



Guidance for Establishing a National Laboratory Quality Framework

To advance implementation of laboratory
quality management systems at all tiers
of the laboratory network

1st Edition, 2021

Guidance for Establishing a National Laboratory Quality Framework

**To advance implementation of laboratory
quality management systems at all tiers
of the laboratory network**

1st Edition, 2021

Contents

Preface.....	iii
Abbreviations.....	iv
Acknowledgments.....	v
Section 1. Introduction.....	1
Section 2. Policy and planning for quality laboratory	4
Services: Purpose and key considerations.....	4
Section 3. The Development of a National Laboratory Quality Policy and Strategic Plan.....	7
Section 4. National Laboratory Quality Policy and Strategic Plan Implementation: Next Steps.....	15
References.....	17
Further Reading.....	19
Supplement.....	20
Blueprint National Laboratory Quality Policy and Strategic Plan.....	20
Annexes.....	37

Preface

The African continent faces disproportionately high burden of diseases and experiences frequent outbreaks that can be detrimental to the lives of its citizens and bottleneck for social and economic development. The health systems in most Member States, even though there are recent improvements, remain extremely weak. This was witnessed during the current Corona Virus Disease (COVID-19) outbreak which claimed thousands of lives. One of the weakest links is limited quality assured laboratory services at all levels of the national health care system. Although many African countries have made progress in strengthening laboratory capacity and improving quality of laboratory services, much of the focus has been on specific disease control programs, leaving general laboratory services fragmented and without adequate resources. Lack of laboratory capacity is one of the major challenges contributing to delayed or inadequate responses to epidemics/pandemics. National laboratory systems have faced significant hurdles in advancing the deployment of Laboratory Quality Management System (LQMS) at all levels of the laboratory network. A national laboratory quality framework document has been prepared to guide and facilitate country-level efforts of strengthening national laboratory systems and networks. The framework will support laboratories in implementing and continued maintenance of laboratory quality management systems. Moreover; the document will be used by the policy makers and health service regulators in the establishment and amendment of national policies aimed at facilitating the implementation of laboratory quality management systems. This document also serves as practical guide for Member States during the development or updating of the national laboratory quality policies and strategic plans.

Abbreviations

AFRAC	African Accreditation Cooperation
ASLM	African Society for Laboratory Medicine
Africa CDC	Africa Centers for Disease Control and Prevention
CDC	(U.S.) Centers for Disease Control and Prevention
CLSI	Clinical and Laboratory Standards Institute
CPE	Continuous Professional Education
EQA	External Quality Assessment
HRM	Human Resource Management
ILAC	International Laboratory Accreditation Co-operation
ISO	International Organization for Standardization
LABNET	Laboratory Network scorecard
LQMS	Laboratory Quality Management System
LTWG	Laboratory Technical Working Group
M&E	Monitoring & Evaluation
MoH	Ministry of Health
NAB	National Accreditation Body
NEDL	National Essential Diagnostics List
NGO	Non-Governmental Organization
NLCT	National Laboratory Coordinating Team
NLQS	National Laboratory Quality Standard
NLWG	National Laboratory Working Group
NMI	National Metrology Institute
PCDA cycle	Plan-Do-Check-Act cycle
SI	International System of Units
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SMART	Specific, Measurable, Agreed, Realistic, and Timebound
SWOT	Strengths, Weaknesses, Opportunities, and Threats
UHC	Universal Health Coverage
WHO	World Health Organization

Acknowledgments

Funding

Fleming Fund

ASLM

Authors

Dr. Tjeerd Datema DATOS

Dr. Dorien Faber DATOS

Dr. Pascale Ondoa ASLM

Beatrice van der Puije ASLM

Reviewers

Dr. Yenew Kebede Africa CDC

Dr. Samba Diallo ASLM

Mr. Patrick Mateta CLSI

Mr. Nqobile Ndlovu ASLM

Consortium partners

National Institute for Communicable Diseases

Technical University of Denmark

Public Health England

Section 1. Introduction

This section describes the purpose of this document and its intended audience, provides background information, and describes the structure of this document.

1.1 Purpose of this document

The purpose of this document is to facilitate country-level efforts to strengthen national laboratory networks and systems to support laboratories with the implementation and continued maintenance and improvement of a Laboratory Quality Management System (LQMS). It aims to guide policy makers and regulators with the establishment and amendment of relevant national policies and strategic plans to build a National Laboratory Quality Infrastructure (see Box 1) and address critical gaps in the laboratory network and system that hamper sustainable LQMS implementation and maintenance. This document guides countries in amending their National Laboratory Policy and/or Strategic Plan with specific quality-related statements and objectives or establishing a separate National Laboratory Quality Policy and Strategic Plan.

Box 1: The National Laboratory Quality Infrastructure

A National Laboratory Quality Infrastructure consists of several key components required for successful implementation and maintenance of LQMS.

- Key is the establishment of a National Accreditation Body (NAB) that is authorized and capable of assessing compliance with LQMS requirements;
- These requirements can be captured in National Laboratory Quality Standards (NLQS) and/or international laboratory quality standards such as ISO 15189 and ISO 17025. Countries with limited resources are encouraged to take a staged approach, where principal requirements for all laboratories are stated as minimum requirements in NLQS while more advanced and national reference laboratories are encouraged to aim at meeting international laboratory quality standards [1,2];
- Staged NLQS also facilitate the establishment of a licensing system for laboratories and laboratory professionals. A licensing system and making compliance with NLQS part of the licensing criteria, enables a country to assure that all laboratory services in both the public and private sectors are of an acceptable level of quality;
- Access to a well-trained, competent laboratory workforce, hence establishment of a strong pre-service and in-service training is indispensable for sustainable high-quality laboratory services;
- Establishment of integrated national External Quality Assessment (EQA) programs for essential laboratory tests with sufficient capacity to serve all laboratories in the country is a necessity for compliance with LQMS requirements and accreditation;
- The same applies to sufficient capacity to maintain and calibrate laboratory equipment with watertight traceability;
- A Monitoring and Evaluation (M&E) framework with definition of sets of quality indicators for the different tiers of the laboratory network is required to objectively assess the quality of services provided by each laboratory;
- A system of tiered supervision whereby laboratories in higher tiers of the laboratory network conduct audits, support LQMS implementation and monitor the quality and performance of laboratories in lower tiers of the network through supportive supervision is another essential component of the National Laboratory Quality Infrastructure.

Detailed information on all components of the National Laboratory Quality Infrastructure is provided in the Supplement.

1.2 Intended audience

Guidance documents and tools such as the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) focus on implementation of LQMS at facility level and do not provide guidance on regulation from a national perspective. Conversely, guidance documents aimed at policy makers and regulators do not provide sufficient practical information to support LQMS advancement. This document aims to inform and support national legislative and executive authorities, policy makers and regulators in creating, refining and implementing a policy, planning and regulatory framework for ensuring the highest standards of laboratory quality management.

It should be noted that this document and the accompanying policy and planning blueprint are intended as guidance and are not intended to replace existing national or international policies and plans. Instead, they support a process of continual improvement leading to effective formulation of policies and strategic plans that drive implementation and continuous maintenance and improvement of LQMS in compliance with relevant national and international standards and agreements, including the International Health Regulations, ISO 15189 and ISO 17025, across the entire laboratory network.

1.3 Background

In 1996, Forsman estimated that laboratory services influenced approximately 70% of medical decisions [3]. Nowadays, it may be assumed that this percentage has increased due to the rapid development and dissemination of new diagnostic tools, automated testing technologies, implementation of data connectivity solutions and advancement of evidence-based medicine. For long time laboratory services in low- and middle-income countries received limited attention from governments and development aid efforts alike (Figure 1) [4–16]. This has led to a vicious cycle whereby neglect of the laboratory sector led to deterioration of laboratory services which in turn caused distrust in, and underuse of, laboratory services by clinicians and other health workers. The tendency to omit laboratory test results from clinical decisions not only contributes to further neglect of laboratory services but also increases the chance of misdiagnoses, leads to symptom-based treatment of diseases, and promotes antimicrobial resistance [17–27]. This impacts both clinical care/Universal Health Coverage (UHC) and public health.



Figure 1: Vicious cycle perpetuating neglect of laboratory services

Around 2008 the tide began to turn [4,9,28,29]: the implementation of an LQMS, a key intervention to strengthen laboratories, was marked as a priority by both the World Health Organization (WHO) headquarters [1,2] and the WHO Regional Committee for Africa [30]. Since then several continent-wide initiatives were launched including the Strengthening Laboratory Management Towards Accreditation (SLMTA) training and mentoring program [31,32] and the SLIPTA program [33,34]. Unfortunately, this has not led to large scale sustainable LQMS implementation and accreditation as initially envisaged. Until 2020, approximately 520 laboratories on the continent received international ISO 15189 accreditation, of which 370 (71%) located in South Africa. Since the launch of SLIPTA 430 laboratories have been assessed. This number was well below the target of 2,500 laboratories enrolled in SLIPTA set by African Society for Laboratory Medicine (ASLM) for 2020 [35].

More than ten years of experience in promotion of LQMS has provided an opportunity to identify the most critical bottlenecks to sustainable LQMS/SLIPTA implementation. Challenges include low political commitment and lack of, or insufficient implementation of policies and regulations [35–37]. Even though improving laboratory quality contributes to the attainment of target 3.8 of the Sustainable Development Goals (achieve UHC including access to quality essential health care services [38]), the absence of political commitment in both word and deed has led to weak laboratory networks and

systems across the continent [39]. Data from the Joint External Evaluations of 54 countries show that laboratory quality management is the most neglected area [35]. This is corroborated by data from eight country evaluations using the laboratory network (LABNET) scorecard which highlight critical weaknesses in quality management including absence of national norms for laboratory certification and/or accreditation [35]. Hence, despite SLIPTA's initial momentum, laboratories participating in the program were unable to maintain their LQMS because of critical gaps in national laboratory networks and systems. Because it is a partner-driven initiative, the program lacks country ownership and gaps in national laboratory networks and systems remain unaddressed.

It is critical that a National Public Health Institutes improves laboratory quality assurance systems and establishes and coordinates national quality assessment schemes that can rely on a strong national laboratory network and system that can meet the laboratory's needs for successful and sustainable implementation and maintenance of LQMS. For example, compliance with LQMS requirements demands that a laboratory has a reliable supply of high-quality consumables and reagents to assure continuity of services. Data from LABNET evaluations highlight critical weaknesses in supply chain systems On the African continent, around 520 laboratories have received international accreditation to date [35]. Other conditions for sustained compliance with LQMS requirements include the availability of competent, well-trained personnel, continuously maintained, calibrated equipment, strong laboratory information management systems, etc. All these attributes must be arranged at laboratory network and system level but LABNET evaluations show critical weaknesses across countries for each of these attributes [35]. herefore, laboratory network and system strengthening are key priorities to facilitate widespread LQMS implementation and maintenance (see Box 2).

Box 2: Recommendations of the joint WHO-Centers for Disease Control and Prevention (CDC) conference on laboratory quality systems in 2008 [1,2]

Many activities associated with quality assurance must be carried out by individual laboratories, but assistance and oversight are required at the national level. The following activities should be planned at a national level, with help and input from laboratories throughout the country:

- Establish and revise national quality standards;
- Establish strategy, aims and measures of quality improvement;
- Ensure that laboratory facilities and infrastructure are adequate and properly maintained for all testing being performed;
- Ensure safety in all health laboratory facilities to protect workers within the laboratory, visitors to the facility, the general public at large and the environment;
- Establish long-term plans for ensuring adequate and sustainable numbers of properly trained personnel for conducting laboratory services;
- Apply appropriate quality assurance measures to all parts of laboratory management and operations, including the procurement process for supplies and equipment;
- Develop national resources for ensuring internal quality control and for EQA;
- Develop a process for monitoring laboratory performance improvement;
- Encourage the development of a structured advisory network for laboratories.

The governments of Member States led by Ministries of Health are urged to involve all stakeholders and interested parties in order to achieve these objectives.

1.4 Structure of this document

This document consists of four sections providing insight in the purpose of, and key considerations for, policy and strategic plan development for quality laboratory services (**Section 2**), practical guidance on amending the National Laboratory Policy and/or Strategic Plan or establishing a separate National Laboratory Quality Policy and/or Strategic Plan (**Section 3**), and key considerations for implementation of a National Laboratory (Quality) Policy and/or Strategic Plan (**Section 4**).

The Supplement provides a blueprint of a National Laboratory Quality Policy and Strategic Plan which can be used to either amend the existing National Laboratory Policy and/or Strategic Plan with statements focusing on establishing the National Laboratory Quality Infrastructure and advancing LQMS, or to develop a National Laboratory Quality Policy and Strategic Plan.

Section 2. Policy and planning for quality laboratory

Services: Purpose and key considerations

This section introduces the overall purpose of, and key considerations for, quality laboratory services policy and planning. Key elements and the structure of a typical National Laboratory Quality Policy and Strategic Plan are also discussed. This section is relevant for countries that will develop a separate National Laboratory Quality Policy and Strategic Plan as well as for countries that need to amend their National Laboratory Policy and/or Strategic Plan with laboratory quality-specific policy statements and/or strategic objectives.

2.1 Purpose of policy and planning for quality laboratory services

Through developing a National Laboratory (Quality) Policy and Strategic Plan, countries can design, focus and harmonize improvement initiatives and activities, both government-owned and those of external partners, to work towards establishment of a national laboratory quality infrastructure and advancement of sustainable LQMS implementation.

Over the past years, many African countries have developed a National Laboratory Policy and/or National Laboratory Strategic Plan. Although LQMS implementation at facility level is addressed in most African national laboratory policies and strategic plans, they often lack sufficient guidance to make the necessary changes to the laboratory network and system so that these can accommodate laboratory facilities in implementing LQMS. If this is the case, a country must either amend its National Laboratory Policy and/or Strategic Plan with laboratory quality-specific statements and strategic objectives, or establish a separate National Laboratory Quality Policy and Strategic Plan.

2.2 Key considerations

This document presents two options that a country can follow to either 1) amend its National Laboratory Policy and/or Strategic Plan with laboratory quality-specific policy statements and/or strategic objectives or 2) establish a separate National Laboratory Quality Policy and Strategic Plan. This subsection discusses key considerations for the establishment of a National Laboratory Quality Infrastructure and advancement of LQMS regardless of the approach taken. The structure of a typical National Laboratory Quality Policy and Strategic Plan is also discussed.

2.2.1 Key elements of policy and strategic planning for quality laboratory services

Establishing a National Laboratory Quality Infrastructure and advancing LQMS implementation requires formulation of policy statements and strategic objectives related to a variety of topics. These include:

- National Laboratory Quality Infrastructure;
- Legal and regulatory framework for Laboratory Quality Management;
- Monitoring, evaluation and continuous improvement mechanisms;
- Financing mechanisms;
- Human resources.

The purpose and contents of each core element are explained in detail in the blueprint National Laboratory Quality Policy and Strategic Plan provided in the Supplement.

2.2.2 Structure of a National Laboratory Quality Policy and Strategic Plan

Any policy and strategic plan needs to include several key ingredients. The same applies to a National Laboratory Quality Policy and Strategic Plan.

Integration of a policy and strategic plan

Many countries (have) tend(ed) to concentrate on developing a strategic plan and skip the policy development phase. However, a policy is the first step in the planning cascade (Figure 2). It provides an overall vision and creates a deep insight in **why** action is necessary and **what** long-term outcomes are required to fulfill this vision. A strategic plan provides a clear, action-oriented roadmap and outlines **how** (elements of) the policy will be implemented in the coming years. Hence, there is benefit in formulating a National Laboratory Quality Policy before developing a National Laboratory Quality Strategic Plan as a policy helps focus the strategies. A policy typically covers a timeframe of 10 years whereas a strategic plan covers a 3 to 5-year timeframe. A strategic plan may be redefined and renewed multiple times during the long term of the policy (i.e. multiple strategic plans can be developed and implemented sequentially in the timeframe of one policy) [40].

A policy and strategic plan can be separate documents but can also be merged into one document. This Guidance Document presents a blueprint which is a combination of the National Laboratory Quality Policy (including policy statements) and the National Laboratory Quality Strategic Plan (including resulting strategic objectives). This has multiple benefits in terms of both development and implementation:

- The development processes of a policy and strategic plan have several identical steps. Hence, formulating policy statements directly followed by formulating strategic objectives results in a more efficient development process.
- Combining the policy and the strategic plan in one document provides a complete overview and direction of why change is needed (=vision), what/which changes are required (=policy), and how this can be realized (=strategy), assuring consistency.

Nevertheless, if a country usually separates national policies from strategic plans, for example, because the ratification and endorsement processes differ, the blueprint National Laboratory Quality Policy and Strategic Plan will still serve as a valuable resource for identifying relevant laboratory quality-specific policy statements and/or strategic objectives to be added to the National Laboratory Policy and/or Strategic Plan, or for drafting a separate National Laboratory Quality Policy and Strategic Plan. The guidance provided by this document remains relevant regardless of whether a country decides to combine the policy with the strategic plan or keep them separate.



Typical outline of a National Laboratory Quality Policy and Strategic Plan

The structure and contents of a policy and strategic plan are not written in stone and may vary per country. However, several key elements should be covered by any policy and strategic plan. These include:

- Vision
The vision describes the ideal picture envisaged by the country for the laboratory sector and which the country strives towards through development and implementation of the

policy and the strategic plan. In the context of a quality policy, the vision can be replaced by a national definition of laboratory quality.

- Overall policy objective
This is a more concrete description of the overall objective which needs to be achieved by development and implementation of the policy and strategic plan.
- Policy topics with their outcomes¹
These can be seen as the different chapters of the policy. The description of the outcome(s) of each policy topic shows what the country aims to realize through implementation of the policy statements.
- Policy statements²
The actual statements of what needs to be done for each policy topic to accomplish the overall policy objective and work towards the vision.
- Strategic objectives²
For each policy statement one or more strategic objectives can be formulated as first step towards implementation of the policy (or vice versa: one strategic objective may be formulated for implementation of multiple policy statements). Because a strategic plan is developed for a shorter timeframe than the policy, multiple strategic plans need to be developed sequentially in the timespan of one policy. Therefore not all policy statements have to be translated into strategic objectives in each strategic plan. This depends on what is realistically achievable in the timeframe of the strategic plan.

The core policy and strategic plan can be further supplemented, for example with the findings of the situational analysis, a statement of government commitment, and any other matters as required by national policy and plan development practices.

A policy and strategic plan shall provide a detailed answer to the following questions:

- What is the ideal situation? – This is described by the vision and policy statements;
- What needs to be done, in broad terms, to achieve the ideal situation? – This is described by the strategic objectives.

A suggested outline of a National Laboratory Quality Policy and Strategic Plan is provided in Box 3. A detailed explanation of the contents of each section is provided in the blueprint National Laboratory Quality Policy and Strategic Plan in the Supplement. Additional sections can be added based on national requirements of a country.

Box 3: Typical outline of an policy and strategic plan. The blueprint National Laboratory Quality Policy and Strategic Plan in the Supplement follows this outline.

Typical outline of a National Laboratory Quality Policy and Strategic Plan³:

- Pre-matter;
- Introduction;
- Vision for quality laboratory services;
- Policy topics, outcomes, statements and strategic objectives per topic;
- Annexes (based on national requirements and at the discretion of the development team):
 - *Outcomes of the situational analysis;*
 - *The way forward;*
 - *National Laboratory Working Group (NLWG) members;*
 - *Any other information deemed important for inclusion.*

¹ In case a policy is developed separately from a strategic plan, the policy topics, outcomes and statements are only included in the policy document and not in the strategic plan.

² In case a strategic plan is developed separately from a policy, the strategic objectives are only included in the strategic plan and not in the policy.

³ A description of the contents of each section is provided in the blueprint National Laboratory Quality Policy and Strategic Plan. Detailed information on how to develop the various sections is provided in Section 3.

Section 3. The development of a National Laboratory Quality Policy and Strategic Plan

This section provides detailed guidance for the procedure to amend the existing National Laboratory Policy and/or Strategic Plan, or, if an amendment is not possible, development of a separate National Laboratory Quality Policy and Strategic Plan. Use Table 1 (below) to determine the action to be undertaken.

Table 1: Decision table to determine whether the National Laboratory Policy and/or Strategic Plan must be amended or a separate National Laboratory Quality Policy and Strategic Plan must be developed.

Does the country have a National Laboratory Policy in place?	Does the country have a National Laboratory Strategic Plan in place?	Action to be taken
Yes	Yes	Check whether the policy and strategic plan sufficiently cover the establishment of a National Laboratory Quality Infrastructure and implementation of LQMS. Use the blueprint provided in the Supplement. Where coverage is insufficient, amend the policy and strategic plan with quality specific statements and strategic objectives using section 3.1 and the blueprint in the Supplement*.
Yes	No	Check whether the policy sufficiently covers the establishment of a National Laboratory Quality Infrastructure and implementation of LQMS. Use the blueprint provided in the Supplement. If coverage is insufficient, amend the policy with quality specific statements using section 3.1 and the blueprint provided in the Supplement*. Develop a National Laboratory Quality Strategic Plan using section 3.2 and the blueprint in the Supplement.
No	Yes	Develop a National Laboratory Quality Policy. Check whether the strategic plan sufficiently covers the establishment of a National Laboratory Quality Infrastructure and implementation of LQMS. Use the blueprint provided in the Supplement. If coverage is insufficient, amend the strategic plan with quality specific strategic objectives using section 3.1 and the blueprint in the Supplement*.
No	No	Develop a National Laboratory Quality Policy and Strategic Plan using section 3.2 and the blueprint in the Supplement.

*If an amendment of the National Laboratory Policy and/or Strategic Plan is not possible (this depends on national practices), develop a separate National Laboratory Quality Policy and/or Strategic Plan as described in Section 3.2.

Figure 3 shows the steps of both the National Laboratory Policy and/or Strategic Plan amendment process and the process for development of a separate National Laboratory Quality Policy and Strategic Plan.

	Amend the National Laboratory Policy with quality policy statements	Amend the National Laboratory Strategic Plan with quality strategic plan objectives	Develop a National Laboratory Quality Policy and Strategic Plan
Preparatory activities			Formation of the NLWG
			Situational analysis/SWOT
Amendment/development	Adapt vision/mission with quality elements if necessary	Adapt vision/mission with quality elements if necessary	Develop vision/mission for quality laboratory services
	Verify which quality policy statements are already covered by the National Laboratory Policy	Verify which quality strategic objectives are already covered by the national laboratory strategic plan	
	Amend outcome per policy topic to the local situation	Amend outcome per strategic plan topic to the local situation	Amend outcome per policy topic to the local situation
	Include additional quality policy statements		Amend policy statements to the local situation
		Include additional strategic objectives	Amend strategic objectives to the local situation
Dialogue & endorsement			Conduct policy dialogue
	Submit the amended National Laboratory Policy for ratification	Submit the amended national laboratory strategic plan for endorsement	Submit the national laboratory quality policy and/or strategic plan for ratification/endorsement

Figure 3: Steps to be taken for both the National Laboratory Policy and/or Strategic Plan amendment process and the process for development of a separate National Laboratory Quality Policy and Strategic Plan

3.1 Amendment of the National Laboratory Policy and/or Strategic Plan

This section must be used for countries that can amend their National Laboratory Policy and/or Strategic Plan with laboratory quality-specific policy statements and/or strategic objectives.

3.1.1 Actors involved and their roles and responsibilities

The amendment of the National Laboratory Policy and/or Strategic Plan with laboratory quality-specific policy statements and strategic objectives is a relatively simple process that can be conducted by the Laboratory Technical Working Group (LTWG)/National Laboratory Coordinating Team (NLCT)/NLWG4 or similar.

Depending on country-specific protocols for policy amendment more actors can be involved. Country protocols may also require another policy dialogue (see Section 3.2) to obtain comments and buy-in from a bigger group of stakeholders. However, unless otherwise required, the amendment procedure should be as pragmatic and simple as possible for the sake of time, efficiency and resources.

4 Detailed information on the NLWG is provided in Section 3.2.1.

3.1.2 Procedure for amendment of the National Laboratory Policy

Below, the steps to be followed for amendment of the National Laboratory Policy and/or Strategic Plan with quality-specific policy statements and strategic objectives are provided.

1) Adapt vision/mission with quality elements if necessary

The vision and mission in the National Laboratory Policy and/or Strategic Plan may need to be amended with laboratory quality-specific elements. To do this, scrutinize and compare the model vision included in the Supplement with the vision/mission currently included in the National Laboratory Policy and/or Strategic Plan and amend as required.

2) Amend the outcome per policy and/or strategic plan topic to the local situation

Use the blueprint National Laboratory Quality Policy and Strategic Plan (Supplement) to amend the description of the outcomes of relevant policy and/or strategic plan topics to reflect the desired level of quality of laboratory services.

3) Verify quality-specific policy statements and strategic objectives already included in the National Laboratory Policy and/or Strategic Plan

Verify which quality-specific policy statements and/or strategic objectives in the blueprint are already covered by the National Laboratory Policy and/or Strategic Plan and which should be used to add to or amend the National Laboratory Policy and/or Strategic Plan.

3) Amend the National Laboratory Policy and/or Strategic Plan

Amend the National Laboratory Policy and/or Strategic Plan with quality-specific policy statements and/or strategic objectives as required.

4) Submit the amended National Laboratory Policy and/or Strategic Plan for ratification and endorsement

Once the National Laboratory Policy and/or Strategic Plan has been amended, the document(s) have to be ratified and/or endorsed by the appropriate authorities. National rules and procedures should be followed.

3.2 Development of a separate National Laboratory Quality Policy and Strategic Plan

If an amendment of the National Laboratory Policy and/or Strategic Plan is not possible, the steps below should be followed to draft a separate National Laboratory Quality Policy and Strategic Plan.

1) Formation of the NLWG

The first step in the National Laboratory Quality Policy and Strategic Plan development process is the formation of a policy development team, referred to as the NLWG, LTWG, NLCT, or similar (in this document the term NLWG is used). The NLWG should consist of a chairperson and an executive secretary and representatives as shown in Box 4. The composition of the NLWG should be flexible but must include representatives of both national-level laboratories and regional laboratories as well as other important stakeholders of the health laboratory services in the country, including the private sector. The NLWG should reflect a sufficient skill mix to ensure availability of adequate knowledge and experience for development of the National Laboratory Quality Policy and Strategic Plan.

Box 4: Possible stakeholders represented in the NLWG

Examples of stakeholders represented in the NLWG:

- Ministry of Health (MoH) and other relevant ministries, such as the Ministry of Agriculture, Ministry of Food Safety, Ministry of Education and Ministry of Environment, or similar;
- Laboratory managers (public sector laboratories: national laboratories, national reference laboratories, vertical program laboratories, regional laboratory representatives and private laboratory association representatives);
- National laboratory associations or societies;
- Universities & training institutes with laboratory education curricula;
- Laboratory accreditation or licensing bodies, national standards body (if different from the first);
- (Inter-)national development partners;
- National Metrology Institute (NMI);
- EQA providers especially if there are local providers;
- If the policy and strategic plan are developed under the One Health concept: representatives from the veterinary, agriculture, food security and/or environment laboratory services.

The terms of reference of the NLWG are:

1. Provide advice and expertise to the government on health laboratory matters.
2. Amend the National Laboratory Policy and/or Strategic Plan or develop the National Laboratory Quality Policy and Strategic Plan, and at a later stage the operational plans.
3. Seek advice from, and reach consensus with, the community of stakeholders of the health laboratory network as part of the policy dialogue phase.
4. Actively explain and promote the importance of quality laboratory services in the country.

NOTE: It is strongly advised that the members of the NLWG complete the ASLM Laboratory Network Leadership and Management Course. In this course, the members will be trained to conduct the complete procedure described in this Section for developing the National Laboratory Quality Policy and Strategic Plan.

2) Situational analysis

It is important to gain a thorough insight in, and understanding of, the current state of quality of laboratory services to select the best improvement strategies during the development of the National Laboratory Quality Policy and Strategic Plan. The National Laboratory Quality Policy and Strategic Plan must also be aligned with other relevant regional, national and provincial policies, plans, and regulations, such as the National Health Policy. The planning cycle of the National Laboratory Quality Policy and Strategic Plan must be aligned with the time frame of the national policy, planning and financial cycles. To ensure that these conditions are met the second step in the development process is conducting a situational analysis to collect the relevant information required.

- Desk review
Conduct a desk review to gain insight in the organization of the laboratory system and overall health system in a country, including its main strengths, challenges, opportunities and threats. Documents to be reviewed may include: the Joint External Evaluation report, Laboratory system assessment reports, health system assessment reports, national diagnostic algorithms, the National Health Policy and Strategic Plan, strategic/operational plans of vertical programs, other policies and plans relevant to the laboratory sector, laws and regulations relevant to the laboratory sectors or to the development of policies in general, relevant ministerial or presidential orders and decrees, statistics on the laboratory network and system, including numbers, functions, types and locations of laboratories, staffing, usage indicators, performance indicators, funding arrangements, etc.
- Laboratory network and system assessment
Conduct a laboratory network and system assessment to obtain up-to-date information and

data on the organization, quality and functioning of the laboratory services, network and system. The ASLM LABNET scorecard⁵ or the WHO Laboratory Assessment Tool⁶ – System Questionnaire can be used to conduct the assessment. Both tools provide a useful high-level insight into the functioning of the various components of the laboratory network and system by scoring each component resulting in graphic visualization of the scores.

- Strengths Weaknesses Opportunities and Threats (SWOT) analysis
Using the information from the laboratory network and system assessment, conduct a SWOT analysis to identify strengths, weaknesses, opportunities, and threats related to quality laboratory services. The procedure for conducting a SWOT analysis is described in the [WHO/Europe Development of a national laboratory strategic plan best practices document and facilitators' guide \(2017\)](#).
- Stakeholder mapping
Conduct a stakeholder mapping exercise to identify important stakeholders that are actively involved in, and directly or indirectly influence laboratory services quality. This provides insight in which stakeholders should be involved in National Laboratory Quality Policy and Strategic Plan development process, either directly as member of the NLWG, or indirectly as part of the policy dialogue phase. A direct benefit of including and engaging a wide range of stakeholders is that the National Laboratory Quality Policy and Strategic Plan will be better tailored to the various beneficiaries and that ownership will be created [40]. A list of possible stakeholders is provided in Box 5.

Box 5: List of possible stakeholders (non-exhaustive)

<u>Government organizations:</u>	<u>Other organizations/institutes:</u>
<ul style="list-style-type: none"> • MoH; • Ministry of Agriculture; • Ministry of Environment; • Ministry of Finance; • Ministry of Economic Affairs; • Ministry of Education; • Provincial health offices; • District health offices; • National data/informatics specialists. 	<ul style="list-style-type: none"> • Health services regulatory authorities; • Universities and training institutes with laboratory education curricula; • National standards body; • NAB; • NMI; • Procurement and supply system/National medical stores; • (Inter)national development partners; • Insurance entities; • Laboratorians professional organizations; • Laboratory consumer organizations.
<p><u>Health service organizations:</u></p> <ul style="list-style-type: none"> • Public sector laboratories; • Private sector laboratories; <ul style="list-style-type: none"> ○ Private-for-profit; ○ Private-not-for-profit: <ul style="list-style-type: none"> ▪ Faith based; ▪ Non-Governmental Organizations (NGO). 	

All data and information obtained in the situational analysis provide the baseline against which the National Laboratory Quality Policy and Strategic Plan is developed.

3) Develop a vision for quality laboratory services

The vision for quality laboratory services describes the ideal state that should be achieved through the implementation of the National Laboratory Quality Policy and Strategic Plan: the

5 A new matrix for scoring the functionality of national laboratory networks in Africa: introducing the LABNET scorecard | Ondoa | African Journal of Laboratory Medicine (ajlmonline.org)

6 WHO | Laboratory assessment tool

policy statements and strategic objectives will be formulated with the vision in mind. Whereas the situational analysis provides insight in the current situation (the starting point), the vision provides insight in where the country wants to go (the end-point).

Use the questions in Box 6 as a check to stimulate thinking on dimensions of quality for incorporation into the vision. An example vision which can be used as basis is provided in Box 7 and in the blueprint (Supplement).

Box 6: Questions to help frame dimensions of quality to local needs for development of the vision for quality laboratory services. Adapted from [40].

Questions that can help to frame the dimensions of quality to local needs	
Effective	Are laboratory services appropriate for the health needs of the population and consistent with knowledge and evidence for achieving the best possible health outcomes?
Efficient	Are resources allocated and used in the best possible manner to achieve outcomes?
Safe & secure	Does the delivery of laboratory services utilize the safest and most secure means possible (including data management) and reduce avoidable harm?
People-centered	Is the experience of laboratory services positive through the eyes of the clients? Is there a sense of trust in the quality of laboratory services?
Timely	Are waiting times for laboratory test results acceptable to the population and sufficiently short to avoid unnecessary harm?
Equitable, accessible	Are there barriers to or disparities in factors related to age, gender, race, ethnicity, geographical location, religion, socioeconomic status, linguistic or political affiliation?

Box 7: Example of a vision for quality laboratory services in the National Laboratory Quality Policy and Strategic Plan. Adapted from [41].

[Country name] shall have well-organized, sustainable network of quality assured laboratory services under the One Health concept that are accessible and affordable to all.

This network is governed and monitored through implemented and regularly updated policies, plans, rules and regulations. Laboratories use paperless information and communication systems according to international standards and a state-of-the-art referral and sample transportation system, thus ensuring optimal patient care and robust surveillance for public health events. Up-to-date pre-service and in-service training programs generate well-trained, qualified and certified staff that is dedicated and well-paid. Trained laboratory managers are competent to manage and lead processes in the laboratory. At all levels of the laboratory networks, technical staff perform evidence-based quality controlled and assured laboratory tests using quality controlled and assured equipment and consumables, standardized methodologies and ethical practices through implementation of a functional Laboratory Quality Management System compliant with national or international laboratory quality standards. Proper biorisk management, infection control and waste disposal systems are implemented and all laboratories are registered and licensed based on a defined National Laboratory Quality Standard and External Quality Assessment programs are widely established. Laboratories are encouraged to pursue international accreditation.

4) Determine the outcome per policy topic

The next step focuses on determining and formulating the desired outcomes for each quality policy topic. The outcomes describe for each policy topic the ideal situation to be achieved by the statements and strategic objectives under that policy topic. Therefore the outcomes are based on the overall vision for quality laboratory services. The blueprint National Laboratory Quality Policy and Strategic Plan provides example outcomes per policy topic that can be scrutinized, changed and amended by the NLWG and, where necessary, the NLWG can formulate different or additional outcomes.

5) Select policy statements and amend to the local situation

Based on the outcomes, the policy statements required for achieving that outcome are determined and formulated. Use the blueprint (Supplement) to select policy statements to be included and amend these to the local situation:

- Delete policy statements that are deemed not applicable;
- Reformulate remaining policy statements as required;
- Supplement the policy statements with additional policy statements until NLWG members agree that the total set of policy statements under each policy topic will suffice to achieve the outcome of that policy topic.

Policy statements are formulated as standards and consists of two parts:

1. The first part describes what needs to be implemented/done/created/etc.
2. The second part describes to what purpose this needs to be done.

As such, a policy statement almost always follows this format: *"There shall be [__description of what needs to be implemented, done, created, ... __] to ensure [__description of the why this needs to be done __]."*

Example:

There shall be a standards law, a licensing & accreditation law and a metrology law which apply to laboratory services to ensure enforcement of the National Laboratory Quality Infrastructure and advancement of LQMS implementation.

6) Select strategic objectives and amend to the local situation

Once the policy statements have been formulated, the NLWG proceeds to the next step of the planning cycle (Figure 2): strategic planning.

Whereas policy statements describe the ideal situation to be achieved to fulfil the vision for quality laboratory services, strategic objectives describe in broad terms the activities to be undertaken to work from the current situation to the implementation of the policy statements. Because the current situation differs between countries, it is not possible to provide one uniform set of strategic objectives that can be used as template for the strategic plan. Therefore, the blueprint National Laboratory Quality Policy and Strategic Plan (Supplement) provides examples of strategic objectives. The NLWG should take this as starting point: select relevant strategic objectives and adapt and incorporate these into the country's National Laboratory Quality Policy and Strategic Plan. Formulate additional strategic objectives where required.

Strategic objectives are formulated in active form, i.e. they always start with an action-oriented verb ("develop, create, implement, establish, ..."). For example: *"Develop and periodically review staffing guidelines based on workload and types of testing."* See the blueprint National Laboratory Quality Policy and Strategic Plan (Supplement) for more examples.

It should be noted that:

- Some policy statements require only one strategic objective;
- Some policy statements require multiple strategic objectives;
- Some strategic objectives are related to/contribute to implementation of multiple policy statements.

Note: the strategic objectives (covering a timespan of three to five years) will not necessarily lead to complete implementation of a policy statement (covering a 10-year period). Strategic objectives and the overall strategic plan should be realistic. The strategic objectives should be achievable within the three to five-year timespan of the strategic plan. If they are not feasible, they may need to be split up into multiple, sequential, strategic objectives. Similarly, the totality of all strategic objectives, hence the overall strategic plan, should be achievable in its three to five-year time span given the available resources. If this is not the case, further prioritization may be necessary to remove strategic objectives and reserve them for later strategic plans until the strategic plan is realistic and its implementation within its timespan is feasible.

Once the strategic plan is finalized, the policy and strategic plan, together with the overall vision for quality laboratory services can be consolidated into the overall draft National Laboratory Quality Policy and Strategic Plan that is ready for the next phase: dialogue and endorsement.

7) Conduct the policy dialogue

A broad consensus on the National Laboratory Quality Policy and Strategic Plan statements and strategic objectives is essential for ownership. Therefore, the NLWG members should go through a round of consultations with all important stakeholders. This will ensure that the policy statements and strategic objectives are supported by as wide an audience as possible. The consultations with stakeholders can be conducted in the form of a formal workshop or conference or as a series of consultation meetings.

Based on the comments from the stakeholders a final draft document will be prepared. When the comments are relatively minor, the final document can be prepared by the Executive Secretary; if the comments are more substantial it may be necessary to organize another meeting of the NLWG. If the country has fixed formats for policy and strategic plan documents, the Executive Secretary and Chairperson of the NLWG should reformat the documents into those formats.

8) Submit the draft National Laboratory Quality Policy and Strategic Plan for ratification/endorsement

The National Laboratory Quality Policy and Strategic Plan remain in draft until the government has officially endorsed the documents. Therefore, the next step is seeking endorsement by submitting the draft National Laboratory Quality Policy and Strategic Plan to relevant government entities (this varies per country) for endorsement/ratification.

Section 4. National Laboratory Quality Policy and Strategic Plan Implementation: Next Steps

Once the amended National Laboratory Policy and/or Strategic Plan, or the National Laboratory Quality Policy and Strategic Plan are endorsed, the process moves to the next phase of the planning cascade: operational planning. Development and implementation of operational plans are outside the scope of this document. However, this section provides some key considerations for the implementation of the policy and strategic plan through development and implementation of costed operational plans.

Relevant ministries and departments will be responsible for implementation of the policy and strategic plan. If the policy and strategic plan are developed and implemented under a One Health approach, the overall process is often led by the MoH, designated as 'Lead Ministry'. An inter-ministerial coordination body is responsible for providing management oversight to the entire implementation process across sectors and ministries.

Operational planning

Development of costed operational plans ensures that the policy statements and strategic objectives are translated into actions that are carried out in an integrated manner at a pace that is in line with the country's managerial and financial resources. Operational plans normally cover a timespan of one year. Development of operational plans requires the support of many sectors of society and the government. It will be of utmost importance that all actors involved in the planning process have realistic and accurate expectations and will operate in an effective, coordinated and timely manner. Operational plans should be Specific, Measurable, Agreed/Assigned, Realistic and Timebound (SMART):

- Specific: the objectives of operational plans are clear and formulated in a manner that allows for only one interpretation;
- Measurable: the objectives are supplemented with indicators for achievement so that the complete and correct achievement of objectives can be verified;
- Agreed/Assigned: the objectives are assigned to specific persons or organizations and these persons/organizations are aware of this and have agreed that they will be able to implement the objective within the timeframe set for the objective;
- Realistic: the objectives should be achievable within the timeframe assigned to the objective;
- Timebound: the objectives are supplemented with a deadline.

The operational plans should be costed to ensure allocation of sufficient funds to allow for their complete implementation.

Operational plans are living documents that are linked back to the objectives of the strategic plan and updated as needed to reflect successes, challenges and lessons learned.

Monitoring and Evaluation

A well-known model which lies at the basis of international quality standards and quality management systems is the Deming cycle, or Plan-Do-Check-Act (PDCA) cycle⁷. The same model should be applied to the policy and strategic planning process: aside from developing and implementing the policy and strategic plan, countries must establish an M&E framework to closely monitor their implementation and reflect on the successes gained, challenges met, and lessons learned. Based on this, countries must adapt and amend the operational plans and the strategic plans to ensure that they remain realistic and are adequate for achieving implementation of the policy statements.

A final remark is related to the implementation process of the policy and strategic plan: the

7 PDCA - Wikipedia

success of efforts to improve quality of laboratory services is influenced by the development and institutionalization of a “culture of quality” in all laboratories. There is no single definition of what a culture of quality entails, but it has been described as “an organization which creates a working environment which is open and participative, where ideas and good practices are shared, where education and innovation are valued, and where blame is used exceptionally” [40]. A culture is influenced by a complex set of factors and values, including cultural, social, personal and work values, and the medico-legal environment. Changing such cultures, as required for implementing the policy and strategic plan and advancing LQMS implementation, may therefore be a slow and challenging process and may be opposed by those threatened by the change.

There is a key role for political and health system leaders and laboratory managers in defining and promoting a culture of quality and leading by example to embed the required values throughout the laboratory system [40]. The process of developing and implementing an policy and strategic plan can in itself be a key driver and mechanism for advocating improvements in quality of care as it can engage and secure buy-in from stakeholders, bring the issue to public and professional attention, and provide an opportunity to demonstrate the value of quality practice to the health system [40].

References

1. Joint WHO – CDC Conference on Health Laboratory Quality Systems. In Lyon: World Health Organisation; 2008.
2. World Health Organization. Joint WHO-CDC conference on laboratory quality systems, Lyon, April 2008- joint statement and recommendations. *Wkly Epidemiol Rec.* 2008;83(32):285–92.
3. Forsman RW. Why is the laboratory an afterthought for managed care organizations? *Clin Chem.* 1996;42(5):813–6.
4. Nkengasong JN, Mbopi-Keou FX, Peeling RW, Yao K, Zeh CE, Schneidman M, et al. Laboratory medicine in Africa since 2008: then, now, and the future. *Lancet Infect Dis.* 2018;3099(18).
5. Nkengasong JN, Birx D. Quality matters in strengthening global laboratory medicine. *Afr J Lab Med.* 2014;3(2):a239.
6. Nkengasong JN. Strengthening laboratory services and systems in resource-poor countries. *Am J Clin Pathol.* 2009 Jun;131(6):774.
7. Nkengasong JN, Mesele T, Orloff S, Kebede Y, Fonjungo PN, Timperi R, et al. Critical role of developing national strategic plans as a guide to strengthen laboratory health systems in resource-poor settings. *Am J Clin Pathol.* 2009 Jun;131(6):852–7.
8. Martin R, Hearn TL, Ridderhof JC, Demby A. Implementation of a quality systems approach for laboratory practice in resource-constrained countries. *AIDS.* 2005 May;19 Suppl 2:S59–65.
9. Nkengasong JN, Nsubuga P, Nwanyanwu O, Gershly-Damet G-M, Roscigno G, Bulterys M, et al. Laboratory systems and services are critical in global health: time to end the neglect? *Am J Clin Pathol.* 2010 Sep;134(3):368–73.
10. Martin R, Barnhart S. Global Laboratory Systems Development: Needs and Approaches. *Infect Dis Clin NA.* 2011;25(3):677–91.
11. Okeke IN. Diagnostic insufficiency in Africa. *Clin Infect Dis.* 2006 May;42(10):1501–3.
12. Bates I, Maitland K. Are laboratory services coming of age in sub-Saharan Africa? *Clin Infect Dis.* 2006 Feb;42(3):383–4.
13. Muula AS, Maseko FC. Medical laboratory services in Africa deserve more. *Clin Infect Dis.* 2006 May;42(10):1503.
14. Berkelman R, Cassell G, Specter S, Hamburg M, Klugman K. The “Achilles Heel” of Global Efforts to Combat Infectious Diseases. *Clin Infect Dis.* 2006;42:1503–4.
15. Guzel O, Guner EI. ISO 15189 accreditation: Requirements for quality and competence of medical laboratories, experience of a laboratory I. *Clin Biochem.* 2009 Mar;42(4–5):274–8.
16. Birx D, de Souza M, Nkengasong JN. Laboratory challenges in the scaling up of HIV, TB, and malaria programs: The interaction of health and laboratory systems, clinical research, and service delivery. *Am J Clin Pathol.* 2009 Jun;131(6):849–51.
17. Reyburn H, Mbatia R, Drakeley C, Carneiro I, Mwakasungula E, Mwerinde O, et al. Overdiagnosis of malaria in patients with severe febrile illness in Tanzania: A prospective study. *Br Med J.* 2004;329(7476):1212–5.

18. Polage CR, Bedu-Addo G, Owusu-Ofori A, Frimpong E, Lloyd W, Zurcher E, et al. Laboratory use in Ghana: physician perception and practice. *Am J Trop Med Hyg.* 2006 Sep;75(3):526–31.
19. Ombelet S, Ronat J-B, Walsh T, Yansouni CP, Cox J, Vlieghe E, et al. Clinical bacteriology in low-resource settings: today's solutions. *Lancet Infect Dis.* 2018 Aug;18(8):e248–58.
20. Petti CA, Polage CR, Quinn TC, Ronald AR, Sande MA. Laboratory Medicine in Africa: A Barrier to Effective Health Care. *Clin Infect Dis.* 2006;42(3):377–82.
21. English M, Esamai F, Wasunna A, Were F, Ogutu B, Wamae A, et al. Assessment of inpatient paediatric care in first referral level hospitals in 13 districts in Kenya. *Lancet.* 2004;363(9425):1948–53.
22. Kehinde AO, Obaseki FA, Cadmus SI, Bakare RA. Diagnosis of tuberculosis: urgent need to strengthen laboratory services. *J Natl Med Assoc.* 2005;97(3):394–6.
23. Berkley JA, Mwangi I, Ngetsa CJ, Mwarumba S, Lowe BS, Marsh K, et al. Diagnosis of acute bacterial meningitis in children at a district hospital in sub-Saharan Africa. *Lancet.* 2001;357(9270):1753–7.
24. Evans JA, Adusei A, Timmann C, May J, Mack D, Agbenyega T, et al. High mortality of infant bacteraemia clinically indistinguishable from severe malaria. *QJM - Mon J Assoc Physicians.* 2004;97(9):591–7.
25. Makani J, Matuja W, Liyombo E, Snow RW, Marsh K, Warrell DA. Admission diagnosis of cerebral malaria in adults in an endemic area of Tanzania: Implications and clinical description. *QJM - Mon J Assoc Physicians.* 2003;96(5):355–62.
26. Andiric LR, Chavez LA, Johnson M, Landgraf K, Milner Jr DA. Strengthening laboratory management toward accreditation, a model program for pathology laboratory improvement. *Clin Lab Med.* 2018;38:131–40.
27. Amexo M, Tolhurst R, Barnish G, Bates I. Malaria misdiagnosis: effects on the poor and vulnerable. *Lancet (London, England).* 2004 Nov;364(9448):1896–8.
28. Andiric LR, Massambu CG. Laboratory quality improvement in Tanzania. *Am J Clin Pathol.* 2015;143(4):566–72.
29. Piot P, Kazatchkine M, Dybul M, Lob-Levyt J. AIDS: lessons learnt and myths dispelled. *Lancet.* 2009;374(9685):260–3.
30. Strengthening public health laboratories in the WHO African region: A critical need for disease control. Resolution: AFR/RC58/R2. Yaounde: Regional Committee for Africa (58); 2008.
31. Yao K, McKinney B, Murphy A, Rotz P, Wafula W, Sendagire H, et al. Improving quality management systems of laboratories in developing countries: an innovative training approach to accelerate laboratory accreditation. *Am J Clin Pathol.* 2010 Sep;134(3):401–9.
32. SLMTA | Strengthening Laboratory Management Towards Accreditation [Internet]. [cited 2019 Dec 12]. Available from: <https://www.slmta.org/accredited-labs>
33. Gershy-Damet G-M, Rotz P, Cross D, Belabbes EH, Cham F, Ndiokubwayo J-B, et al. The World Health Organization African region laboratory accreditation process: improving the quality of laboratory systems in the African region. *Am J Clin Pathol.* 2010 Sep;134(3):393–400.
34. ASLM Laboratory Accreditation / SLIPTA - ASLM [Internet]. [cited 2019 Apr 29]. Available from: <http://www.aslm.org/slipta-map/>

35. Ondoa P, Ndlovu N, Keita M-S, Massinga-Loembe M, Kebede Y, Odhiambo C, et al. Preparing national tiered laboratory systems and networks to advance diagnostics in Africa and meet the continent's health agenda: Insights into priority areas for improvement. *Afr J Lab Med.* 2020;9(2).
36. Datema TAM, Oskam L, van Beers SM, Klatser PR. Critical review of the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA): Suggestions for harmonization, implementation and improvement. *Trop Med Int Heal.* 2012;17(3):361–7.
37. Datema TAM, Oskam L, Broerse JEW, Klatser PR. Review of the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) version 2:2015. *Afr J Lab Med.*
38. United Nations. Sustainable Development Goals [Internet]. [cited 2021 Aug 5]. Available from: https://www.who.int/health-topics/sustainable-development-goals#tab=tab_2
39. Joint External Evaluation Tool and Process Overview. Geneva: World Health Organization; 2016.
40. World Health Organization. Handbook for national quality policy and strategy: a practical approach for developing policy and strategy to improve quality of care. Geneva: World Health Organization; 2018.
41. Islamic Republic of Pakistan National Laboratory Policy. Government of Pakistan; 2017.
42. UNIDO. Quality policy: Technical Guide. Vienna: United Nations Industrial Development Organization; 2018.

Further Reading

- Quality Policy: Technical Guide. United Nations Industrial Development Organization. Vienna: 2018.
- Handbook for National Quality Policy and Strategy: A practical approach for developing policy and strategy to improve quality of care. World Health Organization. Geneva: 2018.
- Development of National Laboratory Policies: Best Practices Document and Facilitators' Guide. World Health Organization Regional Office for Europe. Copenhagen: 2017.
- Laboratory Quality Management System Handbook. World Health Organization. Geneva: 2011.
- Joint WHO – CDC Conference on Health Laboratory Quality Systems. World Health Organization. Geneva: 2008.
- Blueprint National Laboratory Quality Policy and Strategic Plan

Note:

Explanations on contents of the various sections of the National Laboratory Quality Policy and Strategic Plan are provided in grey boxes. These should be deleted when adapting the National Laboratory Quality Policy and Strategic Plan to the country context.

Supplement

Blueprint National Laboratory Quality Policy and Strategic Plan

Pre-matter

Information on contents (delete this box when adapting this framework to the country context):

The contents of the pre-matter are determined by the national practices and/or by the policy development team (in this Guidance Document referred to as the NLWG – see Chapter 3). Examples of contents that could (but do not have to) be included in the pre-matter:

- A message of the minister;
- A message of the secretary of state;
- A message of the director of laboratory services;
- A preface by the director of the National Institute of Health;
- A foreword by the (executive secretary of the) NLWG;
- Acknowledgments.

An important element of a policy is the statement of commitment of the government, for which the pre-matter is a logical place. For example, government commitment can be expressed through the message of the minister indicating that the government assumes overall responsibility for the quality of laboratory services and the effectiveness and efficiency of the laboratory and quality infrastructure by provision of direction, long-term funding and all other means of support as required.

Introduction

Information on contents (delete this box when adapting this framework to the country context):

Similar to the pre-matter, the contents of the introduction are not written in stone and are at the discretion of the NLWG and national practices. The introduction shall provide insight in why the National Laboratory Quality Policy and Strategic Plan is necessary through a description of the background and landscape against which it is developed. This may include a brief description of the historical background of laboratory services in the country and a brief summary of the situational analysis with a description of the main strengths, challenges, opportunities and threats related to laboratory services quality. The introduction should provide insight in how the National Laboratory Quality Policy and Strategic Plan aim to improve this situation. It may further elaborate on the main principles that guided development and provide a summary of the National Laboratory Quality Policy and Strategic Plan development process.

Vision for quality laboratory services

Information on contents (delete this box when adapting this framework to the country context):

A template vision for quality laboratory services is provided below. This can be used to either amend the vision of the National Laboratory Policy and/or Strategic Plan or to add to the country's National Laboratory Quality Policy and Strategic Plan after tailoring by the NLWG to fit the country context.

[Country name] shall have well-organized, sustainable network of quality assured laboratory services under the One Health concept that are accessible and affordable to all.

This network is governed and monitored through implemented and regularly updated policies, plans, rules and regulations. Laboratories use paperless information and communication systems according to international standards and a state-of-the-art referral and sample transportation system, thus ensuring optimal patient care and robust surveillance for public health events.

Up-to-date pre-service and in-service training programs generate well-trained, qualified and certified staff that is dedicated and well-paid. Trained laboratory managers are competent to manage and lead processes in the laboratory. At all levels of the laboratory networks, technical staff perform evidence-based quality controlled and assured laboratory tests using quality controlled and assured equipment and consumables, standardized methodologies and ethical practices through implementation of a functional Laboratory Quality Management System compliant with national or international laboratory quality standards. Proper biorisk management, infection control and waste disposal systems are implemented in all laboratories.

All laboratories are registered and licensed based on a defined National Laboratory Quality Standard and External Quality Assessment programs are widely established. Laboratories are encouraged to pursue international accreditation.

Policy topics, statements and strategic objectives

Information on contents (delete this box when adapting this framework to the country context):

This is the central part of the National Laboratory Quality Policy and Strategic Plan. It contains the policy outcome, policy statements and strategic objectives for all the policy topics. Each policy topic follows a fixed structure:

1. The main outcome(s) to be realized for that Policy Topic;
2. The policy statements to accomplish the outcome(s);
3. The strategic objectives formulate the actions required to implement the policy statements and accomplish the outcome(s). Strategic objectives can link to multiple policy statements, also across different policy topics. Vice versa, multiple strategic objectives may be required to fulfill one policy statement.

In this blueprint, policy statements and strategic objectives for the following policy topics are provided:

1. Quality infrastructure;
2. Legal and regulatory framework;
3. Monitoring and continuous improvement;
4. Finance;
5. Human Resources.

Policy topic 1: National Laboratory Quality Infrastructure

Information on contents (delete this box when adapting this framework to the country context):

It is important to start the National Laboratory Quality Policy and Strategic Plan with statements and objectives to establish the quality infrastructure necessary to support LQMS implementation in all laboratories in the tiered national laboratory network. This policy topic should cater for establishment of a staged NLQS and a licensing system to ensure quality of laboratory services, laboratory personnel, and laboratory education. Laboratories should comply with at least the first level of the NLQS, monitor their performance using quality indicators, and participate in EQA proficiency testing schemes for all tests to become licensed. This ensures that each laboratory has the foundation of an LQMS in place and quality of their results is monitored. In addition, this policy topic should ensure that there is sufficient in-country capacity to calibrate and maintain laboratory equipment. Lastly, this policy topic should cater for establishment/designation of the institutions responsible for these processes, including a National Standards Body and a NAB, an ISO 17025 accredited National Metrology Institute and other ISO 17025 accredited entities offering equipment calibration and maintenance services.

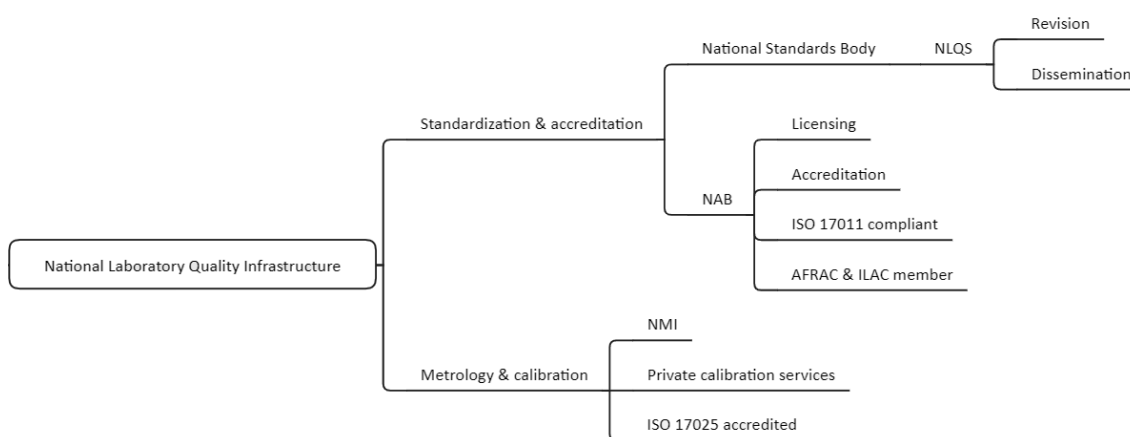


Figure 4: Overview of important elements to be covered by the National Laboratory (Quality) Policy and Strategic Plan related to the National Laboratory Quality Infrastructure.

The National Laboratory Quality Infrastructure consists of several key institutions responsible for standardization, metrology and accreditation of laboratories. If available, countries may consider making use of the existing national quality infrastructure for manufacturing, export and trade of goods and products or establish a separate infrastructure dedicated to laboratory quality management. Pragmatism is key in quality management: countries should select the solution that is most practical and easy to achieve.

- **Standardization & accreditation**

The government must designate a National Standards Body responsible for disseminating, implementing and regularly reviewing and revising the NLQS and a NAB responsible for:

- Licensing and certifying laboratories to the different levels of the NLQS to provide a pathway for incremental improvement. In addition, the NAB could be made responsible for licensing of laboratory professionals (see Policy Topic 5: Human Resources);
- Accrediting laboratories based on international standards (this can also be done by a foreign accreditation body but this is often an expensive and time-consuming process).

It is strongly recommended that the NAB becomes ISO 17011 accredited (ISO 17011 contains the requirements for accreditation bodies accrediting conformity assessment bodies) and recognized by the regional accreditation cooperative (AFRAC). It should also become a member of the International Laboratory Accreditation Co-operation (ILAC) because this ensures that accreditation provided by the NAB is internationally recognized. I.e. the quality of results and services of laboratories accredited by a NAB recognized by AFRAC and members of ILAC are internationally recognized and accepted.

The National Standards Body and the NAB could be already existing institutions of which the scope has to be expanded, or they have to be newly established. Before the NAB is established/designated, the laboratory directorate/department at the MoH may act as an interim accreditation body.

- **Metrology & calibration**

Laboratories work with sophisticated equipment that needs to be regularly maintained and calibrated to provide accurate and reliable measurements which is crucial for quality assurance. Countries must ensure sufficient equipment calibration and maintenance capacity for laboratories. This can be achieved through, for example, establishment of an NMI and/or other equipment calibration and maintenance services (public or private). These must be ISO 17025 accredited to ensure traceability of calibration standards to the International System of Units (SI) and assure quality of calibration services. Often, countries have already established NMIs to facilitate export and international trade. In this case, the scope and expertise of the existing NMI can be expanded to include calibration and maintenance of laboratory equipment.

It is also recommended that countries ensure the availability of sufficient laboratory quality management expertise at the Directorate of Laboratory Services, which is responsible for implementation and coordination of many National Laboratory Quality Policy and Strategic Plan statements and objectives.

Policy outcome

The country has a formalized National Laboratory Quality Infrastructure that supports Laboratory Quality Management System implementation and maintenance in all laboratories in the national tiered laboratory network. All laboratories and laboratory workers in the country are registered and licensed.

Policy statements

Government Structure

1. The Ministry of Health shall have a Directorate of Laboratory Services with quality management experts to ensure availability of relevant quality management expertise at national level. [NOTE: *The Directorate of Laboratory Services can be at federal and provincial level in case of a devolved health system*].
2. The Directorate of Laboratory Services shall be the administrative leader in charge of the implementation and maintenance of laboratory quality management systems based on the staged National Laboratory Quality Standard in all laboratories in the national tiered laboratory network.

Standardization & Accreditation

3. A regularly reviewed and updated staged National Laboratory Quality Standard shall be developed to improve the quality of laboratory services.
4. An institution (either existing or newly established) shall be designated as the National Standards Body for laboratory services. This institution shall be responsible for regular review, revision and dissemination of the staged National Laboratory Quality Standard.
5. An institution (either existing or newly established) shall be designated as the National Accreditation Body. This institution shall be responsible for laboratory licensing and accreditation.
6. The National Accreditation Body shall comply with the requirements of ISO 17011 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

7. The National Accreditation Body shall seek to become a member of the African Accreditation Cooperation (AFRAC) and the International Laboratory Accreditation Cooperation (ILAC).
8. The National Accreditation Body shall seek to become a full member of ILAC.
9. The costs for compliance with the staged National Laboratory Quality Standard shall be included in the national laboratory budget to ensure sustainability of standard implementation as well as the licensing system.
10. There shall be a system of incentives to motivate all laboratories to reach certification to level 2 or higher of the staged National Laboratory Quality Standard and to become accredited to international standards.
11. All reference laboratories shall be encouraged to become accredited to international standards.

Licensing

12. All laboratories (public and private), laboratory professionals, and training institutes providing pre-service and in-service (Continuous Professional Education [CPE]) training for laboratory professionals shall be licensed according to the staged National Laboratory Quality Standard, a defined set of criteria for laboratory professionals, and a defined set of criteria for laboratory training institutes, respectively, to ensure quality of laboratory services.
13. Compliance with the first level of the staged National Laboratory Quality Standard shall be part of the laboratory licensing requirements.
14. Laboratory licensing criteria shall include the use of quality indicators and participation in External Quality Assessment programs for all tests performed.
15. There shall be an auditing system and a licensing body at a national level for licensing of laboratory professionals and institutes offering pre-service and in-service laboratory training to ensure compliance with licensing requirements for laboratory professionals and laboratory training institutes, respectively.
16. Periodic renewal of laboratory, laboratory professionals and laboratory training institutes licenses shall be required based re-inspection to ensure continued compliance with standards and licensing criteria.

Metrology & Calibration

17. A National Metrology Institute shall be established/The scope and expertise of the existing National Metrology Institute shall be expanded*, to include approval, calibration and maintenance of laboratory equipment.
18. The National Metrology Institute shall be ISO 17025 accredited to ensure appropriate competence for laboratory equipment maintenance and calibration.
19. Other entities offering equipment maintenance and calibration services shall be ISO 17025 accredited to ensure quality of these services.

*Keep the preferred option.

Strategic objectives

Information on contents (delete this box when adapting this framework to the country context):

Strategic objectives should be formulated based on situational analysis and a prioritization exercise. Below are some examples of strategic objectives which relate to above policy statements. These

example strategic objectives can be adapted and more strategic objectives must be formulated in line with the situational analysis in the country and based on what is feasible. For more information see section 3.2 of the Guidance Document.

Government Structure

1. Endorse and implement the National Laboratory Quality Policy, Strategic Plan and annual costed operational plans under the One Health approach to ensure Laboratory Quality Management System implementation and maintenance based on the staged National Laboratory Quality Standard.
2. Establish a Directorate of Laboratory Services with quality management expertise to lead and manage implementation and maintenance of Laboratory Quality Management Systems based on the staged National Laboratory Quality Standard.

Standards & Accreditation

3. Develop a staged National Laboratory Quality Standard.
4. Establish a National Standards Body with defined Terms of Reference to regularly review, revise and disseminate the staged National Laboratory Quality Standard. [*NOTE Alternative option: "Expand the mandate of the National Standards Body..." in case a National Standards Body already exists in the country*].
5. Establish a National Accreditation Body with defined Terms of Reference to audit laboratories for licensing and accreditation. [*NOTE Alternative option: "Expand the mandate of the National Accreditation Body..." in case a National Accreditation Body already exists in the country*]
6. Provide the National Accreditation Body with the necessary means to comply with ISO 17011 Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies.
7. Provide the National Accreditation Body with the necessary means to become a full member of the African Accreditation Cooperation (AFRAC) and the International Laboratory Accreditation Cooperation (ILAC).
8. Include costs for compliance with the staged National Laboratory Quality Standard in the national laboratory budget.
9. Establish a system of incentives for reference laboratories to become accredited to international standards and to ensure motivation of all laboratories to reach certification to level 2 or higher of the staged National Laboratory Quality Standard and to become accredited to international quality standards including ISO 15189 and ISO 17025.

Licensing

10. Develop a legal and regulatory framework for mandatory licensing of laboratories based on compliance with the first level of the staged National Laboratory Quality Standard.
11. Make use of quality indicators and participation in an approved External Quality Assessment Program for all tests part of laboratory licensing criteria.
12. Develop and implement a national system for mandatory licensing and periodic re-licensing of laboratory professionals and institutes providing pre-service and in-service laboratory training.
13. Develop licensing, relicensing and monitoring criteria including Continuous Professional Education (CPE) requirements for the different categories of laboratory professionals and for institutes offering pre-service and in-service laboratory training.
14. Train a pool of licensing inspectors that will perform licensing activities under the guidance of the national licensing authority.

15. Create/designate a central regulatory body for registration of licensed laboratory professionals and laboratory training institutes.

Metrology & Calibration

16. Establish a National Metrology Institute with the expertise and defined terms of reference to approve, calibrate and maintain laboratory equipment [*NOTE Alternative: "Expand the mandate of the National Metrology Institute..." in case a National Metrology Institute already exists in the country*].
17. Provide the National Metrology Institute with the necessary means to achieve ISO 17025 accreditation.
18. Make ISO 17025 accreditation mandatory for all entities offering equipment maintenance and calibration services.

Policy topic 2: Legal and Regulatory Framework for Laboratory Quality Management

Information on contents (delete this box when adapting this framework to the country context):

An important element of any policy is to ensure an adequate and up-to-date legal and regulatory framework. This framework provides two important tools a government can use to enforce a policy: legislation and licensing.

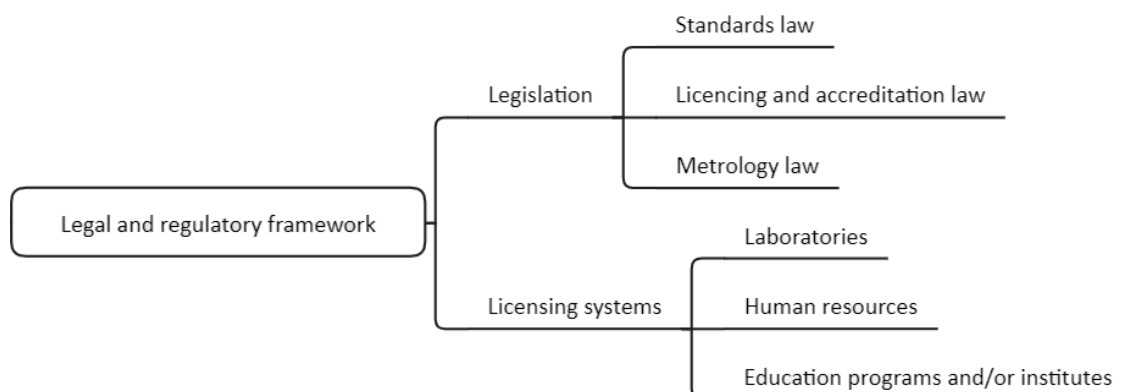


Figure 5: Overview of important elements to be covered by the National Laboratory (Quality) Policy and Strategic Plan related to the legal and regulatory framework for laboratory quality management.

Legislation

Typical examples of legislation that should be considered in the context of laboratory quality management are listed below. Most countries will already have similar laws. A review and revision process must therefore be created to make these laws applicable to the health sector.

- **Standards law:** this law provides for the development, review, renewal and publication of the staged NQLS and their legal standing. It should also provide for the National Standards Body and the NAB, including its governance, responsibilities, activities and finances [1];
- **Licensing and accreditation law:** this law provides for the development of a licensing and accreditation system covering licensing of both laboratories and laboratory personnel (see below) and licensing of pre-service and in-service laboratory education institutes (see Policy Topic 5: Human Resources). Criteria for licensing of laboratories should include compliance with the first level of the staged NLQS, use of quality indicators and participation in EQA proficiency testing schemes for all tests (see Policy Topic 1: National Laboratory Quality Infrastructure);
- **Metrology law:** this law arranges the legal basis for metrology, including calibration and traceability to SI-units. In addition, this law provides the legal basis for establishment of the NMI, including its governance, responsibilities, activities and finances [1].

Licensing systems

A licensing system for both laboratories and laboratory personnel, and for licensing of pre-service and in-service laboratory education institutes (see Policy Topic 5: Human Resources) must be established. The main purpose of a licensing system is to control and assure the quality of laboratory services, personnel and education institutes. Standards and criteria for licensing must be developed and regularly reviewed and revised, and a licensing authority must be established including specification of its responsibilities, activities and financing mechanism(s).

Countries also need to establish remedial action or sanction mechanisms for non-adherence/non-compliance. Sanctions may include revoking of a license and funding and there may be recourse to legal mechanisms including fines or other actions in case of willful malpractice. The need for, and use of, such mechanisms should be carefully considered within the context of the particular country [2].

Policy outcome

A National Laboratory Quality Infrastructure enforced by law.

Policy statements

1. Legislation and regulations related to laboratory services shall be harmonized with the National Laboratory Quality Policy and Strategic Plan and be in line with international recommendations.
2. There shall be a standards law, a licensing & accreditation law and a metrology law which apply to laboratory services to ensure enforcement of the National Laboratory Quality Infrastructure and advancement of Laboratory Quality Management System implementation.

Strategic objectives

Information on contents (delete this box when adapting this framework to the country context):

Strategic objectives should be formulated based on situational analysis and a prioritization exercise. Below are some examples of strategic objectives which relate to the above policy statements. These example strategic objectives can be adapted and more strategic objectives must be formulated in line with the situational analysis in the country and based on what is feasible. For more information see section 3.2 of the Guidance Document.

1. Review and align the existing regulatory and legal framework with the National Laboratory Quality Policy and Strategic Plan and international recommendations to ensure it reflects the latest developments in the field of laboratory services.
2. Establish a standards law (or expand the scope to include laboratory services), a licensing & accreditation law and a metrology law which applies to laboratory services to ensure enforcement of the National Laboratory Quality Infrastructure and advancement of Laboratory Quality Management System implementation.

Policy topic 3: Monitoring, Evaluation & Continuous Improvement

Information on contents (delete this box when adapting this framework to the country context):

Whereas the previous two components focus specifically on establishing the quality infrastructure and legal and regulatory framework for implementation and enforcement of the National Laboratory Quality Infrastructure and advancement of LQMS implementation, the current topic focuses on the mechanisms required at laboratory network and systems level to monitor and continuously improve quality of laboratory services. These include:

- Establishment and implementation of **EQA schemes** with proficiency testing for the essential diagnostic tests conducted in the country, including the designation of laboratories (typically reference laboratories) responsible for organizing EQA proficiency testing schemes, their governance, responsibilities, activities, and financing. EQA providers should be accredited to ISO 17043 (General requirements for proficiency testing).
- Establishment of an **M&E framework** with a definition of sets of **quality indicators** for the different tiers of the laboratory network to objectively assess the quality of services provided by each laboratory.
- Establishment of a **system of tiered supervision** whereby laboratories in higher tiers of the laboratory network conduct audits, support LQMS implementation and monitor quality and performance of laboratories in lower tiers of the network through supportive supervision, at the condition that the supervising laboratories are certified to an NLQS level at least one level higher than the NLQS level of the supervised laboratory/ies.

The use of quality indicators and participation in EQA must be made part of laboratory licensing criteria (see Policy Topic 1 and 2).

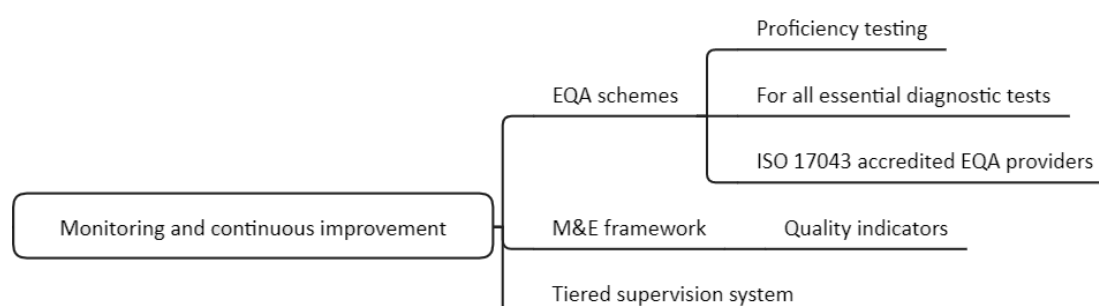


Figure 6: Overview of important elements to be covered by the National Laboratory Quality Policy and Strategic Plan related to monitoring and continuous improvement of laboratory services quality.

Policy outcome

Functional monitoring and evaluation structures for quality assurance and continuous improvement of laboratory services within the national tiered laboratory network.

Policy statements

1. All laboratory testing shall include appropriate controls and quality assurance to ensure reliable results.

External Quality Assessment - Proficiency Testing

2. There shall be designated national and regional entities that provide External Quality Assessment services for all tests on the National Essential Diagnostics List (NEDL) for all laboratories in the country.
3. These entities shall operate in compliance with the requirements of ISO 17043.
4. Reference laboratories shall be encouraged to participate in international External Quality Assessment schemes.
5. Regular successful participation with acceptable results in External Quality Assessment schemes shall be a requirement for licensing and/or accreditation.

Monitoring & Evaluation Framework

6. There shall be a system in place for regular monitoring and evaluation of the functioning of the laboratory network based on quality indicators.
7. There shall be harmonized sets of quality indicators for the different tiers of the laboratory network to objectively assess the quality of the services provided by the laboratory facilities.

Tiered Supervision

8. There shall be a system of tiered supervision to ensure that all laboratories provide quality services meeting the national quality standards.

Strategic objectives

Information on contents (delete this box when adapting this framework to the country context):

Strategic objectives should be formulated based on situational analysis and a prioritization exercise. Below are some examples of strategic objectives which relate to above policy statements. These example strategic objectives can be adapted and more strategic objectives must be formulated in line with the situational analysis in the country and based on what is feasible. For more information see section 3.2 of the Guidance Document.

External Quality Assessment - Proficiency Testing

1. Designate (an) institute(s) for national provision of External Quality Assessment services for all tests on the National Essential Diagnostics List (NEDL).
2. Ensure that national External Quality Assessment programs offer panels for all tests on the NEDL.
3. Ensure that national External Quality Assessment providers work in compliance with ISO 17043. *[NOTE Countries can also choose to participate in ISO 17043 compliant EQA programs provided by a regional EQA provider in absence of ISO 17043 certified national EQA providers].*
4. Develop a mechanism for External Quality Assessment providers to provide timely feedback including suggestions for improvement to External Quality Assessment participants.
5. Create a sustainable mechanism for financing of External Quality Assessment programs and External Quality Assessment participation.
6. Make participation in the External Quality Assessment program mandatory for all public and private laboratories by making it part of licensing requirements and develop a system of repercussions for non-participation or consistently scoring below the threshold.

Monitoring & Evaluation Framework

7. Design a system of standardized monitoring and evaluation to oversee and continuously improve the functioning of the laboratory network based on quality indicators.

8. Develop sets of quality indicators for the different tiers of the laboratory network to oversee and continuously improve the functioning of laboratory facilities.

Tiered Supervision

9. Set up a formalized system of supervision where laboratories from higher tiers regularly supervise the laboratories in the lower tiers of the laboratory network (i.e. ensure that this system is covered by the Terms of Reference of the different tiers of the laboratory network).
10. Ensure that the tiered supervision includes mentoring activities based on External Quality Assessment performance data.

Policy topic 4: Financing of Laboratory Quality Management

Information on contents (delete this box when adapting this framework to the country context):

Adequate and sustainable funding and financing mechanisms for LQMS implementation and the establishment/improvement of the laboratory quality infrastructure at laboratory systems level is crucial. LQMS implementation and quality infrastructure establishment/improvement will require initial investments but will lead to cost savings in the long run. Direct return on investments will be realized through decreased health care costs as result of efficiency and effectiveness gains. Indirect return on investments will be achieved through alleviation of disease burden on national economies.

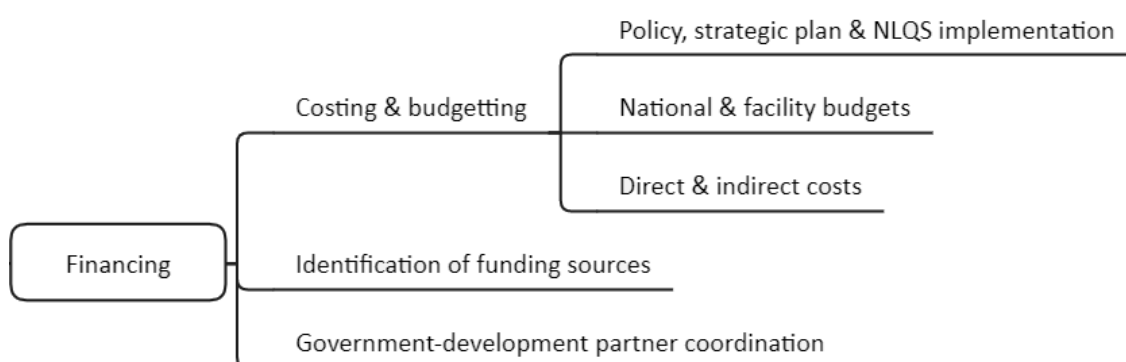


Figure 7: Overview of important elements to be covered by the National Laboratory Quality Policy and Strategic Plan related to financing of laboratory quality management.

Although costing and budgeting exercises are not part of the National Laboratory Quality Policy and Strategic Plan development process (this is part of operational planning), the National Laboratory Quality Policy and Strategic Plan must address establishment of adequate and sustainable financing mechanisms and ring-fenced budgets at national and facility levels for implementation of National Laboratory Quality Policy and Strategic Plan objectives, including the financing of LQMS implementation activities and required laboratory network and system improvements. It is also important that coordination mechanisms between the government and development partners are established to ensure efficient and effective use of financial resources provided by development partners in line with National Laboratory Quality Policy and Strategic Plan objectives.

Policy outcome

Adequate and sustainable funding and financing mechanisms for quality assured laboratory services at all levels.

Policy statements

1. There shall be a rationalized costing methodology including direct as well as indirect costs for establishing and regularly updating the budgets required for quality assured laboratory services.
2. Public laboratory facilities shall have a dedicated budget for compliance with the staged National Laboratory Quality Standard to ensure sustainability of Laboratory Quality Management System implementation and maintenance.
3. Sustained funding support to both pre-service and in-service laboratory education as well as Training of Trainers programs shall be made available to ensure sustainable in-country laboratory quality management education capacity.

4. A dedicated budget for continuous education on laboratory quality management shall be available at institutional level.
5. There shall be dedicated funding for External Quality Assessment schemes, which will cover both External Quality Assessment provision and External Quality Assessment participation costs.
6. There shall be dedicated funding for supervision and mentoring activities as part of the tiered supervision system.
7. There shall be a coordination mechanism for development partner efforts to ensure efficient and effective use of resources in line with the National Laboratory Quality Policy and Strategic Plan and its implementation plans.

Strategic objectives

Information on contents (delete this box when adapting this framework to the country context):

Strategic objectives should be formulated based on situational analysis and a prioritization exercise. Below are some examples of strategic objectives which relate to above policy statements. These example strategic objectives can be adapted and more strategic objectives must be formulated in line with the situational analysis in the country and based on what is feasible. For more information see section 3.2 of the Guidance Document.

1. Develop a methodology for calculating a realistic budget for quality assured laboratory services, taking into account both direct and indirect costs.
2. Make sufficient funding available and budget for laboratory quality awareness, pre-service and in-service Laboratory Quality Management System training and implementation programs in line with the staged National Laboratory Quality Standard.
3. Make sufficient funding available and budget for appointment of a quality focal person in public laboratories.
4. Make sufficient funding available and budget for set up of External Quality Assessment programs for all tests on the National Essential Diagnostics List (NEDL).
5. Include a dedicated budget line for External Quality Assessment participation for all tests in laboratory facility budgets.
6. Make sufficient funding available and budget for supervision and mentoring activities as part of the tiered supervision system.
7. Set up a coordination mechanism for partner activities in line with the National Laboratory Quality Policy and Strategic Plan.

Policy topic 5: Human Resources

Information on contents (delete this box when adapting this framework to the country context):

Quality assurance of laboratory services can only be achieved with competent laboratory personnel.

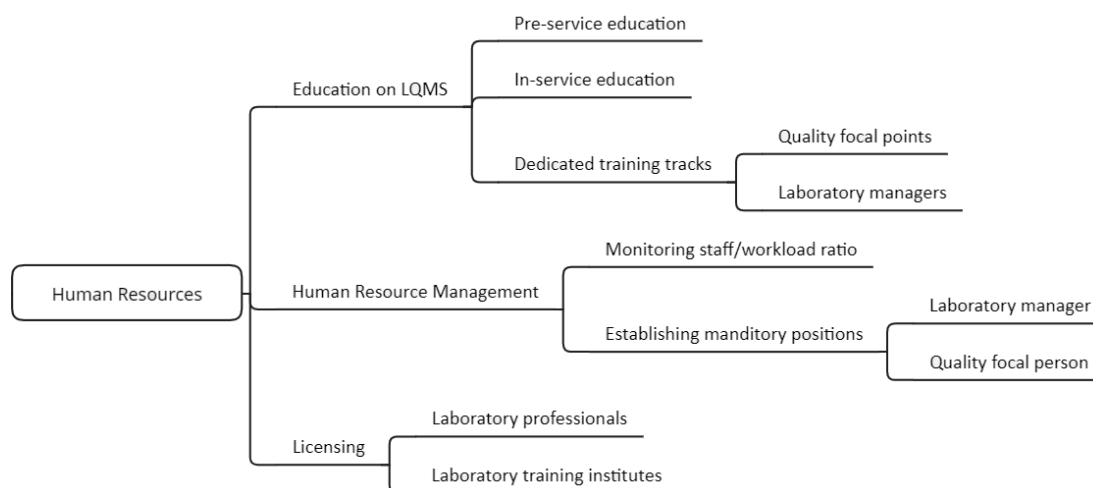


Figure 8: Overview of important elements to be covered by the National Laboratory Quality Policy and Strategic Plan related to Human Resources.

Education on LQMS

The National Laboratory Quality Policy and Strategic Plan should contain statements and objectives to include training on laboratory quality management in pre-service education curricula and in-service training programs to ensure that all laboratory professionals understand the principles of laboratory quality management. In addition, continuous education must be part of the laboratory professionals licensing requirements (see below) to ensure adherence to the continuous education program.

It is also important that the National Laboratory Quality Policy and Strategic Plan includes statements and objectives on creating and implementing awareness and sensitization programs for LQMS implementation. Specific statements and objectives should also be included on implementing a dedicated training track for quality focal points and training on laboratory leadership and management, including change management and financial management, for laboratory managers. This is needed to ensure sufficient facility-based capacity to successfully interpret and implement NLQS requirements and guide the change process that comes with this.

Human Resource Management

Although an LQMS will streamline laboratory operation at a later stage, during its implementation phase it will require additional staff time and effort. This should be anticipated, which is why the National Laboratory Quality Policy and Strategic Plan should include a statement and objective on regularly calculating the staff/workload ratio and taking the necessary actions if this becomes unbalanced.

The National Laboratory Quality Policy and Strategic Plan should also include statements and objectives ensuring that all laboratories have a qualified laboratory manager and quality focal person. These positions are indispensable for the LQMS implementation process as they have a major role in coordinating and guiding this process. These positions can be full-time or part-time, depending on the size of the laboratory and the network tier they are located in.

Licensing system

Already partly covered by Policy Topics 1 and 2: a licensing and relicensing system must be established for laboratory professionals comparable to similar systems for medical doctors. The licensing system must include criteria for education, continuous education and competence to

assure quality of laboratory human resources and, consequently, quality of laboratory services. Countries must establish an intersectoral national database of licensed laboratory workers to ensure quality laboratory human resources in both the public and the private sector.

In addition, to assure quality of laboratory education, it is important that training institutes also have to be licensed. The National Laboratory Quality Policy and Strategic Plan should therefore also include statements and objectives on licensing of institutes offering both pre-service and in-service laboratory training programs.

Policy outcome

Availability of well-trained, competent and motivated staff capable of providing quality laboratory services.

Policy statements

Education

1. Awareness and sensitization programs on the importance of quality shall be developed for laboratory staff, managers and other stakeholders.
2. Support to implementation of the staged National Laboratory Quality Standard shall be provided through standardized training courses and harmonized technical guidelines and tools.
3. Quality management training shall be included in all pre-service education curricula.
4. There shall be a system of continuous education and training on laboratory quality management for all laboratory personnel to improve their skills and knowledge to ensure quality laboratory services.
5. Continuous education and/or re-training shall be part of the laboratory professionals licensing requirements.
6. There shall be specific Laboratory Quality Management System training courses for designated quality focal persons.
7. All laboratory managers shall be trained in Laboratory Quality Management System implementation, laboratory leadership and management (including change management and financial management), to adequately manage and lead the process of Laboratory Quality Management System implementation based on the staged National Laboratory Quality Standard.

Human Resource Management

8. The staff/workload ratio for each laboratory shall be determined and regularly reviewed in an evidence-based way to ensure an appropriate workload, also during implementation of the staged National Laboratory Quality Standard.
9. All laboratories shall have a qualified laboratory manager, quality focal person and biosafety officer.

Licensing

1. All laboratory staff shall have a valid (regularly renewed) license to practice.
2. There shall be an intersectoral national database of laboratory personnel working in both the private and the public sectors.

Strategic objectives

Information on contents (delete this box when adapting this framework to the country context):

Strategic objectives should be formulated based on situational analysis and a prioritization exercise. Below are some examples of strategic objectives which relate to above policy statements. These example strategic objectives can be adapted and more strategic objectives must be formulated in line with the situational analysis in the country and based on what is feasible. For more information see section 3.2 of the Guidance Document.

Education

1. Design and roll-out awareness and sensitization programs on the importance of laboratory quality management for laboratory staff, managers and other stakeholders.
2. Develop training courses for quality management systems, based on international and national quality standards, and incorporate these into the program of pre-service and in-service curricula and training programs of laboratory professionals.
3. Develop a pool of mentors that can assist laboratories with implementation of laboratory quality management systems.
4. Develop and include training on laboratory quality management in all pre-service education curricula.
5. Create a program of continuous education with regularly provided, competency-based courses, including courses on quality management and management and leadership in addition to technical courses.
6. Include continuing education as a mandatory element for periodic relicensing of laboratory staff.
7. Design and implement specific laboratory quality management training courses for laboratory quality focal persons.
8. Ensure that all laboratory managers are trained on Laboratory Quality Management System implementation and laboratory leadership and management, including change management and financial management.

Human Resource Management

9. Ensure that the staff/workload ratio at each laboratory is determined, controlled and regularly reviewed.
10. Establish full-time or part-time positions for a laboratory manager, quality focal person and biosafety officer at each laboratory.
11. Include job descriptions for a laboratory manager, quality focal person and biosafety officer in the Human Resource Management (HRM) system.

Licensing

12. Establish a licensing system for laboratory staff and ensure that all laboratory staff have a valid, regularly renewed license to practice.
13. Develop and implement a national intersectoral database of licensed laboratory professionals.

References

1. UNIDO. Quality policy: Technical Guide. Vienna: United Nations Industrial Development Organization; 2018.
2. World Health Organization. Handbook for national quality policy and strategy: a practical approach for developing policy and strategy to improve quality of care. Geneva: World Health Organization; 2018.

Annexes

Information on contents (delete this box when adapting this framework to the country context):

Each country is free to decide what information will be added as annex to the National Laboratory Quality Policy and Strategic Plan. Annexes of a National Laboratory Quality Policy and Strategic Plan may contain the outcomes of the situational analysis and a description of the way forward. One of the annexes could also list the members of the NLWG who created the draft policies, and the other contributors to the National Laboratory Quality Policy and Strategic Plan (which could both be individuals and organizations).

The way forward

Information on contents (delete this box when adapting this framework to the country context):

This annex briefly describes the next steps and the overall procedure to be followed to implement the National Laboratory Quality Policy and Strategic Plan. It should also describe the role of different actors in this process and can appeal to all actors involved in the planning process to have realistic and accurate expectations and will operate in an effective, coordinated and timely way.

Outcomes of the situational analysis

Information on contents (delete this box when adapting this framework to the country context):

This annex provides information underlying the National Laboratory Quality Policy and Strategic Plan statements and objectives. For countries that already have a National Laboratory Policy and/or National Laboratory Strategic Plan in place: a comprehensive situational analysis should have been conducted during the National Laboratory Policy and/or National Laboratory Strategic Plan development process. In the National Laboratory Quality Policy and Strategic Plan this analysis could be revisited/updated with a focus on laboratory quality management.

It is recommended to start this annex with a brief description of the organization of laboratory services -the landscape- in which the National Laboratory Quality Policy and Strategic Plan is implemented: both the laboratory network(s) present in the country and the laboratory system(s) supporting laboratory services. It may briefly describe the structure and organization of the public laboratory network, including vertical program networks, and the private laboratories/laboratory networks which include the private-for-profit and the private-not-for-profit laboratories. This section may also provide insight in important stakeholders for LQMS implementation.

For a description of the laboratory system the model shown in Figure 9 can be used. In this model, the laboratory system is centered around a typical laboratory network. The system elements are all interrelated and interacting and work towards attaining the overall guiding principles which, in the model, include:

- Access to quality laboratory services;
- Sustainability of quality laboratory services;
- Cost-effectiveness of quality laboratory services;
- Coverage of quality laboratory services.

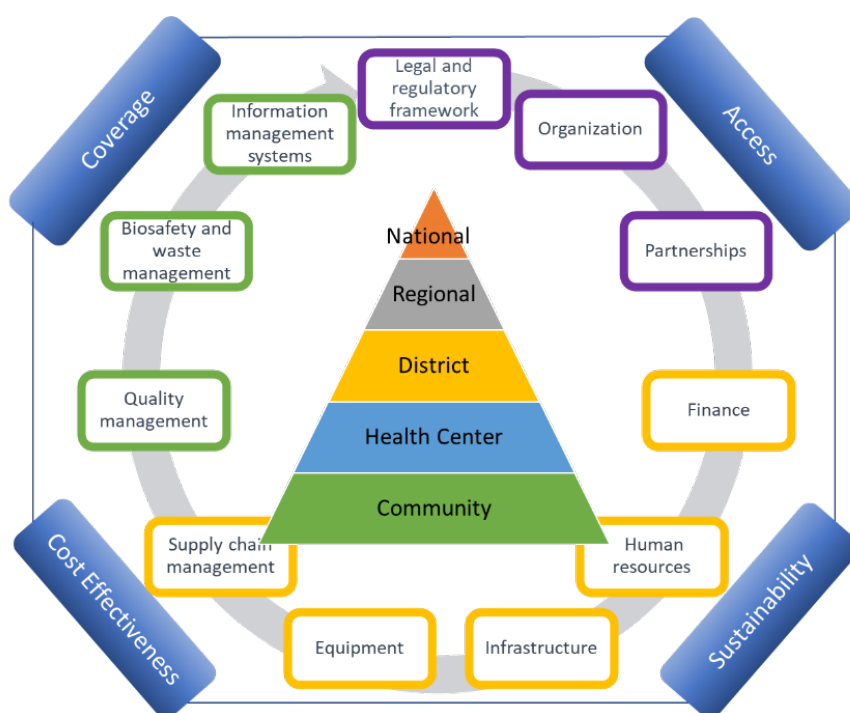


Figure 9: Laboratory network and system model. Note: the number of laboratory network tiers may vary per country and should be harmonized with the overall health system.

Emphasis should be placed on elements that facilitate LQMS implementation and maintenance, including laboratory accreditation, certification and licensing mechanisms. As part of this, information should be provided on:

- The **National Laboratory Quality Infrastructure** is currently in place, including the government structure and the infrastructure for standardization, accreditation, certification, and licensing of laboratories and the metrology and calibration services;
- The **legal and regulatory framework for laboratory quality management**, including information on legislation and regulations related to laboratory services overall and laboratory quality standards, licensing and accreditation specifically;
- The processes for **monitoring and continuous improvement of laboratory quality**, including organization of EQA, with a focus on proficiency testing schemes, and the M&E framework and supervision systems in place (if any);
- The **financing mechanisms** of laboratory services overall and the laboratory quality infrastructure specifically;
- The current processes and systems in place related to ensuring quality of **human resources**, including education of laboratory personnel (both pre-and in-service education) and laboratory HRM;
- The processes and system in place for ensuring quality of **equipment, consumables and reagents**, including procurement and supply chain management and equipment maintenance systems.

The situational analysis chapter will be based on the findings of various assessments, including:

- A desk review of relevant documentation (including other policies, regulations, guidelines, reports, etc.);
- A laboratory system assessment;
- A SWOT analysis of the laboratory network and system with a focus on laboratory quality management;
- Stakeholder mapping.

For more information on conducting a situational analysis see Section 3.2.



Africa Centres for Disease Control and Prevention (Africa CDC),
African Union Commission
Roosevelt Street W21 K19, P. O. Box 3243, Addis Ababa, Ethiopia
Tel: +251-115 517 700 Fax: +251-11-5 517844
Email: africacdc@africa-union.org Website: africacdc.org