ROYAL CENTRE FOR DISEASE CONTROL

SOP No. RCDC/QMS/QSE/SOP/11.2

STANDARD OPERATING PROCEDURE FOR DOCUMENT MANAGEMENT

Version 1.00

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1. ACRONYMS AND DEFINITION

SOP: Standard Operating Procedure

QA: Quality Assurance

NA: Not applicable

IQC: Internal Quality Control

EQA: External Quality Assessment

ID: Identification

Definitions

Document: Information and its supporting medium; digital or physical.

Record: Document stating results achieved or providing evidence of activities performed. Information captured on worksheets, forms and charts.

2. PURPOSE

This procedure explains the overall management of all documents in RCDC.

3. APPLICATION

This SOP applies to all the staff in RCDC for proper document management

4. RESPONSIBILITIES

It is the Responsibility of Quality Manager to:

- Oversee the document management;
- Ensure uniformity throughout the units in assigning an ID Code to all new laboratory documents, completing the distribution list detailed in RCDC/QMS/QSE/SOP-11.5
- establish safeguards against the loss or unauthorized removal of documents, and make requirements and penalties for not following these requirements known to staff
- oversee laboratory test reports and records;

- assure that staff meet their responsibilities of keeping work records in the appropriate testing areas;
- verify that the required document archiving procedure is followed;

All the staff working in the centreall equally responsible in proper management of the documents in compliance with this SOP

5. PRINCIPLE

Document management contributes to the smooth operation of the laboratory's activities by ensuring quick and easy access to information contained in documents; protect documents from inappropriate and unauthorized access; meet statutory and regulatory requirements including archival, audit and oversight activities for documents. Further it provides documents as reference for protection and support in litigation; improve the laboratory's efficiency in obtaining and using information from files, and free up laboratory's space by moving inactive records to storage facilities.

6. ASSOCIATED DOCUMENTS

- SOP Document Distribution and Control: Ref RCDC/QMS/QSE/SOP-11.5
- SOP Long Term Archiving: Ref RCDC/QMS/QSE/SOP-11.4
- SOP Short Term Archiving: Ref RCDC/QMS/QSE/SOP-11.3

7. PRECAUTIONS

Ensure that the soft copies of the documents are securely maintained electronically by password protection system also the hard copies are securely maintained under lock and key.

8. MATERIALS

- Designated area
- Files and Folders
- Computer
- Data base system.

9. PROCEDURE

The life cycle of documents usually consists of four stages:

- Creation and Receipt
- Maintenance and Use
- Archiving
- Disposal.

9.1 Creation and receipt

- Employees are responsible for making records of their work. They create the records needed to their laboratory work. They will record decisions and actions taken and document the activities for which they are responsible.
- Supporting documentation of laboratory test records includes but is not limited to the following:
- Quality Control records including but not limited to the following:
    - Quality assurance records (IQC/EQA)
    - Performance and sterility check of media records
    - Autoclave sterilization records
    - Timers' and hygrometers' calibration certificates
    - Micropipette calibration records
    - Point check calibration of laboratory thermometers records
    - Thermometer calibration certificates
    - Temperature records for incubators, refrigerators and freezers
    - Records for laboratory equipment, such as autoclaves, dishwashers, microscopes, spectrophotometers, etc.
    - Daily record maintenance for instrument/equipment usage.
    - Media/reagent preparation records
    - Media and chemical control number records
    - Incidence record
    - Laboratory Decontamination Record

- Visitors' record.
- The Quality Manager shall date stamp these documents, when received, and check that these documents are properly filed.
- It is important that employees take proper care of documents so that information can be found when needed. This includes:
- Setting up clearly defined directories and files;
- Regularly filing materials in a manner that ensures safe storage and efficient retrieval.
- The minimum requirements for the unique identification of documents are:
- Title
- ID Code
- One or more of: version, current revision date, or revision number
- Number of pages
- Designated staff with authority to issue the document
- Database identification, if applicable.

- The ID Code given to all documents may include, as an example:

  - B XXX for books
  - R XXX for reviews
  - E XXX for equipment notices
  - MN XXX for manufacturer notices
  - ELB XXX for equipment logbooks
  - IQCLB XXX for Internal Quality Control logbooks
  - FLT XXX for forms, records, files, lists, tables and reports
  - P XXX for policies
  - PR XXX for processes
  - **SOP No. RCDC/section/SOP/no.** for Standard Operating Procedures

XXX is the number given according to:

- The referring chapter in the Quality Manual for P, PR, SOP, FLT, IQCLB and ELB
- The time of arrival

- A list, which identifies the current valid revisions and their distribution, is maintained. This list is also referred to as the document control logbook.

- Classifying laboratory documents involves gathering and maintaining the required documents in specific files according to their ID Code. As examples:

  - Personnel files (ID Code: FLT) – includes orientation form, copies of education qualification certificate, training(Both EX-country/In-country) certificate, performance evaluations and continuing education for each laboratory employee. These files are kept in the Section Head's office with restricted access.
  - Procedure manual (ID Code: SOP) – includes procedures for every test performed in the laboratory, with each procedure describing the pre-analytical, analytical and post-analytical phases of testing.
  - Equipment maintenance logbooks (ID Code: ELB) – includes documentation of maintenance. Note: Instrument manufacturers provide a maintenance schedule and often provide a master form to use.
  - Temperature logs (ID Code: IQCLB) – includes daily logs of the room temperature, and, if in use, incubator, refrigerators and freezers temperature logs.
  - Quality control logs (ID Code: IQCLB) – includes documentation of all quality controls for all tests performed in the laboratory.

- Proficiency testing (PT) records (ID Code: FLT) – includes ordering information, copies of results and evaluations, and all other PT related documentation (e.g., corrective actions, correspondence with PT providers).
- Patient test management (ID Code: FLT) – includes requisitions and reporting mechanisms.
- Calibration verification logs (ID Code: IQCLB).
- Method verification logs (ID Code: IQCLB).

9.2 Maintenance and use

- New procedures are distributed to concerned staff and the distribution list is kept, as indicated in SOP Document Distribution. This ensures all staff are aware of any kind of changes taking place in respective unit or in the centre

- Safeguards are established by the Quality Manager against the loss or unauthorized removal of documents.

- Laboratory records are maintained. They include quality performance test reports, biosafety reports, and other test reports produced by the laboratory.

- Documents are controlled as indicated in the RCDC/QMS/QSE/SOP-11.5

- Copies of laboratory test records are kept either in hard copy or electronic database system (the record of a laboratory test is the final printed data report). These records are accessible to only authorized personnel working in the respective area/unit. Records are kept for at least 10 years. After 10 years, record copies are retired to the Record Center due to space limitations.

9.3 Archiving

Appropriate archiving procedures for laboratory documents are followed(e.g. RCDC/QMS/QSE/SOP-11.4and RCDC/QMS/QSE/SOP-11.3).

9.4 Disposal

When a published and distributed document has been revised, the previous version should be stored in an archive for 10 years and later discarded. This includes both the hardcopy and any electronic copies of the document.

- Related documents:
  - SOP Document Distribution and Control Ref RCDC/QMS/QSE/SOP-11.5
  - SOP Long Term Archiving Ref RCDC/QMS/QSE/SOP-11.4
  - SOP Short Term Archiving Ref RCDC/QMS/QSE/SOP-11.3

10.QUALITY CONTROL

SOP on document control ensures the quality of all kind of document management

11.REFERENCE

- https://www.who.int/ihr/training/laboratory_quality/quality_manual/en/