ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

Guidance Document on **Establishment and Implementation of National Certification Programs (NCP) for ISO 15189 compliance in Medical Laboratories in Africa**

CONTENTS

ABBREVIATIONS

ASLM:	African Society for Laboratory Medicine
BSL:	Biosafety Level
CDC:	Center for Disease Control and Prevention
CPD:	Continuous professional development
CLSI:	Clinical Laboratory Standards Institute
HIV:	Human Immunodeficiency Virus
ILAC:	International Laboratory Accreditation Cooperation
LQMS:	Laboratory Quality Management System
MRA:	Mutual Recognition Arrangement
NCDs:	Non-communicable diseases
NCPs:	National Certification Programs
QMS:	Quality Management Systems
RECs:	Regional economic communities
SLIPTA:	Stepwise laboratory Quality Improvement Towards Accreditation
SOP:	Standard Operating Procedures
TB:	Tuberculosis
UHC:	Universal health coverage
WHO AFRO:	World Health Organization Regional Office for AFRICA

Introduction

Reliable and quality-assured laboratory services are a cornerstone of strong and resilient health systems. They underpin timely disease detection, accurate diagnosis, antimicrobial resistance monitoring, outbreak preparedness, and effective patient management. Across the African continent, the role of laboratories in strengthening health security and advancing Universal Health Coverage (UHC) is increasingly recognized.

Despite this recognition, many laboratories face persistent challenges. These include fragmented quality management systems (QMS), shortages of skilled personnel, limited access to standardized tools, poor infrastructure, non-functional equipment due to lack of proper maintenance, lack of resources, and inconsistent regulatory oversight. As a result, laboratory results can vary in reliability and may not meet internationally recognized standards such as ISO 15189.

To address these challenges, the African Society for Laboratory Medicine (ASLM), in collaboration with Africa CDC (Center for Disease Control and Prevention) and the World Health Organization Africa Regional Office (WHO-AFRO) , has developed regional frameworks to support laboratories in their stepwise journey towards accreditation. One of these frameworks, the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), has been successfully implemented across several African Union Member States. SLIPTA has demonstrated that progressive, structured improvement pathways are critical for ensuring sustainable quality gains.

The National Certification Program (NCP) builds on this continental success. It provides a country-owned and sustainable approach to nationalize the SLIPTA process, ensuring that every laboratory, irrespective of its size or location, has a structured pathway to achieve internationally recognized standards of quality and competence.
The NCP seeks to strengthen national laboratory systems by embedding quality management and certification into existing regulatory, policy, and financing structures, thereby reducing dependence on externally driven initiatives. Its primary objectives are to:

- Standardize quality improvement across all tiers of the laboratory network through nationally defined criteria aligned with international standards.
- Promote sustainability and ownership by integrating certification processes into national health strategies, budgets, and regulatory frameworks.
- Enhance public health impact by linking laboratory quality to national priorities such as the Essential Diagnostics List, antimicrobial resistance (AMR) surveillance, outbreak preparedness, and Universal Health Coverage (UHC).
- Expand equitable access to quality laboratory services by progressively including lower-tier and peripheral laboratories that are often excluded from regional programs.

The NCP achieves these goals through a tiered certification model, routine assessments and mentorship, and capacity-building interventions that support continuous improvement. By doing so, it transforms laboratory quality management from a regional aspiration into a nationally owned and locally implemented system, fully embedded within the country's public health architecture and responsive to its evolving needs.While continental frameworks such as SLIPTA have provided critical momentum, their long-term impact depends on country-level ownership and integration into national health strategies. The National Certification Program (NCP) builds on this continental success by providing a country-owned, government-led, and sustainable mechanism to institutionalize laboratory quality management within existing regulatory, policy, and financing structures. The NCP is designed to translate the SLIPTA process into a nationally anchored system that ensures every laboratory—regardless of size, level, or geographic location—has a structured and achievable pathway to attain internationally recognized standards of quality and competence.

By embedding certification within national priorities such as the Essential Diagnostics List, antimicrobial resistance (AMR) surveillance, outbreak preparedness, and Universal Health Coverage (UHC), the NCP ensures that quality laboratory services are no longer perceived as donor-driven initiatives but rather as integral components of resilient health systems. This alignment enhances sustainability, accountability, and equitable access, while also enabling countries to progressively extend quality assurance to lower-tier and peripheral laboratories that are often excluded from regional programs. Ultimately, the NCP transforms laboratory quality from a regional aspiration into a nationally owned and locally implemented system, firmly embedded in the country's public health and development agenda.

Rationale for LQMS Certification in Africa

2.1 The Imperative for Quality in African Laboratories

Africa faces a dual burden of infectious diseases (Human Immunodeficiency Virus (HIV), Tuberculosis (TB), malaria, Ebola, Lassa fever) and rising non-communicable diseases (NCDs), necessitating reliable diagnostic systems. The imperative for quality laboratory systems in Africa cannot be overstated. Laboratories are essential to detecting public health threats, guiding clinical decision-making, and enabling disease surveillance. Weak laboratory systems not only undermine patient safety but also compromise national and cross-border health security.

In many countries, the journey to ISO accreditation and certification remains a significant challenge due to resource limitations, infrastructure gaps, and limited mentorship capacity. Without intermediate recognition systems, laboratories often lack the incentives and structured guidance needed to progressively improve. In this context, intermediate recognition mechanisms such as National Certification Programs (NCPs) are indispensable. They provide laboratories with structured guidance, progressive milestones, and credible incentives to improve their quality management systems. NCPs not only bridge the gap between baseline performance and full accreditation but also embed ownership at the country level, ensuring sustainability and alignment with national health priorities.

Metric	Data	Implications / Notes
Total number of ISO 15189/ accredited medical laboratories (2023)	In 2023, 1,026 medical laboratories across 29 African countries attained ISO/IEC 15189 certification. (BusinessGhana)	This shows substantial growth in accreditation uptake. Useful to contrast with earlier years to show trend.
Geographical concentration of accredited labs	Of the 668 labs accredited by 2020, 55% (396 labs) were in South Africa, 16% (106 labs) in Kenya. (Wiley Online Library)	Indicates inequity — many countries still have low numbers of accredited laboratories, especially outside the stronger accreditation systems.
Number of labs engaged in SLIPTA and meeting ≥ 4 stars / accreditation	Among 475 laboratories enrolled in SLIPTA (2013–2020): 154 (32.4%) reached ≥ 4 SLIPTA stars or full ISO 15189 accreditation, and 113 achieved actual ISO 15189 accreditation. (Wiley OnlineLibrary)	Shows that while many laboratories begin the quality improvement journey, fewer reach the higher levels or full accreditation; the drop-off is an issue.

Metric	Data	Implications / Notes
Tier-level differences	Lower-tier (primary care or district level) labs were much less likely to reach ≥ 4 stars or accreditation — only 7.7% for Tier 1, vs ~30% for higher tiers. (Wiley Online Library)	Suggests that labs closer to the periphery / with less infrastructure face greater challenges; NCP will need to account for tier-specific support.
Rate of increase over time	The number of accredited labs increased by ~75% between 2013 and 2020 (from the baseline in 2013). (Wiley Online Library)	A positive trend; evidence that interventions (SLIPTA, SLMTA etc.) are moving the needle, but scale is still uneven.
Country-level gaps	• In Nigeria: fewer than 30 ISO-accredited labs in the whole country for ~200 million people. (Vanguard News) • In many sub-Saharan African countries, zero accredited laboratories in certain timeframes. Eg survey in 2013 showed 37 of 49 sub-Saharan African countries had no laboratories accredited to international standards. (PubMed)	This underscores the need for national programs that can promote accreditation more broadly, not just in concentrated areas.
Awareness / implementation of QMS tools among NTRLs	Among 49 National Tuberculosis Reference Laboratories (NTRLs) in WHO-AFRO region: ~94% reported awareness of at least one QMS tool (SLIPTA, SLMTA, GLI, etc.). About 43% had staff trained by SLMTA or TB-SLMTA. However, only a small fraction had achieved full accreditation or close to it. (PMC)	Suggests that awareness is high, training is underway in many, but moving from awareness/training to accreditation is slow.
Quality performance baseline	In Ethiopia (baseline studies) and other countries, many laboratories scored less than 50% on essential quality system elements (e.g. internal audit, corrective action, document control) in early assessments. (NCBI)	Demonstrates large gaps in meeting ISO 15189 foundational requirements; supports need for gradual, structured improvement paths.

The landscape of laboratory quality systems across the African continent is characterized by both significant progress and persistent critical gaps. There is a demonstrable upward trajectory in the adoption of international quality standards, evidenced by the growth of ISO 15189 accredited medical laboratories, which reached 1,026 across 29 countries by 2023 (BusinessGhana, 2023). Initiatives such as the Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) have been instrumental in driving this improvement (Gershy-Damet, et al., 2024). However, this growth has been markedly uneven, revealing substantial inequities. The distribution of accredited laboratories is heavily concentrated, with over half located in a single nation as recently as 2020 (Gershy-Damet, et al., 2024), leaving many countries with zero or minimal accredited laboratory capacity for their populations (Gershy-Damet, et al., 2024; Vanguard News, 2023). Furthermore, a significant drop-off exists between engagement in quality improvement programs and the achievement of full accreditation, with lower-tier laboratories facing disproportionately greater challenges in reaching this milestone (Gershy-Damet, et al., 2024).

This context underscores a clear need for a more targeted and tiered approach. While awareness of Quality Management System (QMS) tools is high among reference-level laboratories, baseline assessments consistently reveal foundational gaps in essential quality system elements, hindering the path to accreditation (Gershy-Damet, et al., 2024). The current data indicates that moving from awareness and training to full implementation and sustained accreditation requires more than generalized support. It demands strategic, context-specific guidance that addresses the unique resource, infrastructural, and operational constraints faced by laboratories at different levels of the health system. This guidance document is designed to address this precise need, providing a structured framework to accelerate and consolidate quality improvements towards the ultimate goal of universal accreditation.

2.2 The Role of National Certification Programs

The NCP serves as this bridge, acting as a nationally recognized certification mechanism that integrate country-specific priorities and regulatory needs. Through progressive certification, structured mentorship, and alignment with regional tools, the NCP ensures that laboratories:

- Progress systematically from foundational quality management to advanced accreditation and certification readiness,
- Receive targeted mentorship and support based on their maturity level,
- Contribute to stronger, integrated laboratory networks that enhance disease detection, patient care, and overall health security.
- Operate under consistent regulation and meet nationally defined minimum quality standards to ensure the delivery of reliable, accurate, and high-quality diagnostic services across the health system.

- Are regulated and adhere to minimum national standards to ensure quality diagnostic services.

This approach advocates8 for tiered, sustainable models of laboratory quality improvement.

2.3 Alignment with ASLM's LQMS Strategy

ASLM advocates for stepwise laboratory improvement, emphasizing:

- Incremental progress (e.g. SLIPTA scoring),
- Workforce capacity building through mentorship, and
- Policy integration with national health strategies.

This guidance ensures NCPs align with these principles, fostering sustainable laboratory strengthening across Africa.

Objectives of the National Certification Program

The NCP is designed to achieve the following strategic objectives, in alignment with ASLM's Laboratory Quality Management System (LQMS) goals:

Objective 1:

Establish nationally harmonized quality standards

To establish nationally harmonized quality standards that are aligned with regional and international benchmarks. The program ensures that laboratories operate to consistent, measurable quality standards that safeguard patient safety and promote cross-border comparability of test results.

Objective 2:

Strengthen laboratory workforce competency

To strengthen the competency of the laboratory workforce. This includes building national capacity for assessors, mentors, and laboratory managers through structured training and certification programs, ensuring that quality improvement is driven by a skilled and motivated workforce.

Objective 3:

Provide a stepwise certification pathway

To offer laboratories a stepwise, star-based certification pathway that recognizes incremental achievements and prepares high-performing laboratories for SLIPTA enrollment and eventual ISO 15189 accreditation.

Objective 4:

Ensure long-term sustainability

To ensure long-term sustainability. It is embedded within national health policies and strategic plans, supported by domestic financing and partnerships, and linked to regulatory frameworks that institutionalize continuous quality improvement.

Minimum Standards for African Laboratories

Assessment Framework and Tiered Approach

The NCP adopts the WHO-AFRO SLIPTA checklist as its core assessment tool, ensuring alignment and harmonization with regional quality improvement processes. Countries retain the flexibility to include context-specific indicators that address national priorities, provided these additions do not compromise continental comparability.

Tiered Assessment and Monitoring

The NCP uses a tiered star-rating system to guide laboratories through progressive levels of quality improvement:

- **Laboratories scoring 0–2 stars** undergo **annual assessments** to identify gaps, implement corrective actions, and accelerate performance improvement.

- **Laboratories scoring 3–5 stars** are assessed **biennially** to sustain quality gains, reinforce good practices, and foster continuous improvement.

Progression Pathways

The NCP establishes clear progression pathways that link national certification efforts with regional and international quality standards:

- Laboratories achieving three or more stars are recommended for official SLIPTA enrollment with ASLM.

- Laboratories demonstrating sustained high performance within SLIPTA are prioritized for ISO 15189 accreditation, further strengthening national diagnostic capacity.

- Once laboratories are enrolled in SLIPTA or accredited to ISO standards, they are offloaded from the NCP, maintaining program efficiency and enabling focused support for those still advancing through earlier tiers.

- In countries not yet participating in SLIPTA, the NCP provides a nationally driven pathway toward ISO 15189 readiness, offering an adaptable system that operates independently while remaining compatible with regional frameworks.

Contribution to Health Systems

This tiered, stepwise approach establishes a continuous pipeline of laboratories advancing toward progressively higher standards of quality management.

By embedding quality improvement within national structures and linking it to regional and international standards, the NCP:

- Strengthens national and regional laboratory networks, improving diagnostic reliability and system integration.
- Enhances disease detection, patient care, and health security by ensuring laboratories consistently meet defined quality benchmarks.
- Operates under consistent regulation and nationally defined minimum standards, guaranteeing reliable diagnostic services across all levels of the health system.

Through this approach, the NCP transforms quality improvement from a one-time achievement into a sustained process of excellence, building resilient laboratory systems that are integral to public health preparedness and universal health coverage.

Figure 1 : NCP Star rating

Governance and Institutional Framework

Effective governance is essential for the credibility and sustainability of the NCP. The program is anchored within the Ministry of Health (MoH) and guided by a multi-sectoral NCP Committee, which provides oversight, technical guidance, and policy direction.

5.1 NCP Stakeholder Governance Structure and Roles

The National Certification Program is implemented through a coordinated governance structure that ensures national ownership, technical rigor, and alignment with continental and international quality standards. The NCP governance framework comprises:

- Ministry of Health (MoH) and designated NCP focal points
- NCP Secretariat
- NCP Assessment Team (National Assessors)
- NCP Committee (National Advisory Body)
- Applicant and Enrolled Laboratories
- Regional and Continental Partners including ASLM, Africa CDC, WHO, and other technical and development partners

Ministry of Health (MoH)

The MoH provides stewardship and leadership of the NCP, ensuring integration into national health and laboratory policies. Responsibilities include:

- Appointing a National NCP Focal Point for coordination, oversight, and reporting
- Developing and maintaining an NCP implementation plan with prioritized laboratory enrollment
- Allocating financial and human resources to sustain program operations
- Overseeing corrective action follow-up from NCP assessments
- Integrating NCP activities into national budgets and mobilizing partner support

NCP Secretariat

The NCP Secretariat functions as the operational hub of the program. Key functions include:

- Managing the application and enrollment process for laboratories
- Maintaining the national registry of enrolled laboratories and recognition status

- Coordinating assessor deployment and assessment logistics
- Managing the national roster of certified assessors, including qualifications and training history
- Organizing assessor training and refresher programs in collaboration with ASLM-certified trainers
- Ensuring consistent use of the nationalized SLIPTA checklist with approved country-specific questions
- Serving as the point of contact for MoHs, laboratories, and partners
- Managing official communications, documentation, and records

NCP Assessors

NCP assessors are certified professionals trained through ASLM-led or endorsed training programs. They operate under confidentiality and impartiality requirements. Responsibilities include:

- Conducting assessments using the nationalized WHO/AFRO SLIPTA checklist
- Providing objective, evidence-based scoring
- Delivering structured, constructive feedback to laboratories
- Preparing detailed assessment reports with prioritized recommendations
- Supporting mentorship activities when requested by the NCP Secretariat

NCP Committee (National Advisory Body)

The NCP Committee is the independent technical advisory group for the program. Membership is drawn from the MoH, national public health institutions, professional associations, academia, and relevant partners. Functions include:

- Reviewing and validating assessment reports and star ratings
- Advising on disputes or complex cases
- Ensuring consistent application of standards
- Issuing Certificates of Recognition to eligible laboratories
- Guiding policy updates and national scale-up strategies

Applicant and Enrolled Laboratories

Participating laboratories commit to:

- Meeting all NCP assessment requirements
- Implementing corrective actions within agreed timelines

- Maintaining participation in proficiency testing and inter-laboratory comparisons
- Notifying the NCP Secretariat of major operational changes that may affect recognition status

Regional and Continental Partners

Organizations such as ASLM, Africa CDC, WHO, and other development partners provide:

- Technical assistance and policy guidance
- Assessor training and capacity building support
- Harmonization of standards with regional and global frameworks
- Resource mobilization and facilitation of peer learning through regional networks

This governance arrangement ensures the NCP is nationally led, regionally harmonized, and globally aligned, enabling laboratories to progress from foundational quality management toward SLIPTA recognition and eventual ISO 15189 accreditation

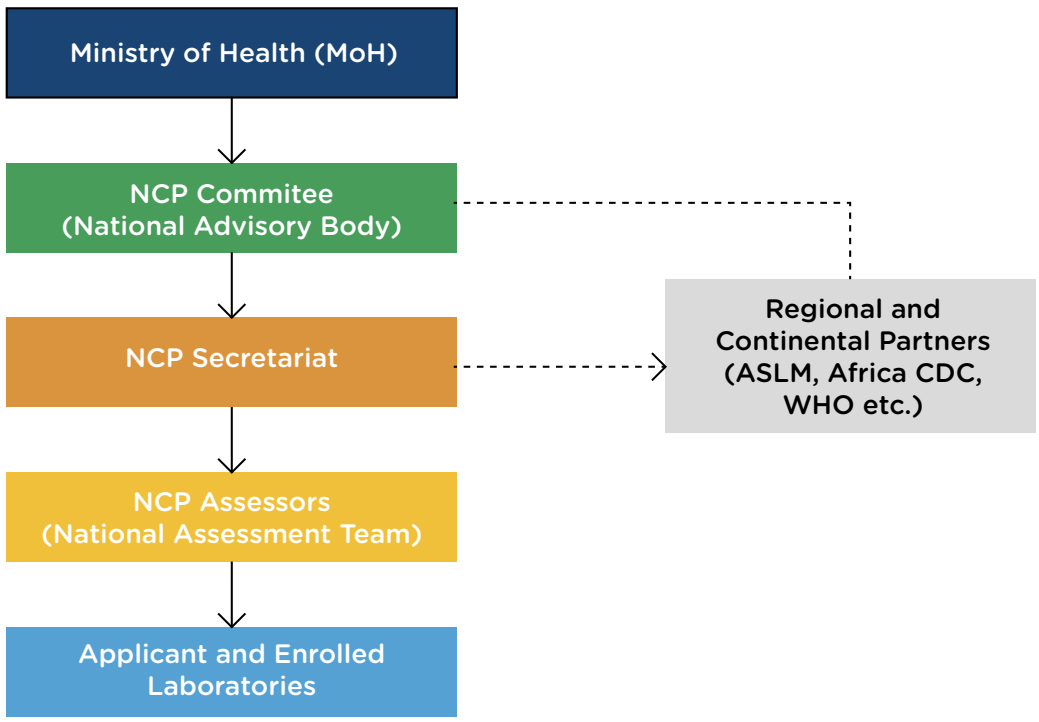


Figure 2: Governance Structure for the National Certification Program

Training and Certification of NCP Assessors

The quality and credibility of the NCP depend on the competence of its assessors. All NCP assessments are conducted by ASLM-certified assessors, or by national assessors trained and certified by a recognized institution or programs.

Training encompasses the application of the SLIPTA checklist, audit methodologies, reporting standards, and ethics of impartial assessments. Assessors are not only evaluators but also play a pivotal role in guiding laboratories toward continuous improvement.

By developing a cadre of nationally certified assessors, countries build self-reliant capacity to sustain laboratory quality improvement efforts.

NCP Assessor Requirements

To ensure alignment and harmonization with the WHO-AFRO SLIPTA framework, the NCP adopts similar minimum requirements for the recognition of assessors. This alignment guarantees consistency in the quality of assessments, credibility of certification outcomes, and interoperability between national and regional quality improvement systems.

To be recognized as an NCP assessor, individuals must meet the following minimum requirements:

- **Educational background:** Hold at least a bachelor's degree in medical laboratory science, microbiology, or a related biomedical field from a recognized institution.
- **Professional experience:** Possess a minimum of five years of post-qualification experience in a medical laboratory setting, including direct involvement in quality management systems (QMS) implementation or oversight.
- **Training and certification:** Successfully complete an approved SLIPTA auditor training course or equivalent national certification program that covers ISO 15189 standards, quality management principles, and assessment methodologies.
- **Assessment experience:** Demonstrate prior participation in laboratory audits or assessments, preferably as part of SLIPTA or similar national quality improvement programs.
- **Professional conduct:** Adhere to established ethical standards, impartiality, and confidentiality requirements in the execution of assessment duties.

By aligning assessor qualifications with SLIPTA standards, the NCP ensures that assessments are conducted by competent, credible professionals who can deliver high-quality, standardized evaluations across all tiers of the laboratory network.

Enrolment and Assessment Process

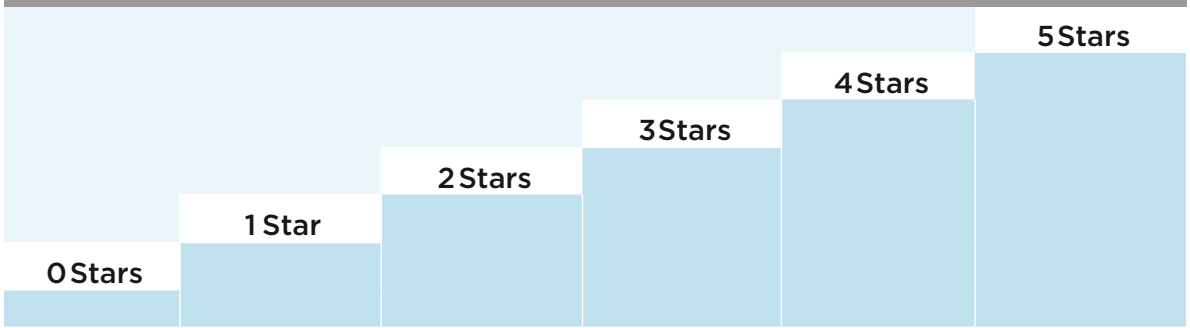
The NCP implements a transparent, structured, and inclusive enrolment mechanism. Laboratories may be nominated by the Ministry/Directorate or may apply directly to the NCP Secretariat. All applications are subject to eligibility screening by the NCP Committee. Eligible laboratories are formally enrolled and provided with an orientation on the certification pathway, associated requirements, and performance expectations. Assessments are evidence-based, participatory, and improvement-oriented. Each assessment includes:

NCP Assessor Requirements

To ensure alignment and harmonization with the WHO-AFRO SLIPTA framework, the NCP adopts similar minimum requirements for the recognition of assessors. This alignment guarantees consistency in the quality of assessments, credibility of certification outcomes, and interoperability between national and regional quality improvement systems.

- An opening meeting to align expectations
- Systematic review of documentation, procedures, and practices
- On-site observation and staff interviews
- Scoring and star rating based on the SLIPTA checklist as shown in Table 1 below

Table 1: SLIPTA tiers of recognition of laboratory quality management



0 -150 pts	151-177 pts	178-205 pts	206-232 pts	233-260 pts	261-275 pts
<55%	55 - 64%	65 -74%	75 - 84%	85 - 94%	≥95%

- A dedicated feedback session to discuss findings and agree on an improvement plan

This two-three-day process—one/two day(s) for assessment and one for structured feedback—ensures laboratories receive actionable recommendations to guide their quality improvement journey.

Structured Mentorship

Mentorship is a core pillar of the NCP and its approach must be sustained capacity building. The NCP recognizes that certification alone is not enough — laboratories require continuous, context-specific support to strengthen their quality management systems (QMS) and progress along the NCP–SLIPTA–ISO 15189 pathway.
Mentorship under the NCP is tiered and tailored to the maturity level of the laboratory, as determined through its assessment star rating:

- **0–2 Star Laboratories (NCP Enrolled)**
  Receive intensive, hands-on mentorship focused on building foundational QMS elements. Support includes frequent on-site visits, structured virtual coaching, and practical guidance on implementing standard operating procedures, record keeping, biosafety, and participation in proficiency testing.

  It is recommended that a mentor spends a minimum of 4-6 weeks of sustained continuous mentorship followed by intermittent visits of at least 1-2 weeks duration

- **3–5 Star Laboratories (NCP Enrolled)**
  Benefit from targeted, gap-closing mentorship that addresses advanced QMS requirements and prepares them for SLIPTA enrollment. Mentorship is less frequent but highly focused on specific improvement areas identified during assessment.

  It is recommended that a mentor spends a minimum of 1-2 weeks of sustained continuous mentorship followed by intermittent visits of at least 1 week duration

- **SLIPTA-Enrolled Laboratories**
  Receive specialized technical mentorship aimed at achieving ISO 15189 accreditation readiness. This includes advanced technical training, method validation support, internal audit strengthening, and preparation for third-party accreditation audits.

  It is recommended that a mentor spends a minimum of 1-2 weeks of sustained continuous mentorship followed by intermittent visits of at least 1 week duration

- **ISO 15189–Accredited Laboratories**
  Are encouraged to serve as national quality champions. These laboratories support peer facilities through experience-sharing, on-site mentoring, and participation in national training programs.

This structured, progressive mentorship model ensures that every laboratory — regardless of its starting point — receives the support needed to achieve and sustain quality improvement. It is aligned with the WHO Laboratory Quality Stepwise Implementation (LQSI) tool and Africa CDC's mentorship models, ensuring both technical rigor and sustainability.

Recognition and Certification

9.1 Decision-Making and Awarding of Recognition

Within two weeks of completing an NCP assessment, the NCP Assessment Team will submit the assessment report, including identified nonconformities, to both the assessed laboratory and the NCP Secretariat. The laboratory will have six weeks to provide documented evidence of corrective actions addressing the nonconformities for reconsideration.

Where necessary, the NCP Assessment Team may provide technical guidance to support the laboratory in implementing corrective actions. If major nonconformities are identified, a follow-up assessment may be conducted within three to six months.

Following review of the corrective actions, the Assessment Team will submit a final report to the NCP Committee through the NCP Secretariat within one week of reconsideration. The NCP Committee will, within two weeks, determine the appropriate star rating and level of recognition to be awarded, based on the nationalized SLIPTA star rating system.
The current recognition status of all laboratories enrolled in the NCP will be maintained on a publicly accessible national database hosted by the NCP Secretariat and, where appropriate, linked to the ASLM website.

Utilization of NCP Assessors in SLIPTA Assessments

To promote sustainability, cost-effectiveness, and stronger regional integration, national NCP assessors who meet ASLM's certification criteria can be recognized and deployed by ASLM to conduct official SLIPTA assessments. This dual recognition strengthens national capacity while reducing reliance on externally sourced assessors. To qualify for participation in ASLM-led SLIPTA missions, NCP assessors must:

(i) have successfully completed an ASLM-endorsed SLIPTA auditor training,

(ii) (ii) demonstrate proficiency through participation in a minimum number of supervised national assessments, and

(iii) (iii) consistently adhere to assessment quality, reporting, and ethical standards as defined by ASLM.

Once endorsed, these assessors become part of a regional pool that ASLM can mobilize for SLIPTA audits within their own countries or across the continent. This approach not only lowers assessment costs and enhances program sustainability, but also fosters continuous skills development and ensures a seamless quality continuum from national certification to regional and international accreditation

9.2 Validity of Recognition and Follow-Up Assessment

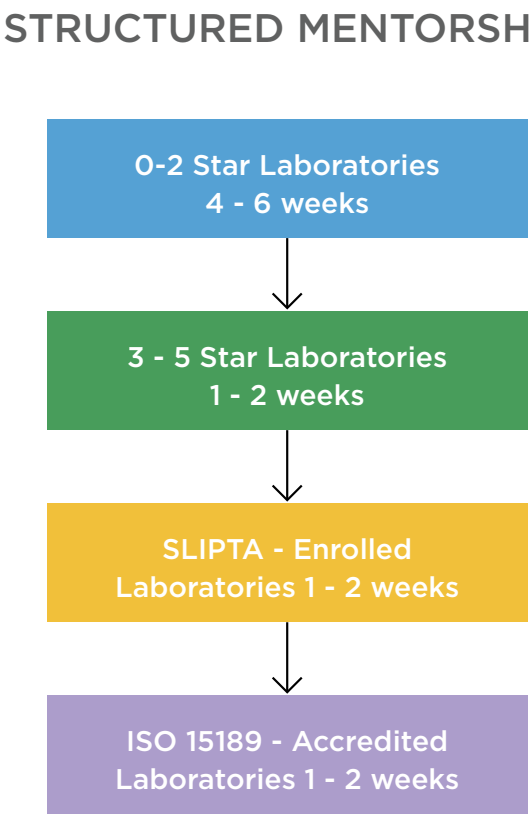


Figure 3: Structured mentorship under the NCP

Recognition under the NCP is granted for a period of two years from the date of issue of the certificate. Laboratories seeking renewal must submit their application six months prior to the certificate's expiry.

The NCP promotes progressive improvement and encourages laboratories to advance along the NCP–SLIPTA–ISO 15189 pathway, with a target for high-performing laboratories to achieve International Laboratory Accreditation Cooperation (ILAC)-recognized accreditation within four years of initial NCP enrollment (i.e., initial certification plus one renewal cycles).

To enable this, Ministries of Health are encouraged to include accreditation services in national strategic plans and budgets and to engage with accreditation bodies for efficient service delivery based on the volume of laboratories. Laboratories achieving ISO 15189 accreditation will be offloaded from the NCP register and their achievement will be recognized nationally and, where relevant, regionally.

9.3 Appropriate Use of Recognition Certificates

Recognition certificates awarded under the NCP are formal acknowledgement of a laboratory's quality management maturity level, expressed as a star rating aligned with the SLIPTA scale. They are not certificates of accreditation and must be used responsibly to reflect the true status of the laboratory.

Laboratories displaying NCP recognition certificates must adhere to the following provisions:

- Display of the certificate does not imply that the NCP Secretariat, ASLM, Africa CDC, or WHO accepts responsibility for activities carried out under the laboratory's scope of recognition.
- A certificate may only be displayed at the specific laboratory site to which it was issued. It cannot be transferred to another laboratory or displayed at another location.
- Certificates must not be altered, amended, or reproduced in any way.
- Certificates must be removed promptly upon expiration or withdrawal of recognition.
- Certificates must not be used in a manner that misleads stakeholders about the laboratory's status or scope of recognition.
- Laboratories must promptly notify the NCP Secretariat in the event of:
    - Significant changes in staffing or management
    - Changes to the test menu or scope of services
    - Discontinuation of participation in proficiency testing or inter-laboratory comparisons
    - Two consecutive failures in proficiency testing performance

Where such changes occur, the NCP Committee may determine that an on-site reassessment is required. Failure to notify the NCP Secretariat of significant changes may result in suspension or withdrawal of recognition.

Monitoring, Evaluation, and Sustainability

The NCP includes a robust monitoring and evaluation system. A national laboratory quality dashboard tracks enrolment, star ratings, mentorship progress, and transitions to SLIPTA or ISO accreditation.

Laboratories are recertified every 2years to ensure sustained compliance and improvement. High-performing laboratories are publicly recognized at national award events, promoting a culture of excellence and motivating others to follow suit.

Importantly, the NCP is institutionalized within national laboratory strategic plans and linked to domestic health financing mechanisms, ensuring long-term sustainability and country ownership.

Objectives	Expected Outcomes	Indicators	Baseline	Targets (3–5 years)	Means of Verification (MoV)	Assumptions
Objective 1: Establish nationally harmonized quality standards	National standards adopted and applied across laboratories	1. Existence of nationally endorsed QMS standards aligned to ISO 151892. % of labs assessed using national certification checklist3. % of labs meeting minimum standards	No formal NCP; limited use of ISO standards	100% of AU Member States adopting standards≥ 70% of labs assessed nationally≥ 50% of labs meeting minimum standards	– Official MoH or regulatory publications– National certification reports– Assessment records	Political commitment sustained; harmonization with regional frameworks accepted
Objective 2: Strengthen laboratory workforce competency	Skilled national cadre of assessors, mentors, and managers	1. # of certified assessors and mentors2. % of lab managers trained in QMS3. Staff competency improvement scores	Few trained assessors/ mentors; <20% managers with QMS training	≥ 100 trained assessors/ mentors per country≥ 60% of managers trained≥ 80% post-training competency improvement	– Training registers– Certification lists– Pre/post-training evaluation reports	Continuous funding for training; staff retention in public sector

Objectives	Expected Outcomes	Indicators	Baseline	Targets (3–5 years)	Means of Verification (MoV)	Assumptions
Objective 3: Provide a stepwise certification pathway	Progressive improvement of laboratories through tiered recognition	1. % of labs at each certification level (1–5 stars)2. % of labs improving ≥1 star within 2 years3. # of labs transitioning to SLIPTA/ ISO 15189	Few labs engaged in SLIPTA; <10% accredited	≥ 70% of labs enrolled in NCP≥ 50% of enrolled labs improve ≥1 star≥ 25% transition to SLIPTA/ISO 15189	– NCP registry– Certification reports– Accreditation body records	Labs willing to participate; resources for mentorship and audits available
Objective 4: Ensure long-term sustainability	NCP institutionalized in national systems with domestic financing	1. NCP integrated into health/lab policies2. % of NCP costs covered by domestic funds3. # of regulatory instruments supporting NCP	No dedicated NCP policies or budgets	≥ 80% of countries integrate NCP in strategies≥ 50% of costs covered by domestic funds≥ 3 supporting instruments (laws/policies) adopted	– National health & lab strategic plans– MoH budgets– Policy/ legal documents	Government financing secured; donor support leveraged during transition

Implementation Procedures

11.1 Cost and Resource Mobilization

The costs associated with NCP assessments, mentorship, and certification will be covered by the Ministry of Health (MoH) and its implementing partners. The MoH is responsible for mobilizing these resources as part of the national laboratory strategic implementation plan, ensuring that NCP activities are sustainably financed through domestic allocations, partner support, and integration into existing quality improvement initiatives.

11.2 Issues Management

During the certification process, circumstances may arise that require the lodging of complaints by laboratories, MoH departments, or other stakeholders. The NCP Secretariat Head and the Chair of the NCP Committee are jointly responsible for ensuring that all complaints are addressed impartially, objectively, and without bias.

All complaints must be submitted in writing to the NCP Secretariat. These may relate to:

- Inappropriate or unprofessional conduct by NCP assessors or Secretariat staff
- Conflicts of interest in assessment or decision-making processes
- Poor quality or integrity of NCP services provided

Upon receipt, complaints will be logged and acknowledged within two weeks. They will be forwarded to the Chair of the NCP Committee for review and resolution. Investigations will be completed within four weeks, and corrective or preventive action will be implemented as appropriate.

11.3 Monitoring of Assessor Performance

The NCP Secretariat will annually monitor and evaluate the performance of all NCP assessors to ensure that high standards of competence, professionalism, and ethical conduct are maintained.

Assessors are bound by strict confidentiality requirements and must be free from any conflicts of interest that could compromise the integrity of the assessment process. Any findings that indicate a breach of confidentiality, impartiality, or ethical conduct will be acted upon promptly by the NCP Committee, with appropriate sanctions applied where necessary.

11.4 Release and Use of Assessment Reports

The name of laboratories enrolled in the NCP may be made public through the national laboratory quality dashboard.

Assessment reports will be handled with controlled disclosure:

- Internal assessment reports: Results will be disclosed by the laboratory director to the Ministry of Health and the NCP Secretariat to support corrective action planning.

- External assessment reports: Results will be formally transmitted by the NCP Secretariat to the laboratory director and the MoH. Members of the NCP Committee will have access to the results after signing a confidentiality agreement affirming that data will not be disclosed to unauthorized parties.

11.5 Conclusion

The NCP is a process that supports laboratories in the implementation of quality management systems and the development of technical competence. The MoH, NCP Secretariat, NCP Committee, ASLM, and NCP assessors cannot accept liability for any laboratory testing outcomes conducted in facilities enrolled in the NCP.

The National Certification Program represents a transformative opportunity for African Union Member States to institutionalize laboratory quality improvement. By nationalizing the SLIPTA program, aligning with Africa CDC and WHO frameworks, and embedding progressive certification within national health systems, countries can:

- Strengthen laboratory quality and diagnostic reliability
- Enhance health security and pandemic preparedness
- Build sustainable pathways to ISO 15189 accreditation
- Contribute to a continent-wide vision of integrated, quality-assured laboratory networks that safeguard the health of all Africans.

This framework is not merely a technical tool—it is a strategic investment in resilient health systems and a prerequisite for achieving universal health coverage and regional health security.

References

1. **Africa Centres for Disease Control and Prevention (Africa CDC).** (2022). Framework for Strengthening Public Health Laboratory Systems in Africa. Addis Ababa: Africa CDC.

2. **African Society for Laboratory Medicine (ASLM).** (2021). ASLM Laboratory Quality Management System (LQMS) Strategy. Addis Ababa: ASLM.

3. **World Health Organization Regional Office for Africa (WHO AFRO).** (2015). WHO Guide for the Stepwise Laboratory Quality Improvement Process Towards Accreditation in the African Region (SLIPTA). Brazzaville: WHO AFRO.

4. **International Organization for Standardization (ISO).** (2022). ISO 15189:2022 Medical laboratories — Requirements for quality and competence. Geneva: ISO.

5. **International Laboratory Accreditation Cooperation (ILAC).** (2017). ILAC Policy on the Use of ILAC Accreditation Symbols and for Claims of Accreditation Status. Sydney: ILAC.

6. **World Health Organization (WHO). (2018).** Manual for Improving the Quality of Laboratory Services: A Stepwise Approach. Geneva: WHO.

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