Center Infectiology Lao-Christophe Mérieux

QUALITY MANUAL

Version 1.0

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Center Infectiology Lao-Christophe Mérieux (CILM)
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PREFACE

This quality manual provides guidance for CILM laboratory on writing policies and procedures that support the quality management system. It is based on both ISO15189 Standard for Medical laboratories – Particular requirements for quality and competence – and CLSI GP26-A4 edition - and provides information and examples to assist with writing a quality manual that addresses all quality system essentials (QSE) that are critical for Quality Management. The manual is organized following the framework developed by CISI and the “Quality System Essentials”, Toolkit1.

A quality manual is required for implementing a quality management system. Such a system aims primarily at archiving customer satisfaction by meeting customer requirements through application of the system, continuous improvement of the system, and prevention of the occurrence of nonconformities.

“We at CILM, we commit to provide Quality Medical Laboratory service in term of generating reliable patient test reports, on time, using appropriate technology of international standards through committed and competent staff, who ensure to abide by the policies and procedures of the laboratory at all times with complete awareness of the required documentations.”

Sincerely

Dr. Ot MANOLIN

Director of Center Infectiology Lao-Christoph Merieaux

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REVISION HISTORY

Version	Author by	Approved by	Effective date	Detail of change
1.0	**Mixivang XAYAVONG**	**Dr. Ot MANOLIN** **Dr. Phimpha PABORIBOUNE**	**16/10/2017**	**Initial version**

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1. INTRODUCTION TO THE QUALITY MANUAL

1.1. OBJECTIVES OF THE QUALITY MANUAL

The CILM quality manual is a compiling document of quality management system in the Center Infectiology Lao-Christophe Mérieux (CILM). Its objective is to describe the structure of the quality management system in CILM centre on how it is implemented and how it's functioning. It further refers to all SOPs of the laboratory for more in-depth instructions.

1.2. SCOPE OF APPLICATION

The quality manual is open to everyone for the following scope:

Internal use	○ To communicate to the staff on laboratory's quality policies and quality objectives; ○ To make the staff familiar with the processes used to achieve compliance with quality requirements; ○ To facilitate the implementation of the quality management system as well as ensure its maintenance and required updates during altering circumstances; ○ To allow effective communication, control of quality related activities and a document for quality system summary used during audits.
External use	○ To inform the CILM's external partners about its quality policy as well as its implemented quality management system; ○ To measures its compliance with quality.

1.3. MANAGEMENT OF THE QUALITY MANUAL

The CILM quality manual is part of the document control system, accessible to everyone on the CILM web site *(http://www.ccm-laos.org/)* and stored properly in CILM main office by the quality officer. It is revised annually with the quality committee.

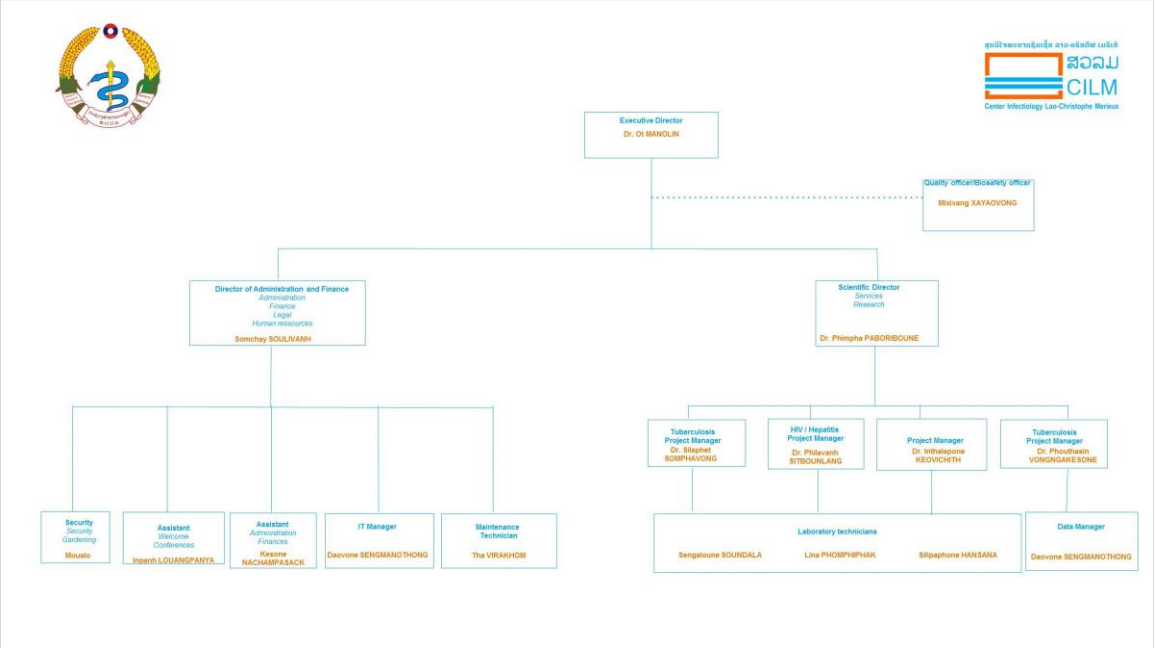
1.4. ACRONYMS AND TERMINOLOGY

BSL	Biosafety Level
CILM	Center Infectiology Lao-Christophe Mérieux
CDC	Centres for Disease Control and Prevention, USA
CISI	Clinical and Laboratory Standards Institute, Wayne, Pennsylvania, USA
EQA	External Quality Assessment
ISO	International Organization for Standardization
LQMS	Laboratory Quality Management System
QC	Quality Control
QM	Quality Manual
QMS	Quality Management System
QSE	Quality System Essential
SOP(s)	Standard Operating Procedure(s)
WHO	World Health Organization

2. ORGANIZATION

2.1. ORGANIZATION CHART

The general director of CILM is appointed by the ministry of health as the management team.



2.2. ACTIVITIES

To conduct its mission, the CILM follow dedicated activities:

- **Routine and specialized biology testing** of; HIV viral load measurement and ARV susceptibility testing; Hepatitis B on serological samples as well as plasma for viral load quantification; Hepatitis C viral load measurement and genotyping; *Mycobacterium Tuberculosis* testing and identification of resistant strains.
- **Applied research** project on infectious disease and respiratory pathogens.
- **Scientific conferences** to share knowledge and strengthen capacity in the field of infectious diseases.

2.3. MISSION AND VISION

The CILM is a biomedical laboratory that provides research and testing for HIV, Tuberculosis, Hepatitis B and C to physicians, health care providers, and epidemiologists for the benefit of the patient and population of Lao PDR. Inaugurated in 2009, the CILM develop diagnostic tools for infectious diseases.

Since 2012, the laboratory has adopted a quality management system for the purpose of effective and efficient use of its resources. All employees are committed to the culture of quality.

CILM three missions

Provide patient with quality diagnostic for improvement care.

Conduct project that address public health issues in Lao PDR.

Contribute to educating student in clinical biology and infection disease and promote high quality training by implementing advanced conferences.

2.4. RESPONSIBILITIES

Positions	Responsibilities
CILM General Director	• Designs, approves, implements and maintains the QMS; • Ensures that the necessary human and material resources, as well as the necessary information, are available to enable effective operation and control of the processes of the QMS • Delegates tasks to qualified personnel; • Selects suppliers; • Ensures adequate training; • Ensures internal and external communication.

Positions	Responsibilities
Quality/Biosafety Officer	• Assesses the facilities, procedures, practices, and training of personnel involved in the laboratory's activities, in regard to the QMS; • Reviews the quality plan annually and recommends any revisions needed to the Laboratory's Director/Manager; • Seeks advice from different departments and specialists and may require assistance from independent experts; • Establishes an internal audit program and informs the laboratory director/manager of audit outcomes; • Ensures that the quality management system is managed and maintained; • Establishes and monitors all processes and procedures for the quality management system; • Resolves nonconformities; • Ensures that action is taken in order to obtain continuous improvement of processes/activities; • Ensures all staff has up-to-date QMS training.
Scientific Director	• Designs, approves the QMS; • Provides and control all laboratory quality procedure • Delegates tasks to qualified personnel; • Selects suppliers; • Ensures adequate training; • Ensures internal and external communication.
Laboratory manager	• Manages, protects, and preserves stock; • Manages and maintains equipment; • Provides technical advice on laboratory quality procedures to personnel; • Reports to the supervisor any significant problems of which he/she becomes aware in daily practice.
Technicians	• Performs the tests; • Controls and maintains equipment; • Reports any significant problems of which he/she becomes aware in daily practice; • Checks performance of internal QC to validate the tests.
CILM Staff	• Preform the assignments according to the job description; • Follow the SOP; • Document on time the tasks; • Reports any significant problems of which he/she becomes aware in daily practice; • Follow meeting and training assigned; • Keep the environment safe.

2.5. QUALITY MANAGEMENT SYSTEM

2.5.1. QUALITY POLICY AND IMPLEMENTATION OF QUALITY POLICY

Quality policy

- to comply with ISO15189:2012 standards at all time;
- to maintain excellence in medical laboratory services using standard technology;
- to ensure compliance with the statutory and regulatory requirements;
- to ensure adequate resources and staff competence, enabling effective professional services;
- to complete the laboratory tests and reports the results in an effective and timely manner;
- to ensure continued patient satisfaction.

Implementation of Quality Policy

The Scientific Director has the authority, competence and responsibility for the services provided.

Laboratory management ensures the following:

- There are no activities that could compromise laboratory performance;
- There are appropriate procedures to ensure ethical respect of patient samples and confidentiality of patient information;
- Duties and responsibilities of laboratory personnel are defined;
- Appropriate communication is established within the laboratory.

2.5.2. ETHIC AND CONFEDENTIAL

The laboratory's obligation is to ensure that the patient's welfare is of the highest priority. CILM team commits to conduct clinical research in accordance with Good Laboratory Practice Clinical.

Confidential includes, but is not limited to, all information of a secret or confidential nature relating to the staff nature related to the affairs of any person whose information is held within the CILM. This will include: patient's relatives and friends, employees and any business or affairs of any other.

2.5.3. NON CONFLIC INTEREST

Laboratory management and personnel are free from any commercial, financial or other pressures and influences that may affect the quality if their work, if the potential conflicts in competing interests exist, they will be openly and appropriately declared.

Laboratory personnel must perform duties as per their job description, avoid involvement in any activities that diminish confidence in its competence, impartiality, judgment or operational integrity and laboratory personnel must read and sign the declaration for conflict of interest form.

2.5.4. PROCESS MAPPING

Quality Management System in the CILM it defined base on 3 objectives as:

management, operational and support process.

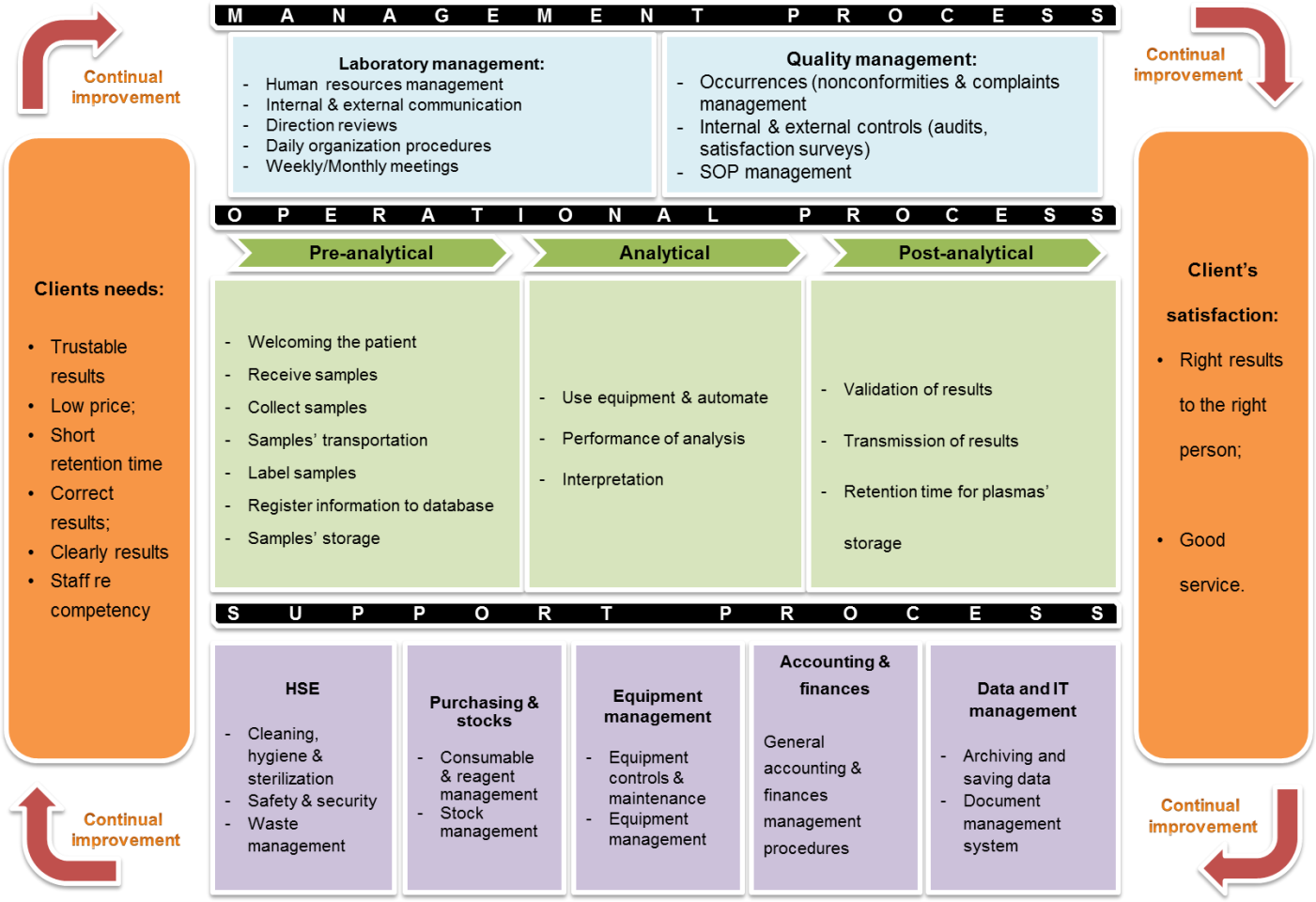
Definitions:

Management is all the general procedure, policy and means of CILM organization.

Operational is the process of performing laboratory activities.

Support process is all the procedure that supports the main activities in the laboratory.

Quality Management System – mapping process:



2.5.5. APPROACH PLAN

Year Plan

CILM draft a Quality year plan yearly based on the audit and assessment performed the previous years, which will summaries all nonconformity items and continuous improvements.

Every month during the quality meeting, the planning of the quality year plan implementation is monitored.

SMART Plan

From the quality year plan, the quality officer designs yearly a new SMART action plan, to achieve the quality year plan.

The quality officer assigns the CILM staff into the plan, to achieve it within the year.

The monitoring of the action plan is performed during the staff meeting every week for deadline reminding and new assignments.

2.5.6. ACCREDITATION

CILM is not yet accredited for ISO15189:2012, but intend to get accredited in 2018.

In order to reach the accreditation, CILM is using LQSI_Tools, 4 phases of WHO *(https://extranet.who.int/lqsi/)*

2.5.7. COMMUNICATION

Communication coordinator system in the CILM is present within two types:

- **Internal communication** takes place within CILM support media with:
  - Yearly board meetings, and quarterly reports to MoH
  - Weekly staff meeting and coordination meetings;
  - Authorized CILM staff only computerized server;
  - Telecommunications;
  - Quality billboard.

- **External communication** is between CILM and the health actors (as hospitals and patients) which use CILM service, with:
  - CILM website http://www.ccm-laos.org;
  - Results reports;
  - Telecommunications;
  - Seminars organization.

3. DOCUMENTS AND RECORDS

3.1. DOCUMENTARY ARCHITECTURE OF THE QMS

The quality manager reviews and approves all requests for amendments to existing documents and the development of new procedures, processes, and policies.

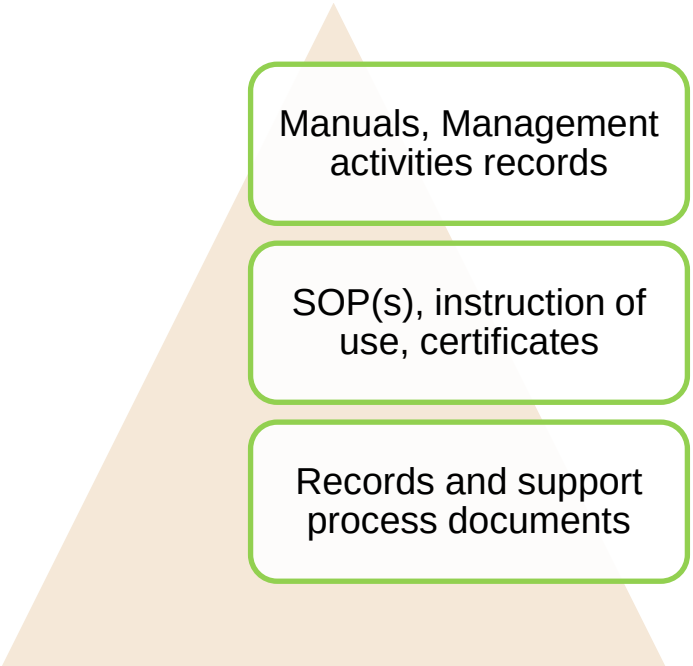
Staffs are not permitted to make temporary amendments to documentation without the prior consent of the quality manager.

When new or modified policies, processes and procedures are instituted, staffs require retraining.

The quality manual is reviewed periodically (establish time frame). All laboratory procedures are reviewed on an annual basis. The responsibility for the annual review lies with the document manager or quality manager.

The document manager or quality manager is responsible for the distribution of new documents, retrieval of old documents and maintenance of records of amendments.

Rankings of quality documents management system similar to the pyramid:



3.2. DOCUMENTS AND RECORDS CONTROL

All documents are uniquely identified with the following included in all documents:

- Data of issue and revision;
- Total number of pages;
- Authorizing signatories.

Documents are signed as a paper copy or authorized electronically.

A document control log is maintained identifying the current valid versions and their distribution

A secure master file is maintained of all documents to prevent unauthorized access, loss or damage ***LRM-DIP003-Master SOP implementing procedure***

3.3. CODING

Each SOP gets a unique code in the header of each page. Codes will not be changed after they have been assigned to a specific document.

Coding is done as shown below:

LRM	*Laboratory Rodolphe-Mérieux*	**PAP**	*General Pre-Analytical*
HRP	*Human Resources Management*	**DHP**	*Diagnosis Hepatitis*
GLP	*General Laboratory Management*	**DVP**	*Diagnosis HIV*
GQP	*Occurrence Management*	**DTP**	*Diagnosis Tuberculosis*
EQP	*External Quality Control*	**RRP**	*Reporting of Results*
ICP	*Internal Quality Control*	**HSP**	*Hygiene & Sterilization*
SSP	*Safety & Security*	**PSP**	*Purchasing & Stocks*
EMP	*Environment Management*	**EQP**	*Equipment*
DIP	*Information Management*	-	-

Example: **LRM – EQPxxx – Name of the document**

3.4. WRITING – APPROVAL – DIFFUSION

Every staff can take the initiative in writing SOPs, in discussion with the Lab Manager (LM) and the Quality Officer (QO). This person should have knowledge and expertise regarding the procedure for which a SOP is written.

Verification of quality document is done by:

- at least one user of the quality document for compliance with practice;
- the Quality officer for compliance with the quality standard.

Authorization of quality documents is done by the Lab Manager.

3.5. ARCHIVING

The quality manager is responsible for the proper archiving of documents and records trough the ***Document Retention Matrix***.

A copy of an obsolete document is kept to provide a means for review if the situation arises.

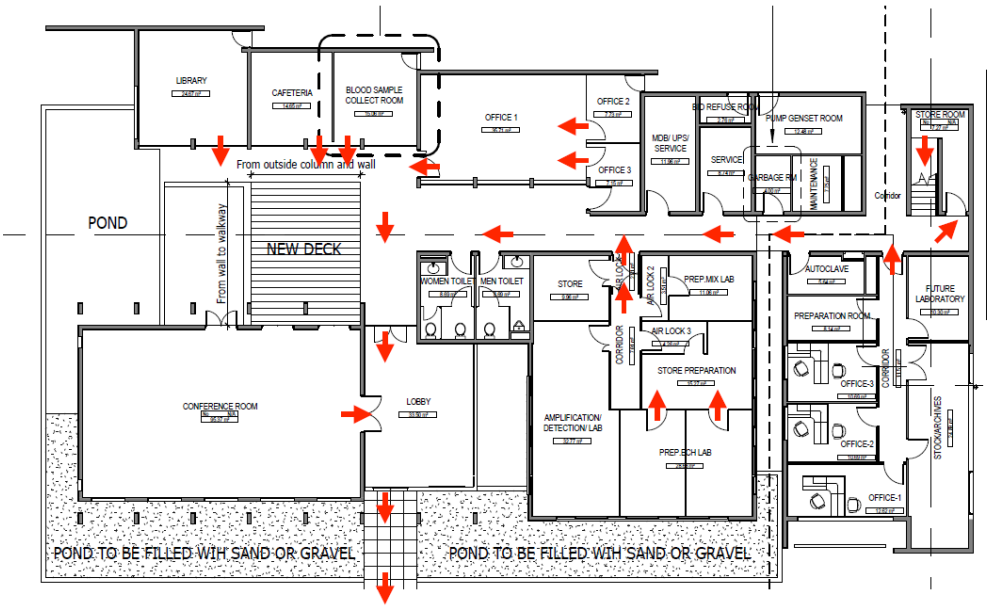
The quality officer monitors the archives by the destruction of documents which passed the time determined in the Document Retention List.

3.6. REFERENCE STANDARDS

The quality officer identifies the external origin's documents relating to the activity of quality office, especially by consulting reference organizations as WHO and ISO.

4. FACILITIES AND SAFETY

4.1. FACILITIES



Gathering point on the parking

CILM facility is provided for all CILM's staffs, patients, visitors, students and conference's participants such as:

- Eight office rooms including: director room, deputy director room, admin and finance room, research assistant room, lab staff room and 3 Mérieux foundation room;
- One reception room to facilitate for patients and visitors;
- One conference room for maximum 70 people and 1 meeting room for maximum 15 people;
- An Electric room, a cleaner room, a dining room, four stock rooms (2 laboratory stocks), an autoclave room and a sample correction room;
- One safety laboratory including: Lab 1 for preparation of mix; Lab 2 extraction room and Lab 3 for PCR testing.

4.2. SECURITY

CILM security is provided for all CILM's staff and all people who come to CILM such as patients, conference's participants and visitors.

- The CILM is clearly marked with the appropriate signage to circle in correct way.
- Security guard available every day from 7 PM to 7 AM.
- An access card regulates access to the laboratory.
- The facilities are linked to an alarm system at the central post of security.
- Limit assess for the important room by key lock.

4.3. WORKING ENVIRONMENT

CILM working environment is regulated by a biosafety and biosecurity officer according the CILM's Laboratory Biosafety Manual Version 1.0.

CILM has adequate space and utilities properly organized for work in a safe environment for the staff, patients, customers and visitors:

- Cleaners to ensure the good housekeeping: general tidiness, cleanliness, hygiene, freedom from rodents and insects.
- Appropriate utilities as: clean water, lighting, ventilation, electric outlets, back-up power, drainage systems, sanitation, pressure and temperature monitoring in the facilities for patients and staff.

Biosafety and biosecurity officer perform once a year biohazard assessment to review the working environment, and monitor the compliance.

4.4. WASTE DISPOSAL

The waste management at CILM is performed according to **LRM-EMP001-Waste Management** in the Laboratory.

To ensure the proper waste disposal and avoid contamination, CILM use:

- Staff training to ensure that all of them had been understanding the regulation and procedure for the waste disposal;
- Signage and labelling the waste bin inside and outside the laboratory
- Special containers used for sharps disposal wastes;
- Waste sorting to separate between infectious and non-infectious waste;
- Autoclave the infectious waste with controlled by spore test;
- Destruction certificate from land fill.

5. EQUIPMENT

5.1. SELECTION OF EQUIPMENT

New equipment selection is defined by a small group, composed with staff member who will use the needed equipment.

The specification will by defined regarding:

- Use
- Prize
- Performance and quality
- Space and environment
- Delivery
- Maintenance and spare parts

Selection of new equipment will be performed as describe in ***LRM-EQP030-Equipment Management Procedure***.

The laboratory manger with the scientific director is in charge to approve the selected equipment.

5.2. INSTALLATION AND TRAINING

Installation and training will be performed as describe in ***LRM-EQP030-Equipment Management Procedure***.

The laboratory ensures prior installation that space, ventilation, humidity and electricity meet specifications for satisfactory performance for the use of the instruments and equipment.

New equipment will be installed by the vendor when defined as critical. The laboratory participates, with a minimum of two staff members, to the installation and will be trained by the vendor.

For the non-critical new equipment, the laboratory will perform the installation and the training.

The vendor will assure that the new equipment is calibrated and the documentation is compliant.

The laboratory will evaluate that the satisfactory performances are met and the documentation is done properly.

All equipment needs to meet all the required criteria prior its first use in the laboratory.

5.3. EQUIPMENT INVENTORY

Equipment inventory will be filled as describe in ***LRM-EQP030-Equipment Management Procedure***.

All equipment is uniquely identified. The identification followed a unique EQU coding system: **EQU + (number starting from 001)**

A general equipment database is maintained for each piece of equipment and recorded on the server:
Z:\Exchange\Quality Management System\4. Equipment\Equipment Database

The following information has to be recorded for all the equipment:

- Name of the equipment
- Brand (manufacturer), Model, Serial number
- Location
- Date of reception
- Condition when received
- Current condition
- Maintenance date, frequency and type
- Calibration date, frequency and type
- Person in charge
- Buying prize
- Supplier and contacts

5.4. VALIDATION

All equipment's needs to be tested prior his use in the routine laboratory work, and present the proper documentation

The performance criteria of the equipment have to reach the test performed by the laboratory.

Calibration have to be performed yearly (or less according to the manufacturer recommendations) by external company/laboratory as defined in SOP ***LRM-PSP003-Stocks Management***.

5.5. PREVENTIVE MAINTENANCE AND REPAIR

The maintenance and the repair of the equipment is the responsibility of the maintenance staff and the laboratory manager/staff.

Maintenance has to be done on all the equipment in the CILM as defined in SOP ***LRM-HSP001- General Maintenance and Cleaning Procedure.***

Preventive maintenance is recorded in the instrument logbook.

Equipment requiring service due to a malfunction is decontaminated following manufacturers requirements.

Serviced or repaired equipment is calibrated to ensure it meets the manufacturer's performance criteria.

Critical equipment's are repaired and maintained at least once a year by the manufacturer.

Maintenance contracts and warranty service are documented and maintained by the *department of service.*

Defective or malfunctioning equipment is identified with label alerting that it is not in use.

5.6. DECOMMISSIONING

Obsolete equipment is decontaminated and removed from the laboratory, with the proper documentation following, as defined in SOP ***LRM-EQP030-Equipment Management Procedure.***

6. PURCHASING AND INVENTORY

6.1. SELECTION AND EVALUATION OF SUPPLIERS

The evaluation of suppliers is carried out according to criteria defined in the SOP ***LRM-PSP002-Selection and evaluation for suppliers.***

6.2. PROCUREMENT

6.2.1. EQUIPMENT

New equipment has to be integrated into the yearly budget plan, and purchased as defined in SOP ***LRM-PSP001-Purchasing***

6.2.2. REAGENTS, CONSUMABLES AND INTERGRATED CLEANER

The purchase is need to perform every 6 months,

- If the cost < $500 only one quotation is necessary.
- If the cost > $500 3 quotations is needed.

Purchasing modalities are described in the SOP ***LRM-PSP001-Purchasing***. And receiving modalities are described in the SOP ***LRM-PSP003-Stock management***.

6.3. STOCKS MANAGEMENT

All the products are recorded in the Stock Management System called "**STOCKS CILM**", guaranteeing thereby their traceability. This Excel also permits the realization of the plan of orders every 6 months.

Products are respectively identified by a unique code. Then, they are made available to the laboratory.

Products management is done according to the modalities of the SOP **LRM-PSP003-Stocks management.**

6.4. REFERRAL LABORATORIES / SUBCONTRACTING

CILM referee to a subcontracting for the following activities:

- Macrogen laboratory in Korea: CILM send PCR product to perform the sequencing of HIV drug resistance genotyping testing.
- Maintenance external consultancy: Daily follow-up and small repairs

7. PERSONNEL

7.1. PERSONNEL FILE / HEALTH FILE

An individual administrative file is established for each staff member (temporary, permanent, trainee, etc.) that contains documents concerning the staff qualifications (diplomas, CV, job descriptions, training certificate, orientation record, competency assessments, training records, continuing education …), and it is stored by the Human Resources department.

Each new staff member or trainee requires a medical check-up within 30 days of arrival.

7.2. INTEGRATION AND CLEARANCE

Staff orientation of all new employees is to be completed within 30 days of hire.

Safety orientation occurs before an employee is assigned to duties.

All newly hired employees are trained comprehensively on all policies and procedures in the department that apply to their job description and assignments.

Refers to ***The CILM Newcomer's handbook***.

7.3. CONFLICT OF INTEREST

CILM is not engaged in any activity that might influence its technical judgment. The laboratory is not committed to any commercial, financial or other pressure provided by any particular organization that could influence its technical judgment or affect its competencies and trust.

7.4. TRAINING

The laboratory provides training for all personnel, which includes the quality management system, assigned work processes and procedures, the laboratory information system, health and safety, ethics and confidentiality.

The effectiveness of the training program is yearly reviewed.

7.5. STAFF COMPETENCY

Staff competencies cover technical and practical skills and general knowledge.

Competency of each new employee is assessed and verified before permitting to perform testing and report results.

All employees are assessed for competency on an annual basis.

7.6. PERSONNEL PERFORMANCE APPRAISAL

Each staff is given the opportunity for annual interview with the laboratory director.

7.7. NON-PERMANENT PERSONNEL AND INTERNS

Non-permanent personnel such as students, post doctorates trainees follow the general laboratory orientation procedures for integration in the laboratory.

8. PROCESS MANAGEMENT

8.1. SAMPLE MANAGEMENT

8.1.1. SPECIMEN COLLECTION AND TRANSPORT

Specimen collection and transportation is describes in **The Sampling manual** *and* ***LRM-SMP001-Pre examination****,* explained during workshops on a yearly basis.

Sample collection:

- In CIML, blood collections perform in the separate room by staff that had certificate with following the SOP ***LRM-SMP001-Pre examination.***
- For the hospital samples, the centre provided patient's form with explication how to act for samples collection.

Transportation:

- For all ARV sites in Laos, CILM provides specimen containers and temperature control's machine to ensure proper transportation and biosafety.

8.1.2. SPECIMEN/SAMPLE RECEIVING

The CIML has three ways to receive samples/specimen of bloods, plasmas and sputum:

- Direct sampling at CILM;
- Sending from Central hospitals < 6 hours;
- Sending from provincial hospitals.

All specimens/samples are inspected according to acceptance/rejection criteria. The laboratory rejects specimens/samples, which are not suitable for processing. In the case of critical specimens/samples, such as one of limited volume, the laboratory management consults with the requestor to prioritize testing.

8.1.3. SPECIMEN/SAMPLE HANDLING, PREPARATION AND STORAGE

The specimen/sample handling, preparation and storage are defined ***Sampling manual***

A unique registration number is assigned to each specimen/sample:

TEST (Year)(Month)(Day)-(No of sample of the day)

Laboratory staff responsible for sample labelling, aliquoting and storage sample in proper temperature and safety condition.

8.2. METHOD VALIDATION

In term to get accreditation, CILM perform method validation following method verification. The following parameters are investigated: repeatability, intermediate accuracy, validity, precision and uncertainty.

In the first HIV-VL-testing will be verified. A full report of the method validation is written.

8.3. LIST OF EXAMINATIONS

HIV	— Viral load testing (VL) — Multi Drugs Resistance testing (MDR) — Early Infant Diagnostic (EID)
HBV	— Viral load testing (VL) — Elisa: Ag-HBs, Anti-HBs, Anti-HBc, Ag-HBe and Anti-HBe
HCV	— Viral load testing (VL)
TB	— Gene-Xpert — Hain test

8.4. REPORTING

All CILM results are recoded in to private database (File maker), and on paper base patient's form. The reporting of the result content:

- Name and Code of patient
- Date of birth
- Hospital name
- Reason for the request of test
- Cut off values
- Treatment used
- Date started of treatment
- Sampling date
- Lab code
- Result values
- Interpretation of result
- Remarks
- Date of publication of result
- Signature

The final report is validated by the Lab director/project manager/lab manager of CILM.

Patient's reports are released:

- directly at CILM, send by E-mail or Fax;
- send to provincial reference sites;
- or exceptionally for TB test, it can be reported via telephone.

8.5. SAMPLE RETENTION AND DISPOSAL

Laboratory manager is responsible for the retention time follow up, and laboratory technician are responsible for proper disposal according biosafety manual.

CILM samples retention delay is as following:

- All PCR products are kept 1 year
- HIV plasma sample are kept for 5 years

9. INFORMATION MANAGEMENT

9.1. INFORMATION SYSTEM – SECURITY

Information system is describes in the SOP ***LRM-DIP001-Information Management***

CILM back up information are on computerized systems or paper base.

- CIML limit access to computerized information by setup user account for every staff for permission and privacy
- Laboratory Information backup and scanning is performing daily
- Patient's documents in hard copy version are stored in archives in lockable cabinet
- All documents can be accessed only the authorized and who is concern or perform the test.

9.2. CONFIDENTIALITY

All CILM personnel (temporary, permanent, student, etc.), whatever the duration of their contract, will sign a confidentiality agreement.

The laboratory has a secure process for archiving and / or data disposal. Refer to **chapter *13. Documents and Records*.**

10. CUSTOMER FOCUS

10.1. CUSTOMERS SATISFACTION MEASUREMENT

CILM performs customer satisfaction survey defined into SOP ***LRM-ICP002-Satisfaction Survey*** at least once per year with all customers' interacting within CILM services:

- patients walk in;
- conference room users;
- doctors council and workshops.

10.2. CLAIMS MANAGEMENT

CILM are caring claims with the complaint box, present at the information desk directly at the entrance. All claims are reviewed at least every quarterly as defined per SOP ***LRM – OCP002 – Complaints Management***

11. ASSESSMENTS

11.1. INTERNAL ASSESSMENTS

11.1.1. INTERNAL AUDITS

Once a year, CILM organize an internal audit, led by the quality officer. The internal audit submits a full internal audit report, with achievements, findings and corrective action.

Twice a year, the quality officer fill LQSI tool checklist to monitor the accreditation process for achievement of compliance, and evaluate the quality at CILM.

Refer to ***LRM-LRM-ICP001-Internal Quality Audit***

11.1.2. REVIEW AND FOLLOW UP OF CORRECTIVE ACTIONS

All corrective actions defined by the internals assessments are undertaken. In term to organize properly all action, a SMART action plan designed. It will be monitored during each quality committee meeting.

11.1.3. QUALITY INDICATORS

Tree quality indicators have been defined by the quality committee:

1. Tractability of the samples forms the reception to the storage after testing.
2. Turnaround time from reception of the sample to the hand out of the report.
3. Reliability of the competence of the technical staff (average of test competency assessment for determined tests).

The performance of satisfaction survey are summarized every quarterly and discussed by the quality committee.

All indicators gaps are conducted as non-conformity.

11.1.4. STAFF SUGGESTIONS

Staff suggestions are tracked during the laboratory weekly meeting within the section of corrective actions. The suggestions are discussed within the laboratory staff and managers, to find a solution.

11.2. EXTERNAL ASSESSMENTS

11.2.1. EXTERNAL QUALITY ASSESSMENT/PROFICIENCY TESTING

CILM participated to external quality assessment testing for all his major tests, to ensure the accuracy of the laboratory results. List of the participation of External Quality Assessment (EQA) programmes:

- Centres for Disease Control and Prevention (CDC) for HIV Viral Load and HIV DNA PCR;
- Quality Control for Molecular Diagnostics (QCMD) for HIV drug resistance typing;
- United Kingdom National External Quality Assessment Schemes (UKNEQAS) for Hepatitis B and C Viral Load testing, for Hepatitis B serology and also for Mycobacterium culture.

11.2.2. EXTERNAL AUDITS

CILM has a yearly external audit from private company, based on ISO15189:2012 and LQSI tool checklist. A full audit report is written with suggestions for improvement.

CILM is part of the Lao national program for the strengthening of health laboratory system, which includes external monitoring and audit performed by WHO and National Centre for Laboratory and Epidemiology quality team.

12. NONCONFORMITIES

All CILM staffs have the authorization to write a nonconformity for any event who occurred which is not compliant with ISO 15189: 2012. And will be report on the Lab weekly meeting. Monitoring of corrective action will be done by quality officer by checking on every weekly meeting and or whenever the nonconformity is closed.

Refer to ***SOP LRM-OCP001-Non-conformity Event Management***

13. CONTINUAL IMPROVEMENT

13.1. QUARTERLY REPORTS

Quarterly reports are drafted every quarter of the year by the quality officer, which include: assessments, year plan, nonconformities, trainings, quality indicators…

It is finalized at the quarterly meeting with the validation of each of the quality committee.

13.2. MANAGEMENT REVIEW

Management review will be organized every year by the Lab Manager to review all the activities of the quality management system that including:

- Previous management review report;
- Internal audit report;
- Assessments;
- Action plan;
- Non-conformities;
- Satisfaction survey;
- SOPs and manuals;
- EQA results;
- Laboratory activities reports;
- LQSI Tools;
- Training plan and certificates;
- Budgets.

13.3. CORRECTIVE ACTIONS

For all nonconforming events recorded (from occurrence reports, claims, audit reports, patient/customer complaints, failed proficiency testing, etc.), a track is set up to identified trends and root cause. With the proper root cause, analyses are performed, and appropriate corrective actions are taken.

The results of occurrence assessment are communicated to management and integrate the periodic management review.

13.4. PREVENTIVE AND IMPROVEMENT ACTIONS

The projects manager and the laboratory manager review all the data produced by the laboratory. In that way, trends can be identified and it allows anticipating eventual nonconforming events in the activities with preventive and improvement action. It will be discussed at the weekly staff meeting, as with the follow up of the implemented actions.

14. HISTORY OF MAIN MODIFICATIONS

Version 1.0 16/10/2017: creation.