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RWANDA FDA Rwanda Food and Drugs Authority	**Title:** **Externally provided product and services including mechanism of recognition and reliance on the Laboratory testing results obtained from other laboratory**	

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SIGNATURE			
DATE	24 August 2020	24/08/2020	24/08/2020

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. TABLE OF CONTENT

2. PURPOSE

The purpose of this procedure is to describe the process of acquisition of suitable externally provided products and services from request to receipt

3. SCOPE

This procedure covers all the processes involved during the purchase, receipt and storage of all Laboratory Externally Provided Products and Services.

4. POLICY

ISO/ IEC 17025:2017, Clause6.6

5. DEFINITION AND ABBREVIATION

In the context of this System Procedure, the following abbreviations and terms are defined as follows in addition to those defined in Quality control laboratory manual:

5.1 Externally Provided Products and Services

Externally provided products and services include: equipment, consumable materials, reference materials and services such as calibration, sampling, testing, facility and equipment maintenance, proficiency testing, assessment and auditing services that affect laboratory activities.

5.2 Laboratory consumables

These are materials used in Quality Control Laboratory other than the Laboratory equipment. Laboratory Consumables include but not limited to the chemical standards, chemical reagents, sampling boats, latex gloves, spatulas, glass ware and cleaning materials.

5.3 Services

These can include but not limited to external training, equipment maintenance and repair, Proficiency test providers and accreditation services.

6. RESPONSIBILITIES

6.1 Request for acquisition of new externally provided products can be initiated once a need is identified either by senior management or by any Quality Control Laboratory personnel according to the customer need.

6.2 In addition to budgetary planning, the Division Manager is responsible for reviewing, approving of purchase requests, submitting technical specification and keep all approved records for purchased goods.

6.3 Division Manager is responsible to ensures that the reception of purchased goods and evaluation are done as per this procedure.

6.4 The Designated Store Keeper is responsible for the reception and storage of the purchased products.

7. SOP-DISTRIBUTION

7.1 Division manager
7.2 Designate Quality management system officer
7.3 All laboratory officer
7.4 All laboratory technician

8. SAFETY PRECAUTIONS

Not applicable to this SOPs

9. PROCEDURE

9.1 Selection and purchase of Laboratory Externally provided products and services

9.1.1 When the budget is available and there is a need for purchasing any Laboratory products it uses; the Division Manager notifies Laboratory officers to prepare technical specifications relevant to the needed products.

9.1.2 Upon the approval of the request or management need, The Division Manager Inquires the technical specification from the Laboratory officers.

9.1.3 the assigned Laboratory officer prepares the technical specification within the communicated time frame and submits to the Division Manager

9.1.4 The Division Manager review and approve specification of externally provided products and submit them to the procurement office for purchase processing.

9.1.5 The selection of externally provided products providers and procurement process in Quality Control Laboratory is done in accordance with public procurement Law modifying and completing the Law n°12/ 2007 of 27/ 03/ 2007 on Public Procurement N°05/ 2013 du 13/ 02/ 2013 (this include but not limited to Announcement of the tender, launching of the tender, evaluation of the tender document of tender documents, approval and contract signing).

9.1.6 On reception, the Laboratory officer ensures that purchased products that affect the quality of tests are not used until they have been evaluated or otherwise verified as complying with technical specification as described in the tender document.

9.1.7 During evaluation, the form QCL/ FOM/039 is used and signed by the evaluator.

9.1.8 After evaluation, the accepted supplies and accompanied documents are kept by the Division Manager and the designated store keeper whilst the rejected ones are returned to the supplier.

9.1.9 Rejected supplies due to deviation from the contract are treated as per public procurement law.

9.1.10 For the accepted supplies the Division Manager provides the supplier with the filled purchase acceptance certificate signed by both parties.

9.1.11 For the Equipment, after physical examination and approval the supplier proceeds with installation and commissioning to ensure the purchased equipment operates in the way it is expected and meets the technical specifications.

9.1.12 In recognition of the equipment commissioning, the Division Manager awards acceptance purchase Form QCL/ FOM/012 (see Appendix A) however the supplier is responsible for any fault or malfunction of the manufacturer source within the manufacturer specified guarantee period.

9.1.13 For the proper management of accepted chemicals and consumables in use, are internally requested using consumable requisition form QCL/ FOM/ 020 in appendix B, and the daily use managed with the use of Chemical management form QCL/ FOM/018 in appendix C is used

9.1.14 Suppliers of critical consumables are evaluated after every individual contract through Rwanda FDA procurement office and evaluation report is submitted to the Rwanda public procurement Authority to take action

U.1

10. Appendices

10.1. Appendix A: Consumable requisition form

Document type: Form		Doc. No: QCL/FOM/020 Revision No: 0 Effective Date:14 August 2020 Review Due Date: 24 August 2022 Ref. Doc: QMS/SOP/001
RWANDA FDA Rwanda Food and Drugs Authority	Document title: Consumable requisition form	

Requested by……..
Date……
Lab ……..
Expected date of delivery……

Serial number	Name of item	Specification	Quantity

Specify any other description of item (if any)
1) ……..
2) ……
….
3) ……
…..

Checked by immediate supervisor

Name……
…
signature……
Date……

Approved by Division Manager

Name……
….
signature……
Date……

10.2. Appendix B: Chemical management Form

Document type: Form		Doc. No: QCL/FOM/018 Revision No: 0 Effective Date:14 August 2020 Review Due Date: 24 August 2022 Ref. Doc: QCL/SOP/001
RWANDA FDA Rwanda Food and Drugs Authority	**Title: Chemical management form**	

Chemical Product name

date	Batch number	Quantity and size before opening	Date opened	Volume/weight Purpose measured	Fully emptying date	Username and signature

10.3. Appendix C: Purchase acceptance Form

Document type: Form		Doc. No: QCL/FOM/012 Revision No: 0 Effective Date:14 August 2020 Review Due Date: 24 August 2022 Ref. Doc: QMS/SOP/001
RWANDA FDA Rwanda Food and Drugs Authority	Document title: Purchase acceptance form	

This is to certify that the following consumable, reagents, culture media, herein included have been supplied (name and address of supplier)

……
……
……
……

And accepted by Quality control laboratory

Serial number	Supply description	Quantity supplied	Quantity not supplied

Observation, comment and Action

Supplier representative

S/N	Names	Position	Signature& date

Rwandafda representative

S/N	Names	Position	Signature &date

10.4. Appendix D: Document history review

Date of revision	Revision number	Author(s)	Changes made and/ or Reasons for revision
14 August 2020	0	Felix TUYISHIME	First issued

11. REFERENCES

11.1 ISO/ IEC 17025: Clause6.6
11.2 Quality control laboratory Manual (QCL/MAN/001)
11.3 RwandaFDA control document (QCL/SOP/001)