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RWANDA FDA Rwanda Food and Drugs Authority	**Title:** Control of records, Data and Information	

RWANDA FDA QUALITY CONTROL LABORATORY CONTROLLED DOCUMENT Tel/Fax : 9707

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INSTRUCTIONS

1. Controlled issues of this manual may **not** be copied;
2. **All** amendments are written on the page provided;
3. **Only** authorized, numbered, stamped copies of this manual as described in the document control section above, are used;
4. This standard operating procedures shall **not** be used outside the Rwanda FDA Quality Control Laboratory without the authority of the authorizing personnel.

1.0 Table of content

2. PURPOSE

The purpose of this procedure is to describe the way generated technical records, data and information are controlled in the manner that ensure proper archiving system.

3. SCOPE

This System procedure applies to control of all technical records, data and information generated in the QCL -LMS.

4. POLICY

ISO/ IEC 17025: 2017 Clause 7.5.1: The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original.

5. DEFINITION AND ABBREVIATIONS

In the context of this System Procedure, the terms and abbreviation defined in Quality control laboratory manual shall apply in addition to the following:

5.1 Record: A document stating results achieved or providing evidence of activities performed.

5.2 Outside parties: Individuals within or outside Quality Control laboratory: who may want to access Quality Control laboratory records for which they do not have the authority.

5.3 Audit trail: A set of records, or source of records that provide documentary evidence of the sequence of activities that have affected at any time a specific operation, procedure, or event

5.4 Data: Information that has been translated into a form that is more convenient to move or process

5.5 Raw data: Also known as primary data, is data which has not been subjected to processing or any other manipulation

5.6 Control: Measures taken to protect data integrity and confidentiality

6. PRINCIPAL RESPONSIBILITIES

All personnel in Quality Control Laboratory are responsible for the implementation of this system procedure.

6.1 The Quality Control Laboratory Division Manager is responsible for the overall quality, integrity and confidentiality of data generated by Rwanda FDA Quality Control Laboratory Division.

6.2 Laboratory Officers is responsible for:

a) Accurate data identification, collection and disposal of records generated within the Laboratory.

b) Ensuring that all data is legible, readily retrievable, stored and retained in such a manner as to prevent modification, damage or deterioration and or loss.

6.3 The designated Quality Management System Officer is responsible for:

a) ensuring that records that are required to demonstrate compliance to the QMS requirements are retained.

b) The disposal of records related to Laboratory Management System.

7. DISTRIBUTION

7.1 Division manager,
7.2 Designate Quality management system officer,
7.3 Designated Quality Management System Officer of Rwanda FDA,
7.4 All laboratory officer,
7.5 All laboratory technician.

8. SAFETY PRECAUTIONS

N.A

9. PROCEDURE

9.1 Generation of records.

9.1.1 All laboratory personnel can participate in the generation of a record; the record may be Quality or technical related.

9.1.2 Quality records include but not limited to audit reports, Laboratory management reviews, preventive maintenance charts, quality control charts, and corrective actions.

9.1.3 Technical records include but not limited to original observations where applicable, worksheets/ workbooks, calibration records, staff records and a copy of each test report issued

9.1.4 These records may be in the form of hardcopy, e.g. work sheet / work books, files, forms, microfilms, photographic, magnetic or electronic media.

9.2 Identification of records

9.2.1 Records are identifiable to the area, dates, product, event and a person who established.

9.2.2 Records are dated and a person who established the record identified.

9.3 Technical records

9.3.1 Quality Control Laboratory Staff ensures that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations are recorded at the time they are made are identifiable with the specific task.

9.3.2 Quality Control Laboratory Staff ensures that amendments to technical records e.g. Certificate of analysis, workbooks or worksheets are tracked to previous versions or to original observations. Both the original and amended data and files are retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

9.3.3 For easy traceability of all the information related to samples tested, workbook/ worksheet is properly filled.

9.3.4 Raw data generated during testing which are to be transferred in the work sheet/Workbooks are recorded and controlled in the same way as worksheets/ workbooks and the registers used are included in the master list of documents of that particular Laboratory.

9.3.5 If retesting of sample is needed for whatever reason, the records of results found should be recorded and controlled in the same manner as the similar first tested results.

9.4 The Work Books/ worksheets contain at least the following information;

9.4.1 Sample identification,
9.4.2 Sample source (option)
9.4.3 Sender, (option)
9.4.4 Sample description,
9.4.5 Physical conditions of the sample,
9.4.6 Reference standard specification if any, (option) 10.4.7
9.4.8 Parameters Requested,
9.4.9 Test method or QCL/ SOP used,
9.4.10 Major Equipment used,
9.4.11 Quality Controls done,
9.4.12 Instrument generated report and charts,
9.4.13 Date Analysis started,
9.4.14 Signature and date reported by the Laboratory officer,
9.4.15 Signature and date checked by supervisor,
9.4.16 Signature and date approved by Director.

9.5 Rules for Work Books/ worksheets

For Traceability and Transparency, the following rules are respected while using Work Books/ worksheets.

9.5.1 No two Laboratory officers are to use one Work Book/ worksheet
9.5.2 The content of Work Book/ worksheet is clear and neat.
9.5.3 No other Laboratory personnel is allowed to correct or cancel the records in the Work Books/ worksheet other than the owner.
9.5.4 For corrections or cancelingthe records in the Work Book/ worksheet by the owner, a single straight line followed by the signature and date shall be used.
9.5.5 Removal of pages from the Work Book is forbidden.
9.5.6 All records and calculations leading to the final results are recorded in the Work Books/ worksheets.
9.5.7 When the pages in a Work Book are used up; the owner forwards it to the Director of Unit for replacement.

9.6 Record legibility and Error Correction

9.6.1 All work performed are recorded legibly in a manner that another individual, competent in the same field, may repeat the work described solely from the description written without additional explanation.
9.6.2 Corrections in hardcopies are made by drawing a single line through the incorrect entry, enter the correct information, sign and date the change.

9.7 Electronic records

9.7.1 Electronic records are backed up to safeguard against the loss of information due to equipment malfunctions or human error and are controlled through the use of strong password and

encryption to give access to the Quality Control Laboratory with limitation depending on the nature of the records

9.7.2 In case electronic records need to be corrected, original data may not be changed, but the changed record needs to be stored using a new filename.

9.8 Access, Filling and storage

9.8.1 All Quality Control Laboratory personnel with the authority and responsibility to maintain specific records, have unlimited access to those particular records.

9.8.2 Access to Quality Control Laboratory records to outside parties are only allowed after the consent of the Division Manager.

9.8.3 There is restricted access to all records and information to prevent unauthorized use and modification information through locked cupboard, limited access to un authorized personnel in the Labs and offices.

9.8.4 Quality Control Laboratory electronic data, records and information are controlled through the use of strong password or encryption that gives appropriate right (s) to the relevant personnel.

9.9 Record, Maintenance and storage

9.9.1 All hard copy records are stored in specific locations as determined by the laboratory personnel with the responsibility for maintenance of records as indicated in different procedures

9.9.2 Records in hard copies are stored in a dry and clean environment.

9.9.3 Cabinets containing records are clearly labeled to display their contents.

9.9.4 Records are not supposed to be stored in private desk drawers or other obscure locations that are not generally known.

9.10 Record retention and disposal

9.10.1 All Quality Control Laboratory records except personnel records are retained for at least five years and there after disposed of.

9.10.2 Personnel records are maintained for the whole period of service in Quality Control Laboratory.

9.10.3 All hard Quality Control Laboratory copy records due for disposal are disposed of through incineration.

9.11 Control of data from equipment

9.11.1. All Rwanda FDA laboratory equipment is calibrated and maintained according to schedule so as to maintain integrity of data generated

9.11.1 Prior to carrying out a test, analysts will ensure that the internal system software verification process has been carried out satisfactorily.

9.11.2 If system software checks read an error the equipment will not be used as the quality of data generated cannot be guaranteed.

9.11.3 Data generated from equipment will be collected, stored and used only in the unit/division.

9.12 Control of Data from analysts

9.12.1 During the course of testing, data generated by analysts will be recorded as hard copy in logbooks and on computers for data processing

9.12.2 Access to computer data will be limited by the use of passwords.

9.12.2.1 Each user shall have a unique Username and Password.
9.12.2.2 Password validity shall be 30days
9.12.2.3 Password shall have at least 8 characters
9.12.2.4 The system shall not acquire last 5 expired passwords
9.12.2.5 Account shall be locked out automatically after 3 wrong log-in attempts. Lock of a user shall be unlocked only by the administrator.

9.12.3 Integrity of computer data is guaranteed through

9.12.3.1 Ensuring analysts are not authorised to change any finalised documents on computers
9.12.3.2 Use of "read only" to avoid overwriting documents

9.12.4 Access to Rwanda FDA analytical data is limited to Rwanda FDA analysts only.

9.12.5 Data confidentiality is maintained by restricting communication to customers through contractual obligations and policies.

9.13 Software for data processing

9.13.1 Both software developed in-house and externally will be validated on installation before use in the units/divisions.

9.13.2 Thereafter, verification will be carried out once a year.

9.13.3 Integrity of data entry, transmission and processing is ensured by checking of analytical reports against the raw data, method and specifications by Director of Unit.

9.14 Control of information management

Quality Control Laboratory staff have access to the data and information needed to perform laboratory activities.

9.14.1 The laboratory information management systems (LIMS) used in Quality Control Laboratory for the collection, processing, recording, reporting, storage or retrieval of data related to tested samples is validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction through verification and retrieval of the entered data and information.

9.14.2 Whenever there are any changes, including laboratory software configuration or modifications to commercial off the- shelf software in Quality Control Laboratory, the competent provider configures the software and the changes are authorized, documented and validated before implementation.

Both computerized and non -computerized laboratory information management system used in Quality Control Laboratory are;

a) Are protected from unauthorized access and safeguarded against tampering and loss through use of passwords and access control to the point of information;
b) Are operated in an environment that complies with provider instructions and Laboratory specified features and in the case of non -computerized systems, the hard copies are kept in lockable cupboards with entry limitation to where they are kept.
c) Are maintained in a manner that ensures the integrity of the data and information, this is done through data entry and modification limitation based on user 's authority and responsibilities.
e) include recording system failures and the appropriate immediate and corrective actions, where recording failures are identified as any other failure in the system and appropriate staff

with authority and responsibility on the particular recording system failures conduct appropriate actions.

9.11.5 When a laboratory information management system is managed and maintained off -site or through an external provider, Quality Control Laboratory ensures that the provider or operator of the system complies with all applicable requirements of ISO/ IEC 17025 :2017 and Laboratories own system eg. declaration of confidentiality and other applicable requirement.

9.11.6 The Quality Control Laboratory Staff ensures that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel and calculations and data transfers are checked in an appropriate and systematic manner.

10. APPENDICES

10.1 Document revision History

Date of revision	Revision number	Author(s)	Changes made and/ or Reasons for revision
14 August 2020	0	Felix T.	First issued
01 June 2021	1	Felix T.	Insertion of clause 7.3
01 June 2021	1	Felix T.	Clause 7.5.1. Rephrased

11. REFERENCES

11.1 ISO/ IEC 17025: 2017 Clause 7.5, 7.11 and 8. 4

11.2 Quality Control Laboratory Manual (QCL/MAN/001)