ROYAL CENTRE FOR DISEASE CONTROL

SOP No. RCDC/QMS/QSE/SOP/11.5

STANDARD OPERATING PROCEDURE FOR DOCUMENT CONTROL

Version 1.00

Date: 09/06/2019

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CONTENTS

1. ACRONYMS AND DEFINITION 1
2. PURPOSE 1
3. APPLICATION 1
4. RESPONSIBILITIES 1
5. PRINCIPLE 1
6. PRECAUTIONS 1
7. MATERIALS AND REAGENTS 1
8. PROCEDURE 1
9. ANNEXURE 4
10. REEFERENCE 6

1. ACRONYMS AND DEFINITION

QM: Quality Manager

SOP: Standard Operating Procedures

2. PURPOSE

This procedure explains how to establish a document control process.

3. APPLICATION

This SOP applies to Quality manager (QM) to ensure document control in the laboratory.

4. RESPONSIBILITIES

The QM will be responsible for the control of documents.

5. PRINCIPLE

This document control is one of the integral essentials of quality management system as to appropriately maintain documents for their purposes

6. PRECAUTIONS

Ensure all records are traceable and easily accessible

7. MATERIALS AND REAGENTS

- Record files
- Dedicated shelves/space to store all the hard copies of documents
- Electronic storage of documents (Document Master list)

8. PROCEDURE

The goal of the document control process is to ensure that all documents are valid, current, approved, and readable.

Documents may exist in either paper or electronic format (or both), but document control shall be maintained in both formats.

The Quality Manager will annually ensure that:

- All documents are uniquely and correctly identified by:
  - Title
  - ID Code
  - One or more of: edition, current revision date, or revision number
  - Number of pages
  - Designated staff with authority to issue the document
  - Database identification, if applicable.
- All documents issued to personnel as part of the Quality Management System are reviewed and approved by authorized personnel prior to being issued (refer to RCDC/QMS/QSE/SOP-11.2 and RCDC/QMS/QSE/SOP-11.1).
- Only currently authorized versions of documents are available for active use at relevant locations.
- Documents are periodically reviewed, revised at least once a year or as and when deemed necessary, and approved for use by authorized personnel. Document action request form (Annex 2) to be used.
- Invalid or obsolete documents are promptly removed from all points of active use.
- Previous versions of documents that are retained or archived (refer to **RCDC/QMS/QSE/SOP-11.3** and**RCDC/QMS/QSE/SOP-11.4**) are appropriately identified to prevent their inadvertent use as the current version.
- Documents remain legible and readily identifiable.
- Documents of external origin:
  - are identified and their distribution controlled
  - are reviewed and approved for adequacy before use.

- A document control logbook (Annex 1) is maintained, which identifies the current valid versions by version number and distribution. Any document with document and version numbers that don't match the version in use, asdesignated by the document control log, is considered invalid or obsolete.
- A record shall be maintained to indicate distribution status of current documents and retrieval status of obsolete documents by Quality Assurance Unit as per annexure 2

9. ANNEXURE

Annexure 1: RCDC Document Master list

Document Master List for Royal Centre for Disease Control												
											Document Issue Record	
No	Type	SOP Number	Version	Document Name	Type	Effective Date	Author	Registered Date	Registered by	Date of Issue	Number of copy	Issued by
1. Standard Operating Procedures (SOP)												

Annexure 2: Document action request form

Document Action Request (DAR)

RCDC/VML/F/000

No_____/_____

Document Type

☐ Quality Manual ☐ Standard Operating Pocedure ☐ Form ☐ Other_____

Request to ☐ New document ☐ Edit ☐ Cancel ☐ Destroy ☐ Other_____

Document Name: _____

Document Number: _____ No. of new revision: _____

Effective Date: _____

Reason of Action: _____

_____

_____

Detail: _____

_____

_____

_____

_____

Attachment: ☐ Document ☐ File soft copy ☐ None

Request by: _____	**Verify by:** _____
Position:_____	Position:_____
Date:____/_____/_____	Date:____/_____/_____

Suggestion of verify person: _____

_____

_____

Approver comment:

☐ Approve

☐ Not approve because: _____

Approve by: _____

Position:_____

Date:____/_____/_____

DAR registered by:_____ Position_____Date___/___/___

10.REEFERENCE

EC. Good Manufacturing Practice Volume 4, Medicinal Products for Human and Veterinary Use,Chapter 4: Documentation. Brussels, Health and Consumers Directorate, European Commission, 2011