ROYAL CENTRE FOR DISEASE CONTROL

SOP No. RCDC/QMS/QSE/SOP-6.1

STANDARD OPERATING PROCEDURE

FOR

INTERNAL AUDIT

Version 1.00

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Prepared by: Kunzang Dorji, Sr.Laboratory Officer, Virology and Molecular Laboratory

Reviewed by: Quality team and Technical Committee, RCDC

Approved by: Dr.Sonam Wangchuk, Head RCDC

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1. ACRONYMS AND DEFINITION

ACRONYMS

- SOP: standard operating procedure
- QA: Quality assurance

Definition

Internal audit: An audit carried out by the laboratory personnel who examine the elements of a quality management system in their laboratory in order to evaluate how well these elements comply with quality system requirements.

2. PURPOSE

This SOP explains how to plan and carry out internal audits.Internal audit provides reasonable assurance regarding the achievement of the following:

- effectiveness and efficiency of procedures
- compliance with the quality policy
- Quality assurance improvement.

3. APPLICATION

This procedure ensures that internal audits are properly planned, and conducted regularly and when problems are identified that need to be investigated.

4. RESPONSIBILITIES

4.1 The Audit Group is responsible for the following internal audit procedures:

- Working with the QA manager to:
    - develop appropriate methodologies and objectives;

- coordinate the preparation of annual and long-range internal audit plans;
- establish documented standards for the conduct, documentation and reporting of audit, consultation and investigation activities.

- Instigating a timely follow-up to assess whether appropriate actions have been taken on reported audit findings.
- Ensuring rotation of auditor assignments to enhance freshness and objectivity of the Audit Group members.
- Determining appropriate minimum levels of staffing for the Audit Group.
- Coordinating the development and archiving of model audit programs to avoid duplication of efforts.
- Facilitating and serving as a conduit for the sharing of information among laboratory audit departments regarding:
  - planned audit efforts;
  - significant audit and investigation findings of mutual interest and concern;
  - audit reports issued;
  - development of improved audit techniques/technologies.
- Being mindful of Audit Group appropriate role versus the role of management and actively promoting and advocating a sound system of internal controls in support of operational effectiveness and efficiency objectives.

4.2The Quality Manager has the responsibility and sets the requirements for:

- planning
- conducting audits

- reporting results and maintaining records.

4.3 The management responsible for the area being audited ensures that actions are taken, without undue delay, to eliminate detected nonconformities and their causes.

5. PRINCIPLE

Internal audit: Examination of the elements of a quality management system in their laboratory in order to evaluate how well these elements comply with quality system requirements.

6. ASSOCIATED DOCUMENTS

- SOP Corrective Actions (ref RCDC/QMS/QSE/SOP-9.2)

7. PROCEDURE

Appropriate selection of auditors and effective audit techniques ensure usefulness, objectivity and impartiality of the audit process. NOTE: Auditors do not audit their own work.

The auditing procedure will:

- take into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits;
- Define the audit criteria, scope, frequency and methods.

The internal audit is a valuable tool in a quality management system. An internal audit can help the laboratory to:

- prepare for an external audit;
- increase staff awareness of quality system requirements;
- identify the gaps or nonconformities that need to be corrected and the opportunities for improvement;

- understand where preventive or corrective action is needed;
- identify areas where education or training needs to occur;
- determine if the laboratory is meeting its own quality standards.

Auditing procedure

The Audit Group will:

- Establish a checklist (QSE/Form-6.1)in accordance with standards established for the internal audit program.
- Conduct audit, consultation and investigation activities as planned.
- Go through the pre-established checklist.

Reports

The Audit Group:

- provides formal reports to the Head of Centre on audit, and at other times as requested.
- meets with the Head of centre to discuss audit matters of concern, to provide information on internal audit initiatives, and to promote consistency of internal audit oversight.

Follow up activities

- Establishment of corrective actions which will be documented as in RCDC/QMS/QSE/SOP-9.2
- Verification and validation of actions taken and results reporting.

8. ANNEXURE

Internal Audit Checklist (ref QSE/Form-6.1)