COMPENDIUM OF QUALITY MANAGEMENT SYSTEM (QMS) TECHNICAL DOCUMENTS FOR HARMONIZATION OF MEDICINE REGULATION IN THE EAST AFRICAN COMMUNITY

VERSION SEPTEMBER 2014
# DOCUMENTS DEVELOPMENT HISTORY

<table>
<thead>
<tr>
<th>STEPS</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of draft harmonized technical documents for Good Manufacturing Practices (GMP) for the East African Community Medicines Regulatory Harmonization Initiative</td>
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</tr>
<tr>
<td>Draft harmonized technical documents approved by the Steering Committee</td>
<td>2nd to 3rd September 2013</td>
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<tr>
<td>Release of draft harmonized technical documents for Public Consultation</td>
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</tr>
<tr>
<td>End of National Consultation (deadline for comments)</td>
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</tr>
<tr>
<td>Incorporation of national stakeholders inputs by EAC Secretariat in collaboration with EAC Partner States</td>
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</tr>
<tr>
<td>Release of revised technical documents for regional and international consultation</td>
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</tr>
<tr>
<td>End of regional and international consultation (deadline for comments)</td>
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</tr>
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<td>Draft technical documents reviewed and adopted by EAC Technical Working Group on Medicines and Food Safety</td>
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</tr>
<tr>
<td>Draft technical documents adopted by the 18th EAC Sectoral Committee on Health</td>
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</tr>
<tr>
<td>Draft technical documents finalized by EAC Secretariat in collaboration with EAC Partner States</td>
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</tr>
<tr>
<td>Final technical documents approved by the 9th EAC Sectoral Council on Health</td>
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<tr>
<td>Date for coming into effect</td>
<td>17th April 2014</td>
</tr>
</tbody>
</table>
This Compendium has been developed to provide guidance to EAC Partners States National Medicines Regulatory Authorities to implement Quality Management System (QMS).

The Compendium was compiled by the East African Community (EAC) Technical Working Group (EWG) on QMS. The EWG relied on available International Standards (ISO 9000 series, ISO/IEC 17020 and ISO/IEC 17025), WHO guidelines, and other experiences from other medicine regulatory authorities.

EAC Secretariat is highly indebted to African Medicines Regulatory Harmonization (AMRH) program partners, Bill and Melinda Gates Foundation (BMGF), the World Bank and the United Kingdom Department for International Development (DFID) for their financial assistance; and African Union New Partnership for Africa’s Development (AU-NEPAD) for high level advocacy.

The EAC Secretariat also recognizes the important contribution of the Clinton Health Access Initiative (CHAI) in the conceptualization of the African Medicines Regulatory Harmonization (AMRH) Initiative. I would like to thank members of the Technical Working Group (EWG) on Quality Management System (QMS) and the WHO expert who contributed to the successful development of the first edition of these Quality Management System documents.

I also wish to thank the staff of EAC Secretariat for their dedicated work and coordination of the implementation of the EAC Medicines Regulatory Harmonization (MRH) Project.

I also acknowledge the oversight role of the EAC Partner States Ministries responsible for Health, Ministries responsible for EAC affairs and the EAC MRH Project Steering Committee.

Finally, I would like to acknowledge regional stakeholders in Sectors of health, trade and industry in EAC for their valuable contribution into the development of this Compendium.

Ambassador Dr. Richard Sezibera
Secretary General
EAC Secretariat
The “Compendium of Quality Management System Technical Documents for Harmonization of Medicines Regulation in The East African Community, 2014” is an EAC publication which sets out the implementation of Quality Management System (QMS) within EAC NMRAs.

This Compendium contains five parts namely:


2. **The EAC Guidelines for the implementation of Quality Management System Requirements for the Regulation of Medicines, Cosmetics, Medical Devices and Diagnostics**, 2014


4. **The Mandatory Documented Procedures**; and


The overall objective of these QMS documents is to facilitate mutual recognition and consistent regulatory services delivery by Partner States NRMAs in the regulation of Medicines, Cosmetics, Medical Devices and Diagnostics in accordance with Chapter 21, Article 118 (c, d and e) of the EAC Treaty in order to safeguard public health and improve economic gains within the Community.
staff of EAC Partner States NMRAs through disclosure of any circumstances that could give rise to a potential conflict of interest related to their work.

The EAC QMS documents will be periodically reviewed to ensure their continued consistency with any changes in the applicable standards.

I would like to thank members of the Technical Working Group (EWG) on Quality Management System (QMS) for Regulations of Medicines, Cosmetics, Medical Devices and Diagnostics under the East African Community Medicines Regulatory Harmonization (EAC-MRH) Project who contributed to the successful development of the first edition of these Quality Management System (QMS) documents that include the EAC Quality Management Requirements, the EAC Guidelines for implementation of the QMS requirements, the EAC Model Quality Manual and the mandatory QMS procedures. I would also like to thank the World Health Organization (WHO) for providing technical assistance towards the development of the QMS documents.

Special thanks go to the Bill and Melinda Gates Foundation (BMGF), the World Bank, the New Partnership for Africa’s Development (NEPAD) for providing financial support.

I am grateful to the staff of EAC Secretariat, the EAC MRH project Steering Committee and EAC Partner States for their effective coordination and implementation of this EAC MRH project.

I also acknowledge the valuable contribution of the national and regional EAC stakeholders who reviewed these EAC QMS documents and provided useful inputs.

Hon. Jesca Eriyo
Deputy Secretary General for Productive and Social Sector
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RESPONSIBILITY FOR IMPLEMENTATION AND LEGAL FRAMEWORK

The EAC Sectoral Council Of Ministers of Health recognizes the work done by the EAC secretariat in conjunction with EAC partner states NRMA:s and supported by development partners in the development of these QMS documents. These QMS documents will facilitate the implementation of QMS in the EAC Partner States NRMA:s.

The EAC Sectoral Council of Ministers of Health approves the use of these QMS documents in the East African Community Partner States’ National Medicines Regulatory Authorities (NRMA:s) in accordance with Chapter 21, Article 118 (c, d,e and f) of the EAC Treaty. Implementation of these documents will facilitate mutual recognition of regulatory decisions and attestation of the quality and safety medicines, cosmetics, medical devices and diagnostics manufactured, produced, imported, exported or traded in East African Community.

The EAC partner states Ministries responsible for Health shall be responsible for the implementation of these QMS documents by their respective NRMA:s.

SIGNED by the Hon. Ministers and Leaders of Delegation this 20th day of September, 2014.

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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>DOCUMENTS DEVELOPMENT HISTORY</th>
<th>i</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOREWARD</td>
<td>ii</td>
</tr>
<tr>
<td>PREFACE</td>
<td>iii</td>
</tr>
<tr>
<td>RESPONSIBILITY FOR IMPLEMENTATION AND LEGAL FRAMEWORK</td>
<td>v</td>
</tr>
<tr>
<td>AUTHORS</td>
<td>vi</td>
</tr>
<tr>
<td>EDITORIAL TEAM</td>
<td>vii</td>
</tr>
<tr>
<td>Table of Content</td>
<td>ix</td>
</tr>
</tbody>
</table>

## PART ONE: EAC QUALITY MANAGEMENT REQUIREMENTS

1. INTRODUCTION
   1.1. Background
   1.2. Objectives
   1.3. Scope of EAC QMS requirements document

## QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS

1. Scope
   1.1. General
   1.2. Application

2. Normative references

3. Terms and definitions

4. Quality management system
   4.1. General requirements
   4.2. Documentation requirements
      4.2.1. General
      4.2.2. Quality manual
      4.2.3. Control of documents
      4.2.4. Control of records

5. Management responsibilities
   5.1. Management commitment
   5.2. Customer focus
   5.3. Quality policy
   5.4. Planning
      5.4.1. Quality objectives
      5.4.2. Quality management system planning
   5.5. Responsibility, authority and communication
      5.5.1 Responsibility and authority
      5.5.2 Management representative
      5.5.3 Internal communication
5.6. Management review
   5.6.1. General
   5.6.2. Review input
   5.6.3. Review output

6. Resource management
   6.1. Provision of resources
   6.2. Human resources
      6.2.1 General
      6.2.2. Competence, training and awareness
      6.2.3. Impartiality and independence
      6.2.4. Confidentiality
   6.3. Infrastructure
   6.4. Work environment

7. Service realizations
   7.1 Planning of service realization
   7.2 Customer-related processes
      7.2.1. Determination of requirements related to the service
      7.2.3. Review of requirements related to the service
      7.2.3. Customer communication
      7.2.4. Complaints and appeals
      7.2.5. Complaints and appeals process
   7.3. Design and development
      7.3.1. Design and development planning
      7.3.2. Design and development inputs
      7.3.3. Design and development outputs
      7.3.4. Design and development review
      7.3.5. Design and development verification
      7.3.6. Design and development validation
      7.3.7. Control of design and development changes
   7.4 Purchasing
      7.4.1 Purchasing process
      7.4.2 Purchasing information
      7.4.3 Verification of purchased product
   7.5. Service provision
      7.5.1 Control of service provision
      7.5.2 Validation of processes for service provision
      7.5.3 Identification and traceability
      7.5.4 Customer property
      7.5.5 Preservation of product
   7.6 Control of monitoring and measuring equipment

8. Measurement, analysis and improvement
   8.1. General
8.2. Monitoring and measurement
   8.2.1. Customer satisfaction
   8.2.2. Internal audit
   8.2.3. Monitoring and measurement of processes
   8.2.4. Monitoring and measurement of service
8.3. Control of nonconforming product
8.4. Analysis of data
8.5. Improvement
   8.5.1. Continual improvement
   8.5.2. Corrective action
   8.5.3. Preventive action

REFERENCES

REVISION HISTORY

PART TWO: EAC GUIDELINES FOR IMPLEMENTATION OF QMS REQUIREMENTS

0. INTRODUCTION
   0.1. Background
   0.2. Objectives
   0.3. Scope of EAC Guidelines for implementing QMS requirements

QUALITY MANAGEMENT SYSTEM

1. General
   1.1. Scope

2. Normative references

3. Terms and definitions

4. Quality Management System
   4.1. General requirements
   4.2. Documentation requirements
      4.2.1 General
      4.2.2 Quality Management
      4.2.3 Control of documents
      4.2.4 Control of records

5. Management responsibility
   5.1 Management commitment
   5.2 Customer focus
   5.3 Quality policy
   5.4 Planning
      5.4.1 Quality objectives
5.4.2 Quality management system planning 32
5.5 Responsibility, authority and communication 32
  5.5.1 Responsibility and authority 32
  5.5.2 Management Representative 33
  5.5.3 Internal communication 33
5.6 Management review 34
  5.6.1 General 34
  5.6.2 Review input 34
  5.6.3 Review output 35

6.0 Resource management 35
  6.1 Provision of resources 35
  6.2 Human Resources 36
    6.2.1 General 36
    6.2.2 Competence, awareness and training 36
    6.2.3 Impartiality and independence 37
    6.2.4 Confidentiality 37
  6.3 Infrastructure 38
  6.4 Work environment 38

7.0 Product realization 38
  7.1 Planning of services realization 39
  7.2 Customer related process 39
    7.2.1 Determination of requirements related to the service 39
    7.2.2 Review of requirements related to the services 39
    7.2.3 Customer communication 40
    7.2.4 Complaints and appeals 40
    7.2.5 Complaints and appeals process 41
  7.3 Design and Development 42
    7.3.1 Design and development planning 42
    7.3.2 Design and development inputs 42
    7.3.3 Design and development outputs 43
    7.3.4 Design and development review 44
    7.3.5 Design and development verification 44
    7.3.6 Design and development validation 44
    7.3.7 Control of design and development changes 44
  7.4 Purchasing 44
    7.4.1 Purchasing process 44
    7.4.2 Purchase Information 46
    7.4.3 Verification of purchased product 46
  7.5 Production and service provision 47
    7.5.1 Control of production and service provision 47
    7.5.2 Validation of processes for production and service provision 47
    7.5.3 Identification and traceability 48
    7.5.4 Customer property 48
7.5.5 Preservation of product 49
7.6 Control of monitoring and measuring equipment 49
8.0 Measurement, analysis and improvement 51
  8.1 General 51
  8.2 Monitoring and measurement 51
    8.2.1 Customer Satisfaction 51
    8.2.2 Internal audit 51
    8.2.3 Monitoring and measurement of processes 52
    8.2.4 Monitoring and measurement of product 53
  8.3 Control of nonconforming product 53
  8.4 Analysis of data 54
  8.5 Improvement 55
    8.5.1 Continual improvement 55
    8.5.2 Corrective action 55
    8.5.3 Preventive action 57

BIBLIOGRAPHY 57
REVISION HISTORY 57

PART THREE: Model Manual on the Implementation of the EAC QMS
Requirements for NMRA 58

0. INTRODUCTION 59
  0.1 Background 59
  0.2. Objectives 59
  0.3. Scope of EAC QMS model manual 59

QUALITY MANAGEMENT SYSTEM 60

1. SCOPE 60
  1.1. General 60
  1.2. Application of the Quality Management System 60
  1.3. Exclusions from the EAC QMS requirements 60

2. NORMATIVE REFERENCES 60

3. TERMS AND DEFINITIONS 60

4. QUALITY MANAGEMENT SYSTEM 61
  4.1. General requirements 61
  4.2. Document requirement 62
    4.2.1 General 62
    4.2.2 Quality Manual 62
    4.2.3 Control of documents 62
    4.2.4 Control of records 62
5. Management responsibilities
   5.1 Management commitment
   5.2 Customer focus
   5.3 Quality policy
   5.4 Planning
      5.4.1 Quality objectives
      5.4.2 Quality management system planning
   5.5 Responsibility, authority and communication
      5.5.1 Responsibility and authority
      5.5.2 Management representative
      5.5.3 Internal communication
   5.6 Management review
      5.6.1 General
      5.6.2 Review input
      5.6.3 Review output

6. Resource management
   6.1 Provision of resources
   6.2 Human resources
      6.2.1 General
      6.2.2 Competence, training and awareness
      6.2.3 Impartiality and independence
      6.2.4 Confidentiality
   6.3 Infrastructure
   6.4 Work environment

7.0 Product realization
   7.1 Planning of product realization
   7.2 Customer related processes
      7.2.1 Determination of requirements related to the product
      7.2.2 Review of requirements related to the product
      7.2.3 Customer communication
      7.2.4 Complaints and appeals
      7.2.5 Complaints and appeal process
   7.3 Design and Development
      7.3.1 Design and Development Planning
      7.3.2 Design and Development Inputs
      7.3.3 Design and Development Outputs
      7.3.4 Design and Development Review
      7.3.5 Design and Development Verification
      7.3.6 Design and Development Validation
      7.3.7 Control of Design and Development Changes

62
62
62
63
63
63
63
63
63
64
64
64
65
65
65
65
65
65
66
66
66
66
66
66
66
66
67
67
67
67
67
67
67
67
68
68
68
68
7.4 Purchasing
   7.4.1 Purchasing process
   7.4.2 Purchasing information
   7.4.3 Verification of purchased product
7.5 Production and service provision
   7.5.1 Control of production and service provision
   7.5.2 Validation of processes for production and service provision
   7.5.3 Identification and traceability
   7.5.4 Customer property
   7.5.5 Preservation of the product
7.6 Control of monitoring and measuring equipment

8.0 Measurement, analysis and improvement
   8.1 General
   8.2 Monitoring and measurement
      8.2.1 Customer satisfaction
      8.2.2 Internal audit
      8.2.3 Monitoring and measurement of processes
      8.2.4 Monitoring and measurement of services
   8.3 Control of non-conforming product
   8.4 Analysis of data
   8.5 Improvement
      8.5.1 Continual improvement
      8.5.2 Corrective action
      8.5.3 Preventive action

REVISION HISTORY
Annex 1- Model Process interaction diagram:
Annex 2: Model Quality Policy.
Annex 3 Medicine Regulations mapping processes

PART FOUR: EAC QMS Model Standard Procedures

0. INTRODUCTION
   EAC Model Procedure for Control of Documents
   EAC Model Procedure for Control of Records
   EAC Model procedure for Conducting Internal Quality Audit,
   EAC Model procedure for Control of Non-Conforming Product
   Doc. # EAC/TF-MED/QMS/FD/SOP
   EAC Model procedure for Handling Customer Complaints and Appeals
   EAC Model procedure for handling Corrective and Preventive Action
   Model standard operating procedure:
PART FIVE: Code of Conduct for EAC Partner States NMRA

0. INTRODUCTION
   0.1 Background
   0.2 Objectives
   0.4 Legal basis

1. CODE OF CONDUCT

2. GUIDANCE ON CONFLICTS OF INTERESTS
   2.1 Meaning of “conflict of interest”
   2.2 Types of Interests
      2.2.1 Direct Interest
      2.2.2 Interests of Others
   2.3 When is the NMRA personnel required to complete a declaration of interests form?
   2.4 Examples of interests that must be disclosed
   2.5 How to analyse the information disclosed?
   2.6 Safety of the filled DOI forms

3. GUIDANCE ON CONFIDENTIALITY
   3.1 Introduction
   3.2 Confidential Information
   3.3 Duty of confidentiality
   3.4 Continuing duty of confidentiality
   3.5 When is the NMRA personnel required to complete a confidentiality undertaking form?

ANNEX 1: DECLARATION OF INTERESTS
PART ONE

EAC QUALITY MANAGEMENT’S REQUIREMENTS
0. INTRODUCTION

0.1. Background

One of the goals of East African Community (EAC) Medicines Regulatory Harmonization Project is to have harmonized and functioning Quality Management System (QMS) within the EAC National Medicines Regulatory Authorities (NMRAs) in accordance with national and internationally recognized standards. This document provides requirements for implementing quality management systems in NMRAs of the EAC. All NMRAs in the EAC have management systems for creating and delivering their services to customers. However, some of the NMRAs lack quality management systems which would lead to wasteful processes, poor services delivery and dissatisfied customers.

This document outlines the quality system requirements for our NMRA QMS. It is intended that each NMRA uses the document as the basis for developing and implementing its own QMS and for preparing its own quality manual. In addition to providing a basis for self-assessment and a reference document for use by external assessors, establishing and maintaining an effective QMS will generate confidence within and between EAC NMRAs in the assessment of QMS compliance.

EAC NMRAs should co-operate with one another in exchanging experiences in the maintenance and operation of quality systems and in the further development of this document.

0.2. Objectives

The overall objective of this document is to ensure that adequate quality standards are maintained in each of the EAC Partner State NMRAs so as to achieve consistency in regulatory service delivery and facilitate mutual confidence and recognition.

The specific objectives of this document are to:

a) enable the establishment, and maintenance of the EAC QMS for all EAC partner states NMRAs;

b) enable EAC partner states to adopt a common standard quality system requirements in order to achieve consistency in services in the EAC NMRAs; and

c) facilitate mutual recognition and confidence amongst EAC NMRAs.

0.3. Scope of EAC QMS requirements document

This document specifies QMS requirements for EAC NMRAs in the regulation of medicines, cosmetics, medical devices and diagnostics.
QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS

1. Scope

1.1. General

This document specifies requirements for a quality management system where an EAC Partner State NMRA:

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable and regulatory requirements.

b) aims to enhance customer satisfaction through the effective application of the system, including processes or continual improvement of the system and the assurance of conformity to customer and applicable laws, statutory and regulatory requirements.

NOTE:
Statutory and legal requirements include national (e.g. national health policy, NMRA Acts, etc); regional (EAC policies on medicine regulation) and international (WHO guidelines, etc) obligations

1.2. Application

1.2.1 The requirements of this document apply to all directorates, departments, units and sections of the EAC Partner States NMRAs. NMRAs may also be required to comply with the following ISO standards and PIC/S guidelines:

a) ISO/IEC 17025: 2005 – General requirements for the competence of testing and calibration laboratories

b) ISO/IEC 17020: 2012 Conformity assessment - Requirements for the operation of various types of bodies performing inspection

c) PI 002_3: 2007 PIC/S - Recommendations on Quality system requirements for pharmaceutical inspectorates

Where any requirement(s) of these EAC QMS requirements cannot be applied due to the nature of an NMRA and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the NMRA's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

2. Normative references

This document has been developed according to ISO 9001:2008 - “Quality Management Systems requirements”. In addition, the following referenced documents are indispensable for the application of the QMS:


b) ISO/IEC 17025: 2005 - General requirements for the competence of testing and calibration laboratories
c) ISO/IEC 17020: 2012 Conformity assessment - Requirements for the operation of various types of bodies performing inspection

d) PI 002_3: 2007 PIC/S - Recommendations on Quality system requirements for pharmaceutical inspectorates EAC Partner states application statutory and legal requirements


f) Any other recognised standard or laws that may be published in the EAC Gazette

3. Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000: 2005 apply. For the NMRAs, the following terms and definitions for "product", "customer" and "Top Management" shall apply:

a) Customer: organization or person that receives a product. EXAMPLE Consumer, client, end-user, retailer, beneficiary and purchaser.

NOTE 1
A customer can be internal or external to the organization.

NOTE 2
"Regulated Customer": Organisation or person who by the nature of their business are subject to regulation by the NMRAs

b) "Unregulated Customer": Organisation or person who is not subject to regulation by NMRAs.

NOTE 3
“Product” : Applies to regulatory services intended for, or required by, the customer (regulated and/or unregulated customer) and to any intended output resulting from the product realization processes of the NMRA (e.g. market authorization or medicine registration certificates, licences, permits, good manufacturing practice certificates, good distribution practice certificates, medicine/drug register)

c) “Top management” person or group of people who directs and controls an NMRA at the highest level.

4. Quality management system

4.1. General requirements

The NMRA shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the EAC QMS requirements in this document.

To design and implement the QMS the NMRA shall:

a) determine the processes needed for the quality management system and their application throughout the NMRA (see 1.2),

b) determine the sequence and interaction of these processes,
c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure where applicable, and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the NMRA in accordance with the requirements of this EAC QMS Requirements.

Where an NMRA chooses to outsource any process that affects product conformity to requirements, the NMRA shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

4.2. Documentation requirements

4.2.1. General

The quality management system documentation shall include:

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures and records required by EAC QMS requirement

d) documents, including records, determined by the NMRA to be necessary to ensure the effective planning, operation and control of its processes.

NOTE:
Where the term “documented procedure” appears within this EAC QMS Requirement, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirement for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

4.2.2 Quality manual

The NMRA shall establish and maintain a quality manual that includes:

a) the scope of the quality management system the documented procedures established for the quality management system, or reference to them,

b) a description of the interaction between the processes of the quality management system

4.2.3. Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4. Control of records

The NMRA shall determine and control the records established to provide evidence of conformity to requirements and of the effective operation of the quality management system. The NMRA shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. A list of the controlled records and their required retention periods shall be established and maintained.

Records shall remain legible, readily identifiable and retrievable.

5. Management responsibilities

Top management shall develop the strategic plan, business plan, mission, vision, core values for the whole NMRA. QMS requirements shall be clearly identified in the strategic plan and business plan of the NMRA

5.1. Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

a) communicating to the NMRA the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2. Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).
5.3. Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the NMRA,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the NMRA, and
e) is reviewed for continuing suitability.

5.4. Planning

5.4.1. Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the NMRA. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2. Quality management system planning

Top management shall ensure that:

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1 as well as the quality objectives, and
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
c) in planning for the QMS, top management shall ensure that a strategic plan is developed.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the NMRA.

a) The NMRA shall establish an organizational chart that clearly shows the inter-relationship and reporting mechanism of the personnel in the NMRA.
b) The NMRA shall establish job descriptions defining the responsibilities and authorities of each of the employee positions on the organizational structure.

Management representative

Top management shall appoint a member of the NMRA’s management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE:
The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the NMRA and that communication takes place regarding the effectiveness of the quality management system.

5.6. Management review

5.6.1. General

Top management shall review the NMRA’s quality management system, at planned intervals, at least once a year, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2. Review input

The input to management review shall include information on:

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3. Review output

The output from the management review shall include any decisions and actions related to:

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.
6. **Resource management**

6.1 **Provision of resources**

The NMRA shall determine and provide the resources needed:

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2. **Human resources**

6.2.1 **General**

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

**NOTE:**

Conformity to service requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2. **Competence, training and awareness**

The NMRA shall:

a) determine the necessary competence for personnel performing work affecting conformity to product requirements,

b) where applicable, provide training or take other actions to achieve the necessary competence,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4)

f) develop a code of conduct in accordance with national public service code of conduct

6.2.3. **Impartiality and independence**

a) The NMRA shall be responsible for the impartiality of its activities and shall not allow commercial, financial or other pressures to compromise impartiality.

b) The NMRA shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present an NMRA with a risk to impartiality.

c) If a risk to impartiality is identified, the NMRA shall be able to demonstrate how it eliminates or minimizes such risk.

d) The NMRA shall have top management commitment to impartiality.
e) The NMRA shall be independent to the extent that is required with regard to the conditions under which it performs its services.

f) The NMRA shall establish a documented procedure to manage impartiality and independence.

6.2.4. Confidentiality

a) The NMRA shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of its regulatory activities. The NMRA shall inform the client, in advance, of the information it intends to place in the public domain. Except for information that the client makes publicly available, or when agreed between the NMRA and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

NOTE: Legally enforceable commitments can be, for example, contractual agreements.

b) When the NMRA is required by law or authorized by contractual commitments to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided.

c) Information about the client obtained from sources other than the client (e.g. complainant, regulators) shall be treated as confidential.

d) The NMRA shall establish a documented procedure to manage confidentiality.

6.3. Infrastructure

The NMRA shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport, communication or information systems).

6.4. Work environment

The NMRA shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE: The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).
7. **Service realizations**

7.1 **Planning of service realization**

The NMRA shall plan and develop the processes needed for service realization. Planning of service realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1 as appropriate).

In planning service realization, the NMRA shall determine the following, as appropriate:

- a) quality objectives and requirements for the service;
- b) the need to establish processes and documents, and to provide resources specific to the service;
- c) required verification, validation, monitoring, measurement, inspection and test activities specific to the service and the criteria for service acceptance;
- d) records needed to provide evidence that the realization processes and resulting service meet requirements (see 4.2.4 as appropriate).

The output of this planning shall be in a form suitable for the NMRA’s method of operations.

7.2 **Customer-related processes**

7.2.1. **Determination of requirements related to the service**

The NMRA shall determine:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) requirements not stated by the customer but necessary for specified or intended use, where known,
- c) statutory and regulatory requirements applicable to the service, and
- d) any additional requirements considered necessary by the NMRA.

7.2.2. **Review of requirements related to the service**

The NMRA shall review the requirements related to the service this review shall be conducted prior to the NMRA’s commitment to provide a service to the customer (e.g. Licensing, Product registration and market authorization, certification, GMP inspection and others) and shall ensure that

- a) service requirements are defined,
- b) service requirements differing from those previously expressed are resolved, and
- c) the NMRA has the ability to meet the defined or new requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the NMRA before acceptance.
Where service requirements are changed, the NMRA shall ensure the relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3. Customer communication

The NMRA shall determine and implement effective arrangements for communicating with customers in relation to:

a) service information,

b) enquiries, new service information including amendments, and

c) customer feedback, including customer complaints

7.2.4. Complaints and appeals

7.2.4.1 The NMRA shall have a documented procedure to receive, evaluate and make decisions on complaints and appeals.

7.2.4.2 A description of the handling process for complaints and appeals shall be available to any interested party upon request.

7.2.4.3 Upon receipt of a complaint, the NMRA shall confirm whether the complaint relates to its activities for which it is responsible and, if so, shall deal with it.

7.2.4.4 The NMRA shall be responsible for all decisions at all levels of the handling process for complaints and appeals.

7.2.4.5 Investigation and decision on appeals shall not result in any discriminatory actions.

7.2.4.6 The handling process for complaints and appeals shall include at least the following elements and methods:

a) a description of the process for receiving,

b) validating,

c) investigating the complaint or appeal, and deciding what actions are to be taken in response to it;

d) tracking and recording complaints and appeals, including actions undertaken to resolve them; ensuring that any appropriate action is taken.

e) gathering and verifying all necessary information to validate the complaint or appeal.

7.2.4.7 The NMRA shall be responsible for gathering and verifying all necessary information to validate the complaint or appeal.

7.2.4.8 Whenever possible, the NMRA shall acknowledge receipt of the complaint or appeal, and shall provide the complainant or appellant with progress reports and the outcome.

7.2.4.9 The decision to be communicated to the complainant or appellant shall be made by, or reviewed and approved by, individual(s) not involved in the original activities in question.
7.2.4.10 Whenever possible, the NMRA shall give formal notice of the end of the complaint and appeals handling process to the complainant or appellant.

7.3. Design and development

7.3.1. Design and development planning

The NMRA shall plan and control the design and development of service.

During the design and development planning, the NMRA shall determine:

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The NMRA shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE:
Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the service and the NMRA.

7.3.2. Design and development inputs

Inputs relating to service requirements shall be determined and records maintained (see 4.2.4).

These inputs shall include:

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3. Design and development outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall:

a) Meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and service provision,

c) contain or reference product acceptance criteria, and;
d) specify the characteristics of the product that are essential for its safe and proper use.

NOTE:
Information for production and service provision can include details for the preservation of product.

7.3.4. Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

7.3.5. Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements.

Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6. Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.7. Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and service already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

The NMRA shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent service realization or the final service.

The NMRA shall evaluate and select suppliers based on their ability to supply product in accordance with the organization’s
requirements. Criteria for selection, evaluation and re-evaluation shall be established.

Procurements in most NMRs are regulated by national laws. The NMRA shall therefore comply with such applicable national legal procurement requirements.

Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including, where appropriate,

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The NMRA shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The NMRA shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the NMRA or its customer intends to perform verification at the supplier’s premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information

7.5 Service provision

7.5.1 Control of service provision

The NMRA shall plan and carry out service provision under controlled conditions. Controlled conditions shall include, as applicable,

a) the availability of information that describes the characteristics of the service,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring equipment,

e) the implementation of monitoring and measurement, and

f) the implementation of service delivery activities.

7.5.2 Validation of processes for service provision

The NMRA shall validate any processes for service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results. The NMRA shall establish arrangements for these processes including, as applicable,
a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records (see 4.2.4), and
e) revalidation.

7.5.3 Identification and traceability

Where appropriate, the NMRA shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the NMRA shall control the unique identification of the product and maintain records (see 4.2.4).

7.5.4 Customer property

The NMRA shall exercise care with customer property while it is under the NMRA's control or being used by the NMRA. The NMRA shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the NMRA shall report this to the customer and maintain records (see 4.2.4).

7.5.5 Preservation of product

The NMRA shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of monitoring and measuring equipment

NMRA shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The NMRA shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall:

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);

b) be adjusted or re-adjusted as necessary;

c) have identification in order to determine its calibration status;
d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the NMRA shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The NMRA shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE:
Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

8. Measurement, analysis and improvement

8.1 General

The NMRA shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity to service requirements,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the NMRA shall monitor information relating to customer perception as to whether the NMRA has met customer requirements.

The methods for obtaining and using this information shall be determined.

8.2.2 Internal audit

The NMRA shall conduct internal audits at planned intervals but at least once every year to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the EAC QMS requirements and to the quality management system requirements established by the NMRA, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits.
The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of the audits and their results shall be maintained.

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

8.2.3. Monitoring and measurement of processes

The NMRA shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results.

When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE: When determining suitable methods, it is advisable that the NMRA consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.4. Monitoring and measurement of service

The NMRA shall monitor and measure the characteristics of the service to verify that service requirements have been met. This shall be carried out at appropriate stages of the service realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3. Control of nonconforming product

The NMRA shall ensure that product, including regulated product, which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
c) by taking action to preclude its original intended use or application;
d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

8.4. Analysis of data

The NMRA shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.

This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:

a) customer satisfaction (see 8.2.1),
b) conformity to product requirements (see 8.2.4),
c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
d) suppliers (see 7.4).

8.5. Improvement

8.5.1. Continual improvement

The NMRA shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2. Corrective action

The NMRA shall take action to eliminate the root causes of nonconformities in order to prevent recurrence.

Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken (see 4.2.4), and
f) reviewing the effectiveness of the corrective action taken

8.5.3. Preventive action

The NMRA shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken, and
e) reviewing the effectiveness of the preventive action taken.

REFERENCES


ISO/IEC 17020:2012(E) - Conformity assessment-Requirements for the operation of various types of bodies performing Inspection, 2nd edition

ISO/IEC 17025: 2005(E) - General requirements for the competence of testing and calibration laboratories, 2nd edition

PI 002_3: 2007 PIC/S - Recommendation on Quality system requirements for pharmaceutical inspectorates

REVISION HISTORY

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<thead>
<tr>
<th>Revision No</th>
<th>Date</th>
<th>Author</th>
<th>Section(s) revised</th>
<th>Description of change</th>
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PART TWO:

EAC GUIDLINES FOR IMPLEMENTATION OF QMS REQUIREMENTS
0. **INTRODUCTION**

0.1. **Background**

One of the goals of East African Community (EAC) Medicines Regulatory Harmonization Project is to have harmonized and functioning Quality Management System (QMS) within the EAC National Medicines Regulatory Authorities (NMRAs) in accordance with national and internationally recognized standards. This document provides guidelines for implementing quality management systems in NMRAs of the EAC.

All NMRAs in the EAC have management systems for creating and delivering their services to customers. However, some of the NMRAs lack quality management systems which would lead to wasteful processes, poor services delivery and dissatisfied customers. A quality management system significantly increase the efficiency and effectiveness of the NMRA and hence, improving processes and services delivery.

An efficient NMRA can be characterized by:

a) explicit awareness of, and concern for, the needs of customers and other stakeholders (e.g. consumers, suppliers, society, staff);

b) senior and middle managers who understand and focus on business needs;

c) a commitment to improve products and services;

d) staff development and training programmes that meet the needs of the organization;

e) processes designed to identify and reduce wasted effort or output;

f) Complete, current, clear and relevant documentation.

0.2. **Objectives**

The overall objective of this document is to provide guidance to EAC partner states in NMRAs in accordance with national and internationally recognized standards. This document provides guidelines for implementing quality management systems in NMRAs of the EAC.

The specific objectives of this document are to:

a) enable the establishment, implementation and maintenance of a QMS in all EAC Partner States NMRAs in accordance with the EAC QMS requirements;

b) Facilitate EAC Partner States NMRAs to develop their quality manuals in accordance with EAC QMS requirements.

0.3. **Scope of EAC Guidelines for implementing QMS requirements**

This document guides EAC Partner States NMRAs in the implementation of EAC QMS requirements.
1. QUALITY MANAGEMENT SYSTEM

1. General

1.1. Scope

These guidelines apply to all directorates, departments, units and sections of the EAC Partner States NMRAs for implementation of EAC QMS requirements.

2. Normative references

These guidelines have been developed according to “EAC QMS requirements, 2014” In addition, the following referenced documents are indispensable for the application of the QMS:


b) ISO/IEC 17025: 2005 - General requirements for the competence of testing and calibration laboratories.

c) ISO/IEC 17020: 2012 Conformity assessment - Requirements for the operation of various types of bodies performing inspection.

d) PI 002_3: 2007 PIC/S - Recommendations on Quality system requirements for pharmaceutical inspectorates EAC Partner states application statutory and legal requirements.

e) EAC Standards, Quality, Metrology and Testing (SQMT) Act (2006) - revised 2013 and any other recognised standard or laws that may be published in the EAC Gazette.

3. Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000: 2005 apply.

For the NMRAs, the following terms and definitions for “product”, “customer” and “Top Management” shall apply:

a) **Customer**: organization or person that receives a product. EXAMPLE Consumer, client, end-user, retailer, beneficiary and purchaser.

NOTE 1: A customer can be internal or external to the organization.

NOTE 2: “Regulated Customer”: Organisation or person who by the nature of their business are subject to regulation by the NMRAs.

NOTE 3: “Unregulated Customer”: Organisation or person who is not subject to regulation by NMRAs.

b) “Outsourced process”: A process that the NMRA needs for its quality management system and which the NMRA chooses to have performed by an external party.

c) “Product”: Applies to regulatory services intended for, or required by, the customer (regulated and/or unregulated customer) and to any intended output resulting from the product realization.
processes of the NMRA (e.g. market authorization or medicine registration certificates, licences, permits, good manufacturing practice certificates, good distribution practice certificates, medicine/drug register)

d) “Top management” person or group of people who directs and controls an NMRA at the highest level.

4. Quality Management System

4.1. General requirements

The NMRA should establish, document, implement and maintain a quality management system that is designed to provide regulatory services aimed at ensuring availability of safe and effective medicines and meeting customer, statutory and legal requirements.

Statutory and legal requirements include national (e.g. National Health Policy, NMRA Acts, etc); regional (EAC policies on medicine regulation) and international (WHO guidelines, etc) obligations.

Implementing and maintaining an effective quality management system is an element of managing an NMRA, for which specific skills in quality management and other management disciplines are necessary.

After initial verification that the quality management system is capable of meeting customer and regulatory requirements and ensuring availability of safe, quality and efficacious Medicines, the NMRA can maintain the effectiveness of its established quality management system through a range of activities, such as:

a) internal quality audits,
b) management review, and
c) independent external quality audits.

Where an NMRA chooses to outsource any process that affects product conformity to requirements, the NMRA should ensure control over such processes. The type and extent of control to be applied to these outsourced processes should be defined within the quality management system.

4.2. Documentation requirements

4.2.1 General

Documented quality management system procedures are required for applicable requirements of “EAC QMS requirements, 2014” and should be consistent with the NMRA’s quality policy.

It is important to recognize that the structure and level of detail required in these procedures should be tailored to the needs of the NMRA, which in turn are dependent on methods used and the skills and qualifications of the NMRA’s personnel performing the activities in question (see also clause 6.2.2 of “EAC QMS requirements, 2014”).
Figure 1: Hierarchy documents of internal origin¹

Figure 2: Hierarchical relationship between documents of external and internal origin²

¹Adopted from International Organization for Standardization, Geneva 2008
²Adopted from Uganda National Drug Authority, Kampala 2010
Documented procedures, including work instructions and flowcharts, define activities and usually describe:

a) what is to be done and by whom,
b) when, where, why and how it is to be done,
c) what materials, equipment and documents are to be used,
d) how an activity is to be monitored and measured, and
e) what records are required.

Documentation should be evaluated with respect to the effectiveness of the quality management system against criteria, such as:

a) functionality (processes and system)
b) human interfaces,
c) resources required,
d) policies and objectives, and
e) interfaces used by NMRAs’ customers and suppliers.

4.2.2 Quality Management

A quality manual is a document specifying the quality management system of organisation. It includes policies for all areas of the business affecting or affected by the quality system. These policies authorize department managers to implement procedures within the boundaries specified in the quality manual.

They also serve to provide a measure for procedures, processes and results.

The organization should establish and maintain a quality manual that includes:

a) the scope of the quality management system, including details of, and justification for, any exclusions (see 1.2 of “EAC QMS REQUIREMENTS, 2014”);
b) the documented procedures established for the quality management system, or reference to them;
c) a description of the interaction between the processes of the quality management system;
d) the NMRAs’ quality policy (showing the NMRs’ commitment to quality);
e) a description of the NMRA (usually in the form of an organization structure).

The policies must cover all areas of the EAC QMS requirements and be traceable (reference) to them. These policies must include:

- how management expects NMRAs operations to function.
- who is responsible to implement these expectations (by function or job title and description).
• where and when the policies are applicable within the organization.

• what interdependencies exist between functions and processes. The quality manual would normally contain no proprietary/confidential information and is usually made available to customers and third party auditors.

The quality manual would normally contain no proprietary/confidential information and is usually made available to customers and third party auditors.

The NMRA should also have the relevant functional level manuals for example the Inspectorate quality manual as per ISO/IEC 17020:2012 and PIC/S PI002-3: 2007 guidelines; the Laboratory quality manual as per ISO/IEC17025:2005 and other functional level manuals as may be required. The functional level manuals should be designed to ensure harmony and consistency with the NMRA’s quality manual.

4.2.3 Control of documents

Controlled documents of the NMRA QMS include:

• Internal documents (generated by the NMRA such as manuals, guidelines, standard operating procedures, specifications, forms, reports, certificates, drug register, guidelines, etc., and

• External documents (such as laws, Acts, statutory regulations; international guidelines, regional guideline, protocols and policies; customer supplied documents etc.).

The system established for the control of internal documents will usually:

a) assign responsibilities for preparation, approval and issue of documents;

b) include periodic review of documents, as required by the quality management system;

c) identify recipients of controlled copies of documents;

d) define a method for recording the implementation date of a document change;

e) ensure that changes and current revision status of document are identified,

f) ensure prompt withdrawal of obsolete copies of controlled documents;

g) ensure that documents of external origin determined by NMRA to be necessary for the planning of QMS are identified;

h) ensure that relevant versions of applicable documents are available at points of use;

i) allow controlled and non-controlled documents to be distinguished; and

j) changes to approved documents are initiated, reviewed and approved in accordance with the procedure for control of documents.
Document control procedures can be assisted by the adoption of a consistent structure for the documents within the quality management system. These procedures should clearly indicate what document control information should be included in each document.

Consideration should be given to the inclusion of:

a) title and scope,
b) document reference number,
c) review due date,
d) date of issue,
e) date effective,
f) date of approval

g) revision status,
h) revision history,
i) originator or author (title, name and signature),
j) person(s) approving it (title, name and signature),
k) person(s) issuing it (title, name and signature),
l) distribution,
m) pagination, and

n) computer file reference, if applicable.

Changes to documents, including computer-based documents, are made by authorized personnel (e.g. persons with an access code to the document file to be changed).

The approval of authorized changes is identified in the document or in its change history. Prevention of unauthorized changes to computer-based documents and data can be facilitated by making “read only” copies available to persons who have a need to use them but are not authorized to change them.

4.2.4 Control of records

Records are a special type of document and should be controlled as described in this clause. Records should be compiled, stored safely, protected from unauthorized access, and protected from unauthorized alteration by the NMRAs. These records should be properly identified, collected, indexed and filed, and readily accessible if needed. They can be stored or copied in any suitable form (e.g. hardcopy or electronic media).

If records are retained on electronic media, consideration of the retention times and accessibility of the records should take into account the degradation of the electronic images and the availability of devices and software needed to access the records. Such copies of records should contain all the relevant information captured in the original records.

Hand-written entries should be made by indelible medium. Persons making authorized entries on forms should do so in clear legible writing, and should confirm the entry by adding their initials, signature or equivalent, and the date.
Good recording practices require the following:

a) enter data and observations as they occur,
b) do not pre-date or postdate records,
c) do not use another person’s initial, signature or equivalent,
d) complete all fields or check-offs when using a form,
e) refer to raw data when transferring data, and have the transcription checked by a second person,
f) check all entries for completeness and correctness, and
g) number the pages to ensure completeness.

If an error is made or detected on a record, it should be corrected in such a manner that the original entry remains legible and the correction is initialled and dated.

If appropriate, the reason for the correction should be recorded. A system should be in place which assures the integrity of electronic records and protects against unauthorized entries.

Record retention period should take into consideration:

a) lifetime of the regulatory service as defined by the NMRAs,
b) legal considerations including national statutory requirements, and
c) the need or advisability of keeping records indefinitely.

NMRAs are required by EAC QMS requirements to define the lifetime of each of regulatory services. In making such a definition, the rationale should be given, but need not be “technical” in nature; e.g., the service lifetime could have a financial or legal basis.

The NMRA should be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of inspection activities. The NMRA should inform the client, in advance, of the information it intends to place in the public domain.

Except for information that the client makes publicly available, or when agreed between the inspection body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and should be regarded as confidential.

NOTE:
Legally enforceable commitments can be, for example, contractual agreements.

When the NMRA is required by law or authorized by contractual commitments to release confidential information, the client or individual concerned should, unless prohibited by law, be notified of the information provided. Information about the client obtained from sources other than the client (e.g. complainant, regulators) should be treated as confidential.

5.0 Management responsibility

Top management should develop the strategic plan, business plan, mission, vision, core values for the whole NMRA. QMS requirements should be clearly identified in the strategic plan and business plan of the NMRA.
5.1 Management commitment

It is important to note the emphasis on “top management” throughout this clause. This is intended to ensure that the quality management system is effective as a result of commitment on the part of management at the highest levels of the NMRAs.

Top management should ensure that processes operate as an effective network. Top management typically analyses and optimizes the interaction of processes, including both realization processes and support processes.

Consideration should be given to:

a) ensuring that the sequence and interaction of processes are designed to achieve the desired results effectively,

b) ensuring that process inputs, activities and outputs are clearly defined and controlled,

c) monitoring inputs and outputs to verify that individual processes are linked and operate effectively,

d) identifying hazards and managing risks,

e) conducting data analysis to facilitate necessary improvement of processes,

f) identifying process owners and process implementers and giving them responsibility and authority,

g) managing each process to achieve the process objectives;

h) appoint the management representative to head the QMS in the organization; and

i) appoint QMS officers (however named) in each directorates or departments and description of their responsibilities and authority.

5.2 Customer focus

The NMRA should identify current and future customer needs, to meet customer requirements and exceed customer expectations. Top Management should ensure that customer requirements are understood and met, by consultative stakeholders meetings and compliance with documented client service charter.

Customer requirements are determined, converted into internal requirements, and communicated to the appropriate staff in the NMRA.

Top management has the responsibility to make certain that customer requirements are understood and the necessary resources are made available, regardless of who in the NMRAs actually undertakes the interaction with the customer.

To successfully discharge this responsibility, top management will have to make sure that resources are available to communicate directly with customers.

Information gathering to this end could involve seeking direct customer input on requirements.
5.3 Quality policy

The quality policy establishes:

a) a commitment to quality and the continuing effectiveness of the quality management system to meet customer and regulatory requirements,

b) the context for quality objectives, and

c) how the NMRA’s objectives relate to its customers’ requirements.

It is important that the NMRA’s quality policy be considered when preparing the overall NMRA policies related to its business operations (e.g., medicines registration, inspection) in order to ensure that all NMRA policies are consistent and supportive of each other.

The quality policy should communicate the NMRA’s commitment to quality, and its overall vision of what quality means to the NMRA’s business and customers. Sub-clause 4.2.1 of the “EAC QMS requirements, 2014” requires the NMRA to state this quality policy in writing.

In order to demonstrate that the NMRA is committed to implementing its quality policy, it will need to identify clear, overall quality goals for the business which are directly relevant to the NMRA and its customers.

Top management’s commitment to the quality policy should be visible, active and effectively communicated. For example, a publicly displayed copy of the quality policy signed by top management is one method which may be used to show that commitment to both employees and customers. Another method is to present and discuss the quality policy at NMRA meetings throughout the year. Top management’s commitment is best communicated through its decisions and actions.

All employees need to understand the quality policy and how it affects them. Top management has to ensure the NMRA decides on the methods which will be used to achieve this understanding.

The quality policy also needs to be reviewed from time to time to determine if it accurately reflects the current quality related goals and objectives of the NMRA. This review is often carried out during the management review required in 5.6.

Top management ensures that the quality policy is communicated to all employees; it is included in new employee training and training on the QMS; and it is posted in prominent places throughout the facility. Top Management reviews the quality policy at each annual management review meeting to determine the policy’s continuing suitability.

5.4 Planning

5.4.1 Quality objectives

In order to put the NMRA’s quality policy and the strategic plan into effect, top management needs to establish clearly defined quality objectives which the NMRA can aim for. In setting objectives and any associated targets, timeframes for achieving the targets are usually established.

Quality objectives should be specific, measurable, attainable, realistic and time-bound (SMART) and related to outcomes, and should be aimed at Directorates/Departments/Units within the NMRA typically establish
Directorate/Departmental/Unit objectives which follow from the overall NMRAs objectives and relate to their specific activities. Quality objectives provide one of the inputs into quality management system planning.

The quality objectives should be reviewed at each annual management review meeting.

5.4.2 Quality management system planning

This clause deals with planning in two areas of activity:

a) with respect to the quality management system, and

b) with respect to service realization.

In order that the quality management system can meet the requirements of EAC QMS requirements, most of this planning will be at the initial stages of development and implementation of the quality management system.

This planning can assist the NMRAs to fulfil its quality objectives. Since quality objectives can, and indeed should, change over time, this planning is likely to be ongoing, and can assist the quality management system to continue to be effective during and after changes.

Inputs into quality management system planning may include:

a) quality policy;

b) quality objectives;

c) regulatory requirements;

d) quality management system standards; and

e) changes required (e.g. as a result of Management Review and/or corrective and preventive action).

The outputs from quality management system planning that demonstrate meeting EAC QMS requirements and the quality objectives may include:

a) the quality manual and supporting documentation

b) results of gap analysis

c) actions plans

d) results of action plans

e) results of gap analysis

e) results of action plans

e) results of change management

The QMS planning should be reflected in the strategic plan (covering five years) for the entire NMRA, and annual work plans for each functional directorate or department.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

This requirement is usually achieved by means of documented position descriptions which include responsibilities and authorities charts which describe the interrelation of personnel. As this documentation forms part of the quality management system it has to be controlled (see 4.2.3). Responsibilities and authorities (including those for substitute personnel) can also be included in documented procedures. NMRAs can “map” quality management system processes to show the linkages between processes and the responsibilities associated with activities to be performed.
Job descriptions and the organizational structure are reviewed and approved periodically by top management for adequacy.

These documents are available throughout the company to help employees understand their responsibilities and authorities.

A responsibility matrix in accordance with each applicable clause in the EAC QMS requirements, showing process owner and process implementers for the established directorates, departments and units within the NMRA should be developed and annexed to the Quality Manual of the NMRA.

5.5.2 Management Representative

The NMRA top management should appoint a member of organizational management as a Management Representative (Head of Quality Management Department) with responsibility and authority to manage the QMS. He/she reports directly to the Chief Executive Officer of the NMRA to enable quick decision making and access/authorization of resources needed by the QMS. The MR should perform the functions as required by EAC QMS requirements.

The Management Representative should coordinate all appointed QMS officers in their functional departments for the effective implementation of QMS. The Directorates or departmental QMS officers should functionally report to the Head of Quality Management Department.

The functions of the Management Representative (MR) may be totally related to quality management system activities or may be in conjunction with other functions and responsibilities within the NMRA. If the MR has other functions to perform, there should be no conflict of interest between the responsibilities for the other functions and those relating to the quality management system. The management representative may, in turn, delegate responsibilities for the quality management system to others in the NMRA. However, only one member of management may be designated by the NMRA top management as its management representative.

5.5.3 Internal communication

For a quality management system to work effectively, effective communication is essential. Top management needs to establish the processes which encourage people within the NRAs to communicate at all levels, without a ‘shoot the messenger carrying bad news’ syndrome. To be effective, communication processes should provide the ability to:

a) transmit and receive information quickly and act on it,
b) build mutual trust,
c) identify examples of effective methods and approaches within the quality management system, and
d) identify opportunities for improvement.

Quality management system related information should be clear and understandable and adapted to the personnel meant to use it. Such information relates to top management’s expectations regarding the quality management system performance and information related to quality management system implementation and effectiveness (for example, results of internal quality audits).
[see 8.2.2], management reviews [see 5.6], external assessments, and regulatory inspections).

Examples of communication methods include:

a) posting information on bulletin boards;

b) holding meetings; and/or

c) circulating information via e-mail.

Internal communication can be facilitated by personnel having familiarity with a variety of activities or functions within the NMRAs. This familiarity can be enhanced, for example, by placing personnel from one function into another function as a part of their personal development.

5.6 Management review

5.6.1 General

Top management should review the quality management system on a regular basis; annually could be acceptable for an established and effective quality management system. If changes are planned or being implemented, more frequent review periods are normally needed. This review should be done before the budget preparation.

To ensure that the entire quality management system is covered, with particular attention being paid to those items needing management consideration, the management review should be carefully planned, organized, and attended. People who participate in reviews should be able to contribute and take action on any outcomes.

The method of carrying out the review should suit the NMRAs’ business practices and could consist of:

a) formal face-to-face management meetings with an agenda, minutes and formally identified action points and implementation plan, and

b) partial reviews at various levels within an NMRAs, reporting to the executive management who review the reports.

Management review records may be in any form which suits the NMRAs, such as notes in a daybook, formal meeting minutes or notes, which can be produced, distributed and stored on paper or electronically.

5.6.2 Review input

To ensure that the entire quality management system is covered, a consistent approach should be followed to ensure that the review covers:

a) the continued suitability of the quality policy and objectives with respect to current needs,

b) how the quality management system is working and whether objectives are being met,

c) analysis of process performance,

d) quality problems and actions taken,

e) customer feedback, including customer complaints,

f) quality audit reports (both internal and external),
g) areas for improvement/changes needed,
h) outstanding actions from previous reviews, and
i) new or revised regulatory requirements

Individual problems should be dealt with as they occur, without waiting for the next management review. The management review is intended to see if the same problems re-occur, if the action taken is appropriate and if the customer and regulatory requirements are being met.

However, the attention given to individual problems should be complemented by a review of the entire quality management system in order to see if it is effective in meeting the NMRAs' quality objectives.

Management reviews should not be devoted to repeatedly discussing relatively insignificant problems. Rather, the management review will be more useful if it is carefully considering reports to obtain a clear overview and not just reviewing a list of small details.

Top management has to analyse and decide on significant trends. The analysis of data as required by clause 8.4 of EAC QMS requirements should also be included in the management review. Other inputs which could be considered include:

a) training needs,
b) supplier problems, and
c) equipment needs, working environment and maintenance.

After identifying these issues and needs, and depending on the outcome of the review, the NMRA can develop and revise its quality, strategic and business plans for future activities. For example, as improvements are achieved and problems eliminated, the NMRA can review the nature and level of its inspection controls. Are they still essential or can some savings be made by modifying them or adopting other controls, since the cause of the problem has been addressed? If the rate of complaints is found to be increasing, a decision can be taken to explore the reasons and to set appropriate objectives.

Reviews and audits are not the same. This is best understood from the fact that the results of audits are inputs to the management review.

5.6.3 Review output

Review output should include a statement regarding the effectiveness of the processes established for the achievement of the quality policy and objectives, and the extent to which those objectives have been achieved based on the established respective metrics. Records of the review should address all points of the review together with a description of any corrective or preventive action to be taken, the responsibility for such actions, the resources which may be needed to complete such actions, and target dates for completion, if known.

6.0 Resource management

6.1 Provision of resources

The provision and maintenance of adequate resources is a prerequisite to the effective initiation, maintenance, and management of quality management system processes. The nature and quantity of such resources will be
determined by the processes involved. Consideration needs to be given by the NMRAs’ management to the identification and provision of adequate resources needed to implement its quality policy and to achieve its objectives, as well as to satisfy customer requirements inclusive of applicable regulatory requirements.

Resources can be people, infrastructure, work environment, information, and financial resources. Responsibility for provision of resources resides with the NMRAs regardless of whether associated processes are performed by the NMRAs itself or outsourced.

Types of resources - financial, human, physical and technological resources

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements should be competent on the basis of appropriate education, training, skills and experience. Conformity to service requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2 Competence, awareness and training

The NMRAs needs to regularly review the experience, qualifications, capabilities and abilities of personnel, especially in those areas which can affect the safety and effectiveness of the regulated services.

Work allocation and assignment of personnel (clause 6.2.1), management review (clause 5.6), corrective action (clause 8.5.2), preventive action (clause 8.5.3) and internal quality audit (clause 8.2.2) are all likely to identify areas which could indicate a need for improving the competence of personnel and the means for such improvement, be it replacement of personnel, further education or training.

All regulatory activities require competence before they can be performed properly or safely (e.g. medicines evaluation, GMP inspection, internal quality auditing). It may be necessary for people to be qualified or formally certified for some activities. Education and training provided for full time, part-time, and contract personnel, should be tailored to the person’s assignment.

Such training and education should cover:

a) the nature of the business,
b) applicable regulations,
c) the quality policy and other internal policies,
d) the role of the employee, and
e) the procedures and instructions of relevance to them.

Training may be carried out in stages, and usually includes follow-up or refresher training, induction training, specific on job training, follow-up training and refresher training as needed and planned. Persons and functions who are assigned responsibility via the documented procedures of the quality management system, should receive training on those procedures.

NMRAs should evaluate the effectiveness of training or other actions taken in order to ensure competency. Evaluation can consist of polling the trained employee to assess
whether he or she feels they have learned the required information, evaluating the work performance of the trained individual, and reviewing the trainer assessment of training effectiveness.

NMRAs should maintain records which show what competencies an employee possesses. Records are also kept of the training an employee has received and any results of that training. Records which show that the training course has been successfully completed and that competence has been achieved can be as simple or complex as necessary. At their simplest, the records may consist of ‘sign-off’ to confirm that personnel can now use certain equipment, carry out specific processes or follow certain procedures. The records should include a clear statement that a person is now deemed to be competent to do the task for which they were trained. The effectiveness of any further education and training should be re-evaluated after a period, to ensure competence achieved and continued competence of the staff.

Training should be carried out by personnel with appropriate skills, qualifications and experience. Records are typically kept to document the qualifications of the personnel used as trainers. The level of documentation required for processes is usually determined by the level of competence required for the personnel intended to perform that process.

6.2.3 Impartiality and independence

f) The NMRA Top management should establish core values that include impartiality, independence and equity, and proactively communicate and ensure all staff understand them.

g) should establish a mechanism for declaration and regular update of personal interest. This interest should periodically be reviewed to identify potential conflict of interest.

h) The NMRA should ensure declaration of interest by staff and external experts with a clearly defined scope. This may be in form of completion of declaration form before engaging in business dealing with the regulated products.

i) The NMRA should identify areas of potential risks of impartially e.g. where NMRA staff are performing regulatory functions with an external party and establish mechanisms to mitigate them

j) The NMRA should identify areas of interest to be declared by staff and external experts’ namely financial interests, work related to the regulated industry including pharmaceutical, food, cosmetic industry and links to any other industry related to the areas regulated.

6.2.4 Confidentiality

a) The NMRA should identify areas that require confidentiality and review them on periodic basis e.g. personal data, client and customer confidential information like patient data, drug master file. This should not unnecessarily impede public right of access to information.
b) The NMRA should have a mechanism for declaration of confidentiality in accordance to existing provisions of the relevant laws.

c) The NMRA should establish a communication policy on information generated within the organization taking into consideration the legal requirements, intellectual property rights and personal data.

d) The NMRA should ensure confidential client information e.g. product dossiers, is handled and stored in an appropriate and secure environment.

6.3 Infrastructure

The NMRAs should ensure that buildings, workspace and associated utilities, process equipment (both hardware and software), and support services (such as transport, communication or information systems) are adequate and effectively utilized and maintained.

Documented procedures should be available for maintenance of buildings and associated utilities, process equipment and support services.

The NMR should determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and c) supporting services (such as transport, communication or information systems).

As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure material / product conformity. Maintenance requirements are documented in preventive maintenance plans, sanitation plans and building maintenance plans.

6.4 Work environment

Quality of services can be influenced by the service delivery work environment. Work environment relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather, organization culture, confidentiality, motivation and rewarding system, capacity/skills development).

7.0 Product realization

The NMRA should provide regulatory services as indicated in the service charter within the specified timelines. The regulatory services includes: Inspection and enforcement, evaluation and registration of medicines, cosmetics and medical devices, licensing of premises, cGMP, Pharmacovigilance, clinical trials, import and export control, laboratory quality control testing and analysis, public education and information sharing on regulated products and services.

Provision of services should be in line with existing legal and statutory requirements within the EAC partner states NMRAs.
7.1 Planning of services realization

Consistent with 5.4.2 of EAC QMS requirements, which requires the planning of the quality management system, clause 7.1 of EAC QMS requirements requires the planning of the processes related to the realization of service.

In planning of product realization the NMRA should consider the scope of its quality management system.

In planning product realization the following should be considered:

a) Quality objectives and requirements for the product;

b) the need to establish processes and documents, and to provide resources specific to the product;

c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4 as appropriate).

The output of this planning should be in a form suitable for the organization’s method of operations.

There is need to establish documented requirements for risk management throughout the service realization and that records of same are to be maintained. The key elements of risk management include risk analysis, risk evaluation, and risk control.

7.2 Customer related process

7.2.1 Determination of requirements related to the service

The NMRA should determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities. This can be done through having consultative meetings, circulars, training workshops, seminars, feedback (suggestion) boxes,

b) requirements not stated by the customer but necessary for specified or intended use, where known such examples could include staff and partners recommendation on improvement service delivery,

c) statutory and regulatory requirements applicable to the product. These may be obtained from national, regional (e.g. EAC Standardization, Quality Assurance, Metrology and Testing Act) and international laws and regulations, and

d) any additional requirements considered necessary by the NMRA which may include internally generated requirements.

7.2.2 Review of requirements related to the services

The NMRA should review the requirements related to provision of the services to the customers. These may include requirements for licensing, product registration and market
authorization, approvals/permits, GMP inspection and others.

This review should be conducted prior to the organization’s commitment to supply a product to the customer and should ensure that:

a) product requirements are defined,

b) product requirements differing from those previously expressed are resolved, and

c) the NMRA has the ability to meet the defined or new requirements.

Records of the results of the review and actions arising from the review should be maintained (clause 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements should be confirmed by the organization before acceptance.

7.2.3 Customer communication

The NMRA should determine and implement effective arrangements for communicating with customers in relation to:

a) Service information. This can be in form of guidelines, circulars, forms etc. to the stakeholders, importers, manufacturers and the general public,

b) enquiries, new service information including amendments, and

c) customer feedback, including customer complaints

Good communication between the NMRA and the customer is essential to identify, mitigate and resolve any misunderstandings, and, if possible, the NMRAs should develop communication processes and should appoint someone to liaise with the customers.

7.2.4 Complaints and appeals

Customer complaints and appeals are the most common indicators of service deficiency which may be subject to correction and corrective or preventive action to prevent recurrence of the problem. Any customer complaint and appeal received by the NMRAs on a service should be evaluated. Customer complaints and appeals can be of either internal or external origin.

Each directorate, department or unit of the NMRA should consider each other within the same NMRA to be customers. In this case internal complaints can be treated as customer complaints and processed accordingly. If non-conforming service is involved, this should also be handled according to the requirements of clause 8.3 of the “EAC QMS Requirements, 2014”.

In evaluating the complaints and appeals, it should be considered whether:

a) the service fails to conform to its specification, or

b) conforms to its specifications but nevertheless causes problems in use (such a complaint may be caused by design fault).

The NMRAs should formally designate a person(s) (by role or position) to collect and coordinate all written and oral customer complaints and appeals about regulatory services. Such person(s) should directly report to the Head of NMRA.
The documented complaints and appeals system should cover the following:

a) establishing responsibility,

b) evaluating the complaint and appeals,

c) creating records and statistical summaries to enable the major causes of complaints and appeals to be determined,

d) taking any corrective action,

e) filing of customer correspondence and other relevant records (the retention time for these should be defined), and

f) the records of complaint and appeals investigations should contain enough information to show that the complaint and appeals was properly reviewed, for example a determination of whether or not there was an actual service failure to perform as per specifications.

An investigation record typically includes:

a) the name of the service,

b) the date the complaint or appeal was received,

c) the control number used,

d) the name and address of the complainant or appellant,

e) the nature of the complaint and appeal,

f) the results of the investigation,

g) the corrective action taken,

h) the justification if no action is taken,

i) the dates of the investigation,

j) the name of the investigator, and

k) the reply (if any) to the complainant or appellant.

7.2.5 Complaints and appeals process

The NMRA should have a documented process to receive, evaluate and make decisions on complaints and appeals. A description of the handling process for complaints and appeals should be available to any interested party upon request.

Upon receipt of a complaint and appeal, the NMRA should confirm whether the complaint relates to its activities for which it is responsible and, if so, should deal with it.

The NMRA should be responsible for all decisions at all levels of the handling process for complaints and appeals.

Investigation and decision on appeals should not result in any discriminatory actions.

The handling process for complaints and appeals should include at least the following elements and methods:

a) a description of the process for receiving,

b) validating,

c) investigating the complaint or appeal, and deciding what actions are to be taken in response to it,
d) tracking and recording complaints and appeals, including actions undertaken to resolve them, and solutions of the problem without bias or judgment;

b) the review, verification and validation that are appropriate to each design and development stage, and;

c) the responsibilities and authorities for design and development.

The NMRA should manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output should be updated, as appropriate, as the design and development progresses.

Design and development review, verification and validation have distinct purposes. They may be conducted and recorded separately or in any combination, as suitable for the regulatory services and the NMRA

7.3.2 Design and development inputs

Inputs relating to regulatory service requirements should be determined and records maintained. These inputs should include:

a) functional and performance requirements which include registration and inspection requirements; timely delivery and quality of service,

b) applicable statutory and regulatory requirements namely the drug laws, new regulations on registration and inspections for the regulated products,
c) where applicable, information derived from previous similar designs, and

b) characteristics of equipment, sources of literature as appropriate

c) characteristics of the service such as reliability, availability and

timeliness

d) other requirements essential for design and development like customer requirements.

d) Templates of the reports, checklists, templates for certificates (physical characteristics).

e) Specifications of the competency (education, skills) of an inspector.

The inputs should be reviewed for adequacy. Requirements should be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development should be in a form suitable for verification against the design and development input and should be approved prior to release.

a) Design and development outputs should:

b) meet the input requirements for design and development,

b) meet the input requirements for design and development,

c) provide appropriate information for purchasing, production and service provision,

c) provide appropriate information for purchasing, production and service provision,

d) contain or reference regulatory service acceptance criteria, and

d) contain or reference regulatory service acceptance criteria, and

e) specify the characteristics of the regulatory service that are essential for its safe and proper use.

e) specify the characteristics of the regulatory service that are essential for its safe and proper use.

Design output for inspection service includes:

Design output for inspection service includes:

a) steps/description of the inspection process;

a) steps/description of the inspection process;

b) characteristics of equipment, sources of literature as appropriate

b) characteristics of equipment, sources of literature as appropriate

c) characteristics of the service such as reliability, robustness and timeliness

c) characteristics of the service such as reliability, robustness and timeliness

d) Templates of the reports, checklists, templates for certificates (physical characteristics).

d) Templates of the reports, checklists, templates for certificates (physical characteristics).

e) Specifications of the competency (education, skills) of an inspector.

Design output for product registration service includes:

Design output for product registration service includes:

a) steps/description of the registration process

a) steps/description of the registration process

b) characteristics of equipment, sources of literature as appropriate

b) characteristics of equipment, sources of literature as appropriate

c) characteristics of the service such as reliability, robustness and timeliness

c) characteristics of the service such as reliability, robustness and timeliness

d) Templates of the reports, checklists, templates for certificates (physical characteristics).

d) Templates of the reports, checklists, templates for certificates (physical characteristics).

e) Specifications of the competency (education, skills) of an evaluator.

e) Specifications of the competency (education, skills) of an evaluator.

f) Attributes of the inspectors for example courtesy, honesty and veracity (behavioural) reliability, punctuality and availability (temporal), punctuality; and

f) Attributes of the inspectors for example courtesy, honesty and veracity (behavioural) reliability, punctuality and availability (temporal), punctuality; and

g) Inspection fees

g) Inspection fees

Design output for product registration service includes:

Design output for product registration service includes:

a) steps/description of the registration process

a) steps/description of the registration process

b) characteristics of equipment, sources of literature as appropriate

b) characteristics of equipment, sources of literature as appropriate

c) characteristics of the service such as reliability, robustness and timeliness

c) characteristics of the service such as reliability, robustness and timeliness

d) Templates of the reports, checklists, templates for certificates (physical characteristics).

d) Templates of the reports, checklists, templates for certificates (physical characteristics).

e) Specifications of the competency (education, skills) of an inspector.

e) Specifications of the competency (education, skills) of an evaluator.

f) Attributes of the inspectors for example courtesy, honesty and veracity (behavioural) reliability, punctuality and availability (temporal), punctuality; and

f) Attributes of the inspectors for example courtesy, honesty and veracity (behavioural) reliability, punctuality and availability (temporal), punctuality; and

g) Inspection fees

g) Inspection fees

Design output for product registration service includes:


diligence and veracity (behavioural) reliability, and availability (temporal)

g) Product Registration fees

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development should be performed in accordance with planned arrangements:

a) to evaluate the ability of the results of design and development to meet statutory and customer requirements

b) to identify any problems and propose necessary actions.

Participants in such reviews should include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions should be maintained.

7.3.5 Design and development verification

Verification should be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions should be maintained.

7.3.6 Design and development validation

Design and development validation should be performed in accordance with planned arrangements to ensure that the resulting regulatory service is capable of meeting the statutory and customer requirements for the intended purpose. Wherever practicable, validation should be completed prior implementation of the regulatory service. Records of the results of validation and any necessary actions should be maintained. Pilot the designed regulatory services by performing several inspections or registrations and evaluate the result of the service before implementation.

7.3.7 Control of design and development changes

Design and development changes should be identified and records maintained. The changes should be reviewed, verified and validated, as appropriate, and approved before implementation.

The review of design and development changes should include evaluation of the effect of the changes on constituent parts and regulatory services already delivered. Records of the results of the review of changes and any necessary actions should be

7.4 Purchasing

7.4.1 Purchasing process

The NMRA should have a documented procedure for purchasing to ensure that purchased material/product/services conform to the specified purchase requirements. The procedure should require terms and conditions in the contract for supply of goods and services to outline the extent of control required for suppliers. Suppliers should be evaluated and selected based on their ability to supply material/product in accordance with requirements as outlined in the procedure.

Criteria for selection, evaluation and re-evaluation should be documented in the contract. Records of the evaluation and any
necessary actions should be maintained as quality records according to the procedure for control of records.

Procurements in most NMRAs are regulated by national laws. The NMRA should therefore comply with such applicable national legal procurement requirements.

The selection of suppliers is a process consisting of establishing criteria for, evaluating; selecting and on-going monitoring of a supplier. The application of the process should be commensurate with the service or service being purchased.

An evaluation can range from auditing of the supplier’s quality management system by the NMRAs, to the acceptance of evaluation reports or approval by reference to historical data like records of past performance, certified services, or quality management system registration.

Regardless of the method of evaluation, the NMRAs is required to demonstrate that they have control over the outsourced process by possessing objective evidence that formal consideration was given to the evaluation of the outsourced process, and that the selection of a supplier was based on appraisals appropriate to the service or service being purchased and the supplier’s ability to enable the NMRAs to meet the customer and regulatory requirements of the regulated product.

When monitoring the performance of suppliers, the NMRAs should consider a supplier’s third party certification status, compliance trends, and conformance history. The NMRAs should define the frequency of such performance monitoring. The NMRAs should also include in the supplier monitoring activities the need for their registration body to visit the supplier for the purpose of obtaining objective evidence that the outsourced processes are under control and that the services or product conform to the NMRAs’ specified requirements which may include customer and regulatory requirements.

The NMRAs’ purchasing data should define appropriate specifications to the supplier to ensure the quality of the purchased service (including technical service requirements), calibration services, and inspection and test activities (including record keeping requirements).

The NMRAs can make reference to applicable technical information such as national or international standards/regulations, test methods, etc. Another approach is for information to be clearly and precisely stated to the supplier on the purchase order. Responsibility for reviewing and approving the purchasing data should be clearly assigned to appropriate personnel to prevent purchasing incorrect materials. The revision status of documents referenced in the purchasing data should be identified to ensure that the correct version of materials is purchased.
Purchasing documents and records may need to be identified and retained for traceability purposes to the extent required by the NMRA. This means that when evaluating the traceability requirements, consideration should be given to what purchasing information and records may also need to be retained to facilitate traceability. For example, if it was important to know to what specification revision a purchased services was ordered, then this information should be kept as part of the purchasing documents or records.

7.4.2 Purchase Information

The NMRA should ensure the adequacy of specified purchase requirements prior to communication to the supplier per process defined in procedure procurement document. Purchase information communicated to the suppliers contains the appropriate data needed to clearly and fully describe requirements for purchased materials and services including suppliers profiles requirements, approval or qualification of product as well as QMS requirements.

7.4.3 Verification of purchased product

The NMRA has an overall responsibility for ensuring the quality of purchased products. Inspection of purchased product for conformity of purchase specification is important for the NMRA to ensure that the purchased product fulfills specified requirements for quality. If the purchased service is claimed to conform to the supplier’s specification, the NMRA should check that the service meets the agreed specification.

This check may be accomplished by various approaches, such as qualification of suppliers, certificates of conformance, skip lot testing, 100% or sampling inspection, as determined by the requirements of the NMRAs’ quality management system.

The NMRAs’ procedures should specify the method of verifying that consignments received are in accordance with specifications, are complete, have proper identity and are undamaged. The procedures should also include provisions for verifying that incoming service is accompanied by the required supporting documentation (e.g. certificates of conformity, acceptance test reports, etc.). Appropriate action in the event of nonconformities should be specified (see clause 8.3) so that they can be dealt with in a consistent manner and without undue delay, including identification, segregation and documentation.

Analysis of previous receiving inspection data, in-house rejection history or customer complaints will influence the NMRA’s decisions regarding the amount of inspection required, and the need to reassess a supplier. Verification of purchased service does not imply that incoming service has to be inspected and tested by the NMRAs. Incoming inspection may not be required if the necessary confidence in the service can be obtained by other defined processes or procedures, particularly if the information given by a supplier is considered sufficient. The NMRAs’ procedures should define who is authorized to allow incoming service to be used before conformance to specified requirements for quality is demonstrated.
Such a procedure ensures that the decision is being taken at a level in the NMRAs which is aware of the possible impact on service realization if the incoming services do not subsequently meet the requirements.

The NMRAs’ procedures should also define how such service will be positively identified and controlled in the event that subsequent inspection finds nonconformities, in order to facilitate corrective action. These requirements apply to all services received from outside the NMRAs’ quality management system, whether payment occurs or not.

Outsourced services should be subjected to the same procedure as described above. Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customers, statutory and regulatory requirements.

The type and extent of control to be applied to the outsourced process can be influenced by factors such as:

a) the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the application of 7.4.

7.5 Production and service provision

7.5.1 Control of production and service provision

The NMRA should plan and carry out service provision under controlled conditions.

Controlled conditions should include,

a) the availability of information that describes the characteristics of the service,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring equipment,

e) the implementation of monitoring and measurement, and

f) the implementation of service delivery and post-delivery activities.

7.5.2 Validation of processes for production and service provision

7.5.2.1 General requirements

The validation of a process is the mechanism or system used by NMRAs to plan, obtain data, record data, and interpret data associated with a particular process.

These activities can be considered to fall into a model consisting of four phases:

a) review and approval of service specifications/requirements;

b) an initial qualification of the equipment used and provision of necessary services - also known as installation qualification (IQ) e.g. equipment for Management Information System (MIS);
c) a demonstration that the process will produce acceptable results and establishment of limits (worst case) of the process parameters - also known as operational qualification (OQ); and

d) and establishment of long term process stability - also known as performance qualification (PQ).

When validation is performed either by the NMRAs or supplier, the validation should include the following:

a) the accuracy and variability of the process parameters, including the settings of the equipment used,
b) the skill, capability and knowledge of personnel to conform to quality requirements,
c) the adequacy of control of any specific environmental parameters,
d) the certification records maintained for personnel e.g. inspectors, processes and equipment, as appropriate, and
e) the appropriateness of the process result.

Any change applied to a service delivery process has to include the consideration for conducting process revalidation and/or for conducting revalidation of the service being produced by the process.

Some processes require that personnel to have extra training and/or be specially qualified or the process itself should have specific approval.

7.5.2.2 Statistical methods and tools for process validation

There are many methods and tools which can be used in process validation. Control charts, capability studies, designed experiments, tolerance analysis, robust design methods, failure modes and effects analysis (FMEA), sampling plans, and mistake-proofing are some of the examples.

7.5.2.3. Computer software used in process control

The requirements of the “EAC QMS Requirements, 2014” regarding the validation of the application of computer software (e.g. MIS) used in process control apply, whether or not such software is purchased, developed, maintained, or modified for automated service or process control purposes. Guidance on the validation of the application of computer software is available in, for example, Good Automated Manufacturing Practice (GAMP) guidelines.

7.5.3 Identification and traceability

To ensure identification and traceability of EAC NMRAs' products, NMRA should develop a procedure for Identification and Traceability. The NMRA should control the unique identification of the certificates, licenses, permits and product registration numbers given to its customers and maintain records.

7.5.4 Customer property

The NMRA should identify responsibilities in relation to property and other assets owned by customers but are under the control of the NMRA, in order to protect the value of the property.
Examples of such property are:

a) samples e.g. drug samples taken for QC testing purposes, confiscated drugs and market authorization product samples,

b) dossiers and applications forms,

c) services provided on behalf of the customer (such as transport of customer property to a third party), and

d) customer intellectual property (including specifications, drawings, site master files for pharmaceutical manufacturing facilities and proprietary information).

e) Pro-forma invoices,

f) drug promotional materials,

g) certificates, and

h) other information and documentation supplied by the customer.

The NMRAs retains the responsibility for the protection and preservation (see clause 7.5.5) of customer property awaiting further processing when it provides these to external body e.g. external laboratory for services such as product testing and analysis.

7.5.5 Preservation of product

The top Management of EAC NMRAs should define and implemented processes for ensuring the integrity of the organization’s and customer products.

The NMRA should preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation should include identification, handling, packaging, storage and protection. Preservation should also apply to the constituent parts of a product.

7.6 Control of monitoring and measuring equipment

The intent of the requirements is to give the NMRAs confidence in the monitoring and measuring equipment which it uses to ensure that what is being controlled meets customer and regulatory requirements.

NMRAs should determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The NMRA should establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment should:

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification should be recorded (see clause 4.2.4);

b) be adjusted or re-adjusted as necessary;
c) have identification in order to determine its calibration status;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the NMRA should assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The NMRA should take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification should be maintained (see clause 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application should be confirmed. This should be undertaken prior to initial use and reconfirmed as necessary.

Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

Statistical methods are important in showing which monitoring and measuring devices are used in a manner which ensures measurement uncertainty is known and is consistent with the required measurement capability.

The requirements of this clause also should be applied by the NMRAs when demonstrating the conformity of the service to the specified requirements.

Documented procedures should include details of equipment type, unique identification, and location, frequency of checks, check method, and acceptance criteria.

Where appropriate, measurement equipment having a significant influence on the results of the inspection should be calibrated before being put into service, and thereafter calibrated according to an established programme.

The overall programme of calibration of equipment should be designed and operated so as to ensure that, wherever applicable, measurements made by the inspection body are traceable to national or international standards of measurement, where available.

Where traceability to national or international standards of measurement is not applicable, the inspection body should maintain evidence of correlation or accuracy of inspection results. Reference standards of measurement held by the inspection body should be used for calibration only and for no other purpose. Reference standards of measurement should be calibrated providing traceability to a national or international standard of measurement.

Where relevant, equipment should be subjected to in-service checks between regular recalibrations.

Reference materials should, where possible, be traceable to national or international reference materials, where they exist.
8.0 Measurement, analysis and improvement

8.1 General

The EAC NMRAs top management should define, plan and implement procedures:

a) to measure, monitor and analyse work processes and products, and functioning of the QMS (e.g., to measure effectiveness in meeting customer requirements);

b) to identify system improvement opportunities (e.g., revising work product requirements to better reflect customer needs); and,

c) to analyse, track, and trend complaints and feedback, corrective actions, and to identify system problems.

8.2 Monitoring and measurement

8.2.1 Customer Satisfaction

Management should recognise that many sources exist for obtaining customer-related information. This information is useful for providing feedback related to the quality of services. The NMRAs should identify relevant sources of such information and establish an effective process to collect, analyse and use the information for monitoring quality problems. The process established has to be documented, so that regulatory requirements are met.

Examples of customer-related information that demonstrates whether or not the requirements of customers and other interested parties have been met include:

a) customer and user surveys,

b) feedback on aspects of service,

c) customer complaints,

d) customer requirements and contract information,

e) market needs,

f) regulatory agency compliance-related communications,

g) peer-reviewed journals, service delivery data,

h) information relating to competition.

8.2.2 Internal audit

The NMRA should conduct internal audits at planned intervals but at least once every year to determine whether the quality management system:

a) conforms to the planned arrangements (see clause 7.1), to the EAC QMS requirements and to the quality management system requirements established by the NMRA, and

b) is effectively implemented and maintained.
In addition to the periodic internal quality audits, a special internal quality audit may be initiated for the following purposes:

a) when evaluating the quality management system initially;

b) when verifying that the quality management system continues to meet specified requirements and is being implemented;

c) when undergoing significant changes in functional areas, for example, revising procedures;

d) when investigating safety, performance or dependability of the services which are, or which are suspected to be, in jeopardy due to nonconformities; and

e) when verifying which required corrective actions have been taken and have been effective.

Planning for internal quality audits should be flexible in order to permit changes in emphasis based on findings and objective evidence obtained during the audit.

Relevant input from the area to be audited, as well as from other interested parties such as customers, corporate audit plans, or third-party assessment NMRAs, should be considered in the development of internal audit plans. All NMRA functional areas including the QMS directorate or department (however named) should be audited.

A series of limited, well-defined audits can be as effective as one single comprehensive audit. Such an audit system can be operated flexibly to give special, or repeat, attention to any areas of weakness or of other concern.

Internal audits can be partially or fully subcontracted.

The results of audits are usually stated in a written report (see clause 4.2.4) which indicates the deficiencies found. Avoiding undue delay is usually accomplished by including appropriate target dates for responding to audit findings. The audit results have to be communicated, and should be used as an input to management reviews (see clause 5.6.2).

8.2.3 Monitoring and measurement of processes

The NMRA should apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods should demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action should be taken, as appropriate.

When determining suitable methods, it is advisable that the NMRA consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to service requirements and on the effectiveness of the quality management system.

The NMRA should develop procedures for monitoring and measuring of the processes as well services provided to the customer.

Each step of the implementation process should be measured based on the different levels of results in the monitoring and evaluation framework. Mechanisms to be adopted monitoring and measurement of processes include; peer review, second assessment.
The design to be adopted include quantitative for tangible and qualitative for non-tangible aspects of process; inputs, activities, outputs, outcomes and impact.

The information generated from the monitoring and measurement processes should guide the management in the decision making process and process improvement. Decisions made by the management should be in a standardized format and should be validated before release.

Dimensions of quality of service to be monitored and measured may include: time and timeliness, completeness, consistency, and accuracy.

8.2.4 Monitoring and measurement of product

The NMRA should monitor and measure the characteristics of the service to verify that service requirements have been met. This should be carried out at appropriate stages of the service realization process in accordance with the planned arrangements (see clause 7.1). Evidence of conformity with the acceptance criteria should be maintained.

Records should indicate the person(s) authorizing release of service for delivery to the customer (see clause 4.2.4).

The release of service and delivery of service to the customer should not proceed until the planned arrangements (see clause 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of nonconforming product

The management of the NMRAs should ensure the establishment and implementation of an effective process and SOP to provide for review and disposition of identified nonconformities. Nonconforming product includes nonconforming service occurring in the NMRAs’ own facilities as well as to nonconforming product received by the NMRAs.

Staff in the NMRAs should be encouraged to report nonconformities at any stage of a process in order to ensure timely detection and disposition of nonconformities.

Procedures established and maintained by the NMRAs should have the following purposes:

a) to determine which product is involved in the nonconformity, for example, what service time interval, service machines or services are involved;

b) to identify the nonconforming product to make sure that it can be distinguished from the conforming product (see clause 7.5.3);

c) to document the existence and source of the nonconformity;

d) to evaluate the nature of the nonconformity;

e) to consider the alternatives for the disposition of the nonconforming product;

f) to decide upon and record what disposition should be made;
g) to control the subsequent processing of the nonconforming product consistent with the disposition decision;

h) to notify others who may be affected by the nonconformity including, if appropriate, the customer and/or consumers.

When a nonconformity is determined, the NMRAs should take steps to investigate and eliminate the reason for the occurrence of the nonconformity (Corrective Action) as well as determine what do to with (disposition of) the nonconforming product. If the nonconforming service is to be used, accepted or released, the NMRAs should decide to do so either by correcting the nonconforming product and then re-evaluating it or by using the service as is.

“Correction” refers to repair, rework, or adjustment and relates to the disposition of an existing nonconformity; whereas the “Corrective Action” relates to the elimination of the root causes of nonconformity (see clause 8.5.2).

The procedures for dealing with non-conformities discovered in product/service which has already been issued market authorization can include taking such actions as:

a) withdrawing product from sale,

b) withdrawing product from distribution,

c) giving advice to customers (this can take the form of checks to be carried out before use, providing additional guidance on the use of the product or the replacement of certain product), or

d) in extreme cases, requesting the physical return or destruction of product.

Information concerning nonconforming product should be provided to all appropriate personnel, so that action is taken, if necessary.

8.4 Analysis of data

Data should be collected and analysed in order to verify the ongoing suitability and effectiveness of the quality management system and to determine if there are any trends or patterns which require attention. Negative trends should be considered for improvement. The results of the analysis of data should be an input to management review.

Analysis of data can help to determine the root cause of existing or potential problems, and thereby to guide decisions about the corrective and preventive actions needed for improvement. For an evaluation of the effectiveness of the quality management system, data and information from all parts of the NMRAs should be integrated and analysed.

The results of this analysis can be used by the NMRAs to determine:

a) trends in service conformance,

b) extent to which customer requirements are being met,

c) process effectiveness,
d) supplier performance, and
e) success of performance improvement objectives.

The analysis of data should provide information relating to:

a) customer satisfaction surveys,
b) conformity to client charter requirements
c) key performance indicators for all functional activities of the NMRA
d) market complaints and product recalls

8.5 Improvement

8.5.1 Continual improvement

The NMRA should continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Actions for improvement include the following:

a) analysing and evaluating the existing situation to identify areas for improvement;
b) establishing the objectives for improvement;
c) searching for possible solutions to achieve the objectives;
d) evaluating these solutions and making a selection;
e) implementing the selected solution;
f) measuring, verifying, analysing and evaluating results of the implementation to determine that the objectives have been met; and
g) formalizing changes.

Results are reviewed, as necessary, to determine further opportunities for improvement. In this way, improvement is a continual activity.

8.5.2 Corrective action

Corrective action is action to eliminate the root cause of a detected nonconformity or other undesirable situation. If nonconforming service is involved, this is handled according to clause 8.3 of EAC QMS Requirements and the action taken to prevent recurrence of the nonconforming service is handled under clause 8.5.2 of EAC QMS Requirements.

The NMRA should have a documented procedure for corrective action which clearly establishes responsibility for taking corrective action, when and how this action will be carried out, and verification of the effectiveness of the corrective action.

An important element in the program is the dissemination of quality problem information to those directly responsible for ensuring quality. Causes of detected nonconformities should promptly be identified so that corrective action can be taken and recurrence prevented.

These causes can include the following:

a) failures, malfunctions or nonconformities in processes, tools, equipment or facilities in which services are handled,
b) inadequate or non-existent procedures and documentation,
c) non-compliance with procedures,
d) inadequate process control,
e) poor scheduling,
f) lack of training,
g) inadequate working conditions,
h) inadequate resources (human or material), and
i) inherent process variability.

Input to corrective action can come from many sources, including the following

a) inspection and test records,
b) validation study results,
c) nonconformity records,
d) observations during process monitoring,
e) audit observations,
f) field, service or customer complaints,
g) customer observations,
h) observations and reports by personnel,
i) supplier problems,
j) management review results,
k) solicited information on new or modified services,
l) published literature, and
m) published reports of failures of similar services.

Key features of the documented procedure(s) necessary to effectively implement corrective action may include

a) clear and accurate identification of the nonconformity,
b) details of the investigation conducted including consideration of what other service(s), process(e) or procedure(s) might have been affected,
c) identification of the root cause of the nonconformity,
d) identification of the action required to prevent recurrence of the problem,
e) any necessary approvals required before any action is taken,
f) a record that the identified corrective action was taken,
g) a check that the corrective action taken was effective (in other words verification that the non-conformance is unlikely to recur).

The extent of corrective action taken should be dependent upon and related to the risk, size and nature of the problem and its effect(s) on service quality.
For example, the level of investigation to determine the cause of the nonconformity, the work done to determine and verify the appropriateness of corrective action, and the level of documentation kept, would be far more extensive for a nonconformity relating to the service compared to a less serious nonconformity such as the failure to conduct an internal audit when scheduled. NMRA should implement corrective action promptly.

8.5.3 Preventive action

“Preventive action” is action to eliminate the cause of a potential nonconformity or other undesirable potential situation. It is taken when a potential nonconformity is identified as the result of an analysis of records and other relevant sources of information.

The extent of preventive action taken should be dependent upon and related to the risk, size and nature of the problem and its effect(s) on service quality. Sources for information for initiating preventive actions include:

a) evidence that previous decisions affecting service conformity were false,
b) services requiring rework,
c) in-process problems, wastage levels,
d) final inspection failures,
e) customer feedback,
f) process measurements,
g) statistical process control documents,
h) difficulties with suppliers (see clause 7.4.1),
i) service reports.

BIBLIOGRAPHY

EAC Quality Management System Requirements, 2014


ISO/IEC 17020:2012 Conformity assessment - Requirements for the operation of various types of bodies performing inspection.

ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories


PI 002_3:2007 PIC/S- Recommendations on Quality system requirements for pharmaceutical inspectorates.

REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision No</th>
<th>Date</th>
<th>Author</th>
<th>Section(s) revised</th>
<th>Description of change</th>
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PART THREE

Model Manual on the Implementation of the EAC QMS Requirements for NMRA
0. **INTRODUCTION**

0.1 **Background**

One of the goals of East African Community (EAC) Medicines Regulatory Harmonization Project is to have harmonized and functioning Quality Management System (QMS) within the EAC National Medicines Regulatory Authorities (NMRAs) in accordance with national and internationally recognized standards. This document provides requirements for implementing quality management systems in EAC NMRAs.

All NMRAs in the EAC have management systems for creating and delivering their services to customers. However, some of the NMRAs lack quality management systems, a situation that leads to wasteful processes, poor services delivery and unsatisfied customers.

This manual acts as a model quality manual for EAC NMRAs in documenting their quality management system as per EAC QMS Requirements. It defines;

a) the scope of the quality management system, including details of and justification for any exclusions;

b) the documented procedures established for the quality management system, or reference to them, and

c) description of the interaction between the processes of the quality management system.

This model manual will enable EAC NMRAs to align and integrate their own quality management system with the EAC QMS Requirements.

0.2. **Objectives**

The objectives of this manual are:

a) To define and describe the quality management system, authorities and responsibilities of the management personnel involved in the operation of the system, and provide references to the general procedures for all activities comprising the quality system of the entire NMRA, based on EAC QMS Requirements.

b) To guide the employees of NMRA through the various requirements of the EAC QMS requirements for NMRAs that must be met and maintained in order to ensure customer satisfaction and continual improvement.

c) To communicate the quality management system to the customers, stakeholders, development partners and other interested parties of the EAC NMRA and to inform them of the specific controls that are implemented by the NMRA to assure quality service delivery to the population of the EAC Partner State.

0.3. **Scope of EAC QMS model manual**

This manual documents the QMS of EAC NMRAs in accordance with EAC QMS Requirements.
QUALITY MANAGEMENT SYSTEM

1. SCOPE

1.1. General

This manual meets the requirements of “EAC QMS Requirements 2014” and applies to all activities that affect the quality of products and services supplied by EAC NMRA. These include key regulatory activities of NMRA such as; Inspection, registration, control of import and export, post marketing surveillance and quality control of medicine, cosmetics, medical devices and diagnostics.

It also includes support functions of NMRA such as finance and audit, quality management, procurement, information communication technology (ICT), legal services, human resource and administration, public relation and others as applicable.

The QMS in this manual shall apply to all directorates, departments, units and sections of the NMRA at all its geographical locations.

1.2. Application of the Quality Management System

All requirements of Quality management systems for the regulation of medicines, cosmetics, medical devices, and diagnostics shall be applicable to the NMRA.

1.3. Exclusions from the EAC QMS requirements

a) All clauses of EAC QMS Requirements 2014 apply and there are no exclusions, or

b) All clauses of EAC QMS Requirements 2014 apply except for Section 7 (specify the clause and provide justification).

2. NORMATIVE REFERENCES

a) EAC QMS Requirements

b) EAC QMS Guidelines

In addition, the following referenced documents are indispensable for the application of the QMS:


b) ISO/IEC 17025: 2005 - General requirements for the competence of testing and calibration laboratories

c) ISO/IEC 17020: 2012 Conformity assessment - Requirements for the operation of various types of bodies performing inspection

d) PI 002_3: 2007 PIC/S - Recommendations on Quality system requirements for pharmaceutical inspectorates EAC Partner states application statutory and legal requirements


3. TERMS AND DEFINITIONS

The terms and definitions given in ISO 9000: 2005 shall apply for purposes of this manual.
The following terms and definitions for “product”, “customer” and “Top Management” shall apply for the EAC NMRAs:

h) **Customer**: organization or person that receives a product, for example, consumer, client, end-user, retailer, beneficiary and purchaser.

**NOTE 1:**
A customer can be internal or external to the organization.

**NOTE 2:**
“Regulated Customer”: Organisation or person who by the nature of their business are subject to regulation by the NMRAs

**NOTE 3:**
“Unregulated Customer”: Organisation or person who is not subject to regulation by NMRAs.

i) **“Product”**: Applies to regulatory services intended for, or required by, the customer (regulated and/or unregulated customer) and to any intended output resulting from the product realization processes of the NMRA (e.g. market authorization or medicine registration certificates, licences, permits, good manufacturing practice certificates, good distribution practice certificates, medicine/drug register)

j) **“Top management”**: person or group of people who direct and control an NMRA at the highest level.

### 4. QUALITY MANAGEMENT SYSTEM

#### 4.1. General requirements

The NMRA has:

a) determined processes needed for the QMS and their applications throughout the NMRA;

b) determined sequence and interactions of these processes (see Annex 1 - NMRA processes interaction);

c) determined criteria and methods needed to ensure that the operation and control of the processes are effective, and has documented them in manuals, guidelines, documented procedures, work instructions, forms and other controlled documents;

d) provided the necessary financial, human, physical and technological resources and information necessary to achieve planned results and continual improvement of these processes. Resources needed for the QMS have also been included in the NMRA approved annual budget;

e) established key performance indicators that monitor, measure and analyze these processes;

f) instituted actions to achieve the planned results and to ensure continual improvement of the processes.
4.2. Document requirement

4.2.1 General

The NMRA has established the following documents of internal origin for the quality management system:

a) quality policy;

b) quality objectives;

c) guidelines and manuals;

d) standard operating procedures, protocols and work instructions;

e) records and process flowcharts and

f) forms

The NMRA has developed registers of documents of internal and external origin, which are updated from time to time (State document numbers of the two registers).

4.2.2 Quality Manual

This is the first level of internal document in the NMRA that describes internal functions, structure and processes with respect to QMS. In addition of this manual, the NMRA has also developed these other relevant manuals.

(The NMRA should state the titles and identification numbers of other manuals that have been developed by the NMRA).

4.2.3 Control of documents

The NMRA has developed a documented procedure (state the SOP number) for the control of internal and external documents (Refer to EAC Model procedure for control of documents, doc.# EAC/TF-MED/QMS/FD/SOP/N1R0).

4.2.4 Control of records

The NMRA has developed a documented procedure (state the SOP number) for the control of records (Refer to EAC Model procedure for control of records, doc.# EAC/TF-MED/QMS/FD/SOP/N2R0).

5. Management responsibilities

5.1 Management commitment

The Top Management has been actively involved in implementing the QMS and has provided the vision and strategic direction for the growth of the QMS, and has also established quality objectives and the quality policy.

Top management has provided the necessary human, financial, physical, technical and technological resources for the successful implementation of QMS (The NMRA should reference documents that provide evidence of commitment e.g. NMRA budget, staff establishment, scheme of service, number of regional offices, hardware and software).

5.2 Customer focus

The top management has identified customers with their particular needs associated with each service offered by the NMRA.

The customer needs have been determined and translated into defined service...
requirements (the NMRA should profile its customers and their requirements).

5.3 Quality policy

The NMRA has developed a quality policy (NMRA should state the quality policy number) which outlines its commitment to implementation of QMS in the entire NMRA and ensuring customer satisfaction.

The quality policy has been formulated to guide the NMRA in the fulfilment of its mission with regard to quality and customer satisfaction (Refer to EAC Model Quality Policy doc.# EAC/TF-MED/QMS/FD/POL/N1R0).

5.4 Planning

5.4.1 Quality objectives

The NMRA has developed quality objectives (NMRA should state the quality objectives document number) including those needed to meet requirements for product and has aligned with strategic objectives of NMRA. The quality objectives are reviewed annually for continuing suitability.

5.4.2 Quality management system planning

The NMRA has developed a strategic plan (refer to the NMRA strategic plan) to give directions to the achievement of the mission and implementation of QMS.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management has defined and communicated responsibilities and authorities throughout the NMRA.

The current organizational structure that clearly shows the inter-relationship and reporting mechanism of the personnel in the NMRA is annexed (The NMRA should annex the current organizational structure).

The top management of NMRA has approved current job descriptions for all members of staff in which the responsibilities and authorities of each of the employee positions on the organizational chart are defined (Refer to NMRA job descriptions).

5.5.2 Management representative

The top management of NMRA has appointed the Head of Quality Management (HQM) (management representative) who reports directly to the Chief Executive Office of the NMRA. The HQM has the overall responsibility and mandate on matters related to QMS in all NMRA sites and with responsibility and authority to:

a) ensure that the requirements of the EAC QMS Requirements are implemented and maintained,

b) resolve all matters pertaining to quality,

c) report to top management on the performance of the Quality Management System and any need for improvement, and

d) liaise with certification and accreditation bodies on matters relating to the Quality Management System.
The detailed duties and responsibilities of HQM are stated in the job description (the NMRA should state the number of the Job description).

In addition, the NMRA top management has also appointed quality management officers as Quality Representatives in each department. The Quality management officers functionally report to the Head of Quality Management Department.

5.5.3 Internal communication

Internal communication in the NMRA is through:

a) Internet,
b) Intranet,
c) Letters,
d) memos,
e) top management, departmental and general staff meetings,
f) management reviews,
g) appraisal and audit meetings,
h) information bulletins,
i) newsletters,
j) circulars.

5.6 Management review

5.6.1 General

Top management reviews the Quality Management System on an annually basis for all sites in order to ensure its continuing suitability, adequacy and effectiveness. An expected outcome of these reviews is the determination of the need for any changes to the Quality Management System, including changes to the quality policy and quality objectives.

The reports and records of management reviews are kept by the Head of Quality Management and are filed in accordance with Control of Records Procedure (state the SOP number). Refer to EAC Model procedure for control of records, doc.# EAC/TF-MED/QMS/FD/SOP/N2R0.

5.6.2 Review input

The input to management review includes information on the following:

a) result of internal and external audits,
b) customer feedback,
c) processes performance and product conformity ,
d) status of preventive and corrective actions (Corrective Action Request response time),
e) follow-up actions from previous Management Review,
f) strategic or operational changes that could affect the Quality Management System,
g) recommendations for improvement, and
h) effectiveness of the training activities for staff of the NMRA.
5.6.3 Review output

The output from the management review includes decisions and actions related to the following:

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs

6. Resource management

6.1 Provision of resources

The Top Management ensures that adequate staff, equipment and materials are available in order to:

a) implement, maintain and improve the Quality Management System processes,

b) ensure customer satisfaction, and

c) meet the quality objectives.

(The NMRA should reference documents that provide evidence of resources that have been provided e.g. NMRA annual budget, staff establishment, scheme of service, number of regional offices, asset register, etc.)

6.2 Human resources

6.2.1 General

The top management continuously ensures that the NMRA has adequate workforce that is trained, motivated, facilitated and empowered to achieve results.

The employees of the NMRA are competent through education, skill, training and experience as necessary. Requirements for education, skills, training and experience are documented in the job descriptions maintained by the Human Resources department.

6.2.2 Competence, training and awareness

The NMRA has:

a) determined the necessary competence for personnel performing work affecting conformity to product requirements (refer to scheme of service, and job specifications and competence matrix),

b) identified the training needs for the employees (refer to the training needs assessment report),

c) developed a training plan which is reviewed and updated at least once a year.

d) a procedure for training employees (state the number of the SOP), and

e) developed key performance indicators to evaluate the effectiveness of the trainings.

Training records, including evidence of certification as applicable are maintained by the Human Resources Department.

6.2.3 Impartiality and independence

Top Management has adopted a code of conduct for all employees of NMRA, which is in line with national public service code of
conduct and professional bodies (indicate document title and the year). Each employee has signed legally enforceable commitments necessary for impartiality and objectivity.

(Refer to EAC Model Guidelines for Declaration of Conflict of Interest, doc.# EAC/TF-MED/QMS/FD/GDL/N2R0).

6.2.4 Confidentiality

The members of the Board, advisory committees and staff of the NMRA have signed legally enforceable commitments, which are in line with national public service code of conduct and professional bodies (indicate document title and the year) for the management of all information obtained or created during the performance of their duties.

(Refer to EAC Model Oath of Secrecy doc.# EAC/TF-MED/QMS/FD/FOM/N1R0).

6.3 Infrastructure

The NMRA has provided adequate offices at the headquarters, regional offices and ports of entry into the country. These offices have been provided with the necessary utilities, process equipment (both hardware and software), and supporting services (such as transport, communication or information systems).

The infrastructure is continually maintained to achieve conformity to product requirements

6.4 Work environment

The NMRA has provided adequate and conducive work environment in all its offices needed to achieve conformity to product requirements.

Physical parameters like lighting, temperature and noise are controlled. Employees are also motivated through several reward systems.

7.0 Product realization

7.1 Planning of product realization

The NMRA has:

a) established quality objectives,

b) determined product characteristics and processes,

c) acquired inspection and test equipment, fixtures, appropriate storage and transportation facilities,

d) The established support departments,

e) established quality assurance measures at different stages of service provision (for example, first and second assessors for the product evaluation of dossiers, peer review of assessment reports and peer review of GMP reports), and

f) established applicable standards, regulatory requirements and forms to be used for the service provision.

7.2 Customer related processes

7.2.1 Determination of requirements related to the product

Requirements specified by the customer have been determined through consultative meetings with customers (e.g. manufactures, importers, exporters, wholesalers and
retail operators, practitioners, consumers organizations), and feedback mechanisms. To meet the product requirements, the NMRA has also considered national, regional and international laws and regulations.

7.2.2 Review of requirements related to the product

The NMRA reviews requirements related to service provided through technical committees. The respective directorates maintain records of these reviews.

7.2.3 Customer communication

The channels used for communication with the stakeholders, importers, manufacturers, distributors, retail and wholesalers of the pharmaceutical products and the general public include: guidelines, circulars, letters, email, bulletins, annual reports, and brochures that are posted on the NMRA website or delivered by hand, post or courier.

The print and electronic media, customer care desk and stakeholders meetings are also used. Communication with the above customers is also through: suggestion boxes, customer satisfaction surveys and complaint handling system.

7.2.4 Complaints and appeals

The NMRA has established a documented procedure (state the document number) for investigation and handling of market complaints and appeals from customer. (Refer to EAC Model procedure for Handling Customer Complaints and Appeals doc.# EAC/TF-MED/QMS/FD/SOP/N5R0).

7.2.5 Complaints and appeal process

The NMRA has established a documented procedure (state the document number) for handling and resolution market complaints and appeals from customer that includes the complaints and appeals process.

7.3 Design and Development

7.3.1 Design and Development Planning

All the processes required for service provision have been identified and assigned to the appropriate functional departments by Top Management. The processes have been identified and re-engineered. Process owners, process implementers and support staff have been identified and trained. The re-engineered processes have been tested, verified and validated.

7.3.2 Design and Development Inputs

All NMRA processes have been re-engineered and rationalized by using management review results, customer feedback reports. Design inputs have been identified for each process.

7.3.3 Design and Development Outputs

Design outputs have been identified for each process. Information on materials, equipment, competencies of personnel, process steps, forms and templates of reports, checklists and mode of services delivery to ensure conformity of the product have been developed.

7.3.4 Design and Development Review

Departmental team reviews, top management review, stakeholder consultations, and Board approval of the designs and development of processes are carried out according to plan.
Records of design reviews are maintained as quality records are kept.

7.3.5 Design and Development Verification

The NMRA has a schedule for the verification of the design and development of its processes. Every process is assessed to verify whether the design and development outputs meet the design and development input requirements. Records of the results of the verification are maintained.

7.3.6 Design and Development Validation

Service provision and performance are validated in service provision specification. These activities typically include piloting to targeted customers under defined operating conditions to determine reliability and consistency, and assessment of customer perception of the service provision. Records of the results of validation are maintained.

At the completion of design and development validation, the NMRA ensures that reports, calculations, test results, piloting results, etc., demonstrate that the service provision meets the specification requirements for all identified operational conditions.

7.3.7 Control of Design and Development Changes

Design changes can result in a change to existing documentation or the generation of new documentation. Design change documentation is reviewed, approved, controlled, recorded and issued in accordance with established change control procedure (state the SOP number) by the same functions involved in the original issue.

Controlled documents, which include drawings, test procedures, etc., are reviewed and approved prior to their initial release or revision in accordance with the documented procedure for document control (state the SOP number).

(Refer to EAC Model procedure for control of documents, doc.# EAC/TF-MED/QMS/FD/SOP/N1R0).

7.4 Purchasing

7.4.1 Purchasing process

Procurements in NMRA are governed by national laws (e.g. Public Procurement and Disposal of Public Assets Act).

Pursuant to the Act, the NMRA has a procedure for purchasing (state the document number) that describes the criteria for selection, evaluation and re-evaluation of suppliers, and award of tenders.

Records arising out of the procurement process including evaluation of suppliers are maintained by the Procurement Department.

7.4.2 Purchasing information

The NMRA develops and maintains purchasing information describing the product to be purchased. This information includes product specifications, procedures and acceptance criteria.

7.4.3 Verification of purchased product

The NMRA ensures that purchased products are inspected and verified against the purchase information before they are accepted.
Goods Receipt Notes are kept as evidence of inspection and verification of the purchased product.

7.5 Production and service provision

7.5.1 Control of production and service provision

The NMRA carries out service provision under controlled conditions using written procedures, work instructions, checklists and qualified equipment. Additional controls include assessment and checking at different levels before final released or approval of the service by the relevant authority.

7.5.2 Validation of processes for production and service provision

Processes for service provision are validated to ensure that they achieve the plan results. Validation protocols that define criteria for review and approval of the processes, qualification of personnel are developed.

Records of validation of service provision are maintained.

7.5.3 Identification and traceability

The NMRA identifies different regulatory product by allocating unique product identification numbers (e.g. Marketing Authorization Number, Permit number, License Number, GMP certificate number, Adverse Event Report Number, Poor quality Medicine Report Number, etc.)

Records (registers) showing the identification numbers of regulatory products are maintained.

7.5.4 Customer property

The NMRA identifies, verifies, protects and safeguards customer property provided for use during services realization while it is under the NMRAs control.

Customer property include Marketing authorization product dossiers and samples, site master files for pharmaceutical manufacturing facilities, proforma invoices, medicine samples taken for QC testing purposes, confiscated medicine, medicine promotional materials, certificates, intellectual property and personal data, other information and any other documentation supplied by the customer.

Where customer property is lost, damaged or otherwise found to be unsuitable for use, the NMRA carries out an investigation to establish the root cause and reports this to the customer.

Records showing the results of the investigations carried out and the corrective actions taken are maintained.

7.5.5 Preservation of the product

The NMRA preserves the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, storage and protection. Preservation of product includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

a) cleaning,

b) prevention from contamination and deterioration,
c) marking and labelling including safety warnings,

d) shelf life, and

e) special handling and storage for temperature-sensitive materials and products.

Secure storage facilities are provided as necessary for storage of material and products pending use or dispatch, to prevent damage or deterioration. (The NMRA to provide information on handling and storage facilities and their locations).

7.6. Control of monitoring and measuring equipment

The monitoring and measurement equipment are controlled and maintained so as to ensure validity of the monitoring and measurement results. Where measuring devices are used the NMRA has established processes to ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measurement requirements by establishing calibration procedures.

Records of calibration of the measuring equipment are maintained by the respective directorate.

8.0 Measurement, analysis and improvement

8.1 General

The NMRA has put in place systems to monitor, measure, analyse and improve processes for the QMS.

NMRA product quality plans are used for planning and defining the necessary monitoring and measurement techniques, including statistical techniques.

Implementation occurs according to the defined plans, the resulting data is analysed and improvements are pursued.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

The success in meeting customer’s requirements and in achieving a high level of customer satisfaction with the NMRA products and services is evaluated on a regular basis. This is done using:

a) in-service performance monitoring,

b) customer complaint analysis, and

c) regular customer satisfaction surveys, at least once a year.

The results are presented to top management during the annual management review meetings.

An efficient method of handling customer inquiries is established to provide a rapid response to NMRA customers who have an urgent need for assistance or a complaint, which would adversely affect customer satisfaction (e.g. hotline, SMS services, NMRA website, social networks, etc.)

8.2.2 Internal audit

The internal audits are conducted according to an established schedule. An audit plan is maintained to ensure that all aspects of the Quality System are properly addressed. The frequency and scope of the audits take into consideration the significance of the process and results of previous audits.
A documented procedure for conducting internal quality audit (state the SOP number) has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

(Refer to EAC Model procedure for Conducting Internal Quality Audit, doc.# EAC/TF-MED/QMS/FD/SOP/N3R0).

The results of the audits are recorded and submitted to the personnel having responsibility in the area audited. The audit is complete when the implementation and effectiveness of corrective actions has been verified and recorded. Audit results become part of the quality records and are presented at management review.

8.2.3 Monitoring and measurement of processes

NMRA has established the monitoring and measurement process to be applied to the realization processes necessary to achieve customer requirements such as Internal Audit and Statistical Techniques. The resulting information is reported to top management to assist in decision making process.

Performance indicators have been established for every NMRA processes and are periodically analysed to determine whether the set targets for the key results areas have been achieved. If the planned results are not achieved, correction and corrective action are taken to ensure the product conformity.

Three approaches will be used for monitoring and evaluation in assessing the NMRA performance with respect to the processes namely; self-reviews (internal), supervisory body reviews (sectoral) and peer reviews (external).

These are detailed below:-

a) Internal Monitoring and Evaluation
   i. Regular departmental and Senior Management meetings,
   ii. Quarterly, semi-annual and annual performance review meetings,
   iii. Internal audits,
   iv. Customer feedback,
   v. Annual management review meetings,
   vii. Mid-term review of the NMRA processes.

b) Sectoral Monitoring and Evaluation
   i. Quarterly, bi-annual and annual reports to Ministry responsible for Health and any other relevant government institution
   ii. Review of NMRA's performance during the Annual Joint Review Mission and the National Health Assembly (Partners review).

c) External Monitoring and Evaluation
   i. External audits (e.g. ISO 9001 certification)
   ii. Statutory audits (e.g. from auditor general)
iii. Other audits

d) WHO Assessment as appropriate.

In the event of process nonconformity, appropriate actions are taken to eliminate the cause of the nonconforming process and evaluate whether the process nonconformity has resulted in product nonconformity. If product nonconformity has resulted this product is identified and controlled according to documented procedures (State the SOP number).

(Refer to EAC Model procedure for Control of Non-Conforming Product doc.# EAC/TF-MED/QMS/FD/SOP).

8.2.4 Monitoring and measurement of services

The NMRA monitors the characteristics of the services to verify that services requirements have been met.

Records indicating the officer(s) authorizing release of services for delivery to the customer are maintained.

Key characteristics of the services have been identified, monitored and controlled at appropriate stages of service provision process in accordance with planned arrangements and evidence of conformity with acceptance criteria is maintained.

Products are withheld from further processing until there is objective evidence that the required inspection and test have been performed.

The in-process inspection and test may be reduced or eliminated with the implementation of proven statistical process control techniques, in accordance with clause 8.4 of this manual. Non-conformances during in-process inspection and test are handled in accordance with clause 8.3.

The NMRA keep records that indicate the person(s) authorizing release of product for delivery to the customer. The release of product and delivery of service to the customer does not proceed until the planned arrangement has been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of non-conforming product

Control of Nonconforming Product procedure, (State the SOP number) defines the responsibilities, authorities and methods used for the identification, segregation, review and disposition of nonconforming products, as well as the implementation of corrective action in order to prevent recurrence of the nonconformity.

(Refer to EAC Model procedure for Control of Non-Conforming Product doc. # EAC/TF-MED/QMS/FD/SOP/N4R0).

Records, clearly identifying the product, the nature and extent of nonconformity, the approved disposition and corrective action taken are maintained and form part of the quality records.

Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and relevant government agencies.

8.4 Analysis of data

NMRA quality management system data is recorded and analysed to determine the
suitability, effectiveness and opportunities for improvement of the quality management system. The data analysis objectives for NMRA are:

a) To assess customer satisfaction levels or to reveal customer dissatisfaction

b) To determine success rates in fulfilling customer requirements

c) To gather knowledge on trends associated with product and processes

d) To maintain awareness of the performance of suppliers.

The NMRA analyse the following data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the QMS can be made;

e) Internal and external audits reports

f) Customer satisfaction surveys reports

g) Key performance indicators for all functional activities of the NMRA

h) Market complaints and product recalls

i) supplier/contractor performance reports;

8.5 Improvement

8.5.1 Continual improvement

The NMRA continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The NMRA’s continual improvement is:

a) A part of the quality policy

b) Reflected in the quality objectives

c) A part of the actions taken upon audit results

d) Driven by opportunities surfacing from data analysis

e) A result of corrective action

f) A result of preventive action

g) A required output from management review

8.5.2 Corrective action

The NRMA carries out corrective actions in accordance with the documented procedures (state SOP number). The needs for corrective action are documented on a Corrective Action Request (CAR) and submitted to the process owner or the supplier, for the identification of the root cause and to initiate appropriate corrective action. The CARs are entered in a central database for tracking and follow-up. The originator ensures that the corrective action is implemented in a timely manner and is effective before closing the CAR. Corrective action requests that are not closed are discussed at the management reviews.

(Refer to EAC Model procedure for handling Corrective and Preventive Action doc. # EAC/TF-MED/QMS/FD/SOP/N7R0).
The NMRA takes action to eliminate the root causes of nonconformities in order to prevent recurrence.

Records of corrective action taken are maintained by the respective departments.

8.5.3 Preventive action

The NMRA determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. A documented procedure for preventive action (state the SOP number) has been established to define requirements for determining potential nonconformities and their causes, evaluating the need for action to prevent occurrence of nonconformities, determining and implementing action needed, and reviewing the effectiveness of the preventive action taken.

(Refer to EAC Model procedure for handling Corrective and Preventive Action doc. # EAC/TF-MED/QMS/FD/SOP/N7R0).

REVISION HISTORY

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<th>Section(s) revised</th>
<th>Description of change</th>
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B. Low Level Process Interaction

Annex 2: Model Quality Policy.

It is the policy of East African Community National Medicines Regulatory Authorities (NMRAs) to ensure safe, quality and efficacious pharmaceuticals and related technologies that satisfy customers while meeting statutory and regulatory requirements.

NMRAs are committed to continually improving the effectiveness of the QMS through customer focus, teamwork; and provision of adequate financial, human, physical and technological resources.

To ensure customer and statutory requirements are met, top management establishes Quality objectives at relevant functional levels.

This quality policy and objectives shall be communicated to all NMRA staff and shall be reviewed periodically for continuing suitability.
Annex 3 Medicine Regulations mapping processes

1. Data Flow Diagram for GMP Inspection Conduction process
2. Diagram for Preparation and Planning for GMP inspection
3. Diagram for New Human Medicine Registration process
4. Diagram for Post Marketing Surveillance process
5. Diagram for Payment Process
6. Diagram for Human Medicine Query response Process
7. Diagram for Rejection Appeal on Human Medicine process
6. Diagram for Human Medicine Query response Process
PART FOUR

EAC QMS Model Standard Procedures
1. **Purpose**

To describe the process for development, approval, use, updating, archiving and disposal of documents within the EAC NMRAs.

2. **Scope**

The SOP applies to:

2.1. All controlled internal documents for all NMRAs

2.2. All controlled external documents used in all NMRAs

3. **Responsibility**

3.1 The NMRA’s management team is responsible for the development of template SOPs to support each process of NMRA.

3.2 The template SOPs must then be completed and implemented by Heads of Departments/Unit in all departments/units. It is their responsibility to ensure all staff are aware of the SOPs and their individual responsibilities are defined within the SOPs.

3.3 All members of staff who have any involvement or responsibilities outlined in the SOP must ensure they have read the SOP and are fully aware of their responsibilities in the procedure.

4. **Distribution List**

4.1 Head NMRA

4.2 Directors

4.3 Head/Managers (Departments/Sections/Division)

4.4 Head Quality Management
5. **Language**

All documents must be written in either English or any other language depending on the area of application and level of fluency of intended users. 

6. **Materials and Equipment**

Document identification stamps:

a) “ORIGINAL COPY”  
b) “CONTROLLED COPY”  
c) “UNCONTROLLED COPY”  
d) “OBSOLETE DOCUMENT”,

7. **Procedure**

7.1 **General**

7.1.1 Drafting of documents must be initiated by user departments.

7.1.2 All documents must be edited at relevant levels before publication.

7.1.3 All obsolete documents must be destroyed by shredding/tearing/burning. 

7.1.4 Unless specified otherwise, all documents must be written using Bookman Old Style, font 11. (The font type and size may vary from one NMRA to another) 

7.1.5 Unless specified otherwise, all documents must be in white, A4 paper size and printed with black ink.

7.1.6 Quality forms shall bear NMRAS log at the left top corner, title of the form at the centre, form number in italic format at the right top corner and its revision level below the form number as per Addendum 3. (This is optional but ensures consistency)

7.1.7 Each department shall keep and maintain a list of departmental documents as prescribed in Addendum 7.

7.1.8 HQM shall keep and maintain a list of EAC NMRAS documents as prescribed in Addendum 7.

7.1.9 All documents must be numbered in the following numbering system: NMRAS/Directorate/Department/Document/Serial Number (e.g. NMRAS/DMC/DMI&E/Doc/xxx for documents generated by department of medicine and cosmetics inspection and enforcement under the Directorate of medicine and cosmetics), where xxx is the serial number. (Numbering may differ from one NMRA to another)

7.1.10 Internal documents shall be denoted by three letters (YYY): e.g. Chart-CHT, Form-FOM, Job Description-JBD and Protocol-PTC

7.1.11 All power-point presentations must be made on template slides as prescribed in Addendum 1.

7.1.12 Documents of external origin shall be received at the registry and stamped “Received” and sent to library prior to distribution in accordance to relevant library procedures.
7.2 SOPs

7.2.1 Preparation of SOPs

7.2.1.1 SOPs must be written in a format as prescribed in Addendum.

7.2.1.2 SOPs developed for use within Directorates shall be initiated by Department Managers or any other person within the NMRA as appropriate a Manager will allocate one of the future users to prepare it.

7.2.1.3 SOPs developed for use between Directorates must be prepared by respective Director, checked by HQM and authorized by Head NMRA (HNMRRA).

7.2.1.4 Draft SOPs must be circulated within the Department for comments before approval.

7.2.1.5 SOPs must be checked by HQM before being authorized by respective Directors and/or HNMRA.

7.2.1.6 SOPs generated by HQM must be prepared by Quality officer, checked by HQM and authorized by HNMRA.

7.2.1.7 The effective date should be indicated by the respective manager after a period of time whereby the SOP have been approved, trained and understood by the users.

7.2.2 Fonts and font size

7.2.2.1 SOPs must be written using Bookman Old Style as follows: (font type and size may vary from one NMRA to another)

a) 10 pt bold for title with capital letters
b) 11 pt bold for major headings
c) 11 pt for text
d) 8 pt for headers and footers

7.2.3 Numbering of SOPs

7.2.3.1 SOPs must be assigned code numbers on the header provided on every page of the SOP.

7.2.3.2 SOP numbers must be in the format MRAS/Directorate/Department/SOP/xxx, where xxx is the serial number.

7.2.3.3 The SOP number must not be changed even if the version has been changed.

7.2.4 Signing of SOPs

7.2.4.1 SOPs must be signed by persons indicated in the header as prescribed in Addendum 2.

7.2.4.2 SOPs must bear approved designations and signatures and therefore considered as original copy.

7.2.4.3 SOPs without three signatures will be considered invalid.

7.2.5 Issuance of SOPs

7.2.5.1 Original SOPs shall bear a red ink stamp with the words “Original Copy”

7.2.5.2 Copies of the original SOPs shall bear a blue ink stamp with the words “Controlled Copy” and should indicate a copy number.
7.2.5.3 Copies to be issued to external customers shall bear a **black ink** stamp with the words “Uncontrolled Copy”

7.2.5.4 SOPs will be issued to users by HQM and records maintained in the “Master Distribution List of EAC NMRAS Documents” prescribed under Addendum 4.

7.2.5.5 Unauthorized SOPs must not be circulated.

7.2.6 Review and validity of SOPs

7.2.6.1 SOPs must be reviewed after two years of use as indicated in the header.

7.2.6.2 Reviews must be initiated within user Department, following procedures described under 7.2.1.2

7.2.6.3 For major SOP changes such as changes in procedures and responsibilities, a new version of the SOP must be written.

7.2.6.5 SOPs shall bear a revision history page in a table on a last page and shall bear revision number, date, Author (responsible person), section modified, a description of change and approvals. See Addendum 8

7.2.6.6 For minor changes such as editorial corrections and layout these should be noted by the user and considered during the next review.

7.2.6.7 Any minor changes made should be signed and dated; the alteration should permit the reading of the original information; where appropriate the reason for the alteration should be recorded.

7.2.6.8 Head Quality Management shall maintain a history of revisions and a file of superseded documents.

7.3 Minutes

7.3.1 Numbering of minutes

7.3.1.1 Minutes of Management meetings shall be numbered in the following numbering system: NMRAS/HNMRA's Office /Type & # of meeting/financial year e.g. NMRAS/HNMRA/MN.1/2011/12 for the first Management meeting held in 2011/12 where HNMRA's Office is responsible for co-ordination. (This may vary from one NMRA to another)

7.3.1.2 Minutes of directorate/department meetings shall be numbered in the following numbering system: NMRAS/Directorate/Type & # of meeting/financial year e.g. NMRAS/DBS/MT.1/2011/12 for the first monthly meeting held in 2007 where DBS is responsible for co-ordination.

7.3.1.3 Minutes of Board of Directors (BOD) meetings shall be numbered in the following numbering system: EAC NMRAS/HNMRA's Office /Type & # of meeting/tenure of office e.g. NMRAS/HNMRA/BoD.1/2010-14 the first BOD meeting held within the period of 2010-2014 where HNMRA's office is responsible for co-ordination.
7.3.1.4. For extra ordinary meetings numbering will be the same except “Type & # of meeting” shall be replaced by “Ex-MN. 1” for Management meetings, “Ex-MT. 1” for Board of Directors meetings and “Ex-BOD.1” for BOD meetings.

7.3.1.5. Various committees shall follow the same numbering system as prescribed in 6.1.5

7.3.1.6 Numbering in between the texts shall be as follows:

a) 1.0, 2.0, etc for major headings.

b) 1.1, 1.2, 1.2.1 etc for sub headings followed by a, b, c… and i, ii, iii(The numbering may differ so long as there is consistency)

7.3.1.7 Bullets must not be used for numbering items of minutes, SOPs and any other documents.

7.4 Guidelines, Manuals and policies

7.4.1 Draft guidelines, manuals and policies shall be prepared by user directorate, reviewed by relevant Technical Committee or a special committee formed for that particular purpose, checked by HQM and approved by HNMRA.

7.4.2 All draft guidelines, manuals and policies intended to be used by customers shall be presented to relevant stakeholders for their feedback before approval

7.4.3 All guidelines, manuals and policies must have a title page as shown in Addendum 5.

7.4.4 The main contents of guidelines, manuals and policies must be as shown in Addendum 6.

7.4.5 Guidelines, manuals and policies must be numbered in the format NMRAS/Directorate/Department/ Guideline, Manual or Policy/xxx, where xxx is the serial number (e.g. NMRAS/DLS/TS/G or M or P/002).

7.4.6 The number must be bolded, italicized and positioned on top and far right of the title page.

7.4.7 The full address of the Authority must be printed at the bottom of the title page (Addendum 5).

7.4.8 Copyright remarks must be shown at the bottom of the back page of manuals and/or policies (Addendum 5).

7.4.9 The name of the document must be written on the header of every page (except title page) and page numbers formatted at the centre of the page.

7.4.10 The date of approval of the document must be indicated at the bottom of the front page.

7.4.11 The revision of guidelines, manuals, and policies are subject to the same review and approval process of the original document.

7.4.12 The guidelines, manuals and policies shall be reviewed after every two years or when need arises.
7.4.13 The approval, review, effective date and revision number of the guidelines, manual and policy shall be indicated in the header as per Addendum 2.

7.4.14 The manuals, guidelines and policies shall bear a revision history page which indicates revision number, date, responsible person, description of change.

7.4.15 Head Quality Management shall issue only controlled copies of the quality manual to be used by EAC NMRAS personnel.

7.4.16 Uncontrolled copies of the Manual, guidelines and policies shall be distributed to external customers and in the websites where appropriate.

7.4.17 Manager Quality Management revises all copies of the quality manual and distributes as required.

7.4.18 A record of all controlled copies of the quality manual, and uncontrolled copies of manuals, guidelines and policies issued is maintained by the HQM.

7.4.19 Review of guidelines, manuals and policies shall be initiated by user directorate, reviewed by relevant Technical Committee or a special committee formed for that particular purpose, checked by HQM and approved by HNMRA.

7.4.20 Authorized MS Word documents must be converted to PDF/A file and stored in the central server and hard copies made available in the library.

8.0 Records

8.0.1 The master distribution list file, and general list of documents shall be kept and maintained by HQM for a period specified by NMRA.

8.1 References

The following documents will be useful when controlling documents of an NMRA;

a) National Laws and regulation for medicines, cosmetics, medical devices and diagnostics

b) National Laws and regulation for archiving

c) The EAC QMS requirements for the regulation of medicines, cosmetics, medical devices and diagnostics.

9.0 Definitions, acronyms and Abbreviations

Definitions

9.1 “Author”: The Author shall be the person(s) who created a document or any subsequent revision of the controlled document.

9.2 “Authorized by”: Endorsement providing authority for a document to become officially valid and to be put into formal use.
9.3 “Checked by”: Endorsement signifying that the internal document is ready for authorization.

9.4 Controlled Document”: document which is distributed to pre-determined persons or staff and if any change or revision is made on the document, the Head Quality Management shall submit the revised document and make sure that the previous (superseded) document is retrieved.

9.5 “Document”: 
a) “Document” means readable information and its supporting medium.
b) A “document” describes any policy, procedure, work instruction or form that is to be controlled.
c) A “document” can be an Act, Regulation, standard, policy statement, manual, plan, guideline, protocol, procedure, work instruction, drawing, specification, form, record, chart, report, certificate, checklist, aide memoir, register, worksheet, textbook, poster, notice, memorandum, software, photograph, drawing, or plan.
d) A “document” may be on various media e.g. paper, magnetic, and electronic or optical computer disc, and may be digital, analog, photographic or written.

9.6 “Effective Date”: A date after the concerned staff or persons have been formally trained on the use of the document and training records maintained, but shall not be later than 10 working days from the revision date.

9.7 “External Document”: 
a) A legal, regulatory or technical document which is not written or created (not internally generated), issued or revised by NMRA.
b) “External document” can be used as reference in writing internal documents or as a manual for operating equipment.

9.8 “Internal Document”: A document which is issued and revised by the NMRA.

9.9 “Master Document”: Original of controlled internal document that contains original signatures of the authorities that approved and authorized the document.

9.10 “Review Due Date”: 
A date three years from the effective date, to ensure continued adequacy and suitability of a document, even if there is no amendment to be done.

9.11 “Review”: Assessment of the correctness, suitability and adequacy of a document including technical, legal, regulatory, health, safety, and environment compliance issues.
9.12 **Reviewer**: The Reviewer shall be the person(s) who assess a document for technical, legal, regulatory, health, safety, and environment compliance issues.

9.13 **Revision Date**: The date when the document is authorized and thereby becoming officially valid.

9.14 **Revision Number**: A numerical figure that changes serially; the first document shall have revision number “0” and its first revision number “1”, second revision number “2” and so on:

9.15 **Uncontrolled Document**: A document which is issued to persons or staff who are not part of the distribution list for that document for information purposes only and if any change or revision is made on the document, the Head Quality Management is not in control of retrieval the previous (superseded) document.

### Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>EAC</td>
<td>East African Community</td>
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<tr>
<td>HNMRA</td>
<td>Head of National Medicines Regulatory Authority</td>
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<tr>
<td>HQM</td>
<td>Head Quality Management</td>
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<td>NMRA</td>
<td>National Medicines Regulatory Authority</td>
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<tr>
<td>QAO</td>
<td>Quality Assurance Officer</td>
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<tr>
<td>QMS</td>
<td>Quality Management System</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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### REVISION HISTORY

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<th>Description of change</th>
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### Addendum 1: Format for Preparation of SOPs

#### 1. Header

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<th>Revision #:</th>
<th>Page: x of y</th>
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#### 2. Purpose

Why should the SOP be developed and used?

6.4 Where necessary other related documents can be annexed to the SOP

#### 3. Scope

The range of activities to which the document is applicable.

6.5 A process chart should be included

#### 4. Responsibility

Who is involved in doing any part of the activity?

7. Records

Refer to the records generated by the respective procedure

#### 5. Distribution List

Who should be provided with authorized copies for use

8. References

List resources that may be useful when performing the procedure; for example, administration policies, government standards and other SOPs

#### 6. Procedure

6.1 Describes in detail what to do, how to do and where to record

6.2 Procedure must be clear and understandable

6.3 It should have no or less abbreviations

6.4 Sentences should be short and clear containing only what is necessary for the work to do

Identify and define frequently used terms or acronyms. Provide additional and/or relevant information needed to understand this SOP.

#### 10. Revision History

Describe the changes made to the SOP
Addendum 2: Format of QMS Forms
Addendum 3: Master Distribution List

MASTER DISTRIBUTION LIST OF EAC NMRAS DOCUMENTS

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<th>DOCUMENT NAME</th>
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<th>REVIEW DATE</th>
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Addendum 4: Title and back pages for EAC NMRAS Guidelines, Manuals & Policies

Title Page

Doc. #: EAC NMRAS/DLS/TS/G or M/002
Rev. No. 0

EAC NMRA

EAC NMRA LOGO

NAME OF DOCUMENT

Date of Approval
(Month and Year)

P. O. Box 77150, EPI Mabibo, Off Mandela Road, Dar es Salaam, Tel: +255-22-2450512/2450751/2452108, Fax: +255-22-2450793,
Website: www.EAC NMRAs.or.tz,
Email: info@EAC NMRAs.or.tz
All rights reserved:

This is a controlled document. It must not be copied without authorization from the Manager Quality Management or Director of Business Support or Director General. Only originals or authorized copies shall be used as working documents.
Addendum 5: Main Contents for EAC NMRAS Guidelines, Manuals and Policies

1. Table of Contents
2. Abbreviations
3. Acknowledgements
4. Preface
5. Executive Summary, where needed
6. Legal framework/Responsibility for implementation
7. Introduction
8. Objectives
9. Scope
10. Main topics/Technical content
11. References/Bibliography
12. Authors / contributors
13. Annexes
Addendum 6: Master List of documents

Documents involved include Process maps, SOPs, Forms, Guidelines, Manuals, Plans (Strategic plan, business plan), Regulations etc.

Addendum 8

10.0 REVISION HISTORY

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<th>Revision No</th>
<th>Date</th>
<th>Author</th>
<th>Section(s) revised</th>
<th>Description of change</th>
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1. **Purpose**

To describe how to identify, store, protect, retrieve, retain, and dispose records

5.1.2 Quality records shall be identified/ coded or referenced in accordance to the SOPs of control of documents NMRAS/HNMRA/QA/SOP/001

2. **Scope**

The SOP applies to all records generated as the result of service realization processes and Human resources records.

5.1.3 General numbering and coding of records shall be NMRAS/ Directorate/Department/Rec/xxx, where xxx is serial number.

5.1.4 General files of records shall be kept at the registry and assigned file reference numbers.

3. **Responsibility**

The Management Representative has overall responsibility for the implementation of this SOP.

4. **Distribution List**

All staff electronically (protected from any alteration)

5. **Procedure**

5.1 **Identification**

5.1.1 Records shall be assigned identification numbers appropriate to the record.

5.2 **Storage**

5.2.1 All records of service realization shall be stored in files which shall be kept in racks/cabinets at the registry or at the respective Departments.

5.2.2 Personnel records and training records shall be maintained at the Human resources Department.

5.2.3 Confidential human resource records shall be maintained at the Head NMRA's office.
5.2.4 Records shall be arranged in cabinets alphabetically, geographically and numerically for easy identification and retrieval.

5.2.5 All active files of records, which are full, shall be closed at the registry and transferred to records centre.

5.2.6 After every three years (in accordance to the NMRA national laws) decongestion of records shall be done at the registry and send all inactive records to records centre.

5.2.7 All soft copy of records shall be maintained in Management Information System (MIS) database or any other system in place.

5.2.8 Records maintained in electronic media shall be subjected to back-up and the back-up information shall be stored in a protected and secured management information system database (MIS) or any other system in place.

5.2.9 Only authorized personnel shall access records in hard and soft copy form.

5.2.10 The NMRA shall observe restrictions on access to information, under the provisions of the law, with the aim to protect confidential information, private life of a person, and national security, as well as to ensure the security of information he/she is responsible for from unauthorized access, modification or damage.

5.3 Storage of closed records

5.3.1 All files of closed records shall be registered in records centre transfer form at the registry and sent to records centre in boxes or any other means in place.

5.3.2 The boxes shall be given a number and the number shall be the same as that indicated in the record centre transfer.

5.3.3 The boxes containing records shall be kept at records centre office.

5.3.4 The appraisal of records shall be done after every three to five (according to national laws) years.

5.4 Protection

5.4.1 Records shall be maintained indelibly. Any person initiating a correction shall cross the wrong information and insert the correct one and then write his/her initials and date where change was made. The alteration should permit the reading of the original information; where appropriate the reason for the alteration should be recorded.

5.4.2 The use of erasing fluid or any other means of rendering information illegible is forbidden.

5.4.3 Approved records shall not be changed.

5.4.4 Records shall not be exposed to any agent of deterioration.
5.4.5 The file movement register at each department shall be used to track the files for easy traceability of the records.

5.5 Retrieval

5.5.1 Only authorized personnel shall retrieve records.

5.5.2 All records shall be organized and stored with a record index to allow retrieval in a timely manner.

5.5.3 General records at the registry shall be retrieved by the registry staff on request.

5.5.4 Confidential human resources records shall be retrieved by the Personal Assistant to the Director General.

5.6 Retention time

5.6.1 Unless specified otherwise in the respective procedures all records shall be retained for a period of five years.

5.6.2 Records that have permanent value shall be kept permanently at the records centre office.

5.6.3 Employee records shall be maintained by human resources Department for a period specified in the National laws and regulation.

5.6.4 Records will be maintained in the register as indicated in the addendum 1

5.7 Disposition

5.7.1 Outdated and/or obsolete records shall be shredded, torn and/or burned.

5.7.2 Obsolete document retained for reference purpose shall be stamped obsolete.

5.7.3 Computer generated records shall be erased from the computer media.

5.7.4 Backup information for soft copy records shall be retained for reference purpose.

5.8 Records Issued to customers

5.8.1 All copies of records issued to customers shall be maintained in their respective customers file at the registry.

5.8.2 Customers shall be informed to keep records issued to them protected for the whole period of validity of the record and then return them once they have expired.
6.0 References

The following documents will be useful when controlling documents of an NMRA;

a) National Laws and regulation for medicines, cosmetics, medical devices and diagnostics

b) National Laws and regulation for archiving

c) The EAC QMS Requirements for the regulation of medicines, cosmetics, medical devices and diagnostics.

7.0 Definition, acronyms and Abbreviation

“Quality Records”: information generated from the processes described in quality system documents, and retained as indicated in this procedure.

The following terminologies and acronyms have been used in this document;

SOP: Standard Operating Procedure
EAC: East African Community
NMRA: National Medicines Regulatory Authority
HNMRA: Head of National Medicines Regulatory Authority
QMS: Quality Management System
HQM: Head Quality Management
QAO: Quality Assurance Officer
REC: Records

8.0 REVISION HISTORY

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<thead>
<tr>
<th>Revision No</th>
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<th>Section(s) revised</th>
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### Addendum 1 - QUALITY RECORDS
(This may vary from one NMRA to another depending on the records generated by the NMRA and National rules and regulations)

<table>
<thead>
<tr>
<th>Quality Record</th>
<th>Filed and Maintained</th>
<th>Media</th>
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1. **Purpose**
   
a) To define how internal quality audit shall be planned, scheduled, organized, conducted and documented so as to verify conformance to QMS requirements and procedures, 

b) To verify that the QMS is effectively implemented and maintained. 

Outlined below are the procedures that will normally be followed when conducting an audit at NMRA

2. **Scope**

The procedure applies to all internal quality audits carried out in the NMRA.

3. **Responsibility**

Head Quality Management is responsible for:

a) Planning for and scheduling audits covering all elements of the QMS covering both management and technical aspects) to be undertaken within a one year’s audit cycle.

b) He / she will appoint a person or team to carry out each audit. The lead auditor will be independent of the area being audited.

c) Ensuring that quality audits are carried out in the NMRA.

d) Ensuring that corrective actions are closed out in a timely fashion, within determined close-out dates whenever possible, this is a joint responsibility with the representative of the area being audited.

e) Ensuring the records of the audit and their results are maintained

Auditor/audit team is responsible for:

a) Arranging a suitable time for the audit with the representative.

b) Reviewing the SOP and from this developing an audit checklist.

c) Completing the audit and audit report.
The Auditee is responsible for cooperating with the auditor, and for providing information and resources necessary to achieve the objectives of the audit.

The section owner of the audited organization is responsible for taking appropriate and timely corrective action on any non-conformity identified during the audit.

The Head of NMRA (HNMRA) is responsible for authorizing the annual internal quality audit schedule and for supporting the implementation of corrective and preventive actions as required.

4. Distribution List

The distribution as per the procedure for control of documents.

5. Procedure

5.1 Diagram of internal quality audit process
Quality audit

The HQM will select lead auditor, who has had training in auditing, to conduct an audit in specified areas of the QMS.

Auditors shall be selected in manner that promotes independence for the activity being audited.

The audit team is responsible for making arrangements with the appropriate auditees’ representative in the area to be audited.

The HQM shall make audit annual plan covering all elements of the quality management system of NMRA (covering both management and technical aspects) to be undertaken at least once in a year.

The auditor(s) will prepare an audit checklist based on the audit criteria.

The lead auditor shall review the audit criteria documents and develop an audit plan which should include, but not limited to:
- The audit objectives, audit scope and audit program (time table) covering all major audit areas.
- The audit program, shall take into considered the status and importance of the processes and areas to be audited as well as results of the previous audits.
- Identification of personnel in areas to be audited, depending the objective and scope of the audit.
- Any findings from previous audits on that area shall be reviewed to follow up any observations and outstanding corrective actions.

The audit plan, when prepared, shall be circulated to the auditee, at least five working days before the audit.

During the audit, objective evidence shall be collected through interview, examination of documents, observation of activities and conditions in the area of concern. Random sampling of records, actual witnessed activities, current document files, and other related records and functions are to be reviewed against documented requirements to verify compliance to the audit criteria.

In addition the audit team shall follow-up audit activities to verify and record the implementation and effectiveness of corrective action taken on any Corrective Action Requests issued.

Evidence of conformity or nonconformity shall be noted on the checklist or audit note book as appropriate.

Nonconformities found during the audit shall be communicated (verbal or written) the same day (whenever possible) to the auditee and shall be identified and reported in terms of specific requirements of the EAC QMS requirements.

All non-conformities found shall be formally agreed between the Lead Auditor and the auditee to ensure effective corrective action of the observed condition and the adoption of system improvements or preventive measures to reduce or preclude the likelihood of recurrence.

The corrective action(s) required shall be entered in the Corrective Action Request Form (enter document number) by the Lead Auditor and submitted to the auditee,
The period required to clear the non-conformities shall be agreed upon between the auditor(s) and the auditee, in any case not more than three months, unless sufficient reason for longer periods have can be justified.

At the conclusion of the audit, an audit report (see Internal quality audit report format in Annex) will be completed and shall include all findings, corrective action raised during the audit and corrective actions followed up from previous audits, as well as any observations noted.

The audit report shall be factual, supported by objective evidence, clear, concise, and understandable.

The audit report and the corrective action request shall be completed by the audit team and submitted to auditee within one month of the audit.

The audit report shall also be distributed to top management, and to the Head Quality Management.

The auditee shall carry out corrective action as per documented procedures for Corrective and Preventive Action (enter document number) through root cause analysis of the identified nonconformities and shall follow up the corrective action process, until the cause of the non-conformities is cleared.

The auditee shall notify the lead auditor in writing when he/she has confirmed that the non-conformities have been cleared.

The lead auditor shall follow-up on the corrective actions and closes them out within the time frame agreed upon as per 5.2.16 above.

5.3. Re-audit

A re-audit can be organised by the HQM to determine if the corrective actions have been effective.

If the corrective actions have not been effective, it is the responsibility of the HQM to initiate further corrective actions, and to inform NMRA management of any problem preventing satisfactory corrective action being taken.

These issues may be formally raised at the NMRA management review meeting.

6. Records

The HQM shall be responsible for the maintenance of the quality audit reports and records of corrective action taken.

The audit reports, corrective action report, checklists, audit schedules shall file in the internal audit reports file and maintained at the registry as per procedures of control of documents.

7. References

The following documents will be useful when conducting internal audits in an NMRA; National Laws and regulation, the EAC QMS requirements for the regulation of medicines, cosmetics, medical devices and diagnostics, and manual on the implementation of EAC QMS requirements.
8. Definitions, acronyms and Abbreviations

The following terminologies and acronyms have been used in this document; This list is not exhaustive, it could be populated as needed.

**SOP:** Standard Operating Procedure
**EAC:** East African Community
**NMRA:** National Medicines Regulatory Authority
**HNMRA:** Head of National Medicines Regulatory Authority
**QMS:** Quality Management System
**HQM:** Head Quality Management
**QAO:** Quality Assurance Officer

8.0 REVISION HISTORY

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<th>Author</th>
<th>Section(s) revised</th>
<th>Description of change</th>
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Annex 1

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**KEY:**
- Audit date planned
- Audit carried out
- Non compliances agreed
- Follow up audit carried out
- Audit closed by follow up
### INTERNAL QUALITY AUDIT CHECKLIST FORM

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<tr>
<th>S/N</th>
<th>QUESTION/ AUDIT POINT</th>
<th>AUDITOR NOTES- OBJECTIVE EVIDENCE</th>
<th>REFERENCE TO REQUIREMENT</th>
<th>REMARKS (C OR NC)</th>
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**ADDITIONAL COMMENTS AND SUGGESTION**
Annex 3

ATTENDANCE REGISTER FOR INTERNAL AUDIT

OPENING/CLOSING MEETING

DATE:

<table>
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<tr>
<th>S/ NO</th>
<th>NAME</th>
<th>DESIGNATION</th>
<th>SIGNATURE</th>
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Annex 4

AUDIT REPORT

1. BACKGROUND

1.1 Auditee
1.2 Auditors
1.3 Audit Criteria
1.4 Purpose of the Audit
1.5 Scope of Audit
1.6 Audit Sampling
1.7 Persons Contacted during the audit
1.8 Summary of Audit

2. FINDINGS

3. NAMES OF LEAD AUDITOR, AUDITORS, AUDITEES AND SIGNATURES

4. RECOMMENDATION

5. CONCLUSION
Annex 5: Corrective action request form

CORRECTIVE ACTION REQUEST FORM

Corrective Action Request (CAR) No: Request Date:

Department / Area audited: ……………………………….Dates of Audit:………………………………………………

Representative: ………………………………………………………………………………………………………………….

Lead Auditor: ……………………………………………………………………………………………………………………

Auditor(s): ………………………………………………………………………………………………………………………

Assessor(s): ……………………………………………………………………………………………………………………

Repeat problem? Yes ☐ No ☐

If yes state CAR reference number: ……………………………………………………………………………………………

1. NON-CONFORMITY (To be completed by Auditor):

State reference to requirement in the applicable standard:

Failure in the System

Signed: ………………………………………. (Auditor)

2. CORRECTIVE ACTION TO PREVENT RECURRENCE (To be completed by Representative of auditee)

Date for completion of Corrective Action: …………………………………………………………………………………

Signed: ……………………………….. (Representative) ………………………………..(Auditor)
Date: ........../........./................

3. FOLLOW-UP AND CLOSE OUT (To be completed by Auditor):

Proposed Follow-Up Date: .................................................................................................................
Follow-Up Details:

CAR  Close Out Date: ........../........./.........  Signed: .................................................................
Auditor

Auditee’s signature………………..  Date of Completion………………………………

5. AUDITOR’S COMMENTS ON FOLLOW UP ACTION

...................................................................................................................................................
...................................................................................................................................................

.................................................................  .................................................................  ...........................................................
Auditor’s Signature    Name    Date

.................................................................  .................................................................  ...........................................................
Auditee’s Signature    Name    Date

6. EFFECTIVENESS OF CORRECTIVE ACTION:

Was the corrective action taken effective?   Yes ☐   No ☐

Details (as necessary):

Signed ………………….  ………………….  …………………
Auditor  Name  Date
EAC Model procedure for Control of Non-Conforming Product  
Doc. # EAC/TF-MED/QMS/FD/SOP/N4R0

1. **Purpose**

To describe the procedure for identification and control of product which does not conform to products requirements to prevent unintended use or delivery.

2. **Scope**

The procedure is applicable for use at NMRA headquarter and its geographical locations for controlling nonconforming products.

This procedure covers products that do not conform to the EAC QMS requirements for the regulation of medicines, cosmetics, medical devices and diagnostics.

3. **Responsibility**

3.1 **Head of Quality Management**;

Has the responsibility and authority to initiate a request for corrective/preventive action, verify the corrective action for completeness, close and communicate the corrective/preventive action results with the affected department(s).

3.2 All members of staff who have any involvement or responsibilities outlined in the SOP or have to have knowledge of the procedure outlined must ensure they have read the SOP and are fully aware of their responsibilities and accountability in the procedure.

All members of staff has the authority and responsibility to initiate a request for preventive/corrective action by notifying their Department Director

It is the responsibility of all members of staff to bring suspected non-conformances with the requirements of the QMS to the attention of the relevant Departmental Manager /Directors or nominated representative.
4. **Distribution List**

a) Head NMRA

b) Directors

c) Head/Managers (Departments/Sections/Division)

d) Head Quality Management

e) All Staff (outlook copy)

5. **Procedure**

**Identification**

5.1.1 Non-conforming products can be detected through internal or external customer complaints, third party audits, internal audit, data analysis, customer satisfaction surveys, relevant Quality Management Systems (QMS) records and process measurements.

Reports of non-conforming products may result from external audits or may occur as part of routine operations, where an individual or department may identify a non-conformance.

5.1 **Recording non-conforming products**

5.1.4 Non-conforming products identified during auditing shall be treated as defined in the procedure for conducting internal audit

5.1.5 All EAC NMRAS staff shall report non-conforming products identified in their respective working place to their immediate supervisors/Head of Department, using the non-conforming products investigation form (NCIF) (see annex …). The supervisor/Head of Department shall review and report the non-conforming product to the HQM. The HQM shall review the non-conforming product and verify whether it is significant or not. If the nonconformity is significant, he/she shall assign an auditor/investigator to undertake the investigation.

**Investigation**

5.1.6 The assigned auditor shall conduct a full investigation to determine the root cause and corrective measures to be undertake. A report shall be prepared using internal audit report F04/HNMRA/QM/SOP/003 (Annex 1) and submitted to the HQM.

**Decision**

The report shall be discussed between the HQM and the responsible Supervisor/Head of department and decision arrived at. Where applicable, the Head NMRA may be consulted for further guidance and decisions as may be necessary.
6. Records

Records shall include non-conformity investigation forms, investigation reports and any subsequent actions taken including concessions. The records shall be filed in internal audit file and maintained at the registry office for a period of five years before being destroyed by tearing/shredding/burning or by any other appropriate means.

These should be controlled in accordance with the procedure for control of documents.

7. References

EAC QMS Requirements


EAC NMRA Quality Manual

8.0 REVISION HISTORY

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<th>Approval Process</th>
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</table>
Addendum 1: Non-conforming Product investigation form

EAC NMRA LOGO

F01/HNMRA/QM/SOP/004

NON CONFORMANCE INVESTIGATION FORM

Part 1: (To be filled by reporter)

Date: ........................................... Directorate: ............................. Dept/Unit: .................................

Description of non-conformance: ........................................................................................................

Reported by: ..................................................... Signature: ...............................................................

Part 2: Review of non-conformance by Immediate Supervisor/Head of Department
Comments by supervisor:

Name: ............................................................. Signature: ............................. Date: ..........................

Part 3: Head Quality Management (HQM)

Non-conformity number: .................................

Is non-conformance significant?

Yes ☐ No ☐

If yes go to part 4.

Comments by HQM:

............................................................. .............................................................

Signature of MQM Date

Part 4: Auditor/Investigator

Investigation findings/Root cause Analysis (Attach audit report)
Part 5: Recommended correction, corrective action:

Investigee's name:  
Signature:  
Date:

Part 6: Auditor/ Investigator comments on follow up

Investigator's name:  
Signature:  
Date:

Investigee's name:  
Signature:  
Date:

Part 7: Closure of Non-conforming product investigation

Investigator's name:  
Signature:  
Date:

Investigee's name:  
Signature:  
Date:
1. **Purpose**

The procedure sets out the processes the EAC NMRA employs for effective handling and investigation of complaints and appeals in a fair, equitable and timely manner.

2. **Scope**

The procedure is applicable for use by the EAC NMRA at the Headquarters and in NMRA offices in other geographical locations in handling complaints and appeals in relation to the operations, policies or other activity related to, or incidental to the execution of NMRA’s mandate.

3. **Responsibility**

a) The HQM is responsible for coordinating the implementation of this procedure to ensure that customer complaints and appeals are received, registered, investigated and corrective actions taken.

b) The Head of department is responsible for proposing Corrective and preventive action, and their implementation.

c) The Head of NMRA is responsible for ensuring that all customer complaints and appeals are handled appropriately to a satisfactory conclusion.

d) All staff of NMRA shall take due responsibility in relation to this procedure.

4. **Distribution List**

a) Head NMRA

b) Directors

c) Head Quality Management (HQM)

d) Head Customer Relations

e) Quality Assurance Officer (QAO)

f) All Staff
5. **Procedure**

**Receiving and registering customer Complaints**

5.1 Any person who has a complaint regarding the operation or implementation of any activity of NMRA shall fill the Customer Complaint Report Form Part 1 document number ***** (see Appendix 11.1), available on the NMRA website (www.NMRA.or.ug), NMRA head office or NMRA branches.

5.2 Complaints may also be received in written, verbally, or by telephone. In this case, the NMRA officer receiving complain shall enter details of the complaint on the Customer Complaint Report Form Part 1.

5.3 A Complaint may be due to delay or quality of service delivered, review or contract, technical issues, any misconduct by staff attitude during service delivery or complaint related to quality and/or safety of regulated products.

5.4 The complainant shall deliver the filled Customer Complaint Report Form Part 1 to NMRA by dropping it in the secured transparent Customer complaints and feedback boxes located at the NMRA head office or its branches. The complaint may also be sent to the Head NMRA or a designated person as the case may be by e-mail, fax, post or courier.

5.5 The transparent customer complaints and feedback boxes shall be opened by a designated person in the Quality Management Unit as soon as a complaint form is seen inside any of the boxes.

5.6 Customer.

5.7 All customer complaint report forms shall be forwarded to the Head Quality Management who will do the following:

a) Stamp the complaint form with a “Received date” stamp. (See Appendix 11.2).

b) Allocate a unique sequential number to each complaint and write it on the Customer Complaint Report Form Part 1 and Part 2.

c) Register the complaint by completing the electronic Customer Complaint Register document number ***** (see Appendix 11.3).

d) Fill sections 2.1 to 2.4 of the Customer Complaint Report Form Part 2 (see Appendix 11.4), make severity classification of the complaint using the Complaint Severity Classification Criteria, Doc. No. ***** (see Appendix 11.5) and submit the form to the HNMRA to approve the investigation team.

e) Send email response to the complainant acknowledging receipt of the complaint, within two working days after receipt of the complaint, using standard response format Doc. No. ***** (see Appendix 11.6).
5.8 Where samples or exhibits are presented to NMRA together with the complaint, the Head Quality Management shall take photographs of the sample and insert their electronic photo files in the electronic Customer Complaints Register.

5.9 The sample or exhibits shall be preserved throughout the period of investigation of the complaint.

5.10 The head of quality management shall send the complaints to the relevant units/department responsible for the investigation of the complaint.

5.11 The relevant department/unit shall initiate the investigation of the complaint within 72 hours of receiving the complaint to investigate the complaint.

The Head of the Department or Unit shall assign an investigation team to undertake the investigation of the reported complaint.

5.12 Persons on the investigation team shall not have been involved in the original activities in question or dispute if their presence may affect the outcome of the investigations.

In investigating the complaint, the investigation team shall determine the following:

a) Nature, type and severity classification of the complaint
b) Objective of the investigation
c) Methodology of collecting evidence
d) Findings

5.13 The investigation team shall collect all available evidence, (oral, written, primary, secondary), and ensure that all relevant information is obtained and recorded during the investigation and that the chain of evidence is maintained.

5.14 Depending on the nature of the suspected defect and product, and the complexity of any further testing or investigation, it may take several weeks before any conclusions can be drawn.

5.15 On conclusion of the investigation, the investigation team shall:

a) Carry out a root cause analysis and establish the root cause of the problem
b) Write a detailed report to the Head, NMRA with recommendations on corrective and preventive actions to be taken.

5.16 The Management team shall, review the report of the investigation team and resolve on the appropriate action to be taken.

5.17 Where the investigation report is found to be inadequate or incomplete in resolving the complaint, the Head, NMRA shall
defer the report and refer the matter back to the investigation team or appoint another investigation team to handle the complaint.

**Resolution of a Complaint and Feedback to the Complainant**

5.18 When a complaint has been resolved, NMRA shall take the following actions:

a) Implement the corrective and/or preventive actions as per procedure for Corrective and preventive Action (refer Doc. No. *****)

b) Communicate to the complainant, in writing, the outcome of the investigation and the actions taken.

c) Advise the complainant to undertake an appeals process within 14 working days in case of dissatisfaction with the outcome of the investigation.

d) Where necessary, arrangements for following-up of any necessary corrective and/or preventive actions shall be discussed with the complainant and documented.

**Disputes and Appeals**

5.19 Where a complaint is not resolved to the satisfaction of the complainant, he/she may appeal the decision.

5.20 A written appeal against the resolution of the complaint may be lodged in by the complainant to the Head of NMRA.

5.21 The head of NMRA with the technical input from the investigation team, relevant departments and the Legal Services Unit shall set up an Appeal Panel to review and analyze the appeal.

5.22 The Appeals Panel shall not comprise of individuals or persons who were involved in the original activities in question or dispute.

5.23 The Appeals Panel shall review the existing and any new evidence/information and determine if there is sufficient objective evidence to justify the appeal and shall report its findings to Management team for hearing.

5.24 If the Appeal Panel is appointed by the NMRA’s Board then the Panel shall report its findings to the Board, which will then communicate the final decision to the head of NMRA for action.

5.25 The head of NMRA shall then communicate the decision to the appellants and those in dispute, in writing.

5.26 Where no further action is raised from the appellant or disputing party concerning the decision within 21 working days, NMRA will presume the decision to be satisfactory to the client and the file will be closed by the Head of NMRA.
5.27 Where the appellant is not satisfied with the decision of the board, he or she can seek legal redress according to the applicable Member State National Laws.

5.28 Summary of all complaints/customer feedback shall be reviewed in the management review meetings.

6. Complaints received at Branches of NMRAs

6.1 Complaints received at Branches, shall be register and submit a periodic report shall be sent to the head NMRA by the Branch managers except for those complaints that are beyond their authority levels particularly policy related issues. Such complaints shall be forwarded to the head of NMRA at the headquarters for action as per clause 7.

6.2 At Branch level, Branch manager shall review the complaint and conduct investigation (if necessary) and communicate the outcome to the complainant.

6.3 Depending on the outcome of the investigations, the Branch manager may take corrective action.

6.4 In case the complainant is not satisfied with the outcome/feedback on the complaints submitted, the complainant may appeal to the head of NMRA.

7. Data analysis

7.1 HQM shall analyse data collected from customer complaints register against the quality policy and quality objectives, clients’ service charter, time to deliver service, accuracy, reliability, consistence and others to determine opportunity for improvement using appropriate statistically methods including MS Excel as per complaints analysis form ****.

7.2 The results of data analysis shall be one of agendas in management review meeting(s).

8. Records

The records include completed customer complaint form, customer complaint register and complaints analysis form and shall be filed in customer complaints file and maintained at the register for a period of five years and then disposed off by tearing/burning/shredding or any other appropriate method.

9. References

EAC QMS Requirements


ISO/IEC 17020:2012; conformity assessment-requirements for the operation of various types of bodies performing inspections

EAC NMRA Quality Manual
**1. Purpose**

This procedure describes how corrective and preventive actions shall be undertaken to eliminate causes of detected, and of potential nonconformities within quality management system for continual improvement of services delivered by NMRA.

**2. Scope**

This procedure is applicable for use in the EAC NMRA at the Headquarters and in NMRA offices in other geographical locations for undertaking corrective actions and preventive action (CAPAs) that affect the quality of products or services.

**3. Responsibility**

The Management is responsible for reviewing and ensuring that corrective and preventive actions are implemented for continual improvement of the quality management system (QMS).

**4. Distribution List**

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<tbody>
<tr>
<td>a)</td>
<td>Head NMRA</td>
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<tr>
<td>b)</td>
<td>Directors</td>
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<tr>
<td>c)</td>
<td>Head Quality Management (HQM)</td>
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<td>d)</td>
<td>Head Customer Relations</td>
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<td>e)</td>
<td>Quality Assurance Officer (QAO)</td>
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<td>f)</td>
<td>All Staff</td>
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</table>
5. Areas to be considered

5.1 Corrective and preventive actions may be undertaken as a result of, but not limited to the following:-

• Complaints
• Application of new methods
• Trends established after data analysis
• Internal feedback for improvement
• Management review of the QMS
• Equipment monitoring
• Quality control activities indicating need for such actions.
• Non conformance
• Audit findings(internal and external)

6. PROCEDURE

6.1 Corrective Action

6.1.1 The HQM shall collect information required for analysis of detected nonconformity. Statistical analytical methodology shall be employed where necessary to detect recurrence and trends of nonconformity.

6.1.2 HQM shall issue CA number and assigns the identified CA to the responsible department investigation team which shall investigate the root cause of nonconformity relating to product, processes or quality system.

6.1.3 The responsible department completes the CA Form No. **********.

6.2 CA investigation

6.2.1 The department or investigation team will perform a cause-and-effect analysis to identify the root cause and suggest possible corrective actions to eliminate the cause of detected nonconformity.

6.3 Identification of required action(s)

6.3.1 The team in consultation with the management shall identify the most appropriate corrective action(s) needed to eliminate the cause of nonconformity and prevent its recurrence. A cause and effect analysis may suggest retraining of staff, amending of procedures, modifications of space, among others.

6.3.2 Once a Corrective Action has been identified, written and reviewed by the CA investigation team in consultation with the management, a copy will be given to the responsible Department and it will be their responsibility to implement the corrective action(s).

6.4 Verify and validate

6.4.1 The HQM shall verify and validate the Corrective action for purposes of monitoring the
6.5 **Implement and record changes**

6.5.1 The Head of department shall ensure that changes in methods and procedures are implemented and recorded.

6.6 **Disseminate information**

6.6.1 The HQM shall ensure that information related to the detected non-conformity and corrective action(s) taken is disseminated to those directly responsible for assuring the quality of the concerned products or services.

6.7 **Management Review**

6.7.1 The HQM shall submit relevant information on implementation of CA to the management review

6.8 **CA closure**

6.8.1 CA shall be closed as per CA request form.

6.9 **Preventive Action**

6.9.1 NMRA will determine the action required to eliminate the causes of potential nonconformities in order to prevent their occurrence using information from quality audit results, quality records and complaints.

6.9.2 Actions shall be appropriate to the effects of the potential nonconformities.

6.9.3 Potential nonconformities and their causes shall be determined during the Management review.

6.9.4 Any staff member can submit a Preventive Action Request Form No. …

6.9.5 These reports are evaluated and action required to prevent the occurrence of nonconformities is determined.

6.9.6 The action required is then implemented and documented in the Management Review.

6.10 **Identification of required action(s)**

6.10.1 The team in consultation with the management shall identify the most appropriate preventive action(s) needed to eliminate the cause of potential nonconformity. A cause and effect analysis may suggest retraining of staff, amending of procedures, modifications of space, among others.

6.10.2 Once a preventive action has been identified, written and reviewed by the team in consultation with the management, a copy will be given to the responsible Department and it will be their responsibility to implement the preventive action(s).
6.11 Verify and validate

6.11.1 The HQM shall verify and validate the preventive action for purposes of monitoring the implementation of such actions to ensure they are effective and does not adversely affect the goods and services provided.

6.12 Implement and record changes

6.12.1 The Head of department shall ensure that changes in methods and procedures are implemented and recorded.

6.13 Disseminate information

6.13.1 The HQM shall ensure that information related to the detected non-conformity and preventive action(s) taken is disseminated to those directly responsible for assuring the quality of the concerned products or services.

6.14 Management Review

6.14.1 The HQM shall submit relevant information on implementation of PA to the management review.

6.15 Preventive Action Closure

6.15.1 PA shall be closed as per PA request form.

6.16 Records

6.16.1 Records include CA and PA request form, cause and effect analysis report, management review report shall be documented and maintained.

7. Definitions, acronyms and Abbreviations

Definitions:

- **Correction**: repair, rework or adjustment and relates to the disposition of an existing non-conformity
- **Corrective Action**: an action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.
- **Nonconformity**: non-fulfilment of a specified requirement.
- **Opportunity**: any situation that has potential to be a problem or an improvement.
- **Preventive Action**: an action taken to eliminate the cause of a potential nonconformity, defect or other undesirable situation in order to prevent recurrence.
- **Root Cause Analysis**: Root cause analysis is a method used to identify the immediate, underlying and root causes of an incident. The root causes are then used to recommend remedial action that will prevent incidents of a similar nature taking place in the future.
Acronyms and Abbreviation

SOP: Standard Operating Procedure
EAC: East African Community
NMRA: National Medicines Regulatory Authority
HNMRA: Head of National Medicines Regulatory Authority
QMS: Quality Management System
HQM: Head Quality Management
QAO: Quality Assurance Officer
QMS: Quality Management System.
CAPA: Corrective and Preventive Action

8. Amendment/Revision History

AMENDMENT / REVISION HISTORY

<table>
<thead>
<tr>
<th>Date of revision</th>
<th>Particulars of affected document</th>
<th>Type of changes</th>
<th>Effective date for changes</th>
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<tbody>
<tr>
<td>Issue No.</td>
<td>Rev No.</td>
<td>Section</td>
<td>Para No.</td>
</tr>
</tbody>
</table>

It is the responsibility of the holder of this document to ensure that amendments are appropriately implemented
Nonconformities / Opportunities results from:
- Internal audit findings
- Third party audit findings
- Complaints (internal or external)
- Observation
- Incidents
- Housekeeping inspections
- Checklist findings
- Monitoring agencies

NC / OP Detected

Immediate Action to correct/mitigate impacts

Report to QMS responsible

Report to Supervisor

Action record

Cause Analysis

Corrective / Preventive Action

Management Review

Verification of Effectiveness of Action
1.0 Purpose

To describe how management review meetings shall be conducted for the purpose of reviewing Quality Management Systems (QMS) to ensure that continual improvement.

2.0 Scope

The documented procedure applies to NMRAs top management for conducting management review meeting for the QMS.

3.0 Responsibility

The HNMRA is responsible for implementing the resolutions which are made in the meeting. It is the responsibility of Head Quality Management (HQM) to schedule the meeting, to prepare the agenda and ensure that meetings are held as planned.

4.0 Distribution List

Distribution is done as per documented procedures for control of documents.

5.0 Procedure

5.1 The HQM shall schedule management review meeting at least once a year.

5.2 Management review meetings shall be attended by members of top management of NMRA and any other staff deemed necessary.

5.3 The Head of NMRA shall chair the meeting and HQM shall be the secretary.

5.4 HQM shall draw up agenda for each meeting, which shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

5.5 The agenda and supporting documents with information to be discussed during the management meeting shall be sent to all members of top management of NMRA and any other staff.
5.6 During the management review meeting, the information to be presented shall include:

5.6.1 Results of internal and external quality audits,

5.6.2 Customer feedback (complaints, compliments, suggestions, etc.)

5.6.3 Key performance indicators for the regulatory processes,

5.6.4 Status of preventive and corrective actions,

5.6.5 Follow-up actions from previous management reviews,

5.6.6 Changes that could affect the quality management system, and

5.6.7 Recommendations for improvement.

5.7 Top management shall make resolution on areas which includes actions related to:

5.7.1 Improvement of the effectiveness of the quality management system and its processes,

5.7.2 Improvement of product related to customer requirements, and

5.7.3 Resources needed.

5.8 The HQM shall record Improvement items related to QMS, products or services provided or resources needed shall be recorded as Action Items in the meeting minutes together with identification of the responsible officers in charge of implementation or further investigations.

5.5 Minutes and action items shall be recorded in the management review meeting reporting form (indicate form number).

6 Records

Records include management review minutes, correspondences and agenda supporting documents shall be filed in the management review file and maintained as per documented procedures for control of records.
Annex 1: Management review meeting reporting form

NMRA form no.
REV#: 0

MINUTES OF THE MANAGEMENT REVIEW MEETING

.......................................................... ..........................................................
Chairperson Secretary

..........................................................
Date Date
PART FIVE

CODE OF CONDUCT FOR EAC PARTNER STATES NMRA
0. **Introduction**

0.1 **Background**

To be effective, the work of EAC NMRAs must be perceived to be objective and independent and performed by irreproachable personnel who observer the following principles.

a) **Integrity**

b) **Objectivity**

c) **Respect for others**

d) **Transparency**

0.2. **Objectives**

In order to ensure success of Medicine Regulation Humanization, each NMRA needs to:

a) Assure the highest personal standards of integrity, honesty and independence

b) Foster the spirit of loyalty and commitment to the goals of the NMRA

c) Assure impartiality and discretion to applicants

d) Develop public confidence in the transparency of or the NMRA’s processes.

The Code of Conduct sets out the practice for members of the NMRA’s Management Board, Advisory Committees, experts and staff on direct and indirect interests, and the necessity to declare them in order to avoid and manage potential conflicts of interests.

It also addresses financial or other interests in the pharmaceutical industry that could affect their impartiality.

0.3. **Scope**

This Code of Conduct applies to the members of the NMRA’s management board, advisory committees and staff.

This Code also applies to other persons working for the NMRA such as persons employed under private law contracts, experts on secondment, trainees or other relevant persons.

0.4. **Legal basis**

NMRA Partner States have laws and regulations that govern the code of conduct of public servants. These laws and regulation shall be followed in the line with this EAC code of conduct.

1. **CODE OF CONDUCT**

All NMRA personnel shall behave, conduct and observe the Code of Conduct as stipulated herein below:

a) Strive to achieve the highest ethical and performance standards in carrying out medicines regulatory activities;

b) Uphold the honour and dignity of the NMRA personnel and avoid association with any enterprise of questionable character or apparent conflict of interest;

c) Protect and promote the interests of the EAC Partner State to the best of his/her ability and knowledge,
recognizing that the NMRA has placed trust and confidence onto him/her;

d) Strive to acquire new knowledge and skills continuously and use them effectively;

e) Conduct medicines regulatory activities in a manner that will assure independence from outside influence and interest, which would otherwise compromise his/her ability to render a fair and impartial opinion regarding any medicines regulatory activity conducted;

f) Promptly disclose to the NMRA any interest in any business related to medicines which may affect the quality, or the result of his/her work or remediation;

g) Not use his/her position for personal gain;

h) Make every effort to uphold, maintain and improve the integrity and reputation of the NMRA.

i) Perform duties diligently, honestly and impartially to avoid circumstances that may lead to conflict of interest;

j) Maintain confidentiality whenever accessing confidential information as a result of medicines regulatory activity;

k) Assess facts quickly and take rational and sound decisions without delay;

l) Not solicit, force or accept bribes from a person whom he/she is serving, already served or will be serving either by doing so himself/herself or by using another person;

m) Not receive presents in form of money, entertainments or any service from a person that may be regarded as geared to compromising his/her integrity;

n) Disclose fraud or abuse of power and corruption to the top management of NMRA;

o) Avoid the use of rude and abusive language;

p) Report findings truthfully and accurately;

q) Make decisions in line with authorized standards and procedures;

r) Commitment to work;

s) Conserve customer and NMRA property and shall not use it for private gain.

t) Endeavour to avoid any actions that create an appearance and circumstance that are violating the law or ethical standards as determined by the perspective of a reasonable person with the knowledge of the relevant facts.

u) Adhere to the laid down laws, regulations, rules and standard operating procedures in executing his/her functions.
v) Maintain personal hygiene and dress in respectable attire in accordance with acceptable norms of the NMRA.

2. GUIDANCE ON CONFLICTS OF INTERESTS

2.1. Meaning of “conflict of interest”

In the context of these Guidelines, the term “conflict of interest” means any interest in any business related to medicines declared by NMRA personnel that may affect or reasonably perceived to affect the quality, or the result of his/her work or remediation.

NMRA’s conflict of interest rules are designed to avoid potentially compromising situations that could undermine or otherwise affect the work of the NMRA personnel, or activity in which the NMRA personnel is involved or NMRA as a whole. Consequently, the scope of the inquiry is any interest that could reasonably be perceived to affect the functions that the NMRA personnel is performing.

2.2. Types of Interests

2.2.1. Direct Interest

A conflict of interest is usually financial and arises where the inspector receives income or support that is related to or can affect the outcome of the medicines regulatory activity involved. The conflict could involve personal financial gain, such as consulting income or honoraria, a business interest, such as a partnership or joint venture; an investment, such as stocks or bonds; financial support for research from the private sector given directly to the inspector or to his university or research institution; or an intellectual property interest, such as a patent or copyright. A conflict could also arise where NMRA personnel’s participation in an activity accords him or her access to proprietary information or gives the NMRA personnel a commercial competitive advantage.

2.2.2. Interests of Others

A conflict of interest usually relates to the expert’s own interests. However, it could also be created by interests of others who may, or may be perceived to, unduly influence the NMRA personnel’s views. A typical example is where an inspector’s work can affect or be affected by interests held by the inspector’s family, rather than the inspector personally. Accordingly, relevant interests of the inspector’s immediate family members must be declared. Under these Guidelines, the term “immediate family member” includes the inspector’s spouse and children. “Spouse” includes a partner with whom the inspector has a similar close personal relationship.

In addition, if the NMRA personnel is aware that the outcome of the medicines regulatory activity would benefit or adversely affect other parties with whom the inspector has substantial common interests -- whether personal, professional or financial -- disclosure of those affected interests is also necessary. Examples of other parties include the inspector’s siblings, parents, employer, close professional colleagues, administrative unit or department.
2.2.3. **Public statements and positions**

NMRA personnel’s independent judgment could also be affected by **public statements made and positions held**. For example, an inspector may have taken a definite position related to a manufacturer to be inspected by providing testimony as part of a regulatory or judicial process. The inspector may serve on a board or hold an office in an organization that has taken a position, on the subject, and he or she is expected to represent or defend it. To the extent that such public statements and positions are declared in a DOI Form and/or known to the relevant NMRA, then such information must be subject to a conflict of interest assessment.

2.3. **When is the NMRA personnel required to complete a declaration of interests form?**

1. All NMRA personnel must complete Declaration of Interest (DOI) form (see Annex 1) before their recruitment can be confirmed and during the course of employment.

2. Board members and advisory committee members shall complete this form during their swearing in ceremony and before any meeting.

3. Expert and consultants shall complete this DOI form before providing any expertise or consultancy to the NMRA.

4. A DOI Form must be completed whenever NMRA personnel are asked to participate in medicines regulatory activities in a personal capacity and/or as representative of his or her institution.

5. DOI Forms should be completed and submitted by the concerned party and evaluated by NMRA before the concerned party begins to perform the tasks. This is necessary in order to enable the NMRA to make a conflict assessment in relation to medicines regulatory activity and the interests held at that time by the concerned party.

6. If the concerned party decline to complete a DOI Form, or if he/she refuses to disclose a potentially significant conflict to NMRA, the concerned party must not be permitted to participate in the NMRA tasks.

2.4. **Examples of interests that must be disclosed**

1) Financial interests and investments (stocks, compensation or otherwise);

2) Financial support for research activities provided by the private sector directly to the NMRA personnel or indirectly to his/her university or research institution;

3) Patents or other form of intellectual property that are held by a concerned party or that he/she is a beneficiary of and that relate to the subject matter of the activity;

4) Consultancies, employment relationships or other external professional activities as well as the name of the entities with whom the concerned party has or has had a
relationship as well as a general statement of the duration of such relationship, if known;

5) Speaking fees from, or sponsored participation in, lectures, symposia and seminars.

Examples of disclosure statements:

a) Shareholding in applicant pharmaceutical industry

b) Short-term or long-term consultancy for applicant pharmaceutical industry

c) Travel and/or accommodation paid by applicant pharmaceutical

d) When the concerned party is involved in a business related or similar to that of the applicant.

e) Has received any amount of money or gifts with a value of more than 200 USD from the applicant within the past 2 years.

2.5. How to analyse the information disclosed?

1. The DOI Form consists of a series of questions requesting disclosure of any interest relevant to the medicines regulatory activity activities to be performed in which the NMRA personnel has been invited to participate. If the inspector answers any question in the affirmative, he/she is asked to supply further details at the end of the form.

2. An affirmative answer in the DOI Form does not automatically disqualify the concerned party. Rather, affirmative answers are screened by the NMRA to determine if a potential conflict of interest exists.

3. The NMRA should request from the concerned party both an updated curriculum vitae (CV) where applicable. The NMRA should evaluate the responses in the DOI Form in conjunction with information in the concerned party CV, since one may provide relevant information that is not apparent from the other.

2.6. Safety of the filled DOI forms

1. All completed DOI Forms will be kept confidential and will only be used to evaluate whether the NMRA personnel’s declared interests constitute a real, potential or apparent conflict of interests. The form itself is a working document of the NMRA and should not be distributed or made public, also to protect legitimate privacy concerns of the inspectors. In this regard, the concerned unit in NMRA should not in any statement or document relating to a piece of work state that the DOI Form itself will be made available to the public or any other third party.

2. DOI forms should be retained by the concerned unit for at least five years. The DOI Forms should be filed and maintained in a manner consistent with general procedures for the retention of
confidential documents. In particular, the Forms should be in the custody of a senior officer of the concerned unit in segregated files kept in a locked cabinet.

3. GUIDANCE ON CONFIDENTIALITY

3.1. Introduction

Confidentiality is a set of rules or a promise that limits access or places restrictions on certain types of information.

EAC NMRAs have been entrusted with the important duty of protection of public health and the evaluation of medicinal products on behalf of consumers, patients and the pharmaceutical industry. Members of the Management Board, members of advisory committees, experts and NMRA staff members must treat information on the NMRA work with the utmost discretion and confidentiality.

EAC NMRAs face potentially conflicting obligations, requiring them to weigh the duty to protect public health, transparency and granting public access to documents, with the need to respect confidentiality of information that the NMRA holds, where appropriate as legally required.

Significant amount of information will be available and shared among EAC Partner States NMRAs. This access to information within the EAC, however, shall be balanced by the rules of professional secrecy for NMRA personnel and other concerned persons and the obligation to respect EAC and international laws on the protection of commercially confidential data in the pharmaceutical sector.

In the course of discharging NRMA functions NMRA personnel and other concerned persons will gain access to certain information, which is proprietary to the NMRA or entities collaborating with the NMRA, including the regulated industry. They undertake to treat such information (hereinafter referred to as “Confidential Information”) as confidential and proprietary to the NMRA or the aforesaid parties collaborating with the NMRA.

3.2 Confidential Information

“Confidential Information” shall include all information or material that has or could have commercial value or other utility in the business in which Disclosing Party (Herein referred to as NMRA’s clients or suppliers) is engaged.

NMRA personnel should be required to complete and submit the confidentiality agreement (annex II) after been permitted to participate in the medicines regulatory activity but before tasks of medicines regulatory activity begun.

All NMRA personnel shall be bound by this confidentiality undertaking.

3.3 Duty of confidentiality

All NMRA personnel shall be bound by this confidentiality undertaking;

a) To protect personal data and respect confidential information among the EAC NMRA, pharmaceutical companies and patients;

b) to exercise care when answering questions so as not to supply information to third parties regarding
specific products where this information is not public;

c) to exercise discretion when discussing professional work with third parties, including family and friends, and with colleagues or third parties in a public place, e.g. restaurant, public transport;

d) not to use the Information for any other purpose than discharging your employment obligations;

e) Not to use the information for commercial purpose

f) not to disclose or provide the Information to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

g) undertake not to communicate your deliberations and findings and/or those of other employees, as well as any resulting recommendations to, and/or decisions of, the NMRA to any third party, except as explicitly agreed by the NMRA.

h) To ascertain the provenance of the party putting a question and when needed for the party to put in writing;

i) To apply common sense when answering indirect questions seeking to obtain information

j) To follow a laid down procedures for handling of requests for access to information;

k) Not to speak directly to journalists and the wider media without express permission from the head of the NMRA.

l) To seek guidance from the top management in case of doubt.

However the NMRA personnel will not be bound by any obligations of confidentiality and non-use to the extent that they are clearly able to demonstrate that any part of the Information:

a) was known to you prior to any disclosure by or on behalf of the NMRA (including by the manufacturer(s)); or

b) was in the public domain at the time of disclosure by or on behalf of the NMRA (including the manufacturer(s)); or

c) becomes part of the public domain through no fault of your own; or

d) becomes available to you from a third party not in breach of any legal obligations of confidentiality.

3.4. **Continuing duty of confidentiality**

NMRA's management board, advisory committees, staff, other persons working for the NMRA such as persons employed under private law contracts, experts on secondment, trainees and other relevant persons have a life-long duty of confidentiality even after they have ceased their relationship with the NMRA. This covers all information of the kind covered by the obligation of professional secrecy. NMRA staff are required to behave with
integrity and discretion after leaving the NMRA for a period of two years following departure from the NMRA. Former NRMA staff should not exploit their relationship with former colleagues to obtain professional advantage or information of a specific or regulatory nature for personal advantage. NMRA shall apply a distance policy to former staff to ensure that its interests are protected and that such problems do not arise.

Staff leaving the NMRA are able to use the skills acquired in the course of their employment at the NMRA so long as such use is, for a period of two years, not in conflict with the legitimate interests of the service and does not interfere with their obligation of confidentiality.

This is, in particular, intended to prevent breaches of confidentiality that would be detrimental to the public interest, interests of the NMRA, EAC Partner States, applicants or holders of marketing authorisations.

3.5. **When is the NMRA personnel required to complete a confidentiality undertaking form?**

1. All NMRA personnel must complete Confidentiality Undertaking (CU) form (see Annex 2) before their recruitment can be confirmed and during the course of employment.

2. Board members and advisory committee members shall complete this form during their swearing in ceremony and before any meeting.

3. Expert and consultants shall complete this CU form before providing any expertise or consultancy to the NMRA.

4. If the NMRA personnel decline to complete the CU form, then he/she must not be recruited or engaged in NMRA.
1) **Instructions for declaration of conflict of interest**

Members of the Board, advisory committees and Staff of NMRAs, including other persons working for the NMRA such as persons employed under private law contracts, experts on secondment, trainees or other relevant persons may have interests related to their work.

To ensure the highest integrity and public confidence the NMRA personnel mentioned above shall disclose any circumstances that could represent a potential conflict of interest (i.e. any interest that may affect, or may reasonably be perceived to affect, the NMRA personnel’s objectivity and independence).

The NMRA personnel must disclose on this Declaration of Interest (DOI) form any financial, professional or other interest relevant to the NMRA. They must also declare relevant interests of their immediate family members (see definition below) and, if they (Staff, Board members and advisory committee) are aware of it, relevant interests of other parties with whom they (Staff) have substantial common interests and which may be perceived as unduly influencing their judgment (e.g. employer, close professional associates, administrative unit or department).

All staff must complete this form before their recruitment can be confirmed and during the course of employment.

Board members and advisory committee members shall complete this form during their swearing in ceremony and before any meeting.

All NRMA personnel must also promptly inform the NMRA if there is any change in this information prior to, or during the course of their service to the NMRA.

Answering “Yes” to a question on this form does not automatically disqualify you from service to the NMRA. Your answers will be reviewed by the NMRA to determine whether you have a conflict of interest relevant to the subject at hand. One of the outcomes listed in the next paragraph can occur depending on the circumstances (e.g. nature and magnitude of the interest, timeframe and duration of the interest).

The NMRA may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If, however, a declared interest is determined to be potentially or clearly significant, one or more of the following three measures for managing the conflict of interest may be applied.

The NMRA may:

a) allow full employment, with public disclosure of your interest;

b) mandates partial exclusion (i.e., you will be excluded from that portion of the work related to the declared interest and from the corresponding decision making process); or

c) mandates total exclusion (i.e., you will not be employed).

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**ANNEX 1: DECLARATION OF INTERESTS**

1146
Completing this DOI form means that you agree to these conditions. If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist and the NMRA may decide that you be totally excluded from the meeting or work concerned, after consulting with you.

Where there is sufficient evidence that the NMRA personnel has conflict of interest relevant to the NMRA and failed to disclose such conflict of interest on the Declaration of Interest (DOI) form this may lead to disciplinary action being taken against the concerned personnel.

2. **Form for Declaration of Interest**

Please answer each of the questions below. If the answer to any of the questions is “yes”, briefly describe the circumstances on the last page of the form. The term “you” refers to yourself and your immediate family members (i.e., spouse or partner with whom you have a similar close personal relationship and your children).

*Commercial entity* includes any commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the NMRA.

*Organization* includes a governmental, international or non-profit organization.

Name and Surname: ....................................................................................................................................
Position: ....................................................................................................................................................
**EMPLOYMENT AND CONSULTING**

Within the past 4 years, have you received remuneration from a commercial entity or other organization with an interest related to NMRA work?

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>1a Employment</td>
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<tr>
<td>1b Consulting, including service as a technical or other advisor</td>
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<tr>
<td>Previous year: Yes</td>
<td>No</td>
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<td>Name of company + product name:</td>
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<td>(please specify dates):</td>
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<td>More than 1 year ago but less than 3 years ago: Yes</td>
<td>No</td>
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<td>Name of company + product name:</td>
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<td>More than 3 years ago: Yes</td>
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<tr>
<td>Name of company + product name:</td>
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**RESEARCH SUPPORT**

Within the past 4 years, have you or has your research unit received support from a commercial entity or other organization with an interest related to NMRA work?

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<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>2a Research support, including grants, collaborations, sponsorships, and other funding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2b Non-monetary support or gift valued at more than US $250 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.). Support (including honoraria) for being on a speaker’s bureau, giving speeches or training for a commercial entity or other organization with an interest related to NMRA services?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If yes give details:
INVESTMENT INTERESTS

Do you have current investments or business (valued at more than US$ 5000 overall) in a commercial entity with an interest related to the NMRA? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>3a Stocks, bonds, stock options, other securities (e.g., short sales)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3b Commercial business interests related to NMRA work (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

INTELLECTUAL PROPERTY

Do you have any intellectual property rights that might be enhanced or diminished by working with the NMRA?

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>4a Patents, trademarks, or copyrights (including pending applications)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4b Proprietary know-how in a substance, technology or process</td>
<td></td>
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</tbody>
</table>

PUBLIC STATEMENTS AND POSITIONS *(during the past 4 years)*

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5a As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to regulated products, for a commercial entity or other organization?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5b Have you held an office or other position, paid or unpaid, where you represented interests or defended a position related to regulated products?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### ADDITIONAL INFORMATION

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6a</strong> If not already disclosed above, will your work enable you to obtain access to a competitor’s confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6b</strong> To your knowledge, would the outcome of the work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6c</strong> Excluding NMRA, has any person or entity paid or contributed towards your travel costs in connection with this NMRA work?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6d</strong> Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EXPLANATION OF “YES” RESPONSES:** If the answer to any of the above questions is “yes”, check above and briefly describe the circumstances on this page. If you do not describe the nature of an interest or if you do not provide the amount or value involved where relevant, the conflict will be assumed to be significant.
DECLARATION

I hereby declare on my honor that the disclosed information is true and complete to the best of my knowledge. Should there be any change to the above information, I will promptly notify the NMRA and complete a new declaration of interest form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

Date: .................................. Signature .........................................................
ANNEX 2: CONFIDENTIALITY DECLARATION

....... In the course of discharging your functions as an NMRA staff, you will gain access to certain information, which is proprietary to the NMRA or entities collaborating with the NMRA, including the regulated industry. You undertake to treat such information (hereinafter referred to as “the Information”) as confidential and proprietary to the NMRA or the aforesaid parties collaborating with the NMRA. In this connection, you agree:

a) not to use the Information for any other purpose than discharging your employment obligations; and

b) not to disclose or provide the Information to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

However, you will not be bound by any obligations of confidentiality and non-use to the extent that you are clearly able to demonstrate that any part of the Information:

a) was known to you prior to any disclosure by or on behalf of the NMRA [including by the manufacturer(s)]; or

b) was in the public domain at the time of disclosure by or on behalf of the NMRA [including the manufacturer(s)]; or

c) becomes part of the public domain through no fault of your own; or

d) becomes available to you from a third party not in breach of any legal obligations of confidentiality.

You also undertake not to communicate your deliberations and findings and/or those of other employees, as well as any resulting recommendations to, and/or decisions of, the NMRA to any third party, except as explicitly agreed by the NMRA.

You will discharge your responsibilities under the terms of employment. In this connection, you confirm that the information disclosed by you in the Declaration of Interest is correct and that no situation of real, potential or apparent conflict of interest is known to you, including that you have no financial or other interest in, and/or other relationship with, a party, which:

a) may have a vested commercial interest in obtaining access to any part of the Information referred to above; and/or

b) may have a vested interest in the outcome of the evaluation of the product(s), in which you will participate (such as the manufacturers of those products or of competing products).

You undertake to promptly advise the NMRA of any change in the above circumstances, including if an issue arises during the course of your employment with the NMRA.

I hereby accept and agree with the conditions and provisions contained in this document.

Signed: ............................................ Place: ......................................... Date: ...................................
Name (typewritten):