THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

INSPECTOR'S MANUAL FOR PREMISES DEALING WITH SELLING, DISTRIBUTION AND USE OF MEDICAL DEVICES, DIAGNOSTICS AND LABORATORY EQUIPMENT

First Edition

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Contents

LIST OF ABBREVIATIONS

ADDO	-	Accredited Drugs Dispensing Outlet
ADR	-	Adverse Drugs Reactions
CHMT	-	Council Health Management Team
CoA	-	Certificate of Analysis
CoC	-	Certificate of Conformity
DMD	-	Directorate of Medical Devices and Diagnostics
HSA	-	Health Sciences Authority
IMDRF	-	International Medical Device Regulators Forum
ISO	-	International Organization for Standards
LGAs	-	Local Government Authorities
NC	-	Non-compliant
NEMC	-	National Environmental Management Council
POE	-	Ports of entry
RAS	-	Regional Administrative Secretary
RHMT	-	Regional Health Management Team
RIMS	-	Regulatory Information Management System
TMDA	-	Tanzania Medicines and Medical Devices Authority
ToR	-	Terms of Reference

DEFINITION OF TERMS

Adverse Event

In relation to a medical device; means any debilitating, harmful, toxic or detrimental effect that the medical device has been found to have or to be likely to have on the body or health of humans when such device is used by or administered to humans;

An Inspector

Means; any officer appointed, authorized and recognized as such under section 105 of the Tanzania Medicines and Medical Device Act, Cap 219. To attain full authority all appointed Inspectors must be published in the Government Gazette

Compliance

The act of fulfilling and conforming to official requirements.

Device Inspection

Based on the definition of inspection, is an act of examining or looking closely at all the attributes of medical devices, diagnostics and laboratory equipment including the official review of documents, records and general conditions of all premises which deal with storage, selling, distribution and using of the same in order to ensure their conformity with requirements.

Disposal

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";

Import Permit

Means a permit issued to importer by the Authority, authorizing him to import medical devices into the country

Inspect

Means; to look closely at something, especially to check that everything is in good order." "Inspection" is, therefore, the act of looking closely at something to ensure that it meets certain prescribed or known standards, specifications and/or requirements

Laboratory Equipment

Are tools and equipment used by scientists to perform experiment and take measurement or tests in the laboratory.

Label

Means any written, printed or graphic representation that appears on or is attached to the medical device or any part of its packaging, and includes any informational sheet or leaflet that accompanies the medical device when it is being supplied;

Medical Device or Devices

Refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, In Vitro Diagnostic (IVD's), or other similar or related article, including any component, part or accessory which is –

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

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

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

Permit

Means certificate of approval to import and export medical devices.

Premises

Means a location that is used for activities dealing with medical devices, including sale, storage and manufacture;

Registered Premises

Premises dealing in selling, distribution, storage and use of medical devices, diagnostics and laboratory equipment shall be inspected by checking for

Recall

In relation to a medical device, means any action taken by its manufacturer, importer, supplier or registrant to remove the medical device from the market or to

retrieve the medical device from any person to whom it has been supplied, because the medical device may: -

(a) be hazardous to health;

(b) fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or performance; or

(c) not meet the requirements under regulation 65;

Unfit Medical Devices

Means medical device that are expired, improperly sealed, damaged, improperly stored, improperly labelled, counterfeit, substandard and prohibited or unauthorized;

ACKNOWLEDGEMENTS

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Dr. Kissa W. Mwamwitwa
Director, Medical Devices and Diagnostics Control

FOREWORD

Inspection is an essential regulatory function in controlling quality, safety and effectiveness of regulated products. It is the responsibility of TMDA to ensure that all dealers of Medical Devices and Diagnostics comply with the laid down legal and regulatory standards and requirements in order to protect public health. In view of this, TMDA inspects premises dealing with all activities involved in research, development, manufacture, distribution and supply of medical devices, diagnostics, laboratory equipment and like products.

Qualified and experienced Medical Devices and Diagnostics Inspectors constitute an indispensable component of an effective inspection system. Medical Devices and Diagnostics Inspectors serve as the eyes and ears of the Medical Devices and Diagnostics regulatory body and are on the front line in maintaining the quality, safety, and performance of the products manufactured and marketed in any country. In this respect, TMDA Medical Devices and Diagnostics Inspectors have an important role in protecting consumers of products regulated by TMDA. Succinctly, the inspector's job is law enforcement.

The Authority has crafted this very first edition of inspection manual to provide guidance on how to conduct inspection of medical devices, diagnostics and laboratory equipment. The inspectors shall take immediate action to control and manage any risk which may arise from contravention of the act pending any further action as may be found suitable by the Authority.

Inspectors should perform their duties according to what has been delineated in the inspection manual together with other tools. The Manual is intended to serve as a quick reference for Medical Devices and Diagnostics Inspectors when discharging their inspection duties and responsibilities.

Dr. Adam M. Fimbo
DIRECTOR GENERAL

INTRODUCTION

This inspection manual has been developed to elaborate procedures for regulated products to be inspected as per Tanzania Medicines and Medical Devices Act, Cap.219 namely medical devices, diagnostics and laboratory equipment.

The manual is aimed at providing guidance to Medical Devices and Diagnostics inspectors when preparing and performing inspection of premises dealing with selling, distribution and using of medical devices, diagnostics and laboratory equipment. It also serves as a reference document for inspectors prior and during inspection so that inspection activities are consistently done and thus avoiding bias and double standards. Consistency in conducting inspection activities is very important in ensuring quality assurance of medical devices, diagnostics and laboratory equipment.

In order to achieve that goal, inspectors need to be provided with this manual which contain sufficient working tools needed for observing, checking, investigating and reaching conclusions in a particular inspection.

It is also expected that; the manual shall help inspectors to conduct inspection with integrity and diligence. The code of ethics and conduct and the responsibilities of inspectors have also been outlined with the objective to remind them on their ethical and moral obligations when engaged in inspection activities.

The manual is applicable for all types of inspections for medical devices, diagnostics and laboratory equipment with the exception of quality audit.

The document is divided into six (6) chapters which provide information in regard to: -

a) Introduction to Inspection
b) Medical devices and diagnostics inspector, Qualification of an Inspector and Powers of Inspector
c) Inspection Process
d) Inspection Techniques
e) Handling of Unfit Medical Devices, Diagnostics and Laboratory Equipment
f) Compliance and Enforcement Activities

Inspectors are urged to read carefully and use this manual accordingly together with Tanzania Medicines and Medical Devices Act, Cap.219 and Regulations made there under

1.0 INSPECTION FRAMEWORK

1.1 Meaning of Medical Device Inspection

Device inspection; based on the definition of inspection, is an act of examining or looking closely at all the attributes of medical devices, diagnostics and laboratory equipment including the official review of documents, records and general conditions of all premises which deal with storage, selling, distribution and using of the same in order to ensure their conformity with requirements.

1.2 Purpose for Inspection of Medical devices, Diagnostics and Laboratory Equipment

Device inspection is conducted for two major reasons:

a) to ensure that medical devices and diagnostics either domestically manufactured or imported meet the set standards of safety, quality and performance in all its life cycle in order to protect public health;

b) adherence to laws and regulations governing distribution, importation, exportation, storage, use and promotion of medical devices, diagnostics and laboratory equipment

1.3 Areas of Inspection

In order to ensure that medical devices, diagnostics and laboratory equipment entering or circulating in the Tanzanian market are of acceptable quality, safety and performance, the following areas should be inspected:

a) Ports of entry (POEs)

b) Distribution points (outlets) i.e., importers, retail and wholesale, ADDO shops, healthcare facilities including hospitals, health laboratories, warehouses, vehicles and any other establishment or premises where medical devices, diagnostics and laboratory equipment may be found.

c) Promotional adverts

1.4 Types of inspection

There are five types of inspections: -

a) Routine inspection
b) Concise inspection
c) Follow-up inspection
d) Special or investigative inspection
e) Audit inspection

1.4.1 Routine inspection

Routine inspection entails full review of all aspects and components within a facility. They are generally intended for: -

- a new establishment
- an establishment that has applied for a permit to extend its scope of operations or made important changes in its key personnel or changed to new premises
- an establishment that has not been inspected for a long time
- an establishment with consistent records of non-compliance.

This inspection should be announced except when it has not been conducted for a long time, an unannounced inspection would be the norm.

1.4.2 Concise Inspection

Concise inspection is the evaluation of limited aspects relating to compliance of a premises. A limited number of requirements are selected by the inspector to serve as indicators of the overall compliance of a facility. The inspector also has to identify and evaluate any significant changes that could have been introduced by the premises since the last inspection.

Collectively, the selected indicators and the changes identified indicate the premise's attitude towards compliance to requirements. A concise inspection is conducted under the following circumstances: -

- Where the premises have consistent records of compliance with routine inspections in the past.

- Where a sample of aspects can be taken as a good indication of the overall level of compliance with requirements.

However, if the concise inspection uncovers evidence that the level of compliance has fallen, a more comprehensive or full inspection should be performed soon after the concise inspection. These inspections can be announced or unannounced.

1.4.3 Follow-up Inspection

A follow up inspection is also referred to as a re-inspection or a re-assessment of premises. It is carried out to ensure that corrective measures have been undertaken following advice and notice given during a previous inspection.

Depending on the nature of defects and the work required, the duration for follow-up inspection shall be as per previous inspection recommendations. Where a time limit was given to rectify the anomalies, the inspection should be unannounced.

1.4.4 Special or Investigative Inspection

A special inspection is undertaken to do spot checks which could focus on one product, a group of related products, or specific operations e.g. false labelling. This inspection should be unannounced. It is conducted under the following circumstances: -

- When there are complaints about a specific product
- To gather specific information, or to investigate specific operations of a facility.

1.4.5 Audit Inspection

Audit inspections are carried out to guide, support and assist audited part in carrying out inspection activities. The aim of audit inspection is to determine effectiveness, correctness and efficiency of the inspection activities and it covers all areas that inspection activities are carried out. Audit inspection helps to:-

- Ensure uniformity in conducting inspections
- Enhance compliance with legal requirements
- Assist Inspectors in improving their performance
- Identify problems and institute timely interventions
- Maintain and reinforce the administrative and technical links between higher and lower levels
- Make follow up of implementation of previous audit inspection recommendations
- Identify resource needs for inspection activities.

As a minimum requirement, audit inspection shall be conducted annually and is usually announced.

1.4.6 Inspection and Reporting Levels

There are four recognized levels of inspection of medical devices, diagnostics and laboratory equipment: -

a) Inspection at Zonal level
b) Inspection at Headquarter level

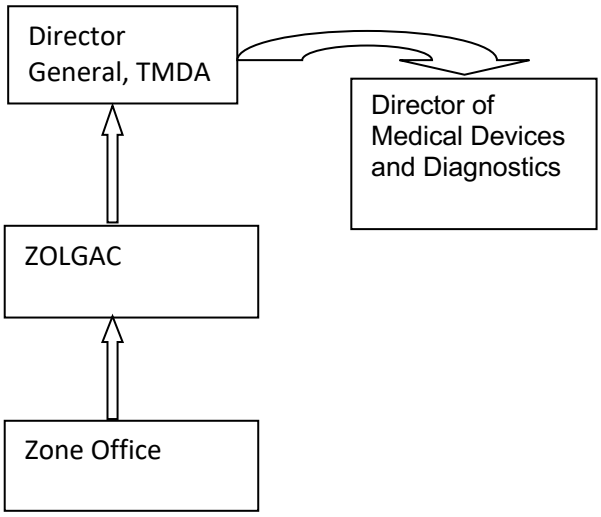
1.4.7 Inspection at Zonal Level

These inspections are conducted by TMDA Zonal Offices to cover all regions within respective TMDA zone. Inspections are conducted in collaboration with councils and regional teams. They include routine inspections, concise inspections, follow-up inspections, special or investigative inspections and audit inspections where applicable. Audit inspections are conducted to determine effectiveness, correctness and efficiency of the inspection performed at council and/or region level.

1.4.8 Headquarters' Inspections

These are normally inspections organized at headquarters level and conducted jointly with all TMDA zone offices and other stakeholders at least once a year or more. They are intended to cover large part of the country and specifically aimed to target expired, substandard, falsified, prohibited, restricted, withdrawn or any other illegal product on the market.

Figure 1: Illustrates medical devices, diagnostics and laboratory equipment inspection structure and chain of command/ reporting level



2.0 MEDICAL DEVICES AND DIAGNOSTICS INSPECTOR

This chapter describes an Inspector, appointment and powers of Inspectors, qualities of Inspector and procedure to be followed by an Inspector once he/she is transferred or ceased to be an Inspector.

2.1 Who is an Inspector?

An inspector is any officer appointed, authorized and recognized as such under section 105 of the Tanzania Medicines and Medical Device Act, Cap 219. To attain full authority all appointed Inspectors must be published in the Government Gazette.

2.2 Qualification of an Inspector

An inspector should have the necessary qualifications in order to effectively take part in inspection activities. The qualifications of the Inspector shall be based on the following: -

a) Academic qualification
b) Training
c) Experience

2.3 Academic education

Inspectors of medical devices, diagnostics and laboratory equipment should have at least a minimum of diploma or degree in pharmacy, medicine, dentistry, veterinary medicine, laboratory technology, biology, biomedical Sciences, radiology or related fields from recognized institution.

Where persons other than the above-mentioned professions are employed as Inspectors, they should be adequately experienced in medical devices, diagnostics and laboratory equipment control affairs and suitably trained on inspection activities.

2.3.1 Training

In order to be competent to carry out inspections, inspectors will be required to undergo training in inspection activities. Such training would provide them with knowledge and skills needed when planning for, carrying out and reporting inspections.

Apart from basic training, inspectors will also be required to undergo on the-job training conducted by senior Inspectors. Such training should involve both theory and practical that cover inspection techniques, communication and management skills as well as conducting inspections and report writing as trainees.

Continuous training should be provided to inspectors to keep them abreast with the current knowledge and techniques in carrying out inspections. This would be through

attending training programmes, seminars, scientific meetings, conferences and exhibitions organized either by the Authority or other recognised institution.

2.3.2 Experience

Experience as a general concept comprises knowledge or skills to participate in some activities or events, or knowledge or skills gained through involvement in or exposure to those activities or events.

The inspector shall be deemed experienced when he/she has worked for a minimum of three (3) years continuously in inspection activities and demonstrate competence in that area.

2.4 Appointment of Inspector

The Director General shall appoint inspectors from TMDA and Local Government Authorities (LGAs) based on qualification and training. Upon appointment Inspectors will be provided with identity cards and their names will be published in the official Government Gazette.

Identity cards of inspectors from LGAs will be valid only in their specific duty stations and not transferable. An inspector who has changed duty station would be given a new identity card after returning back the previous one to Director General. Any person who is no longer an inspector shall be required to hand over the identity card to the former employer immediately upon cessation of employment.

2.5 Powers of Inspectors

The appointed Inspectors shall have the following powers:

2.5.1 At all reasonable times enter:

i. Any set of premises which is on the register of premises
ii. Any premises in which any person whose name is entered in any register under TMDA Act, carries on any business.
iii. Any premises in respect of which any person is licensed under TMDA Act.

2.5.2 At any time enter any premises, stall, vehicle, vessel or conveyance or any premises suspected to be dealing with products regulated under this act for the purpose of ensuring compliance.

2.5.3 Examine or inspect any certificate of registration, license, book, electronic information storage system or other documents in the premises and for that purpose, he may do such other things including the taking of extracts from documents in the possession of the person as may be necessary to effectual the examination or inspection.

2.5.4 Seize and retain any regulated products or articles consisting of, or containing any medical devices or diagnostics which he/she has reasonable cause to suspect it is liable to forfeiture under TMDA Act.

2.5.5 Close the premises found to contravene the law and institute criminal proceedings.

2.5.6 Order the return to the country of origin of any product regulated under TMDA Act imported into the country in contravention of the provisions of the Act.

2.6 Qualities of Inspectors

The Inspector should at least possess the following qualities: -

a) Good knowledge of medical device, diagnostics and laboratory equipment.
b) Good knowledge of the laws and regulations to be enforced
c) Good command of technical terms and excellent communication skills
d) Awareness of the probable methods of using forged or false documents for transactions and skill in determining the genuineness of documents presented for examination
e) Exercise honesty and integrity
f) Responsible conduct which commands respect
g) Willingness to accept challenges
h) Ability to organize their own work with minimum supervision
i) Ability to assess character and honesty
j) Good public relations image with key personnel or in charge of premises while remaining firm, fair and resolute
k) Ability to hold discussion with administration at completion of inspection.

3.0 INSPECTION PROCESS

3.1 Components of Inspection Process

Inspections comprise of a series of events that proceed in the same order with all inspectors. The process starts with planning and scheduling an inspection as indicated in the process flow, figure 2.

During planning an inspector should have a register of all premises dealing in medical devices, diagnostics and laboratory equipment, access of the database of all registered premises which includes their record of compliance together with previous inspection reports.

Planning will also include budgeting, ToR, tools, schedule, transport and personnel. An inspection plan shall be developed to allow frequency and scope of inspections to be determined using a formalized risk-based approach.

3.1.1 Notifying and Scheduling an Inspection

Inspector shall schedule an inspection based on the identified premises to inspect then contact the inspectee. The inspector may choose to show up unannounced at any premise if it will result to a clear picture and benefit the inspection activity.

3.1.2 Opening Inspection

The inspector shall meet with the inspectee and convey the following: -

a) introduce themselves;
b) describe the objectives of the inspection;
c) outline the scope of the inspection;
d) get an understanding of the nature of activities of the premise or establishment;
e) ask for cooperation.

3.1.3 During Inspection

Inspector shall conduct inspection as per section 4.1, inspection techniques. The inspector may also interview staff in areas of the premises where necessary.

3.1.4 Gathering and Assessing Data.

The inspector shall assess compliance based on the interviews, tour and review of documented records. The inspector will also collect and review sample medical device, diagnostics and laboratory equipment. The review will take into account of the classification of devices (i.e. Class A, B, C or D).

All data obtained through inspection is considered as ‘objective evidence’ of the inspection activity.

When looking the evidence, the inspector shall note a deviation, deficiency or failure to comply with the regulations as an observation. Throughout the inspection the inspector shall inform the inspectee on observed deviations, deficiencies and/or failures.

3.1.5 Closing Inspection

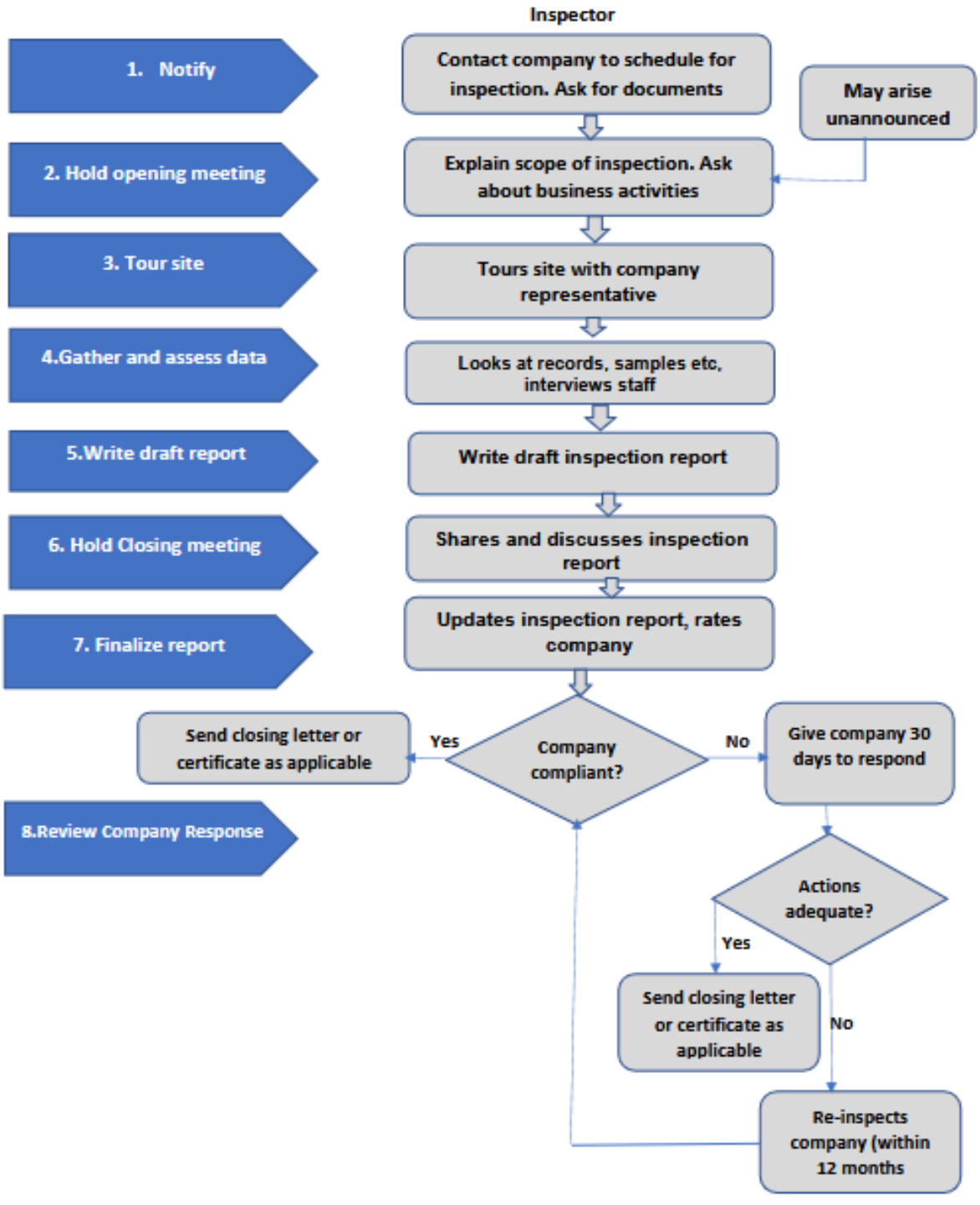
The inspector shall fill the observation form and checklist together with seizure/confiscation form and/or sample collection form where necessary and do the following: -

a) Leave a copy of signed observation form, seizure/confiscation form and/or sample collection to the inspectee.
b) Verify that inspectee understand the observations
c) Inform the inspectee of which records and documents are needed to meet the regulations.

3.1.6 Inspection Report

Inspection report should be written and submitted to supervisors together with imprest retirement not more than fourteen (14) days after inspection activities.

Figure 2: Illustrates medical devices, diagnostics and laboratory equipment Inspection process flow



4.0 INSPECTION POINTS AND TECHNIQUES

4.1 Inspection at the Ports of Entry (POEs)

Inspection of imported medical devices, diagnostic and laboratory equipment shall be done by checking:

a) Correctness and relevance of Importation documents to the respective consignment (Invoice, TMDA importation permits, airway bills, TANSAD)

b) Certificate of Analysis (COA) and/or Certificate of Conformity (COC) where applicable.

c) Presence of instruction for use and/or device manual

d) Physical inspection of the device in relation to submitted device details/descriptions

In case of large medical devices and radiation emitting devices, the inspector shall recommend follow-up inspection of the said devices at the point of installation/use.

4.2 Inspection of Premises

4.2.1 New Premises Inspection

Inspection of new premises is to be conducted as per inspection checklist for medical devices TMDA/DMD/MDC/C/002 where key points shall be noted down in the observation form TMDA/DMC/F/003.

4.2.2 Registered Premises

Premises dealing in selling, distribution, storage and use of medical devices, diagnostics and laboratory equipment shall be inspected by checking for:

a. Presence and validity of the Licence of the premises

b. General condition of the premises. (size of the premises and partitioning, cooling system, temperature and humidity conditions, cleanliness, confined areas for unfit devices, single entrance, strong and well secured doors and windows, ceiling board, lightening, external environment, durable and smooth floor,)

c. Presence of a responsible and certified technical personnel based on the risk nature/class of the devices dealt with in the respective premises

4.3 Inspection of Products

Inspection of Medical devices, diagnostics and laboratory equipment shall be conducted considering the risk class of devices by checking;

4.3.1 Physical Appearance:

Comparison between description of the device details versus the actual sample. Check for package integrity, damages, leakages etc.

4.3.2 Compliance to Labelling Requirement:

Presence of device manual and instruction for use, language used, storage instructions versus actual sample storage and device's specific ISO standard requirements. Labelling requirements include: -

a) Product name and product identification number (product code/catalogue number),
b) Name of manufacturing site and physical address,
c) Manufacturing and expiry dates where applicable.
d) Storage condition
e) Warning and precautions
f) Lot/batch and/or serial number,
g) The words "Sterile" if the manufacturer intends to sell the device in a sterile condition,
h) Statement "For Single Use Only" for single use devices,
i) "For In vitro diagnostics use" if it is for in vitro diagnosis.
j) Where a component is too small to contain all the above information, it must at a minimum contain Name, lot number, expiration date, volume, and storage conditions.

NB: Most of the details in the label are represented by symbols.

4.3.3 Legality of Possession:

a) Check for documentation related to importation, purchasing, distribution and use of the device where applicable. In case of donated devices check for presence of donation certificates or letter or issue voucher.

b) Identification of unauthorized devices: Check labels for presence of the words such as MSD, GOT, NOT FOR SALE, Manufactured for Government/Ministry of Health or other countries.

4.3.4 Packaging Material:

Check for suitability and integrity of the packaging material.

4.3.5 Registration Status of the Product

Verify the registration status of the device by:

a) Checking for registration number on the device package where applicable or registration certificate of the product/ device,

b) Using Adverse events/Incidence Reporting tool,

c) Using Spreadsheet in RIMS,

d) Using TMDA website,

e) Contact registration and importation sections for verification of issued registration certificates and import permits.

During inspection, the inspector shall verify if the product(s) is registered or notified.

4.3.6 Inspection of Large Medical Equipment

When inspecting large medical equipment, the following parameters should be evaluated to ensure safety, performance, and compliance to regulatory requirements and also to ensure that the equipment operates efficiently, safely, and reliably, reducing risks to both patients and operators:

a) Operational Performance

i. Verify the equipment is functioning as intended.

ii. Assess the accuracy and reliability of its output (e.g., imaging quality for MRI or CT machines).

iii. Check for any unusual noises, vibrations, or delays during operation.

b) Safety Features

i. Inspect emergency stop buttons and other safety buttons.

ii. Ensure safety guards and covers are intact.

iii. Verify radiation shielding (for X-ray and other radiological devices).

c) Calibration and Accuracy

i. Confirm the equipment is properly calibrated for accurate diagnostics.

ii. Review calibration logs and certificates to ensure compliance with standards.

d) Mechanical and Structural Integrity

i. Look for visible wear, corrosion, or damage to components.

ii. Test the stability of the structure (e.g., support arms or gantries).

iii. Check all moving parts, hinges, and locks.

e) Electrical Systems

i. Inspect wiring for damage, fraying, or loose connections.

ii. Test power supply, including battery backup (if applicable).

iii. Verify that grounding and insulation meet safety standards.

f) Software and User Interface

i. Check the software version and ensure it is up-to-date.

ii. Test the responsiveness and functionality of the user interface.

iii. Verify data storage, retrieval, and network connectivity.

g) Hygiene and Sterilization

i. Ensure surfaces are easy to clean and free of contaminants.

ii. Inspect sterilization components (e.g., autoclaves or disinfecting units).

h) Regulatory Compliance

i. Verify the equipment meets local and international medical equipment standards (e.g., ISO, FDA, CE if applicable).

ii. Check for any recalls or safety advisories related to the device.

iii. Check for notification/registration status of the equipment (if applicable)

i) Maintenance Records

i. Review past maintenance and service logs.

ii. Check if regular preventive maintenance schedules are followed.

j) Environmental Compatibility

i. Verify proper environmental controls (e.g., temperature, humidity, ventilation).

ii. Assess noise levels and electromagnetic interference in the operating area.

k) Operator Training and Documentation

i. Ensure user manuals, guidelines, and protocols are accessible and updated.

ii. Verify that operators have been properly trained to use the equipment safely.

iii. Verify warrant documents validity if available

iv. Verify importation documents (import permit, CoC, ISO 13485:2016 certificate)

l) Accessories and Consumables

i. Inspect any accessories (e.g., probes, cables, or attachments) for wear or damage.

ii. Verify availability and compatibility of consumables (e.g., filters or reagents).

NB: Conduct inspection of large medical equipment as per checklist number ***TMDA/DMD/MDL/C/011***

5.0 HANDLING OF UNFIT MEDICAL DEVICES

5.1 Handling of Unfit Medical Devices, Diagnostics and Laboratory Equipment

In the course of inspection, an inspector may encounter unfit medical devices which may include:

5.1.1 Substandard Medical Devices

The inspector has to establish the quantity found to decide on whether to confiscate if the quantity is small and instruct the inspectee to pay disposal fee or take samples for further investigation where applicable. In the event the samples are taken, the inspector shall seize the remaining stock pending investigation.

If the consignment is big, the inspector shall seize and issue further instructions to the inspectee.

5.1.2 Falsified Medical Devices

In case of confirmed falsified devices, the inspector shall call upon a neutral witness who shall serve the purpose once the matter is taken for filing a case and court proceedings.

Incase no court proceedings is pursued, the inspector shall institute penalty as per the Tanzania Medicines and Medical Devices Fees and Charges Regulations, 2021 part III Regulation 11 and 12.

5.1.3 Expired Devices Found on Shelves

In case of small quantity, the inspector shall confiscate the consignment and institute penalty as per the Tanzania Medicines and Medical Devices Fees and Charges Regulations, 2021 part III Regulation 11 and 12. If the consignment is big, the inspector shall seize and direct the inspectee to list the expired product and establish the value which will be used to impose penalty applicable as per fees and charges Regulation in force. The inspectee will then be instructed to carry out disposal within 14 days.

5.1.4 Unregistered/Unnotified Devices

The inspector shall establish source of unregistered product. In case of lack of purchase documents, the inspectee shall be required to submit in writing the source of the product. The inspector shall confiscate the products and institute penalty as per the Tanzania Medicines and Medical Devices Fees and Charges Regulations, 2021 part III Regulation 11 and 12.

5.1.5 Disposal of unfit medical devices

Disposal of unfit medical devices shall be done in accordance with the Guideline for Handling of unfit medical devices first edition June 2023.

In ensuring that no person shall sell or supply or offer or expose for sale or supply or have in his possession for the purpose of sale or supply unfit products, Inspectors shall perform verification of products requested for disposal as per procedure for Handling of unfit Products.

The inspector shall supervise disposal exercise in the presence of other government Institutions like NEMC, Health Officer, owner/representative, Police officer. Disposal will be carried out as per approved method and site.

After completion of verification and disposal, the inspector is expected to enter details on RIMS in order to prepare Certificate of destruction.

5.2 Recalls, Reject and Withdrawal

In case of initiated recall, the inspector is expected to conduct follow up inspection to obtain the distribution list of the device to be recalled in order to establish the quantity imported, names and addresses of premises where the devices were distributed, batch numbers/lot numbers involved. The role of the inspector is mainly to verify the effectiveness of recall and that the inspectee submits periodic reports to DMD on the progress of the recall.

The inspector shall ensure that the disposal of recalled/rejected/withdrawn products from the market shall be effected within one month after completion of exercise.

6.0 COMPLIANCE AND ENFORCEMENT

6.1 Compliance and Enforcement Activities

During the course of inspection, the inspector shall determine the level of compliance of any premises or regulated product. The possible inspection ratings are compliant (C) and non-compliant (NC).

Compliant (C) – At the time of the inspection, the regulated party has demonstrated that the activities it conducts and devices are in compliance with the Act and its associated regulations. A compliance (C) rating does not mean that there are no observations or corrective actions required.

Non-compliant (NC) – At the time of the inspection, the regulated party has not demonstrated that the activities it conducts and devices are in compliance with the act and its associated regulations.

In the case of non-compliance, the inspector shall undertake/recommend appropriate enforcement actions.

Enforcement actions include any regulatory actions the Authority takes to compel or induce compliance in order to mitigate the risk identified by non-compliance with the Act. Hence TMDA takes enforcement actions to:

i. Bring a regulated party, product, activity or process into compliance with the Act;
ii. Prevent future non-compliance; and
iii. To address detected public health risks.

In exercising their powers for ensuring compliance with the Act and for proper administration of inspections; inspectors shall take immediate actions on the following scenarios which contravene the Act or regulations made therein Table 1.

Table 1: Examples of violations and their enforcement measures

S/N	Violations	Enforcement measures
1.	Premise operating business regulated under the Act, without registration certificate or license contrary to section 18 and 20 of the Act.	Remedial order be implemented within 14 working days, if not implemented close the premise
2.	Regulated products in the market containing or consisting of any poison or any other thing which constitute or contain evidence of breach of any provision of the Act	Seizure/detention of those products as per section 106 (1) d & e of the Act and issue a warning letter.
3.	Repeated trend of a product quality failure for three batches or more of the same manufacturer within a period of six months.	Seizure/detention of those products as per section 106 (1) d & e of the Act and advise suspension or revocation of product registration license
4.	Imported product regulated under the Act contravenes any provision of the Act	Detain and order disposal or return of such product(s) to the country of origin as per section 106 (1) g.
5.	Imported product at the wrong PoE as per authorized permit	Detain and order submission of import permit with appropriate PoE as per section 106 (1) g.
6.	Missing of supporting and correct importation documents relevant to the imported consignment	Detain and order application of importation permit and supportive document relevant to the imported consignment
7.	Falsification of importation documents	Detain and institute legal proceedings
8.	Premises operating without a technical personnel	First time inspection Issue directives to recruit technical personnel within 14 days. Follow-up inspection close the premise.
9.	Falsified Professional credentials e.g. ADDOs certificate etc.	Liaise with respective professional bodies and/or councils
10.	Registered and licensed premises by other Authorities with regulated products found with expired license	Order renewal of license within 14 working days. If not implemented, liaise with the respective Authority

S/N	Violations	Enforcement measures
11.	Registered premises not conforming to the requirement of that business e.g. regulated products stored under improper conditions	Order remedial actions within 14 working days
12.	Lack of proper documentation and no record-keeping	Remedial order be implemented within 14 working days.
13.	Found in possession of falsified/misbranded products	Seize the products and institute criminal proceedings in a competent court
14.	Illegally imported products or found in possession of unregistered products or sale of unauthorized products in a registered premise	Seize the product, order disposal at owner's cost and issue a warning letter
15.	Sale of expired products	Order stop sell, confiscate products for destruction at owner's cost (25% of the total value of the product(s)) and where necessary issue a warning letter
16.	Found in possession of products belonging to Government	Seize the products and institute criminal proceedings in a court of law
17.	Promotion and advertisement without TMDA authorization	Issue warning letter and stop promotion/advertisement order

Notwithstanding measures instituted by the authority or inspectors the authority shall be at liberty to institute any criminal proceedings before a competent court of Law.

6.2 Appeals

In the interest of transparency and fairness, Inspectors' decision maybe disputed by regulated parties through an appeal process.