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Ministry of Health, Community Development, Gender, Elderly and Children

National Framework for Point of Care Testing Certification

First Edition

October 2017

National Framework
For
Point of Care Testing Certification

First Edition

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FOREWORD

During the last few years, Point of Care Testing (POCT) has expanded globally and has gained popularity. It has not only continued to be used for primary health care in low income countries, but has also been used in high income countries where rapid testing is predominant in the National Health Care System. Non laboratory professionals have been trained to perform specific blood and urine tests so that testing is made available at all levels of the health care system. Since this has happened, a need was identified to monitor quality of performance of testers and sites.

In the process of addressing the weaknesses identified in existing HIV related POCT programmes, the Government of Tanzania (GoT) revised the Health Laboratory Practitioners Act 22 in 2007 to demand licensing of health care workers performing laboratory testing. Also "WHO handbook on *Improving the Quality of HIV-Related Point-of-Care Testing: Ensuring the Reliability and Accuracy of Test Results"* has been customised to support implementation of this law to promote Quality Assurance (QA) and Quality Improvement (QI) processes for HIV-related POCT. This framework describes certification processes developed to assist the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC), health-care providers, and stakeholders in planning, implementing, monitoring and sustaining QA for POCT. It also provides a continuum of integrated planned activities that supports and promotes the accuracy and reliability of HIV related POCT.

Although, the framework has been carefully developed and modified basing on comments received from various experts and National Health Authorities, there may still be issues and views that, unintentionally, have not been included. Working within this framework, HealthCare Workers (HCWs), facility managers, policy makers and program managers will have an opportunity to define and put in place the requirements for establishing HIV and other tests certification requirements for POCT site and tester. They will also implement and support the Quality Assurance Cycle (QAC) in POC HIV testing that has been tested in pilot projects or other field tests and proven successful. The framework will support monitoring and maintaining quality and reliability of testing processes hence test results.

This framework will need to be updated at least every five years or when there is a critical need to do so to reflect changes in country policies and guidelines, new quality approaches, lessons learned and new evidence from operational research.

This document is part of a collaboration of technical expertise from the following organizations: MoHCDGEC, Muhimbili University of Health and Allied Sciences (MUHAS), National Health Laboratory Quality Assurance and Training Centre (NHLQATC), Amref Health Africa Tanzania, Health Links Initiative (HLI) and Health Care Workers from Municipalities of Morogoro, Iringa and Ilala.

The framework will achieve the purpose of improving the quality of testing at POCT sites and contribute to improvement of health and wellbeing of the people.

Mpoki

Dr. Mpoki M. Ulisubisya
PERMANENT SECRETARY

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This framework was written by groups of Clinical and Laboratory Experts and other professionals from a range of background and specialties from different institutions and countries. The MoHCDGEC is sincerely gratefully for their time and support.

The MoHCDGEC would also like to acknowledge all stakeholders who contributed in developing and customizing this framework including representatives from Regional Administrative Secretaries of Dar es Salaam, Iringa and Morogoro; Muhimbili University of Health and Allied Sciences (MUHAS); the U.S. Centers for Disease Control and Prevention (CDC) through the University of Cheick Anta Diop, Senegal (CADU); Amref Health Africa Tanzania; the Medical Laboratory Scientists Association of Tanzania (MeLSAT) and Health Links Initiative (HLI).

The Ministry especially wishes to recognize the valuable and insightful inputs from Dr. Mohamed A. Mohamed, Dr. Dorothy Gwajima, Dr. Charles Massambu and Dr. Fausta Mosha of the MoHCDGEC, Professor Mecky Matee and Dr. Mtebe Majigo of MUHAS, Ms. Viola Msangi of Health Laboratory Practitioners Council (HLPC), and Dr. Donan Mmbando of HLI. Special thanks also to National Health Laboratory Quality Assurance and Training Center (NHLQATC) who in reviewing this framework, helped inspire subsequent revisions. Furthermore, the Ministry wishes to acknowledge Mireile Kalou from CDC Atlanta for her expertise, support and guidance provided throughout the development of this framework

The Ministry will feel indebted if special thanks are not given to HLI for its technical and material support to enable completion of this document. Funding for the development of this Framework, which was provided by U.S. Presidential Emergency Plan for AIDS Relief through the Centers of Disease and Control and Prevention (CDC), is gratefully acknowledged.

It may not be easy to mention every individual here; hence, a list of all participants who had worked on this document is available in annex 2.

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ABBREVIATIONS AND ACRONYMS

ASCP	American Society for Clinical Pathology
ASLM	African Society for Laboratory Medicine
CADU	Cheik Anta Diop University
CDC	Centers for Disease Control and Prevention
CHW	Community Health Worker
CHMT	Council Health Management Team
CLSI	Clinical and Laboratory Standards Institute
CQI	Continuous Quality Improvement
DCS	Division of Curative Services
DHMT	District Health Management Team
HQAD	Health Quality Assurance Division
EQA	External Quality Assessment
FIND	Foundation for Innovative new Diagnostics
HCW	Health Care Worker
HLI	Health Links Initiative
HLPC	Health Laboratory Practitioners Council
HTC	HIV Testing and Counseling
HTS	HIV Testing Services
ISO	International Organization for Standardization
JCI	Joint Commission International
M&E	Monitoring and Evaluation
MUHAS	Muhimbili University of Health and Allied Sciences
MoHCDGEC	Ministry of Health, Community Development, Gender and Children
NGO	Non-Governmental Organization
NSSG	National Supportive Supervision Guidelines
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PHLB	Private Health Laboratories Board
POCT	Point-of-Care Testing
PPE	Personal Protective Equipment
QA	Quality Assurance
QAC	Quality Assurance Cycle
QC	Quality Control
QI	Quality Improvement
QMS	Quality Management System
QSE	Quality System Essential
RDT	Rapid Diagnostic Test
RHMT	Regional Health Management Team
RLT	Regional Laboratory Technologist
SPI-RT	Stepwise Process for Improving the Quality of HIV Rapid Testing
TANA	Tanzania Nurses Association
TARENA	Tanzania Registered Nurses Association
TB	Tuberculosis
QIT	Quality Improvement Team
WHO	World Health Organization

STRUCTURE OF THIS FRAMEWORK

This framework is sub-divided into five distinct sections followed by glossary, references and annexes.

Section 1. The overview of POCT framework, which describes:

- 1.1 Introduction
- 1.2 Purpose
- 1.3 Audience
- 1.4 Scope

Section 2. National certification process, which describes:

- 2.1 Benefits
- 2.2 Establishment of POCT certification program
- 2.3 Governance structure
- 2.4 Monitoring and evaluating POCT certification program

Section 3. POC tester certification process, which describes:

- 3.1 Benefits
- 3.2 Key considerations for POC tester certification
- 3.3 Roles and responsibilities of facility management and POC testers
- 3.4 Training and maintenance of certification
- 3.5 Certification examinations
- 3.6 Scoring
- 3.7 Reporting mechanism and documentation of examination results
- 3.8 Corrective action and remediation plan
- 3.9 Certification process
- 3.10 Monitoring and evaluation

Section 4. POCT sites certification process, which include:

- 4.1 Benefits
- 4.2 Key considerations for site certification
- 4.3 POCT site certification stakeholders and roles
- 4.4 Standardized auditors training
- 4.5 Selection criteria for auditors
- 4.6 Elements of an effective audit process
- 4.7 POCT site audit checklist
- 4.8 Types of audits, frequency and certification level
- 4.9 Reporting and documenting mechanism
- 4.10 Remediation plan
- 4.11 Certification process
- 4.12 Monitoring and evaluation
- 4.13 Dissemination of evaluation reports

Section 5. Implementation Strategy for POCT Framework, which include:

- 5.1 Certification road map
- 5.2 Establishment of certification program
- 5.3 Sustainability
- 5.4 TOR for POCT steering committee

SECTION 1: OVERVIEW OF POCT FRAMEWORK

1.1 Introduction

Rapid diagnostic, recently Point of Care (POC) technologies, have become widely available in the last few years and have been shown to play a major role in increasing access to diagnostics. As access to POCT expands in Tanzania, there is a need for simple, practical and low cost innovative approaches to ensure sustainable quality assurance practices that lead to accurate and reliable testing results and improved public health outcomes.

In the process of addressing weaknesses identified in existing HIV related POCT programmes, the Government of Tanzania (GoT) in 2006 revised the *Health Laboratory Practitioners Act 12 of 1997 to come up with Act 22 of 2007* to demand licensing of Non – Laboratory Health Care Workers performing laboratory testing.
There are Non-laboratory health care workers who have been trained to perform POCT and are required to be certified according to the laws and regulations.
Therefore, this framework sets standards and processes for certification of POCT in Tanzania.

1.2 Purpose

The purpose of this framework is to provide guidance to strengthen National certification process for POCT sites and testers. This was recommended in the WHO handbook "*HIV Diagnostics Improving the Quality of HIV-Related Point-of-Care Testing: Ensuring the Reliability and Accuracy of Test Results Version 1 of September 2016".* It aims at informing the development of policies, processes, procedures and standards for implementation of National certification for POC testers and sites.
This document seeks to:

- To describe National Standards for POCT certification.
- Provide approaches to achieve certification of testing sites and testing providers including the Quality Management Approach
- Strengthen testing sites and provider certification practices
- Share recommended best practices and tools in the areas of testing sites

1.3 Audience

This framework document is intended for:

- Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) for policy development, planning, and implementation
- Ministries, Departments and Agencies (MDAs) owning Health Facilities including Uniformed Forces.
- Presidents' Office, Regional Administration and Local Government – The Health, Social Welfare and Nutrition Services Division.
- Regional Administration, Local Government Authorities, program managers, Faith Based Organizations (FBO), Private for Profit, developing and implementing partners for translation into action and monitoring.
- Testers, POCT site supervisors, managers and quality officers involved in the oversight and execution of POCT services.

1.4 Scope

This framework addresses all HCWs who are not laboratory professionals but are assigned to perform any kind of POCT working in Public, Private, MDA and FBO. The implementation of this framework has started with certification of HIV POCT sites and testers as shown in Figure 1 below:

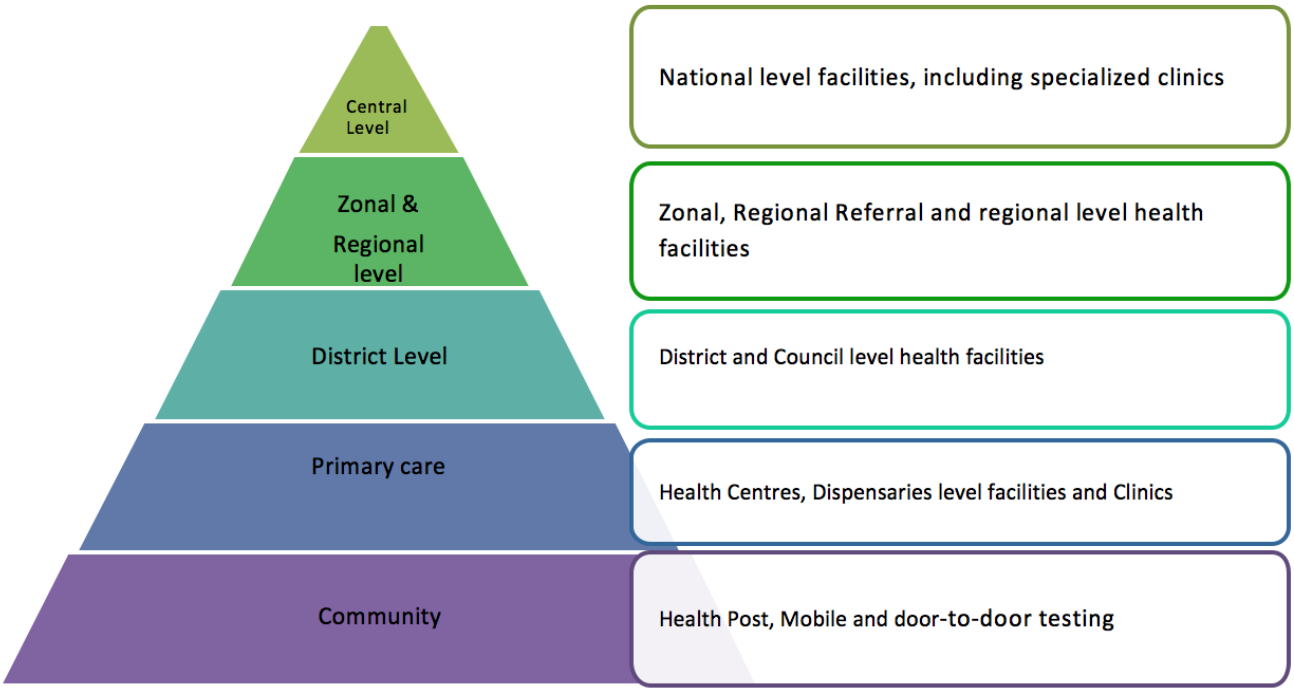

Figure 1: POCT across the tiered National Health System

SECTION 2. NATIONAL CERTIFICATION PROCESS

In Tanzania, certification gives a formal recognition of site and tester by Health Quality Assurance Division (HQAD) and Health Laboratory Practitioners Council (HLPC) respectively to carry out POCT services. Under normal circumstances testers and sites shall maintain certification after every two years once they meet the requirements under section 3 item 3.9.2 and section 4 item 4.11.2 respectively. The certification will be renewed after every two years to ensure maintenance of standards and reliability of results generated to support clinical and public health activities by the POCT site and tester.

Site certification verifies that testing procedures are in place and followed, results are technically valid, only competent staff performs testing and confirms that the site conforms to Quality Management System. Tester certification verifies that the tester performing POCT is adequately trained, has demonstrated competency and therefore s/he is authorized to do so.

2.1 Benefits

The benefits of a National POCT Certification Process program include the following:

- Gives confidence to the site and tester for availing the services and results generated
- Provides recognition of technical competence
- Facilitates implementation of Health Laboratory Practitioners' Council Act 22 of 2007
- Facilitates the implementation and maintenance of an effective Quality Management System
- Helps in defending the sites while dealing with legal disputes pertaining to results
- Reduces the operating costs of POCT by getting reliable and accurate test results

2.2 Establishment of POCT Certification Program

The following elements are critical to establish the National POCT Certification program

- Establishing the governance structure
- Developing of POCT framework
- Adopting Standards and Regulations
- Institutionalizing a mechanism for implementation of POCT services.

The following steps define a fully functioning certification system:

a. Endorse the certification process

   The Government of Tanzania (GoT) has established a National Laboratory Quality System, at all levels and extended it to the Private Sector. It has also established a National, Zonal, Regional and District Quality Assurance teams with the responsibilities to:

   - Develop and/or review policies and processes for ensuring reliability and accuracy of tests for POCT sites
   - Define how the process is integrated within the current QA framework
   - Identify and/or leverage resources needed for implementation of POCT services

b. Set National certification requirements focused on measurable quality goals
The Government has established these National Quality Standards to meet National Quality goal and objectives of this framework tailored to the requirements of POCT sites and testers certification.

c. Define requirements for site certification auditing and tester certification assessment
The requirements for tester and site certification have been defined in this framework (see Section 3 and Section 4 respectively)

d. Establish the authority to oversee policy, procedures and certification process
The MoHCDGEC has created a National Steering Committee for POCT, which is tasked to oversee the certification process. The parties involved are:
- Division of Curative Services (DCS)
- Health Quality Assurance Division (HQAD)
- Health Laboratory Practitioners Council (HLPC)
- National Health Laboratory Quality Assurance and Training Centre (NHLQATC)

e. Define process for recognizing testers and testing sites
Testing sites are certified by HQAD and testers are certified by HLPC.

f. Establish mechanism for gathering, analyzing, and reporting program data
MoHCDGEC has established Stepwise Process for Improving Quality of HIV Rapid Testing (SPI-RT) tool for gathering, analyzing and reporting POCT data. Additional tools are developed for specific requirements. Data for POC Tester and sites are managed by HLPC and HQAD respectively.

g. Identify resources for a sustainable certification process
Human and material resources for a sustainable certification process have been identified at all levels of health system. HQAD and HLPC have human resources at national level, while Local Government provides human resources at lower levels (Dispensary to Regional level). The Government prepares the annual budget to support HLPC and HQAD while Implementing partners fill in gaps identified by the Government. These include office equipment, furniture and other accessories, human resources for coordination, capacity building according to training needs and other technical support.

2.3 Governance Structure

Successful certification process involves stakeholders with specific roles at all levels (Figure 2).

i. National level: MoHCDGEC holds the ownership role and provides the resources for capacity building (stage 1)
ii. Certifying body and Steering Committee: Oversees the implementation of the certification process (stage 2)
iii. Zonal, Regional and District: Support the implementation of the certification process (stage 3)

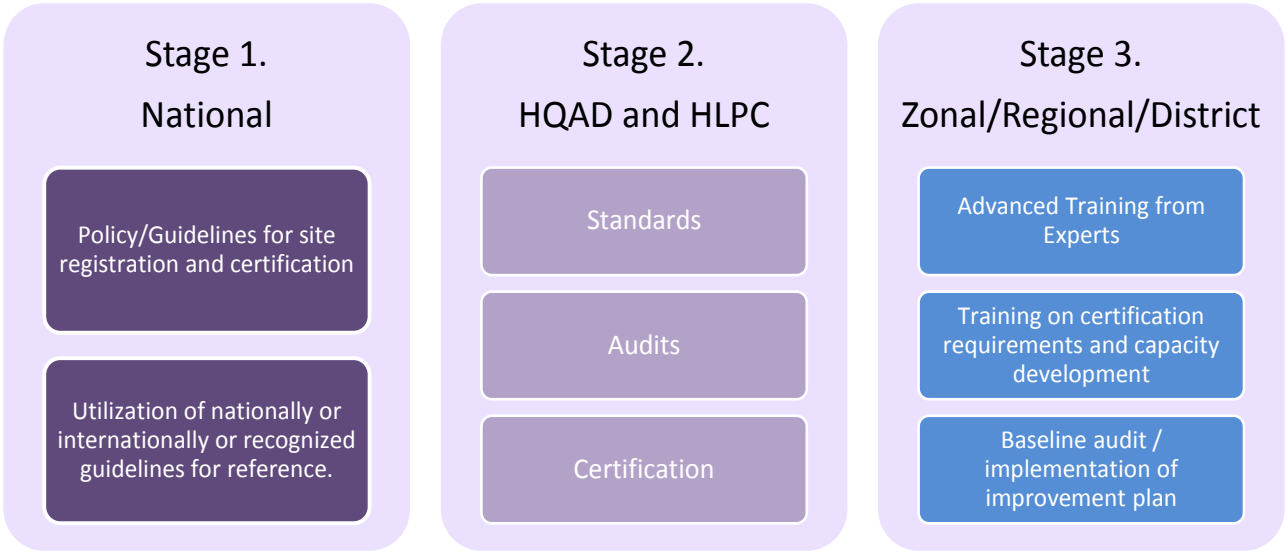

Figure 2: ***Stages of successful National POCT Certification Program***

2.3.1 Roles and responsibilities for each stakeholder

The specific roles and responsibilities of key stakeholders involved in the certification process at different levels are shown in Table 1.

a. National Government Institutions

The National Level is responsible for:

- Administration of the overall certification process
- Mobilizing resources
- Mandating the certification for testers and POCT sites
- Developing and reviewing the guidelines
- Developing rollout plans
- Providing guidance on implementation
- Setting the certification standards, and audit and evaluation criteria
- Overseeing the auditors and evaluators training
- Issuing certificates to sites and providers non-lab testers
- Monitoring and evaluating process of implementation

b. Certifying Bodies

HQAD as a site certifying body has the responsibility to:

- Determine the quality standards for the participating POCT site
- Identify auditors to conduct the activity (*HQAD members may also carry out competency assessment after appropriate trainings)*
- Establish and disseminate scoring system for the site certification
- Establish the implementation approach for site self-evaluation and quality improvement *(personnel at sites will perform internal audits to upgrade themselves and maintain standards)*
- Coordinate implementation within a defined rollout plan and clear timelines
- Monitor submission by each region of the appropriate detailed activities and budget for site certification
- Analyze and plan adjustment for subsequent year
- Maintain database of national auditors and trainers

- Audit site eligible for certification
- Issue certificate for eligible sites
- Maintain certification databases
- Develop corrective actions for remediation
- Submit quarterly certification reports to other members of National POCT Steering Committee
- Coordinate stakeholders meeting for appraisal of the evaluations reports

HLPC as a tester certifying body has the following responsibilities:

- Identify the evaluation standards and methods for testers certification
- Establish and disseminate scoring system for the personnel certification program
- Identify proctors and the competency evaluators
- Maintain database of National trainers, proctors and evaluators
- Establish the implementation approach for self-evaluation and quality improvement
- Coordinate implementation within a defined roll out plan and clear timelines
- Issue personnel evaluation examinations for certification
- Issue certificates for eligible testers
- Disseminate personal evaluation reports and develop corrective actions for remediation
- Submit quarterly certification reports to National POCT Steering Committee
- Coordinate stakeholders meeting for appraisal of the evaluations reports

c. Zonal/Region/Local Government Authority (LGA)/Implementing Partners

Zonal, Region, Council Management and Implementing Partners assist as program implementers and reinforce the implementation of the policies and guidelines established by the Government (Figure 3). They support training efforts for auditors' capacity building, provide mentorship to sites, and conducting baseline audits of sites. RHMTs and CHMTs are responsible for overseeing personnel competency assessment; in addition they may act as proctors.

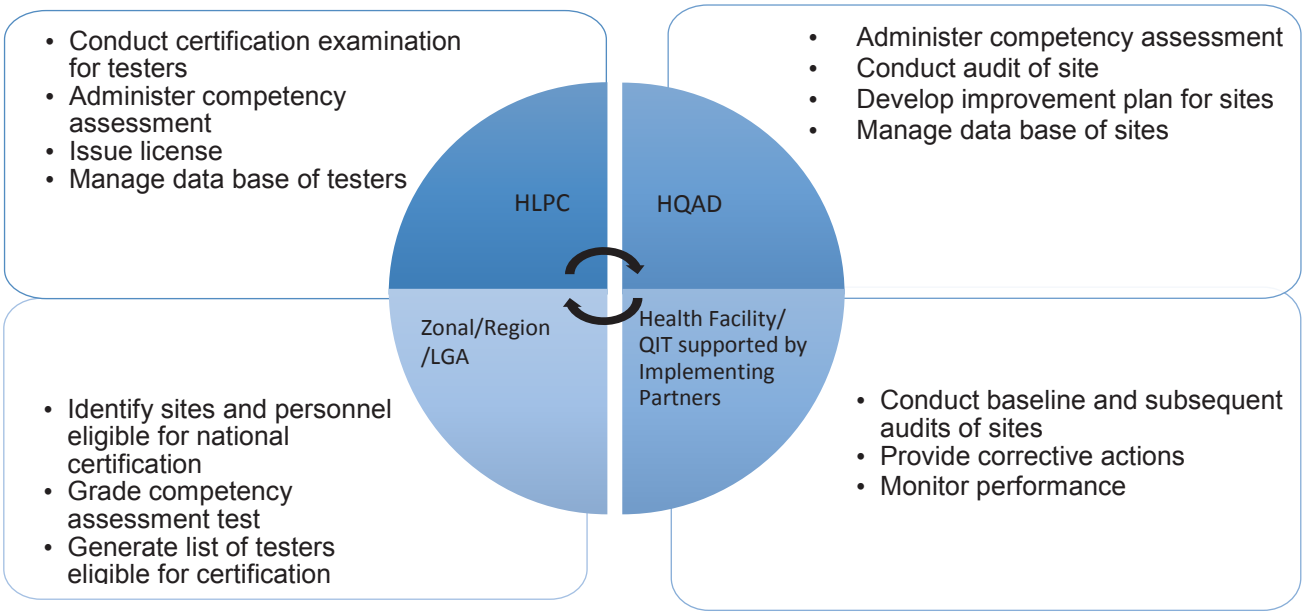

Figure 3. Relationship of HLPC, HQAD, RHMTs, CHMTs and Implementing Partners

d. Management and Personnel at POCT Site

Site management and POCT site personnel, as the primary recipients of the certification process, play a critical role for a successful certification implementation. They are engaged at all time and their roles and responsibilities in the process are clearly outlined. This group of individuals will:

- Demonstrate commitment to ensure reliability and accuracy of test results at POCT sites
- Demonstrate clear understanding of applicable National, Zonal, Regional, Council and Health facility guidelines, policies and regulations and comply with them
- Have a list of appropriate tools available to perform internal audit as well as external audits
- Compile audit findings, develop and implement the corrective action plan and provide a report of their findings and recommendation to laboratory leadership and supervisors.

Table1. Roles and Responsibilities of different stakeholders during certification process

Task	Who	What	How
Oversee Implementation	MoHCDGEC (HQAD, HLPC)	Develop method and plan for auditing POCT sites	Coordinate supportive supervisory visits
			Train and certify evaluators and auditors (reference laboratories)
			Collate data centrally from assessments
			Coordinate certification of all point- of – care testing sites
			Work with RLTs, managers and supervisors to rollout quality improvement activities
		Analyze findings from assessments	Develop summary report and disseminate
			Use data for monitoring and evaluation purposes
			Provide feedback to sites
			Site supervision, audits for certification and external quality assessment, panel distribution specific for certification activities
Support HQAD and HLPC in implementation and follow up across all levels	MoHCDGEC, PO-RALG and Implementing Partners	Support site supervision	Funding of human resources (including quality officers) for regular supportive supervisory visits to all testing sites
	RHMTs, CHMTs	Ensure that sites are ready for certification and implement quality improvement activities	Use rapid diagnostic testing and POCT checklists for assessing all sites currently performing or planned for POCT
			Provide feedback to sites and follow-up for corrective action

Task	Who	What	How
Build capacity for HCWs to support the certification processes	MoHCDGEC	Develop and approve training materials Coordinate site training in a phased approach Coordinate supportive supervision of sites	Through National and international engagement for technical assistance and other resources.
			Assess changes to be made
			Develop training of trainers programs
			Set assessment and proficiency criteria for certification and accreditation
			Coordinate and execute annual training plan
			Collect data from training for monitoring and evaluation
			Develop and execute supervisory plan with appropriate human resources dedicated to POCT
Fund quality assured training and certification	Development Partners	Support the development of training materials Support training and certification of POCT	Provide the resources (i.e., funding of technical working group)and technical assistance to develop and produce high – quality training tools
			Provide resources (i.e., Funding) for training related activities
Conduct Monitoring and Evaluation of certification program	HLPC, HQAD, RHMTs, CHMTs, Partners focal persons	Assist in developing training materials	Through RLTs and DLTs as they are part of technical working group for POCT and contribute to the development of the training materials
		Set indicators and targets to gauge process	HLPC and HQAD will consult stakeholders in order to set indicators and targets
			RLTs and DLTs disseminate indicators that will show progress RLTs will follow up on activities, targets and indicators and report to partners and management teams at their jurisdiction
			Conduct site audits and competency of testers using approved standards Inform relevant authorities of evaluation (supportive supervision, audits and competency assessment)

2.3.2 Standards for POCT certification

The developments of standards followed the WHO guidelines and were customized during series of consultative meetings with National and International organizations. The following standards were used as reference resources: -

- ISO/IEC 17025:2005; pertains to general requirements for the competence of Testing and Calibration Laboratories.
- ISO 15189:2012; addresses Medical Laboratories-Requirements for Quality and Competence ISO 22870:2006 provides standard for POCT in regards to quality testing and competency of testers.

It is important to ensure that the standards for POCT certification are assessed for compliance. Auditing and assessment tools and checklists are based on the agreed upon standards (Table 2).

Table 2.Instrument based POCT Checklist, Sections and Standards

Sections	Standards
1.0 Integration of POCT service for Patient Care	POCT services are offered such that results are interpreted and utilized to support health care, in accordance with National guidelines, policy and regulations
2.0 Personnel Training, Competency, and Certification	Personnel undergo/peruse a nationally approved training curriculum, participate in internal and external quality assessment program and certified by the certifying bodies
3.0 Physical Facilities	The POCT facility/site is adequate to provide safe and effective POCT services.
4.0 Safety	The POCT facility/site is adequate to prove a safe and effective POCT services, including providing for safety of staff, patients, and community.
5.0 Pre-Testing Phase	The POCT facility/site provides a standardized system for patient handling and identification, specimen collection and processing and recording of patient/specimen information.
6.0 Testing Phase	The POCT facility/site provides a standardized system to perform POCT and include QC testing and troubleshooting guides
7.0 Post-Testing Phase	The POCT facility/site provides a standardized HIV testing log book to record and report POCT results
8.0 Supplies, Reagents, and Equipment	The POCT facility/site provides adequate and reliable stocks of supplies and reagents, functional equipment instruments and reliable storage facility.
9.0 Monitoring Quality	The POCT facility provides a quality monitoring system to ensure accurate and reliable POCT results.

2.3.3 Auditing and assessment for compliance to standards

a. Introduction to POCT certification programs

For a certification process of POCT to self-sustain, HQAD and HLPC provide an enabling environment, which allows for increasing demands by POCT sites and testers. They inform all stakeholders about the standards and requirements used for both POCT sites and testers certification programs.

HQAD and HLPC engage Zones, Regions and LGAs to prepare sites and testers for audits and national examination. Subsequent audits, training and examinations will improve performance and ensure that personnel competency and site compliance are maintained.

b. Objectivity of the certification process

The HQAD and HLPC operate with impartiality (i.e. equal treatment, fair operation) irrespective of the settings, the testers training background and the organizations' affiliation (i.e., Government, Private, NGO). This is demonstrated objectively and not merely by declaring policy.

c. Addressing conflict of interest

The certification process is totally free from interference by the top management as this can adversely affect the credibility of the certification process. Conflict of interest of HQAD and HLPC are always declared through communication, information sharing and merging of activities. Conflict of interest is minimized or eliminated by ensuring that HLPC and HQAD are mandated to register all Personnel and Facilities respectively to make decisions for certification. A site will have personnel who will be responding to the auditor. Personnel conducting audits are trained on what to focus on. The same goes with evaluators for competency assessment.

d. Addressing complaints from POCT sites and testers

Allowing POCT sites and testers the chance to accept or reject personnel involved in the certification process is important for avoiding conflicts of interest. However, the HLPC and HQAD takes action only if the POCT site or tester can provide valid reasons by writing through the Medical Officer in charge, DMO/RMO to the Permanent Secretary of the MoHCDGEC; and not merely express subjective feelings or personal reasons for not accepting a particular person.

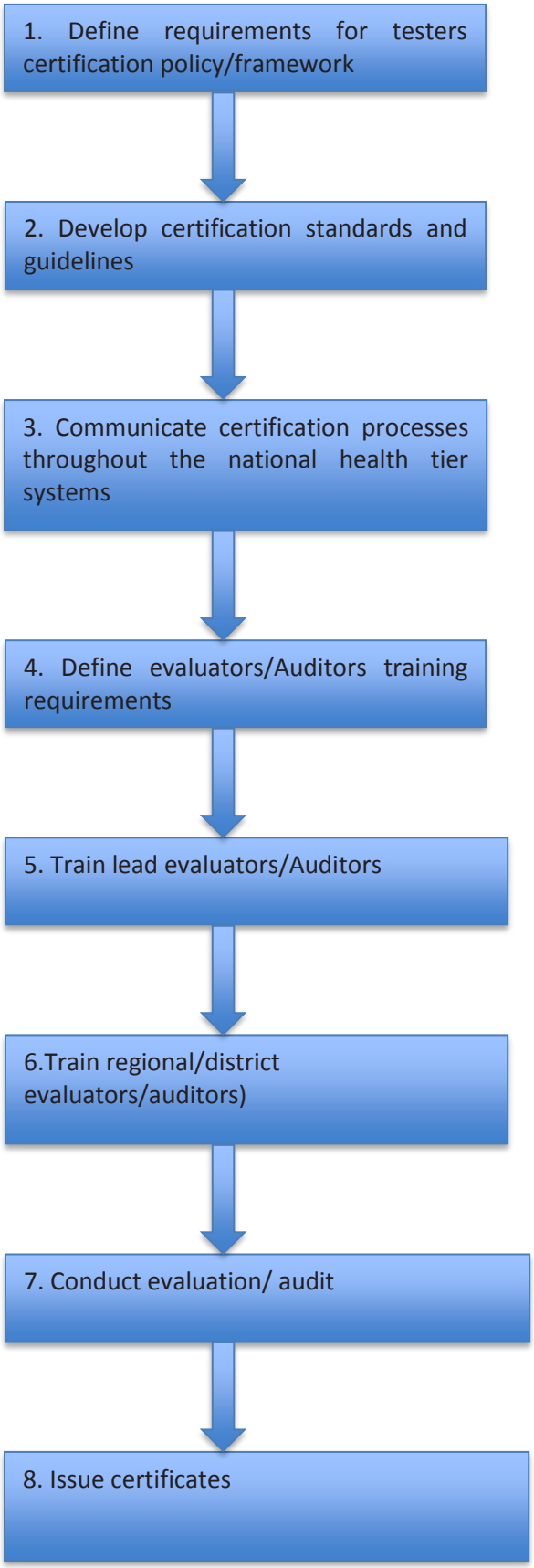

Figure 4: Major Steps for establishing POC testers and Sites certification process

2.4 Monitoring and Evaluation Of POCT Certification Program

Monitoring and evaluation defines program outcomes, connects outcomes to the goals or impact and measure them with indicators as described in section 3 and 4 of this document to ensure that the tester and site certification process are meeting its goals. The monitoring and evaluation include:

- Action Plan (Annex 1)
- Structured set of indicators
- Provisions for collecting data and managing records
- HLPC &HQAD gather, analyze, and report program data
- M&E findings are reported back for decision making processes

POCT certification bodies collaborate with MoHCDGEC M&E unit during certification process to allow easier data capture and analysis as well as to leverage and strengthen M&E programs in other health laboratory services countrywide. In addition, cell phones, tablets, portable electronic scanners, etc. are used to capture M&E data and linked to data base management at National, Zonal, Regional and LGA levels

SECTION 3. POC TESTER CERTIFICATION PROCESS

3.1 Benefits

National tester certification process ensures that all testing personnel are properly trained and competent to conduct POCT and produce accurate, timely and reliable test results. This entails that the POC tester successfully completes the initial training as well as passes both the theory and the practical examinations for certification/licensing to practice. Personnel certification/licensing promotes: -

- Personal achievement
- Professional recognition
- Demonstration of competence in theoretical and practical testing skills.

3.2 Key Considerations for POCT Tester Certification

For tester certification to be implemented, there are key areas that have been identified in Tanzania:

- Endorsement by the Government, establishment of standards, maintenance of the database and communication.
- The process is a stepwise approach starting with the HCWs pursuing a nationally recognized POCT training program
- Involvement of key partners and Non-governmental Organizations in respective areas
- Addressing the staff shortage by involving the Work Improvement Teams (WITs), Quality Champions and volunteers.
- Addressing the disparity in uptake of quality improvement through mentoring training program, supportive supervision, data collection, internal audits, networking and identification of problems, troubleshooting them and best practice sharing.
- Figure 5 below shows the major components needed for a certification program. These components comprise of Governing Bodies and critical documents to run processes and communicate between levels. The triangular shape also indicates level of effort or frequency or magnitude required. The Ministry level endorses the process thorough the framework once and after every five year review. At the base of the triangle is where one finds more activities, tools and procedures; this is where actual testing is done. Each tester has SOPs for each testing assay, undergoes continuing education related to testing and all these are recorded. Placing these at the base is an indication of the magnitude of these activities, documents and records in the certification process. Also they are the basis of a successful certification process.

Figure 5: Essential Components of National POC Testers Certification process

The following members will assist in the process of POC testers certification:

- HLPC and HQAD
- National POCT Steering Committee as mentioned in section 5 item 5.4.4
- RHMTs, CHMTs and Hospital Management Teams (HMTs)

3.3 Roles and Responsibilities of Facility Management and POCT Testers

Management and POC testers ensure all components of National tester certification process are implemented successfully.

3.3.1 Health facility management

- Supervise testing personnel and provide annual performance feedback to POC Testers
- Facilitate annual competency assessments for all testing personnel
- Promote and motivate personnel to participate in continuing education
- Maintain training files/documentation for all testing staff, which can contain the following:
    - Initial training completed on POCT and related quality assurance training
    - Initial certification documentation
    - Refresher trainings and continuing education completed
    - Recertification status and documentation
    - Competency assessment results
    - Corrective action and remedial plan
- Serve as proctors during written and practical examinations
- Serve as site points-of-contact for certification process to officially recognize testing personnel who successfully complete National tester certification and recertification processes

3.3.2 POC testers

- Complete national certification processes including standardized training, examinations and assessment components

- Maintain skills knowledge and competency through continuing education, refresher trainings attended, competence assessments to ensure their recertification requirements are met
- Familiarize with the certification processes

3.4 Training and maintenance of certification

To ensure all testers are competent and maintain the competency overtime, they undergo initial National training using approved curriculum and receive periodic refresher training

- Recommended minimum training programs for testers
    - POCT specific nationally approved standardized training program
    - POC testing specific refresher training program
- Training formats such as:
    - Direct observation (site training)
    - Mentoring (at work area or distantly)
    - Classroom training
    - Distance learning
    - Continuous education opportunities (i.e. seminars, conferences workshops)

3.5 Certification Examinations

3.5.1 Examination format

All certification examinations have both theory and practical sessions and have to be undertaken within a month.

- Theory examination: 20-25 multiple-choice questions
- Practical examination: Minimum of 5 blinded specimens

3.5.2 Development of examination

- HLPC is responsible in developing examinations. These are related to their standardized job descriptions, training guidelines essential skills, tasks, and background requirements to meet necessary competencies and be deemed proficient.
- The formation of a two-part certification examination will measure both theoretical knowledge and hands-on skills.
- The standardized theory examination content (e.g. multiple-choice questions) aims to cover all three testing phases (Pre-Testing, Testing and Post Testing) aspects whereas the practical skills assessment content (e.g. checklist items) will allow evaluators and proctors to directly observe the testers.
- The written examination questions will be randomly generated: The randomization occurs every time the testers log into a distance-learning portal with their credential. The questions can also be randomized to generate paper copies of the examination, using a Random Questionnaire Generator created in Excel. *Note:* a systematic tracking system will help ensure that the evaluators and the testers certifying body monitors each examination generated. The number of questions drawn from a Competency Assessment question bank is pre-defined for each section and identical for each examination generated. One set of 25 questions has questions from seven-quality element. However, the actual questions will vary each time.

- The minimum requirements to take and successfully pass the two-part examination in order to be nationally recognized as a certified POC Tester are:
    - 80% minimum passing score for the theory examination
    - 100% of sample results (blinded samples) during practical examination
    - ≥90% adherence to testing procedures during practical examination
        - **Note:** The average of sample results and adherence to testing procedures is the final practical score.
    - Two attempts are allowed to retake the two-part certification examination and within a six months period if the tester fails to obtain minimum passing score during initial examination.
    - Certification examinations are done within three months of completing the national approved POC trainings.
    - The testers who take the certification examination have attained at least Form Four education level with medical background.
    - Certification identification numbers are assigned to successful examinees according to certification guidelines and traceable in database.

3.5.3 Examinee preparation and study tools

The following are the preparatory guide and study tools for testers who are preparing for certification.

- Examination topic outlines
- Examination reading lists
- Examination administration procedures

Proctors will access all the study tools from HLPC and present to testers at least one month before examination.

3.6 Scoring

All POCT personnel must pass the two-parts (theoretical and practical) certification examination to be considered certified or eligible for recertification.

Table 3. Minimum passing score for tester certification examinations

Tester Certification/ Recertification		**Extension of Certification**	
Examination Type	**Suggested Minimum Passing Score (MPS)**	**Examination Type**	**Suggested Minimum Passing Score (MPS)**
Theory	80%	Theory	80%
Practical	95%	Practical	95%

3.7 Reporting Mechanism and Documentation of Examination Results

3.7.1 Reporting mechanism

- Feedback for online theory examination is provided immediately by the system.
- Feedback for classroom theory examination results is communicated to examinee within one week through email, courier or phone communication.
- Feedback for direct observation practical examination is communicated immediately after practical examination by evaluator

- Feedback for classroom practical examination is provided on the same day
- Results and hard copies for each examinee are submitted by proctor to HLPC through email, courier or phone communication within seven working days.

3.7.2 Documentation

- All results are documented on the standard result reporting form
- A copy of result is retained at site; another copy is submitted to HLPC within seven working days after completion of the examination.
- Examination results including the overall performance score are recorded in the personal file available at the facility
- A copy of certificate of successful completion will be kept in the personnel file available at the facility.

3.8 Corrective Action and Remediation Plan

Examinee and supervisor develop and start implementation of remediation plan immediately after examination.
Remediation involves mentoring that encompasses:

- Direct observation by approved supervisor
- Annual competency assessments
- Participation in Proficiency testing (EQA) program
- Refresher training
- Continuing education

3.9 Certification Process

3.9.1 Initial Certification

Initial certification is granted to a tester who:

- Begins with successful completion of National Standardized Tester Training
- Passing in theory and practical examination specific for certification

3.9.2 Extension of certification

Extension is granted to tester who did not exceed the certification period whereby:

- Certification for license to practice is valid for two years
- Granted upon completion of specific certification extension requirements, which can include the following:
    - Pursuing extension certification examination (two-parts: theory and practical)
    - Annual competency assessments (two-parts: theory and practical which may be by direct observation by any nationally approved party) conducted within valid license period.
    - Performance of at least one Proficiency Testing panel per year.

3.9.3 Recertification

Recertification is granted to tester who exceeds the certification period. This person fulfills the following:

- Submit recertification request to the HLPC
- Submit payment to the HLPC
- Pursue and pass theory and practical examination

3.9.4 Withdrawal

The HLPC develops and documents the procedures for withdrawing certification from tester personnel. Circumstances warranting withdrawal of tester certification are listed below:

- Three consecutive poor performances during national certification examination process
- Lack of participation in national recertification or extension process in the set time
- Lack of successful completion in national recertification process
- Deemed Biologically incompetent (for example semi or full blindness, color blindness or mental illness)

3.10 Monitoring and Evaluation

The M&E plan will be developed to ensure that the outcome evaluations of certification program are implemented and performance measurement are identified for performance monitoring and effectiveness of the program. M&E Plan will use national level specific indicators to track and monitor program efficacy and impact. Performance report of certification activities implemented will be measured in a quarterly basis and finally annual report will be generated. Evaluation to assess on how the implementation of the certification program has improved the quality of testing will be measured yearly. Monitoring and evaluation will be performed four times a year to track tester efficacy by the following indicators but not limited to:

- Number of testers enrolled in PT program
- Number of testers evaluated in both theory and practical
- Number of testers nationally certified
- Percent of testers nationally certified among trained testers
- Percent of testers nationally recertified among certified
- Number of testers below pass mark
- Number of remediation action plans developed.

SECTION 4. POCT SITE CERTIFICATION PROCESS

4.1 Benefits

This National certification process is used to ensure compliance with standards and quality improvement processes are continuously implemented in POCT sites. Certification offers the opportunity to recognize that POCT site has the ability to offer quality POCT services and provide confidence to the users of services.

4.2 Key Considerations for Site Certification

The transition from laboratory based testing to point of care and near point care testing requires that a systematic approach to verify that testing processes and procedures are in place, adhered to and properly documented. The HQAD oversee the implementation of the process in a phased manner. Auditing of the sites is conducted by Certified trained POCT sites auditors.

The HQAD and HLPC maintain and update database of certified auditors and POCT sites and testers respectively.

4.3 POCT Site Certification Stakeholders and Roles

As outlined in Section 1, under Roles and Responsibilities, the POCT site certification calls for commitment from all stakeholders. These include the POCT sites management and staff, Region/LGA auditors, National teams (HQAD, HLPC, National POCT steering committee as mentioned in section 5 item 5.4.4). Each one of them plays a critical role that should be clearly defined and widely communicated (Figure 6).

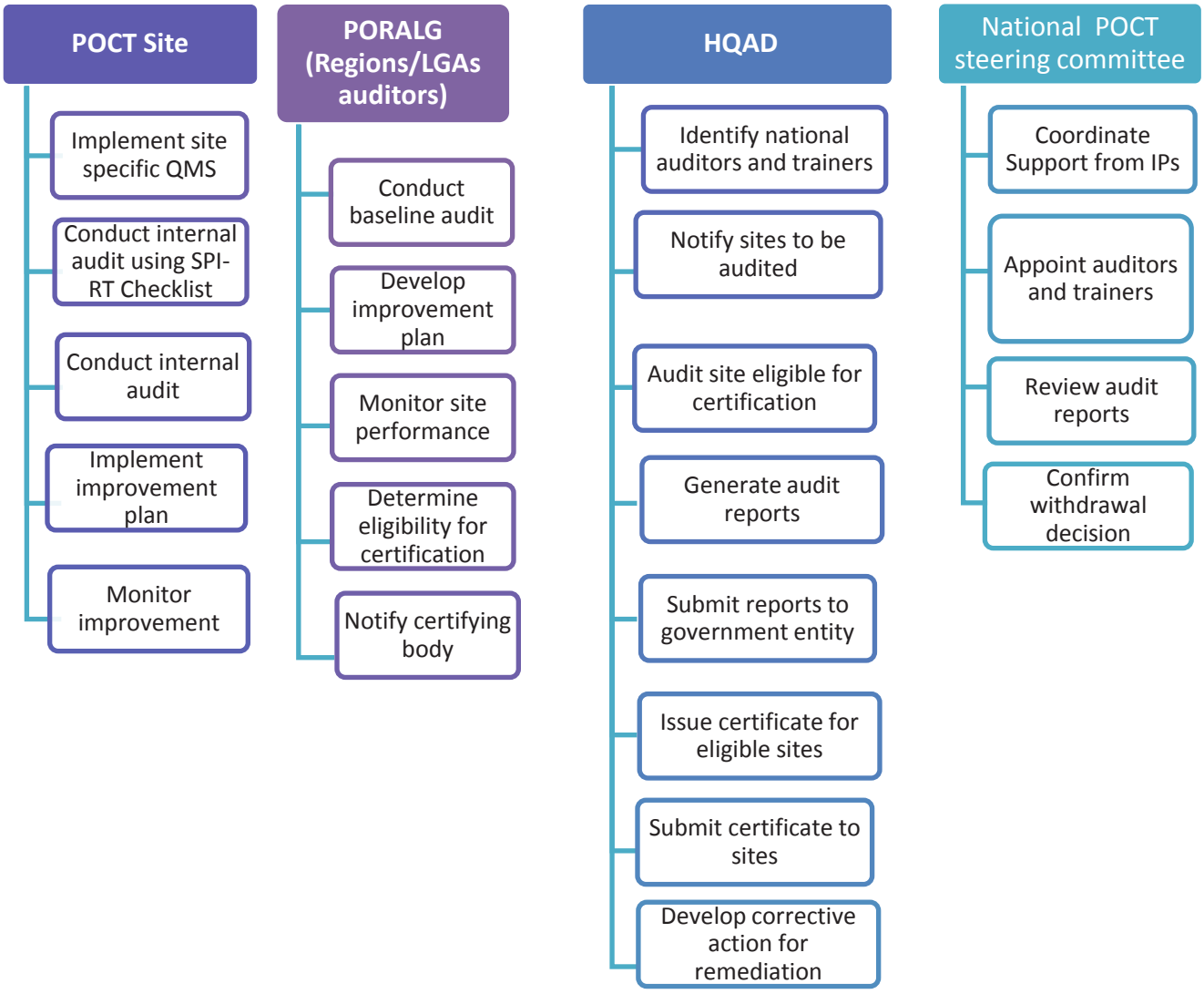

Figure 6: ***Roles of POCT Site certification stakeholders***

4.4 Standardized Auditors Training

4.4.1 Categories of auditors and roles

In the certification of POCT sites, auditors play a key role in assessing implementation of Quality Management System. There are commonly two categories of auditors:

- **System auditors:** These are HCWs trained as lead auditors, certified and approved by the MoHCDGEC.
- **Technical Auditors:** These are experts working in specific laboratory disciplines who keep up-to-date with technology and know-how.

4.4.2 POCT site auditors training requirements

At minimum POCT site auditors are required to:

- Participate in a standardized training for POCT sites auditors
- Conduct audits under the mentorship of a trainer or an experienced auditor

- Maintain competency by participating in continuing education to ensure that their knowledge is up to date

Formal training for auditors include the following:

- Availability and following audit checklists and tools
- Case studies, group exercises and actual site audits
- Professionalism (including ethics) and effective communication
- Actual site audit and report writing

4.4.3 Managing POCT site auditors database

The data to be captured in the database include but are not limited to:

- Auditor's demographics (name and contact information, job title and most recent location)
- Date of initial training and training certification
- Information on continuing education to maintain competency
- Information on most recent training certification and validity period

The POCT site auditors' database is updated quarterly.

4.5 Selection Criteria for Auditors

The HQAD develops and reviews the POCT site auditor's terms of reference based on essential background requirements and skills to meet the requirements for POCT site auditors. Also the HQAD outlines the auditors' tasks and resources necessary to conduct the audits.

Table 4. Eligibility criteria for POCT sites auditors

Attributes	**Required**	**Recommended**
Understanding of the POCT site audit tools *(e.g. SPI-RT Checklist)*	✓	
Knowledge of National recommendations and requirements of POCT sites	✓	
Understanding of POCT program specific guidelines and policies *(e.g. National HIV Testing Services guidelines, etc.)*	✓	
Knowledge of all testing phases requirements for certification	✓	
Understanding risk specific audit		✓
Communication skills *(to include interviews with staff involved in testing, documentation, record keeping stock management, and other relevant activities)*.		✓
Knowledge of safety and waste management practices as recommended by National Infection, Prevention and Control (IPC) manuals	✓	
Ethics responsibility and conflict management		✓
Familiar with POCT site processes and procedures, personnel training and competency requirements		✓
Knowledge of External Quality Assessment (EQA) programs specific to the POCT sites being audited		✓

4.6 Elements of an Effective Audit Process

The following elements are included to ensure the audit process is effective and efficient.

a. Risk-based audit: This type of audit focuses on elements that:
    - Pose greater risk to the safety of testing site personnel,
    - Affect the quality of service rendered and the accuracy of test results.
b. The timeframe for addressing the deficiencies identified during an audit is dependent on:
    - The criticality of the findings
    - The level of risk they pose to the staff and to the client
c. The deficiencies should be addressed within 3-6 months of the audit.
d. Adequate Human Resources: These are required to serve as mentors to support the POCT sites and assist with troubleshooting and addressing quality related deficiencies.
e. Written guidelines and procedures: These describe the process of conducting the audits and should be available, understood and used by all certified auditors.
f. Verification of compliance: This ensures that there is documentation, and that the testing site is compliant and meets the requirement for national certification.
g. Complaint Resolution: POCT sites audited are given the opportunity to discuss an audit report and resolve concerns, if any, in a timely manner.
h. Audit schedule: An audit schedule of 6-12 month period is scheduled to coordinate audit process and adequately allocate resources.

4.7 POCT Site Audit Checklist

Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) checklist is used to standardize the rapid testing site audits. The checklist is available as a separate document or e in electronic devices e.g. android tablets etc.

The checklist also provides:

- Guidance on Quality Assurance (QA) practices for sites using HIV rapid tests to diagnose HIV infection and other POCT in seven areas of quality.
- Minimum standards for POCT
- Scoring guide
- Guidelines for continuous quality improvement.

Using the SPI-RT Checklists the POCT site gauge its level of compliance to national requirements and thus determines its level of eligibility for certification. The higher the number of points obtained, the higher the level of compliance and the closer to certification the site will be (table 5).

4.7.1 Preparing for the audit

In preparation for the site certification, it is critical to engage all key players particularly POCT site personnel and management for an impactful outcome (figure 7). Trained and capable non-biased auditors are facilitated to conduct the audit using appropriate checklists.

4.7.2 Conducting the audit

The auditor conducts audit based on both evidence and observation related to the following quality elements:

- Personnel and Training
- Physical Facilities
- Safety Items and Procedures
- Pre testing Procedures
- Testing Procedures
- Post testing Procedures
- External Quality Assessment

4.7.3 Scoring

Scoring is based on a 70 points system, which is a maximum score for a site. The score is then converted into percentage.

Formula for calculating percentage score: Score obtain by the site/Max score (70) X 100

Table 5. Five-point level for compliance with quality standards for POCT sites certification using the SPI – RT checklists

Levels	% Score	Description of results
Level 0	Less than 40%	Needs improvement in all areas and immediate remediation
Level 1	40% - 59%	Needs improvement in specific areas
Level 2	60%-79%	Partially eligible
Level 3	80%-89%	Close to national site certification
Level 4	90% or higher	Eligible to national site certification

Note: For POCT sites that attain the highest level (level 4) during internal audit; the - Regional team will notify the certifying body to schedule an auditor.

After the audit, the auditor provides verbal feedback and a summary of findings and recommendations for improvement to the site management.

Once audit is completed, national mentors approved by the MoHCDGEC will mentor POCT sites. Mentorship will help POCT sites to implement Quality Management System (QMS) and perform quarterly internal audits using SPI- RT Checklist to document and address deficiencies identified.

The records retained from internal audit usually include, but are not limited to:

- Completed Audit Checklists and/or marked up procedures
- Notes on any other observation
- Audit findings documented (e.g. Auditor's Summation Report for SPI-RT Audit)

4.8 Types of Audits, Frequency and Certification Interval

Establishing reasonable timelines for site audits is important for planning and resource allocation. The table below outlines the frequency of site audits based on the type of audits and the level of compliance attained. The validity of the certification should not exceed two years.

Table 6. Types of Audits, Frequency and Certification Interval

Quarterly	Semi-annually	Annually	Two yearly
•Internal audits by POCT site •Records of identified gaps and corrective actions should be maintained •Sites conduct internal audit until they move from level 0 to 2 •If the sites score level 2 and above it should notify RHMTs/CHMTs •Mentoring of the site by lab staff or QI team	• Sites scored level 2 or above will be audited •Audits by RHMTs/CHMTs •If the site scored level 4, Regional team will notify the certifying body •Mentoring by RHMTs/CHMTs including Q-corps	•Level 4 sites will be audited •Audits by certification body (HQAD) •Initial certificaton	•After initial certification •Audits by Certification body •Recertification

The HQAD develops a database to track the POCT site certification data. The information captured includes but not limited to the following:

- Site general characteristics information as outlined in the SPI-RT checklist, including contact of site representative
- Sites eligible for national certification
- Sites audited and certified (including dates of audit and certification)
- Main deficiencies identified
- Sites audited but not certified (including dates of audit and reasons for not being certified)
- Expiration date of sites certified
- Resubmission of audit request (including date – should not exceed 90 days following the previous audit)

4.9 Reporting and Documenting Mechanism

All audits performed are documented in a report and shared with the POCT site staff. Formal written report on the audit findings is provided to the facility management within a month after the audit, including the corrective measures. The final steps of audit reporting include writing effective recommendations that the site audited can follow in order to achieve the desired results. Auditors' recommendations must be:

- Action-oriented
- Convincing and feasible
- Well-supported
- Effective
- Clear and concise

4.10 Remediation Plan

It is recommended that the site personnel review the findings of the audit and begin the process of corrective actions to address the deficiencies within 30 days of the audit. A written procedure on audit (internal and external) should be available at the site and include information on frequency of audit, internal audits as well as time allotted to perform and complete corrective actions.

4.11 Certification Process

Site certification is endorsed by MoHCDGEC and granted by HQAD, which is mandated to perform the function.

4.11.1 Initial certification

Once notified, the HQAD identifies the team of certified auditors to audit the POCT sites, which have obtained ≥90% score (level 4) in the internal SPI-RT audit. HQAD schedules the audit and notifies the facility management and testing sites. Certified auditors perform:

- Review internal audit reports and previous certification audit reports
- Audit of the sites
- Document audit findings.

If all documentation and requirements are in compliance with national certification requirements, the site is awarded a certificate valid for two years.

4.11.2 Recertification

In order to maintain continued conformity with certification criteria, the POCT site seeks recertification from HQAD through RHMTs and CHMTs every two years.

4.11.3 Remediation plan

The site personnel review the findings of the audit and implement the recommended corrective actions within 30 days of the audit. Supportive supervision by the facility in-charge, CHMTs, RHMTs, or implementing partners will be conducted to meet the requirements for the national site certification

4.11.4 Withdrawal of certificate

Circumstances that may lead to withdrawal of certification are listed below:

- Major deviations on one or more certification requirements that are not resolved by site in a timely and acceptable manner. These include, but not limited to safety gear and processes, lack of viable and correct test kits and lack of a suitable testing area
- Site delays, limits, or denies access to records, documentation
- Unable to verify and confirm compliance to certification requirements

4.12 Monitoring and Evaluation

The M&E plan is developed to ensure that the outcome evaluations of certification process are implemented and performance measurement are identified for performance monitoring and effectiveness of the process. M&E Plan uses the National level specific indicators to track and monitor program efficacy and impact. Performance report of certification activities implemented will be measured on quarterly basis and finally annual report will be generated. Evaluation to assess how the implementation of the certification program has improved the quality of testing will be measured yearly.

Examples of potential specific indicators to track and monitor site certification program efficacy and impact include but not limited to the following:

- Number of sites enrolled in program during a specific timeframe
- Number of sites audited
- Number of sites certified nationally
- Percentage of sites with improved performance

- Percentage of sites nationally recertified
- Distribution of QSEs with scores

4.13 Dissemination of Evaluation Reports

This will take place through:

- National and International professional conferences and meetings
- Supportive supervision visits
- During planned sectorial trainings
- Health related campaigns

SECTION 5: IMPLEMENTATION STRATEGY

5.1 Certification Roadmap

Certification of HIV testing sites and respective personnel, the following are the key steps that Tanzania will take together with key stakeholders in the implementation process:

1. To establish a certification program for HIV RT testers and testing sites
2. Build and maintain pool of auditors and evaluators
3. To certify testers and testing sites
4. Monitor and evaluate progress

5.2 Establishment of Certification Program

The system includes, but not limited to:

5.2.1 Conduct continuous advocacy to key stakeholders

This is identified as a major benchmark to continuously identify resources and their respective providers. It is a continuous process to enable understanding and embracing the process at all levels by all stakeholders as well as creating a sense of ownership and sustainability. The LGAs and Facility Management Teams, incorporate certification activities in comprehensive council health plans. Also, MoHCDGEC should support certification process through providing funds to HLPC and HQAD.

5.2.2 Support to HLPC and HQAD

a. The registrar of HLPC and Director of HQAD are responsible in ensuring that testers and sites are certified, information is channeled to the respective authorities, track testers and their certification status and support laboratories to actively oversee quality of testing in their areas of work. Certifying bodies are provided with engine for generating evaluation packages, tablets for conducting audits, database for managing all certification information and equipment with the database. Initial training will be conducted by the support of respective partner.
b. The PORALG ensure availability of adequate qualified and trained HCWs; appropriate infrastructures (reliable water and power supplies testing supplies).
c. Laboratory coordinators in LGAs, NGOs, Zonal, National level facilities and IPs are trained to become evaluators and auditors. System Auditors will also be trained. Other competent laboratory personnel are identified and trained to become evaluators and auditors. Selection criteria also include geographical location, ability to follow up and successfully passing the training course. After deemed competent they participate in coordination and performing audits and evaluations using standardized methods explained in this document. Reports will be prepared after every audit or evaluation and given to facility management, local government authorities, Regions, National level authorities and shared with relevant IPs.
d. Facilities participate in identification of candidates to be trained as evaluators and/or auditors and provide feedback on deficiencies.

5.2.3 Conduct evaluation of testers and site audits

Implementing Partners start supporting actual certification process for both testers and sites. Costs for certificates of personnel are covered by testers/personnel; other mechanism to support this will be explored. Implementing partners will collaborate with the Government to ensure that testers are retrained towards competency and subjected to council examinations and site audits. The Implementing Partners to discuss with local authorities on areas of support. Payments for certification of the sites are billed to local governments as facility owners.

5.2.4 Maintain team of evaluators and auditors

Registrar of HLPC and Director DHAD are responsible to maintain the list of current evaluators and auditors for tester and site certification respectively. They will also track new sites and testing personnel. Progress Reports on certification process will be shared to POCT Steering Committee, PORALG and Implementing partners

5.3 Sustainability

In order to ensure sustainability, the MoHCDGEC works with PORALG to incorporate certification program in the Comprehensive Council Health Plan and task facilities both public and private health facilities to participate in the program. This is important because HIV testers are maintained in all facilities so as to sustain quality HIV testing services. Certification of testers and sites are managed as per organogram as shown in figure 7 below:

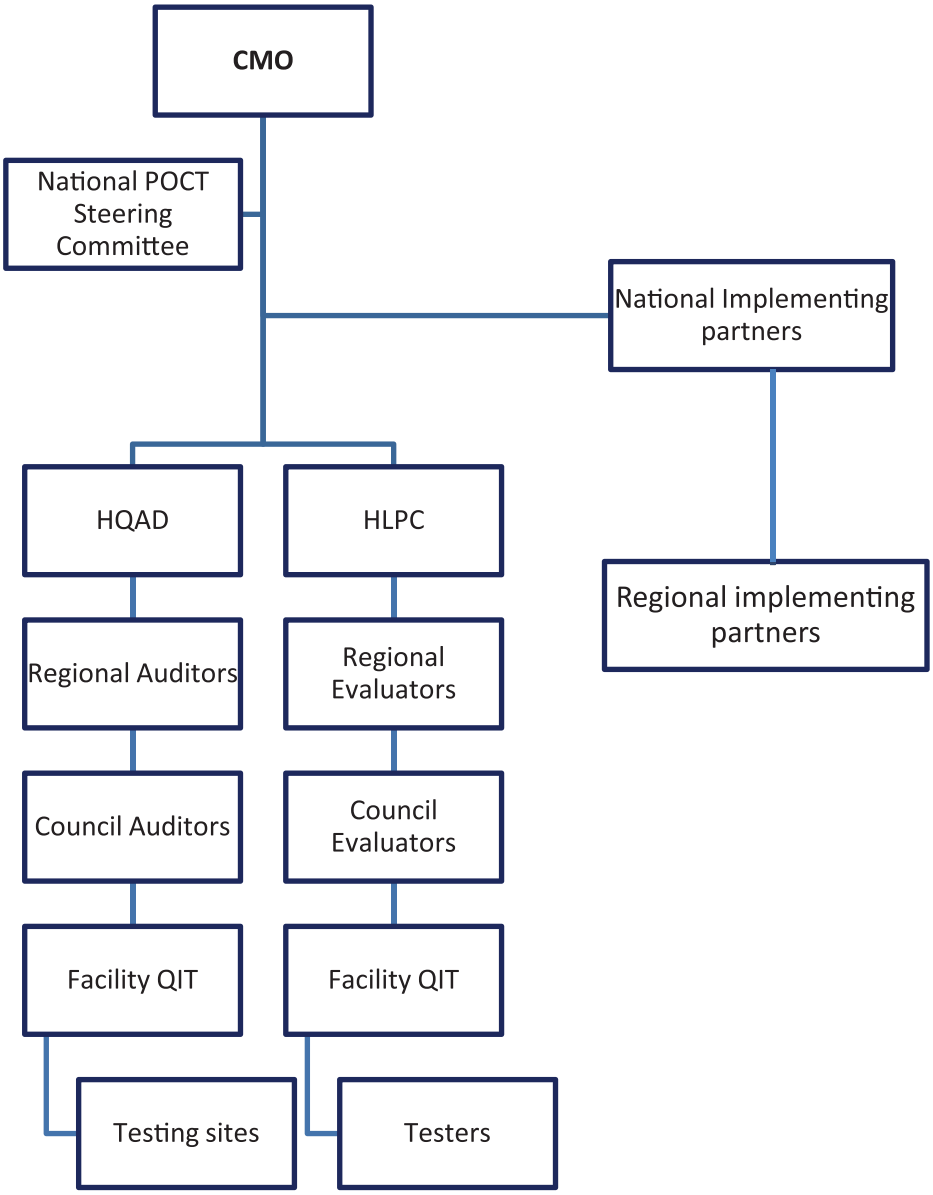

Figure 7: Organogram for Management of POCT Certification Process

5.4 TOR for POCT Steering Committee

5.4.1 Introduction

Steering committee for POCT is acknowledged as an important element to facilitate the implementation of the certification framework.

Steering committee is instrumental to the Ministry of Health, Community Development, Gender, Elderly and Children's (MoHCDGEC) ability to capture the value of certification process in Tanzania.

The steering committee will unfold many positive influences on success of this program. The committee will also be instrumental in the implementation of POCT certification process.

5.4.2 Purpose

The purpose of POCT steering committee is to maintain and enhance MoHCDGEC reputation by ensuring that high standards are consistently set and applied towards:

- Competency assessment of testers and site auditing
- Maintain approved standards set in the certification framework and other HIV testing services guidelines of the MoHCDGEC

5.4.3 Duties

Duties of POCT steering committee are to:

- Support development and maintain professional standards and ensure that this reflects the needs of testers and recommending changes to the respective certification body.
- Oversee implementation and review of certification framework
- Set standards for Continuing Professional Development (CPD)
- Approve policy guidelines used in assessing the competency
- Maintain link with other structures of the MoHCDGEC, PORALG and IPs so as to ensure effective communication, information sharing, and joint working an awareness of key issues across the health sector.

5.4.4 Membership

Members of the committee shall be as follows:

i. Chief Medical Officer (CMO) - Chairperson
ii. Director for Health Quality Assurance – Secretary
iii. Director of Curative Services -
iv. Director of Preventive Services
v. Director of Policy and Planning
vi. Director of Health, Social Welfare and Nutrition Services Division (PO-RALG)
vii. Director of NHLQATC
viii. Assistant Director Technical and Diagnostic Services
ix. Assistant Director RCH Services
x. Registrar for HLPC and Chairperson
xi. Registrar for PHLB
xii. Program Manager NACP
xiii. Program Manager NMCP
xiv. Program Manager NTLP
xv. Representative from Development Partners
xvi. Association of Private Health Facilities Tanzania (APHFTA)

5.4.5 Quorum

The quorum necessary for the meeting to take place shall be not less than 50% of members. Members will work towards consensus model for decision- making.

5.4.6 Frequency of meetings

The committee shall conduct meeting twice a year or when necessary

5.4.7 Steering committee meetings

- Meetings of the committee shall be called by secretary of the committee at the request of the committee chairperson
- Unless otherwise agreed, notice of each meeting confirming venue, time and date, together with an agenda items to be discussed shall be forwarded to each member of the committee and to any other person required to attend no later than **five (5)** working days before the date of the meeting.

Supporting papers shall be sent to committee members and other attendees, as appropriate, at the same time**.**

The secretary shall minute the proceedings and resolutions of the committee meetings, including the names of those present and in attendance.

5.4.8 Terms of Reference (TOR) for different stakeholders

i. HQAD and HLPC

- Coordinate certification activities
- Manage certification data including hardware replacement and software updates as the need arise
- Conduct documents development and review
- Issue certificates within the time set
- Withdraw certificates according to set criteria
- Regularly inform POCT Steering committee and other authorities on the progress of certification program

ii. PORALG

- Competent testers are equitably available at all sites.
- Ensure availability of appropriate infrastructures (reliable water and power supplies testing supplies).
- Monitoring certification activities and indicators

iii. RHMTs

- Oversee certification process for the region
- Participate in audits and evaluation within the region
- Identify personnel and sites due for certification and notify the National certification Bodies
- Identify personnel and sites due for withdrawal of license and notify the National Certification Bodies.

iv. CHMTs

- Oversee certification process for the Council
- Participate in audits and evaluation within the Council
- Identify personnel and sites due for certification and notify the region
- Identify personnel and sites due for withdrawal of license and notify the region

v. Facility Management

- Ensure and/ or facilitate competent testers are equitably available at all sites.
- Follow up on sites and tester certification

- Conduct and/or facilitate internal tester evaluation and site audits
- Conduct and/or evaluate external quality assessments including Testers proficiency testing, Supportive supervision, tester evaluations and site audits
- Participate in document reviews
- Provide budget for certification by including certification in their Comprehensive Council Health Plans
- Facilitate continuous mentorship for testers

vi. Quality Improvement Team at the facility level

- Oversee implementation of quality improvement indicators related to HIV-Rapid Test
- Conduct internal audits
- Ensure active laboratory technical (mentorship in testing procedures) support for testers

GLOSSARY

Accreditation
Procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks (modified from ISO/IEC17000)

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

Audit
The systematic, independent and documented process for obtaining audit 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])

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

Certification Body
Organizations or agencies with the authority to inspect a facility or assess competency of HCW and provide written evidence of compliance with regards to set standards

Certification Maintenance
The process by which individuals or sites possessing certificates perform or maintain certain specified requirements in order to retain their certification to demonstrate continued competence and performance

Competence
The demonstration of personal attributes and the demonstration of the ability to apply knowledge and skills (ISO 9000[3.1.6])

Competencies
A set of defined behaviors that provide a structured guide enabling the identification, evaluation and development of the behaviors in individual employees

Competency
An ability or skill (Merriam-Webster Dictionary)

Continuous Quality Improvement
Recurring activity to increase the ability to fulfill requirements (ISO 9000 [3.2.13]) 3;
Also known as continuous improvement, includes the actions taken throughout an organization to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to the customer and organization (CLSI: QMS06-A3)

Corrective Action
The action 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
A person whose job is to judge the quality, importance, amount, or value of something (Cambridge Dictionary) *e.g., in the setting of judging the quality of competencies in HIV-testing personnel*

Examinee
A person who is examined (Merriam-Webster Dictionary) *e.g., sitting for an examination to measure competencies in the subject area of HIV-testing*

External Quality Assurance (EQA)
Inter laboratory comparison to determine if testing service can provide correct result and diagnosis (WHO, HIV testing Services Guideline 2015)

Governance
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.

Mentor
An experienced and trusted advisor who provide teaching and advise to other persons in order to find the right direction.

Mentoring
The process of practical training and consultations that fosters on-going professional development to yield sustainable high quality clinical service outcome (NSSG 2017)

Monitoring and Evaluation
A process that helps to improve performance and achieve 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 those are relevant to the audit criteria being used.

Point of Care Testing (POCT)
POCT is 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)

Proctor
A person appointed to keep watch over students at examination.

Proficiency Testing (PT)
Evaluation of participants' performance against pre-established criteria by means of inter-laboratory comparison (ISO 17043:2010)

Program
The group of interrelated activities managed in a way to obtain results that are not achievable if they are attempted individually.

Quality Corps (Q-Corps) volunteers
A group of volunteers or interns recruited temporarily to assist with quality assurance activities. This concept is based on a successful pilot program in Africa to recruit volunteer personnel from the community where testing is carried out who are trained in specific elements of quality assurance and can undertake these activities such as expedited dispatch of proficiency panels, quality control specimens or standardized logbooks and rapid return of results, enabling deeper access and penetration at rural sites where testing is being carried out.

Quality Improvement
This is a systematic effort to improve the quality of health system development and the delivery of health care services, including all methods of performance assessment and readjustment according to all available resources, thereby serving the health and welfare of the people.

Quality Improvement Team (QIT)
This is a group of selected, multilevel, multidisciplinary staff tasked to oversee improvement on the day-to-day performance in a health facility, conduct periodic performance assessments and liaise with the management on improvement strategies and activities.

Quality Management System (QMS)
This is a set of policies, processes and procedures required for planning and execution (production/development/services) in the core functions of an organization

Quality System Essential (QSE)
The management infrastructure necessary to support any health care organization or services' path of workflow.

Rapid Diagnostic Testing (RDT) or Rapid Test (RT)
A medical diagnostic test that is quick and easy to perform. RDTs are suitable for preliminary or emergency medical screening and for use in medical facilities with limited resources.

Remedial Action
The change made to a nonconforming product or service to address the deficiency.

POCT Site
This is a location where point-of-care testing is performed with rapid diagnostic devices outside clinical laboratory settings.

Site Certification
The procedure by which a third party gives written assurance that a service (such as POCT results) conforms to specified requirements at any location.

Standards
A standardized authoritative “document” setting for the criteria for performance and characteristics (RHuD1.7CD/CLSI). Standards may be issued by national, regional, or international standards bodies.

Supervisory
An action of observing and directing an activity or a person

Tester
A person who performs testing *e.g., medical personnel performing point of care testing*

Tester Certification
The procedure by which a third party gives written assurance that an individual performing point-of-care testing conforms to specified requirements outside clinical laboratory settings.

Tester Certification Maintenance
The process by which an individual performing HIV rapid diagnostic testing and HIV-related point-of-care testing demonstrates continuing theoretical and skills competence

Training
A process by which someone is taught the skills and knowledge that are needed for performing a new art, profession, or job to improve existing knowledge and skills.

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ANNEXES

Annex 1: Action Plan for Establishing Certification System for POCT Testers and Testing Sites

No	Objective	Activities	Target	Responsible Party	Inputs
1	To establish system for evaluating and Certifying HIV RT testers and Testing Points.	1.Provide certification working tools to all RLTs and evaluators and relevant authorities	Documentation tools for conducting practical and theory available Result sheet (theory 1000, practical 1000) SOPs for evaluation	Local Government, IPs	Printing and photocopying services
			100 Certification framework documents printed and distributed	IPs	
		2. Conduct advocacy in Certification to relevant authorities	Three (3) National conferences per year attended (RMO, TANA TARENA, MeLSAT)	HLPC, HQAD, PORARG	Allowances for technical personnel
					Allowances for support staff
					Fuel
			Eight (8) Zonal advocacy meetings for MoHCDGEC and Local Government Authority representatives conducted	IPs, HQAD, HLPC	Allowances for technical personnel
					Allowances for dignitaries
					Allowances for support staff
					Fuel
					Conference package
			2 International conferences attended	IPs, HQAD, HLPC	Allowances
					Air ticket
					Registration costs
		3. Build capacity at Registrar's office to manage data on certification	Hardware for data management in use	IPs	Computer, server and accessories procurement and installation
			Theory questions generated at Registrar's office	HLPC	Software installation
					Software user training
			International Technical support provided	IPs	Allowances
					Return air ticket

					Accommodation
No	**Objective**	**Activities**	**Target**	**Responsible Party**	**Inputs**
2	To evaluate 1500 HIV rapid testers by December 2017 and audit 500 sites	1.Conduct evaluation in 50 councils per year for HIV RT testers	50 councils identified		
			1500 HIVRT testers assessed for competency using physical methods		Allowances
					Driver
					Fuel
					Air ticket
					Printing result sheets
					1500 X6 blood sample panels
		2.Provide Licenses to successful testers and sites	- Print 750 certificates for testers -Print certificates for the qualified sites		Printing
			750 testers licensed - Provide certificates to the qualified sites		Certificates
		3.Conduct biannual POC steering committee meetings	2 meetings conducted	Steering Committee	Allowance
			List of successful testers and sites available		Fuel
			Meeting minutes produced		Air ticket
					Conference package
		4.Provide additional support to Council to manage data	Adequate personnel available	PORALG	4 data clerks (periodic employment)
			Reports available on time		Extra duty allowance for preparations, reports
			Real time data available		
3	To increase	1. Identify	List of identified personnel for training	HQAD,	

	pool of Evaluators and Auditors and maintain them	potential evaluators and auditors for training	(potential Evaluators/auditors)	HLPC, Regional Authority	
		2. Conduct training to 100 evaluators and auditors at Dodoma, and Mwanza, Mtwara and Mbeya	120 personnel trained (evaluation)	IPs	Facilitators' allowances
					Participants' allowances
					Bus tickets
			50 personnel (auditor)	IPs	Fuel
					Air ticket
					Minibus for field work
					Conference package
		3. Inform appropriate authorities on successful evaluators/auditors	List of successful trainees (Evaluators/auditors) available at appropriate authorities	HLPC and HQAD	Letter to Local Government Authorities
4	To monitor and evaluate the process on a regular bases	1.Conduct Supportive supervision to 1000 testing sites at all levels of HIV RT testing	1000 testing points supervised	QIT, WIT, CHMTs, RHMTs, HQAD, HLPC, IPs	Supervisor allowances
					Driver allowances
					Data clerk allowances
			Supervision report submitted to steering committee		Fuel
					Air ticket
		2. Acquire external technical assistance on certification	Follow up report	IPs	In country travel fuel
			Certification verification report		Local return air ticket
			Feedback meeting report		Local technical person allowance

		process			Allowance for technical advisors
					International return air ticket
					Allowance for steering committee
					Conference package
		3. Conduct regulatory task force meetings (CHMTs/RHMTs)	Three meetings conducted per year	POLARG	Allowances
			Three meeting reports submitted per year		
		4. Conduct 2 Council and 2 Division meetings in 8 zones	1000 evaluations discussed	HLPC	Allowances
			500 audits discussed	HQAD	Fuel/ Air ticket
					Conference package
		5. Conduct bi-annual National POCT Steering Committee meetings	Two meetings conducted per year	HQAD, HLPC	Allowances technical staff
			List of successful testers available		Allowances for support staff
			List of successful sites available		Fuel/Air ticket
					Conference package

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FIND
Because diagnosis matters

ASLM
African Society for Laboratory Medicine

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