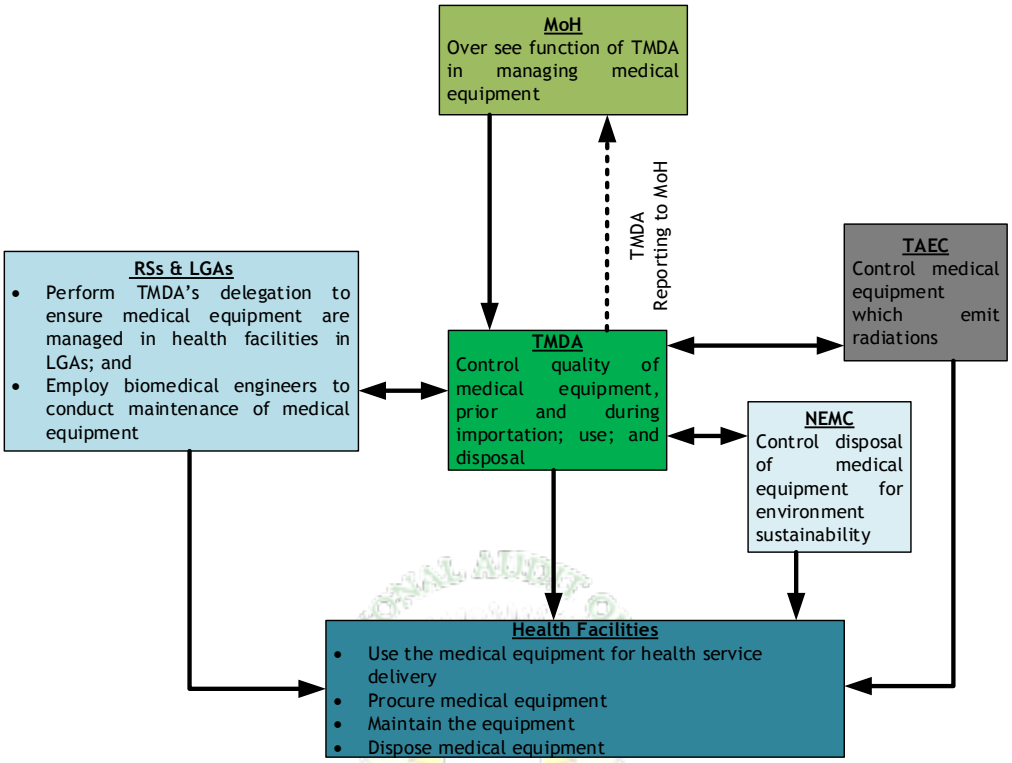
Figure 2. 5: The roles and responsibilities of other stakeholders in the regulation of Medical Equipment



Source*: Auditors' Analysis of Information from Acts and Guidelines of TAEC, NEMC, PO-RALG, Health Facilities and MoF (2023)*

The relationship between actors and stakeholders in the Regulation of Medical Equipment is summarised in **Figure 2.6** as follows

Figure 2.6: The relationship between stakeholders in the regulation of Medical Equipment



Source*: Auditors' Analysis of Interviews and Reviews of Relevant Legislations on the Regulation of Medical Equipment (2023)*

2.4 The Resources for the Regulation of Medical Equipment

Regulation of Medical Equipment requires both financial and human resources. To realise this, the Government has allocated both financial and human resources to MoH and TMDA as detailed as follows:

2.4.1 The resources allocated to MoH

Human resources at MoH

Detailed aspects of human resources at the MoH Directorate of Preventive Service are presented in **Table 2.2.**

Table 2.2: The human resources for managing Medical Equipment at MoH

Positions	Role	Required Personnel	Available Personnel	Gap of Required Personnel	% of the Gap of Required Personnel
Laboratory Scientist	Manage and make the best use of medical equipment	5	1	4	80
Laboratory Technologist	Manage the best use of medical equipment	5	0	5	100
Radiographers	Manage and advise health facilities on the use of medical equipment	2	1	1	50
Biomedical Engineers	Install, maintain, repair and provide technical support to health facilities	7	2	5	71
Total		**19**	**4**	**15**	79

Source*: Personnel Enrolment of Staff from MoH (2021)*

Table 2.4 shows a gap of 79% of people responsible for the regulation of medical equipment at the Ministry of Health.

2.4.2 The resources allocated at TMDA and the Tanzania Medicine and Medical Devices Authority (TMDA)

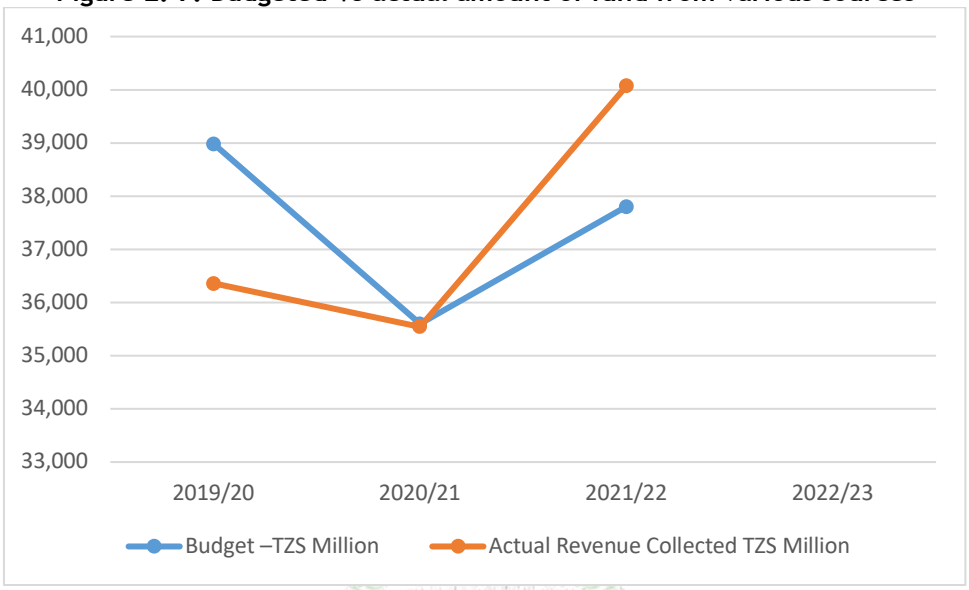
The Financial resources at TMDA

TMDA's operational budget is mainly derived from three different sources: internal revenue generated from fees and charges, allocation from the Government budget for employee salaries, and financial support from other development partners.

The budget and actual financial resources from the three sources for four (4) years from 2019/20-2022/23 allocated at the Directorate of Medical

Product Control (DMC) and Directorate of Laboratory Services are detailed in **Figure 2.7** as follows.

Figure 2. 7: Budgeted Vs actual amount of fund from various sources



Source*: TMDA's Annual Implementation Reports (2015/16-2019/20)*

Figure 2.3 shows that, the budget for the financial year 2019/20 and 2020/21 was not attained by 2,630 Million and 58 Million, respectively, while for the financial year 2021/22, the set budget was superseded by 2,270 Million of the funds collected.

The human resources for managing Medical Equipment in the country

Various departments at the TMDA are involved in managing medical equipment in the country. **Table 2.3** shows the status of human resources in the Directorate of Medical Product Control (DMC) and Directorate of Laboratory Services, which are directly involved in managing medical equipment at TMDA.

Table 2.3: The human resources for Managing Medical Equipment

Name of Directorate	Positions	Required Personnel	Available Personnel	Gap of Required Personnel	Gap (%)
Medical Products Control (DMC)	Director	1	1	0	0
	Managers	4	4	0	0
	Principal Medical Devices Registration Officer	5	3	2	40
	Principal Medical Devices Inspector	10	1	9	90
	Senior Medical Devices Inspector	10	4	6	60
	Medical Devices Registration Officer	85	37	48	56
Sub Total 1		***170***	***80***	***90***	53
Laboratory Services	Biomedical Engineers	15	3	12	80
	Senior Analyst	11	1	10	91
	Analyst	26	8	18	69
	Laboratory Technician	28	21	7	25
	Assistance Laboratory Technician	3	3	0	0
Sub Total 2		***83***	***36***	***47***	57
Total		**451**	**202**	**249**	55

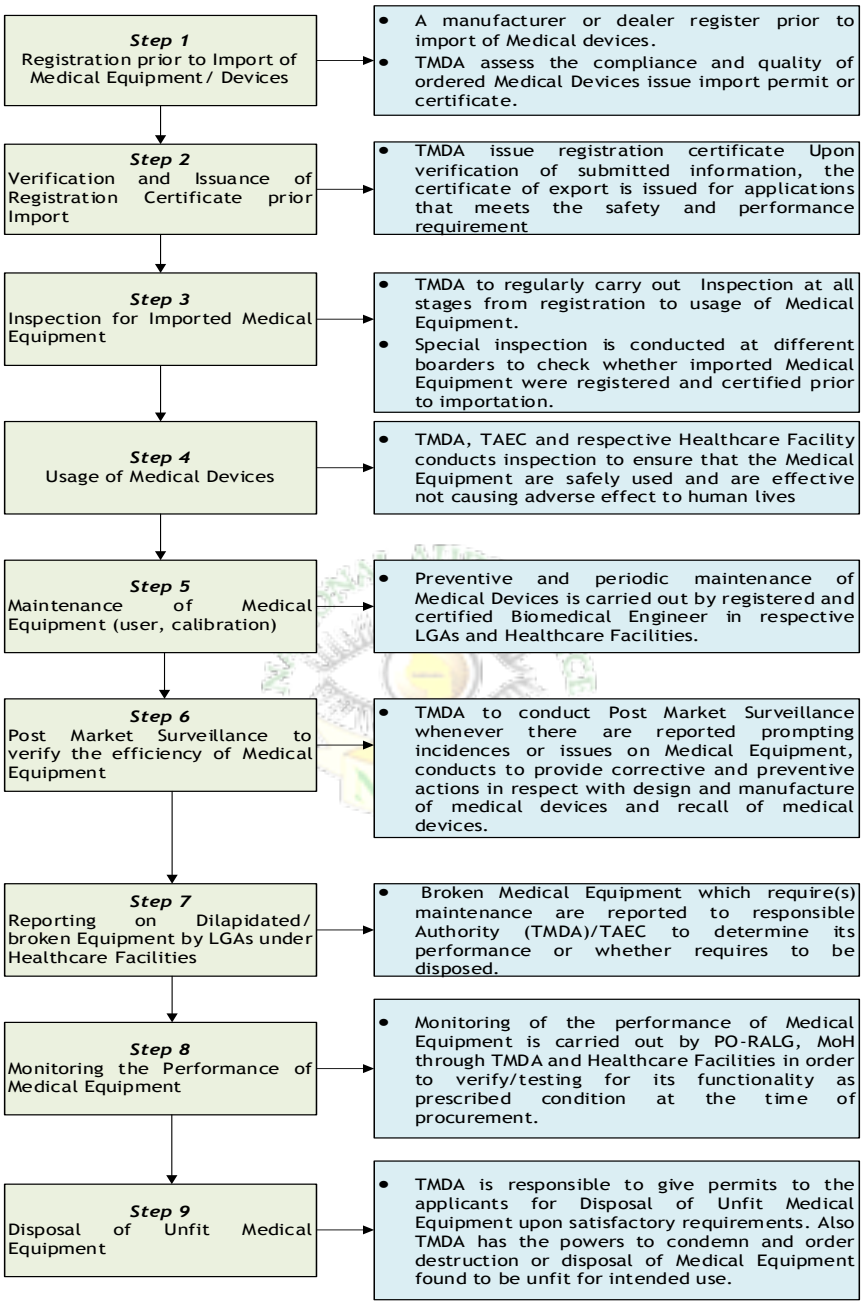
Source*: Auditors' Analysis of Personnel Enrolment of Staff from TMDA (2023)*

Table 2.4 shows an overall gap of 55% of personnel responsible for the regulation of medical equipment at TMDA.

2.5 The Key Processes for the Regulation of Medical Equipment

The processes for the regulation of medical equipment or devices include various steps. These include registration before import of medical equipment, verification and issuing registration certificate before import, inspection for imported medical devices, maintenance of medical equipment (user, calibration), post-market surveillance to verify its efficiency, and reporting unfunctional medical equipment by LGAs under health facilities and monitoring on performance of medical equipment. The process for regulation of medical devices is presented in **Figure 2.8.**

Figure 2. 8: The Process of the Regulation of Medical Equipment and responsible key stakeholders



Source: *Auditors' Analysis of the extract from Control of Medical Devices Regulations, 2015, Interview with TMDA and MoH Officials Responsible for Regulation of Medical Equipment (2023)*

The Stages of the Regulatory Control of Medical Equipment

The equipment life cycle comprises its entire lifespan, from manufacture, purchase, and planning to installation, acceptance inspection, everyday use, daily maintenance, and eventual disposal and retirement. Throughout this life cycle, TMDA regulates medical equipment, as summarised as follows:

Table 2.4: The stages of the regulatory control of Medical Equipment

Stage	Pre-Market	Placing on-Market	Post-Market
Control/Monitor	Product	Sale	After-Sale/Use
Person	Manufacturer	Establishment Manufacturer	User Establishment Manufacturer
Items or activities regulated	Medical equipment attributes • Safety and performance	Establishment registration • List of products available or in use • Requires establishment to fulfill the after-sales obligation	Surveillance/Vigilance • After-sale obligations • Monitoring of the device's clinical performance • Problem identification and alerts
	Manufacturing • Quality systems	Advertising (representation) • Prohibits misleading or fraudulent advertisement	
	Labelling (representation) • Accurate description of the product • Instruction for use		

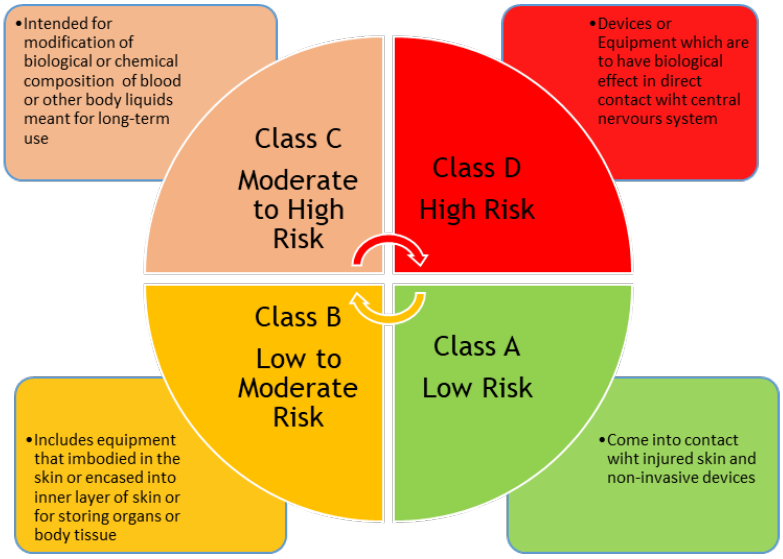
Source: *Auditors' Analysis of the extract from Control of Medical Devices Regulations, 2015, Interview with TMDA and MoH officials responsible for the regulation of medical equipment (2023)*

The TMDA regulatory functions are based on the typical life span for medical equipment, as suggested by the WHO Regulation of Medical Devices Step-by-Step Guide, 2016, and are attached in **Appendix 5.**

2.6 The Categories of Medical Equipment

The Medical Devices Regulations of 2015 categorised Medical Equipment into four (4) risk classes, as illustrated in **Figure 2.9**.

Figure 2. 9: The Categorisation of Medical Equipment based on Risk Classes



Source: *Auditors' Analysis of Information from Medical Devices Regulations (2023)*

However, medical equipment can be found in more than one class depending on the use, and in most cases, the class with higher risks is where the device belongs. In combination, different classes of medical devices can form a higher risk class. Thus, identification depends on the rule used as stipulated in the Regulations.

CHAPTER THREE

AUDIT FINDINGS

3.1 Introduction

This chapter presents the audit findings on regulating medical equipment in public health facilities. Specifically, this chapter focuses on the findings related to the existence of unfunctional medical equipment in public health facilities, registration of medical equipment, inspection of imported medical equipment, monitoring of the performance of medical equipment in public health facilities, disposal of unfit medical equipment and the coordination between actors on the regulation of medical equipment. Below are the detailed findings.

3.2 The Existence of Non-functional Medical Equipment in the Country.

The audit noted the presence of unfunctional medical equipment in the public health facilities that existed across public health facilities located in all geographical zones [9]in the country, as detailed in the subsequent subsections:

3.2.1 The Existence of unfunctional Medical Equipment in public health facilities

In line with paragraph 4 of the Health Sector Strategic Plan (HSSP) 2021/22 – 2025/26), the government aimed to systematically implement preventive maintenance practices to guarantee the sustained functionality and upkeep of healthcare infrastructure and equipment. Similarly, TMDA Strategic Plan for 2016/17-2020/21[10] mandated the Tanzania Medicines and Medical Devices Authority (TMDA) to enhance oversight and ensure the quality, safety, and efficacy of medical equipment and diagnostic tools through more rigorous regulatory measures.

The data abstract for medical equipment obtained from the Directorate of Radiology and Imaging Services at the Ministry of Health revealed the presence of various unfunctional medical equipment in the country. The status of unfunctional medical equipment in the country is presented in **Table 3.1** as follows.

[9] MoH provided data from the Radiology and Imaging Directorate only; hence, data considered for assessment of existence of unfunctional medical equipment was from that directorate only.

[10] This Strategic Plan was Revised in 2017 to cover the period from 2017/18–2021/22.

Table 3.1: The status of the existence of unfunctional Medical Equipment in the country

Equipment Name	Available	Functional	Unfunctional	% of Unfunctional
Digital Fluoroscopy	15	9	6	40
Digital C-Arm	14	10	4	29
Digital Mammography Machines	5	4	1	20
Digital Periapical X-Ray	18	17	1	6
Basic Ultrasound Machines	23	21	2	9
Digital X-Ray	68	63	5	7
Standard Ultrasound Machines	67	59	8	12
Advance Ultrasound Machines	102	99	3	3
CT - Scan	42	41	1	2
Total	**354**	**323**	**31**	**14**

Source*: Auditors' Analysis of MoH Database of Medical Equipment (2023)*

Table 3.1 shows that 14% of the selected medical equipment under the audit in the country was found to be non-functional. The Digital Fluoroscopy machine counted at 40% as the highest percentage of unfunctional medical equipment, followed by the Digital C-Arm at 29%. Comparatively, CT-Scan was the least unfunctional medical equipment, with only 2% of them being unfunctional.

On the other hand, the observation made by the audit through physical verification of the sampled health facilities noted that there was unfunctional medical equipment in the visited health facilities. The status of unfunctional medical equipment in the visited public health facilities is presented in **Table 3.2.**

Table 3.2: The status of the existence of unfunctional Medical Equipment in the Public Health Facilities visited

Zone Visited	Number of Health Facilities Visited	Number of the Observed Medical Equipment	Number of Observed Unfunctional Medical Equipment	% of Unfunctional Medical Equipment
Central Zone	5	115	37	32
Eastern Zone	5	222	57	26
Northern Zone	4	65	15	23
Lake Zone	4	90	26	29
Total	18	**492**	**135**	**27**

Source: *Auditors' Analysis of the Observed Medical Equipment during the Physical Verification in the Visited Health Facilities (2023)*

Table 3.2 shows that, 135 out of 492 observed medical equipment, equivalent to 27%, were unfunctional. The largest percentage of unfunctional medical equipment was noted in the Central zone, with 37 unfunctional medical equipment out of 115, equivalent to 32%.

The monitoring report for laboratory and radiology Services at Muhimbili National Hospital of 2019, stipulated that, the rationale behind the recurring non-functionality of Medical Equipment was due to non-implementation of the existing Planned Preventive Maintenance.

In other cases, the analysis indicated that unfunctional medical equipment was attributed to a lack of preventive maintenance in public health facilities. However, interviews with MoH officials revealed that non-functional medical equipment is comprised of outdated equipment that has been replaced with others with advanced technology. This implies that, there have been a transition from analogue to digital medical equipment in health facilities. The presence of unfunctional medical equipment due to a lack of planned preventive maintenance in the public health facilities is presented in **Table 3.3** as follows.

Table 3.3: The status of the existence of unfunctional Medical Equipment in Public Health Facilities due to lack of planned preventive maintenance

Status of medical equipment	*Equipment with PPM*	*Equipment with No PPM*	*Working*	*Unfunctional*
Equipment with PPM	1			
Equipment with No PPM	0.15	1		
Working	0.84	0.61	1	
Unfunctional	0.54	0.74	0.66	1

Source: *Auditors' Data Analysis from Physical Verification in the Selected Public Health Facilities (2023)*

Based on the findings in **Table 3.3**, the lack of planned preventive maintenance in Public Health Facilities is highly correlated by 0.74 with the presence of unfunctional Medical Equipment. This implies that, lack of planned preventive maintenance is attributed to unfunctional medical equipment.

Consequently, the existence of unfunctional medical equipment in the country led to the inability to realise the objective of providing quality, safe, effective, and productive health services to the citizens. Likewise, the existence of unfunctional Medical Equipment led to overloading the Medical Equipment at the Health Facility. This was due to the reliance on the only functional Medical Equipment at the visited Health Facilities.

3.2.2 The existence of unfunctional Medical Equipment across Health Facilities in the country

A review of the radiology medical equipment database noted the existence of unfunctional medical equipment across health facilities from the national level to the health centre level. The details on the distribution of medical equipment in zones and Health Facilities are presented in **Table 3.4.**

Table 3.4: The distribution of unfunctional Medical Equipment across Health Facilities in the zones

Zones	Unfunctional Medical Equipment per level of Health Facilities					
	National Level Hospital	Zonal Level Hospitals	Regional Level Hospitals	District Level Hospitals	Health Centres	Total
Central	-	-	1	3	-	4
Eastern	16	-	5	5	3	29
Lake	-	3	5	7	2	17
Northern	-	-	4	4	4	12
Southern	-	-	1	1	1	3
Southern Highland	-	2	9	9	-	20
West	-	-	3	3	-	6
Total						**91**

Source: *Auditors' Analysis of Extracted Information from the MoH Database of Medical Equipment (2023)*

Based on the findings in **Table 3.4**, it is revealed that, 29 was the largest number of unfunctional medical equipment in the eastern zone. Meanwhile, three (3) were found to be the smallest number of unfunctional medical equipment noted in the southern zone.

Moreover, the findings indicate that 91 non-functional medical equipment were in the public health facilities for the financial year 2022/23. This implies that non-functional medical equipment dominates across national health facilities. Meanwhile, no record was taken by the MoH regarding the presence of unfunctional medical equipment in the public health facilities from the financial year 2019/20 to 2021/22. The distribution of unfit medical equipment per facility type is indicated in **Table 3.5**.

Table 3.5: The Distribution of Unfunctional Medical Equipment at all levels of Health Facilities in the Country

Category of Health Facilities	Number of Health Facilities	Number of Unfit Medical Equipment	Ratio of Defective Equipment per Facility
National Referral Hospitals	7	16	2.3
Zonal Referral Hospitals	6	5	0.8
Regional Referral Hospitals	28	28	1
District Hospitals	137	32	0.23
Health Centres	117	10	0.09

Source: *Auditors' analysis of information from the MoH database of medical equipment (2023)*

From **Table 3.5**, it was noted that, the National Referral Hospital had the highest ratio of 2.3, Zonal Referral Hospitals had a ratio of 0.8, a ratio of 1, a ratio of 0.23, and Health Centres had the lowest ratio of 0.09.

In this regard, the largest ratio of 2.3 non-functional Medical equipment in Health Facilities at the national level was attributed to a lack of frequent medical equipment maintenance, as elaborated in sub-section 3.2.1 of this report.

3.3 Inadequate Procedures for the Registration of Medical Equipment

TMDA was mandated to register Medical Equipment manufactured within and outside the country before use. In this respect, the audit noted the following inadequacies regarding the procedures for registration of medical equipment:

3.3.1 Deficiency in Record Keeping on the Procedures for the Registration of Medical Equipment

The Audit noted that, documentation of procedures during the registration of medical equipment for four (4) financial years from 2019/20 to 2022/23 missed records regarding the specified date for the application for the registration and the issuance of the certificate for the registration of medical equipment. This deficiency was noted in 56% of all medical equipment registered in the Financial Year 2019/20 to 2022/23, as detailed in **Table 3.6**.

Table 3.6: Inadequate records on the application and issuance of the Certificate for the registration of Medical Equipment

Financial Year	Registered medical equipment	Registered medical equipment with no record for the specified date of application and issuance of the certificate for the registration	% of medical equipment registered while no record of specified date for application or issuance of the certificate
2019/20	103	103	100
2020/21	50	28	56
2021/22	35	12	34
2022/23	21	7	33
Total	209	150	56

Source: *Auditors' Analysis of Information from the TMDA's Register of Medical Equipment (2023)*

Based on the findings in **Table 3.6**, it is indicated that, 150 out of 209 registered medical equipment were noted to have their records missing regarding the specified date of the application for the registration or the

specified date on which the certificate for the registration was issued in the TMDA's register of medical equipment for the period of the financial year 2019/20 to 2022/23.

In this regard, the missing information in the procedures for the registration of medical equipment was attributed to TMDA data migration from manual recipient of dossiers, namely the Integrated Management Information System (IMIS)to the Regulatory Information Management System (RIMS), which led to deletion and addition of different stages in the registration process. However, RIMS has been officially in use since 1st July, 2020.

This implies that the registered medical equipment without records on the specified date of the application and issuance of the certificate led to TMDA lacking information on the specified expiration date for the licence of the registered medical equipment after their registration.

Consequently, the deficiencies in record-keeping would result in compromised data integrity, raising questions about the reliability of the TMDA used in the registration process of the registered devices during that time.

3.3.2 TMDA Delayed Processing the Applications for the Registration of Medical Equipment

Paragraph 1.10 of the Guidelines on Submission of Documentation for the Registration of Medical Devices, 2020 and Paragraph 8.1 of the (Service Standards) of the Tanzania Medicines and Medical Devices Authority Clients' Service Charter, 2020, required that, once an application for registration of medical equipment had been accepted and evaluation fees paid. The processing of applications for registration of medical equipment class A shall take 45 working days, and for classes B, C, and D, it shall take 90 working days.

However, a review of the registration status of medical equipment for the financial year 2019/20 to 2022/23 revealed that, out of 59 selected Medical Equipment with information of the specified date for the application for registration and the issuance of the certificate. It was found that only five (5) medical equipment were registered within 90 working days, whereas the remaining 54 registered medical equipment were found to be registered in more than 90 working days, as detailed in **Table 3.7**.

Table 3.7: The delays in processing registration of Medical Equipment

Financial Year	Equipment with information for application and Issuance of Certificate	Processed Application for Registration within 90 working days	Processed Application for Registration in more than 90 working days
2019/20	0	0	0
2020/21	22	0	22
2021/22	23	2	20
2022/23	14	3	11

Source: *Auditors' Analysis of information from the TMDA's Register of Medical Equipment (2023)*

Table 3.7 shows that, the registration of Medical Equipment for the year 2020/21 was completed beyond the required time for registration. In the year 2021/22, only two (2) requests for registration of medical equipment were registered within 90 working days. Meanwhile, in the year 2022/23, only 3 out of 14 medical equipment were registered within 90 working days from the date of application submission for registration to TMDA.

TMDA delayed registration of Medical Equipment class A, B and C

Upon further review of the information on the registration of 59 Medical Equipment, the audit noted TMDA delays in registering medical equipment based on the time the registrant lodged their application for registration to TMDA, as shown in **Table 3.8.**

Table 3.8: The delays in the registration of Medical Equipment class A, B, C

Medical Equipment Class	Total Equipment Registered	Equipment Registered within 45 (Class A) or 90 (Class B, C) working Days after application	% of Medical Equipment within 45 or 90 working days after the application
Class A	4	0	0
Class B	33	3	9
Class C	22	2	9
Class (A+B+C)	59	5	8

Source: *Auditors' Analysis of Information from the TMDA Register of Medical Equipment (2023)*

Table 3.8 indicates that, TMDA managed to register only 8% of the Medical Equipment within the required registration time. However, all class A equipment experienced delays in registration later than the required 45 days.

However, the delay in the registration of medical equipment was attributed to TMDA not clearly stipulating timelines for each step involved in the registration process. For instance, the Clients' Service Charter does not

provide the expected duration for each step of the medical equipment registration process. Ultimately, the delays in the registration of medical equipment by TMDA would lead to delays in the provision of health services.

On the other hand, the delays in the registration of medical equipment by TMDA may stifle the advancements in healthcare technology and limit the availability of state-of-the-art equipment. This is due to the fact that, it may discourage the manufacturers from introducing or importing new and innovative medical devices to the Tanzania market.

3.3.3 Ineffective Renewal of Medical Equipment Certificates of Registration by TMDA

Section 53 (7) of the Tanzania Food, Drugs and Cosmetics Act, 2003, as amended by section 24 of the Finance Act, 2019requires a certificate of registration issued by TMDA to be renewed 5 years after the date of issuance. Likewise, Regulations 17 (4) & (5) of the Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 require TMDA to ensure that, the renewal of registration is made at least 90 days before its expiry. It further specifies that the renewal should be made no later than 90 days after the expiry date, providing grace.

However, analysis of the database from the extract of the Regulatory Information Management System (RIMS) of TMDA indicated that, on average, TMDA did not ensure timely renewal of 53% of the expired certificates for the period of four (4) financial years, namely 2019/20-2022/23. The detailed status of the renewal of the registration certificate for medical equipment is indicated in **Table 3.9.**

Table 3.9: The details for the renewal of registration Certificate of Medical Equipment

Financial Year	Number of Licences Due	Number of Licences Renewed Timely	Number of Licences not Renewed Timely	% of Licences not Renewed Timely
2019/20	37	37	0	0
2020/21	100	51	49	49
2021/22	84	29	55	65
2022/23	1563	25	1538	98
Averaged (%)				**53**

Source: *Auditors' Analysis of the Extract from the Regulatory Information Management System (RIMS) of TMDA (2023)*

Table 3.9 indicates that, for the financial year 2019/20, all licences of medical equipment were timely renewed, while the percentage of delayed renewed licences increased from 49% to 98% from the financial year 2020/21

to 2022/23, respectively. During interviews with officials from TMDA and a review of registration information, the audit noted that, the ineffective renewal of certificates of registration of medical equipment was due to TMDA not having an effective framework for the regulation of medical equipment for their clients regarding the expiry of certificates for registered medical equipment. Similarly, TMDA did not have a mechanism to enforce the renewal of medical equipment registration within the accepted 90 days.

Consequently, the ineffective renewal of certificates of registration of medical equipment contributed to TMDA not receiving the post-market surveillance on the medical equipment required under Regulation 17(3) of the Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015, which states that, Registrants must submit biennial post-marketing surveillance reports, including any adverse occurrences experienced. This ultimately led to the loss of revenue collection because TMDA would have collected a sum of TZS 10,261,473,750 from renewing the certificate of registration, as indicated in **Table 3.10**.

Table 3. 10: Uncollected fees from unrenewed registration of Medical Equipment by TMDA

Financial Year	Number of Unrenewed Licences	Charges Required Per Licence (USD)	Uncollected Revenue (USD)	Uncollected Revenue (TZS)
2019/20	0	2,500	0	0
2020/21	49	2,500	122,500	306,219,375
2021/22	55	2,500	137,500	343,715,625
2022/23	1538	2,500	3,845,00	9,611,538,750
Total (TZS)				**10,261,473,750**

Source: *Auditors' Analysis of the Extract from the Regulatory Information Management System (RIMS) of TMDA (2023)*

Further analysis of information from **Table 3.10** indicates that, the largest number of unrenewed registrations of medical equipment by TMDA was noted in the financial year 2022/23, in which TMDA did not collect an amount of TZS 9,611,538,750 from 1,538 medical equipment. Meanwhile, the least number of unrenewed medical equipment was noted in the financial year 2020/21, whereby TMDA did not collect an amount of TZS 306,219,375 from 49 medical equipment.

3.3.4 Ineffective Collection of Samples of Medical Equipment Applied for the Registration and during Importation

Regulation 7(2) (b) of Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) regulations, 2015, requires TMDA to collect samples or samples for every application for the registration of medical equipment.

However, through the review of registration documents at TMDA, the audit noted that, TMDA was not taking samples of medical equipment before and after registration to allow the medical equipment to circulate into the market in the country. This fact was confirmed during interviews with TMDA officials, who revealed that, TMDA did not verify the performance of medical equipment by collecting samples during registration and after installation in respective health facilities.

Moreover, interviews with TMDA officials further revealed that, the inability to fulfil the requirement for taking samples of medical equipment by TMDA was due to an oversight of such a provision by TMDA in the development of such regulation and other guidelines for the control of medical devices.

In this regard, TMDA focused only on small medical devices such as syringes, surgical sutures, examinations and surgical gloves, as mentioned in the Tanzania Foods and Drugs Authority (TFDA) Ten Years of regulating food, Medicines, cosmetics and medical devices milestones attained. On the other hand, it was attributed to the lack of space by TMDA to accommodate large medical equipment or laboratories for testing samples of such medical equipment.

Consequently, the inadequate collection of samples for medical equipment verification during and after registration would jeopardise TMDA's adherence to regulations. This would ultimately affect the equipment's sustainability and the ability to replace some spare parts to enhance its durability. This was confirmed by the audit team during observation, which noted that, the medical equipment was unfunctional in the visited healthcare facilities due to the absence of spare parts. The hospitals with unfunctional medical equipment due to lack of spare parts are detailed in **Table 3.11** as follows.

Table 3. 11: Unfunctional Medical Equipment due to lack of spare parts

Visited health facility	Medical equipment lacked spare parts
Benjamini Mkapa Hospital	Chemistry Analyser and Full Blood Picture Machine
Mawenzi Regional Referral Hospital	2 -Oxygen Concentrators
Ocean Road Cancer Institute	Cobalt 60, C-arm

Source: *Auditor's Physical Verification of Medical Equipment in Visited Health Facilities, (2023)*

Table 3.11 indicates that, 3 out of 18 visited health facilities, namely Benjamini Mkapa Hospital, Mawenzi RRH, and Ocean Road Cancer Institute (ORCI), had unfunctional medical equipment due to a lack of spare parts for maintenance.

3.3.5 TMDA Did Not Ensure the Registrants for Medical Equipment Effectively Pay an Annual Retention Fee for their Registered Medical Equipment

Regulation 17 (2) of the Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 states that, every registrant shall, in addition to the fees related to registration of each medical device, pay annual retention fees before the 31st January of each calendar year.

The audit team, through the review of the payment for retention fees, noted that, 51% of registrants did not pay the annual retention fee as required. The audit further noted that, for the period of 4 financial years, 2019/20 to 2022/23, TMDA did not take any action against the defaulters, as detailed in **Table 3.12**.

Table 3.12: The status of retention fee payment for the selected registered Medical Equipment

Financial Year	Registrant (1 year above)	Registrants who did not pay the retention fee	% of Registrant who did not pay for retention fees
2019/20	135	53	39
2020/21	238	133	56
2021/22	288	150	52
2022/23	323	188	58

Sources: *Auditors' Analysis of the TMDA Extract data from RIMS and Payment System (2023)*

Table 3.12 indicates that, in the financial year 2022/23, most registrants defaulted on paying retention fees for the registered medical equipment. In this respect, 188 out of 323 registrants did not pay for the retention fee. Likewise, a small percentage of registrants who did not pay a retention fee was noted in the financial year 2019/20. In this regard, 53 out of 135 registrants did not pay for the retention fee.

Moreover, the review of registrant information extracted from the RIMS and Payment System of TMDA did not reveal whether the TMDA suspended the registration of medical equipment for defaulters who failed to pay the retention fee. This was contrary to regulation 18(g) of the Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) regulations, 2015, which requires TMDA to suspend or cancel the registration of medical equipment when the registrant fails to pay the prescribed retention fee within the specified time.

Through interviews with officials at the TMDA, it was stated that, the registrant continued to exist without paying the retention fee because the TMDA system did not allow the registrant to import medical equipment anymore until they paid their previous annual retention fees. This implies that the presence of defaulters who did not pay the annual retention fees led TMDA to not collect a significant amount of revenue, amounting to TZS 241,040,000. Details of the revenue that TMDA did not collect from the annual retention fees are shown in **Table 3.13:**

Table 3.13: Uncollected annual retention fees from registered Medical Equipment

Financial Year	Expected Collection (TZS)	Collected Amount (TZS)	Uncollected Amount (TZS)
2019/20	62,457,581.57	37,937,197.70	24,520,383.88
2020/21	110,110,403.10	48,578,119.00	61,532,284.07
2021/22	133,242,840.70	63,845,527.83	69,397,312.86
2022/23	149,435,547.00	62,457,581.57	86,977,965.45

Source: *Auditors' Analysis of the TMDA Extract data from RIMS and Payment System (2023)*

Table 3.13 indicates that, a higher amount of uncollected retention fees of TZS 86,977,965.45 was noted in the financial year 2022/23. However, the trends show that, there was an increase in the amount not collected from annual retention fees from an amount of TZS 24,520,383.88 in the financial year 2019/20 to an amount of TZS 86,877,965.45 in the financial year 2022/23.

3.4 Ineffective Regulation on Medical Equipment Imported by the Public Health Facilities

The mandate of (TMDA) is to oversee the safety and efficacy of medical equipment imported by the public health facilities in the country. Based on this fact, the following challenges were identified by the audit as described as follows.

3.4.1 TMDA Did Not Verify and Inspect the Imported Medical Equipment Before their Utilisation

Regulation 56 (1) of the Tanzania, Food, Drugs and Cosmetic Regulations on Control of Medical Devices Regulations, 2015 requires that no imported medical equipment shall be removed from the port of entry or any other place before it is inspected by the inspector and released. Likewise, at the time of importation, medical devices and in vitro diagnostics must have a valid shelf life of not less than 60% of the original shelf life (Where applicable).

However, an audit review of the import permit certificates and the inspection reports for imported medical equipment for the financial years 2019/20 to 2022/23 noted that, the reports and certificates for the importation of medical equipment lacked details regarding the inspection conducted at the port of entry. This was confirmed in interviews with officials from TMDA, who revealed that, the lack of inspection and reporting on the inspection of imported medical equipment was attributed to a lack of human resources within the ports of entry with the required skills to verify the quality of imported medical equipment.

It was further elaborated that, the inspectors at the ports of entry who mainly deal with the inspection of medical equipment were mostly pharmacists and doctors of medicine with inadequate knowledge and skills of biomedical engineering. On the other hand, there were no tools for inspecting medical equipment at the port of entry, especially a checklist for inspections.

Consequently, the lack of inspection for verification of medical equipment resulted in the existence of medical equipment in the country that is already in use without registration from TMDA prior to its use. This was confirmed through a review of the TMDA Post Market Surveillance report of 2022/23, which indicated that, 61 medical equipment out of 220 in the programme, equivalent to 28%, were not registered in health facilities. The report further indicated that, medical equipment was imported and installed without verification of its efficiency. This, in turn, poses risks to patient safety, as devices may not meet the required quality and standards. This leads to malfunctions or adverse health effects for patients and hinders the traceability of medical equipment in the market as well.

3.4.2 Non-provision of Import Permit to Procure Medical Equipment by Public Health Facilities

Regulation 45 of the Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 requires that, no person shall import a medical device regulated under this regulation unless he/she holds a valid permit issued by the authority.

However, in the analysis of the internal audit report from October to December 2019, it was found that TMDA did not effectively issue import permits for all procured medical equipment. This was because TMDA did not appropriately consider all import permit application criteria as stated in Paragraph 1.5.3 (b) of the Guidelines for the Importation and Exportation of Medical Devices, including in Vitro Diagnostics, 2015. This requires an application for an import permit to be submitted along with a letter that clearly stipulates the reasons for the importation of such equipment from the applicant or qualified medical practitioner such as a dentist, veterinary surgeon, or any other authorised practitioner.

Contrary to these regulations and guidelines, the audit found that, the permit with reference number TFDA-WEB0318/MDR/SIPER/0038 in 2018 was issued by considering only the proforma invoice attached in the Integrated Management Information System (IMIS). Similarly, the import permit issued to Bilila Lodge Investment Ltd for importing a Digital X-ray Machine and Integrated Portable Vital Monitor had its application submitted with only a proforma invoice. These practices were contrary to Paragraph 1.5.3. (b) of the Guidelines for Importation and Exportation of Medical Devices.

In this regard, the non-provision of import permits for all procured medical equipment contributed to TMDA's inability to take into account the issue of registration of imported medical equipment for public health facilities. Therefore, this inappropriate issuance of import permits resulted in an overreliance on special import permits for importing unregistered medical equipment. This ultimately increases the likelihood of falsified and substandard medical equipment.[11]

[11] Table 10: SWOC Analysis of TMDA strategic plan 2021/22-2025/26.

3.4.3 Non-establishment and Keeping the Reference Standards for Medical Equipment as per the International Standards Organisation

According to Paragraph 1.6 of the TMDA Business Plan, 2020 Document with reference number. TMD.A/DBS/PI/BP/2 indicates that, TMDA's commitment to comply with the requirements of ISO 9001:2015 Standard to improve the effectiveness of the Quality Management System to manage and provide resources for continuous improvement of services to ensure customers' satisfaction.

On the other hand, Paragraph 4.2.3 of ISO 13485 of Medical Devices - Quality Management requires TMDA to establish and maintain one or more files containing or referencing documents generated for verification of compliance to the requirement of the International Standard and applicable regulatory requirements.

However, the audit noted that, TMDA had not effectively established and kept files of international standards and regulatory requirements for reference for each medical equipment and medical device family. During interviews with TMDA officials, it was revealed that ISO charges for subscriptions to its standards. Thus, TMDA had to pay a subscription fee to access the service.

Moreover, a review of MTEF for the financial years 2019/20 to 2022/23 noted that TMDA did not allocate funds to acquire the reference code for the medical equipment standards. Also, it lacked clear processes and guidelines for establishing and keeping such standards. **Table 3.14** indicates the budget allocated for compliance with ISO, which excluded funds for the acquisition of standards for medical equipment.

Table 3.14: The budget allocated for the compliance to ISO, excluding funds for acquisition of standards for Medical Equipment

Financial Year	Purpose of Funds Allocation	Amount of Funds Allocated (TZS in Million)	Total Allocation of Funds on a Financial Year (TZS in Million)
2019/20	Implementation of (QMS) ISO 17025 for accreditation of laboratories that have an acceptable quality management system in place	43	146
	Agency fees	100	
	Accreditation application fee	3	

Financial Year	Purpose of Funds Allocation	Amount of Funds Allocated (TZS in Million)	Total Allocation of Funds on a Financial Year (TZS in Million)
2020/21	Implementation of (QMS) ISO 17025 for accreditation of laboratories that have an acceptable quality management system in place	21	161
	Agency fees	117	
	Implementation of QMS requirement on risk management and assessment	23	
2021/22	Implementation of QMS (WHO prequalification & ISO/IEC 17025) through internal audit and management review meeting at TMDA quality control laboratory	48	48
2022/23	Implementation of one internal audit and 15 days of QMS training on WHO prequalification and ISO/IEC 17025 to 40 staff	77	77
Total			**432**

Source: *Auditors' Analysis of MTEF (2023)*

Table 3.14 indicates that, in the period of four (4) financial years, 2019/20 to 2022/23, TMDA allocated a total amount of TZS 432 million for the implementation of quality management required by the International Standards Organisation. However, in all four (4) financial years, it was indicated that there was no allocation of funds for purchasing medical equipment standards. This implies that, TMDA did not prioritise establishing and maintaining the reference standards for medical equipment.

On the other hand, TMDA indicated that the national and international guidelines and standards are referenced when assessing and approving devices, including medical equipment. TMDA further indicated that international guidelines and specific ISO standards for a particular device and function are accessed online while applications for device registration are assessed.

However, this inability of TMDA to establish and keep the standards of the medical equipment for reference could result in non-compliance with ISO 13485, regulatory non-compliance with applicable requirements, and a lack of traceability and transparency in tracking compliance to standards and regulations based on the respective standards for the medical equipment.

Also, this could result in an inadequate understanding of the required standards of medical equipment among the officials from the regulatory authority and other stakeholders involved in the regulation of medical equipment.

3.4.4 Ineffective Practice of Using the Standard Operating Procedures for Medical Equipment at Health Facilities

Basic Standards for Health Facilities III & IV, 2017 required health facilities to develop standard operating procedures for medical equipment and ensure the standard operating procedures are kept and used in operating medical equipment in health facilities.

However, during observation through site visit for verification, it was noted that, SOPs were not used at the visited health facilities. It was further noted that, SOPs were unavailable for medical equipment in some health facilities, as indicated in **Table 3.15**.

Table 3.15: Medical Equipment operated with and without SOPs

Equipment Name	No of Equipment	Equipment with SOPs	Equipment with No SOPs
Anaesthetics Machine	34	1	33
Centrifuge Machine	43	9	34
Chemistry Analyser	61	46	15
CT - Scan Machine	7	7	0
Dental X-Ray	4	0	4
Diathermy Machine	20	0	20
ECG - Machine	15	5	10
ECHO Machine	1	1	0
EEG - Machine	5	0	5
Haematology Analyser	32	22	10
Major Operating Light - 1	38	1	37
MRI Machine	3	3	0
Ultrasound Machine	46	17	29
Urine Analyser	7	2	5
Ventilator Machine	83	37	46
X-Ray Machine	30	15	15
Total	**429**	**166**	**263**

Source: *Auditors' Analysis of Statistics Recorded from the Health Facilities during Physical Verification (2023)*

Based on the findings in **Table 3.15**, it is indicated that, 263 out of 429 medical equipment at the visited health facilities were operated without

the presence of SOPs. This was attributed to a lack of adequate enforcement from TMDA and MoH as the follow-up on the implementation of the recommendations issued by MoH during supportive supervision and TMDA monitoring was not done. This includes awareness programmes to familiarise them with SOPs and take appropriate action against non-compliance. This also resulted in the non-functionality of some medical equipment as they operated without having SOPs, as detailed in the analysis in **Table 3.16.**

Table 3.16: The Correlation of Medical Equipment being working when operated with SOPs

	Working	Not Working	Equipment with SOPs	Equipment with No SOPs
Working	1			
Not Working	0.78	1		
Equipment with SOP	0.85	0.74	1	
Equipment with No SOP	0.491	0.57	0.036	1

Source: *Auditors' Analysis of Statistics Recorded from the Health Facilities during Physical Verification (2023)*

Table 3.16 indicates that there is a positive correlation of 0.85 for medical equipment working when there are SOPs. Additionally, it was shown that the medical equipment would likely not work if there were no SOPs.

This implies that, a lack of SOPs for the medical equipment could lead to frequent breakdowns while operating the equipment, increased repair costs and delays or disruptions of the intended health services.

3.5 The Public Health Facilities did not adequately Maintain Medical Equipment

The audit noted that, the MoH did not have a functional mechanism to ensure that, medical equipment was adequately maintained. The availability of resources for medical equipment maintenance was also noted as a challenge. In this regard, insufficient calibration of medical equipment and inadequate maintenance of medical equipment in public health facilities were the noted major issues, as detailed in the following sub-sections.

3.5.1 There was no functioning mechanism to ensure that Medical Equipment was adequately maintained in Health Facilities

Paragraph 7.2 of the Standard Medical Radiology and Imaging Equipment Guidelines (SMRIEG), 2018, requires MoH to ensure that, public health

facilities provide maintenance services, tools, testing equipment, and spare parts and conduct preventive maintenance to keep equipment working condition and conduct corrective maintenance to fix equipment.

The review of the development report of MoH regarding the system for tracking the maintenance of medical equipment indicated that, for the period from the financial year 2019/20 to the financial year 2022/23, MoH did not have a functional system to ensure the maintenance of medical equipment in the public health facilities.

However, in interviews with MoH officials, it was revealed that, the absence of a system for medical equipment maintenance was attributed to the Ministry of Health not allocating a budget to develop the system to ensure that, medical equipment in health facilities was timely and adequately maintained.

Consequently, the lack of a functional system for the maintenance of medical equipment in health facilities for the period under the audit is attributed to the presence of unfunctional medical equipment in the public health facilities. This was evidenced by the audit during observation through physical verification, which noted that, 72% of health facilities possessed medical equipment that was not maintained as expected. Further details are shown in **Table 3.17.**

Table 3.17: The Health Facilities with untimely maintained Medical Equipment

Zone Visited	Number of Facilities Visited	Number of Facilities with Untimely Maintained Equipment
Central Zone	5	3
Eastern Zone	5	4
Lake Zone	4	3
Northern Zone	4	3
Total	**18**	**13**

Source: *Auditors' Analysis from Verification in the Public Health Facilities (2023)*

Table 3.17 indicates that, 13 out of 18 visited health facilities had existing untimely maintained medical equipment, while most facilities were found in the eastern zone. Therefore, the absence of a functioning mechanism to ensure that medical equipment are adequately maintained in public health facilities may lead to an increased risk of equipment malfunctions, deterioration of equipment reliability and increased operational costs.

3.5.2 The Ministry of Health did not ensure adequate maintenance of Medical Equipment for the Public Health Facilities in accordance with their respective Operational and Service Manual

Paragraph 12.3 of the National Guideline for Safecare Standards for Dispensaries, Health Centres, and District Hospitals, 2014, requires health

facilities to ensure that, appropriate medical equipment is always available and ready for use and properly maintained to meet the needs of the patient population.

During observation through physical verification of selected health facilities from 4 zones, namely, central, eastern, northern, and lake zones, the audit team noted that unmaintained medical equipment existed in the respective health facilities. Details on the status of unmaintained medical equipment from visited health facilities are presented in **Table 3.18**.

Table 3.18: Unmaintained Medical Equipment in the visited Health Facilities

Zones	Visited Facilities	Medical Equipment	Unmaintained Medical Equipment	% of Unmaintained Medical Equipment
Central	Mirembe National Mental Hospital	21	16	76
	Benjamin Mkapa Hospital	25	5	20
	Dodoma RRH	41	5	12
	Bahi DH	14	9	64
	Makole HC	14	2	14
Eastern	Muhimbili National Hospital	147	33	22
	Ocean Road Cancer Institute	26	8	31
	Amana RRH	25	5	20
	Mnazi Mmoja DH	12	7	58
	Buguruni HC	12	4	33
Lake	Chato ZRH	34	6	18
	Geita RRH	33	16	48
	Geita RH	16	3	19
	Kasamwa HC	7	1	14
Northern	Mawenzi RRH	21	5	24
	Kibong'oto Infectious Dieses Hospital	13	1	8
	Siha DH	15	4	27
	Siha HC	3	2	66
Total		**479**	**132**	**28**

Source: *Audit Verification during the visit to the selected Health Facilities (2023)*

From **Table 3.18**, the most unmaintained medical equipment was observed at the Mirembe National Mental Health Hospital, with 76% of medical equipment found unmaintained, while the least number of unmaintained medical equipment was at Kibong'oto Infectious Diseases Hospital, with 8% of unmaintained equipment. Other Health facilities had a percentage of unmaintained facilities ranging between 12% and 66%.

Moreover, interviews with officials in the visited health facilities revealed that each medical equipment has its own maintenance schedule. Therefore, biomedical engineers schedule the intervals for maintenance according to SOPs and the Operational Manual of the Equipment. In this regard, the maintenance of Medical Equipment in most cases is delayed for 1 to 3 years, while the plan indicates maintenance to be done at intervals of 1, 3, 6 or 12 months, based on the type and specifications of the equipment. This implies that medical equipment in most health facilities are not maintained, and when maintained, it is not in accordance with the required maintenance schedule.

Moreover, the presence of unmaintained medical equipment in health facilities was attributed to non-adherence to the planned maintenance schedule as described in subsection 3.2.1 of this report. On the other hand, it was noted that, health facilities did not allocate a budget for medical equipment maintenance. The existence of unfunctional medical equipment led to the overloading of other available functional medical equipment at the health facilities. This was observed in the health facilities of Benjamin Mkapa Hospital, Muhimbili National Hospital, and Kibong'oto Infectious Diseases Hospital. Therefore, the existence of unmaintained medical equipment in the country led to the objective of providing quality, safe and productive health services not being realised.

3.5.3 Ineffective Enforcement of Calibration and re-calibration of Medical Equipment in Health Facilities

Para 1.3.9, Page 5 of the Basic Standards for Hospitals at Level III & IV and Super Specialised Clinics at Level III of 2017 of the Ministry of Health revealed that, health facilities must ensure periodic calibration, verification, validation and maintenance of all medical equipment.

Through audit visits to the public health facilities, it was noted that, the calibration and recalibration of medical equipment was commonly done to centrifuge machines. The rest of the equipment was not calibrated. This situation was noted in all 18 visited health facilities under this audit, three (3) at the National Level and Regional Level, District Level, and Health centres two (2) at the Zonal Level and Super Specialised Hospitals, respectively.

During interviews with officials in the visited health facilities, it was revealed that, uncalibrated medical equipment was attributed to health facilities not allocating a budget for the calibration of medical equipment to ensure the results from the use of medical equipment in treatment are reliable and meet the required standard and intended purpose. In this regard, inadequate calibration of medical equipment resulted in health

facilities being unreliable in terms of their efficiency in diagnostics and treatment, thus compromising the patient's health and safety.

Therefore, it is emphasised that, without regular calibration and re-calibration, the performance of medical equipment may deteriorate over time. This can increase wear and tear, leading to higher maintenance costs and a shorter device lifespan.

3.5.4 Ineffective use of the Available Resources for the Maintenance of Medical Equipment in the Public Health Facilities

The staffing level for hospitals at level IV (National Hospital) requires a minimum of four (4) biomedical engineers and three (3) biomedical technicians. Also, the staffing level for level III hospitals is required to have one (1) Biomedical Engineer and two (2) Biomedical Technicians as stipulated in the Basic Standards for Health Facilities Volume 3 of the year 2017.

Through reviews of human resource establishments and observation through physical verification in the visited health facilities, it was noted that, regardless of the availability of human resources for medical equipment maintenance in respective health facilities, they were ineffectively utilised for maintaining medical equipment. During interviews with officials in the visited health facilities, it was revealed that, the inadequate utilisation of human resources for medical equipment maintenance was attributed to inadequate training in specific technologies under the medical equipment.

Further, reviews of the training reports of the Ministry of Health, it was noted that, for the financial year 2022/23, the Ministry of Health managed to conduct one training for Biomedical Engineers in Districts and Regional Hospitals, but for the financial year 2019/20 to 2021/22 training for Biomedical Engineers or allocation of budget for the same was not done.

The findings imply that, to ensure effective utilisation of the available human resources, building on maintenance of medical equipment is required on the available human resources through training and development. The list of the available human resources for the maintenance of medical equipment in the visited health facilities is indicated in **Table 3.19**.

Table 3.19: Staffing level in the sampled Health Facilities

Region	Name of Health Facility	Number of biomedical technologists	Number of biomedical engineers	Total
Dar es Salaam	Amana Regional Referral Hospital	0	1	1
	Muhimbili National Hospital	2	2	4
	Ocean Road Cancer Institute	1	1	2
	Buguruni Health Centre	0	0	0
	Mnazi Mmoja District Hospital	0	0	0
Dodoma	Benjamin Mkapa Hospital	2	2	4
	General Hospital	2	2	4
	Mirembe National Mental Hospital	0	0	0
	Bahi District Hospital	1	0	1
	Makole Health Centre	0	0	0
Geita	Geita Regional Referral Hospital	2	2	4
	Chato Zonal Referral Hospital	1	2	3
	Geita District Hospital	0	0	0
	Kasamwa Health Centre	0	0	0
Kilimanjaro	Kibong'oto Infectious Diseases Hospital	0	1	1
	Mawenzi RRH	0	2	2
	Siha Health Centre	0	0	0
	Siha District Hospital	0	1	1

Source: *Auditor's Analysis of the Staff in the visited Health Facilities (2023)*

Table 3.19 shows that the highest number of human resources for maintenance of medical equipment in health facilities was noted at Muhimbili Hospital, Benjamini Mkapa Hospital, General Hospital, and Geita Regional Hospital, with four (4) staff members each. On the other hand, 4 Health facilities, namely, Amana Hospital, Bahi Hospital, Kibong'oto Hospital and Siha District Hospital, had only one (1) staff. Meanwhile, six (6) health facilities, namely, Buguruni Health Centre, Mnazi Mmoja Hospital, Mirembe Hospital, Makole Health Centres, Geita Hospital, Kasamwa Health Centre and Siha Health Centre, did not have any staff responsible for the maintenance of their medical equipment. The findings

imply that there is inadequate staff for maintaining medical equipment. This results in the existence of unfunctional medical equipment.

3.6 TMDA Did Not Monitor the Performance of Medical Equipment in Public Health Facilities

TMDA, being the regulator, is responsible for monitoring the performance of medical equipment in health facilities through inspections, post-market surveillance and vigilances. The audit noted that, TMDA did not effectively monitor the performance of medical equipment as planned. The noted shortcomings in monitoring the performance of medical equipment by TMDA are as follows:

3.6.1 TMDA Did Not Plan for Inspections of Medical Equipment in public Health Facilities

According to paragraph 4.5 of the TMDA's Strategic Plan 2017/18-2020/21, TMDA was required to monitor medical equipment through post-market surveillance of medical testing and analysing medical equipment.

The audit noted that TMDA did not plan to inspect medical equipment regularly in health facilities. This was noted through a review of TMDA annual Plans for the financial years 2019/20 to 2022/23, whereby the plans for the inspection of medical equipment in health facilities were not taken into account in the annual plan.

Similarly, it was found that the plan developed for post-marketing surveillance covering the financial years 2017/20 to 2020/21 and 2020/21 to 2022/23 did not include provisions for regular inspection of medical equipment in health facilities. Instead, the plan focused on post-marketing surveillance inspection of medical supplies.

However, interviews with officials at TMDA revealed that, TMDA did not plan to inspect medical equipment in the public health facilities. This is due to the fact that there was a gap in human resources for exercising their duties since the biomedical engineers and biomedical technologists were missing. In this regard, officials assigned to inspect medical equipment were mainly drug Inspectors who were experts only in medicine and pharmacy; thus, such kinds of inspections were not performed.

Consequently, a lack of a plan for the regular inspection of medical equipment in health facilities resulted in medical equipment in the health facilities remaining with unknown or unmonitored performance, which could not assure the users and the operators of the quality, safety and efficiency.

3.6.2 Inadequate Inspection of Medical Equipment in the Public Health Facilities

TMDA is required to monitor through-market surveillance of medical equipment, as well as testing and analysing medical equipment. Also, TMDA is required to produce quarterly post-market surveillance reports (Result Framework paragraph 4.5 of the TMDA's Strategic Plan 2017/18-2020/21).

Reviews of the TMDA annual Implementation reports for the financial years 2019/20 to 2021/23 did not indicate that TMDA conducted regular inspections of medical equipment in public health facilities. However, the post-market surveillance reports implemented in the year 2022/23 indicated that, the inspection of public health facilities was carried out in 14 Public Health Facilities in 4 Regions, as no other inspections were previously conducted with regard to medical equipment in public health facilities.

Moreover, the audit noted that, in the post-market surveillance for medical equipment conducted by TMDA in the financial year 2022/23, none of the health facilities selected by the audit were covered by TMDA's scope. During interviews conducted with officials of TMDA, it was emphasised that, TMDA had never prioritised or budgeted for the inspection of the performance of medical equipment in public health facilities because previously, the authority did not have a specified department[12] responsible for medical devices but rather had a section with a role for inspecting drugs and not medical equipment in the health facilities in the country.

The findings imply that, the authority is in transition to fully realising its duty on inspection of medical equipment as the audit noted that, the inspectors were mainly pharmacists and veterinarians, whereas biomedical engineers and technologists were missing.

Therefore, inadequate inspection of medical equipment in public health facilities resulted in unfunctional medical equipment, use of medical equipment without SOPs, and no implementation of planned preventive maintenance as observed in the visited public health facilities.

[12] At the time of the audit, TMDA indicated that the process of establishing a unit with the role for Inspection of Medical Devices was in Progress.

3.6.3 TMDA Did Not ensure the Effective Submission of Biennial Post-Market Surveillance Reports of the Medical Equipment in use

Regulation 17 (3) of the Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015, states that, the registrant shall submit biennial post-marketing surveillance reports, including any adverse events. The biennial post-marketing surveillance reports will serve as the basis for monitoring the performance of medical equipment in use and in case of adverse effects/events. They will also serve as the basis for the decision on the inspection of medical equipment in health facilities.

Notwithstanding the provision of Regulation 17, the Authority may suspend or cancel the registration of medical devices if the authority has reasonable grounds to believe that, the registrant has failed to submit biannual post-marketing surveillance as provided under Regulation 18(h) of the Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015.

In reviews of the TMDA annual implementation reports for the period under the audit, it was noted that the registrant of medical equipment did not provide reports to TMDA regarding the performance of medical equipment in health facilities. Also, TMDA did not provide any evidence on the reported biennial post-market surveillance for the period under the audit for the medical equipment in health facilities.

During the interviews with officials from TMDA, it was revealed that the Authority did not have plans for biennial reports on the performance of medical equipment in health facilities. Similarly, TMDA did not have a system that enforce registrants to ensure registrants report on the biennial performance of medical equipment.

Based on these facts, the absence of Biennial post-marketing surveillance from the registrant of medical equipment leads to the non-issuance of recommendations regarding the performance of medical equipment in the country. Also, it led to registered Medical Equipment having their registration expired while still in the market from the financial year 2019/20 to 2022/23.

3.6.4 TMDA Did Not Effectively Communicate the Monitoring Results to key Stakeholders for Actions

TMDA is required[13] to conduct monitoring of medical devices on the market, prepare and disseminate reports on post-marketing surveillance related to medical devices, and maintain an updated database of reports on field

[13] Para 3.1.2 (i), (v) and (vi) of the Approved Functions and Organisation Structure of the Tanzania Medicine and Medical Devices Authority (TMDA), 2021.

safety, performance, adverse reactions, and events associated with the use of medical devices.

However, in the review of monitoring reports of medical equipment in public health facilities, it was found that, TMDA communicated the results to all 14 health facilities covered in the monitoring process.

In the review of the TMDA strategic plan, 2021/22-2025/26 indicated that, TMDA did not communicate the monitoring results to key stakeholders such as TAEC and LGAs for actions due to inadequate leverage of information and communication technologies (ICT) in service provision. In interviews with TMDA officials, it was also confirmed that, the engagement of key stakeholders, such as TAEC, was not in place due to the absence of a memorandum of understanding between the two entities.

From the findings, it can be deduced that, the ineffective communication of monitoring results to key stakeholders for the appropriate actions to be undertaken contributed to inadequate branding, as revealed in paraph 2.5.6 of objective F of TMDA's strategic plan 2021/22-2025/26.

3.6.5 TMDA Did Not Conduct Follow-ups on the Implementation of Recommendations issued to Healthcare Providers

Section 5(1)(o) of the Tanzania Food, Drugs and Cosmetics Act, 2003, as amended by section 24 of the Finance Act, 2019requires the Tanzania Medical Devices Authority (TMDA) to promote, monitor and ensure successful implementation of the provisions of the Act. To ensure the medical equipment's safety, efficacy, and performance, TMDA is required to conduct post-market surveillance and issue recommendations to health facilities.

During the audit, there was insufficient evidence to determine the frequency and consistency of follow-ups conducted on implementing recommendations issued to health facilities by TMDA. This is because the available information did not provide insights into TMDA's post-recommendation monitoring practices and whether they regularly followed up with health facilities to ensure the implementation of the recommendations. This is because there was no information regarding the implementation of the issued recommendations.

This was attributed to the absence of a monitoring plan and guiding processes for regular assessments, clear timelines, and effective communication with health facilities regarding the follow-up on the implementation of the issued recommendations.

Therefore, the absence of effective follow-ups regarding the issued recommendations on the performance of medical equipment could have affected patient safety and healthcare quality, which may have been compromised due to increased risks due to non-compliance to safety standards and regulatory requirements.

The findings imply that, the issues noted could persist as they may have remained unaddressed. As a result, it hinders the improvement of the healthcare system and undermines the TMDA's objective of conducting post-market surveillance to assess the performance and quality of medical equipment.

3.7 Inadequate Disposal of unfunctional[14] Medical Equipment

Unfunctional medical equipment is to be disposed of once it is no longer in use or exhibits deficiencies in quality, safety, and performance to the extent of being beyond repair. Despite the existence of these conditions, the audit noted weaknesses in the disposal process of medical equipment in public health facilities nationwide. In this respect, TMDA and the Ministry of Health lacked a functioning system to ensure the effective disposal of medical equipment.

This implies that, TMDA did not verify information related to the disposal of medical equipment in health facilities since a coordination gap was observed in handling the disposal of medical equipment with the responsible stakeholders. The audit found that no information or request regarding the disposal of medical equipment in the public health facilities was found to be submitted to TMDA.

3.7.1 Non-disposal of Medical Equipment in Health Facilities

Regulation 59 of Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015, states that, no person shall dispose of any unfunctional Medical Devices unless he/she has requested the Authority and Secured approval to proceed with the disposal procedure.

A review of the disposal reports at TMDA for the financial year 2019/20 to 2022/23 revealed that, TMDA did not initiate or receive requests to approve the disposal of medical equipment for 4 Financial Years 2019/20 to 2022/23. Instead, it received reports only for the disposal of other regulated products like syringes and gloves.

[14] The unfit medical equipment referred for disposal are those which have deficiency in quality; deficiency in safety; and deficiency in performance (Para 7 & 14 of the TMDA Guideline for Handling Unfit Medical Devices and Diagnostics, 2023).

Moreover, interviews conducted with TMDA officials revealed that, the existence of undisposed medical equipment in the country was attributed to TMDA not having guidelines for the disposal of medical equipment. This could be an important tool to facilitate TMDA in initiating and guiding the disposal of medical equipment. While facilitating public health facilities to request approval and advice from TMDA on the appropriate method to dispose of such equipment as is the practice for other regulated products.

In the same vein, regulation 60 of the Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 did not clearly define under which circumstance TMDA shall initiate the disposal of medical equipment. Based on this, TMDA did not initiate the process of disposing of medical equipment.

Consequently, the lack of guidelines for the disposal of non-functional medical equipment led to 6 out of 18 health facilities being visited with an accumulation of non-functional medical equipment that was not disposed of. For instance, observation through physical verification at the Benjamin Mkapa Hospital revealed an accumulation of unfunctional medical equipment in the warehouse, which remained undisposed, as shown in **Photo 3.1.**

Photo 3.1: ***Undisposed medical equipment placed in a warehouse at Benjamini Mkapa Hospital (Photo Taken by Auditors on June 2023)***

Photo 3.1 shows accumulated, non-functional medical equipment that is not disposed of at Benjamin Mkapa Hospital in Dodoma.

Moreover, interviews conducted with officials at Benjamin Mkapa Hospital revealed that they had never disposed of any of the medical equipment since the hospital began providing health services. Instead, they utilise the

spare parts from unfunctional medical equipment for maintenance of other medical equipment. These spare parts and unfunctional medical equipment were accumulated in the health facility warehouse.

As a result, the accumulated unfunctional medical equipment in health care facilities occupies space designated for functions other than storing unfunctional medical equipment in health facilities, posing a risk to users whenever the accumulated equipment contains radiation sources.

Furthermore, interviews conducted with officials in other visited health facilities revealed that, the main reason for an accumulation of unfunctional medical equipment without disposal was that, health officials lacked awareness of the guidelines on the procedures to be followed for the disposal of medical equipment since no guidelines were developed and disseminated to health facilities to facilitate the disposal of medical equipment. **Photo 3.2**, taken by the auditor on 26 September 2023, indicates the store used by Geita RRH to accumulate unfunctional medical equipment at Geita District Hospital[15].

Photo 3.2: ***Undisposed Medical Equipment at Geita District Hospital (Photo Taken by Auditors in October 2023)***

Photo 3.2 show presence of undisposed Medical Equipment of Geita Regional Referral Hospital stored at Geita District Hospital.

[15] When we visited Geita Regional Referral Hospital, the Management said that, they have store for accumulating unfit medical equipment beyond repair. This store is located in the Geita Town Council Hospital which was Geita RRH before shifting to new buildings located about 10km from Town Centre.

During observation through physical verification of Geita Regional Referral Hospital, the audit found that there was a store that used to accumulate non-functional medical equipment instead of disposing of it.

Similarly, Interviews conducted with officials in the visited health facilities revealed that, the accumulation of medical equipment was due to officials in Health facilities not being aware of the guidelines that detail the procedures required for the disposal of medical equipment after use.

In this regard, the non-disposal of unfunctional medical equipment led to the accumulation of medical equipment, whereas some may carry pathogens or contaminants, and storage without sterilisation can increase the risk of infection transmission for both patients and healthcare workers.

Likewise, long-term inappropriate medical equipment storage, as shown in photo 3.2, can pollute the environment. This is due to the fact that, medical equipment containing hazardous materials can be released and impact soil and water quality as well.

3.7.2 TMDA Did Not Verify the Information on Medical Equipment for Disposal from Health Facilities

Regulation 62 (1) (3) of Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 requires the Authority, upon receipt of the request for disposal, to appoint an inspector to verify and authenticate the information submitted about the consignment to be disposed of.

In addition, Para 8.1 (8) of Tanzania Medicines and Medical Device Authority Client Service Charter 4th Edition of April 2020 requires TMDA to provide service standards for issuing a disposal certificate for unfunctional medical equipment.

In a review of disposal records at TMDA, it was noted that, TMDA, for the period under the audit 2019/20 to 2022/23, never recorded or verified the disposal of all kinds of medical equipment. However, during the audit verification in the visited public health facilities, nonfunctional medical equipment that could not be repaired accumulated in health facilities, as shown in **Table 3.20**.

Table 3.20: The accumulation of unfunctional Medical Equipment in the Health Facilities beyond repair

Zone	Number of Health facilities	Health facilities accumulated Unfit Medical Equipment	% of Health facilities accumulated unfit Medical Equipment
Central Zone	5	2[16]	50
Easter Zone	5	2[17]	40
Northern Zone	4	1	25
Lake Zone	4	1[18]	25

Source: *Auditors' Analysis of Information obtained from Physical Observation in visited Health Facilities (2023)*

Table 3.20 shows that, the central zone had 50% of the facilities with accumulated unfuctional medical equipment, and the eastern zone had 40% of the facilities. Meanwhile, the Northern and Lake Zones had 25% of the facilities that accumulated non-functional medical equipment.

Moreover, it was noted that, one of the causes of non-verification of unfunctional medical equipment was that, all visited health facilities were unaware of the guidelines from TMDA that state the procedures for the disposal of medical equipment. This situation could lead to improper disposal of medical equipment without prior informing TMDA.

Furthermore, interviews with TMDA zonal officers on lack of awareness regarding the requirement of verification and advice on the appropriate methods for the disposal of medical equipment in health facilities revealed that, TMDA never conducted training for capacity building to raise awareness in the health facilities regarding the disposal of medical equipment. This fact was confirmed in interviews conducted with officials in the visited health facilities, who revealed that they had never received training related to the disposal of medical equipment.

Additionally, accounting officers in the visited health facilities, as noted by the audit, did not initiate the process for disposal of medical equipment from health facilities nor request advice from TMDA regarding the appropriate method and procedures for the disposal of medical equipment.

In this regard, unfunctional medical equipment accumulated without any initiation for disposal by the accounting officers. Likewise, TMDA did not emphasise its importance, though it is mandated to ensure that unfunctional

[16] Benjamin Mkapa Hospital and Dodoma Regional Referral Hospital
[17] Ocean Road Cancer Institute and Mnazi Mmoja Hospital
[18] Geita Town Council Hospital

medical equipment is verified before disposal. This was contrary to Paragraph 15.1.2 of the TMDA Inspector's Handbook of 2023, which indicates that Inspectors from TMDA need to inspect medical equipment from various areas, including public health facilities, to ensure standards of safety, quality, and efficacy to protect public health. Therefore, TMDA's inability to verify unfunctional medical equipment may result in the disposal of such equipment without compliance with the required safety procedures.

3.7.3 TMDA Did Not Coordinate the Disposal/Destruction of Unfunctional Medical Equipment with TAEC, NEMC and LGAs

Section 5(1)(e), (2)(a) of the Tanzania Food, Drugs and Cosmetics Act, 2003, as amended by section 24 of the Finance Act, 2019, requires TMDA to foster cooperation with LGAs, Health Facilities, TAEC and NEMC and maintain a system of consultation and cooperation with Tanzania Atomic Energy Commission (TAEC).

Similarly, Regulations 62 (1), (2), (3) and (4) of Tanzania, Food, Drugs and Cosmetics Control of Medical Devices, Regulations, 2015 require TMDA to approve requests for the disposal of unfunctional Medical Devices from NEMC and LGAs that are accompanied by an approval from Accountant General declaring that the products have been written off and that are subject to disposal as required by the Public Finance Act and Regulations in force for the time being.

Since no records were available on the disposal of medical equipment that had been carried out in the country, the condition of cooperation between TMDA and other stakeholders regarding the disposal of medical equipment could not be adequately verified.

3.7.4 Health Facilities Inadequately Informed TMDA of the Existence of Unfunctional Medical Equipment

Regulation 63 (2), (a) and (b) of Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 states that every dealer of Medical Equipment shall maintain a register of unfunctional Medical Devices.

The audit noted that, no report on unfunctional medical equipment was submitted to TMDA. In the visited health facilities, it was noted that, the records of all medical equipment were available. However, the status of unfunctional medical equipment was not documented.

However, the reports stated that the absence of information on non-functional medical equipment in health facilities was mainly caused by the

absence of a register for non-functional medical equipment and an appropriate storage of non-functional medical equipment.

Therefore, the absence of information on unfunctional medical equipment from health facilities resulted in ineffective management of unfunctional medical equipment. Also, it can lead to compromised patient safety and challenges in tracking and managing equipment.

3.8 Improper Coordination of Stakeholders Involved in the Management of Medical Equipment

Regarding the coordination among stakeholders involved in the management of medical equipment, the following deficiencies were noted:

3.8.1 TMDA Ineffectively co-operated with key Stakeholders During Post Market Surveillance of Medical Equipment

Sect. 5(1) (e), (2) (a) of the Tanzania Food, Drugs and Cosmetics Act, 2003, as amended by section 24 of the Finance Act, 2019requires TMDA to foster cooperation with LGAs, health facilities, TAEC and NEMC and maintain a system of consultation and cooperation with Tanzania Atomic Energy Commission (TAEC).

A review of the post-market surveillance programme for medical equipment, as outlined in the first report of the financial year 2021/2022 and the second report of the financial year 2022/2023, indicated that, TMDA conducted their post-market surveillance programme for medical equipment without cooperation with LGAs and TAEC. Officials from TMDA indicated that health facilities had the role of seeking certification from TAEC to own and administer medical equipment that emits radiation.

On the other hand, a review of post-market surveillance reports indicated that, TMDA included checking whether the health facilities had a radiation safety report from TAEC. However, there was no evidence to indicate whether TAEC were informed of any case of radiation safety precautions.

The ineffective cooperation and communication between the Tanzania Medical Devices Authority (TMDA) and the Tanzania Atomic Energy Commission (TAEC) regarding the post-market surveillance programme for medical equipment emitting radiation were caused by weaknesses in the planning and execution of the PMS programme involving TAEC, which was responsible for regulating radiating medical equipment.

Also, there was an absence of officially structured communication mechanisms hindering joint inspections and information sharing, as officials from TMDA indicated that, TAEC had its own establishment. This implies that, there was no common platform for TMDA and TAEC to conduct joint

activities with regard to the inspection of medical equipment in health facilities.

This could result in ineffective regulation and monitoring of medical equipment emitting radiation, posing significant risks to patients, healthcare workers and public safety. Also, it could result in health facilities continuing to use radiating medical equipment without appropriate authorisation, which is dangerous for the health facilities.

3.8.2 Ineffective Feedback Mechanism on the Inspection of Medical Equipment in Health Providers

Section 121 of the Tanzania Food, Drugs and Cosmetics Act, 2003 as amended by section 24 of the Finance Act, 2019 states that the Minister of Health, upon consultation with the TMDA when considered fit and proper by order published in the Gazette, delegate to any other person, institution, or body of persons some of the functions or powers of the Authority conferred upon it by the Tanzania Food, Drugs and Cosmetics Act, 2003 as amended by section 24 of the Finance Act, 2019. Furthermore, Section 57(2) of the Local Government (Urban Authorities) Act, 1982, gives TMDA power to delegate some of its functions to LGAs in the country.

The audit noted that, TMDA delegated some of its functions to LGAs, such as conducting routine inspections for premises and Medical Equipment and preparing inspection reports to be submitted to the Tanzania Medicines and Medical Devices Authority through the Regional Administrative Secretary to obtain feedback on the functionality of medical equipment in health facilities.

Regardless of paragraph 3 of the Guidelines for Medical Devices Vigilance System in Tanzania, 2022 specifies collaboration with stakeholders and defining the roles in the vigilance of medical equipment in Tanzania. There was a notable lack of effective communication and feedback to the Tanzania Medicines and Medical Devices Authority (TMDA). This was evidenced during site visits to 18 health facilities, where a number of medical equipment issues were found but were not reported to TMDA for appropriate action to be taken. On the other hand, TMDA officials indicated a lack of follow-up with the LGAs on the submission of quarterly reports for delegated activities such as inspection of premisses and medical equipment in public health facilities.

Consequently, the ineffectiveness of receiving quarterly inspection reports on medical equipment at health facilities undermines the aim of TMDA, which is to ensure the medical equipment remains safe and performs as

intended based on the manufacturer's specifications. Also, the ineffective mechanism to obtain inspection reports from LGAs on medical equipment in health facilities may lead to delayed recognition of safety concerns and potential risks of using medical devices that are not properly functioning and safe, thus compromising patients' and operators' safety.

Therefore, non-submission of quarterly reports by LGAs can impede the timely dissemination of important information, hindering the TMDA's ability to take prompt regulatory actions. This jeopardises the effectiveness of regulatory oversight and may impact public health.

3.8.3 Ineffective Coordination between TMDA and key Stakeholders in Relation to Medical Equipment in public Health Facilities

According to the TMDA Guideline for Medical Devices vigilance system in Tanzania of 2022, TMDA, in collaboration with stakeholders such as health facilities and their various roles and responsibilities regarding vigilance of medical equipment to ensure that, the medical equipment remains safe and performs effectively as intended in accordance with manufacturer's specifications.

In the review of internal audit reports from 2019/2020 to 2022/2023, it was noted that, there was no coordination system mechanism toward collaboration between TMDA and key stakeholders to facilitate the effective functioning of medical equipment in public health facilities.

The ineffective coordination between the Tanzania Medicines and Medical Devices Authority (TMDA) and key stakeholders responsible for facilitating the effective functioning of medical equipment in public health facilities was due to various factors. These included unclear and untimely communication channels hindering coordination efforts. Also, unclearly defined roles and responsibilities of stakeholders, insufficient resources to facilitate coordination, and a lack of collaboration with TAEC further compounded the challenges.

Therefore, ineffective coordination between the Tanzania Medicines and Medical Devices Authority (TMDA) and key stakeholders could compromise patient safety and outcomes due to the use of unfunctional medical equipment. Similarly, ineffective coordination between the Tanzania Medical Devices Authority (TMDA) and key stakeholders for medical equipment in public health facilities can hinder and delay taking regulatory actions on unfunctional medical equipment, potentially compromising health safety.

CHAPTER FOUR

AUDIT CONCLUSION

4.1 Introduction

This chapter presents the conclusions of the audit, which are categorised into two main parts: general and specific audit conclusions. The conclusions are based on findings drawn based on the audit's overall and specific objectives of this Performance Audit Report.

4.2 General Audit Conclusion

The audit concludes that, the Ministry of Health (MoH), through TMDA, has ineffectively regulated medical equipment in terms of efficiency, quality, and safety. This is due to the fact that, they have not sufficiently ensured adequate functionality to procedures for registration of medical equipment, maintenance of medical equipment, quality of imported medical equipment, performance of medical equipment in health facilities, ineffectively disposing unfunctional medical equipment and cooperating with other stakeholders involved in medical equipment. This means that, they were not in a position to enhance the provision of healthcare services and safeguard the environment and citizens of the country through adequate regulation of medical equipment used in the health facilities.

Generally, TMDA has not ensured that medical equipment is effectively regulated through the effective registration of medical equipment, adequate monitoring of the performance of medical equipment in health facilities, adequate disposal, and cooperation with stakeholders responsible for medical equipment. This is evidenced by the delay in the registration of medical equipment and the existence of unfunctional medical equipment in health facilities.

These have mainly been attributed to TMDA's inadequate control of medical equipment. In this regard, TMDA inadequately inspected the imported medical equipment in health facilities during importation and post-market surveillance. This has also been attributed to inadequate allocation of human, physical (tools) and financial resources for maintaining and conducting post-market surveillance.

Regardless of such inadequacies, the audit acknowledges the efforts to improve the availability of medical equipment to provide the best healthcare services to the citizens of Tanzania.

4.3 Specific Audit Conclusions

4.3.1 The Procedures for the Registration of Medical Equipment are Not Adequately Functioning

There is a significant deficiency in the current record-keeping procedures for registering medical equipment spanning from the financial years 2019/20 to 2022/23. Approximately 56% of the currently registered medical equipment lacks crucial information regarding the application and certificate issuance dates. This deficiency is attributed to the ongoing data migration from the Integrated Management Information System (IMIS) to the Regulatory Information Management System (RIMS), resulting in the deletion and addition of other information. Consequently, the Tanzania Medicines and Medical Devices Authority (TMDA) lacks essential details about the expiration dates of licenses for the registered medical equipment.

Similarly, there are delays in processing applications for the registration of medical equipment, spanning from the financial years 2019/20 to 2022/23. Despite existing guidelines that specify processing times for different classes of medical equipment, a significant percentage failed to meet these deadlines. For instance, in 2020/21, all registrations were completed outside of the specified timeframe, and other years had a limited number of registrations completed within the specified timeframe. Notably, all class A equipment was registered out of the specified timeframe of 45 days. This is attributed to the lack of clear timelines for each registration step and the absence of specified durations in the existing Clients' Service Charter. The delays have resulted in prolonged delays in delivering services to the citizens.

Tanzania Medicines and Medical Devices Authority (TMDA) has experienced delays in renewing certificates of registration for medical equipment from the financial year 2019/20 to 2022/23, averaging a 53% delay in the process. Meanwhile, non-renewal income reached 98% in the financial year 2022/23. This inefficiency is attributed to the lack of an effective client reminder system and the absence of mechanisms to enforce timely renewals within the mandated period of 90 working days. This consequently led to hindrances in submitting the required post-market surveillance reports and a significant amount of uncollected revenue, accounting for TZS 10,261,473,750. In this regard, the largest portion of unrenewed registration fees accounted for TZS 9,611,538,750 in the financial year 2022/23, with a total number of 1,538 medical equipment unrenewed.

Besides the revenue losses highlighted in this report, TMDA's lapses in maintaining essential information records for about 56% of licenses issued from the financial year 2019/20 to 2022/2023. This poses a significant risk to the safety of citizens and health facilities when using these medical equipment. This is an awakening call to question TMDA's capacity to receive, manage, and

ensure accurate information regarding the safety, quality, and efficacy of this medical equipment in the market. Also, the act raises concerns from other international medical device regulatory authorities about the reliability of TMDA information on medical equipment registration and licensing process.

4.3.2 TMDA has Not ensured the Procured Medical Equipment Meets the Required Standard

TMDA lacked adequate capacity in its existing laboratory to test all medical equipment parameters. This was evidenced by the fact that, 100% of procured medical equipment in the visited health facilities lacked quality test reports of different parameters, such as quality of performance and assurance of minimum effects to users and patients.

Based on this fact, TMDA has not effectively verified and inspected imported medical equipment by Public health facilities. The audit found that, there were no details in import permit certificates and inspection reports for medical equipment from the financial year 2019/20 to the financial year 2022/23. The absence of comprehensive inspection records was attributed to insufficient human resources at entry ports, especially the absence of biomedical engineers. On the other hand, TMDA is facing resource constraints of humans and equipment/materials necessary for performing inspections of medical equipment in ports of entry. As a result, from 2016/17 to 2017/18, TMDA inspected less than 50% of imported medical equipment. Consequently, the importation and installation of medical equipment occurred without thoroughly verifying their efficiency by TMDA, posing risks to safety and efficacy.

Also, the Tanzania Medicines and Medical Devices Authority (TMDA) has not adequately complied with international standards for medical equipment. Despite commitments to ISO 9001:2015 and ISO 13485, TMDA has not established effective reference files for international standards and regulatory requirements. This is attributed to a lack of allocated funds and clear processes. Hence, unestablished standards may lead to non-compliance, regulatory gaps, and transparency. This deficiency poses potential risks to regulatory effectiveness and public health. Also, it undermines the authority's credibility at the international level, adversely impacting its credibility and ability to foster trust and collaboration with other medical regulatory bodies.

Likewise, Standard Operating Procedures (SOPs) for medical equipment in health facilities are ineffectively applied as required by Basic Standards for Health Facilities III & IV, 2017. It was found that, among 426 medical equipment, 263 lack proper SOP enforcement. The Tanzania Medicines and Medical Devices Authority (TMDA) and the Ministry of Health's insufficient

enforcement and a lack of follow-up on recommendations contribute to this shortfall. Deficient SOP implementation risks the quality of care and delays in providing essential health services.

4.3.3 Maintenance of Medical Equipment in Public Health Facilities is not Adequately Done

Medical equipment in public healthcare facilities is not adequately maintained. The Ministry of Health does not have a functional system to ensure timely and adequate medical equipment maintenance in public health facilities, mainly due to the absence of budget allocations to develop such a system. As a result, 72% of audited health facilities have medical equipment that is not maintained per standard schedules. This lapse in maintenance practices may compromise the effectiveness and reliability of medical equipment, potentially affecting the quality of healthcare services provided in these facilities.

The Ministry of Health inadequately maintains medical equipment in public health facilities, which is evident across various zones, with a prevalence of unmaintained equipment ranging from 8% to 72%. Non-compliance with maintenance schedules and the absence of budget allocations compromise service quality, safety, and productivity. On the other hand, health facilities rarely allocate funds for maintaining medical equipment, and in most cases, they do not plan to procure spare parts. As a result, most medical equipment remains unrepaired and unfunctional. This increases the cost of procuring different items to maintain unrepaired medical equipment. This situation has resulted in the overloading of other available functional equipment in specific facilities, adversely impacting the goal of delivering quality, safe, and productive health services in the country.

Also, calibration and recalibration enforcement in public health facilities are deficient, with only centrifuge machines undergoing this process across all 18 visited health facilities. The lack of allocated budgets for calibration is a key factor affecting the reliability of results from medical equipment used in diagnostics and treatment. This deficiency in calibration could compromise the overall efficiency of health facilities in achieving accurate and reliable outcomes from their medical equipment.

Medical equipment maintenance in public health facilities is hindered by inefficient resource utilisation, inadequate training for allocated personnel, inadequate staffing levels across facilities, and insufficient support from the Ministry of Health regarding training and budget allocation for biomedical engineers in previous financial years. This has led to the prevalence of unfunctional medical equipment in various health facilities.

4.3.4 TMDA has not Effectively Monitored the Performance of Medical Equipment used in Health Facilities

TMDA has not effectively monitored the performance of medical equipment used by the health facilities to assess their performance. From 2016/17 to 2020/21, none of the TMDA's post-market surveillance covered the performance of medical equipment in health facilities. This leads to the certainty of the quality of healthcare services and the questionable performance of medical equipment. Therefore, the inability to monitor the performance of medical equipment could expose healthcare, manufacturers, suppliers and the TMDA to legal consequences in the event of patient harm or non-compliance with the standard.

There is a lack of routine inspections on the performance of medical equipment in public health facilities. A pilot inspection occurred in the financial year 2022/23, marking the first instance of inspection of medical equipment in these facilities. However, none of the selected health facilities were covered during post-market surveillance in 2022/23. The absence of a dedicated department for medical devices and reliance on drug inspectors, mainly medical doctors and pharmacists, contribute to this oversight. Inadequate inspections result in unfunctional medical equipment, usage without Standard Operating Procedures (SOPs), and the negligence of planned preventive maintenance, as observed in the visited public health facilities.

Moreover, TMDA has not adequately planned for the inspection of medical equipment. The post-marketing surveillance plans for the same period focus on medical supplies, overlooking essential inspections of medical equipment in health facilities. The shortage of critical human resources, specifically biomedical engineers and technologists, currently hinders the implementation of these inspections. Therefore, the lack of a structured plan for regular inspections leads to the performance of medical equipment in health facilities being unknown and unmonitored, posing risks to users' and operators' quality, safety, and efficiency.

Furthermore, TMDA does not ensure the effective submission of biennial post-market surveillance reports for medical equipment, as mandated by regulations. TMDA's annual implementation reports indicate that, registrants are not submitting these reports, and the authority is not providing evidence of their receipt. Consequently, the absence of biennial post-marketing surveillance hampers the issuance of appropriate recommendations and results in the automatic cessation of registration validity for all medical equipment items from 2019/20 to the financial year 2022/23. It is concluded that, TMDA

does not conduct sufficient follow-ups on implementing recommendations issued to health facilities. The lack of a monitoring plan and clear processes for regular assessments and communication contributes to this issue. This deficiency in follow-up practices poses risks to patient safety, compromises healthcare quality, and undermines regulatory compliance. It hampers improvements in the healthcare system and contradicts TMDA's objective of ensuring the performance and quality of medical equipment through post-market surveillance.

4.3.5 Ineffective Disposal of Unfunctional Medical Equipment

The audit concludes that, TMDA has not ensured that, the disposal of medical equipment is done effectively. Health facilities use open pit burning or burying unfunctional equipment instead of a high-temperature incinerator. This is an appropriate disposal method to avoid air pollution and toxic ash from polluting the surroundings.

Also, health facilities have been disposing of medical equipment without involving other key stakeholders like TMDA, which is mandated for issuing disposal permits. Meanwhile, NEMC is responsible for environmental protection and other stakeholders. Non-involvement of key stakeholders may cause improper disposal of Medical Equipment, especially equipment requiring specialisation, particularly equipment that emits radiation, which must involve TAEC.

Therefore, weak management of the disposal of unfunctional medical equipment from TMDA and MoH contributes to the improper disposal of medical equipment. Also, health facilities lack plans for the disposal of medical equipment and are not equipped with adequate knowledge of handling nonfunctional medical equipment.

4.3.6 The Coordination between Ministries (MoH and PO-RALG), TMDA and Health Facilities in Regulating Medical Equipment is not effectively done

The audit concluded that, neither MoH nor TMDA has adequately strengthened stakeholder coordination to regulate medical equipment. As a result, similar activities, such as the inspection of radiation medical equipment, have been implemented by both TMDA and TAEC at different times and in different ways. Although TMDA delegated some of its functions for inspecting and monitoring the performance of medical equipment to LGAs, issues regarding unfunctional medical equipment were still not reported.

The ineffective coordination between the Tanzania Medicines and Medical Devices Authority (TMDA) and key stakeholders responsible for facilitating the effective functioning of medical equipment in public health facilities is due to various factors. These include unclear and untimely communication channels hindering coordination efforts.

Also, unclearly defined roles and responsibilities of stakeholders, insufficient resources to facilitate coordination, and the absence of structured collaboration with key stakeholders like TAEC further undermine stakeholders' coordination efforts.

CHAPTER FIVE

AUDIT RECOMMENDATIONS

5.1 Introduction

This chapter contains recommendations for the Ministry of Health (MoH) and Tanzania Medicines and Medical Devices Authority (TMDA) regarding the regulation of medical equipment in the country.

The National Audit Office believes that, based on the 3Es, namely Economy, Efficiency and Effectiveness principles. These recommendations need to be fully implemented to ensure improvements in the management of medical equipment in the country.

5.2 Recommendations to the Ministry of Health and TMDA

5.2.1 Recommendations to the Ministry of Health

The Management of the Ministry of Health is urged to:

(a) Ensure an operable and functional system for inventory and maintenance of medical equipment in public health facilities;

(b) Enhance preparation and integration of information on unfunctional medical equipment in health facilities, to be shared with TMDA for verification and suggestions on the proper mode of disposal.

5.2.2 Recommendations to Tanzania Medicines and Medical Devices Authority (TMDA)

The Management of Tanzania Medicines and Medical Devices Authority is urged to:

(a) Enhance registration procedures for medical equipment by taking into account sample collection and timelines for each step involved;

(b) Ensure the presence of human, physical (tools) and financial resources for the inspection of imported medical equipment;

(c) Devise mechanisms for post-market surveillance to cover medical equipment in health facilities and issue advice on proper maintenance and use. This should involve planning and developing tools to track key performance indicators of medical equipment effectively;

(d) Collaborate with TAEC, LGAs and NEMC to establish a functioning system that will enable health facilities to report unfunctional medical equipment and their disposal based on the required standard (specific and stringent safety rules); and

(e) Enhance regulation of unfunctional medical equipment that involves initialling disposal, examination of disposal requests and ordering disposal of unfunctional medical equipment.

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19. Medical Equipment Maintenance Programme Overview, WHO Medical Device Technical Series, 2011.

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22. https://www.thecitizen.co.tz/tanzania/news/-heads-to-roll-at-the-health-ministry-as-report-reveals-loss-of-sh27billion-in-drug-scam-3309006.

23. https://hfrs.moh.go.tz/web/index.php?r=portal%2Findex, Accessed on 6th June, 2023.

APPENDICES

Appendix 1: Responses from the Audited Entities

This part covers responses from the Audited Entities, the Ministry of Health and the Tanzania Medicines and Medical Devices Authority. The responses are divided into two parts, namely General and Specific comments, as detailed *below:*

Appendix 1(a): Responses from the Ministry of Health

General Comment

We concur with the auditor's recommendations. However, the MoH has formulated a system for monitoring medical equipment inventory and its status in the medical equipment and infrastructure management information system (MEIMIS). The improvement of integrating Laboratory Equipment Management (LEM) with a live screen image stream is still in the process. However, the use of MEIMIS is not at its respected level to cover all health facilities in the country. MEIMIS Guideline, URL address: www.hfrs.moh.go.tz

Specific Comments

SN	Recommendation	Comments from MoH	Planned Action(s)	Implementation Timeline(s)
1.	Ensure an operable and functional system for inventory and maintenance of Medical Equipment in Public Health Facilities.	Management agrees with the auditors' recommendation, however. -The MoH is currently updating the medical equipment inventory and its status in the medical equipment and infrastructure management information system (MEIMIS) done by health facilities. -MEIMIS will support all issues related to medical equipment	-Ensure that the medical equipment inventory and its status are updated in the medical equipment and infrastructure management information system (MEIMIS). -Finalize establishment of National, Zonal and Regional centres for medical equipment calibration to become operational - To train Biomedical engineer personnel on the use of MEIMIS - To Conduct medical equipment	By June 2025

SN	Recommendation	Comments from MoH	Planned Action(s)	Implementation Timeline(s)
		management, including maintenance, and provide individual functional statuses for medical equipment at the facility level. The information can be accessed and reviewed by higher levels of the Health management system. - MoH is finalizing the establishment of National, Zonal and Regional centres for medical equipment calibration, which will improve the quality of medical equipment maintenance and functionality. -MoH has conducted training on equipment maintenance and calibration for 33 biomedical Technicians and engineers	maintenance. Supportive supervision is provided at all levels of health facilities. -To ensure 5% of health facilities budgets is set for medical equipment maintenance	

SN	Recommendation	Comments from MoH	Planned Action(s)	Implementation Timeline(s)
		in the year 2023. - Regarding the maintenance program, Tanzania is in line with the WHO suggested plan: "A good completion rate goal is to be above 90%'. Currently, the National average equipment maintenance rate is at 72% from the auditing draft -Also, in collaboration with PO-RALG, the MOH ensures that at least 5% of the health facility budget is set for equipment maintenance. -Contracts for procurements of medical equipment include the provision of training and comprehensive maintenance for the period of three to		

SN	Recommendation	Comments from MoH	Planned Action(s)	Implementation Timeline(s)
		five years after the warrant period.		
2	Enhance preparation and integrate information on unfit medical equipment in health facilities, to be shared with TMDA for verification, and suggestion on of proper mode of disposal.	Management agrees with auditors' recommendation, however -The MoH is currently updating medical equipment inventory and their status in medical equipment and infrastructure management information system (MEIMIS) and in this system there is a module for to identify outdated equipment from inventory list and make a disposal indicator. The indicated equipment unfit equipment list will be extracted and shared to TMDA to plan a proper means of disposal.	Ensure MEIMIS is updated and able to produce/extract the proper list of unfit equipment from facility inventory list in Quarterly basis.	By June 2025

Appendix 1(b): Responses from the Tanzania Medicines and Medical Devices Authority

Specific Comments

S/N	Recommendation	Comments from TMDA	Planned Action (s)	Implementation timelines (s)
1	Enhance registration procedures for Medical Equipment by taking into account sample collection and timelines for each step involved;	We concur with the auditors' recommendation and shall consider timelines for each step involved in registering medical equipment. We shall also review the regulations to define the types of medical devices that require submission of samples during the marketing authorization process.	Review of Clients' Service Charter Review of Regulations for marketing authorization of medical devices	June 2025
2	TMDA ensure the presence of resources and tools for inspecting the imported Medical Equipment.	We concur with the auditors' recommendation. We have reviewed the checklist for the inspection of medical equipment at PoE.	Disseminate inspection checklist Conduct hands-on training of inspectors.	June 2024
3	Enhance its mechanism for post-market surveillance to cover medical equipment in health facilities and issue advice	We concur with the auditors' recommendation. The PMS activity and routine inspection of medical equipment to Zone offices will	Disseminate annual PMS plans and tools for routine inspection of medical equipment.	January 2024

S/N	Recommendation	Comments from TMDA	Planned Action (s)	Implementation timelines (s)
	on proper maintenance and use. This should involve planning and developing tools to effectively track key performance aspects of medical equipment.	be extended from January 2024 to cover many health facilities and equipment. We shall strengthen follow-up, including informing the relevant authorities on the proper usage and maintenance of medical equipment.	Orient inspectors on developed tools for routine inspection of medical equipment	
4	In collaboration with TAEC, LGAs and NEMC to establish a functioning system that will enable Health Facilities to report defective Medical Equipment and dispose of them following the required standard (specific and stringent safety rules)	We acknowledge the auditors' recommendation and wish to clarify that procedures for reporting and disposal of defective/unfit medical equipment are clearly outlined in the Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations, 2015 (Reg. 60 – 62) and are well known by health facilities. In addition, TMDA developed Guidelines for Handling Unfit Medical Devices and Diagnostics.	Disseminate the guidelines to health facilities through TMDA Zonal Offices. Conduct sensitization to healthcare workers and orient them to tools for reporting and disposing of defective/unfit medical equipment.	March 2024 Continuous
5.	TMDA enhance regulation of Unfit Medical Equipment that involves initialling	We acknowledge the auditors' findings; however, we would like to	Sensitize healthcare facilities on the procedures for disposal of	June 2025

S/N	Recommendation	Comments from TMDA	Planned Action (s)	Implementation timelines (s)
	disposal, examination of disposal requests and ordering disposal of unfit Medical Equipment.	clarify that TMDA has guidelines for handling medical devices and diagnostics. These guidelines provide healthcare facilities with sufficient information on how to initiate the disposal of unfit medical devices, including medical equipment.	unfit medical equipment.	

Appendix Two: Main and Sub-audit Questions

This part provides the list of five main audit questions and their respective sub-questions:

Audit Question 1	**To what extent does the available medical equipment meet the required standards?**
Sub-question 1.1:	Are there unfit medical equipment in public health facilities?
Sub-question 1.2:	To what extent is the unfit medical equipment distributed across health facilities in the country?
Audit Question 2	**Are the procedures for registration of medical equipment adequately functioning?**
Sub-question 2.1:	Does TMDA ensure the timely processing of applications for the registration of medical equipment?
Sub-question 2.2:	Does TMDA ensure the effective renewal of the medical equipment certificate of registration?
Sub-question 2.3	Does TMDA effectively collect and test samples of medical equipment applied for registration?
Sub-question 2.4	Does TMDA effectively ensure that registrants pay annual fees for the registered medical equipment in a timely manner?
Audit Question 3	**Does TMDA controls ensure that procured medical equipment by health facilities meets standards[19]?**
Sub-question 3.1:	Does TMDA effectively verify and inspect imported medical equipment before its utilization?
Sub-question 3.2:	Does the TMDA ensure that import permits are provided for all medical equipment procured by public health facilities?
Sub-question 3.3:	Does the TMDA effectively establish and maintain files demonstrating conformity to international standards and compliance with regulatory requirements for each medical device type or medical device family?
Sub-Question 3.4	Does TMDA ensure that procured medical equipment is accompanied by a user manual with detailed maintenance and troubleshooting information?
Audit Question 4	**Does the Ministry of Health ensure that public health facilities adequately maintain medical equipment?**
Sub-question 4.1:	Is there a functioning mechanism to ensure that medical equipment is adequately maintained?
Sub-question 4.2:	Does the Ministry of Health ensure that health facilities adequately maintain medical equipment per their respective operational and service manuals?
Sub-question 4.3:	Is there an effective enforcement of calibration and re-calibration of medical equipment in health facilities?
Sub-question 4.4:	Are the available resources (human resources, tools and equipment, workshop) necessary for effective maintenance of medical equipment in health facilities efficiently used?

[19] To ensure they are safe, efficacious and of acceptable quality

Audit Question 5	**Does TMDA effectively monitor the performance of medical equipment in public health facilities?**
Sub-question 5.1:	Does TMDA effectively plan regular inspections of the medical equipment in healthcare services?
Sub-question 5.2	Does the TMDA Conduct inspections to ensure that medical equipment in public Health Facilities are fit for use[20]?
Sub-question 5.3*:*	Does TMDA effectively ensure that registrants submit biennial post-market surveillance reports, including any adverse event?
Sub-question 5.4:	Does TMDA effectively communicate the results of monitoring to key stakeholders for actions?
Sub-question 5.5:	Does TMDA frequently conduct follow-ups on implementing recommendations issued to healthcare providers?
Audit Question 6	**Is the disposal of unfit Medical equipment done effectively?**
Sub-question 6.1:	Is there a functioning system to ensure that the disposal of medical equipment is effectively done per the required standards?
Sub-question 6.2:	Does TMDA *effectively* verify the medical equipment information for disposal from health facilities?
Sub-question 6.3:	Does TMDA adequately coordinate the disposal/destruction of unfit medical equipment with TAEC and LGAs?
Sub-question 6.4:	Do health facilities adequately inform TMDA of the existence of unfit medical equipment?
Audit Question 7	**Is the coordination among actors in the management of medical equipment effectively done?**
Sub-question 7.1:	Does TMDA and MoH effectively cooperate with other key stakeholders (TAEC & health facilities) responsible for medical equipment?
Sub-question 7.2*:*	Is there an effective mechanism for obtaining feedback from healthcare providers on the functioning of medical equipment?
Sub-question 7.3*:*	Does the level of coordination between TMDA and key stakeholders facilitate the effective functioning of medical equipment in the provision of healthcare services?

[20] Maintained, repaired and calibrated to ensure it is safe, efficacious and of acceptable quality

Appendix Three: List of Reviewed Documents and Reasons for Reviewing them.

This part presents the lists of documents that were reviewed and the reasons for reviewing them during the execution of the audit.

Category of the documents	Title of the documents	Reasons for reviewing
TMDA controls procured medical equipment by health facilities	• Records of procured medical equipment 2019/20-2021/22. • TMDA Inspection Records of the Procured Medical Equipment, 2019/20-2021/22 • Inspection reports of imported medical equipment for the year 2019/20 to 2022/23 • Records of import permits provided for all Medical Equipment • Files of conformity to international standards and compliance with regulatory requirements for medical device type or medical device family • User manual with detailed information on maintenance and troubleshooting of medical equipment • Records of TMDA enforced non-compliance issues with the procured medical equipment	• Gather information on whether health facilities adequately plan to procure medical equipment with their associated spare parts for maintenance. • Assess whether the records kept by TMDA on the procured medical equipment match the actual medical equipment in health facilities.
Strategies and plans from MoH and TMDA	• Health Sector Strategic Plan IV (HSSP-IV) 2015-2020 • TMDA Strategic Plan 2017/18-2021/22 • TMDA Revised Strategic Plan 2017/18-2021/22 • TMDA Strategic Plan 2021/22-2025/26 • TMDA Annual Plans, 2019/20-2022/23.	To assess: • To what extent did HSSP and the TMDA strategic Plans envisage the management of Medical Equipment • Whether the management of medical equipment is well-planned and budgeted • Whether TMDA allocate a budget for monitoring the performance of medical equipment and quality control checks of procured medical equipment
Annual plans and reports of the curative	• Annual Plan for the Curative Services Department under the	To assess whether: • The Ministry of Health monitor the quality and

Category of the documents	Title of the documents	Reasons for reviewing
services directory of the Ministry of Health	Ministry of Health for Years 2019/20-2022/23 • Annual implementation reports of the Ministry of Health Curative Services directorate (2019/20-2022/23) • Database of registered medical equipment under the MoH	maintenance of medical equipment in Health Facilities • Assess whether the allocated resources for the maintenance of medical equipment are effectively utilized.
TMDA's Performance Reports on the Management of Medical Equipment	• The TMDA annual reports (2019/20-2022/23) • TMDA Quarterly reports on management of medical equipment (of 2019/20 to 2022/23) • Database of registered medical equipment (2019/20 to 2022/23) • Biennial Surveillance Report of medical equipment of the selected Health Facilities (2019/20 to 2022/23)	• To assess whether TMDA effectively regulates the procured medical equipment and those in use in health facilities. • To assess whether TMDA adequately monitor the performance of medical equipment in health facilities
Assessment reports on medical equipment	In-Depth Assessment of the management system of medical equipment in Tanzania of the Ministry of Health and TMDA	• To assess whether TMDA ensures that recommendations issued to health facilities are implemented and the medical equipment remains within the margin of prescribed quality and officious.
Published reports on the performance of medical equipment	• Medical equipment performance Reports • Customer satisfaction reports • Vendor service contracts • Quarterly reports on the management of medical equipment from RSs and LGAs, which were submitted to TMDA's zonal offices of 2019/20 to 2022/23 • Reports of Regular Inspections of medical equipment in health facilities of 2019/20 to 2022/23	To assess whether • The medical equipment was operated in accordance with the operating standard procedures. • Customers are satisfied with the diagnostic services provided at health facilities through medical equipment. • The contracts for procured medical equipment have the vendor service clause and are enforced.

Source: Auditors' Analysis, (2023):

Appendix Four: Officials interviewed during the audit

This part provides the details of the Officials from various entities interviewed during the audit.

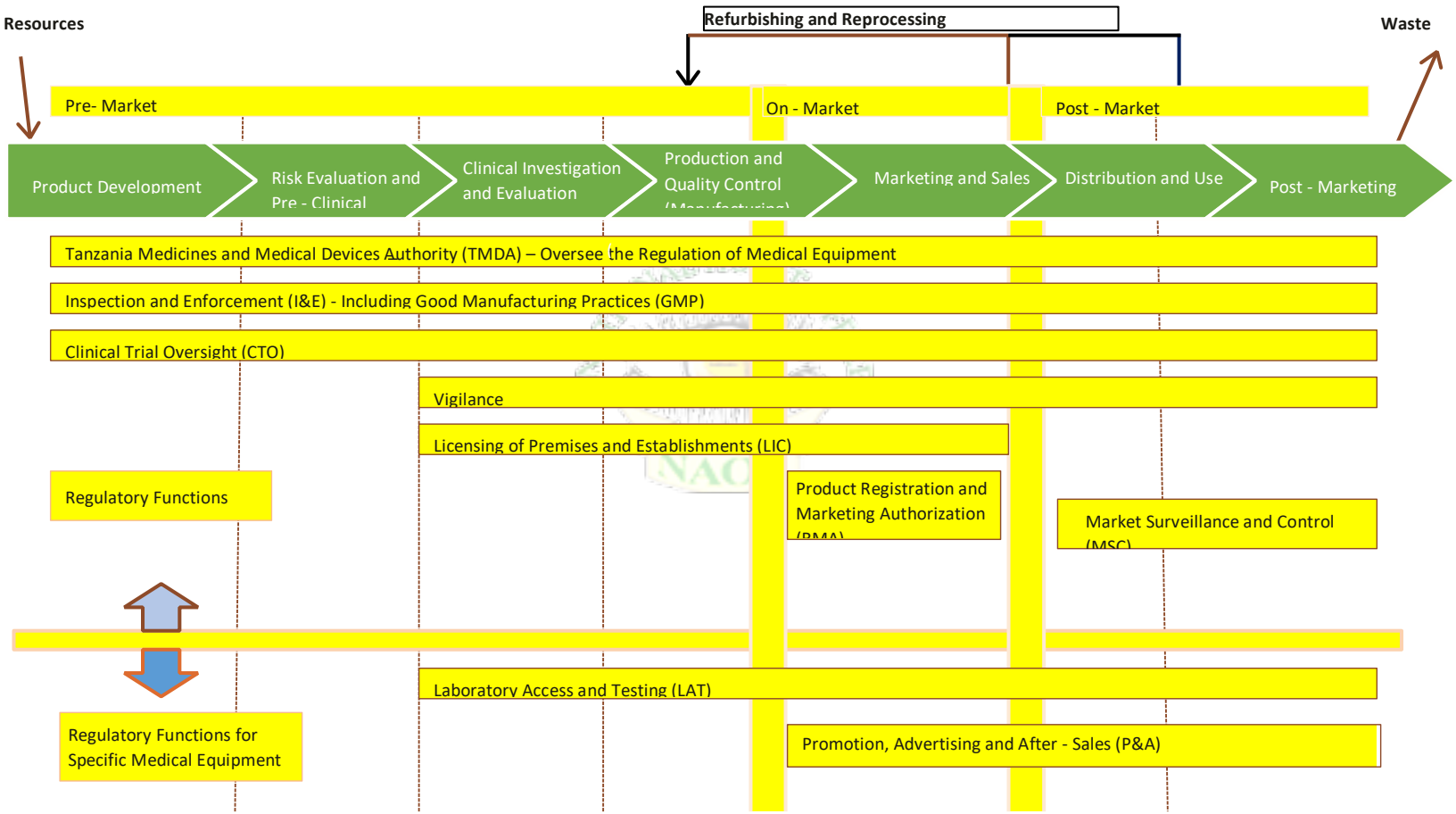
Institution Covered	Title of official Interviewed	Reasons for interviewing
Ministry of Health (MoH)	Director, Curative Services	To assess: • The performance of MoH in the formulation, review and overseeing the implementation of policies, laws, regulations, and guidelines on the management of medical equipment; and • effectiveness of coordination in the provision of diagnostic services as well as management of medical equipment
	• Assistant Director, Diagnostic and Healthcare Technical Services Section	To assess the level of: • Monitoring the quality of medical equipment, including those used for diagnostic services. • Capacity building to staff operating medical equipment such as laboratory and radiography staff
Tanzania Medicine and Medical Devices Authority (TMDA)	• Director of Medical Devices and Diagnostics Directorate at the TMDA Head Quarter offices;	To assess the: • Effectiveness of TMDA in controlling the quality of medical equipment during the importation and while in use by the health facilities • The capacity of TMDA to manage the quality of medical equipment • Coordination between TMDA and other Stakeholders such as LGAs, RSs and TAEC in

Institution Covered	Title of official Interviewed	Reasons for interviewing
		discharging its function related to the management of medical equipment in the country • Adequacy of TMDA in verifying unfit medical equipment and supervising their destruction or disposal
	• Managers of the diagnostic section, Vigilance and Post Marketing Surveillance section and Devices Licensing and Compliance Section at the TMDA Head Quarter offices;	To assess the: • The effectiveness of TMDA in ensuring the procured medical equipment meets the quality is officious and is safe for the improved human being. • Effectiveness of TMDA in conducting inspection and verification of medical equipment • Effective registration of medical equipment
	• Manager of Medical Devices and Diagnostic Control Section at Zonal Offices;	Assess Whether: • Effective regulation and management of medical equipment is done at a zonal level that includes inspections, reports on unfit medical equipment, regulating disposal of unfit medical equipment
	• Officials responsible for the management of medical devices (registration, evaluation and inspection);	To assess: • Effectiveness of TMDA in inspection and verification of the quality of medical equipment at the port of entry and those already in use
	• Manager, Medical Device Testing Section.	• To assess:

Institution Covered	Title of official Interviewed	Reasons for interviewing
		• Effectiveness of TMDA in conducting verification test medical equipment to assess the level of quality and officious.
Selected Health Facilities	• Medical Officers; • Health Secretaries; • Laboratory Technologists; • Biomedical Engineers; • Radiographers;	To assess the adequacy of: • Procedures for managing medical equipment in health facilities; • Maintenance of medical equipment in health facilities • Handling of unfit medical equipment in health facilities • Plans for procuring medical equipment and their spare parts

Source: Auditors' Analysis (2023):

Appendix Five: TMDA Regulatory Functions Based on Typical Life Span for Medical Equipment, as Suggested by WHO Regulation of Medical Devices Step-by-Step Guide, 2016



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