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NATIONAL PUBLIC HEALTH LABORATORY

ROADMAP FOR THE IMPLEMENTATION OF THE QUALITY MANAGEMENT SYSTEM IN THE LABORATORY NETWORK

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LIST OF ACRONYMS AND ABBREVIATIONS

Acronym/Abbreviation	Meaning
ASLM	African Society for Laboratory Medicine
CAMNEQAS	Cameroon National External Quality Assessment Scheme
CBCHS	Cameroon Baptist Convention Health Services
CDC	Centre for Disease Control Atlanta
CHAI	Clinton Health Access Initiative
CMA	District Health Centre/hospital
CPC	Centre Pasteur du Cameroun
CRESAR	Centre de Recherche pour la Santé des Armées
DPML	Directorate of Pharmacy, Medicines and Laboratories
EQA	External Quality Assessment
EGPAF	Elizabeth Glaser Pediatric AIDS foundation
EID	Early Infant Diagnosis
FTP	Financial and Technical Partner
GBEA	Good Analysis Practices Guide
GHSS	Global Health Systems Solutions
HIV	Acquired Immunodeficiency Virus
IDDS	Infectious Disease Diagnosis and Surveillance
IHC	Integrated Health Centre
IQC	Internal Quality Control
ISO	International Organization for Standard
JEE	Joint External Evaluation
LABNET	Laboratory Network
LANAVET	National Veterinary laboratory
MOH	Ministry of Public Health
NDAL	National Laboratory of Analysis and Diagnosis
NPHL	National Public Health Laboratory
NICD	National Institute for Communicable Diseases
PEPFAR	President Emergency Plan for Aids Relieve
PSNDL	National Strategic Plan for the Development of Laboratories
QA	Quality Assurance
QMS	Quality Management System
RAM	Antimicrobial Resistance
RH	Regional Hospital
SLIPTA	Stepwise laboratory Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SWOT	Strengths Weaknesses Opportunities Threats
TDR	Terms of Reference
WHO	World Health Organization
WHO AFRO	Africa Office of the World Health Organization

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BACKGROUND

Laboratory services are a fundamental component of health services and must develop to accompany the expansion of disease prevention and surveillance services. However, most laboratories are not only poorly equipped, but also operate with reduced capacity.

The quality of services rendered by laboratories has become an international concern. Indeed, laboratory quality management system aims to ensure the production of accurate, reliable and timely results for effective patient care. The implementation of a quality management system includes systematic activities to monitor all phases of laboratory analysis and takes into account the following: Human resources, documents and records, the choice of material resources (equipment, etc), analysis process, quality assessment, and the mechanism for result transmission, communication with clients, the preservation and archiving of documents.

In Cameroon, the concept of quality management system was introduced in 2010 through the Stepwise Laboratory Improvement Process Towards Accreditation /Strengthening Laboratory Management Towards Accreditation (SLIPTA/SLMTA) program. To date, there is no national quality policy for laboratories in the country. In addition, there is inadequate national regulation for quality management system in laboratories. Consequently, there is a lack of harmonization in the biological diagnosis of diseases.

The adoption of the good analysis practice guide in 2009, initiated the harmonization of laboratory quality management practices in laboratories. However, this regulatory framework has not been sufficiently disseminated and applied. To date, this document has not been revised. However, a National Strategic Plan for the Development of Laboratories (PSNDL 2018-2022) has been developed up by the DPML.

Later, in 2017, with the creation of the National Public Health Laboratory (NPHL), the Quality Assurance Centre was created. The latter's mission is to implement quality management system within Cameroon’s laboratory network. It is within this framework that an Operational Plan for the laboratory network (2019-2021) has been developed.

For its functioning, the NPHL benefits from the support of various technical and financial partners: PEPFAR/CDC, GHSS, METABIOTA, CHAI, EGPAF, ASLM, IDDS, CBCHS, etc.

This roadmap describes the stages of implementation of quality management system in Cameroon's laboratory network.

SITUATIONAL ANALYSIS

1. SWOT analysis of the laboratory system in Cameroon

In 2017, the performance of Cameroon's national laboratory system was evaluated using the JEE tool, to highlight its weakness. A second evaluation, which was performed in February 2019 using the LABNET Scorecard to supplement the previous one, revealed shortcomings in indicators D.1.2 (Quality Management System) and D.1.4 (Sample Transport System). Table I below presents a SWOT analysis of these results.

Table I: SWOT analysis of LABNET evaluation results

STRENGTHS	**WEAKNESSES**
- Some reference laboratories participate in EQA programs (e.g., NHPD, WHO/NICD for bacteriology). - Existence of the good analysis practice guide - There is a NSDPL and a Laboratory Network Operational Plan. - The decree creating the NPHL mentions quality - Availability of national expertise to strengthen laboratories in the network (SLIPTA/SLMATA auditors, Mentors, Trainers) - Presence of accredited laboratories (e.g. LANAVET de Garoua ISO 17025, EID Mutengene, Bamenda Regional Hospital, Buea Regional Hospital, CPC ISO17025 and ISO 15189) - Vertical programs are engaged in the QMS	- IQC only available for a few tests - EQA is not systematic within the network - Not all reference laboratories are enrolled in an EQA program. - Supervision is not systematic - No formal identification of quality managers in the laboratory network - The good analysis practice guide is not implemented and is obsolete - No national funding dedicated to the implementation of the NSLDP - Insufficient mobilization of funds for the implementation of the NSLDP - Staff retention problem - Lack of a national body in charge of the accreditation of laboratories
OPPORTUNITIES	**THREATS**
- Planned implementation of an EQA program for priority diseases - Support from the various TFPs (GHSA, IDDS, GF, PEPFAR, WHO, RESOLVE etc.) - Multifaceted support to NPHL for capacity building (e.g. PEPFAR for HIV serology EQA) - Existence of the Multi-sectorial Collaborative Platform at the Prime Ministry for the implementation of the One Health approach	- The implementation of the NSLDP depends on external financing (sustainability). - insecurity in some parts of the country

2. Priority actions identified

Based on the evaluation of laboratory systems, the following priority actions were identified

- Develop national policy for quality management in the national laboratory network (RENALAB).
- Elaborate/acquire and disseminate quality standards for laboratories.
- Develop a roadmap for the implementation of QMS activities in the laboratory network.
- Make official the appointment of quality managers in the. laboratory network
- Establish national bodies for accreditation and certification of laboratories.
- Reinforce the mobilization of financial and human resources for the implementation and maintenance of the QMS in the laboratory network.

3. Available human resources

At the national level, the capacity for implementation is limited to strengthening the competencies of human resources. Some laboratory staff have been trained in quality management system. The following profiles are available:

Trained in SLMTA	333	SLMTA trainers	30
SLIPTA internal auditors	51	ASLM certified SLIPTA auditors	07
Trained in basic QA	2300		07

At the level of the NPHL, staff received several trainings on quality management system (confer table II)

Table II: Status of staff training at the NPHL

N°	**Trainings**	**Year**	**No. of people trained**
1	SLIPTA Internal Audit Training	2014/2017	3
2	SLMTA (Strengthening Laboratory Management Towards Accreditation)	2016-2019	24
3	Training in auditing HIV testing sites with the SPI RT-QI checklist	2017-2019	10
4	Training on how to organize an HIV EQA program	2017-2019	7
5	Training of Trainers on Quality Assurance and Rapid HIV Screening in the Laboratory	2019	4
6	Training of trainers in quality assurance of EID POC sites	2019	3

7	Training in auditing viral load laboratories with the VL/EID scorecard	2019	4
8	Training in auditing and evaluation of POC EID testers and sites with the SPI-POCT checklist	2019	3

OBJECTIVES

1. General objective

Implement a laboratory quality management system (QMS) in the laboratory network, using a progressive method (SLIPTA) centered on the NPHL and reference laboratories, and strengthen quality management system coordinated by the NPHL according to the One Health approach under the supervision of the DPML.

2. Specific objectives

- Implement QMS according to a nationally validated roadmap.
- Support the NPHL to coordinate QMS at lower levels.
- Hold periodic coordination meetings to monitor the implementation of the QMS in the laboratory network within the framework of "One Health".
- Define the minimum quality requirements for the certification and accreditation of public and private clinical laboratories, within the framework of Cameroonian regulations.
- Draft an action plan for the accreditation, certification, and compliance with the good analysis practice guide in the laboratory network according to their respective levels.

JUSTIFICATION

In Cameroon, the NPHL desires a progressive implementation of the quality management system within the laboratory network. To accomplish this, it intends to follow the recommendations of WHO AFRO, by adopting the SLIPTA approach for the progressive improvement of quality.

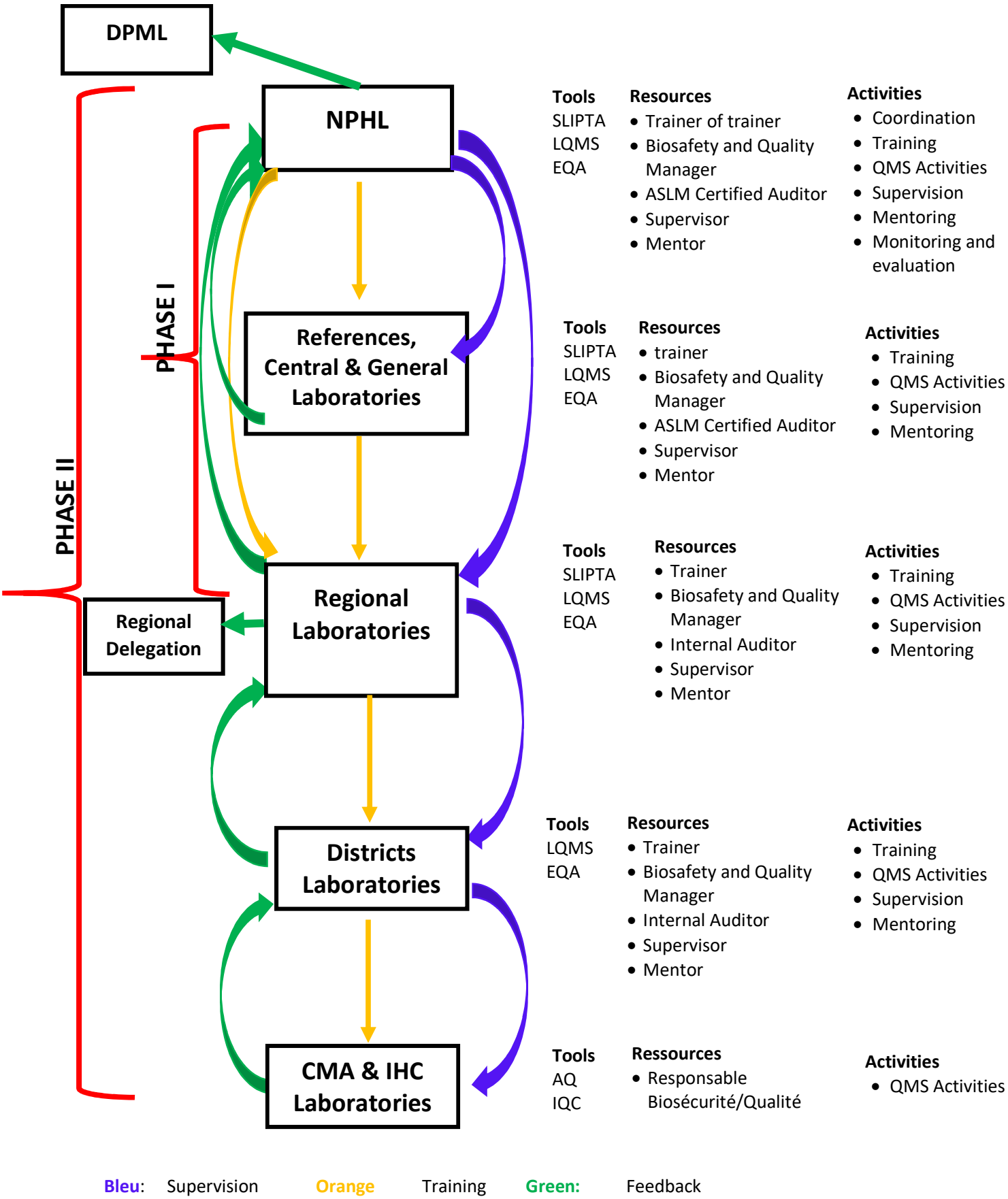
STRATEGY

The strategy that will be used to implement QMS will be the top-down approach. Thus, in the first phase, the capacities of the NPHL and central laboratories will be reinforced. The latter, in turn, will provide support to laboratories in regional, district hospitals and medical centres (CMAs)
For the initial phase, efforts will be concentrated on strengthening level IV (reference, General and central) and III (regional) laboratories selected according to the following criteria:

- Multi-sectorial approach and One Health: representation of the civil and military sectors of human health, animal health, etc.
- Geographical coverage: representation of the 10 regions of Cameroon
- Take into account similar ongoing activities
- High disease burden areas with epidemic potential (prioritize sentinel sites in areas without level IV and III laboratory facilities).
- The patient turn out
- The level of implementation QMS
- Available financial resources
- Commitment of Managers of the facilities

In order for the NPHL and level IV laboratories to accompany other laboratories in the network, the following profiles could be developed: supervisors, certified SLIPTA auditors, mentors, trainers, internal auditors (see Appendix 1: Profile Definition and task).

Within the framework of the implementation of the QMS, it would be important to have a network of competent personnel to conduct activities. The latter must have skills in training, evaluation/auditing and mentoring. The NPHL will play a major role in leadership, mentoring, training, evaluation and supervision. In view of the human resource profiles available and the top-down deployment strategy, the NPHL must have competent supervisors. Thus, there is a need for the following trainings: ASLM certified SLIPTA auditors and laboratory mentors. These profiles might also serve as supervisors, auditors and trainers.



Bleu: Supervision **Orange** Training **Green:** Feedback

Figure 1: Process of QMS implementation in the laboratory network

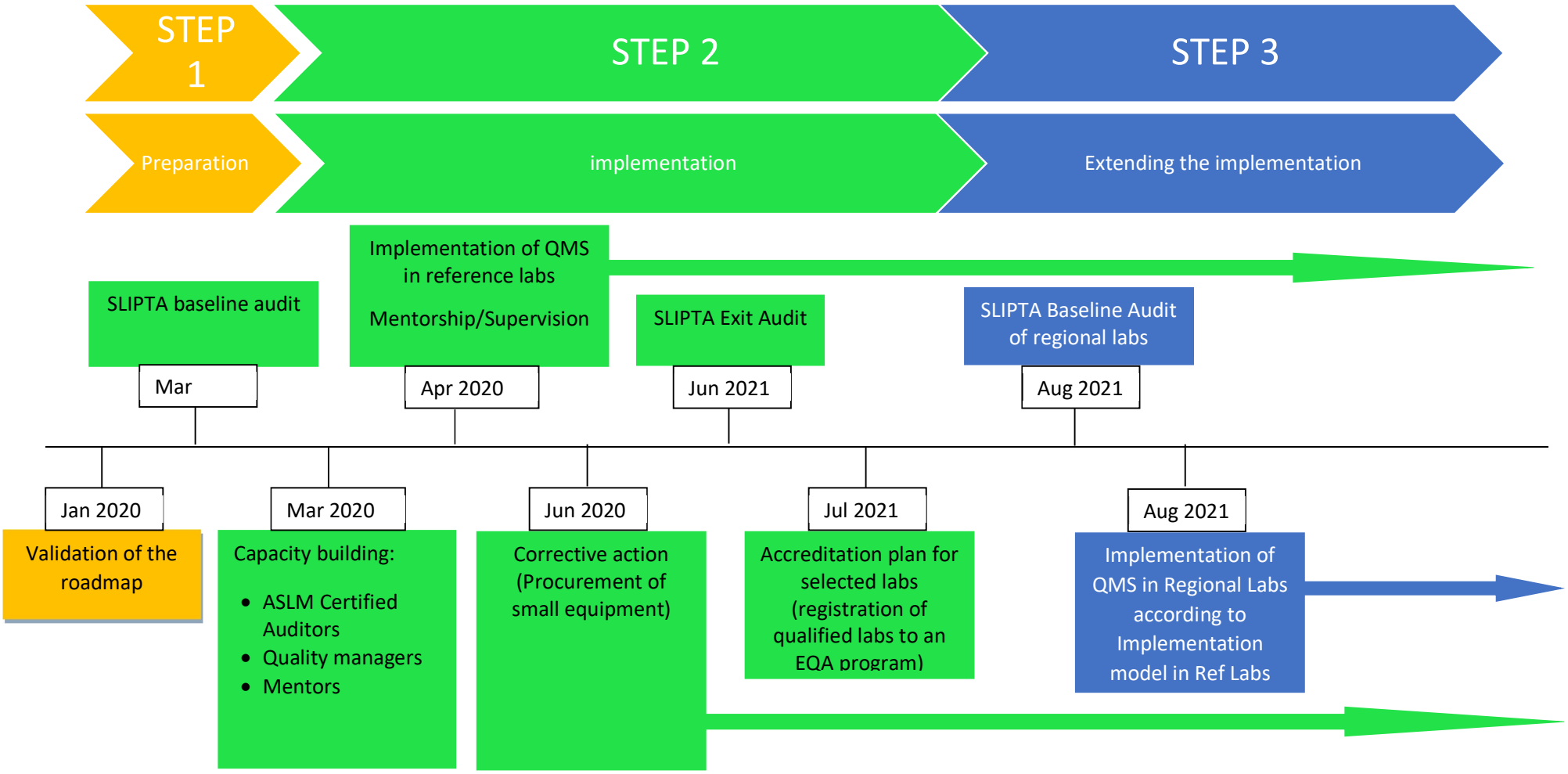


Figure 2: Steps for the implementation of Quality Management System in the laboratory network

Appendix 1: Profile Definition and task

1. **Supervisor**: a person with technical skills in laboratory and quality management. As such, he is responsible for:
   - Ensuring the implementation of directives, technical and quality requirements ;
   - Assist in gap analysis and identification of corrective actions ;
   - Ensure the continuous training of staff on site ;
   - Make recommendations for the implementation of the guidelines and requirements.
2. **Mentor**: is a person with technical skills in laboratory, quality management and techniques for supporting the implementation of quality management systems. As such, he is responsible for:
   - the elaboration of a support plan for the laboratory, both on site and remotely;
   - Support laboratories in the implementation of the quality management system ;
   - Develop/strengthen the technical skills and/or quality of the staff
   - Assist in analyzing variances and identifying corrective actions ;
   - Support the development of corrective action plans ;
   - Monitor the implementation of corrective actions and continuous improvement projects;
   - Contribute to build team spirit and the culture of quality in the laboratory
3. **Trainer**: is a person with technical and/or quality management skills and training techniques. As such, he is responsible for:
   - Designing and developing training modules;
   - Ensuring the transfer of knowledge and know-how;
   - Assessing the acquisition of knowledge and skills ;
   - Identify training needs.
4. **Laboratory auditor**: this is a person with technical and/or quality management skills, a good mastery of norms/standard frameworks and trained in auditing techniques. This may be an internal or external SLIPTA auditor (ASLM certified). As such, he/she is responsible for:
   - Verifying compliance with regulatory and normative requirements ;
   - Identifying gaps ;
   - Making recommendations ;
   - Approve the corrective actions to be implemented.

Appendix 2: Contributors

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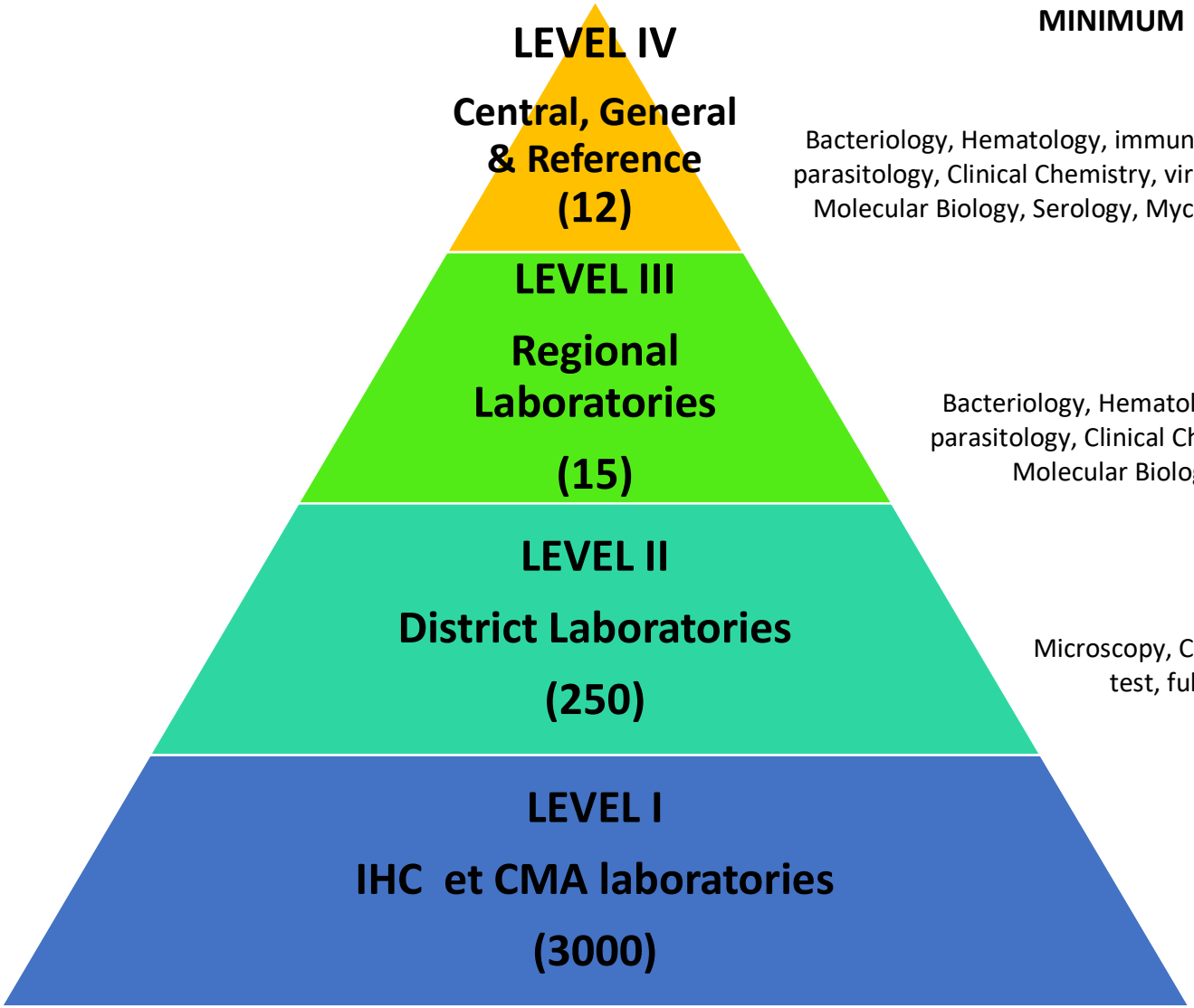
Appendix 3: Key implementation phases

Table III: Timeline for implementation

STEP 1: PREREQUISITES		Deadline	Responsible
1.	Finalize the QMS roadmap (elaboration draft 0, sharing for inputs, draft 1 validated)	December 24, 2019	NPHL, DPML, FTP
2.	Have the roadmap and accompanying documents approved by the DPML/MINSANTE	28 January 2020	NPHL, DPML, LANAVET, FTP
3.	Adopt the validated roadmap (28/01/2020 in Mbalmayo)	Feb 2020	NPHL, DPML,
STEP 2: IMPLEMENTATION OF THE QMS ROADMAP			
1.	Finalize the Quality Assurance Guide (Quality Management Policy for Laboratory Network)	July 20020	DPML, FTP
2.	Revise and disseminate the "Guide de bonne exécution des analyses (GBEA)"	July 20020	DPML, NPHL, FTP
3.	Strengthen the institutional capacity and visibility of the NPHL (Creation of a logo for the NPHL, creation of a Website, setting up of a Newsletter, elaboration and implementation of a communication plan for the NPHL)	July 20020	NPHL, FTP
4.	Design and dissemination of a template for lab activity reports	July 20020	NPHL, FTP
5.	Hold a meeting to raise awareness among the managers of the enrolled Labs (human and animal health).	February 2020	NPHL, DPML, FTP
6.	Perform Basic SLIPTA Audits of 07 selected reference labs	February 2020	NPHL, DPML and FTP
7.	Buying standards (ISO 15189, ISO 9001, ISO 17025)	February 2020	NPHL, FTP
8.	Train a pool of certified SLIPTA auditors (15) and mentors at the central level (NPHL and reference laboratories).	March 2020	NPHL, FTP

9.	Train Quality and Biosafety Managers in selected laboratories on basic QMS, Biosafety, ISO 15189/ ISO 17025	April 2020	Pools of trained auditors/mentors
10.	Organize support for the reference laboratories selected for the implementation of the QMS (selection of mentors, TDRs, lab assignments, schedule of visits)	March 2020	NPHL, Mentors, TFPs
11.	Mentorship visits to the selected reference laboratories	According to schedule	Mentors
12.	Carry out biannual supervisory visits	June and December 2020	NPHL (Supervisors)
13.	Provide corrective measures and acquire small equipment (thermometer, mutinies, etc.) for enrolled laboratories.	July 2020	NPHL, DPML, FTP
14.	Conduct the SLIPTA audit at 18 months of implementation	June 2021	NPHL, FTP
15.	Certification of SLIPTA auditors	June 2021	NPHL, FTP
16.	Develop and implement accreditation plans for 2 and 3 qualified laboratories	August 2021	NPHL, FTP
17.	Enroll the laboratories (2 or 3) with the highest ranking in the 18-month SLIPTA audit for accreditation in the relevant international QAE program.	June 2021	NPHL, FTP
STEP 3: EXTENSION OF QMS IMPLEMENTATION TO REGIONAL LABS			
1.	Perform Basic SLIPTA Audits of 03 regional labs	June 2021	NPHL, Reference Labs
2.	Implement the QMS of the 03 regional labs enrolled on the model described in Step 2 (QMS in reference labs)	July 2021	NPHL, Reference Labs

Appendix 4: The Tier Laboratory Network



MINIMUM PACKAGE

Bacteriology, Hematology, immunology, parasitology, Clinical Chemistry, viral load, Molecular Biology, Serology, Mycology

Bacteriology, Hematology, immunology, parasitology, Clinical Chemistry, viral load, Molecular Biology, Serology

Microscopy, Clinical Chemistry, rapid diagnostic test, full blood count, Parasitology

Diagnosis using Rapid Diagnostic Test and Microscopy