

Noguchi Memorial Institute for Medical Research Institutional Policy

Number : Mgt-040-1.0

Title : Quality Management Systems (QMS) Policy

Department : All Departments

This Policy supersedes: None or older versions Draft, Photocopied, and Obsolete versions of this document are not to be used.

EFFECTIVE: 14th June 2024

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1. Introduction

Quality Management is at the core of all activities carried out at the Noguchi Memorial Institute for Medical Research (NMIMR), University of Ghana (UG).

High-quality research, teaching, and biomedical services are attained by implementing and upholding an efficient Quality Management System (QMS) across all administrative, managerial, and technical services. Effective planning, monitoring, and continous improvement are essential for the successful management of a biomedical research facility such as NMIMR, UG.

2. Definitions

Quality management system: set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives.

Process: set of interrelated or interacting activities that use inputs to deliver intended result.

3. Purpose

- a. Management of NMIMR, UG, UG is committed to ensuring appropriate and sustainable QMS.
- b. This QMS policy applies to every staff, students and visitors of the Institute
- c. The policy also applies to all management and technical activities related to regulatory requirement which includes but not limited to International Organization for Standardization (ISO).

4. Responsibility

4.1 Institute Management Committee (IMC)

- a. The Institute Management Committee (IMC) shall:
 - i. Define the organization of the quality management structure in the NMIMR, UG, UG.
 - Specify the responsibility, authority, lines of communication and interrelationship of all personnel who manage the institutional quality management system.

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- b. Establish and maintain the quality policy and objectives.
- Ensure staff have the authority and resources needed to carry out their duties. c.
- d. Ensure an optimum quality management system through the application of continuous risk management.

4.2 Institutional Quality Office

The Institutional Quality Office (IQO) shall be headed by the Institutional Quality Manager (IQM) and shall constitute the Institute Quality Management Team, and Departmental Quality Managers. The office shall:

- a. Implement, maintain and continually improve the NMIMR, UG quality management system. The IQM shall be responsible for the management of the audit (internal and external) programme.
- b. Identify deviations from the quality management system including initiation of actions to minimize such deviations.
- c. Report to the IMC on the performance of the quality management system and any need for improvement, at all review meetings.
- d. Ensure the integrity of the quality management system in the Institute is maintained when changes to the quality management system are planned and implemented.
- e. The Institutional Quality Office shall liaise with the Institutional Safety Office on safety issues

4.3 Heads of Department

The Heads of Department shall:

- a. Provide leadership and ensure the effectiveness of biomedical and administrative activities.
- b. Assign responsibility, authority, lines of communication and interrelationship of all personnel who manage the departmental quality management system.
- c. Ensure the integrity of the quality management system in the department is maintained when changes to the quality management system are planned and implemented.
- d. Support the Institute's commitment to the quality management system with resources
- e. Provide opportunity for staff to develop their competencies, through appropriate development programmes.

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4.4 Departmental Quality Managers

Each department shall have a quality manager who shall:

- a. specify procedures to ensure the consistent application of laboratory/administrative activities and the validity of results.
- b. ensure the effectiveness of the quality management system in the department.
- c. Facilitate the application of risk management to all aspect of the department activities.

Policy Statements

4.5 Non-conforming events management

- a. Where necessary, NMIMR, UG shall take actions to eliminate the causes of nonconformities to prevent their recurrence as well as undertaking appropriate corrective actions considering the impact of the problems encountered.
- b. Personnel of the Institute shall be responsible for the identification, reporting and where applicable resolution of non-conforming events relating to administrative, managerial, laboratory and research activities as described in the approved procedure.
- c. Coordination for resolving non-conforming events shall be the Institutional Quality Office (IQO)'s responsibility. The IQO will collaborate with relevant offices and portfolios of the institute to ensure all non-conforming activities are duly resolved.
- d. Actions taken to correct non-conforming events shall be commensurate to the risk of recurrence of the non-conforming events. All records associated with the resolution of non-conforming events shall be adequately maintained and retained.

4.6 Document and records management

- The NMIMR, UG shall have a documented Management System. Documents defining a. or relating to the Management System (Controlled Documents) are approved and / or authorized prior to their issue and after every review. They are also subjected to controls (including their periodic and systematic review) to ensure they remain effective and that all NMIMR, UG staff have access to the right version of the document at the right time.
- b. Management policies shall be maintained in a quality binder. Policies including their revisions shall be communicated by the Institute Director to all staff
- c. All controlled documentation of the NMIMR, UG management system shall not be removed from the Institute without prior approval of the Director.

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4.7 Assessments

a. The NMIMR, UG shall maintain procedures to ensure internal and external audits are conducted by trained auditors at scheduled times to maintain and continually improve the adequacy and suitability of the quality management system.

4.8 Complaints and feedback

- a. The IMC shall demonstrate commitment to seeking and receiving feedback and complaints about services, systems, processes, procedures and complaint handling.
- b. All staff and other stakeholders of the Institute are encouraged to provide feedback on the effectiveness and efficiency of all aspects of the institute and its quality management system.
- c. Investigation and resolution of complaints shall not result in any discriminatory actions. The resolution of complaints shall be made by or reviewed and approved by persons not involved in the subject of the complaint in question.

4.9 Management System Processes

- a. NMIMR, UG shall establish and implement a management system in accordance with the requirements of ISO/IEC 15189, ISO 9001 and ISO 17025
- b. NMIMR, UG shall for the purpose of the continual improvement of the effectiveness and efficiency of its management put in place appropriate policies, processes and procedures as provided in its quality policy and quality objectives.
- c. The responsibilities and levels of authority of staff shall be provided in the job descriptions and appointment letters.
 - d. The IMC shall define and document the UG-NMIMR, UG Quality Policy and ensure that measurable quality objectives are consistent with its quality policy as established at all levels of its functions.

5. Attachments

a. n/a

6. Related documents

- Risk policy
- Personnel management policy
- Equipment policy
- Information security policy

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- Ethics policy
- Scientific misconduct policy
- Communications policy
- Policy on services
- Specimen management policy
- Equipment Maintenance policy
- Quality objectives

7. References

N/A

8. Policy Revision History

N/A

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9. Approval Page

Approved by Director

Name: Prof. Dorothy Yeboah-Manu

Signature:

Date: 10th June 2024

10. Policy Revision History

Policy #: Mgt-040-1.0 Triennial Review Date: 13th June 2027 Revised: