ROYAL CENTRE FOR DISEASE CONTROL

SOP No. RCDC/QMS/QSE/SOP/11.1

STANDARD OPERATING PROCEDURE FOR SOP MANAGEMENT

Version 1.00

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1 ACRONYMS AND DEFINITION

SOP: Standard Operating Procedures

QA: Quality Assurance

RCDC: Royal Centre for Disease Control

2 PURPOSE

Explains the management of all SOPs

3 APPLICATION

This procedure ensures correct management of SOPs.

4 RESPONSIBILITIES

- The Quality Manager is responsible for organizing and supervising SOP management.
- The technical staff is responsible for writing SOPs.
- The technical committee upon recommendation of QA team reviews the SOPs.
- The Quality team and the Biosafety Committee review and, if applicable, comment on quality- and biosafety-specific aspects of SOPs.
- The Laboratory head authorizes release of SOPs.
- The QA Manager is responsible for providing printed copies of SOPs.

5 PRINCIPLE

This SOP management is one of the critical components of ensuring competency of laboratory

6 PRECAUTIONS

Ensure SOPs on implementation are traceable and readily accessible

7 MATERIALS AND REAGENTS

- SOP files

- Dedicated shelves/space to store all the SOP hard copies

8 PROCEDURE

8.1 Methodology

- Managing Standard Operating Procedure (SOP) documents is a critical responsibility and a cooperative process between all users of the SOP document set.
- The SOPs need to be written, reviewed, authorized, published, distributed, revised and archived.

8.2 SOPs type

- SOPs provide step-by-step instructions to the laboratory's staff with respect to performing laboratory tests (analytical SOP), using a piece of equipment (equipment SOP), or successfully carrying out any kind of procedure/non-test activity (procedural SOP, e.g. SOP Document Distribution).

Each type of SOP follows the same general format:

- Acronyms & definition
- Purpose
- Application
- Responsibilities
- Principles
- Associated documents
- Sample requirements
- Materials and reagents
- Procedures
- Quality controls
- Limitations

- Annexures
- References

- Analytical SOPs also details for each laboratory test: principle, sample, equipment, reagents, and quality control.
- Equipment SOP details for each piece of equipment: description, safety, start up, calibration, validation, maintenance, operation, and troubleshooting.

8.3 Creation and editing

- SOPs are generally adopted from the RCDC's SOP templates and adapted to various kinds of SOPS(analytical, equipment, procedural). Each section of the template is completed or deleted if not applicable. Once a draft of the document is ready, it should be sent to the technical committee for review and comments.
- A copy should be sent to the Quality team and Biosafety Committee for review of any quality and biosafety aspects of the SOP.

8.4 Review and authorization

- The technical committee, along with the Quality team and Biosafety Committee whenever applicable, review the first draft of each SOP and make notes or comments on the draft. Any necessary revisions of the draft are made by the author(s). This review and revision process continues until the reviewers accept a final version.
- Each SOP is then sent to the Laboratory Head for authorization of release. Once the SOP is authorized, it is sent to the QA managerfor hardcopies to be printed.
- The authorization of the final SOP version is noted by the Laboratory Head signature on one dated copy. The author(s) and reviewer(s) also sign this copy.

8.5 Publishing

- Authorized SOPs should have sufficient copies printed for distribution.
- Signed documents (originals) should be stored in file cabinets.
- Electronic versions of SOPs should be stored on a secure file server with access restricted to authorized users.

8.6 Distribution

- Finalized and authorized SOPs are distributed to the staff that requires them for reference
- The Quality Manager will keep track of which staff members need specific SOPs, and will determine who has actually read and demonstrated comprehension of the documents as will the Biosafety Officer where needed (refer to SOP Document Distribution).

8.7 Revision of existing SOPs

- Each SOP is reviewed every year or whenever deemed necessary. The review can result, or not, in modification(s) of the SOP. The review process is coordinated by the Quality Manager.
- The decision to modify a laboratory procedure should not be made casually, but should only be recommended after thorough consideration. The reasons for the revision and the changes shall be sufficiently documented to ensure that the rationale for the revision is clear.
- If possible, changes to existing procedures should be made by the original author(s). If not, the Quality Manager coordinates the changes with the appropriate staff.
- After a decision to modify a procedure has been reached, the Quality Manager will serve as the point of contact responsible for ensuring that the new procedure is properly reviewed, authorized, and recorded for use.

- After a SOP has been revised, the following shall be identified on the front page of the document:
  - the date of the revision,
  - the person making the revision,
  - the changes made (and the reasons for the revision).
- Laboratory personnel and Quality team may determine that an SOP requires modification during the time the SOP is already in use. If the need for modification is urgent and requires that change(s) must be made in the field, the modified procedures should be thoroughly documented in the existing SOP. The justification for SOP modification should be communicated to the Quality Manager at the earliest possible time following the field modifications, followed by a copy of the revised SOP.

The Quality Manager will manage verification and validation the SOP modifications.

8.8 Archiving SOP versions

- When a published and distributed document has been revised, the previous version should be stored in an archive for 5 years and later discarded. This includes both the hardcopy and any electronic copies of the document. (Refer to RCDC/QMS/QSE/SOP-11.3 and RCDC/QMS/QSE/SOP-11.4).

9 REFERENCE

- Quality manual template
  WHO: https://www.who.int/ihr/training/laboratory_quality/quality_manual/en/