FOREWORD ........................................................................ iii
ACKNOWLEDGEMENT ................................................................. iv
SECTION ONE ........................................................................ 1
INTRODUCTION ....................................................................... 1
1.1 Objectives of the Guideline .............................................................. 1
1.2 Scope of the Guideline ................................................................... 1
SECTION TWO .................................................................... 2
TERMS AND DEFINITIONS .......................................................... 2
Audit ....................................................................................... 2
Audit Criteria .......................................................................... 2
Audit Inspection ...................................................................... 2
Audit Inspectors ..................................................................... 2
Audit team ............................................................................... 2
Inspection ............................................................................... 2
Investigative Inspection .............................................................. 2
Follow-Up Inspection ................................................................ 2
Routine Inspection .................................................................. 3
Special Inspection ................................................................... 3
SECTION THREE ................................................................. 4
AUDIT INSPECTION ................................................................ 4
3.0 What is Audit Inspection? .............................................................. 4
3.1 Objectives of Audit Inspection ......................................................... 4
  3.1.1 General objective .................................................................... 4
  3.1.2 Specific objectives .................................................................. 4
  3.1.3 Scope of Audit Inspection ........................................................... 4
3.2 Type of Inspections to be audited ..................................................... 5
3.3 Qualities of Audit Inspectors ........................................................... 5
3.4 Levels of Audit Inspection ............................................................... 5
3.5 Major areas to be audited ................................................................. 5
  3.5.1 Inspection reporting ................................................................. 5
  3.5.2 Documentation ........................................................................ 6
  3.5.3 Sampling of Inspection recently carried out ................................ 6
  3.5.4 Follow up of corrective actions previously recommended ........ 6
  3.5.5 Follow up of rectification orders agreed previously .................. 6
  3.5.6 Operational plans and budgets ................................................... 6
  3.5.7 Monitoring and evaluation ......................................................... 7
  3.5.8 Collection of Fees and charges ................................................... 7
  3.5.9 Implementation of Special programme ...................................... 7
  3.5.10 Adverse health effects of regulated products .......................... 7
  3.5.11 Human resource problems ......................................................... 7
  3.5.12 Complaint handling ................................................................. 7
  3.5.13 Working Infrastructures ........................................................... 7
SECTION FOUR ................................................................. 8
ACTUAL AUDIT INSPECTION ................................................... 8
  4.0 Conducting of Audit Inspection ...................................................... 8
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECTION FIVE</td>
<td>10</td>
</tr>
<tr>
<td>AUDIT INSPECTION REPORT</td>
<td>10</td>
</tr>
<tr>
<td>5.0 Contents of the Audit inspection report</td>
<td>10</td>
</tr>
<tr>
<td>References</td>
<td>12</td>
</tr>
</tbody>
</table>
FOREWORD

These guidelines have been developed to give general guidance to inspectors and auditors on how audit inspection shall be conducted at all levels. On the other hand, they give the auditee a perceptive of what is to be audited by the auditor. In this case the auditee will use the guidelines as a yardstick to maintain the required level of compliance to performance.

The guidelines are coming up at a time when the TFDA is delegating some of its functions to Local Government Authorities. Using the guidelines, TFDA will audit inspections activities delegated to the Local Authorities. However, in general terms these guidelines maybe applied by any level to audit inspection activities conducted by lower level. Therefore, the guidelines provide procedures, terms of references and general guidance on how the upper level (Auditor) will plan and conduct audit inspection at the lower level (Auditee) in order to verify compliance to set standards and specifications.

Since TFDA strives to offer quality regulatory services to its customers, it is expected that the guidelines will be effectively and efficiently implemented so as to achieve a desired goal of protecting and promoting public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices. Application of the document will provide an opportunity for users to identify weaknesses, challenges and inspection non-conformances that need corrective measures for continuous improvement of the control system. It is my expectation that audit inspectors will fully utilize these guidelines for the purpose of ensuring quality inspection services and enhancing adequate protection of consumers’ health.

M. Ndomondo-Singonda
Director General
Tanzania Food and Drugs Authority
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Preparation of these guidelines would not have been possible without the contribution of key people who worked tirelessly in drafting, reviewing and refining them through its development stages. We would like to thank the management of TFDA for guiding and participating actively in the whole process of development of these guidelines. Special thanks go to the staff of TFDA and in particular Mr. Raymond Wigenge, Dr. Judicate Ndengerio-Ndossi, Mr. Didas K. Mutabingwa, Mr. Justin D. Makisi, Mr. Adonis Bitegeko, Mr. John Emmanuel and Mr. Florent Kyombo for drafting, reviewing and refining these guidelines.

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Dr. S. S. Ngendabanka
Director of Business Support
Tanzania Food and Drugs Authority
SECTION ONE

INTRODUCTION

1.0 An Overview

Tanzania Food and Drugs Authority (TFDA) is empowered under section (5) of the Tanzania Food, Drugs and Cosmetics Act, 2003 to regulate all matters relating to quality and safety of food, drugs, cosmetics and medical devices. Over a period of time there has been a need to develop audit inspection guidelines in order to differentiate between audit inspection and other types of inspections.

These guidelines are intended to give general guidance to audit inspectors on how to conduct audit inspection in a consistent manner. Similarly the outcome of audit inspection shall be used as a yardstick to measure performance of compliance and enforcement level.

Audit inspection is a management function planned and carried out in order to guide, support and assist audited part in carrying the assigned tasks. It involves on job transfer of knowledge and skills between the auditor and the one being audited through opening of administrative and technical communication channel at all levels (National, Regional, District and Ward).

During these inspection audit inspectors shall give emphasis on how inspections are actually operated and compare this to the inspection operations as describe in the law, work instructions, procedures, inspection guidelines and manuals, checklists, standards or any other quality documentation. The system described in the documents, and the system as it operates in the real world must be in accordance.

Conduction of audit inspections is a step towards TFDA commitment to implement ISO/IEC Standard 17020 - General Criteria for the Operation of Various Bodies Performing Inspection.

1.1 Objectives of the Guideline

To guide Audit Inspectors on how to carry out audit inspection so as to determine effectiveness and efficiency of the control system in implementing planned inspection activities for improving the quality of services.

1.2 Scope of the Guideline

These Guidelines shall apply to audit inspection activities concerning food, drugs, cosmetics and medical devices at all levels.
SECTION TWO
TERMS AND DEFINITIONS

2.0 For the purpose of these guidelines the following terms and definitions shall apply.

Audit
A Systematic and independent examination to determine whether quality activities and related results comply with the planned arrangement and whether these arrangements are implemented effectively and are suitable to achieve the objectives.

Audit Criteria
Set of policies, procedures or requirements that are used as reference against which audit evidence is compared.

Audit Inspection
A Systematic and independent examination to determine whether inspection activities and related results comply with the planned arrangement and whether these arrangements are implemented effectively and are suitable to achieve the objectives.

Audit Inspectors
TFDA inspector or any person with the competence appointed by TFDA to conduct audit inspection for TFDA control activities.

Audit team
One or more auditors conducting an audit inspection.

Inspection
Inspection is the examination of a product design, product, service, system, process and premises in order to determine their conformity with requirements. NOTE: Inspection of system and processes includes personnel, facilities, technology and methodology.

Investigative Inspection
An investigative inspection is undertaken to deal with specific complaints received about lapses or noncompliance with standards of professional practice. The inspection should be unannounced.

Follow-Up Inspection
A follow up inspection is normally carried out to ensure that corrective measures and corrective actions have been undertaken following instructions from previous inspections.
Guidelines for Conducting Audit Inspection

**Routine Inspection**
Routine inspections are scheduled inspections that are carried out for purpose of checking compliance with the legislation. They may be conducted to a new establishment or for an establishment that has applied for a permit to extend its scope of operations, made important changes in its key personnel, changed to new premises, or has not been inspected for a long time. These inspections can be announced or unannounced.

**Special Inspection**
A special inspection is one in which a special reason prompts the need to carry out an inspection for purpose of verifying a particular premises and/or product safety control measure or their implementation.
SECTION THREE
AUDIT INSPECTION

3.0 What is Audit Inspection?

Audit Inspection is a management function planned and carried out in order to guide, support, and assist audited part in carrying out the assigned tasks. It usually involves on job transfer of knowledge and skills between the Auditor and the one being audited through administrative and technical communication channel. The aim of Audit Inspection is to determine effectiveness, correctness and efficiency of the control system in implementing planned activities. Audit Inspections shall cover all areas where inspection activities are carried out such as manufacturing, transportation, storage, distribution, selling, import and export, and monitoring of implementation of programmes (Salt Iodations, BMS, ADDO, and Quality Assurance for Drugs e.t.c). As a minimal requirement, every district/municipality/city shall be audited at least once every twelve months.

3.1 Objectives of Audit Inspection

3.1.1 General objective

The broad objective of carrying out audit inspection is to enhance efficiency and effectiveness of inspection activities for continual improvement.

3.1.2 Specific objectives

i) to ensure uniformity in conducting inspections as per set inspection standards;
ii) to enhance compliance of the regulated industry with legal requirements;
iii) to assist inspectors in improving their performance;
iv) to help identify problems and institute timely interventions;
v) to maintain and reinforce the administrative and technical links between higher and lower levels;
vii) to make follow up of implementation of previous audit inspection recommendations and
vii) to identify resource needs.

3.1.3 Scope of Audit Inspection

Audit Inspections shall cover all areas where inspection activities are carried out including all documents relating to the control of food, drugs, cosmetics and medical devises such as databases, files, reports and accountable books for fees and charges.
3.2 **Type of Inspections to be audited**

These include:

i) Routine inspection  
ii) Follow-up inspection  
iii) Investigative inspection  
iv) Special inspection

3.3 **Qualities of Audit Inspectors**

Audit inspectors are among inspectors appointed as per section 105 of the Tanzania Food, Drugs and Cosmetics Act. They are required to comply with the Code of Ethics and Conduct accompanying their appointment and the Code of conduct for Civil servants.

In addition to the above, the audit inspectors must posses the following qualities:

i) be knowledgeable, experienced and competent in the relevant area of expertise and must poses good communication skills;  
ii) be capable of exercising confidentiality of information obtained in the course of performing audits;  
iii) be able to exercise integrity, confidentiality, trustfulness and discretion;  
iv) must be fair, truthful and accurate in presenting the audit reports;  
v) must be impartial and objective to the audit conclusion. Auditors should not audit their own work; and  
vi) must have evidence based approach i.e. the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process.

3.4 **Levels of Audit Inspection**

The levels of audit inspection takes into account the existing inspection administrative set up from National, Regional to the Local Government Authorities. Each level can carry out audit inspection at the lower levels.

Inspectors from The Ministry of Health & Social Welfare and TFDA shall carry audit inspection at the Regional Administration and Local Government Authorities. Regional level can conduct the same to the Local Government Authorities. Within Local Government Authorities inspectors at the District/Council level can conduct audit inspections at ward level.

3.5 **Major areas to be audited**

3.5.1 Inspection reporting
Guidelines for Conducting Audit Inspection

i) Check whether there is reporting format.
ii) Check whether the format is being used as intended.
iii) Ask whether there are any problems associated with the use of the format.

3.5.2 Documentation

i) Check for availability of inspection guidelines and standard operating procedures (SOPs).
ii) Check how inspection and other reports are filed and their accessibility and retrieval when required.
iii) Check availability of electronic (e.g. data bases, intranet sites) and paper base (e.g. reports) information resources for inspection activities.
iv) Systems available to managerial information regarding to inspections.
vi) Check whether the reports are numbered, dated and given codes for the record keeping and document control.
vi) Check whether records and other documents are maintained to avoid damage loss and deterioration and maintain their integrity (shelves, files etc).
vii) Check whether the reports are adequately signed and filed and
viii) Check whether relevant forms are dully filled.
ix) Evaluate the correctness of the instruction /recommendation/advice given.

3.5.3 Sampling of Inspection recently carried out

i) Verify a few recently done inspections by inspecting the sites and comparing them with what is in their reports.

3.5.4 Follow up of corrective actions previously recommended

i) Check whether time for a follow up inspection is indicated in the reports and
ii) Check whether follow up inspections are conducted as scheduled.

3.5.5 Follow up of rectification orders agreed previously

i) Check whether legislative and administrative actions are instituted against non compliances identified during the inspections and whether they are in line with TFDC Act.

3.5.6 Operational plans and budgets

i) Check whether they are written operational plans;
ii) Methods used (sampling techniques, inspection manuals, other tools and materials);
iii) Check whether there are operational principles, processes and procedures for conducting inspection;
iv) Number and type of clients/premises served
v) Number of premises per inspector;
vi) Proportion of premises inspected and
vii) Check whether there is a budget for the execution of plans.

3.5.7 Monitoring and evaluation

i) Check whether the tools for monitoring and evaluation are provided.

ii) Check whether the tools are adequate and are used as intended.

3.5.8 Collection of Fees and charges

i) Verify whether the fees and charges for services provided are paid appropriately.

ii) Verify whether revenues collected are properly utilised.

iii) Check whether required percentage of revenue is remitted to TFDA.

3.5.9 Implementation of Special programme

i) Check whether TFDA special programmes are implemented and monitored as intended.

3.5.10 Adverse health effects of regulated products

i) Check whether adverse effects are reported and interventions employed.

3.5.11 Human resource problems

i) Check the adequacy of qualified personnel against the work load.

ii) Technical knowledge and skills of inspectors (Scope of specialised training on the TFDA regulated products).

iii) Access to training (including refresher courses).

iv) Assess level of commitment.

v) Management of conflict of interest.

3.5.12 Complaint handling

i) Check whether there is mechanism for handling of customer complaints e.g. procedures

3.5.13 Working Infrastructures

i) Check availability of working facilities and

ii) Check availability of inspection and sampling equipment and supplies
SECTION FOUR

ACTUAL AUDIT INSPECTION

4.0 Conducting of Audit Inspection

Process of audit inspection consists of four stages which include:

Stage 1: Preparation of Audit

a) Before audit inspection, the team should familiarize itself with the following:

i) The conceptual framework for inspection planning to be audited;
ii) The understanding of inspection system;
iii) The main objective of audit inspection;
iv) The essential interventions for safety and quality control of regulated products;
v) The meaning of quality food, drugs, cosmetics and medical devices control services;
vii) The roles and responsibilities of staff to be audited.

b) Preparation of audit plan
   i) working tool (checklist, guidelines, Act, regulations, circulars, policies, audit plan, inspection and sampling kits e.t.c) 
   ii) review previous inspection and audit reports 
   iii) literature review 
   iv) timetable 
   v) logistics (Communication, transport, financial support)

Stage 2: Audit inspection procedure

a) An auditor shall make a courtesy call to the respective authorities:
   i) introduce him/her self 
   ii) explain the purpose of the audit 
   iii) requesting for an officer to accompany him/her during the audit if necessary 
   iv) ask for assistance where needed 

b) During actual audit, the auditor shall:
   i) scrutinize inspection reports, inspection data etc 
   ii) check whether inspection guidelines, checklist, working procedures are followed. 
   iii) sampling of areas to be inspected
iv) on site verification (inspection, taking sample, action taken, advice and recommendations)
v) prepare a brief report

Stage 3: Post-audit inspection briefing

This is an activity that takes place after audit inspection has been carried out. The objective of this stage is generally to convey audit inspection findings/observations in brief to the audited part. Auditors are required to provide both positive and negative findings. Any suggestions for improvement may also be communicated.

The findings shall be filled in a corrective action form which shall be signed in duplicates by the auditor and audited part indicating the major non conformances, suggested corrective measures and the time frame. One copy shall remain with the audited part.

Stage 4: Audit Inspection Report

A final report need to be prepared which should incorporate all findings. Audit inspection report should be written immediately after completing the audit. The compilation and submission of the report should take not more than 10 working days on completion of audit inspection and arrival at working station. Sufficient details should be provided to enable an independent assessment, comprehension and easy decision making. The format as well as the content requirements of the report which auditors should follow when writing report is prescribed in Section Five of the guidelines. The report shall be submitted to the Director General (DG), TFDA. After consent by the DG, the report shall be circulated to the Regional Administrative Secretary (RAS) and Executive Director of the respective Region and District/Municipality/City audited for reference and follow-up of implementation of corrective measures to non-conformances.
SECTION FIVE

AUDIT INSPECTION REPORT

5.0 Contents of the Audit inspection report

In spite of the type and format of the audit inspection report, the report should contain the following information;

i) Title of the report;
- Name of institution
- Name of author/Audit inspectors
- Name and signature of the person approving/endorsing
- Heading of the report indicating place, date and duration (e.g. THE AUDIT INSPECTION REPORT CONDUCTED AT LAKE ZONE FROM 25TH JULY TO 22ND AUGUST 2008).

ii) Acknowledgement;
- An appreciation of the contribution and participation of groups of people, stakeholders and individuals involved in one way or another during audit inspection

iii) Acronyms;
- List of abbreviations commonly used in the report.

iv) List of Figures and Tables
- Title of figure/tables and pages to locate them

v) Table of contents
- List of topics and pages to be located

vi) Executives summary

vii) Introduction
- General overview.
- Scope of audit
- Purpose of audit
- Methodology

viii) Main body of the report
- Situation analysis, needs, services and systems
- Observations/Findings
- Analysis of findings

ix) Conclusion and Recommendations

x) Name of Audit inspectors and Signature
- Names and signature of audit inspectors participated in that
xi)Appendices
- List of tools used.
References


