



NATIONAL CERTIFICATION FRAMEWORK FOR HIV RAPID TESTING

'Ensuring the reliability and accuracy of HIV rapid test results'

February 2025

2nd Edition

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Foreword

The Government of Uganda has consistently prioritized the fight against HIV and AIDS, incorporating it into the core strategies of our national health agenda. Revising and updating the "*National Certification Framework for HIV Rapid Testing*" is integral to our commitment to ensuring the reliability and accuracy of HIV testing services nationwide. This framework aligns with our Health Sector Development Plan, the National HIV and AIDS Strategic Plan, and the National Health Policy.

HIV Testing Services (HTS) in Uganda have evolved significantly since their inception in 1990, with differentiated models of delivery and policy revisions enhancing universal access, equity, and coverage. Despite these advancements, challenges in maintaining quality and consistency in HIV testing have persisted, particularly with the decentralization of testing services and the involvement of lay testers.

The revised National Certification Framework addresses these challenges by establishing comprehensive standards and procedures for certifying HIV rapid testing sites and testers. This framework is designed to ensure that all testing sites and personnel meet stringent quality requirements, thereby minimizing the risk of misdiagnosis and improving the overall reliability of HIV test results.

Key to the success of this framework is the rigorous training and certification of HIV testers and sites following audits and evaluations, respectively, along with the implementation of robust quality assurance measures. By adhering to these standards, we aim to provide accurate HIV diagnoses, link individuals to appropriate care and treatment promptly, and ultimately reduce the transmission of HIV within our communities.

This document serves as a crucial resource for policymakers, programmers, healthcare providers, researchers, and all stakeholders involved in HIV testing and prevention. It outlines the processes for certification, the roles and responsibilities of various stakeholders, and the monitoring and evaluation mechanisms to ensure continuous improvement in HTS.

As we move forward, I urge all actors in the HIV response in Uganda to support the implementation of this framework. Together, we can enhance the quality of HIV testing services, ensure accurate and reliable test results, and make significant strides toward achieving the UNAIDS 95- 95- 95 targets by 2030.

Thank you to everyone who has contributed to the development of this important document and for your continued dedication to improving the health and well-being of all Ugandans.



Dr. Charles Olaro
Acting Director General of Health Services

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It is my sincere hope that these certification guidelines for HIV testers and sites will significantly improve the quality of HIV testing services in Uganda and ensure accurate results for all individuals testing for HIV. This tool will support the Country Program's efforts to fast-track the National HIV and AIDS Strategic Plan target of identifying 95 percent of HIV-infected Ugandans and linking them to HIV care and support services, to eliminate AIDS by 2030. Finally, we express our gratitude to the following organizations for their financial support of the guidelines' development process: PEPFAR/CDC through the Uganda Virus Research Institute (UVRI).



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Abbreviations and Acronyms

ACP	AIDS Control Programme
AHPC	Allied Health Professionals Council
CBO	Community-based Organization
CHEW	Community Health Extension Workers
CDC	U.S Centers for Disease Control and Prevention
CPHL	Central Public Health Laboratories
CQI	Continuous Quality Improvement
CSOs	Civil Society Organizations
DHO	District Health Officer/Office
DHT	District Health Team
DICs	Drop-in Centers
DGHS	Director General of Health Services
EQA	External Quality Assurance
HBHCT	Home-Based HIV Counseling and Testing
HCT	HIV Counseling and Testing
HCW	Health Care Workers
HSDP	Health Sector Development Plan
HTS	HIV testing services
ICC	Independent Certification Committee
ISO	International Organization for Standardization
LQMS	Laboratory Quality Management Systems
MARPs	Most at Risk Populations
M&E	Monitoring and Evaluation
MOH	Ministry of Health
NCTC	National HIV Counseling and Testing Committee
NHLDS	National Health Laboratory and Diagnostic Services
PCDA	Plan Do Check Act
PEPFAR	Presidential Emergency Plan for AIDS Relief
PLHIV	Persons Living with HIV

PITC	Provider Initiated HIV Testing and Counselling
POCT	Point of care (POC) technologies
PPE	Personal Protective Equipment
PT	Proficiency Testing
QA	Quality Assurance
QAD	Quality Assurance Department
QC	Quality Control
QI	Quality Improvement
QMS	Quality Management System
RRH	Regional Referral Hospital
SPI-RT	Stepwise Process for Improving the Quality of HIV Rapid Testing
UNHCO	Uganda National Health Consumers Organization
VCT	Voluntary Counseling and Testing
VHT	Village Health Teams
VMMC	Voluntary Medical Male Circumcision
UVRI	Uganda Virus Research Institute
WHO	World Health Organization

1.0. Introduction

This section offers an overview of the HIV situation in Uganda, outlines the history of HIV testing services, and elaborates on the rationale for a National certification framework for HIV rapid testing sites and testers.

1.1 Situational Analysis of HIV and AIDS in Uganda

Uganda's HIV epidemic is described as mature, generalized, and heterogeneous. Heterosexual intercourse and mother-to-child are the main modes of transmission. HIV prevalence is 5.8% (7.2% among women and 4.3% among men), corresponding to approximately 1.3 million adults living with HIV in Uganda. HIV incidence among children 0–14 years declined from approximately 23,000 in 2010 to 5,300 in 2020. Despite the significant reduction in AIDS-related deaths from the year 2010 to 2020, females aged 15 years and above remain disproportionately affected, contributing to an estimated 9,100 AIDS-related deaths in 2020. The young women aged 15-24 years accounted for 79% of all new HIV infections among young people in the same year.

By the end of 2020, 81% of people living with HIV in Uganda were aware of their HIV status (UPHIA 2020/21)¹. Of these, 96.1% were receiving lifelong antiretroviral therapy (ART) while 92.2% of those on ART were virally suppressed.

1.2 HIV Testing Services in Uganda

HTS in Uganda began in 1990 with Voluntary Counselling and Testing (VCT) as the primary delivery approach.

The country developed its first VCT policy in 2000 to expand HIV testing coverage. The first policy review conducted in 2005 introduced Provider Initiated HIV Testing and Counselling (PITC) and Home-Based HIV Counseling and Testing (HBHCT) to supplement VCT. During this time, emphasis was placed on expanding entry points, scaling up HCT for children, utilizing Lay Providers, and community testing. Consequently, HIV Counseling and Testing (HCT) service points more than doubled from 554 sites in 2007 to 1,215 sites in 2009.

The second review in 2010 separated the HCT implementation guidelines from the HCT policy and aimed to enhance coverage for HCT services to achieve universal access. This review also facilitated the introduction of HTS into new programs, particularly Voluntary Medical Male Circumcision (VMMC), Most at Risk Populations (MARPs), special groups, and quality improvement (QI).

As a result, by the end of 2014, approximately 3,565 HTS sites were established nationwide. In 2016, the key focus was to align existing policy guidelines with the WHO 2015 HTS guidelines and the national HIV/AIDS strategic plan, as well as to address HTS-related legal issues arising from the HIV Prevention and Control Act 2014.

During this same period, Uganda adopted the 90-90-90 strategy and streamlined testing for children and adolescents. By the end of 2017, there were over 7,000 testing sites in the country. The increase in the number of testing points, along with the task-sharing of HIV rapid testing with non-laboratory professionals and insufficient supervision, led to several quality challenges regarding the accuracy and reliability of test results.

The Uganda Virus Research Institute is mandated by the Ministry of Health to coordinate HIV-related quality assurance programs and quality improvement processes for HIV rapid testing in collaboration with the Quality Assurance Department of the Ministry of Health. The UVRI quality assurance program initially targeted laboratory professionals.

However, the decentralization of HIV rapid testing at various testing points involving lay testers created a need to encompass all testers within the program. The national HIV External Quality Assessment (EQA) report for October to December 2023 indicates that the Proficiency Testing (PT) pass rate stands at 92.4%, with 7.6% of all testers providing inaccurate HIV test results.

In 2015, WHO recommended that individual countries develop mechanisms for assessing HIV testers and testing sites to enhance the quality of HIV rapid testing and ensure zero HIV misdiagnosis². Uganda adopted the WHO recommendation to certify all HIV rapid testers and testing sites as stipulated in the 2016 National HIV Testing Services Policy and Implementation Guidelines³. In 2018, Uganda developed its first certification framework for HIV rapid testing with the ultimate goal of ensuring accurate HIV results for every client seeking HTS services, and to date, nearly 25% of sites and testers have been assessed for certification, yielding several lessons learned.

In 2022, Uganda revised its HTS policy and implementation guidelines, emphasizing the scaling up of national certification of sites and testers to improve case identification in alignment with the attainment of the UNAIDS mandate of 95-95-95 by 2030.

1.3 The National Certification Program

Certification is the process by which an independent and authorized agency assesses the quality system of a facility/site and/or the competency of a provider based on certain pre-defined standards. Certification gives formal recognition that a facility/site or tester is authorized to carry out a specific task, such as HIV rapid testing for diagnosing HIV infections².

National certification programs are an effective way to ensure the reliability and accuracy of test results and encourage continuous quality improvement for HIV rapid testing. A successful certification program requires the involvement of stakeholders with specific roles at all levels.

The benefits of a National HTS Certification Program are listed below:

- Facilitates the implementation and maintenance of an effective quality management system
- Gives confidence to users in the services provided
- Gives confidence to the site and user for the results generated
- Provides recognition of technical competence
- Provides legal cover to the tester/testing site
- Reduces the operating costs of HIV testing by getting results right the first time and every time.

Certification is done at regular intervals to ensure the maintenance of standards. Provider certification verifies that the provider performing HIV rapid testing is adequately trained, is authorized to do so, has evidence of demonstrated competency, and that the testing sites adhere to minimum HIV rapid testing requirements.

1.4 Justification

The 2022 National HIV testing services policy and implementation guidelines and Uganda National Health Laboratory Services Strategic Plan 2021-2025^{5, 6} provide for tester and site certification as a key strategy to enhance the quality of HIV testing services.

Point-of-care testing (POCT) technologies have become widely available in the last few years and play a major role in achieving increased access to diagnostics. As access to POCT expands in low- and middle-income countries, there is a need for simple, practical, and low-cost innovative approaches to ensure sustainable quality assurance practices that lead to accurate and reliable HIV rapid test results and improved public health outcomes. However, challenges remain regarding the implementation of quality assurance programs.

In Uganda, a standardized national HIV rapid testing algorithm is recommended for use in the diagnosis of HIV⁵. Despite the many interventions put in place to strengthen the quality of testing, it is noted that gaps in quality assurance still exist, as observed in the national support supervision reports as well as the National EQA performance reports from UVRI.

During the implementation of the 2018 national certification framework for HIV rapid testing, there is notable quality improvement in both competency and standards of testers and sites, respectively. However, quality gaps still exist in HIV rapid testing, as evidenced by the proportion of testers and testing sites that met the certification requirements.

This revision, therefore, aims at strengthening the implementation of the framework by addressing the identified challenges, aligning with the current National HTS policy and implementation guidelines, and meeting the requirements for the current HIV testing modalities.

The certification program will continue to support testing sites and testers in improving and maintaining the quality of testing while leveraging existing resources. It will also provide clinical governance to support healthcare providers involved in testing. Clinical governance creates an enabling environment for healthcare providers to be accountable for providing quality HIV Rapid testing services and safeguarding high standards of care and excellence in clinical care. Implementation and maintenance of an HIV rapid testing site and tester certification program will add credibility to testing processes, provide means to ensure and monitor adherence to quality standards, and instill confidence in the results for patient care.

The national certification program for HIV rapid testing sites and testers provides an umbrella under which all aspects of quality HIV rapid testing will be gathered and continuously monitored. Site certification, together with regular on-site supervision, mentorship, and site audits, will be used as the key methods to meet and maintain the quality of HIV rapid testing in Uganda. Likewise, tester certification, along with standardized hands-on training and ongoing supervision and reassessment to ensure competency, will ensure accurate and reliable HIV rapid diagnostic results.

Quality improvement requires reassessing and addressing current weaknesses across all quality system essentials. Addressing the common quality-related causes of incorrect results and errors requires making concerted efforts at all levels to systematically improve and assure the quality of testing.

This document further underscores the need for strong leadership, dedicated funding for quality assurance, advocacy, innovations, and better coordination for continuous quality monitoring and improvement. This will result in increased uptake, coverage of quality practices, and access to accurate and reliable test results.

1.5 Purpose and Objectives

1.5.1 Purpose

The purpose of this document is to provide a framework for planning, designing, implementing, monitoring, and evaluating the national HIV rapid testing certification program for sites and testers.

This framework aims to:

- Provide a standardized coordination mechanism to achieve and maintain national certification of HIV rapid testing
- To set standards that should be followed to certify sites and testers for HIV rapid testing
- To guide the implementation approaches for site and tester certification of HIV rapid testing
- To guide the monitoring and evaluation of the national HIV rapid testing certification program

1.5.2 Goal of the framework

To ensure that sites and testers accurately and reliably perform HIV rapid testing as per the set national standards.

1.5.3 Objectives

- i) To increase the number of competent testers and certified sites for HIV rapid testing.
- ii) To maintain a transparent and robust certification process for sites and testers.
- iii) To ensure all sites and testers maintain their certification status for HIV rapid testing.

1.6 Scope and Target Audience

This framework applies to programs and organizations that implement HIV rapid testing in Uganda. It provides guidance for site and tester certification for HIV rapid testing conducted in both laboratory and non-laboratory settings. This applies to both public and private sectors across the different levels of service delivery.

This framework targets different stakeholders, including policymakers, HTS programmers and planners, AIDS development partners (ADPs) and donors, district health teams, health facility managers, facility HTS coordinators/supervisors and focal persons, Quality officers, HIV rapid testers, PLHIV and HIV activists, researchers and beneficiaries of HTS.

2.0 Uganda Certification Program

The national certification framework for Uganda details the governance and coordination structure, roles and responsibilities of stakeholders, standards for HIV rapid testing, the process of auditing and assessing for compliance, as well as monitoring and evaluation.

2.1 Governance and Coordination Structure

This section describes the governance and coordination structures for the implementation of the HIV rapid tester and site certification program. It encompasses the levels of governance, composition of the independent certification committee, certifying body, and their respective roles and responsibilities.

Uganda's certification framework benchmarks the National HTS and Quality Assurance coordination structures, and it is synchronized with the Health Sector Development Plan (HSDP)⁴. It comprises different stakeholders acting at different levels as below;

- National
- Regional
- District
- Facility
- Community

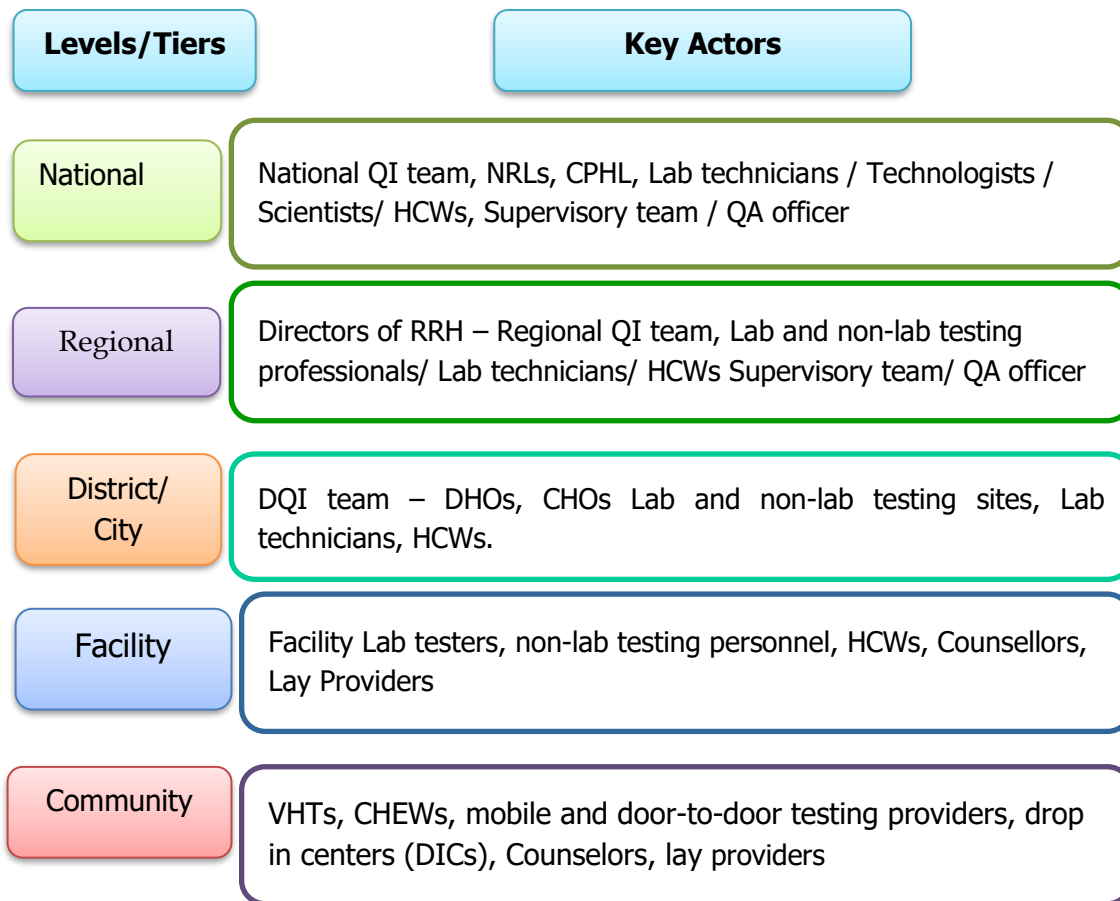


Figure 1: Levels of service delivery in Uganda

2.1.1 National Health Governance

National health governance refers to the Ministry of Health, technically headed by the Director General of Health Services (DGHS). The DGHS shall provide oversight for the HIV rapid testing certification program through the AIDS Control Program (ACP) HIV testing services unit. The NCTC, which provides technical guidance for various tasks, including quality assurance for HIV testing services, supports the HTS unit. Together with partners, the Ministry of Health shall mobilize resources for the certification program.

Independent Certification Committee

This shall be a multi-sectoral committee with diverse membership to increase objectivity, minimize bias, and address conflicts of interest. It will be comprised of technical people from the following institutions: UVRI, AHPC, NHLDS, ACP, QAD, CSOs, Ministry of Trade, Industry and Cooperatives, Uganda National Bureau of Standards, Ministry of Education, testers, Academia, NDA, Private practitioners, Uganda Healthcare Federation, UNHCO,

and PLHIV Networks. Members serving on this committee shall be assigned by the DGHS and MOH and will serve for a four-year term before new members are nominated. The recommending authority, upon satisfactory performance, may renew the four-year term for each member of the independent certification committee (ICC).

Certifying Body

Uganda Virus Research Institute is mandated by the Ministry of Health to ensure quality assurance for HIV rapid testing in Uganda. In this role, UVRI shall be the Certifying Body for HIV rapid testing sites, auditors, evaluators, and testers. UVRI will work closely with the ACP and the Quality Assurance Department of the MOH to fulfill its role in the certification program. The certifying body shall execute its roles with impartiality, irrespective of the setting (laboratory vs. non-laboratory), the testers' training background, and the organization's affiliation.

2.1.2 Regional level

The certification program shall leverage the existing regional health structures to provide support to respective regions, districts, health facilities, testers, and testing sites. At the regional level, the Director of the Regional Referral Hospital will be responsible for quality issues in a specific region, working very closely with the regional quality improvement committees. The regional implementing partner will supplement the mandate of the Regional Referral Hospitals.

2.1.3 District/City level

At the district and city/municipal levels, district and city/municipal health offices will work closely to support health facilities and testing sites. The following officers shall be essential in implementing this framework: District Health Officers (DHOs), City/municipal Health Officers, District and City Laboratory Focal Persons, and HTS Focal Persons.

2.1.4 Facility and HIV rapid testing site level

HIV rapid testing sites and testers are the primary target audience of the certification program and, therefore, play a critical role in a successful program. HTS focal persons working closely with the Laboratory focal persons and the facility quality improvement committee will perform managerial roles to ensure the quality of HIV rapid testing. Testers will be expected to adhere to the standard operating procedures.

Laboratory management shall hold ultimate responsibility for ensuring that appropriate processes and procedures are in place to monitor the quality and accuracy of POCT results. The laboratory shall establish appropriate training, coaching, mentorship, and supervision for POCT(s), including internal audits for conformity with the requirements of quality.

2.1.5 Community

VHTs, CHEWs, mobile and door-to-door testing providers, drop-in centres (DICs), Counselors, and lay providers who offer testing within the facility or community shall follow the standard for certification of both testers and POCTs as guided by this document. The standards of the Point of Care Testing sites within the facility and community setting must be organized, and operations must follow guidelines, including considerations for training, mentorships, coaching, audits, and evaluations.

Each stakeholder will have specific roles and responsibilities, as detailed in section 2.2 below. The coordination structure for the certification program for HIV rapid testing is summarized in the figure below.

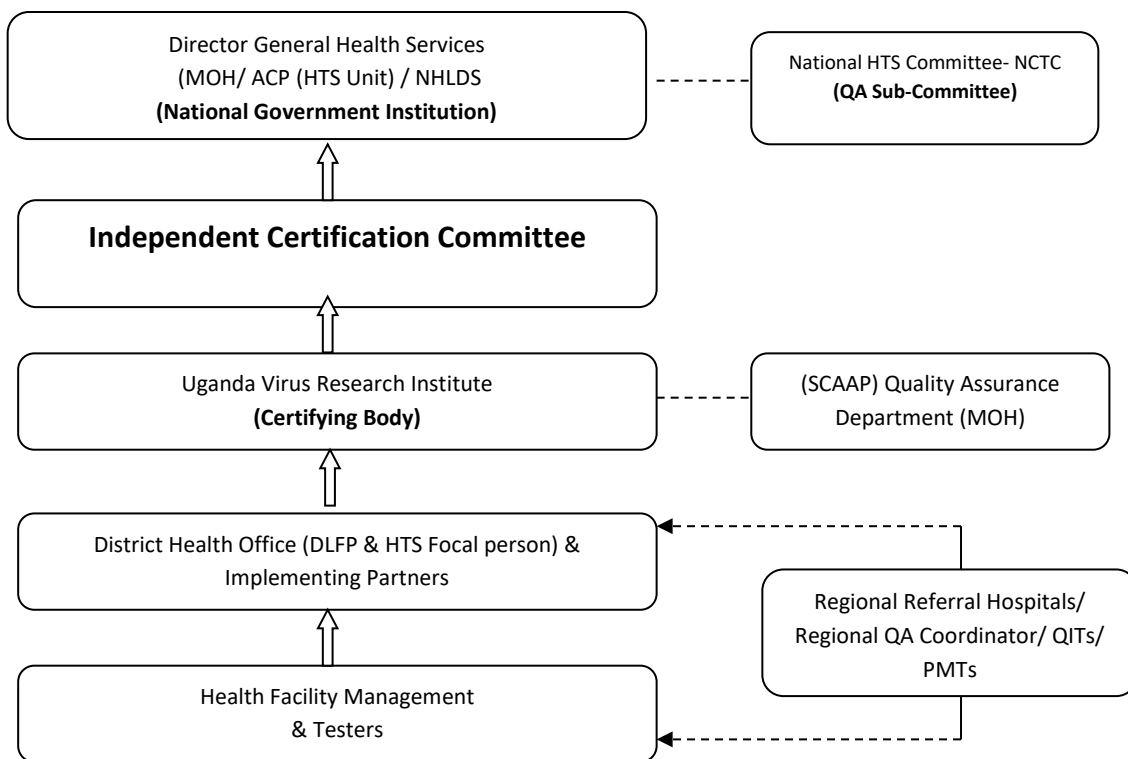


Figure 2: Governance and coordination structure for the HIV rapid testing site and tester certification

2.2 Roles and Responsibilities of Stakeholders

Different stakeholders will perform specific roles at different levels, as detailed in Table 1 below.

Table 1: Roles and responsibilities of stakeholders

Stakeholder	Roles and Responsibilities
National Level	
<p>The National Government institution (Ministry of Health)</p>	<p><u>Oversight and guidance</u></p> <ul style="list-style-type: none"> • Policy formulation and review • Identify a certifying body • Establish a certification committee <p><u>Setting implementation guidelines</u> (standards)</p> <ul style="list-style-type: none"> • Site-Certification standards • Personnel evaluation criteria • Development and review of the Training Curriculum • Advocate for sites and personnel certification by disseminating the standards and requirements for certification <p><u>Coordination & Supervision</u></p> <ul style="list-style-type: none"> • Overseeing testers’ training and refresher training • Overseeing the auditors' and evaluators' training • Certification and decertification • Developing roll-out plans with clear timelines • Coordination of implementing Partners and Development Partners <p><u>Monitoring and Evaluation</u></p> <ul style="list-style-type: none"> • Design data collection tools • Data quality checks • Monitoring data access to ensure data security • Review quarterly reports and give timely feedback <p><u>Resource Mobilization</u></p> <ul style="list-style-type: none"> • Partner coordination for efficiency • Advocacy for resource allocation
<p>Certifying Body (UVRI)</p>	<p><u>Implement standards</u></p> <ul style="list-style-type: none"> • Implementation of the framework • Ensure compliance with quality standards for the certification program. • Identify and train national auditors and evaluators. • In collaboration with MOH, provide oversight to facility-based internal audits and internal audit training • Support regions to train intra-district HIV site auditors and tester evaluators <p><u>Conduct Site Audits and Tester evaluation</u></p> <ul style="list-style-type: none"> • Develop and share a schedule for site Audits and tester Evaluation • Audit sites and assess testers for certification • Manage and ensure the conflict of interest among auditors and evaluators • Respond to complaints resulting from the audit and evaluation process <p><u>Reporting, Monitoring, and Evaluation</u></p> <ul style="list-style-type: none"> • Develop corrective and remedial actions and share with testers for follow-up • Submit quarterly progress reports to MOH • Ensure controlled access while maintaining the security and privacy of certification data or information • Maintain and update a robust certification database (Testers and testing sites, auditors, evaluators) and related certification information to support decision making.

Stakeholder	Roles and Responsibilities
	<ul style="list-style-type: none"> • Generate and submit audit information/reports to the ICC • Organize Quarterly review meetings for the ICC • In collaboration with MOH-ACP, document and ensure implementation of recommendations from ICC • Disseminate approved certificates to sites and testers • Seek feedback on the certification results from site testers and other users • Conduct semiannual review meetings for the implementation of certification with key stakeholders <p><u>Disciplinary action</u></p> <ul style="list-style-type: none"> • In case of non-compliance, UVRI will recommend disciplinary action to the independent certifying committee.
Independent Certification Committee (ICC)	<p><u>Validation of certification processes</u></p> <ul style="list-style-type: none"> • Verify audit reports • Provide an independent opinion on the performance of sites & testers presented for certification • Recommend sites and testers to the DGHS office for certification and decertification • Evaluate the performance of the auditors <p><u>Conflict Resolution</u></p> <ul style="list-style-type: none"> • Address complaints from sites and testers, and other conflicts within the certification process • Receive and manage appeals arising from users of the certification program • Ensure impartiality through the audit process
Regional	
Office of the Director of Regional Referral Hospital (RRH)	<p><u>Coordination</u></p> <ul style="list-style-type: none"> • Mentorships to the districts • Data quality checks • Generate quarterly reports and submit them to the certifying body • Coordinate HIV testing supplies in the region <p><u>Quality Assurance</u></p> <ul style="list-style-type: none"> • Develop site-specific quality improvement plans • Provide technical support to the regional quality improvement teams • Perform competency assessments for the DLFPs in the regions
District/City	
District Health Office (DHO) City Health Office (CHO)	<p><u>Supervision</u></p> <ul style="list-style-type: none"> • Supervision and mentorship of testing sites within the district <p><u>Coordination</u></p> <ul style="list-style-type: none"> • Coordination of different implementing partners • Notification to the certifying body of any testing site(s) that need the certifying body's intervention <p><u>Monitoring and Evaluation</u></p> <ul style="list-style-type: none"> • Data Quality Assessment • Monitor site & tester performance <p><u>Quality Improvement</u></p> <ul style="list-style-type: none"> • Develop quality improvement plans for the District Health Team (DHT) • Conduct intra-district audits before National site audits • Supervise QI Activities

Stakeholder	Roles and Responsibilities
Health facility	
Health facility managers	<p><u>Quality Improvement</u></p> <ul style="list-style-type: none"> • Ensure all HIV rapid testing sites implement comprehensive CQI and prioritize sites for enrollment in the certification program. • Ensure sites meet minimum requirements for site certification • Promote and discuss the benefits of CQI towards site and tester certification and the national requirements for certification. • Ensure implementation of internal audit program activities • Conduct periodic reviews of certification-related activities, e.g., Internal audits using the SPIRT checklist, participation of testers in EQA, training, and CPDs to both laboratory and POCT testers • Quarterly supervision of POCT HIV sites • Maintenance of schedules for site and tester audits for certification <p><u>Adherence to National Standards</u></p> <ul style="list-style-type: none"> • Develop SOPs in line with national standards • Ensure adherence to the national HTS standard • Select and train teams to conduct internal audits using appropriate tools and address all gaps through training of staff and development of necessary corrective actions. <p><u>Advocacy</u></p> <ul style="list-style-type: none"> • Create awareness among personnel about site and tester certification requirements. <p><u>Monitoring and evaluation</u></p> <ul style="list-style-type: none"> • Conduct Risk assessment and manage identified risks related to assessments at the facility. • Maintain records of certification and competency assessments at the facility • Data capture and verification
Testers	<ul style="list-style-type: none"> • Conduct HIV rapid testing to ensure reliability and accuracy for certification • Perform HIV rapid testing using applicable national guidelines, policies, and regulations • Utilize appropriate tools available for self-assessment (e.g., SPI-RT) for CQI • Summarize audit findings and corrective actions in a report and submit it to the laboratory in charge. • Maintain updated registers of all clients tested and shared as required. • Maintain certification standards
Implementing Partners (IPs)	<p>Training</p> <ul style="list-style-type: none"> • Support training for sites and testers • In collaboration with MOH and the certifying body, train intra-district auditors and evaluators • Training of facility internal auditors <p>Quality Improvement</p> <ul style="list-style-type: none"> • Support CQI activities at the regional and district level • Support implementation of corrective and remedial action • Provide technical support in the certification process • Facilitate mock/intra-district audits
AIDS Development Partners (ADPs)	<ul style="list-style-type: none"> • Provide financial support • Provide technical assistance

3.0 Standards for certifying HIV Rapid testing sites and testers

The result of a laboratory test, performed within or outside the laboratory, is an essential and life-saving support within the health care system. Therefore, quality-assured testing of all samples is critical for decision-making in patient care management. International standards are now widely used in implementing quality in developed countries as well as developing countries. ISO 15189:2022 provides specific requirements for POCT regarding quality testing and competency of testers. The standards to certify HIV rapid testing sites and personnel will thus be based on this standard.

Uganda adopted the WHO Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) for the HIV rapid testing site certification. A question bank has been developed with an HTS-related context from which theoretical examinations will be set, coupled with practical examinations to assess personnel competency.

3.1 Quality Standards for HIV Rapid Testing

This encompasses quality standards for HIV rapid testers and sites.

3.1.1 Quality standards for HIV rapid testing sites

An HIV rapid testing site refers to a location where point-of-care testing is performed with rapid diagnostic devices. Each site should have minimum quality standards to provide safe and effective HTS, which include:

a) Physical facilities

The physical facility/site should have:

- Adequate space, lighting, and environmental control (temperature and humidity)
- Organized and clean workspace
- Secure storage facilities for reagents, supplies, and equipment

b) Safety

The site should have organized systems and processes in place, providing for the safety of staff, clients, and the community.

- Documented procedures for:
 - Handling and disposal of bio-hazardous materials and safety in the workplace
 - Manage spills of blood and other body fluids
 - Post-exposure prophylaxis (PEP)
- Have facilities for safe waste management
- Clean Water and Soap
- Have appropriate disinfectants

- PPE should be available, properly and consistently used
- Have and maintain appropriate first aid material
- All testing personnel trained on handling bio-hazardous material, workplace safety, and spill management, evidenced by documentation of these trainings

c) Pre-testing phase

The testing site should have a standardized system for client handling and identification, specimen collection and processing, and records of patient/specimen information. The site should have:

- National HTS guidelines specific to the program
- National HIV rapid testing algorithm in use
- SOPs and/or job aids in place for HIV rapid tests used in the testing algorithm
- Nationally approved HIV rapid kits within the expiration dates
 - Kits labeled with the date opened, "in use," and initials
- A stock management process (stock cards, order forms & inventory)
- Job aids on client sample collection are available and posted at the testing point
- Nationally approved HMIS tools for HTS

d) Testing phase

The testing site should provide a standardized system to perform HIV rapid testing and include QC testing and troubleshooting guidelines. There should be:

- SOPs and/or job aids on HIV rapid testing procedures are posted at the testing points and adequately followed
- Timers are routinely used for HIV rapid testing
- Positive and negative quality control (QC) specimens are routinely used (e.g., bi-weekly, when new lots and batches are received and when environmental changes are recognized) according to country guidelines
- QC results properly recorded, including the invalid QC result where applicable.

e) Post-testing phase

The testing site should have a standardized system for HIV rapid testing results to be recorded and reported, with a provision for recording QC results. An HIV rapid testing site should have:

- A daily activity register for recording HIV tests with all the key quality elements captured correctly;
 - with total summaries at the end of each page compiled accurately
 - With invalid test results recorded, including repeated tests where applicable
- Client documents and records are securely kept throughout all phases of the testing process.

- Registers/logbooks and other documents are kept in a secure location when not in use.
- Registers/logbooks are properly labeled and archived when full
- QC records are routinely reviewed by the person in charge

f) External Quality Assessment

All personnel providing HIV rapid testing must demonstrate proficiency by participating periodically in EQA/PT. Quarterly supervisions and mentorships at national, regional, district, and facility levels should be conducted, and reports should be generated to inform corrective action where applicable.

- The testing point should be enrolled in an EQA/PT program
- All testers at the testing point should participate in EQA/PT and attain satisfactory results
- In-charge at the testing point should review the EQA/PT results before submission to NRL
- EQA/PT feedback received from NRL should be reviewed by testers and/or those in charge at the testing point
- Testing point should implement corrective action in case of unsatisfactory results
- All HIV rapid testing points should receive quarterly supervisory visits and documented feedback

3.1.2 Certification requirements for HIV rapid testers

- All HIV rapid testers should have a minimum educational background of at least 'Ordinary level' or its equivalent
- All testers MUST be trained and deemed competent in HIV rapid testing using the MOH-approved curriculum
- All testers MUST pass a final assessment of HIV rapid testing in both theory (with a minimum of 80%) and practical (100%)
- Must be evaluated for competency every three years
- HIV testers should regularly update their knowledge through refresher and in-service training

3.1.3 Certification requirements for auditors and evaluators

a) HIV certification requirements for an auditor

- Must be a qualified medical laboratory professional.
- Must be a certified HIV rapid tester.
- Must be trained and qualified in SPI-RT fundamentals.
- Must be successfully evaluated for competency every three years
- Must know about laboratory quality management systems (LQMS)

b) HIV certification requirements for an Evaluator.

- Must be a qualified health professional.
- Must be a certified HIV rapid tester
- Must be successfully evaluated for competency every three years
- Must be trained using the evaluators' curriculum and qualified

c) HIV Certification requirements for Trainers of Testers (TOT)

- Should be certified HIV rapid tester
- Should be qualified in medical laboratory science (minimum of a Diploma)
- Should have at least three years of experience in laboratory practice
- Should be in active health practice
- Should have good facilitation and communication skills.
- Should be knowledgeable in the National HTS policy.
- Should be periodically evaluated for competence.

3.1.4 Implementation of Certification.

The implementation describes the process of assessments/audits of the testers and testing sites, certification, decertification, recertification, monitoring, and evaluation.

i) Site certification process

- Enroll sites in the certification program
- Conduct intra-district audits
- Results from intra-district audits will determine the next step
 - If sites attain certification scores or near certification scores (>80%), national audits will be conducted
 - For sites that attain scores <80%, corrective actions will be implemented quarterly & intra-district audits will continue to ensure they meet the target.
- Sites attaining scores above 80% from the intra-district audits will be eligible for National audits for certification
- If National audits are completed, reports will be submitted to the Independent Certification Committee for final decision regarding certification
- Sites that are eligible for certification (scoring >90%) will be certified
- Sites with scores <90% will be given three months for improvement before another National audit is conducted
- Upon successful scores, sites will be certified

ii) Frequency of HIV Rapid Testing Site Assessment

Site Assessments will be conducted at the intra-district and national levels, as indicated in the table below.

Table 2: Frequency of site assessments

TYPE OF AUDIT	DESCRIPTION	FREQUENCY			
		Initial	Quarterly	Semi-Annual	Every three years
Intra-district audit	<i>This will be performed by certified auditors within the district.</i>		✓		
National audit	<i>The certifying body performs the site audit for certification and recertification.</i>	✓			✓

iii) Decertification and recertification of an HIV rapid testing site

Decertification

Testing sites may be decertified within three years or after the expiry of the three-year certification period.

- Scenarios under which decertification may occur include:
 - Closure of the site due to regulatory non-compliance
 - Cessation of HIV rapid testing at a particular site
 - Failure to participate in HIV-EQA programs for four consecutive PT cycles

Recertification

Sites that are decertified can be recertified upon corrective action and passing the certification criteria. The flow chart below describes the process of HIV rapid testing site certification, de-certification, and re-certification.

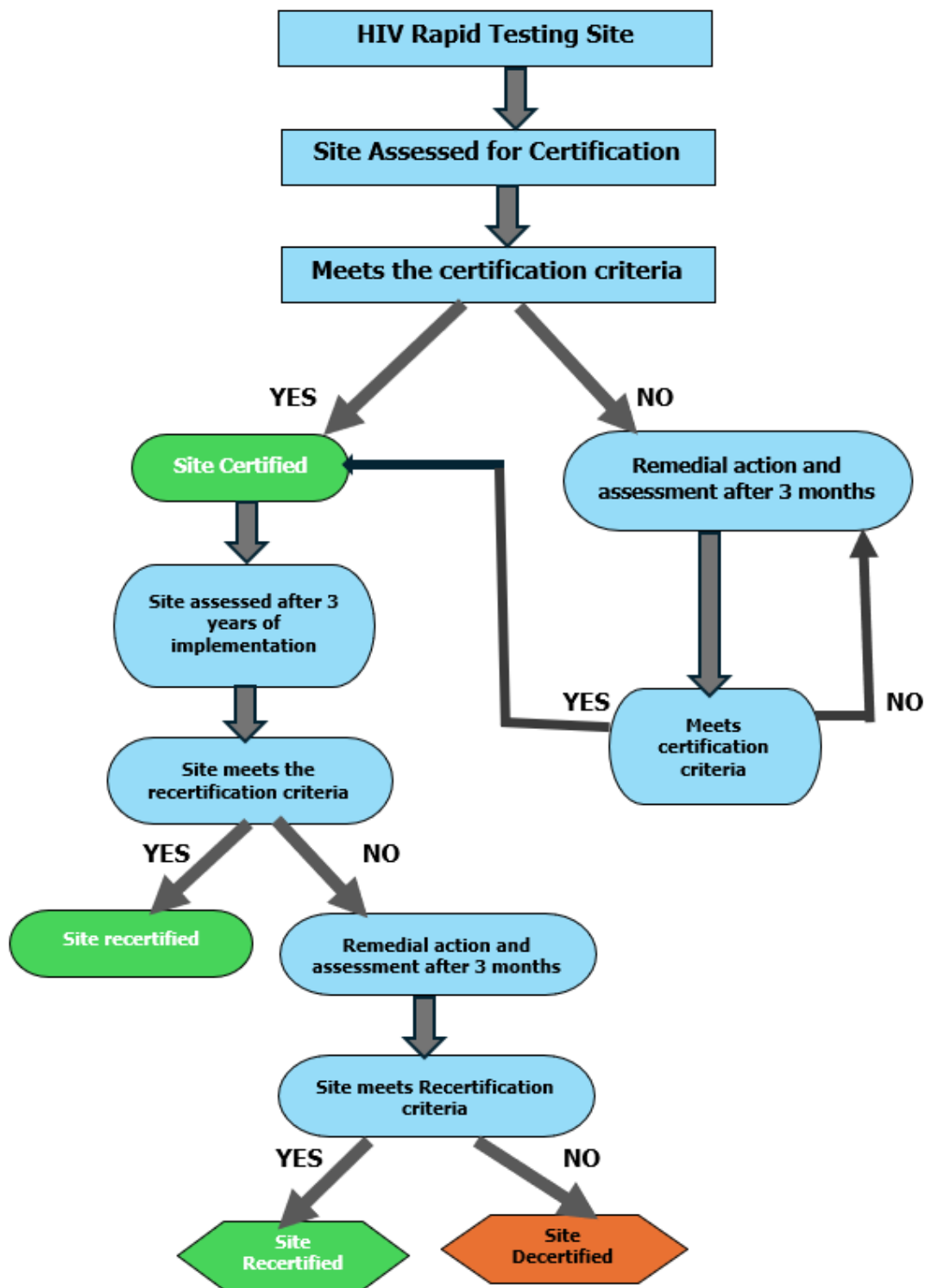


Figure 3: Process of HIV rapid testing site certification, de-certification, and re-certification

3.1.5 Tester certification process

1. Enroll Tester for certification
2. Subject tester to certification examinations (theory & Practical)
 - Pass mark for theory/written exams should be $\geq 80\%$
 - The practical examination will be in two forms
 - Using (Dried Tube Specimen (DTS) samples (100% pass mark)
 - Direct observation of testing process ($\geq 90\%$ pass mark)
3. A tester who scores the above-defined pass marks will be eligible for certification
4. Failure to score the pass marks will lead to the initiation of appropriate remedial actions for three months before re-assessment. HIV Rapid testing will be performed by the tester under the supervision of a certified tester.
5. A tester who does not attain the pass mark will be given three opportunities to be reassessed within three years
6. If the tester does not pass after three consecutive evaluations, he/she shall cease to perform HIV Rapid tests.

An illustration of the tester certification process is shown in Figure 4 below.

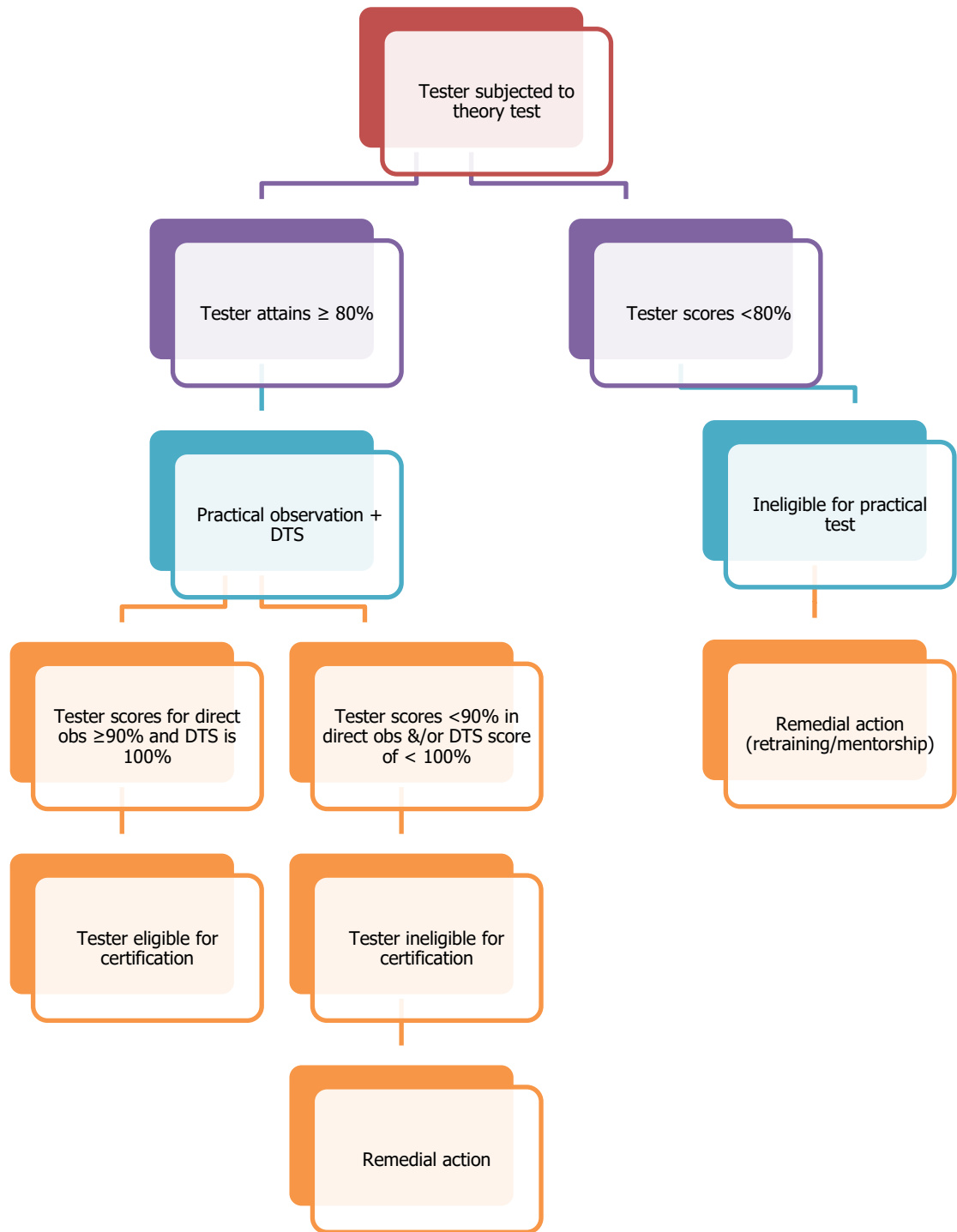


Figure 4: Tester certification process

3.1.6 Decertification of a tester

Decertification of testers may occur within two years or when the certification expires. Decertification may occur in the following scenarios;

- If the tester does not participate in the HIV rapid test PT panel for two years
- Tester participates but fails two consecutive HIV rapid test PT cycles.
- Tester exhibits behavior contrary to the ethical code of conduct.

3.1.7 Recertification of HIV Rapid Testers

Testers who are decertified can be recertified upon completion of remedial action and passing the certification criteria. The flow chart below describes the process of HIV rapid tester certification, de-certification, and re-certification.

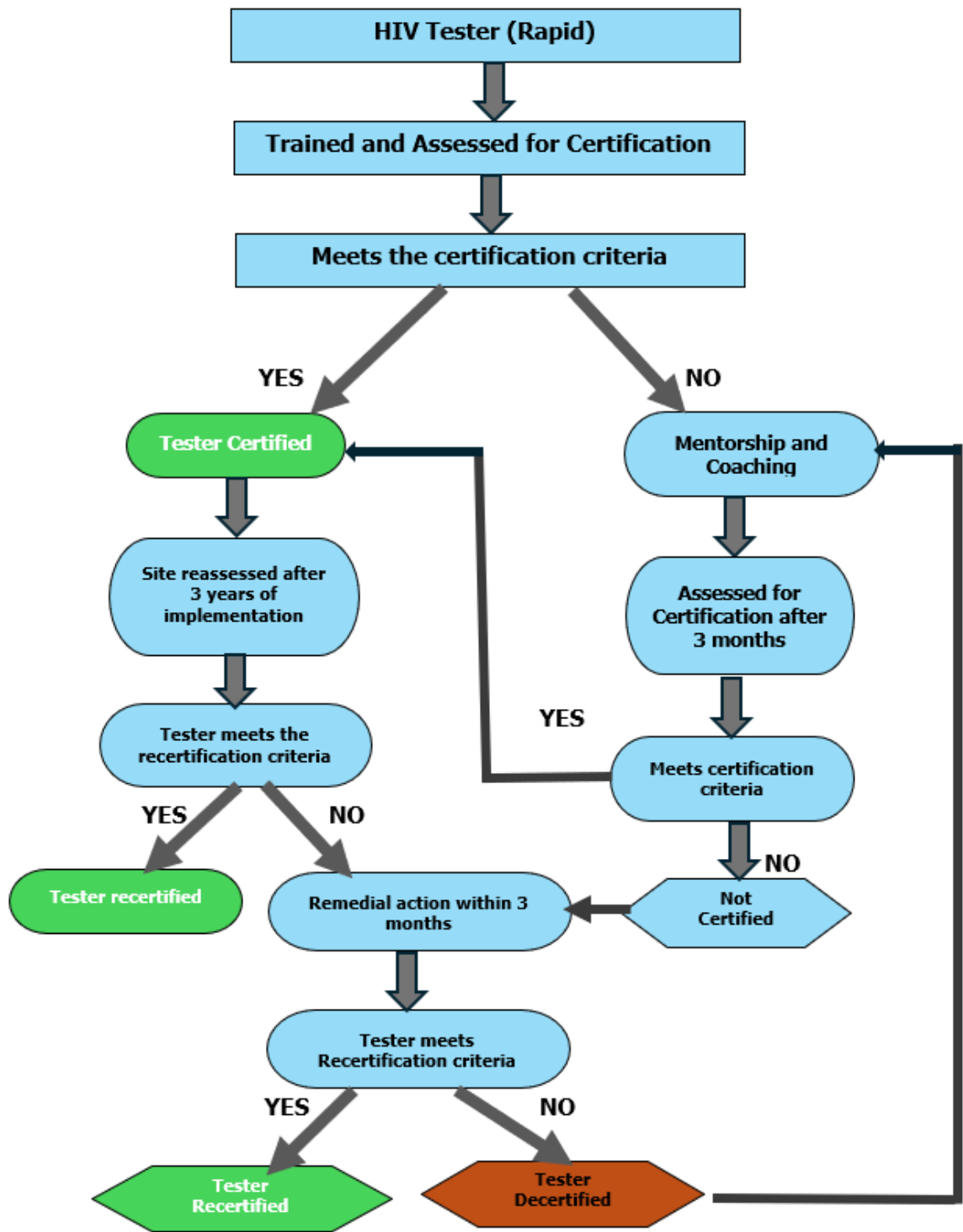


Figure 5: Process of HIV rapid tester certification, de-certification and re-certification

3.1.8 Auditor Certification Process

Auditors for site certification shall be identified as experienced medical laboratory practitioners who have undergone relevant site audit training.

- Auditors shall be trained using an approved curriculum
- They will be subjected to practical and theoretical examinations
- To certify a trainee as an auditor, an average score of 80% in the theory exam and $\geq 90\%$ in practical auditing skills must be attained. Certification will expire in three years.
- Re-certification of auditors will be after three years. An auditor will be expected to audit at least 20 sites within three years.

3.1.9 Certification of Evaluators

Evaluators for tester certification shall be identified from experienced health professionals who have undergone relevant tester Evaluation training. Recertification will be every two years based on the following;

- Successful completion of 50 tester evaluations within two years.
- Passing the evaluator competence assessment

4.0 Maintenance of site and tester certification.

This will be done using the following approaches;

a) Mentorship

A national mentorship guide is to be used at the site by:

- Quality officers
- Trainers of testers
- Auditors
- Experienced POCT testers

NB: The site should be mentored at least quarterly, and there should be mentorship reports.

b) Support Supervision

This shall be conducted quarterly using the national support supervision tool.

c) Continuous Education

Testers shall undergo refresher training. They will be expected to participate in continuous professional development (CPD) by the nationally approved curricula.

d) Participation in HIV EQA

All testers must participate in and pass the national HIV PT program at least once a year.

e) Competency Assessments

The competency of the tester shall be assessed at least once a year based on their PT performance.

4.1 Maintenance of certification for evaluators

- Must evaluate at least 50 HIV rapid testers in two years.
- Must undertake refresher training in the evaluators' course every two years.
- A fellow evaluator to conduct a spot check once a year to ensure the reliability of assessment results (Peer-to-Peer review).
- An independent committee will review the evaluator's assessment reports once a year to ensure objectivity.

4.2 Maintenance of certification for Auditors

- Auditors must audit a minimum of 20 HIV rapid testing sites every two years.
- Must undertake refresher training in SPI-RT every two years
- Must participate in mentorship training every two years
- A fellow auditor must conduct a spot check once a year to ensure the reliability of audit results.
- An independent committee will review the auditor's reports once a year to ensure objectivity.

4.3 Partnerships in Supporting National Certification Program

This framework recommends a multi-stakeholder approach at all levels. Key partnerships should be established involving:

- CBOs
- Political leadership
- Implementing partners
- CSOs
- Development partners
- Professional bodies
- Religious sectors
- Training institutions
- Other relevant ministries/agencies

5.0 HIV Rapid Testing Continuous Quality Improvement Activities

Continuous Quality Improvement (CQI) is a process that ensures that the certification program is systematically and intentionally improving and increasing positive outcomes for HTS provided to clients. CQI is a cyclical, data-driven, proactive, and not reactive process. The CQI program will follow a typical plan-do-check-act (PDCA) cycle and should be conducted across the tiered testing cascade from laboratories and POCTs, including community-based testing sites. The following CQI activities should be conducted across the levels of service delivery from National to sub-national as guided below;

i) National Level

- Quarterly support supervision, and mentorships
- Organize initial and refresher training for National auditors, evaluators, and trainers
- QMS training, e.g., Management of Non-conformities and corrective action, Management reviews, auditing course for district and regional supervisors, Training in the use of SPIRT checklist for auditing, and tester evaluation techniques
- Conduct Data Quality Assessments for HIV testing records
- Post-market surveillance and customer satisfaction surveys
- National performance review meetings (semi-annually)

ii) Regional level

- Training and refresher training for testers
- Support supervision and mentorships to include monitoring of EQA
- Support intra-district site audits for improvement using the SPIRT checklist
- Regional performance review meetings (Quarterly)

iii) District/City/Municipal level

- District-level support supervision by DLFPs and CLFPs, including monitoring EQA performance
- Conduct intra-district/mock audits of sites enrolled in the certification program
- Support follow-up for corrective/remedial actions
- Conduct Quarterly review meetings

iv) Facility Level

- Conduct periodic internal audits
- Design & conduct quality improvement projects
- Conduct scheduled CPDs, including the POCT staff
- Laboratory quarterly supervision to POCT

- Testing and monitoring of the performance of test kits- testing using QC materials
- Conduct periodic site-level performance review meetings to include HIV rapid testing
- Participation in EQA

v) Community testing sites (DICs, Outreaches)

- Participate in quarterly supervisions
- Participate in training for HTS and safety practices

6.0 Monitoring and Evaluation

6.1 Introduction

Establishing an effective monitoring and evaluation system will ensure that the tester and site certification program meets its objectives and, subsequently, its goal, and will be used to determine the progress of the HIV rapid testing certification program in ensuring that every person tested receives accurate results. The M&E system articulates measurable program objectives, a structured set of indicators, and provisions for collecting data. This section describes the monitoring and evaluation plan for the certification framework and details the objectives, inputs, outputs, and means of verification, as below.

Table 3: Monitoring and Evaluation Matrix

LEVEL	EXPECTED RESULT	INDICATORS	BASELINE	TARGET Year 1	TARGET Year 2	TARGET Year 3	TARGET Year 4	FINAL TARGET Year 5	The data source of verification	Comments
IMPACT	Improved accuracy and reliability of HIV rapid testing	The proportion of HIV rapid testers who participated and passed the PT.	92.4%					100%	Impact assessment report	To be conducted at the end of 5 years
Objective 1: To increase the number of competent testers and certified sites for HIV rapid testing										
OUTCOME 1.1	Increased availability of competent personnel and sites for HIV rapid testing	The proportion of HIV rapid testers certified	TBD	40%	40%	60%	90%	90%	Annual Tester evaluation reports	
		Proportion of HIV rapid testing sites certified	TBD					90%	Annual site assessment reports	
OUTCOME 1.2	Increased conformity of HIV rapid testing sites to the set standards	Proportion of sites audited and certified	40%	50%	90%	90%	90%	90%	Annual site assessment reports	
Output 1.1.1	Evaluators trained	Number of evaluators trained	96	100	100				UVRI Training Reports	25 trained per quarter
Output 1.1.2	Testers trained and deemed competent	Number of testers trained and deemed competent	TBD	3000	3000	3000	3000	3000	IP training reports, Mentorship and support Supervision reports	Initial testers trained in the first and second years will need retraining
Output 1.1.3	Testers evaluated for certification	Number of testers evaluated for certification	TBD	3000	3000	3000	3000	3000	tester evaluation reports	
Output 1.1.4	Sites audited for certification	All targeted sites audited	TBD	100%	100%	100%	100%	100%	Site audit reports	At least 1000 sites per year

LEVEL	EXPECTED RESULT	INDICATORS	BASELINE	TARGET Year 1	TARGET Year 2	TARGET Year 3	TARGET Year 4	FINAL TARGET Year 5	The data source of verification	Comments
Output 1.1.5	Site auditors trained (refresher)	Number of site auditors trained	TBD	20	20	20	20	20	Training reports	
Output 1.1.6	Supportive supervision and mentorship visits were conducted	Proportion of sites supported and mentored	TBD	100%	100%	100%	100%	100%	Support supervision reports	Any site should be visited at least once a year
Output 1.1.7	Intra-district audits conducted	Proportion of districts conducting audits	TBD	100%	100%	100%	100%	100%	Annual intra-district audit reports	Each site should have been 'mock audited' at least once a year
Output 1.2.1	Testers actively participating in the HIV rapid test PT with satisfactory passing.	Proportion of testers who participate in HIV RT PT and return results	76.7%	80%	85%	100%	100%	100%	UVRI-HRL Quarterly reports	
		The proportion of HIV rapid testers who participate and pass the PT.	92.4%	100%	100%	100%	100%	100%	UVRI-HRL Quarterly reports	
Output 1.2.2	Internal Quality Control for HIV rapid test kits done at the facility	Number of facilities conducting monthly IQC	TBD						Daily activity logs, Supportive supervision visit reports (IPs, UVRI, NHLDS, MOH)	Each facility should conduct IQC at least once a month.
Objective 2: To maintain a transparent and robust certification process for sites and testers										
OUTCOME 2	Transparent and robust certification	The proportion of eligible testers certified	TBD	100%	100%	100%	100%	100%	Minutes of ICC meetings	

LEVEL	EXPECTED RESULT	INDICATORS	BASELINE	TARGET Year 1	TARGET Year 2	TARGET Year 3	TARGET Year 4	FINAL TARGET Year 5	The data source of verification	Comments
	process for testers and sites	Proportion of sites certified	TBD	100%	100%	100%	100%	100%	Minutes of ICC meetings	
Output 2.1	A system is in place to address appeals and complaints from testers and sites.	The proportion of complaints received and addressed by the ICC	TBD	100%	100%	100%	100%	100%	Complaint Resolution Records	
Output 2.2	Clear certification criteria and standards are available	Guidelines, protocols, and requirements for certification are publicly available	TBD						MOH Website,	Yes/ No. Indicators will be assessed during the evaluation.
Output 2.3	ICC meetings conducted	Number of ICC meetings conducted	3	4	4	4	4	4	Minutes of ICC meetings	The ICC should meet once every quarter
Output 2.4	National performance review meetings are conducted	Number of national performance review meetings conducted		2	2	2	2	2	Meeting minutes	Meetings to be held semi-annually
Output 2.5	Regional performance review meetings are conducted	Number of regional performance review meetings conducted		16	16	16	16	16	Meeting minutes	Meetings to be held quarterly
Objective 3: To ensure all certified sites and testers maintain certification status in HIV rapid test results.										
Outcome 3	Consistent certification status of sites and testers	Proportion of certified sites that maintain their certification status							Re-certification reports	
		Proportion of certified testers that							Re-certification reports	

LEVEL	EXPECTED RESULT	INDICATORS	BASELINE	TARGET Year 1	TARGET Year 2	TARGET Year 3	TARGET Year 4	FINAL TARGET Year 5	The data source of verification	Comments
		maintain their certification status								
Output 3.1	Regular audits of testing sites are conducted	Number of testing sites audited							Quarterly Site audit reports.	
Output 3.2	Comprehensive records of certification and recertification for all testers and sites are maintained.	Up-to-date certification records are available.							Tester and site assessment reports, ICC meeting minutes	
Output 3.3	Refresher training for testers conducted	Number of testers trained							Training reports	

6.2 Monitoring

Performance monitoring shall be conducted routinely for personnel, sites, and HIV rapid testing processes. The following indicators should be tracked every quarter and reported as part of the quarterly reporting processes in the country.

The target is to certify 90% of the sites and 90% of the testers by 2029.

6.2.1 Indicators for monitoring personnel and sites

The indicators for tracking the performance of sites and testers are highlighted in Table 3 above.

6.2.2 Reporting/Data Flow

A standard reporting template will be designed for reporting. The tool shall incorporate elements from the internal, district, and national tools.

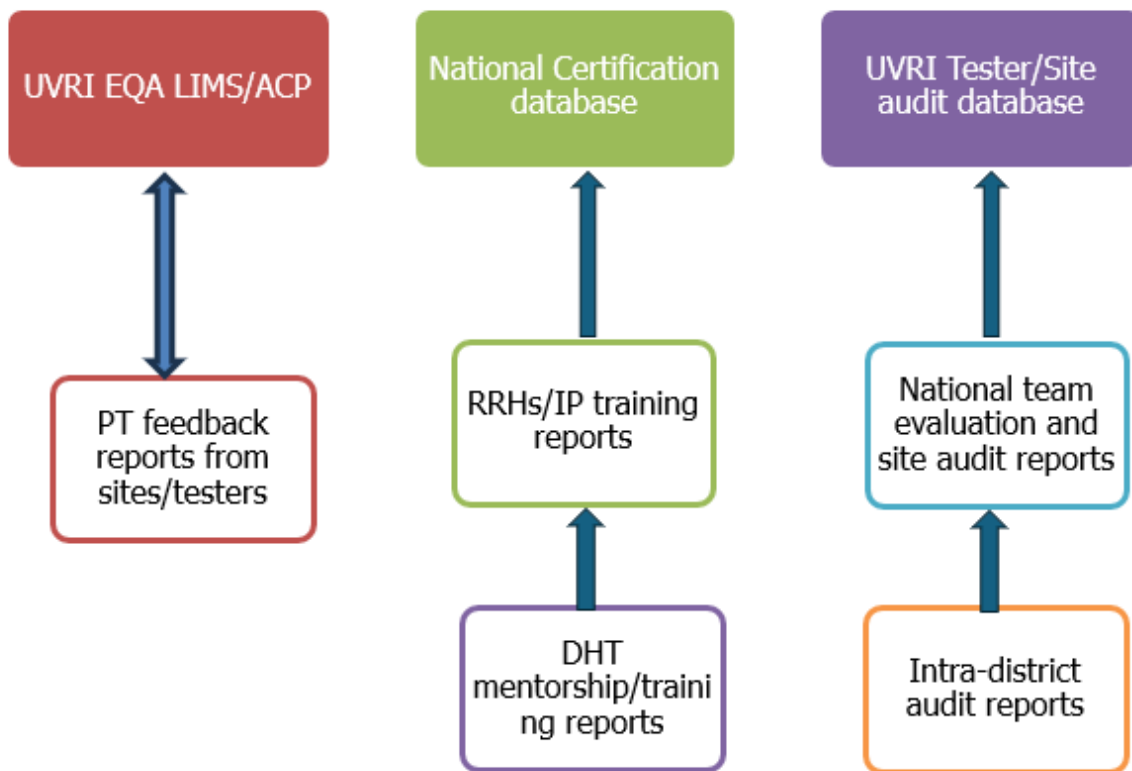


Figure 6: Reporting and Data Flow

6.2.3 The following reports will be generated

Site level

- Corrective action reports
- Internal audit reports from sites (quarterly)

District level

- District Audits report to UVRI (quarterly)
- Corrective action reports

Regional level (RRHs)

- Support supervision and mentorship reports(quarterly)

National level (UVRI/MOH-ACP)

- Corrective action reports
- Site audit reports (annually)
- Tester evaluation reports (annually)
- Training reports (annually)

6.2.4 Data security and confidentiality

A database shall be used to track the certification processes. UVRI will host the mother database, which will include all sites, auditors, and testers, irrespective of their certification status. This database will be accessible to MOH and other stakeholders. Additionally, records of all HTS training will be kept in the National certification data hosted by UVRI. The national certification system shall allow interoperability with other National QA systems/dashboards.

The Database administrators will update and ensure the security of the databases, issue access rights, and generate quarterly reports for stakeholders.

6.2.5 Evaluation

The systematic and objective assessment of the program will follow the following criteria;

- **Relevance:** If the plan makes sense to various stakeholders, including frontline health workers who are implementing HTS.
- **Effectiveness:** The use of the plan as a guide leads to the intended results of targeted HIV testing with maximum yield.
- **Efficiency:** Testing the right clients comes with enormous benefits, ranging from efficient use of HR time, reduced costs per identification through testing fewer clients.
- **Impact:** If the use of the plan has contributed to ending the epidemic.

- **Sustainability:** Optimized testing can continue for years after the plan has been implemented

Evaluation will be done as part of the annual program reviews, including review and update of program targets at the following intervals.

- Midterm after 3 years
- End term – at the end of 5 years

6.2.6 Financing the Program

The Government of Uganda, through the Ministry of Health, will finance the implementation of this program. MOH shall lead resource mobilization efforts with development partners to support the rollout and implementation of this program at the National and sub-national levels.

7.0 Communication Plan

This plan describes how information on HIV rapid testing Certification shall be transmitted to different stakeholders within the right timeframe. It will take into account the goal, objectives, message themes, activities, different channels and modes of communication, as well as the desired outcomes to facilitate successful HIV rapid testing certification processes.

7.1 Goal

To guide the design, dissemination, implementation, and evaluation of the communication process in promoting the HIV rapid testing certification program. This plan will ensure that all relevant stakeholders are effectively informed, engaged, and aligned with the objective of the HIV rapid tester and site certification framework.

7.2 Objectives

- To create awareness among all stakeholders on the HIV rapid testing site and tester certification requirements and processes.
- To provide a clear communication channel for the effective flow of information among all stakeholders.

7.3 Communication approaches

Different approaches shall be employed for effective communication with all stakeholders about the HIV rapid testing certification program. Mobilization approaches should be tailored to the needs and contexts of different target audiences. These approaches shall include, but not be limited to:

- Interpersonal Communication for identifying and mobilizing different stakeholders for the HIV RT certification program and addressing any possible challenges. This shall be employed in resource and community mobilization, health education talks, health worker training, and satisfied user feedback and testimonies.
- Communication material/media: This shall include print, electronic, digital platforms, social media, and apps.
- All HIV rapid testing certification messages should be designed to address the unique needs of the targeted audiences.

A detailed communication plan is shown in Table 4 below.

Table 4: Communication plan for HIV RT Certification process

Communication Objectives	Anticipated Issues	Levels	Target Audience	Main Activity Strategy	Message Themes	Channels	Materials / Mode of communication	Desired Outcome
1. To create awareness among all stakeholders	Laxity from some stakeholders Misconception among stakeholders Resource constraints Competing priorities Political interference	National level	MOH, CSOs, NGO's, Partners	National dissemination of the framework Training Development, (Translation of IEC) Dissemination of IEC materials and training. National performance review meetings	Rationale and process of HIV rapid testing Certification Specific benefits of HIV rapid testing certification	Stakeholders' meetings, media, and training workshops.	Brochures Flyers Posters PowerPoint presentation. Media briefs Talking billboards	Availability of IEC materials Increased knowledge of the certification program among the different stakeholders.
		Regional	Directors of RRHs, Regional IPs, and Regional focal persons	Regional dissemination of the framework Training Mentorship and coaching Sensitization of political leaders. Regional performance review meetings	Rationale and process of HIV rapid testing Certification Specific benefits of HIV rapid testing certification	Stakeholders meetings, media, and training workshops.	Brochures Flyers Posters PowerPoint presentation. Media briefs Talking billboards	Availability of IEC materials Increased knowledge of the certification program at the regional level.
		District/City	DHO & DHT/CHO & CHT	Mentorship and coaching Sensitization of political leaders.	Rationale and process of HIV rapid testing Certification Specific benefits of HIV rapid testing certification	Training workshops and meetings.	Speeches & presentations Brief & FAQs Brochures	Trained and certified testers. Continuous monitoring and supervision of testers. Availability of IEC materials at different facility levels

		Facility	Facility in charge, Testers, lab management	CPD Review meetings Client sensitization Display IEC materials	Rationale and process of HIV rapid testing Certification Specific benefits of HIV rapid testing certification	Meetings CMEs Health education talks	Speeches & presentations Brief & FAQs Brochures	Increased tester knowledge of the importance of certification
2. Provide a clear communication channel for an effective flow of information among all stakeholders		Community	VHT, CSOs, CHEWs, CBOs, PLHIV, and other HIV activists and opinion leaders.	Sensitization on the benefits of accessing services from certified sites by certified testers. Distribution of IEC materials.	Rationale and process of HIV rapid testing Certification, Accessing HIV rapid testing from certified sites by certified testers.	Community meetings, home visits, cultural/religious, and other social gatherings.	Speeches Brief & FAQs Brochures Posters Flyers.	Community members accessing HTS from certified sites.

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Assessment: The systematic process of collecting and analyzing data to determine the current, historical, or projected status of an organization, person, or project.

Assessor: A competent person trained and certified to conduct an assessment based on defined criteria.

Audit: The systematic, independent, and documented process for obtaining evidence (ISO 9000 [3.9.4]) and evaluating it objectively to determine the extent to which audit criteria are fulfilled (ISO 9000 [3.9.1])

Auditor: An individual who performs an audit.

Certification: The procedure by which an authorized body gives written assurance that a product (test results), process, or service (tester and/or site) conforms to specified requirements (modified from ISO/IEC 17000)

Certifying Body: Organization or agency with the authority to inspect a facility and provide written evidence of its compliance with a standard.

Certification Maintenance: The process by which testers/sites possessing a national certification perform certain specified requirements to demonstrate continued competence /conformance.

Competence/Competency: (ISO 9000[3.1.6]) The ability to apply knowledge and skills to achieve intended results.

Corrective Action: The process to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000[3.6.5])

Evaluation: Rigorous analysis of completed or ongoing activities that determine or support the accountability, effectiveness, and efficiency of an activity or program.

Evaluator: Refers to a person whose job is to rate the quality of competencies in HIV testing personnel

External Quality Assessment: Refers to a system for objectively checking the test site's performance using an external agency or facility. It includes the pre-examination, examination, and post-examination phases.

Governance: It refers to the establishment of policies and continuous monitoring of their proper implementation by the members of the governing body of an organization. It includes the mechanisms required to balance the powers of the members (with associated

accountability) and their primary duty of enhancing the prosperity and viability of the organization.

Mentoring: Refers to a professional relationship in which an experienced person assists another in developing specific skills and knowledge that will enhance his/her professional and personal growth.

Monitoring and Evaluation (M&E): A process that helps to improve performance and achieve desired results. Its goal is to improve current and future management of outputs, outcomes, and impact.

Objective Audit Evidence: Information that is verifiable and generally consists of records and other statements of fact(s) that are relevant to the audit criteria being used.

Point of Care Testing (POCT): Refers to testing that is performed near or at the site of a patient utilizing a device that measures and/or records a clinical observation (a test result) with the result leading to possible change in the care of the patient (ISO 22870).

Proficiency Testing (PT): Evaluation of participant performance against pre-established criteria using inter-laboratory comparisons (ISO17043). In the context of HIV rapid testing and related POCT, the inter-laboratory comparison may include both laboratory and non-laboratory settings.

Quality assurance: This systematic process determines whether a product or service meets specified requirements.

Quality Improvement: Refers to a process of applying appropriate methods and tools to close the gap between the current and the expected level of performance as defined by standards.

Site Certification: The procedure by which an authorized body gives written assurance that a site conforms to specified requirements.

Tester: Refers to an individual who performs point-of-care testing.

Tester Certification: The procedure by which an authorized body gives written assurance that an individual performing point-of-care testing conforms to specified requirements.

Testing Site: A location where point-of-care testing is performed.