



LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

*P. O. Box 1994
Monrovia, Liberia
Cell: +231 – 777140555/888140555
Email: info@lmhra.gov.lr Website: www.lmhra.gov.lr*

REGULATIONS FOR SUB-CONTRACTING OF TESTING SERVICES



Regulation Code. : LMHRA-R-[SUBCON]-22-011
Date of Adoption : 10TH April 2023
Version No. : 01

Table of Contents

DECLARATION.....	3
CHAPTER I PRELIMINARY	4
Section 1: Title	4
Section 2: Application and Scope.....	4
Section 3: Purpose	4
Section 4: Definitions	4
CHAPTER II GENERAL CONSIDERATIONS	5
Section 1: Background	5
Section 2: Rationale for Subcontracting.....	6
Section 3: Prohibition of subcontracting	6
CHAPTER III SELECTION PROCESS OF SUBCONTRACTED LABORATORIES	7
Section 1: Criteria for Selection of a Subcontracted Laboratory	7
Section 2: The Selection Process.....	8
Section 3: The Sub-contractual Agreement – Memorandum of Understanding	9
CHAPTER IV RESPONSIBILITIES OF THE CONTRACTOR (LMHRA QC LAB) AND THE SUBCONTRACTED LABORATORY	10
Section 1: The Contractor (LMHRA Quality Control Laboratory).....	10
Section 2: The Subcontracted Laboratory	10
CHAPTER IV OFFENSES AND PENALTIES.....	11
Section 1: Breach and Penalty for the Contractor (LMHRA Quality Control Laboratory).....	11
Section 2: Breach and Penalty for the Subcontracted Laboratory	11
ANNEX 1: CONTRACT LABORATORY APPROVAL FORM	12

DECLARATION

This Regulation is made in fulfillment of the Liberia Medicines and Health Products Regulatory Authority Act of 2010, which confers upon the Authority the responsibility of regulating medicines and health products within the Republic of Liberia. The Board of Directors by consensus, hereby promulgates this regulation designed for Medical Devices this **20th** day of **April**, 2023.

CHAPTER I PRELIMINARY

Section 1: Title

This Regulation shall be cited as the Regulation for Sub-Contracting of Testing Services and shall come into operation on the date of publication.

Section 2: Application and Scope

This Regulation shall apply to medicines and health products intended for quality control testing at external, accredited laboratories.

Section 3: Purpose

The purpose of this Regulation is to provide a legal framework for the sub-contracting of testing services to external, accredited laboratories.

Section 4: Definitions

In this regulation, unless the context otherwise requires, the following abbreviations, words, and phrases shall have the meanings as ascribed to them in this section.

“Accredited laboratories” means testing laboratories that have been audited regularly by an independent third party and have proven that they meet international management and technical system requirements of the standard and said laboratories have adequate equipment to perform the tests or calibrations.

“Compendial Methods” Means all materials including reference standards, chemicals, reagents, glassware, etc. required for the analysis of medicines.

“IEC” Means International Electrotechnical Commission

“ISO” Means International Organization for Standardization

“Lab Commodities” Means all materials including glassware, reference standards, chemicals & reagents, etc. which are required for the conduct of laboratory analysis.

“MoU” Means Memorandum of Understanding

“Subcontracting/ Outsourcing” Means hiring the services of a third-party, accredited laboratory to perform testing of products that cannot be performed internally, to meet turnaround time or external testing for confirmation.

CHAPTER II GENERAL CONSIDERATIONS

Section 1: Background

Subcontracting is the delegation by one party (the contractor) of some or all of its obligations under a contract to a third party (the subcontracted laboratory) for performance by the subcontracted laboratory. The general rule is that contractual obligations that do not require personal performance by the contractor may be subcontracted unless otherwise prohibited by the contract itself.

Subcontracting, also known as outsourcing, does not exonerate the contractor from being liable for any nonperformance by the subcontracted laboratory, even if the customer consents to the subcontracting. There are several reasons for outsourcing which include a lack of capacity to perform the task (logistics & human resources), cost of testing, for confirmatory testing and experience.

Testing laboratories are governed by the international standard ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories. ISO/IEC 17025 defines all aspects of a laboratory's quality system, from management requirements and document control to sampling of products and creating test reports. ISO/IEC 17025 also provides specific guidance for subcontracting.

The international standard provides the following four requirements:

1. The subcontracted laboratory chosen meets the requirements of ISO/IEC 17025.
2. The contractor must inform the customer and gain their approval for subcontracting.
3. The contractor is responsible for the subcontracted laboratory's work.
4. The contractor must maintain a register of all the subcontracted laboratories it uses for testing and record evidence of compliance with ISO/IEC 17025.

Proof of subcontracted laboratory's compliance with ISO/IEC 17025 can be demonstrated through accreditation from accreditation bodies. Conducting an audit of the potential subcontracted laboratory is always a good idea. The audit allows a hands-on evaluation of the laboratory's competence in the areas in which work will be subcontracted to them.

Section 2: Rationale for Subcontracting

Why subcontract? There are many reasons, but the most important ones are to meet the client's expectations for turnaround time and to re-assure the quality of the test results. Many factors could prevent a product-testing laboratory from meeting the expectations of the client, but using competent subcontracted laboratories by maintaining a subcontracted laboratory program can help eliminate these factors.

The first reason testing laboratories should maintain subcontracted laboratory programs is for situations in which excessive workload or temporary incapacity occurs. Whether a laboratory is bursting at the seams with work, or testing instruments and/or test benches are not operating properly and need repair, there are times when a client cannot afford to wait. In those situations, testing can be performed promptly by utilizing a reputable subcontracted laboratory.

The second reason why testing laboratories can benefit from maintaining subcontracted laboratory programs is in situations in which the requested testing is beyond the scope or expertise of a testing laboratory. For example, if a client requests specialized testing, such as microbiological testing, a laboratory that specializes in microbiological testing would be subcontracted to perform the requested test. Developing the resources (material, personnel, etc.) needed to conduct this type of testing would lead to excessive costs and extended completion timelines.

Perhaps the most convincing reason testing laboratories should maintain subcontracted laboratory programs is to monitor laboratories' work. Performing testing in two different laboratories provides an excellent opportunity to monitor the results of the approved subcontracted laboratories. Comparison testing can also be performed by the laboratory requesting the subcontracting and a laboratory that is an approved subcontracted laboratory to ensure the work the laboratory requesting subcontracting performs is accurate. All parties involved with this process benefit because any discrepancies between the results will be addressed and resolved.

Section 3: Prohibition of subcontracting

It is forbidden to subcontract the planning of any proficiency test scheme, the evaluation of performance, or the authorization of the final report.

CHAPTER III SELECTION PROCESS OF SUBCONTRACTED LABORATORIES

Section 1: Criteria for Selection of a Subcontracted Laboratory

- a. Testing laboratories are subject to meeting the requirements of ISO/IEC 17025 if they are to be used as subcontracted laboratories. Testing laboratory's compliance is usually established through a facility audit. However, these laboratories have additional means of verifying competence for the analyses they conduct.
- b. The level of detail and record-keeping required for the selection of subcontracted laboratories varies based on the quality management system standard(s) that the laboratory may be required to follow. Subcontracted laboratory evaluation gives the laboratory assurance that the quality of external services used is on par with the high quality associated with the laboratory.

The following is a list of criteria to be used for the selection of subcontracted laboratories:

1. The subcontracted laboratory must have the capacity to perform the required test(s) using official and recognized methods (compendia or validated in-house methods).
2. The subcontracted laboratory must be WHO-prequalified and/or accredited to ISO/IEC 17025 standards (current versions).
3. The scope of accreditation of the subcontracted laboratory must include the test parameters being requested by the contractor (LMHRA Quality Control Laboratory).
4. The subcontracted laboratory must demonstrate a sense of urgency in testing the samples of LMHRA.
5. The subcontracted laboratory must be willing to pick up the samples when they are sent and must be willing to start testing immediately upon the arrival of the sample.
6. The subcontracted laboratory must not only provide test results but also interpret the results if needed.
7. The subcontracted laboratory must allow 2nd-party audits once a two-year or the frequency can be changed considering the number of samples analyzed in the contracted laboratory or as and when required.
8. The subcontracted laboratory must be willing to allow LMHRA to review any previous audit report for compliance.
9. The subcontracted laboratory must have the ability to suggest test parameters that are possibly more appropriate, in addition to or in place of the test parameters being requested by the LMHRA Quality Control Laboratory.

10. The subcontracted laboratory must demonstrate evidence of participation in proficiency testing and must allow LMHRA to review said proficiency test results.
11. The cost of testing must be reasonable.

Section 2: The Selection Process

Selection of the subcontracted laboratory shall be done in the following manner:

1. The contractor (LMHRA QC Lab) shall establish its needs from the laboratory to be subcontracted.
2. The contractor (LMHRA QC Lab) shall search to select potential laboratories to be subcontracted. The Quality Control Manager shall serve as the lead person for this process.
3. Once the potential laboratories are identified, the Quality Control Manager shall submit a ***contract laboratory approval form*** (Annex I) to each of the laboratories that would have been selected for evaluation. The information on the form shall include but not be limited to:
 - a. Contact information
 - b. Capabilities
 - c. WHO Pre-qualification and/or ISO/IEC 17025 certification
 - d. References
 - e. Pick-up program
 - f. Response time
 - g. Audit record
 - h. Ability to offer other options
 - i. Pricing
4. When the filled-in forms shall have been submitted, the forms shall be evaluated by an Evaluation Team comprised of the Quality Control Manager, Quality Assurance Manager, and Laboratory Director. This Evaluation Team shall determine the laboratory to be subcontracted based on the selection criteria indicated in Section 1.
5. The selected laboratory to be subcontracted shall be notified about its selection.

Section 3: The Sub-contractual Agreement – Memorandum of Understanding

The Contractor (LMHRA QC Lab) and the Subcontracted Laboratory shall sign a Memorandum of Understanding (MoU). The content of this MoU shall spell out the responsibilities of the Contractor and the Subcontracted Laboratory as indicated in the subsequent chapter (Chapter 4). Notwithstanding, the terms of the MoU shall be mutually agreed by the Contractor (LMHRA QC Lab) and the Subcontracted Laboratory.

CHAPTER IV RESPONSIBILITIES OF THE CONTRACTOR (LMHRA QC LAB) AND THE SUBCONTRACTED LABORATORY

Section 1: The Contractor (LMHRA Quality Control Laboratory)

- a. The Contractor (LMHRA Quality Control Laboratory) shall provide all samples to be tested in their original packages as per the sample schedule which shall be provided by the Subcontracted Laboratory.
- b. The Contractor (LMHRA Quality Control Laboratory) shall ship all samples to the Subcontracted Laboratory at the expense of the Contractor.
- c. The Contractor (LMHRA Quality Control Laboratory) shall pay all fees to be charged by Subcontracted Laboratory. Said payment shall be made to the bank account to be designated by the Subcontracted Laboratory, along with all associated bank charges.
- d. The Contractor (LMHRA Quality Control Laboratory) shall provide all other relevant information as may be required by the Subcontracted Laboratory.

Section 2: The Subcontracted Laboratory

- a. The Subcontracted Laboratory shall provide the sample schedule and fee schedule to the Contractor (LMHRA Quality Control Laboratory).
- b. The Subcontracted Laboratory shall analyze all samples sent by the Contractor (LMHRA Quality Control Laboratory) in line with the provision of the current version of WHO-Prequalification Standards or ISO 17025 and per the test parameters that may be requested by the Contractor.
- c. If the Subcontracted Laboratory is incapacitated to perform any test parameters requested by the Contractor, the Contractor shall be formally informed of said incapacitation within fifteen (15) days after receipt of the samples is confirmed.
- d. The Subcontracted Laboratory shall communicate all test results thru PDF-formatted electronic means, and send to the Contractor (LMHRA Quality Control Laboratory), a hard copy of the said result, via courier services or other means at the expense of the Subcontracted Laboratory.
- e. The Subcontracted Laboratory shall make a report (Certificate of Analysis) to the Contractor (LMHRA Quality Control Laboratory) not more than forty-five (45) days after delivery of the Sample by the Contractor (LMHRA Quality Control Laboratory) and receipt by the Subcontracted Laboratory.

CHAPTER IV OFFENSES AND PENALTIES

Section 1: Breach and Penalty for the Contractor (LMHRA Quality Control Laboratory)

The Contractor (LMHRA Quality Control Laboratory) shall be liable for a breach of any term or condition of the Memorandum of Understanding (MoU) that would be signed with the Subcontracted Laboratory. In such a situation, the Subcontracted Laboratory is at liberty to abandon her obligation under the MoU, provided that said breach is communicated by the Subcontracted Laboratory within twenty-one (21) days or a reasonable period, and that the Contractor (LMHRA Quality Control Laboratory) neglected or failed to remedy the situation.

Section 2: Breach and Penalty for the Subcontracted Laboratory

The Subcontracted Laboratory shall be liable for a breach of any term or condition of the Memorandum of Understanding (MoU) that would be signed with the Contractor (LMHRA Quality Control Laboratory). In such a situation, the Contractor (LMHRA Quality Control Laboratory) is at liberty to terminate the contract and demand a refund of all funds remitted under the agreement for analysis of the particular sample, and seek legal redress for consequential damages, provided that the breach was communicated to the Subcontracted Laboratory and she neglected or failed to adequately remedy the situation in twenty-one (21) days of the communication of the breach.

ANNEX 1: CONTRACT LABORATORY APPROVAL FORM

DETAILS OF THE LABORATORY TO BE SUBCONTRACTED	
Name of the lab to be subcontracted:	
Address:	
Contact person:	
Accreditation Status:	
Accreditation Scope:	
Audit Record:	
Capabilities:	
References:	
Pick-up Method:	
Ability to offer other options	
Price	
Signature of Contact	

This Regulation shall take effect immediately upon the approval of the Board of Directors.

A Regulation for Subcontracting Laboratory Services is Hereby Promulgated and Submitted for Approval to the Board of Directors on this 20th Day of April A. D. 2023 by the Managing Director of the Authority.



***Dr. Keturah C. Smith-Chineh
Managing Director / LMHRA***

A Regulation for Subcontracting of Testing Services is Hereby Approved by the Board of Directors.

Approved This 20th Day of April A. D. 2023

A handwritten signature in black ink, appearing to be 'L. Bawa', is written over a horizontal line. The signature is stylized and somewhat cursive.

**Pharm. Luke Bawa
Chairman / Board of Directors/LMHRA**