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Foreword

The Government of Uganda (GoU) has made the fight against HIV and AIDS one of its top priorities. The strategies aimed at responding to the HIV and AIDS epidemic, are an integral part of the Health Sector Development Plan 2016-2020, National HIV and AIDS Strategic Plan (NHSP 2015/16-2019/20) , the National Health Policy (NHP II). and the Health sector HIV strategic plan (HSHSP 2018/19-2022/23). HIV Testing Services are provided within a legal and human rights framework ensuring quality counselling, confidentiality, informed consent, giving of correct results and connecting those tested to further care and prevention. MoH acknowledges the need to continuously adopt new approaches in response to the changing epidemic. This enables the country to appropriately focus the response to target priority areas and population groups; hence the need for periodic policy reviews to incorporate new evidence-informed approaches.

HIV Testing in Uganda began in 1990 with Voluntary Counselling and Testing (VCT) as the main mode of delivery. The test, by policy was initially performed in the Laboratory by qualified Laboratory personnel ranging from Laboratory assistants to technologists. The country developed the first VCT policy in 2002 with an aim of scaling up HIV testing services. The review of the 2005 policy introduced Routine HIV testing and counselling and Home-Based HIV Testing and Counselling (HBHCT) to complement VCT. In 2010, the country further reviewed the policy to ensure universal access is achieved.

These reviews also allowed lay testers (non-laboratory personnel) to conduct HIV testing at different testing points other than the main laboratory.

The decentralization of testing services from the laboratory and training of lay testers resulted in significant achievements. The number of facilities providing HCT services increased to 3,565 by 2014; including all public and private hospitals and HC IVs. There has been a progressive increase in the number of positive Individuals Identified to about 72% of the estimated positives by 2017 (UPHIA, 2017).

Quality assurance for HIV testing services in Uganda is performed through supervision, periodic assessments and panel proficiency testing. Over the years, more testers have enrolled for the PT program. Each year, the Ministry of health through the Uganda Virus Research Institute dispatches DTS panels to all (100%) of these testers. As at the end of 2017, 78% of these testers were participating in the Program and only 96% of them were passing the proficiency test as opposed to the 100% National and WHO target. Of the 7474 testing sites in the country from the 3,565 facilities, only 49%, during an audit by MOH and UVRI were eligible for certification.

The Uganda National HTS policy and Implementation guidelines, 2016 provides for HIV tester and site certification as required by WHO. The Uganda HIV prevention and control bill 2014, requires that HIV testing shall be conducted by Individuals authorized by the Minister of health. This certification framework is, therefore, aligned to the 2015 World Health Organization Consolidated HTS guidelines, the Uganda HIV Prevention and Control Act, 2014 and the National HTS and Implementation guidelines 2016.

The development of these guidelines is, therefore, aimed at galvanising efforts to achieve the correct first 90 and ensuring zero misdiagnosis of all HIV positive individuals.

This document provides guidance on how HIV tester and site certification should be planned, delivered/implemented, monitored and evaluated. Therefore, the document serves as a useful resource for policy-makers and planners, AIDS Development Partners (ADPs), HTS implementers, academicians, researchers and service providers.

The guidelines development process was participatory and included establishment of a Technical Working Group (TWG) to spearhead the process; a rapid performance audit and assessment of HIV testers and testing sites, Stakeholder consultations and MOH senior management and HPAC consultations.

It's my conviction, therefore that this policy is based on cutting-age clinical laboratory and field evidence, vast experiences in planning and delivering HIV testing services and addresses diverse quality concerns in both facility and community HIV Testing programs. I call upon all actors in the HIV response in Uganda to support the Implementation of these guidelines.



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Ag Director General Health services

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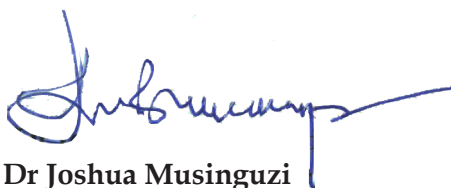
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Special gratitude is extended to the stakeholders and members of the National HIV Counseling and Testing Committee (NCTC) for providing backstopping support to the development process.

It is my sincere hope that these certification guidelines for HIV testers and sites will tremendously 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 efforts to fast-track the National HIV and AIDS Strategic Plan target towards identifying 95 percent of HIV infected Ugandans and linking them to HIV care and support services and eliminate AIDS by 2030.

Finally, we express our gratitude to the following organizations for the financial support towards the guidelines development process; PEPFAR through CDC, UVRI, FIND and AFENET and the Global Fund.



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Abbreviations and Acronyms

ACP	AIDS Control Programme
ADP	AIDS Development Partners
AHPC	Allied Health Professionals Council
CHEW	Community Health Extension Workers
CDC	Centers for Disease Control and Prevention
CHC	Communication for Healthy Communities
CLSI	Clinical and Laboratory Standards Institute
CPHL	Central Public Health Laboratories
CQI	Continuous Quality Improvement
CSOs	Civil Society Organizations
DQIT	District Quality Improvement Team
DHO	District Health Officer/Office
DGHS	Director General of Health Services
EQA	External Quality Assurance
HBHCT	Home Based HIV Counseling and Testing
HCT	HIV Counseling and Testing
HTS	HIV testing services
HCW	Health Care Workers
ICC	Independent Certification Committee
ISO	International Organization for Standardization
M&E	Monitoring and Evaluation
MOH	Ministry of Health

NCTC	National HIV Counseling and Testing Committee
NDA	National Drug Authority
PEPFA	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
QA	Quality Assurance
QAD	Quality Assurance Department
QC	Quality Control
QI	Quality Improvement
QMS	Quality Management System
RDT	Rapid Diagnostic Test
RTQII	Rapid HIV Testing Quality Improvement Initiative
SPI-RT	Stepwise Process for Improving the Quality of HIV Rapid Testing
UMLTA	Uganda Medical Laboratory Technology Association
UNHCO	Uganda National Health Consumers Organisation
VCT	Voluntary Counseling and Testing
VHT	Village Health Teams
UVRI	Uganda Virus Research Institute
WHO	World Health Organization

Introduction

This section provides an overview of the HIV situation in Uganda, describes the history of HIV testing services and elaborates the justification for a certification framework for HIV rapid testing sites and personnel.

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. The estimated national HIV prevalence rate is 6.2% among men and women aged 15 – 64 years (UPHIA 2017). Estimated number of people living with HIV is 1,300,000 in 2017.

1.2. HIV Testing Services in Uganda

HIV testing remains pivotal in HIV response. HIV testing services (HTS) in Uganda began in 1990, with Voluntary Counselling and Testing (VCT) as the main approach to service delivery where HIV test results were obtained after 2 weeks.

The country developed the first VCT policy in 2002, with an aim of scaling up VCT. The first policy review which was done in 2005 introduced Provider Initiated HIV Testing and Counselling (PITC) and Home Based HIV Counselling and testing (HBHCT) to complement VCT. This review also provided for the use of HIV rapid diagnostic tests which ensured same-day test results. During this period, emphasis was put on new models of HCT, expansion of entry points, scale up of HCT to children, use of Lay Providers and testing in the community. As a result, HIV Counseling and Testing (HCT) service points more than doubling from 554 sites in 2007 to 1,215 sites in 2009 [10].

A second review of the policy was done in 2010 with the aim of increasing coverage for HCT services to achieve universal access and by the end of 2014, about 3,565 HTS sites were spread across the country.

By the end of year 2017, there were more than 7,000 testing sites in the country. The increase in the number of testing points as well as task-sharing for HIV testing with non-laboratory professionals coupled with inadequate supervision led to several quality challenges related to accuracy and reliability of test results.

The Uganda Virus Research Institute (UVRI) 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 Ministry of Health in the country. The UVRI quality assurance program originally targeted laboratory professionals. However, the decentralization of HIV testing at different testing points with the involvement of lay testers led to a need to cover all testers with in the program. The national PT passing rate currently stands at 96% with 4% of all testers providing unintended false HIV test results.

In 2015, WHO recommended individual countries to develop mechanisms for assessment of HIV testers and testing sites to improve the quality of HIV rapid testing to ensure zero HIV misdiagnosis [7]. Uganda adopted the WHO recommendation of certifying all HIV rapid testers and testing sites as stipulated in the National HTS policy and Implementation guidelines 2016.

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 competency of a provider on the basis of 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 infections [1].

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 on 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 maintenance of standards. Provider certification verifies that the provider performing HIV testing is adequately trained, is authorized to do so and there is evidence of demonstrated competency.

1.4. Justification

The national HIV testing policy 2016 and the National Health Laboratory strategic plan 2016-2020 {8} provide for tester and site certification as a key strategy to enhance the quality of HIV testing services.

Rapid diagnostic and recently technologies have become widely available in the last few years and have been shown to play a major role in achieving the 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 patient results and improved public health outcomes. However, challenges remain regarding the implementation of quality assurance programs for HIV rapid testing.

In Uganda, a standardized National HIV rapid testing algorithm is recommended for use in the diagnosis of HIV [2]. Despite the many interventions put in place to strengthen quality of testing, it is noted that gaps in quality assurance still exist as observed in the support supervision reports from the national team and implementing partners as well as PT performance reports from UVRI.

The HIV Rapid Testing Quality Improvement Initiative (RTQII) pilot that was conducted in two districts of Uganda (i.e. Wakiso and Jinja) further revealed gaps in all areas of quality assurance affecting HIV testing. These included few and/or inadequately trained staffs, unavailability of testing supplies, lack of post market surveillance practices, deviation from testing procedures, low participation and performance rates in proficiency testing program and under-utilization of testing data for timely corrective actions. Periodic audits conducted at the RTQII pilot sites indicated that the testers did not have evidence of comprehensive training on HTS.

Moreover, it was recognized that the lack of a national certification program for both testing sites and testers concurred to jeopardizing the accuracy of testing as the country rolls out Test and Start strategy to meet global and national treatment targets.

Although, concerns may be raised about cost of implementing the certification programme and/or comprehensive quality assurance programs for HIV related rapid testing as a whole, the costs associated with both attaining and failing to attain accurate and reliable test results are inestimable. These include cost of initiating treatment for patients who do not otherwise require any or missing an HIV-infected case and essentially, any cost that would not have been expended if quality measures were adequately and consistently implemented. An investment in a national certification program for HIV rapid testing may prove to be not only a healthcare cost saving approach, but also an expansion of quality of care.

The certification program will assist testing sites and testers in improving and maintaining the quality testing, while leveraging existing resources. It will also provide clinical governance to support health care providers involved in testing. The clinical governance will create an enabling environment for health-care providers to be accountable for providing the quality of HIV Rapid testing services and safeguarding high Standards of care and excellence in clinical

care. Implementation and maintenance of HIV rapid testing site and tester certification program will add credibility to any testing site, 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 testing sites and testers will provide 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 quality of HIV rapid testing in Uganda. Likewise, provider certification, along with standardized hands-on training and ongoing supervision and reassessment to ensure competency, will be adopted to 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 a concerted effort at all levels to systematically improve and assure the quality of testing. This certification framework will adopt a quality improvement approach to ensure the implementation of certification of testing sites and testers. Moreover, the certification framework will therefore be used to verify that the site is adequately equipped and adheres to quality standards and that personnel are competent to conduct HIV rapid testing according to the national testing guidelines.

This document further underscores the need for strong leadership, dedicated funding for quality assurance, advocacy, new innovations and better coordination for continuous quality monitoring and improvement, which will result in increased uptake and 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 personnel.

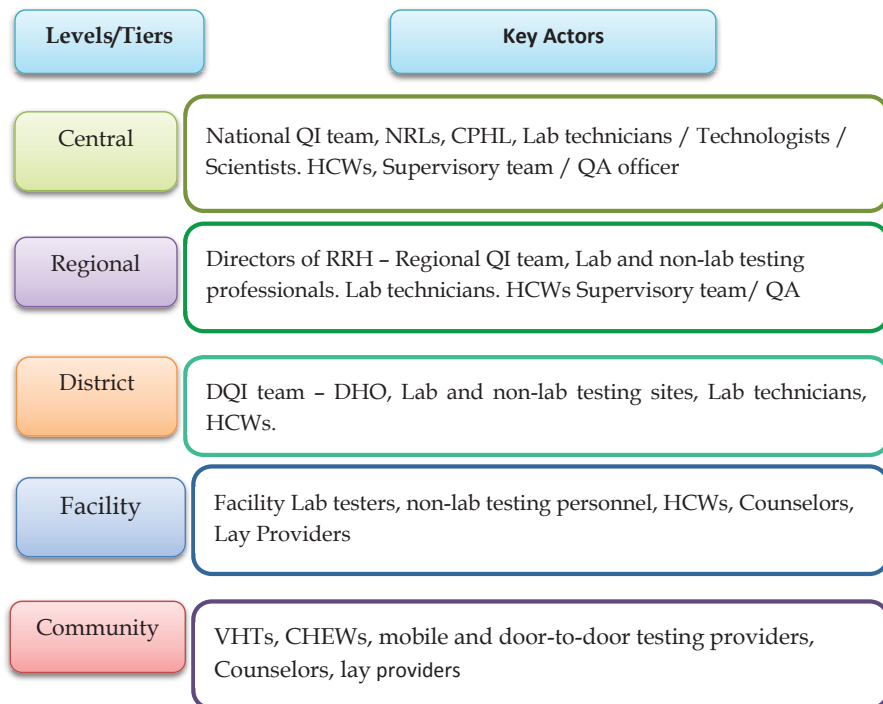
1.5.2. Objectives

- a. To provide a standardized coordination mechanism to achieve and maintain national certification of HIV testing sites and testers
- b. To set standards that should be followed to certify sites and testers for HIV rapid testing
- c. To provide guidance on the implementation approaches for site and tester certification of HIV rapid testing
- d. To provide guidance for monitoring and evaluation of the national HIV rapid testing certification program

1.6. Scope and Target Audience

This framework is applicable to programs and organizations which implement HIV testing in Uganda. It provides guidance for site and tester certification for HIV rapid testing conducted in both laboratory and non-laboratory settings for both public and private sectors across the different levels of service delivery including community, facility, district, region and central levels as shown in the figure below (Figure 1).

This framework targets different stakeholders including: policy makers, HTS programmers and planners, AIDS development partners and donors, programme and health facility managers and in-charges, district and facility HTS coordinators/supervisors and focal persons, Quality officers, People Living with HIV (PLHIV) and HIV activists, researchers and beneficiaries of HIV Testing Services.

Figure 1. Different levels of service delivery in Uganda

1.7. Process of Developing the Framework

This document is a product of collaboration and technical input from a range of stakeholders at different levels. Following the release of the 2015 WHO Handbook on *Improving the quality of HIV related point of care testing: Ensuring reliability and accuracy of test results*, and the subsequent dissemination of the Certification Framework template developed by several PEPFAR partners (Douala, Cameroon, 11-16 July 2016), the Ministry of Health through UVRI constituted a technical working group (TWG) to develop the country specific certification framework. The TWG was composed of technical representatives from the AIDS Control Program HIV Testing Services Department, UVRI, UNHLS/CPHL, CDC and other stakeholders.

A draft was developed and reviewed by technical officers from CDC, FIND, ASLM, and CLSI.

A team of national stakeholders comprised of district health officers, implementing partners, ADPs, CSOs, professional councils and associations (Allied Health Professionals Council, UMLTA etc), the academia and networks of PLHIV participated in a workshop organized to further refine the draft framework.

The national advisory committee on HIV Testing Services (NCTC) reviewed the document for recommendation to the National Health Policy Advisory Committee and MOH top management for approval.

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 Goal of the framework

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

2.1.1 Specific Objectives

1. Ensuring adherence to national standards of delivering HIV rapid testing
2. Ensure availability of competent personnel for HIV rapid testing
3. Ensure conformity of sites to national standards in order to ensure quality results
4. To establish a transparent and robust certification process for sites and testers

2.1.2 Governance and Coordination

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.

2.1.3 Governance Structure

Uganda's certification framework benchmarks the National HTS and Quality Assurance coordination structures [11] and it is synchronized with the Health Sector Development Plan (HSDP)[4]. It comprises of different stakeholders, acting at different levels as below;

- National
- Regional
- District
- Facility
- Testing site

2.1.4 The National Government Institution

In Uganda the national government institution refers to the Ministry of Health headed technically 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. This unit is supported by the National Counselling and Testing Committee (NCTC) which provides technical guidance for various tasks including quality assurance for HIV testing services. Together with partners, the Ministry of Health shall mobilize resources for the certification program.

2.1.5 Independent Certification Committee

This shall be a multi-sectorial committee with diverse membership to increase objectivity, minimize bias and address conflict of interest. It will be comprised of technical people from the following institutions: UVRI, AHPC, CPHL, UMLTA, ACP, QAD, CSOs, Ministry of Trade (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, MOH and will serve for a two-year term before new members are nominated. The two-year term for each member of the independent certification committee may be renewed by the recommending authority upon satisfactory performance.

2.1.6 The certifying Body

The Uganda Virus Research Institute (UVRI) is mandated by the Ministry of Health to conduct quality assurance for HIV rapid testing in Uganda. By virtue of this role, UVRI shall be the Certifying Body for HIV rapid testing sites, auditors, evaluators and testers. UVRI shall work closely with the AIDS Control Program and the Quality Assurance Department of MOH in fulfilling her role in the certification program. The certifying body shall execute its roles with impartiality irrespective of the settings (laboratory vs non-laboratory), testers' training background and organization affiliation.

2.1.7 Regional support

Whereas in the decentralization structure for Uganda there is no administrative structure at regional level, the ministry of health has established regional structures to streamline delivery of health services. The certification program shall leverage the existing regional structures to provide additional support to the districts, testers and testing sites. At 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, regional QA coordinators, regional laboratory coordinators and regional performance monitoring teams.

2.1.8 District level

At the district, the district health office and implementing partners will work closely to support facilities and testing sites. The following structures shall work very closely: District Health Officer, District Laboratory Focal Person and HIV Testing Services Focal Person.

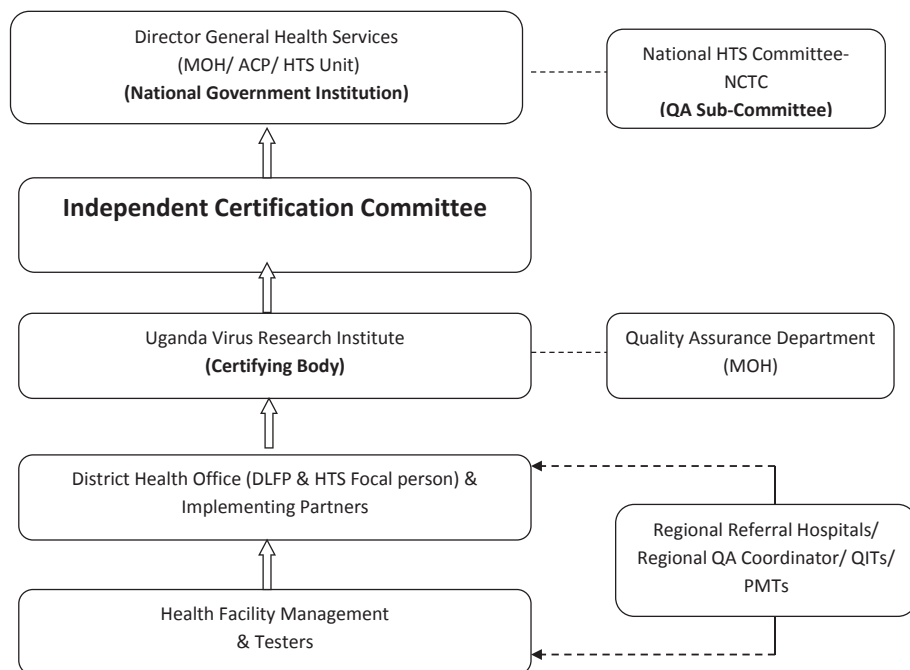
2.1.9 Facility and HIV rapid testing site level

Site management and HIV rapid testing site personnel are the primary recipients of the certification program and therefore play a critical

role for a successful program. The HTS focal person working closely with the Laboratory focal person and facility quality improvement committee will perform managerial roles to assure the quality of HIV rapid testing. The testers will be expected to adhere to the standard operating procedures to ensure quality test results.

Each stakeholder will have specific roles and responsibilities as detailed in *section 2.1.2 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 HIV rapid testing site and tester certification



2.1.10 Roles and Responsibilities of Stakeholders

Different stakeholders will perform specific roles at different levels as detailed in the table 1

Stakeholder	Roles and Responsibilities
National Level	
The National Government institution (Ministry of Health)	<p>Policy formulation and review</p> <ul style="list-style-type: none"> • Identify a certifying body • Establish a certification committee <p>Setting implementation guidelines (standards)</p> <ul style="list-style-type: none"> • Site-Certification standards • Personnel evaluation criteria and standards • Development and review of the Training curriculum • Advocate for sites and personnel certification through disseminating the standards and requirements for certification <p>Coordination & Supervision</p> <ul style="list-style-type: none"> • Overseeing trainings and refresher trainings • Overseeing auditors and evaluators training • Issue and withdraw certificates <p>Coordination</p> <ul style="list-style-type: none"> • Developing roll out plans with clear timelines • Coordination of implementing Partners • Coordination of Development Partners <p>Monitoring and Evaluation</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>Resource Mobilization</p> <ul style="list-style-type: none"> • Partner coordination for efficiency • Advocacy for resource allocation

Certifying Body (UVRI)	<p>Implement standards</p> <ul style="list-style-type: none"> • Implementation of the framework • Ensure compliance to quality standards for the certification program. • Identify and train national auditors and evaluators. <p>Conduct Site Audits</p> <ul style="list-style-type: none"> • Audit sites for certification • Notify sites to be audited • Manage and ensure conflict of interest amongst auditors and evaluators <p>Conduct Personnel evaluation</p> <ul style="list-style-type: none"> • Develop corrective and remedial actions • Submit progress reports quarterly to MOH <p>Monitoring and Evaluation</p> <ul style="list-style-type: none"> • Maintain the certification database (Testers and testing sites) • Maintain database of national auditors and evaluators • Generate and submit audit reports to Independent Certification Committee (ICC) • Print and send signed certificates to sites and testers <p>Disciplinary action</p> <ul style="list-style-type: none"> • In case of non-compliance, UVRI will recommend disciplinary action to the independent certifying committee.
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Independent Certification Committee	<p>Validation of certification processes</p> <ul style="list-style-type: none"> • Verify audit reports • Provide independent opinion on performance of sites & testers presented for certification • Recommend sites and testers to DGHS office for certification and decertification • Evaluate the performance of the auditors <p>Conflict Resolution</p> <ul style="list-style-type: none"> • Address complaints from sites and testers and other conflicts within the certification process
Regional	
Office of the Director of Regional Referral Hospitals	<p>Coordination</p> <ul style="list-style-type: none"> • Mentorships to the districts • Data quality checks • Generate quarterly reports and submit to the certifying body • Coordinate HIV testing supplies at the region <p>Quality Assurance</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

Districts and Health sub-district	
District Health Office	<p>Supervision</p> <ul style="list-style-type: none"> • Supervision and mentorship of testing sites within the district <p>Coordination</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>Monitoring and Evaluation</p> <ul style="list-style-type: none"> • Data Quality Assessment • Monitor site & tester performance <p>Quality Improvement</p> <ul style="list-style-type: none"> • Develop quality improvement plans for the District Health Team • Supervise Quality Improvement Activities
Health facility	
Health facility managers	<p>Quality Improvement</p> <ul style="list-style-type: none"> • Ensure all HIV rapid testing sites are implementing comprehensive CQI and prioritize sites to be enrolled 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 set national requirements for certification. <p>Adherence to National Standards</p> <ul style="list-style-type: none"> • Develop SOPs in line with national standards • Ensure adherence to national HTS standard • Select and train teams to conduct internal audits using appropriate tools, address all gaps through training of staff and development of necessary corrective actions.

	<p>Supervision</p> <ul style="list-style-type: none"> • Conduct Internal Audit. <p>Advocacy</p> <ul style="list-style-type: none"> • Create awareness among personnel about site and tester certification requirements. <p>Monitoring and evaluation</p> <ul style="list-style-type: none"> • Develop a contingency plan for situations that may arise during the audit, for example internal audit findings that need immediate attention, such as conditions that may present an immediate risk to patient care or employee safety. • Maintain records of certification and competency assessments at 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 to self-assessment (e.g., SPI-RT) for CQI • Summarize audit findings and corrective actions in a report and submit to laboratory in charge. • Maintain updated registers of all clients tested and share as required • Maintain certification standards

Implementing Partners	<ul style="list-style-type: none"> • Support trainings for sites and testers • Support CQI activities at regional and district level
	<ul style="list-style-type: none"> • Support implementation of corrective and remedial action • Provide technical support in the certification process
AIDS Development Partners	<ul style="list-style-type: none"> • Provide financial support • Provide technical assistance

3.0 Standards for certifying HIV testing sites and personnel

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 22870:2006 provides specific requirements for POCT in regards to quality testing, competency of testers and it's used in conjunction with ISO 15189. The standards to certify HIV rapid testing sites and personnel will thus be based on these standards.

Uganda adapted 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 HTS related context from which theoretical examinations will be set, coupled with practical examination to assess personnel competency.

3.1 Quality standards for HIV rapid testing

3.1.1 Quality standards for HIV testing sites

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

a) *Physical facilities*

The physical facility/site should have:

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

b) *Safety*

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

- Documented procedures for:
 - handling and disposal of bio-hazardous materials, and safety in the work place
 - manage spills of blood and other body fluids
 - Post exposure prophylaxis (PEP)
- Have facilities for safe waste management
- Clean water and Soap
- Have appropriate disinfectant
- PPE should be available, properly and consistently used
- Have and maintain appropriate first aid material
- All testing personnel should be trained on handling bio-hazardous material, workplace safety, and spill management evidenced with 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 testing guidelines specific to the program e.g. HTS available at facility.
- National HIV testing algorithm in use
- SOPs and/or job aides in place for HIV rapid test used in the testing algorithm
- Nationally approved HIV rapid kits within the expiration dates
 - Kits labeled with date “in use” and initials
- A stock management process (stock cards, order forms & inventory)
- Job aides on client sample collection available and posted at the testing point
- Nationally approved HMIS tools for HTS

d) *Testing phase*

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

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

e) *Post testing phase*

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

- A daily activity register for;
 - Recording HIV tests and in use 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.
- Client documents and records securely kept throughout all phases of the testing process
- Registers/logbooks and other documents kept in a secure location when not in use

- Registers/logbooks properly labeled and archived when full
- QC records routinely reviewed by the person in charge

f) External quality audit (PT, Supervision)

All personnel providing HIV testing must demonstrate proficiency in HIV testing by Participating periodically in External quality assessments/Proficiency testing. Quarterly supervisions and mentorships at national, regional, district and facility level should be conducted and reports generated to inform corrective action.

- 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 /PT results before submission to NRL.
- EQA/PT feedback received from NRL should be reviewed by testers and/or in charge at the testing point
- Testing point should implement corrective action in case of unsatisfactory results
- All HIV testing points should receive quarterly supervisory visit and feedback documented

3.1.2 Certification requirements for 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 minimum of 80%) and practical (100%)
- Must be evaluated for competency every two 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 health professional
- Must be certified HIV rapid tester
- Must be trained and qualified in SPI-RT fundamentals
- Must be successfully evaluated for competency every after two years
- Must have knowledge in laboratory quality management systems (LQMS)

b) HIV certification requirements for an Evaluator.

- Must be qualified health professional.
- Must be certified HIV rapid tester
- Must be successfully evaluated for competency every after two years
- Must Have knowledge in Laboratory quality management systems
- Must be trained using the evaluators curriculum and must be qualified

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

- Must be certified HIV rapid testers
- Must be qualified in medical, laboratory (Diploma and degree)
- Must have at least two years' experience in laboratory practice
- Must be based in health practice
- Should have good facilitation and communication skills
- Must be knowledgeable with the National HTS policy
- Must be evaluated for competency every after two years

3.2 Implementation of Certification.

The implementation describes the process of assessments/audits of the testers and testing sites, certification, decertification, recertification, Monitoring and Evaluation

3.2.1 Site certification process

- Enroll sites on the certification programme
- Conduct Intra district audits
- Results from intra district audits will determine the next step
 - If sites attain certification scores or near certification grades (>90%), national audits will be conducted
 - For sites that attain scores < 90%, corrective actions will be implemented quarterly & intra district audits will continue to ensure they meet the target
- Sites attaining scores above 90% 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 (ICC) for final decision in regards to certification
- **Note:** Independent Certification Committee (ICC) constitutes the following:
 - MOH Secretariat, UVRI, development partners' representative, NCTC representative, CPHL/UNHLS, professional bodies: - AHPC, Medical & Dental, Nurses, Pharmacy
- sites that are eligible for certification (scoring >90%) will be certified
- Sites with scores <90% will be given three months' period for improvement before another National audit is conducted.
- Upon successful scores, sites will be certified

3.2.2 Frequency of site Assessment

Site Assessments will be conducted at 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	Biennial (2 years)
Intra – district audit	<i>This will be performed by certified auditors within the district</i>		✓		
National audit)	<i>Certifying body performs the site audit for certification and recertification</i>	✓			✓

3.2.3 Decertification and recertification of testing site

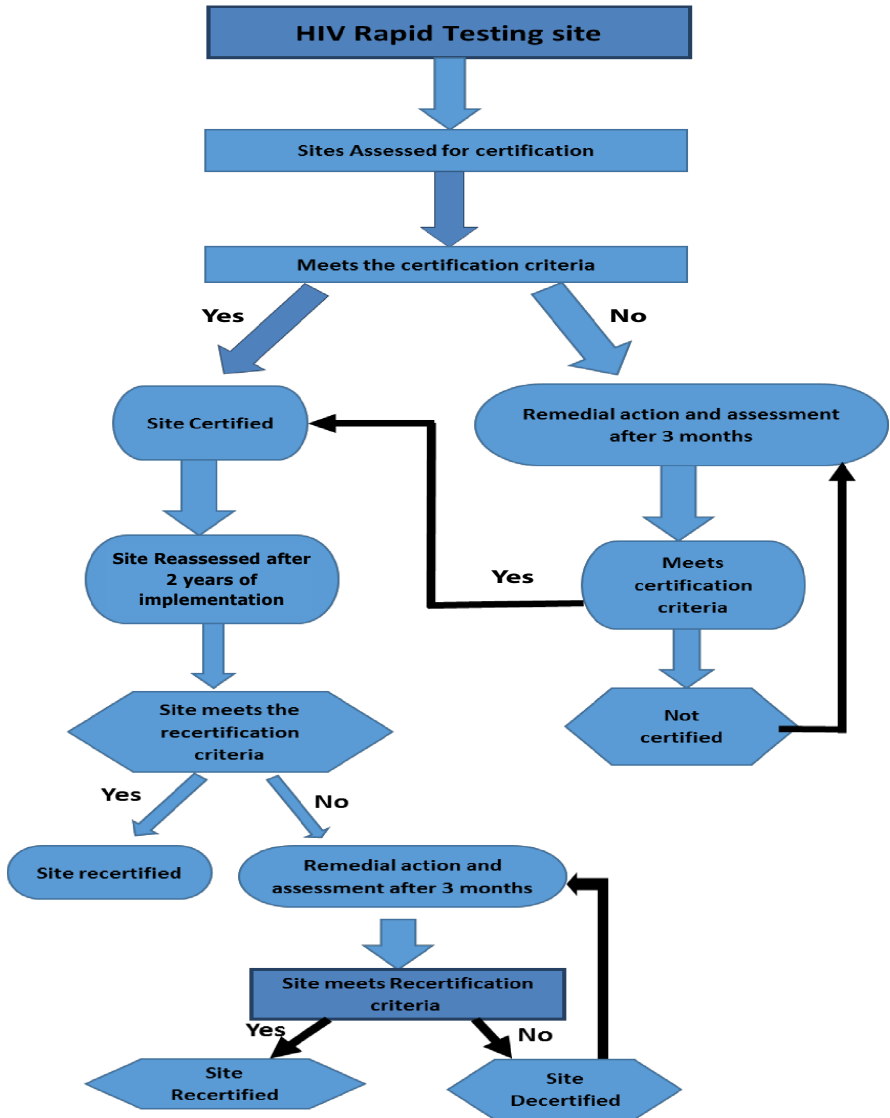
Testing sites may be decertified within the 2 years’ or after expiry of the two years’ certification period.

- Scenarios under which decertification may occur includes:
 - Closure of site due regulatory non compliance
 - Cessation of HIV testing services at a particular site

Recertification

Sites that are suspended can be re-certified upon corrective action and passing the certification criteria. The flow chart on page 26 describes the process of HIV rapid testing site certification, de-certification and re-certification.

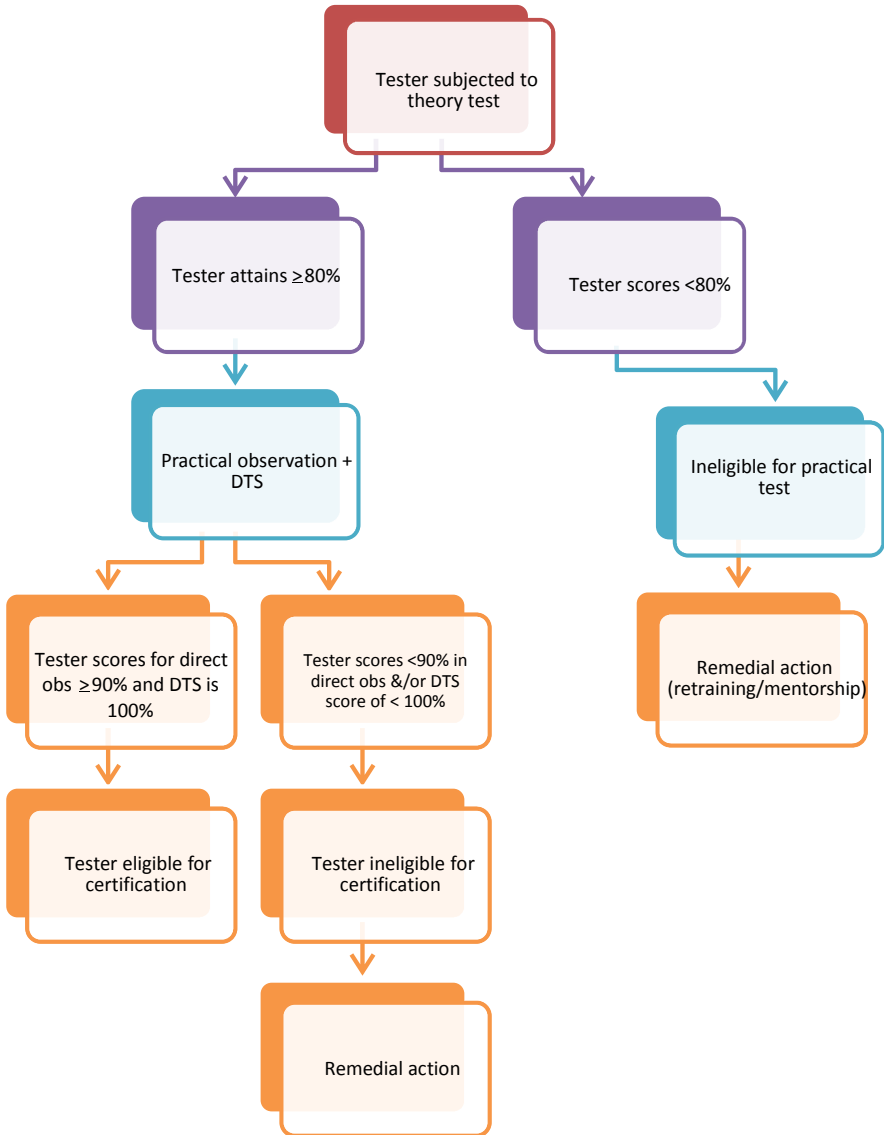
Figure 3: Process of HIV rapid testing site certification, de-certification and re-certification



3.2.4 Tester certification process

- Enroll tester for certification
- Subject tester to certification examinations (theory & Practical)
 - Pass mark for theory/ written exams should be $\geq 80\%$
 - 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)
- The tester who scores the above defined pass marks will be eligible for certification
- Failure to score the pass marks will lead to initiation of appropriate remedial actions for a period of three months before re-assessment. HIV Rapid testing will be performed by this tester under supervision by a certified tester.
- Tester who does not attain the pass mark will be given three opportunities to be re-assessed within two years
- If this tester does not pass after the three consecutive evaluations, he/she shall cease to perform HIV Rapid testing.

Fig 4: Tester Certification Process



3.2.5 Suspension of tester certification

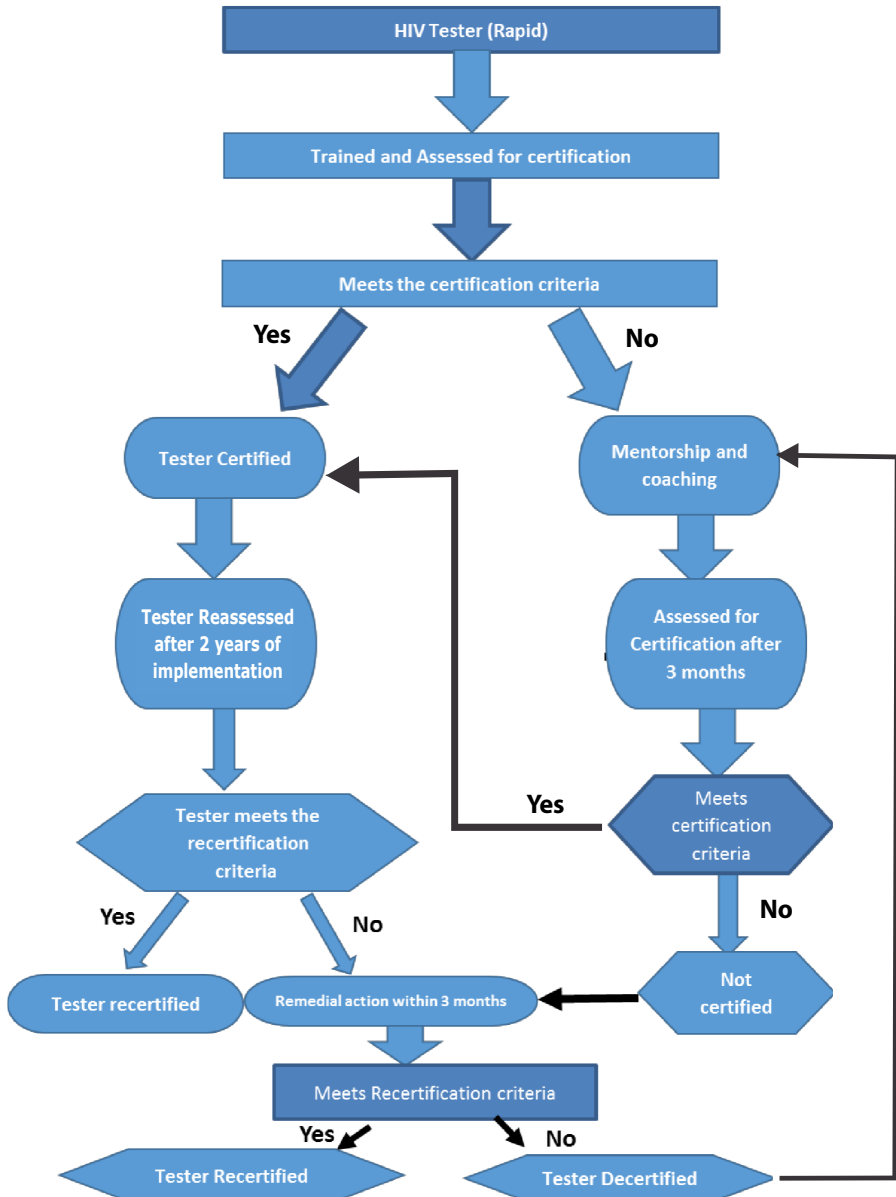
Suspension of testers may occur within the period of two years or when the certification expires. Suspension may occur in the following scenarios;

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

3.2.6 Recertification of Testers

Testers whose certification has been suspended can be re-certified upon completion of remedial action and passing the certification criteria. The flow chart below describes the process of HIV rapid testing tester certification, de-certification and re-certification

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



3.2.7 Auditor Certification Process

Auditors for site certification shall be identified from experienced health practitioners who have undergone relevant site audit training.

- Auditors shall be trained using an approved curriculum
- They will be subjected to practical and theory 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 after a period of two years.
- Recertification of auditors will be after two years. An auditor will be expected to audit at least 20 sites with in a period of two years.

3.2.8 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 upon;

- Successful completion of 50 tester evaluations within two years.
- Passing 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: 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) in accordance with the national approved curricula.

d) **Participation in HIV EQA**

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

e) **Competency Assessments**

The competency of the tester shall be assessed once a year.

4.1 Maintenance of certification for evaluators

- Must evaluate at least 50 HIV rapid testers annually.
- Must undertake refresher training in evaluators training every after two years.
- A fellow evaluator to conduct a spot check once a year to ensure reliability of assessment results (Peer to Peer review).

- Evaluator's assessment reports will be reviewed by an independent committee once a year to ensure objectivity.

4.2 Maintenance of certification for Auditors

- Auditors must audit a minimum of 20 HIV testing sites every year.
- Must undertake refresher training in SPI-RT every after two years.
- Mentorship training every two years
- A fellow auditor to conduct a spot check once a year to ensure reliability of audit results.
- Auditor's reports will be reviewed by an independent committee 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:

- CBO'S
- Political leadership
- Implementing partners
- Development partners
- Professional bodies
- Religious sectors
- Training institutions
- Other relevant ministries/agencies

5.0 Monitoring and Evaluation

5.1 Goal

Establishing an effective monitoring and evaluation system will ensure that the tester and site certification program meets its goals and will be used to determine the efficacy of the HIV rapid testing certification program in ensuring that every person tested receives accurate results.

5.2 M&E framework

This section introduces the monitoring and evaluation plan for the certification framework and details the objectives, inputs, outputs and means of verification. The M&E system articulates measurable program objectives, structured set of indicators and provisions for collecting data.

Objective	Activity	Indicators	Means of verification
1. Ensuring adherence to national standards of delivering HIV rapid testing	1.1 Develop/review HIV testing SOPs 1.2 Disseminate the SOPs	1. Number of SOPs reviewed 2. Number of SOPs disseminated	1. Current SOPs available at the HIV testing sites 2. Number of sites having SOPs
2.Ensure competency of HIV rapid testing personnel	2.1 Conduct skills gap/needs assessment	Number of assessments conducted	Availability of Assessment reports
	2.2 Curriculum development/review	Curriculum developed/reviewed	Availability of Training curriculum
	2.3 Training and re-training	<ul style="list-style-type: none"> Number of trainers of testers trained Number of testers trained Percentage of testers nationally certified 	Availability of training report
	2.3 Onsite mentorship and supervision	Mentorships and supervisions conducted	Availability of mentorship reports
	2.4 Participation in Proficiency Panel Testing	Number of times a tester participates in PT testing Number of times a tester has passed PT	PT results report

3. Ensure conformity of sites to national standards	3.1 On site audits	<ul style="list-style-type: none"> • Number of sites audited (disaggregated by site type) • Number of sites passing certification audits (disaggregated by passing level) 	Availability of onsite evaluation reports
4. To ensure effective implementation of the certification framework	4.1 Perform site audit 4.2 Perform tester evaluation 4.3 Hold certifying body meetings 4.4 Hold independent certifying committee meetings	<ul style="list-style-type: none"> • Total number of sites recommended for certification by the Certifying body • Proportion of certified sites • Total number of testers recommended for certification by the Certifying body • Proportion of certified testers 	Site audit reports Tester evaluation report Certifying body meeting minutes Independent certification committee meeting minutes Site and tester certificates issued

5.3 Monitoring

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

The target is to certify 90% of the sites and 90% of the testers by 2021.

5.3.1 Monitoring Personnel:

- Number of testers certified
- Number of testers that received corrective and remedial action

5.3.2 Reporting/ data flow

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

5.3.3. The following reports will be generated

Site level

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

District level

- District Audits-Quarterly report to UVRI every 6 months
- Corrective action reports

National level

- Corrective action reports
- National audits –one in two years

Include Frequency of reporting

5.3.4 Data security and confidentiality

A data base 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 data base will be accessible by MOH and other stakeholders.

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

5.3.5 Evaluation

Baseline –initial assessment of the level of conformity of the various sites to the standards

Midterm-after 3 years

End term –at the end of 5 years

Performance indicators vs impact indicators- highlight these very well.

5.3.6. Financing the program

MOH working with partners shall agree on implementation strategy.

- PEPFAR's COP 18 may support this.

5.4. Communication Plan

This plan describes how information on HIV Testing Certification shall be transmitted to different stakeholders within the right timeframe surrounding this activity. This plan 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 testing certification process.

5.4.1. Goal

To guide the design, dissemination, implementation and evaluation of the communication process in promoting HIV testing certification.

5.4.2. Objectives:

- To create awareness on the certification program.
- To increase the number of sites and testers certified.

5.4.3. Communication approaches

The following will guide the development of messages for the communication process to guide effective implementation of the HIV Testing Certification programme.

- Mobilization of approaches should be tailored to the needs and contexts of different target audiences.
- Interpersonal Communication should be used in identifying and mobilizing different stakeholders for HIV RT certification program and address any possible challenges.
- Communication material development should follow the standard process of situation analysis, design, testing and production.
- All HIV testing certification messages should be designed to address the unique needs of the targeted audiences.

5.4.4. 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
Create awareness on the certification program.		National level	MOH, CSO's, NGO's, Partners	Development, (Translation of IEC) Dissemination, of IEC materials and trainings.	Rationale and process of HIV Testing Certification,	Stakeholders meetings, media, training workshops.	Brochures Flyers Power point presentation. Media briefs Talking bill boards	Availability of IEC materials at the district level. Increased knowledge on the program among the different stakeholders.
	Lack of knowledge on HIV Rapid Testing Certification	District	DHT	Distribution of IEC materials training of testers at different facility levels.	Rationale and process of HIV 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
Create awareness on the certification program.		Community	VHT, CSO's, CHEW's, CBO's, PLHIV and other HIV	Sensitization on benefits of accessing services from certified sites by certified testers.	Rationale and process of HIV Testing Certification, Accessing HIV testing from certified site by	Community meetings, home visits, cultural/ religious and other social gatherings.	Speeches Brief & FAQs Brochures Posters Flyers.	Community members accessing HTS from certified sites.

			activists, opinion leaders.	Distribution of IEC materials.	certified testers.	Interpersonal communication,	Presentations	
Increase the number of HIV testing sites and testers certified.	Low coverage of HIV Rapid testing certification process. Political interference	National level	MOH, UVRI Professional Councils, CSO's, NGO's, Partners, political leadership	Developing M&E tools. Mentorship and coaching (Continuous medical Education(CMEs), Sensitization of political leaders. Refresher training	Specific benefits of HIV testing certification which include; Effective quality management system, Confidence to users and the providers on the services offered, provides recognition of technical competence, legal defense pertaining results if need arises, reduces the operating costs of HIV testing by getting timely and accurate results.			All sites and testers certified at national level.

			District	DHT , Political leadership	Monitoring and evaluation, support supervision, mentorship and coaching.	Process of site and tester certification. Specific benefits of HIV testing certification Only certified sites and testers shall offer HIV Testing services.	Trainings, meetings.	Presentations, briefs, FAQs, Brochures.	To have all HIV Testing sites and testers certified at district level.
			Community	VHT, CSO's, CHEW's, CBO's CDO's PLHIV and other HIV activists, opinion leaders.	Sensitization benefits of accessing services from certified sites by certified testers. Distribution of IEC materials.	Rationale and process of HIV Testing Certification, Accessing HIV testing from certified site by certified testers.	Community meetings, home visits, cultural/reli gious and other social gatherings.	Speeches Brief & FAQs Brochures Posters Flyers.	Increased demand of services from certified sites and testers.

Key Messages

- Emphasize the HIV Testing certification process
- Emphasize the benefits of HIV Testing Certification
- Only certified sites and testers shall perform HIV RT.

6.0 References

1. WHO 2016, Framework for national certification program for HIV and other point of care testing: Ensuring the reliability and accuracy of point of care test results.
2. Ministry of Health Uganda 2016, National HIV testing policy and implementation guidelines
3. Uganda AIDS Commission 2015, National HIV and AIDS Strategic plan 2015/16-2019/20
4. Ministry of Health 2015, National Health sector Development plan 2015/16-2019/20
5. General requirements for the competence of testing and calibration laboratories (ISO /IEC 17025
6. ISO 15189: requirements for quality and competence in medical laboratories
7. WHO 2015, improving the quality of HIV related point of care testing : ensuring reliability and accuracy of test results.
8. MOH 2015, Uganda National Health Laboratory Strategic Plan 2015/16-2019/20.
9. Uganda Bureau of statistics 2012. Uganda demographic health survey 2011
10. MOH The national quality improvement framework and strategic plan 2016-2020

Glossary

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 authorised 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 regards to 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 (EQA): 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 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 the 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 results) 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 by means of 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 is a systematic process that 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.

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

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.