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Guidance for Establishing a National Laboratory Quality Framework

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

2nd Edition, 2024

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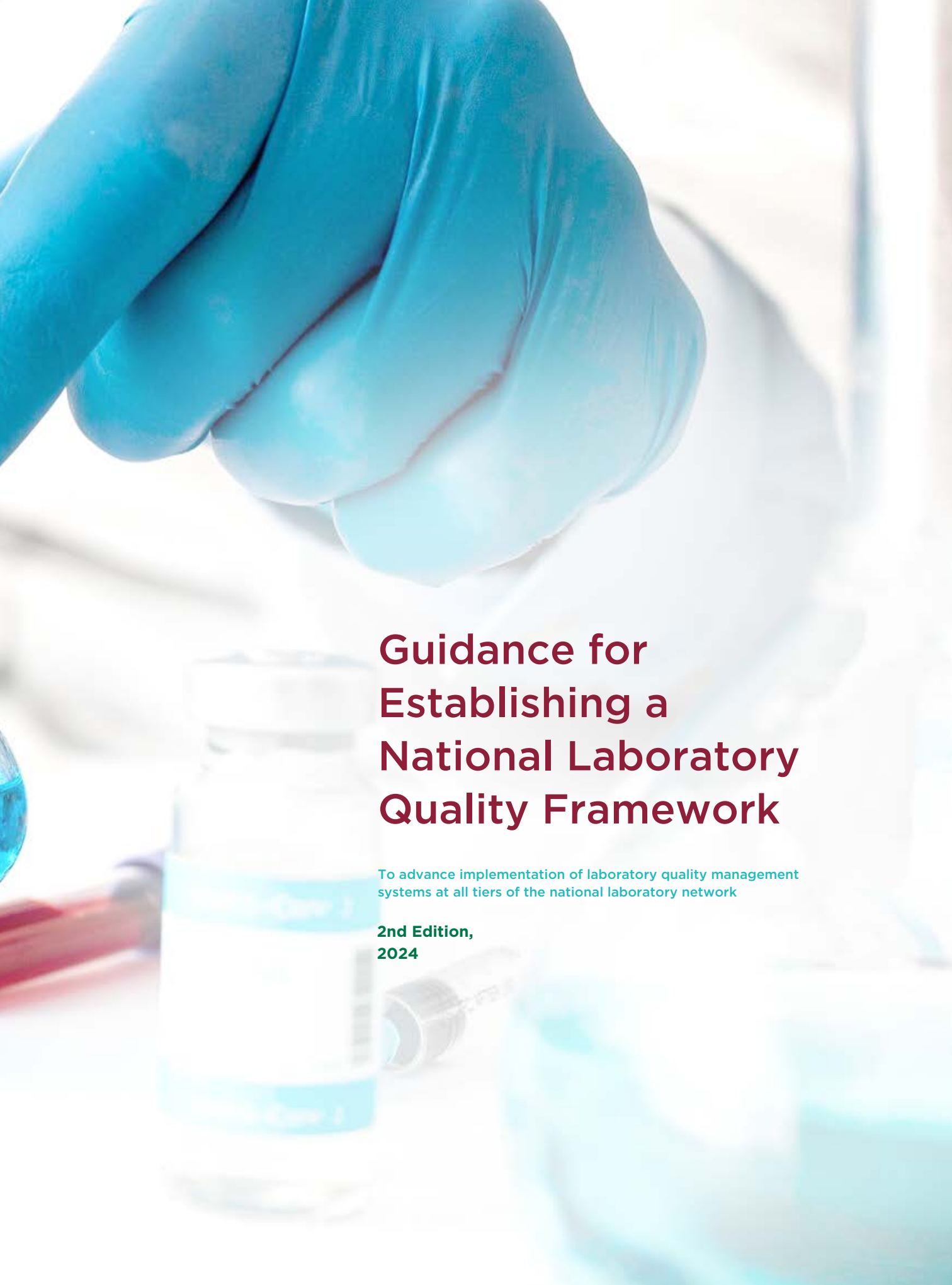

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Preface

The African continent faces disproportionately high burden of diseases are experiences frequent outbreaks that can be detrimental to the lives of its citizens and bottleneck for social and economic development. Though there have been recent improvements, the healthcare systems in most Member States, remain extremely weak. This was witnessed during the Corona Virus Disease (COVID-19) outbreak which claimed millions of lives. One of the weakest links is limited quality assured laboratory services at all levels of the national healthcare system. Although many African countries have made progress in strengthening laboratory capacity and improving the 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 and quality is one of the major challenges contributing to delayed or inadequate responses to epidemics and pandemics.

Implementing management System is key to ensuring reliable diagnostic testing and to contributing to clinical care and public health. In the last decade, considerable efforts have been deployed to advance Management Systems in laboratory facilities through various programs and initiatives including but not limited to Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), Strengthening Laboratory Management Towards Accreditation (SLMTA), the World Health Organization (WHO) Laboratory Quality Stepwise Implementation (LQSI) tool, and disease specific efforts such as the Global Laboratory Initiative (GLI) tool and the Foundation for Innovative New Diagnostics (FIND) Score-TB Package. Around 1026 medical laboratories across the continent had achieved ISO 15189 accreditation by end Dec 2023. Additionally, most laboratories conduct quality assurance and quality control activities on and off, outside any structured continuous quality improvement process, and others not at all. More is needed to ensure that Management System implementation at facility level translates into sustainable and meaningful health outcomes across diseases and at all level of the tiered network.

Given this background, Africa Centers for Disease Control and Prevention (Africa CDC) and the African Society for Laboratory Medicine (ASLM) have developed the 'Guidance for Establishing a National Laboratory Quality Framework (NLQF)'. This document provides practical guidance to policy makers and health service regulators on how to solidify Management Systems implementation efforts into a national laboratory quality framework through national policy and planning this will help to generate country-wide, sustainable and impactful efforts of strengthening national laboratory systems and networks such that they are capable of adequately supporting laboratories in implementing and continuously maintaining the Management Systems.

This is the second version of the NLQF. This document was developed to incorporate the lessons learned from implementing the first version and is aligned with the new version of the international standard for quality and competence of medical laboratories: ISO 15189:2022.

Abbreviations

AFRAC	African Accreditation Cooperation
ASLM	African Society for Laboratory Medicine
CDC	(U.S.) Centers for Disease Control and Prevention
CPE	Continuing Professional Education
EQA	External Quality Assessment
FIND	Foundation for Innovative New Diagnostics
GLI	Global Laboratory Initiative
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Co-operation
ISO	International Organization for Standardization
LABNET	Laboratory Network scorecard
LQSI	Laboratory Quality Stepwise Implementation
LTWG	Laboratory Technical Working Group
M&E	Monitoring & Evaluation
MoH	Ministry of Health
NCP	National Certification Program
NEDL	National Essential Diagnostics List
NGO	Non-Governmental Organization
NLQS	National Laboratory Quality Standard
NLWG	National Laboratory Working Group
PDCA	Plan-Do-Check-Act
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

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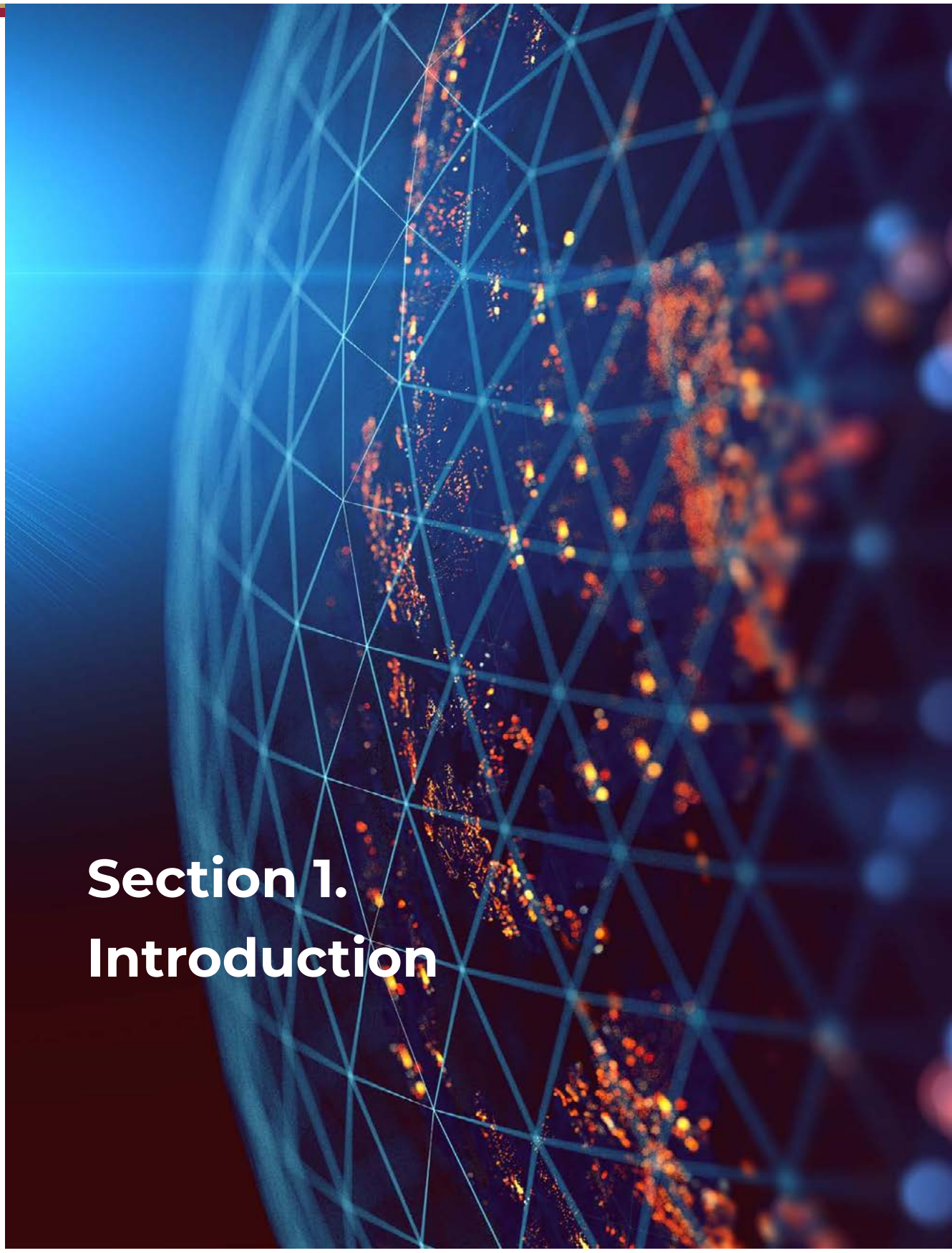


Section 1. Introduction

This section describes the purpose of this document, defines the intended audience, provides background information and describes the structure of the 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 through establishment of a National Laboratory Quality Infrastructure (see Box 1) to support laboratories with the implementation and continuous maintenance and improvement of Management Systems. It aims to guide the healthcare system and stakeholders with the establishment and amendment of relevant national policies and strategic plans to build a National Laboratory Quality Infrastructure and address critical gaps in the laboratory network and additionally, it hamper sustainable Management Systems implementation and maintenance. Guides countries in amending their National Laboratory Policy and/or Strategic Plan with specific quality-related statements and/or objectives, or in establishing a separate National Laboratory Quality Policy and/or Strategic Plan.

Box 1: The National Laboratory Quality Infrastructure

A National Laboratory Quality Infrastructure consists of several key components recommended for successful implementation and maintenance of Management Systems:

- **National Accreditation Body**

  Key is the establishment of a **National Accreditation Body** that is authorized and capable of assessing compliance with Management Systems requirements [1]. Although the establishment of a National Accreditation body other is the ideal solution, an intermediate alternative solution is the use of any accreditation bodies until a national accreditation body is established;

- **Quality Standards / National Certification Program**

  Management Systems requirements can be captured in a **National Laboratory Quality Standard (NLQS)/ National Certification Program (NCP)** or international laboratory quality standards such as ISO 15189 and ISO/IEC 17025 (ISO: International Organization for Standardization and IEC International Electrotechnical Commission). Countries with limited resources are encouraged to take a staged approach, where principal requirements for all laboratories are stated as minimum requirements in the staged NLQS/ NCP while more advanced and national reference laboratories are encouraged to pursue international laboratory quality standards [2–4]; This process forms part of NCP to ensure that all laboratories are assessed for quality and provided with a certificate to recognize their status..

- **Licensing System**

  A staged NLQS also facilitates the establishment of a **licensing system** for both laboratories and laboratory professionals.

a. Human Health Care Laboratory Professionals register with a professional body that recognizes and also gives permission to practice in the laboratory environment. This body may also enforce continuing professional development or continuing educational units of these professionals by monitoring relevant activities and aligning them to renewal of registration at prescribed intervals.

b. The professional body keeps a register of all laboratories in the country. Both Private and Public laboratories must comply with the prescribed standards to be registered or licensed to practice. The professional body will use a set criteria to issue licenses to the laboratories and also monitor compliance to the set criteria to ensure continued compliance. The licensing system enables a country to assure that all laboratory services in both the public and private sectors are of an acceptable level of quality;

- **Laboratory Workforce**

  Access to a well-trained, competent laboratory workforce, is essential in the provision of quality laboratory services. Therefore, establishment of **pre-service and in-service training** is indispensable for sustainable high-quality laboratory services;

- **National External Quality Assessment (EQA) programs**

  Establishment of integrated **national EQA programs for essential diagnostic tests** with sufficient capacity to serve all laboratories in the country is a necessity for compliance with Management Systems requirements and accreditation;

- **Laboratory Equipment**

  Sufficient **capacity to maintain and calibrate laboratory equipment** (with watertight traceability) is also a critical element for compliance with Management Systems requirements and accreditation;

- **Monitoring and Evaluation (M&E) framework**

  A Monitoring and Evaluation (M&E) framework that defines 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;

- **Tiered Supportive Supervision System**

  A system of **tiered supportive supervision** whereby laboratories in higher tiers of the laboratory network conduct audits, support Management Systems implementation and monitor the quality and performance of laboratories in lower tiers of the network, 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

Existing guidance documents and tools mostly focus on the implementation of a Management System at facility level but do not provide guidance on policy and regulation from a national perspective. 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 to ensure the highest standards of laboratory quality management at all levels of the healthcare system.

It should be noted that this document and the accompanying policy and planning blueprint are intended as guidelines and do not replace existing national or international policies and plans. Instead, they support a process of continuous improvement that leads to the effective formulation and improvement of policies and strategic plans to strengthen laboratory networks and systems to support Management Systems implementation, continuous maintenance, and compliance with relevant national and international standards and agreements (including ISO 15189, ISO/IEC 17025, and the International Health Regulations) through establishment of a National Laboratory Quality Infrastructure.

1.3 Background

In 1996, Forsman estimated that laboratory services influenced approximately 70% of medical decisions [5]. Presumably, this percentage has only increased due to the rapid development and dissemination of new diagnostic tools, automated testing technologies, implementation of data connectivity solutions and the advancement of evidence-based medicine. For a long time, laboratory services in low- and middle-income countries received limited attention from governments and development aid efforts alike which impacted both clinical care/Universal Health Coverage (UHC) and public health [6,7,16–18,8–15].

Around 2008, the tide began to turn [6,8,19,20]. The implementation of Management Systems, a key intervention to strengthen laboratories, was marked as a priority by both the World Health Organization (WHO) headquarters [2,3] and the WHO Regional Office for Africa [21]. Since then, several continent-wide initiatives such as the Strengthening Laboratory Management Towards Accreditation (SLMTA) training and mentoring program [22,23] and the SLIPTA monitoring program [24,25] were launched. Unfortunately, in some countries this did not lead to large scale sustainable Management Systems implementation and accreditation as initially envisaged [1,26,27]. Although the in number of ISO 15189 accredited laboratories increased from 668 to 1029 between 2013 -2023 [1], this falls short of the anticipated targets. This is largely attributed to absence of national level support to laboratory facilities implementing QMS.

The more than ten years of experience in the promotion of Management Systems provided an opportunity to identify the most critical bottlenecks that hampered sustainable Management Systems implementation. Challenges included low political commitment and lack of (or insufficient) implementation of policies and regulations to support and promote Management Systems implementation [1,26,28–30]. 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 [31]), the absence of political

commitment in both word and deed has led to weak laboratory networks and systems across the continent [32]. Data from the Joint External Evaluations of 54 countries shows that laboratory quality management is the most neglected area [26]. This is corroborated by data from eight country evaluations using the laboratory network (LABNET) scorecard, which highlights critical weaknesses in quality management, including absence of national norms for laboratory certification and/or accreditation [26]. It has been identified that many laboratories have not been able to maintain their Management Systems because of critical gaps in national laboratory networks and systems.

For successful and sustainable implementation and maintenance of a Management System, a laboratory must be able to rely on a strong national laboratory network and system that can provide and cater for its needs [1,26]. For example, compliance with Management Systems requirements demands that a laboratory has a reliable supply of high-quality consumables and reagents to assure continuity of services. Data from LABNET evaluations highlights critical weaknesses in supply chain systems. Other conditions for sustained compliance with Management Systems requirements include the availability of competent and well-trained personnel, continuously maintained and calibrated equipment, strong laboratory information management systems, etc. All these attributes must be arranged at the laboratory network and system level, but LABNET evaluations show critical weaknesses across countries for each of these attributes [26]. Therefore, laboratory network and system strengthening are key priorities to facilitate comprehensive implementation and maintenance of Management Systems as already stated by WHO in 2008 (see Box 2).

Box 2: Recommendations of the joint WHO-Centers for Disease Control and Prevention (CDC) conference on laboratory quality systems in 2008 [2,3]

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 to conduct 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: Section 1 Introduces the NQLF Guidance, Section 2: Provides insight into the purpose of and key considerations for policy and strategic plan development to advance quality laboratory services. Section 3: Presents, 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 4: describes key considerations for implementation of a National Laboratory (Quality) Policy and/or Strategic Plan.

The Supplement provides a blueprint of a National Laboratory Quality Policy and Strategic Plan that can be used to either amend the existing National Laboratory Policy and/or Strategic Plan, or develop a National Laboratory Quality Policy and/or Strategic Plan to establish a National Laboratory Quality Infrastructure and advance Management Systems implementation

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. The key elements and the structure of a typical National Laboratory Quality Policy and Strategic Plan are also discussed. This is relevant for countries that will develop a separate National Laboratory Quality Policy and/or Strategic Plan as well as for countries that need to amend their existing National Laboratory Policy and/or Strategic Plan by adding quality-specific policy statements and/or strategic objectives.

2.1 Purpose of policy and planning for quality laboratory services

Through the development of a National Laboratory (Quality) Policy and/or Strategic Plan, countries can design, focus and harmonize improvement initiatives and activities - both government-owned and those of external partners - to work towards the establishment of a National Laboratory Quality Infrastructure and sustainable implementation of Management Systems. Over the past years, many African countries have developed National Laboratory Policies and/or National Laboratory Strategic Plans. Although Management System 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 to support laboratory facilities in implementing and maintaining Management Systems. In such a situation, a country must either amend its National Laboratory Policy and/or Strategic Plan with quality-specific statements and strategic objectives, or establish a separate National Laboratory Quality Policy and/or Strategic Plan, depending on what is most feasible and practical.

2.2 Key considerations

This document presents two options that a country can follow:

- Amendment of the existing National Laboratory Policy and/or Strategic Plan by incorporation of additional quality-specific policy statements and/or strategic objectives
- Establishment of a separate National Laboratory Quality Policy and/or Strategic Plan if a country has no National Laboratory Policy and or a Strategic Plan.

This subsection discusses key considerations for establishing a National Laboratory Quality Infrastructure and advancing Management Systems, regardless of the approach chosen. The structure of a typical National Laboratory Quality Policy and Strategic Plan is also discussed.

2.2.1 Key policy and strategic plan elements to advance quality laboratory services

Establishing a National Laboratory Quality Infrastructure and advancing Laboratory Management Systems implementation requires the formulation of policy statements and strategic objectives related to a variety of topics, namely:

- The National Laboratory Quality Infrastructure;
- The legal and regulatory framework for laboratory quality management;
- Monitoring, evaluation, and continuous improvement mechanisms;
- Financing mechanisms;
- Human resources;
- Human Management System;
- Procurement and Supply Chain (for equipment and reagents).

The purpose and contents of each 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

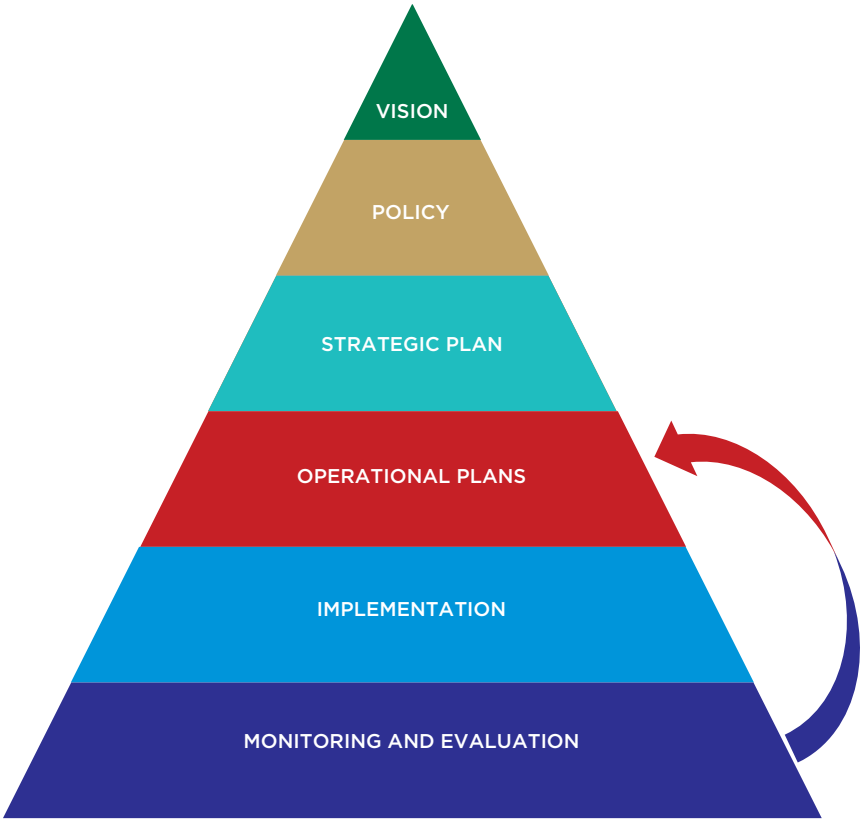
Any policy and strategic plan including a National Laboratory Quality Policy and/or Strategic Plan - need to include several key ingredients.

Integration of a policy and strategic plan

In the past, many countries have tended to concentrate on developing strategic plan and skipping the policy development phase. However, a policy is the first step in the planning cascade (Figure 1). It provides an overall vision and creates a deep insight into 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 policy before developing a strategic plan, as a policy helps to focus the strategies. A policy typically covers a timeframe of 10 years, whereas a strategic plan covers a three to five-year timeframe. A strategic plan may be redefined and renewed multiple times during the longer term of the policy (i.e. multiple strategic plans can be developed and implemented sequentially in the timeframe of one policy) [33].

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

- The process of developing a policy and a strategic plan comprise a number of identical steps. Hence, formulating policy statements, followed immediately by the formulation of strategic objectives, results in a more efficient development process,
- For some countries, 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), thus assuring consistency.



Nevertheless, if a country usually separates policies from strategic plans, for example because the ratification and endorsement processes differ, the blueprint National Laboratory Quality Policy and Strategic Plan still serves as a valuable resource for identifying relevant 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/or Strategic Plan. Guidance provided by this document remains relevant regardless of whether a country decides to combine the policy with a 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, the following key elements should be covered by any policy and strategic plan:

- **Vision**

  The vision describes the ideal picture for the laboratory sector envisaged and pursued by the country through the 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**

  The overall policy objective is a more concrete description of the overall objective that needs to be achieved by the development and implementation of the policy and strategic plan.

- **Policy topics with their outcomes**

  Policy topics 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 statements**

  Policy statements are the actual statements of what needs to be done for each policy topic to accomplish the overall policy objective and work towards the vision.

- **Situation Analysis**

  Situation Analysis specifies the current situation while identifying challenges and possible areas for improvement from internal or external origin

- **Strategic objectives**

  For each policy statement, one or more strategic objectives can be formulated as a 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 covers a shorter timeframe than a policy, multiple strategic plans need to be developed sequentially over 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 during the timeframe of the strategic plan.

- **Operational Plan and Budget**

  The operational plan outlines detailed activities that are needed to ensure that the set target is met.

The budget allocated for each section allows management and execution of the identified plans.

Monitoring and Evaluation (M&E) Framework

M & E Framework is a tool developed to ensure that activities are well measured and monitored following agreed milestones

The policy and strategic plan can be further supplemented, for example with the findings of the situational analysis, a statement of the government's commitment, and any other matters as required by national policy and strategic plan development practices.
It is important that a policy and strategic plan provide a detailed answer to the following questions:

- What is the ideal situation? – The ideal situation is described by the vision and policy outcomes and 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 the requirements of a country.

Box 3: Typical outline of a 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 Plan[1]:

- 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] 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 on the procedure to amend existing National Laboratory Policy and/or Strategic Plan, or, if amendment is not possible, development of a separate National Laboratory Quality Policy and/or Strategic Plan. Use Table 1 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/or 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?	Advice on action to be taken:
Yes	Yes	Use the blueprint provided in the Supplement Check whether the policy and strategic plan sufficiently cover the establishment of a National Laboratory Quality Infrastructure and the implementation of Management Systems. Where coverage is insufficient, amend the policy and strategic plan with quality specific statements and strategic objectives by using Sections 3.1 and 3.2, respectively, and the blueprint in the Supplement*.
Yes	No	Use the blueprint provided in the Supplement Check whether the policy sufficiently covers the establishment of a National Laboratory Quality Infrastructure and the implementation of a Management Systems. If coverage is insufficient, amend the policy with quality specific statements by using Section 3.1 and the blueprint provided in the Supplement*. Develop a National Laboratory Quality Strategic Plan by using Section 3.2 and the blueprint in the Supplement.
No	Yes	Use the blueprint provided in the Supplement Develop a National Laboratory Quality Policy by using section 3.3 and the blueprint in the Supplement. Check whether the strategic plan sufficiently covers the establishment of a National Laboratory Quality Infrastructure and the implementation of Management Systems. If coverage is insufficient, amend the strategic plan with quality-specific strategic objectives by using Section 3.2 and the blueprint in the Supplement*.
No	No	Develop a National Laboratory Quality Policy and Strategic Plan by using Section 3.3 and the blueprint in the Supplement.

* If 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 3.3.

Figure 2 shows the steps to be followed in amending the National Laboratory Policy and/or Strategic Plan, as well as in developing a separate National Laboratory Quality Policy and/or Strategic Plan.

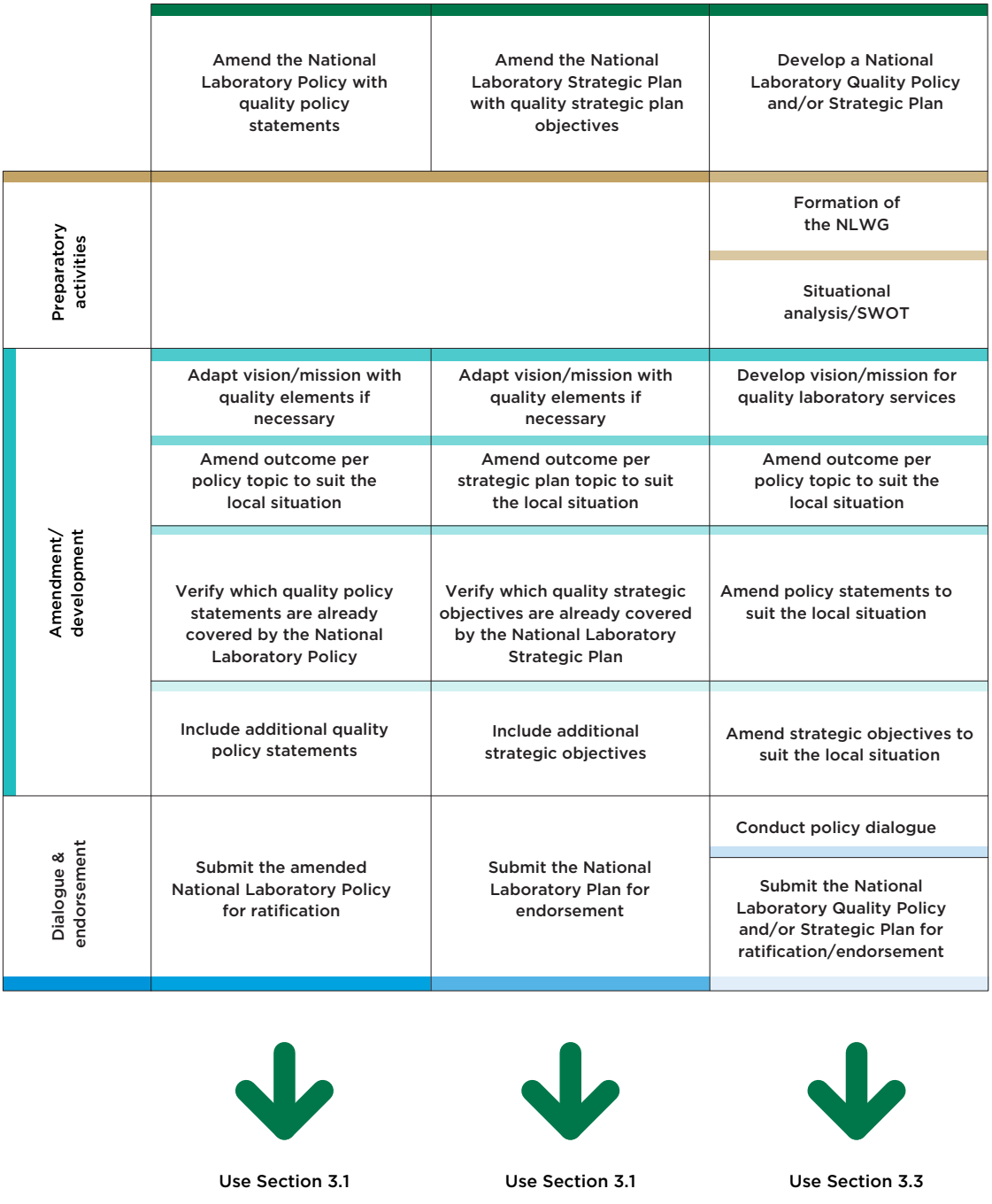


Figure 2: Steps to be taken to amend the National Laboratory Policy and/or Strategic Plan and to develop a separate National Laboratory Quality Policy and/or Strategic Plan

3.1 Amendment of the National Laboratory Policy

This section is for use by countries that are able to amend their National Laboratory Policy by introducing additional quality-specific policy statements.

3.1.1 Actors involved and their roles and responsibilities

The amendment of the National Laboratory Policy with quality-specific policy statements is a relatively simple process that can be conducted by the Laboratory Technical Working Group (LTWG)/National Laboratory Coordinating Team/NLWG[2] or similar body.
Depending on country-specific protocols for policy amendment, more actors could be involved. Such protocols may also require further policy dialogue (see Section 3.3) to collect feedback and buy-in from more stakeholders. However, unless otherwise required, it is recommended to keep the amendment procedure as pragmatic and simple as possible for the sake of time, efficiency and resources. A stakeholder analysis may be required to identify important stakeholders to be included.

3.1.2 Procedure for amendment of the National Laboratory Policy

Listed below are the steps for amending the National Laboratory Policy through the addition of quality-specific policy statements.

i. Adapt vision/mission with quality elements if necessary

- The vision and mission expressed in the National Laboratory Policy may need to be amended by adding 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 amend it as necessary.

ii. Amend the outcome per policy topic to suit the local situation

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

iii. Verify quality-specific policy statements already included in the National Laboratory Policy

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

iv. Amend the National Laboratory Policy

- Amend the National Laboratory Policy adding quality-specific policy statements.

v. Submit the amended National Laboratory Policy for ratification and endorsement

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

[2] Detailed information on the NLWG is provided in Section 3.3.1.

3.2 Amendment of the National Laboratory Strategic Plan

This section is for use by countries that are able to amend their National Laboratory Strategic Plan by introducing additional quality-specific strategic objectives.

3.2.1 Actors involved and their roles and responsibilities

The amendment of the National Laboratory Strategic Plan with quality-specific strategic objectives is a relatively simple process that can be conducted by the Laboratory Technical Working Group (LTWG)/National Laboratory Coordinating Team/NLWG[3] or similar body. It is essential that an all-inclusive stakeholder consultation be conducted when developing and or amending the Strategic Plan to collect feedback and buy-in.

3.2.2 Procedure for amendment of the National Laboratory Strategic Plan

Listed below are the steps for amending the National Laboratory Strategic Plan through the addition of quality-specific strategic objectives.

i. Adapt vision/mission with quality elements if necessary

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

ii. Amend the outcome per strategic plan topic to suit the local situation

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

iii. Verify quality-specific strategic objectives already included in the National Laboratory Strategic Plan

- Verify which quality-specific strategic objectives in the blueprint are already covered by the National Laboratory Strategic Plan and which ones should be added to or amend the National Laboratory Strategic Plan.

iv. Amend the National Laboratory Strategic Plan

- Amend the National Laboratory Strategic Plan adding quality-specific strategic objectives as required.

v. Submit the amended National Laboratory Strategic Plan for ratification and endorsement

- Once the National Laboratory Strategic Plan has been amended, the document has to be endorsed by the appropriate authorities. National rules and procedures should be followed.

[3] Detailed information on the NLWG is provided in Section 3.2.1.

3.3 Development of a separate National Laboratory Quality Policy and/or Strategic Plan

If 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/or Strategic Plan.

1. Formation of the National Laboratory Working Group (NLWG)

The first step in the process of development of the National Laboratory Quality Policy and/or Strategic Plan is the formation of a team responsible for development. In this document the term NLWG is used for this team. The NLWG should consist of a Chairperson, an Executive Secretary, and representatives as shown in Box 4. The composition of the NLWG should be flexible must include representatives of both national and regional laboratories as well as other important private sector stakeholders of the health laboratory services in the country. The NLWG should reflect a sufficient mix of skills to ensure the availability of adequate knowledge and experience for the development of the National Laboratory Quality Policy and/or 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 ministries,
- Laboratory Managers (public sector laboratories: national reference laboratories, vertical program laboratories, regional laboratory representatives and private laboratory association representatives);
- National laboratory associations or societies, and Regulatory council (that regulate the profession)
- Universities and training institutions with laboratory education curricula,
- Laboratory accreditation or licensing bodies and the National Standards Body,
- National and International development partners,
- National Metrology Institute,
- 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 should include the following:

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/or 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 have sufficient knowledge of laboratory network leadership and management and policy and strategic plan development. Training should be provided to those in need.

2. Situational analysis

It is important to gain insight into - and obtain a thorough understanding of, the current state of laboratory services to select the best improvement strategies for developing a National Laboratory Quality Policy and/or Strategic Plan. The National Laboratory Quality Policy and/or Strategic Plan must also be aligned with other relevant regional, national, and provincial policies, plans, and regulations, (e.g. the National Health Policy). The planning cycle of the National Laboratory Quality Policy and/or Strategic Plan must be aligned with the time frame of the national planning and financial cycles. Thus, the second step in the development process involves conducting a situational analysis to collect the relevant information. The situational analysis consists of the following activities:

- **Desk review**

  Conduct a desk review to gain insight into the organization of the laboratory system and the overall health system in the 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, performance, 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 scorecard[4] or the WHO Laboratory Assessment Tool [5] – System Questionnaire can be used to conduct such an assessment. By scoring each component and providing a graphic visualization of the scores, both tools provide a useful high-level insight into the functioning of the various components of the laboratory network and system.

- **Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis**

  Use the information from the laboratory network and system assessment to conduct a SWOT analysis to identify strengths, weaknesses, opportunities, and threats related to quality laboratory services. The procedure for conducting

[4] 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 [5] WHO | Laboratory Assessment Tool

a SWOT analysis is described in the WHO/Europe Development of a national laboratory strategic plan best practices document and facilitators' guide.

- **Stakeholder mapping**

  Conduct a stakeholder mapping exercise to identify important stakeholders that are actively involved in, or that directly or indirectly influence the quality of, laboratory services. This provides insight into the stakeholders who should be involved in the National Laboratory Quality Policy and/or Strategic Plan development process, either directly as members 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/or Strategic Plan will be better tailored to the various beneficiaries and ownership will be created [33]. A list of possible stakeholders is provided in Box 5.

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

Government organizations

- Ministry of Health,
- 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.

Health service organizations

- Public sector laboratories,
- Private sector laboratories,
  - ***Private for-profit,***
  - ***Private-not-for-profit:***
    - ***i. Faith-based,***
    - ***ii. Non-Governmental Organizations (NGO).***

Other organizations/institutes

- Health services regulatory authorities,
- Universities and training institutes offering laboratory education curricula,
- National Standards Body,
- National Accreditation Body,
- National Metrology Institute,
- Procurement and supply system/National medical stores,
- National and International development partners,
- Insurance entities,
- Laboratorians professional organizations,
- Laboratory consumer organizations.
- IVD regulators

All data and information obtained from the situational analysis will provide the baseline against which the National Laboratory Quality Policy and/or 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/or Strategic Plan. All policy statements and strategic objectives should therefore be formulated with the vision in mind. Whereas the situational analysis provides insight into the current situation (the starting point), the vision provides insight into where the country wants to go (the endpoint).

Use the questions in Box 6 as a checklist to stimulate thinking on dimensions of quality to be incorporated into the vision. An example of a vision is provided in Box 7 and in the blueprint (Supplement).

Box 6: Questions to help frame dimensions of quality and meet local needs for developing a vision for quality laboratory services (adapted from [33]).

Questions that can help to frame the dimensions of quality and meet local needs	
Aspect Effective	Question 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 and secure	Does the delivery of laboratory services utilize the safest and most secure means possible (including data management) and does it reduce/avoid 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 and 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/or Strategic Plan (adapted from [34])

[Country name] shall (under the One Health concept) have a well-organized, sustainable network of quality-assured laboratory services 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 of public health events. Up-to-date pre-service and in-service training programs generate well-trained, qualified and certified staff members that are 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. They use quality-controlled and assured equipment and consumables, standardized methodologies and ethical practices through implementation of a functional Management System that is 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 NLQS, EQA 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. These outcomes describe for each policy topic the ideal situation to be achieved through implementation of the statements and strategic objectives under that policy topic. Therefore, the outcomes must be based on and contribute to achieving the overall vision for quality laboratory services. The blueprint National Laboratory Quality Policy and Strategic Plan provides examples of outcomes per policy topic that can be scrutinized, changed, and amended by the NLWG and/or the NLWG can formulate different or additional outcomes.

5. Select policy statements and amend them to fit the local situation

Next, the policy statements required for achieving a specific outcome must be formulated. Use the blueprint (Supplement) to select policy statements to be included and amend them to suit 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. The NLWG members must agree that the total set of policy statements under each policy topic are sufficient to achieve the outcome of that policy topic.

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

1. The first part describes what needs to be implemented/done/created, etc.
2. The second part describes for 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 and accreditation law and a metrology law which apply to laboratory services to ensure enforcement of the National Laboratory Quality Infrastructure and advancement of implementing a Management System.

6. Select strategic objectives and amend them to fit the local situation

Once the policy statements have been formulated, the NLWG must proceed to the next step of the planning cascade (Figure 1), namely 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 move from the current situation to implementation of the policy statements. The current situations differ between countries therefore, it is not possible to provide a uniform set of strategic objectives that can be used as template for the strategic plan. The the blueprint National Laboratory Quality Policy and Strategic Plan (Supplement) provides examples of strategic objectives. The NLWG can start with selection of relevant strategic objectives from the blueprint, adapt and incorporate them into the country's National Laboratory Quality Strategic Plan, followed by formulation of additional strategic objectives where required. Strategic objectives are formulated in active form, i.e. always start with an

action-oriented verb (develop/create/implement/establish/etc.). 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.

The following should be noted:

- Some policy statements require only one strategic objective,
- Some policy statements require multiple strategic objectives,
- Some strategic objectives are related to or contribute to the implementation of multiple policy statements.

Note:

The strategic objectives (covering a timespan of three to five years) do not necessarily have to 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 this is 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 the three to five-year time span if resources are available. If this is not attainable, further prioritization is necessary until the strategic plan is realistic and its implementation within its timespan is feasible.

Once the strategic plan has been finalized, the policy and strategic plan, together with the overall vision for quality laboratory services can be consolidated into a 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/or Strategic Plan 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 form of a formal workshop, a conference, or as a series of consultation meetings.

Based on the comments from the stakeholders a final draft of the National Laboratory Quality Policy and/or Strategic Plan must 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 configure the documents into those formats.

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

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

Section 4.

National Laboratory Quality Policy and/or Strategic Plan implementation: next steps

Once the amended National Laboratory Policy and/or Strategic Plan, or the National Laboratory Quality Policy and/or Strategic Plan have been endorsed, the process moves to the next phase of the planning cascade, namely operational planning. Development and implementation of operational plans are outside the scope of this document. However, this section suggests 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 the implementation of the policy and the strategic plan. If these documents 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

The 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 and at a pace that is in line with the country's managerial and financial resources. Operational plans normally cover a timespan of one year. The development of operational plans also requires the support of many sectors of society, partners, and the government. It is of utmost importance that all actors (that can be) involved in the planning process are identified through a thorough stakeholder analysis, 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/organizations that are aware of this and have agreed to implement the objective within the timeframe set for the objective,
- **Realistic:** the objectives should be achievable within the timeframe assigned to them,
- **Timebound:** the objectives have 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 & Evaluation (M&E)

A well-known model that lies at the basis of international quality standards and quality management systems is the Deming cycle, or Plan-Do-Check-Act (PDCA) cycle[6]. The same model should be applied to the policy and strategic planning process: in addition to developing and implementing the policy and strategic plan, countries must establish an M&E framework to closely monitor implementation and reflect on the successes gained, challenges met, and lessons learned. Based on this, countries must adapt and amend the operational and strategic plans to ensure that they remain realistic and are adequate for implementing the policy statements.

The success of efforts to improve the 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 can be 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" [33]. A culture is influenced by a complex set of factors and values, including cultural, social, personal and work values, as well as by the medico-legal environment. Changing such cultures to implement the policy and strategic plan and to advance Management Systems implementation may therefore be a slow and challenging process that is opposed by those threatened by the change.
Political and health system leaders and laboratory management play a key role in defining and promoting a culture of quality and in leading by example to embed the required values throughout the laboratory system [33]. ISO 15189:2022 now explicitly requires laboratory management to provide evidence of commitment to the development and implementation of the quality management system and to continually improve its effectiveness (clause 8.2.3) [35]. The same must apply to political and health system leaders at national level when it comes to creating the National Laboratory Quality Infrastructure to support laboratories implement and maintain Management Systems successfully.

The process of developing and implementing a policy and strategic plan can in itself be a key driver and a mechanism for advocating improvements in quality of care - 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 [33].

References

1. Odhiambo CO, van der Puije B, Maina M, Mekonen T, Diallo S, Datema T, et al. Examining 7 years of implementing quality management systems in medical laboratories in sub-Saharan Africa. Trop Med Int Health. 2022 Dec 8;
2. Joint WHO – CDC Conference on Health Laboratory Quality Systems. In Lyon: World Health Organisation; 2008.
3. 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.

6 PDCA - Wikipedia

4. World Health Assembly. Strengthening diagnostics capacity. WHA76.5. 2023.
5. Forsman RW. Why is the laboratory an afterthought for managed care organizations? Clin Chem. 1996;42(5):813–6.
6. 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).
7. Nkengasong JN, Birx D. Quality matters in strengthening global laboratory medicine. Afr J Lab Med. 2014;3(2):a239.
8. Nkengasong JN, Nsubuga P, Nwanyanwu O, Gershy-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.
9. Martin R, Barnhart S. Global Laboratory Systems Development: Needs and Approaches. Infect Dis Clin NA. 2011;25(3):677–91.
10. Okeke IN. Diagnostic insufficiency in Africa. Clin Infect Dis. 2006 May;42(10):1501–3.
11. Bates I, Maitland K. Are laboratory services coming of age in sub-Saharan Africa? Clin Infect Dis. 2006 Feb;42(3):383–4.
12. Muula AS, Maseko FC. Medical laboratory services in Africa deserve more. Clin Infect Dis. 2006 May;42(10):1503.
13. 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.
14. 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.
15. 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.
16. Nkengasong JN. Strengthening laboratory services and systems in resource-poor countries. Am J Clin Pathol. 2009 Jun;131(6):774.
17. 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.
18. 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.
19. Andiric LR, Massambu CG. Laboratory quality improvement in Tanzania. Am J Clin Pathol. 2015;143(4):566–72.
20. Piot P, Kazatchkine M, Dybul M, Lob-Levyt J. AIDS: lessons learnt and myths dispelled. Lancet. 2009;374(9685):260–3.
21. 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.

22. 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.

23. SLMTA | Strengthening Laboratory Management Towards Accreditation [Internet]. [cited 2024 Apr 12]. Available from: https://www.slmta.org/accredited-labs

24. Gershy-Damet G-M, Rotz P, Cross D, Belabbes EH, Cham F, Ndihokubwayo 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.

25. ASLM Laboratory Accreditation / SLIPTA - ASLM [Internet]. [cited 2024 Apr 12]. Available from: http://www.aslm.org/slipta-map/

26. 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).

27. African Society of Laboratory Medicine. ASLM2020: Strategies and vision to strengthen Public Health Laboratory Medicine in Africa [Internet]. [cited 2024 Apr 10]. Available from: https://www.eiseverywhere.com/ file_uploads/ e46acabb2952cbecd2d610ca4cbfd45c_ASLM2020.pdf

28. 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.

29. 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.

30. Ndihokubwayo JB, Maruta T, Ndlovu N, Moyo S, Yahaya AA, Coulibaly SO, et al. Implementation of the World Health Organization regional office for Africa Stepwise Laboratory Quality Improvement Process Towards Accreditation. Afr J Lab Med. 2016;5(1):a280.

31. United Nations. Sustainable Development Goals [Internet]. [cited 2024 Apr 12]. Available from: https://www.who.int/health-topics/sustainable-development-goals#tab=tab_2

32. Joint External Evaluation Tool and Process Overview. Geneva: World Health Organization; 2016.

33. 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.

34. Islamic Republic of Pakistan National Laboratory Policy. Government of Pakistan; 2017.

35. ISO 15189:2022 Medical Laboratories - Requirements for quality and competence. Geneva: International Organization for Standardization; 2022.

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.

Supplement

Blueprint National Laboratory Quality Policy and Strategic Plan

Note:
Explanations about the 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's context.

2nd Edition, 2024

Pre-matter

Information on content

The content of the pre-matter section is determined by the national practices and/or by the policy development team (in this Guidance Document this team is referred to as the NLWG – see Chapter 3).

Example of content that could (but does not have to) be included in the pre-matter:

- A message from the relevant Minister,
- A message from the Secretary of State,
- A message from 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,
- Acknowledgements.

An important element of a policy is the statement of commitment by the government, for which the pre-matter is a logical place. For example, government commitment can be expressed through the message from Minister to indicate that the government assumes overall responsibility for the quality of laboratory services, for the effectiveness and efficiency of the laboratory, and for the National Laboratory Quality Infrastructure by providing direction, long-term funding and all other means of support as required.

1. Introduction

Information on content

Similar to the pre-matter, the content of the introduction is not carved in stone but depends on the discretion of the NLWG and national practices. However, the introduction must provide insight into the need for a National Laboratory Quality Policy and/or Strategic Plan and describe the background against which it was developed. A brief historical background of laboratory services in the country and a short summary of the situational analysis can be included, indicating the main strengths, weaknesses, opportunities and threats related to the quality of laboratory services. The introduction should explain how the National Laboratory Quality Policy and/or Strategic Plan aims to improve the current situation. It may also elaborate on the main principles that guided the development; and a summary of the National Laboratory Quality Policy and/or Strategic Plan development process.

2. Vision for quality laboratory services

Information on content

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

[Country name] shall (under the One Health concept) have a well-organized, sustainable network of quality-assured laboratory services 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, as well as a state-of-the-art referral and sample transportation system, thus ensuring optimal patient care and robust surveillance of public health events in compliance with international standards.

Up-to-date pre-service and in-service training programs generate well-trained, qualified and certified staff members that are dedicated and well-paid. Trained laboratory managers are competent to manage and lead processes in the laboratory and are committed to the development and implementation of the quality management system and to continually improving its effectiveness. At all levels of the laboratory network, technical staff perform evidence-based, quality-controlled and quality-assured laboratory tests using high quality equipment and consumables, standardized methodologies and ethical practices. A functional Laboratory Quality Management System which is compliant with national or international laboratory quality standards and proper biorisk management, infection control and waste disposal systems is 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.

3. Policy topics, statements, and strategic objectives

Information on content

This is the central part of the National Laboratory Quality Policy and/or 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. **Policy outcome:** the main outcome(s) to be realized for that policy topic;
2. **Policy statements:** guiding principle of what needs to be done to accomplish the policy outcome(s);
3. **Strategic objectives:** Description of the actions required to implement the policy statements and accomplish the policy outcome(s). Strategic objectives can link to multiple policy statements, also across different policy topics. Conversely, multiple strategic objectives may be required to fulfill one policy statement.

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

1. National Laboratory 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 content

It is important to start the National Laboratory Quality Policy and/or Strategic Plan with statements and/or objectives to establish the quality infrastructure necessary to support the implementation of Management Systems in all laboratories in the tiered national laboratory network. Thus, the first policy topic should cater for the establishment of a staged NLQS and a licensing system to ensure a high 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 will ensure that each laboratory has a Management System in place to monitor the quality of their results. Furthermore, this policy topic (i.e. National Laboratory Quality Infrastructure) should ensure that there is sufficient in-country capacity to calibrate and maintain laboratory equipment. It should also cater for the establishment/designation of the institutions responsible for these processes, including a National Standards Body and a National Accreditation Body, an ISO 17025 accredited National Metrology Institute and other ISO 17025 accredited entities offering equipment calibration and maintenance services.

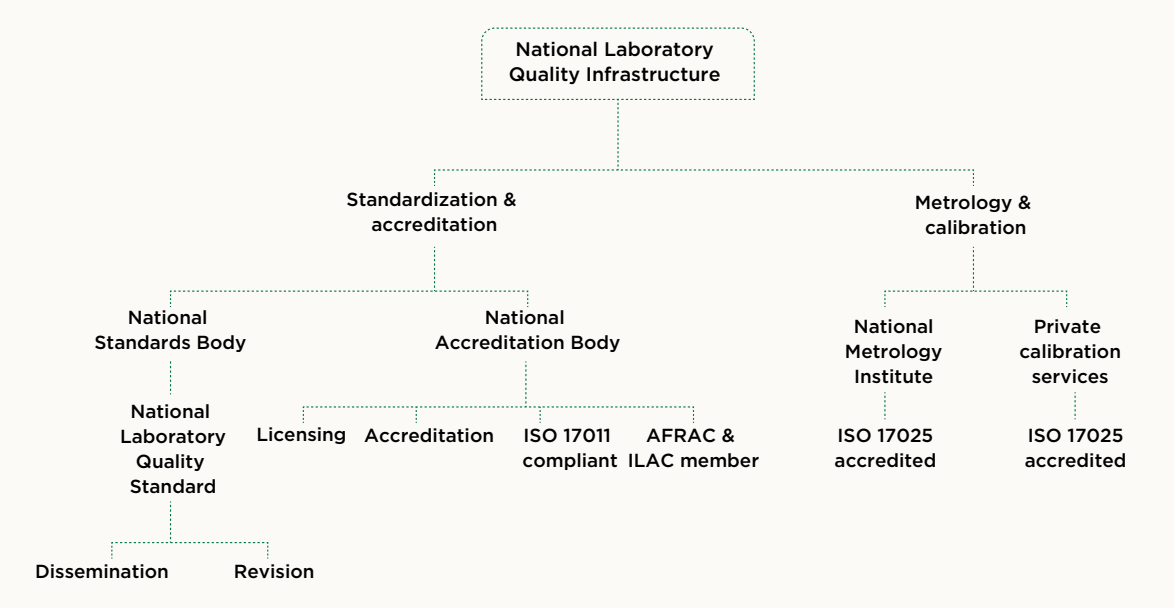


Figure 3: Overview of important elements to be covered by the National Laboratory (Quality) Policy and Strategic Plan related to the National Laboratory Quality Infrastructure

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

- **Standardization and accreditation**
  - The government must designate a National Standards Body responsible for disseminating, implementing, and regularly reviewing and revising staged NLQS.
  - A National Accreditation Body should also be established and made responsible for:
- Licensing and certifying laboratories to the different levels of the staged NLQS.
- Licensing of laboratory professionals (see Policy Topic 5: Human Resources);
- Accrediting laboratories based on international standards. This task can also be carried out by a foreign accreditation body but this may prove to be an expensive and time-consuming process.

It is strongly recommended that the National Accreditation Body implements the requirements of ISO 17011 for accreditation bodies accrediting conformity assessment bodies. The National Accreditation Body should also become recognized by the regional accreditation cooperative (AFRAC) and become a member of the International Laboratory

Accreditation Co-operation (ILAC) because this ensures that accreditation provided by the National Accreditation Body is internationally recognized. That is to say the quality of results and services of a laboratory accredited by a National Accreditation Body that is ISO 17011 compliant, recognized by AFRAC, and member of ILAC are internationally recognized and accepted.
Both the National Standards Body and the National Accreditation Body could be newly established or already-existing institutions whose scope is expanded. Before the National Accreditation Body is established/designated, Laboratory Directorate or Department at the MoH may act as interim accreditation body.

- **Metrology and calibration**

  Laboratories work with sophisticated equipment that need to be regularly maintained and calibrated to provide accurate and reliable measurements traceable to international standards. This is crucial for quality assurance. Countries must ensure sufficient equipment calibration and maintenance capacity for laboratories, which can be achieved through, for example, the establishment of a National Metrology Institute and/or other equipment calibration and maintenance services (public or private). Such services must be ISO 17025 accredited to ensure the quality of calibration services and traceability of calibration standards to the International System of Units (SI). Many countries have established National Metrology Institutes to facilitate export and international trade. The scope and expertise of this National Metrology Institute could be expanded to include the 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. The latter is responsible for implementation and coordination of the National Laboratory Quality Policy and/or Strategic Plan statements and/or objectives.

Policy outcome

The country has a formalized National Laboratory Quality Infrastructure that supports implementation and maintenance of Management Systems 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 the availability of relevant quality management expertise at national level. [NOTE: The Directorate of Laboratory Services can be at federal and provincial level in the 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 Management Systems, based on the staged NLQS or international standards, in all laboratories in the national tiered laboratory network.

Standardization and Accreditation

3. A regularly reviewed and updated staged NLQS shall be developed to improve the quality of laboratory services. The NLQS shall include requirements to control and assure the quality of Point-Of-Care Testing (POCT).
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 the regular review, revision and dissemination of the staged NLQS.
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 Co-operation (ILAC).
8. The costs for compliance with the staged NLQS or international laboratory standards shall be included in the national laboratory budget to ensure sustainability of standard implementation as well as the licensing system.
9. There shall be a system of incentives to motivate all laboratories to reach certification level 2 and higher of the staged NLQS and to become accredited to international standards.
10. All reference laboratories shall be encouraged to become accredited to international standards.

Licensing

11. All laboratories (public and private), laboratory professionals, and training institutes providing pre-service and in-service (Continuing Professional Education [CPE]) training for laboratory professionals shall be licensed according to the staged NLQS.

The staged NLQS shall include a set of defined criteria for laboratory professionals, and a defined set of criteria for laboratory training institutes , to ensure quality of laboratory services.

12. Compliance with the first level of the staged NLQS shall be part of the laboratory licensing requirements.
13. Laboratory licensing criteria shall include adequate assessment and management of risks, the use of quality indicators, and participation in EQA programs for all tests performed.
14. There shall be an auditing system and a licensing body at national level for the licensing of laboratory professionals and institutes that offer pre-service and in-service laboratory training. This body will ensure compliance with the licensing requirements for laboratory professionals and laboratory training institutes.
15. Periodic renewal of the licenses of laboratories, laboratory professionals, and laboratory training institutes shall be required based on re-inspection to ensure continued compliance with standards and licensing criteria.

Metrology and Calibration

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

* Keep the preferred option.

Strategic objectives

Information on content

Strategic objectives should be formulated based on a situational analysis and a prioritization exercise. Below are some examples of strategic objectives that relate to the above policy statements. These example strategic objectives can be adapted and more strategic objectives can be formulated in line with the situational analysis based on what is needed and feasible. For more information see Section 3.3 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 Management Systems implementation and maintenance based on the staged NLQS.
2. Establish a Directorate of Laboratory Services with quality management expertise to lead and manage the implementation and maintenance of Management Systems based on the staged NLQS or international standards. [Note: countries may opt to create a dedicated position of National Quality Manager at the directorate].

Standards and Accreditation

3. Develop a staged NLQS and ensure that this includes requirements for POCT.
4. Establish a National Standards Body with defined Terms of Reference to regularly review, revise and disseminate the staged NLQS. [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. [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 Co-operation (ILAC).
8. Include costs for compliance with the staged NLQS or international standards in the national laboratory budget.
9. Establish a system of incentives to ensure motivation of all laboratories to reach certification level 2 and higher of the staged NLQS 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 NLQS.
11. Make assessment and management of risks, use of quality indicators, and participation in an approved EQA program for all tests, part of laboratory licensing criteria.
12. Develop and implement a national system for the mandatory licensing and periodic re-licensing of laboratory professionals and institutes that provide pre-service and in-service laboratory training.

13. Develop licensing and relicensing criteria including 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 who will perform licensing activities under the guidance of the national licensing authority.
15. Create/designate a central regulatory body for the registration of licensed laboratory professionals and laboratory training institutes.

Metrology and Calibration

16. Establish a National Metrology Institute with the expertise and defined terms of reference to approve, calibrate and maintain laboratory equipment. [Alternative option: "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 content

It is important to include an element focused on ensuring the establishment of an adequate and up-to-date legal and regulatory framework supporting the National Laboratory Quality Infrastructure and laboratory services. This framework provides two important tools which a government can use to enforce a policy: legislation and licensing.

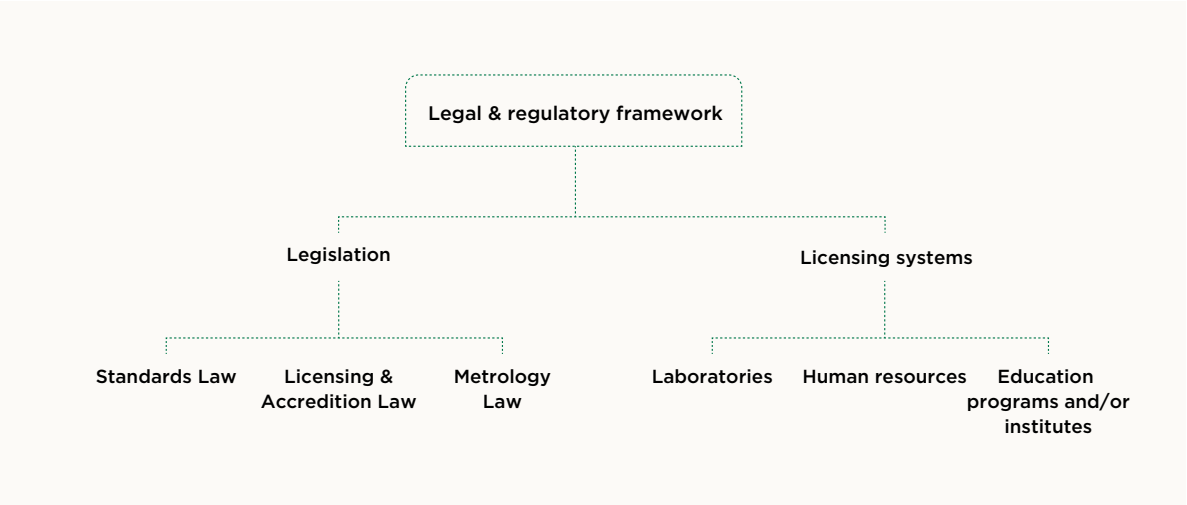


Figure 4: Overview of important elements to be covered by the National Laboratory (Quality) Policy and Strategic Plan related to the legal and regulatory framework for laboratory quality management.

Legislation

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

- Standards law: This law provides for the development, review, renewal and publication of the staged NLQS and its legal standing. It should also provide for the National Standards Body and the National Accreditation Body, including its governance, responsibilities, activities and finances [1];
- Licensing and accreditation law: This law provides for the development of a licensing and accreditation system that covers the licensing of both laboratories and laboratory personnel, and the licensing of pre-service and in-service laboratory education institutes. Criteria for the licensing of laboratories should include compliance with the first level of the staged NLQS, adequate assessment and management of risks, 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 comprises the legal basis for metrology, including calibration and traceability to SI-units. In addition, it provides the legal basis for establishment of the National Metrology Institute, including its governance, responsibilities, activities and finances [1].

Licensing systems

A licensing system for both laboratories and laboratory personnel, and for the licensing of pre-service and in-service laboratory education programs and 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 programs and institutes. Standards and criteria for licensing must be developed and regularly reviewed and revised, while a licensing authority must be established and its responsibilities, activities, and financing mechanism(s) must be specified.

Countries also need to establish remedial action or sanction mechanisms for non-adherence or non-compliance. Sanctions may include revoking of a license and funding as well as recourse to legal mechanisms, 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 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/or Strategic Plan and be in line with international recommendations.
2. There shall be a standards law, a licensing and accreditation law, and a metrology law, all of which apply to laboratory services to ensure the enforcement of the National Laboratory Quality Infrastructure and the advancement of Management Systems implementation.

Strategic objectives

Information on content for Strategic objectives should be formulated based on a situational analysis and a prioritization exercise. Below are some examples of strategic objectives that relate to the above policy statements. These examples of strategic objectives can

be adapted and more strategic objectives can be formulated in line with the situational analysis and based on what is needed and feasible. For more information see Section 3.3 of the Guidance Document.

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

Policy Topic 3: Monitoring, Evaluation & Continuous Improvement

Information on content

Whereas the previous two topics focused specifically on establishing the National Laboratory Quality Infrastructure and its enforcement through the legal and regulatory framework, policy topic 3 focuses on elements and mechanisms required at laboratory network and system level to monitor and continuously improve the quality of laboratory services:

- Establishing and implementing 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 (Conformity Assesssment: General requirements for the competence of proficiency testing providers).
- Establishing an M&E framework and a defined set of quality indicators for the different tiers of the laboratory network to objectively assess the quality of services provided by each laboratory.
- Establishing a system of tiered supervision whereby laboratories in higher tiers of the laboratory network conduct audits, support implementation of Management Systems, and monitor quality and performance of the laboratories in lower tiers of the network. This is on condition that the supervising laboratories are certified to a NLQS level that is at least one level higher than that of the supervised laboratory/-ies.

Assessment and management of risks, use of quality indicators, and participation in EQA must be made part of laboratory licensing criteria (see Policy Topics 1 and 2).

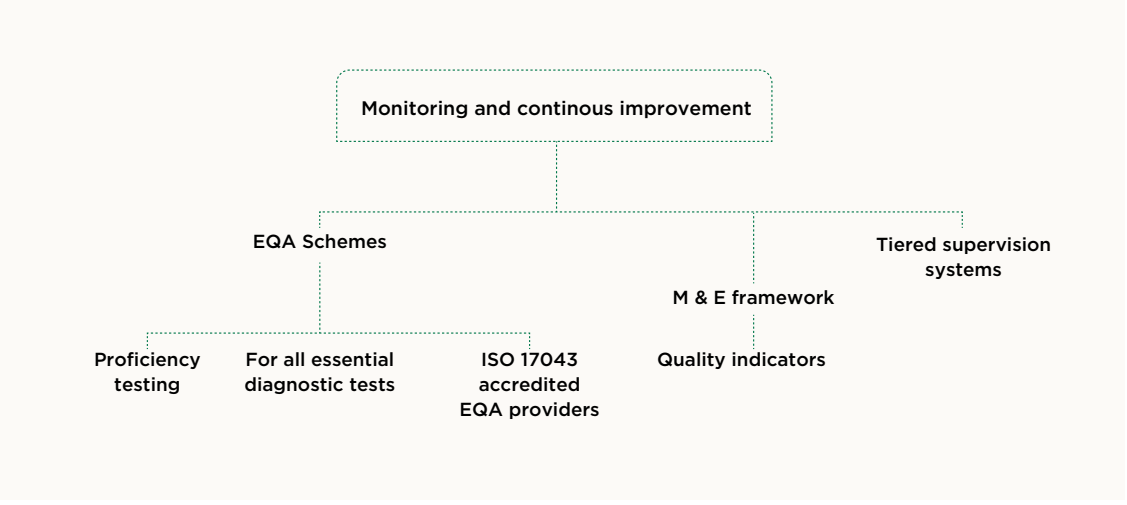


Figure 5: Overview of important elements to be covered by the National Laboratory Quality Policy and/or Strategic Plan related to monitoring and continuous improvement of laboratory services quality.

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 EQA 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 EQA Assessment schemes.
5. Regular participation and acceptable results in EQA schemes shall be a requirement for licensing and/or accreditation.

Monitoring & Evaluation Framework

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

Tiered Supervision

8. There shall be a system of tiered supervision to ensure that all laboratories provide quality services in compliance with the NLQS.

Strategic objectives

Information on content

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

objectives can be formulated in line with the situational analysis and based on what is needed and feasible. For more information see Section 3.3 of the Guidance Document.

External Quality Assessment – Proficiency Testing

1. Designate (an) institute(s) for the national provision of EQA services for all tests on the National Essential Diagnostics List (NEDL).
2. Ensure that national EQA programs offer panels for all tests on the NEDL.
3. Ensure that national EQA providers work in compliance with ISO 17043. [Note In the absence of ISO 17043 accredited national EQA provider, the country can also choose to participate in EQA programs provided by an ISO 17043 accredited regional EQA provider.
4. Develop a mechanism for EQA providers to provide timely feedback and suggestions for improvement of the EQA program.
5. Create a sustainable mechanism for the financing of EQA programs and EQA participation.
6. Make participation in the EQA program mandatory for all public and private laboratories as part of licensing requirements and develop a penalisation system for non-participation or for consistently scoring below the threshold.
7. Encourage reference laboratories to participate in international EQA schemes that are ISO 17043 accredited.

Monitoring & Evaluation Framework

8. Develop sets of quality indicators for the different tiers of the laboratory network to monitor and continuously improve the functioning of laboratory facilities.
9. Design a system of standardized monitoring and evaluation to monitor and continuously improve the functioning of the laboratory network based on quality indicators.

Tiered Supervision

10. Set up a formalized system of supervision where laboratories from higher tiers regularly supervise the laboratories in the lower tiers of the laboratory network and ensure that this system is covered by the Terms of Reference of the different tiers of the laboratory network.
11. Ensure that the tiered supervision includes mentoring activities based on EQA performance data.

Policy Topic 4: Financing of Laboratory Quality Management

Information on content

Adequate and sustainable funding and financing mechanisms for the Management Systems implementation; establishment and improvement of the National Laboratory Quality Infrastructure is crucial. Management Systems implementation and National Laboratory Quality Infrastructure establishment 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 a result of efficiency and effectiveness gains. Indirect return on investments will be achieved through alleviation of the disease burden on the national economy.

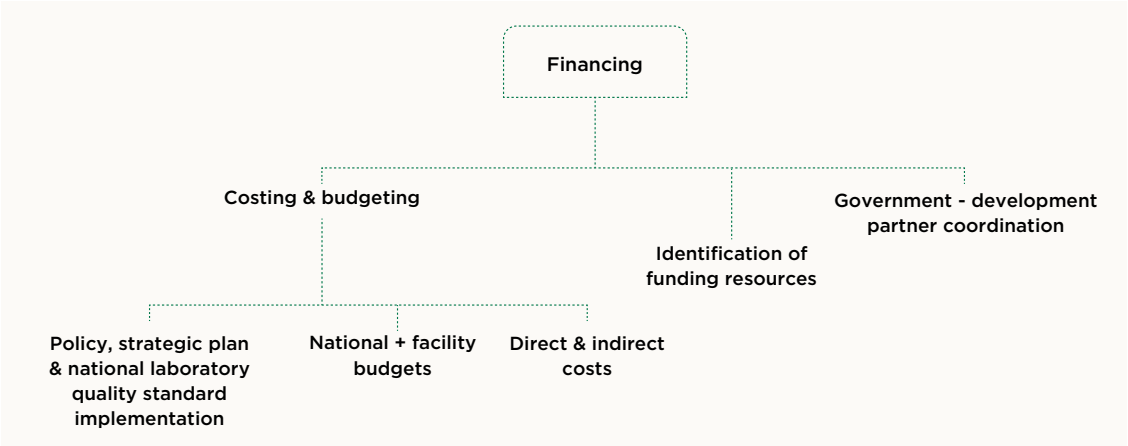


Figure 6: Overview of important elements to be covered by the National Laboratory Quality Policy and/or Strategic Plan related to the financing of laboratory quality management.

Costing and budgeting exercises are not part of the process of developing the National Laboratory Quality Policy and/or Strategic Plan (these exercises are part of operational planning). However, the National Laboratory Quality Policy and/or Strategic Plan address the establishment of adequate and sustainable financing mechanisms and ring-fenced budgets at national and facility level for the implementation of its objectives, Management Systems implementation activities, and required laboratory network and system improvements. It is also important that coordination mechanisms are established between the government and development partners to ensure efficient and effective use of financial resources provided by development partners in line with National Laboratory Quality Policy and/or 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 that includes 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 NLQS to ensure the sustainability of Management Systems implementation and maintenance.
3. Sustained Funding for pre-service and in-service laboratory education as well as Training of Trainers programs shall be made available to ensure sustainable education capacity for in-country laboratory quality management.
4. A dedicated budget for continuing education on laboratory quality management shall be available at institutional level.
5. There shall be dedicated funding for EQA schemes, which will cover the costs of both EQA provision and EQA participation.
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/or Strategic Plan and its implementation plans.

Strategic objectives

Information on contents

Strategic objectives should be formulated based on a situational analysis and a prioritization exercise. Below are some examples of strategic objectives that relate to the above policy statements. These examples of strategic objectives can be adapted and more strategic objectives can be formulated in line with the situational analysis and based on what is needed and feasible. For more information see Section 3.3 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 Management Systems training and implementation programs in line with the staged NLQS.
3. Make sufficient funding available and budget for the appointment of persons responsible for the Management Systems in public laboratories.
4. Make sufficient funding available and budget for the setting up of EQA programs for all tests on the National Essential Diagnostics List (NEDL).

5. Include a dedicated budget line for EQA 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/or Strategic Plan.

Policy Topic 5: Human Resources

Information on content

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

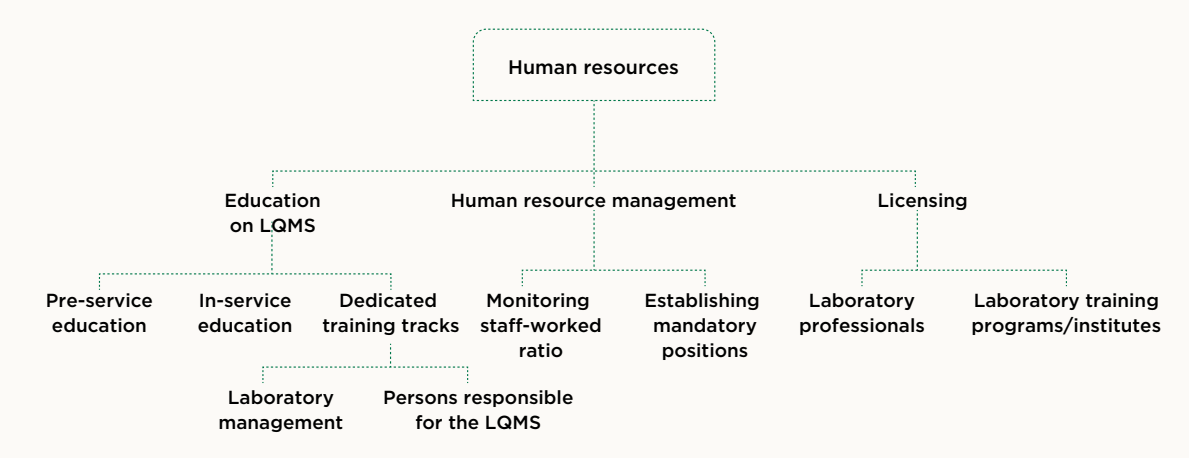


Figure 7: Overview of important elements to be covered by the National Laboratory Quality Policy and/or Strategic Plan related to Human Resources.

Education on Management Systems

The National Laboratory Quality Policy and/or Strategic Plan should contain statements and/or objectives aimed at including 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, continuing education must be part of the laboratory professionals' licensing requirements to ensure adherence to the continuing education program.

It is also important that the National Laboratory Quality Policy and/or Strategic Plan include statements and/or objectives on creating and implementing awareness and sensitization programs for Management Systems implementation. Specific statements and/or objectives should be included on implementing a dedicated training track for persons responsible for the Management Systems and 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 a Management Systems will streamline laboratory operation at a later stage, during its implementation it will require additional staff time and efforts. This should be anticipated, which is why the National Laboratory Quality Policy and/or Strategic Plan should include a statement and/or objectives on regularly calculating the staff/workload ratio and taking the necessary actions if this becomes unbalanced.

The National Laboratory Quality Policy and/or Strategic Plan should also include statements and/or objectives ensuring that all laboratories have a qualified laboratory manager and one or more persons responsible for the Management Systems. These positions are indispensable for the Management Systems implementation process as they play 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, comparable to similar systems for medical doctors, must be established for laboratory professionals. The licensing system must include criteria for education, continuing education, and personnel competence to ensure the quality of laboratory human resources and, consequently, the 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, licensing of laboratory training programs and institutes is important in assuring the quality of laboratory education. Therefore, the National Laboratory Quality Policy and/or Strategic Plan should include statements and/or objectives on the licensing of programs and institutes that offer pre-service and/or in-service laboratory training programs.

Policy outcome

Availability of sufficient, 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 for the implementation of the staged NLQS 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 for continuing education and training on laboratory quality management for all laboratory personnel to improve their skills and knowledge to ensure provision of quality laboratory services.
5. Continuing education and/or re-training shall be part of the licensing requirements for laboratory professionals.
6. There shall be specific training courses for persons responsible for the Management Systems.

7. All laboratory managers shall be trained in Management Systems implementation, laboratory leadership and management (including change management and financial management), in order to adequately manage and lead the process of implementing the Management Systems, based on the staged NLQS.

Human Resource Management

8. The staff/workload ratio for each laboratory shall be determined and reviewed regularly in an evidence-based way during implementation of the staged NLQS to ensure an appropriate workload.
9. All laboratories shall have a qualified laboratory manager, one or more persons responsible for the Management Systems, and a biosafety officer.

Licensing

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

Strategic objectives

Information on content

Strategic objectives should be formulated based on a situational analysis and a prioritization exercise. Below are some examples of strategic objectives that relate to the above policy statements. These examples of strategic objectives can be adapted and more strategic objectives can be formulated in line with the situational analysis and based on what is needed and feasible. For more information see Section 3.3 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 standardized training courses and harmonized technical guidelines and tools to support the implementation of the staged NLQS.
3. Develop a pool of mentors to assist laboratories with the implementation of the Management Systems.
4. Develop course content to include training on laboratory quality management based on national and international standards in all pre-service education curricula.
5. Create a program of continuing education that is regularly provided, competency-based courses, that includes courses on quality 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 persons responsible for the Management Systems.
8. Ensure that all laboratory managers are trained on Management Systems implementation, 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, person(s) responsible for the Management Systems, and a biosafety officer at each laboratory.
11. Include job descriptions for a laboratory manager, person(s) responsible for the Management Systems, and a biosafety officer in the Human Resource Management system.

Licensing

12. Establish a licensing system for laboratory professionals and ensure that all laboratory staff have valid, regularly renewed licenses 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 content

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

The way forward

Information on content

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

Outcomes of the situational analysis

Information on content

This annex provides information underlying the National Laboratory Quality Policy and/or Strategic Plan statements and/or 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 development of this policy/plan. For existing National Laboratory Quality Policy and/or Strategic Plan, this analysis could be revisited and 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/or Strategic Plan is implemented (both the laboratory network(s) in the country and the laboratory system(s) supporting laboratory services). The annex could briefly describe the structure and organization of the public laboratory network, including vertical program networks, private laboratories or laboratory networks which include the private-for-profit and the private-not-for-profit laboratories. This section could provide insight into important stakeholders for Management Systems implementation.

For a description of the laboratory system the model shown in Figure 8 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 they work towards attaining the overall guiding principles which, in the model, include the following:

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

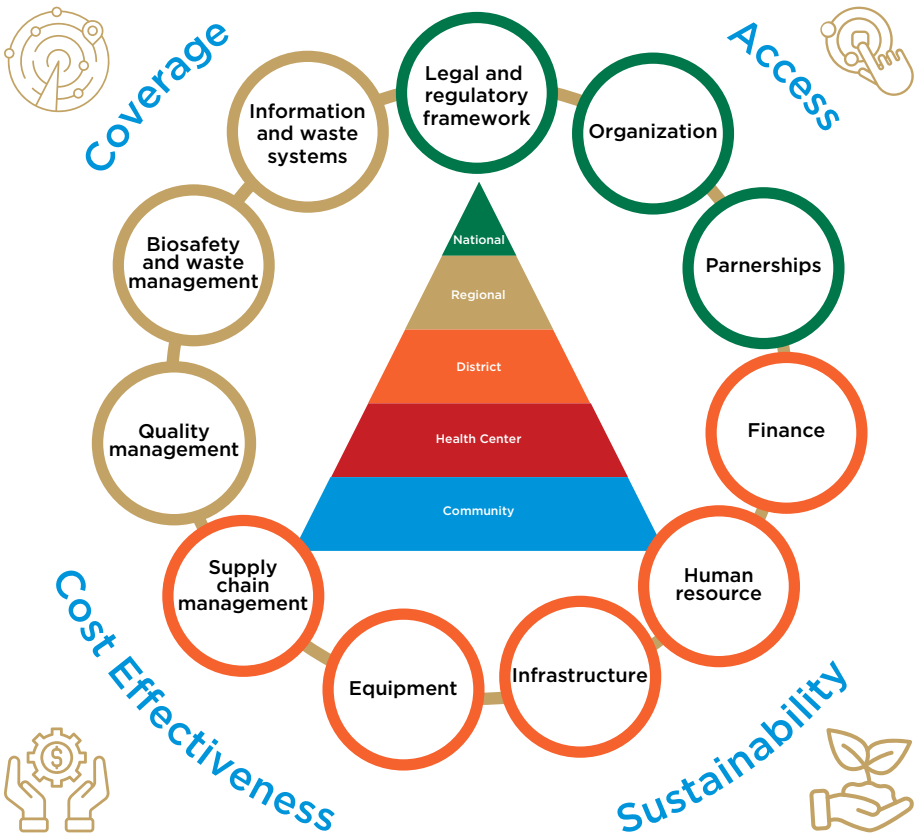


Figure 8: Laboratory network and system model. Note: the number of laboratory network tiers may vary per country and should be harmonized with the health system.

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

- The National Laboratory Quality Infrastructure currently in place, including the government structure, the infrastructure for standardization, accreditation, certification, and licensing of laboratories and the metrology and calibration services, education programs and institutes, and laboratory personnel,
- The legal and regulatory framework for laboratory quality management, including information on legislation and regulations related to laboratory services in general and to laboratory quality standards, licensing, and accreditation in particular,
- The processes for monitoring and continuous improvement of laboratory quality, including organization of EQA, with a focus on proficiency testing schemes, 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 the education of laboratory personnel (both pre-

and in-service education) and the improvement of laboratory human resource management,

- The processes and system in place for ensuring quality of equipment, consumables and reagents, including procurement and supply chain management, as well as equipment maintenance systems.

The situational analysis chapter will be based on the findings of the following assessments:

- A desk review of relevant documentation (including other policies, regulations, guidelines, reports, etc.),
- A laboratory network and 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 3.3.

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