Framework For National Certification Program For HIV And Other Point Of Care Testing

Ensuring the Reliability and Accuracy of Point of Care Test Results

IMPLEMENTING THE WHO HANDBOOK ON IMPROVING THE QUALITY OF HIV RELATED POCT

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Developed in collaboration with the following partners

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Disclaimer

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ABBREVIATIONS AND ACRONYMS

ASCP	American Society for Clinical Pathology
CLSI	Clinical and Laboratory Standards Institute
CQI	Continuous Quality Improvement
EQA	External Quality Assessment
HTC	HIV testing and counselling
HTS	HIV testing services
ISO	International Organization for Standardization
JCI	Joint Commission International
M&E	Monitoring and evaluation
MOH	Ministry of Health
NGO	Nongovernmental organization
POCT	Point-of-care testing
PPE	Personal protective equipment
QA	Quality assurance
QC	Quality control
QI	Quality improvement
QMS	Quality management system
QSE	Quality system essential
RDT	Rapid diagnostic test
SPI-POCT	Stepwise Process for Improving the Quality of HIV-related Point-of-Care Testing
SPI-RT	Stepwise Process for Improving the Quality of HIV Rapid Testing
TB	Tuberculosis
WHO	World Health Organization

EXECUTIVE SUMMARY

The recently released WHO handbook on *Improving the Quality of HIV-Related Point-of-Care Testing: Ensuring the Reliability and Accuracy of Test Results* was developed to address the weaknesses identified in existing HIV related point-of-care testing (POCT) programmes and to assist countries and service providers in adhering to a new set of minimum standards that promote and ensure quality assurance (QA) and quality improvement (QI) processes for HIV-related POCT within existing national QA/QI frameworks.

The Quality Assurance Cycle (QAC) outlined in the WHO handbook describes a three-phase process developed to assist ministries, health-care providers, and stakeholders in planning, implementing and sustaining QA for POCT. Conceptualized in a cycle, the QAC is a continuum of integrated planned activities that supports and promotes the accuracy and reliability of HIV related POCT.

One of the innovative minimum standards emphasized in the handbook is the certification program for POCT personnel and sites.

This framework has been designed for resource limited countries and is a living document which will need to be updated at regular intervals to reflect changes in country policies and guidelines, new quality approaches, lessons learned and new evidence from operational research. Working within the framework, healthcare workers, facility managers, policy makers and program managers will have an opportunity to understand the requirements for establishing a HIV related certification program while implement the QAC as described in the WHO handbook. This document provides practical examples and tools for easy adaptation and use.

This document is part of a collaboration of technical expertise from the following organizations: African Society for Laboratory Medicine (ASLM), American Society for Clinical Pathology (ASCP), Clinical and Laboratory Standards Institute (CLSI)

1. PURPOSE

The purpose of this document is to provide guidance to establish and/or strengthen national certification programs for POCT site and tester as recommend in the WHO handbook, *HIV Diagnostics: Improving the Quality of HIV-Related Point-of-Care Testing: Ensuring the Reliability and Accuracy of Test Results.* It aims to inform the development of policies, processes and procedures for implementation of national certification programs for POCT tester and site.

This document seeks to:

- provide multiple possible approaches to achieve national certification of testing sites and testing providers including the Quality Management Approach;
- strengthen existing testing site and provider certification practices;
- highlight the importance of leveraging existing resources to achieve certification and related quality improvement targets; and
- share recommended best practices and tools in the areas of testing site and provider certification program development, planning, implementation and monitoring & evaluation.

This process will help countries to identify the performance of testing sites and testers, thus allowing for the implementation of corrective actions where needed.

2. AUDIENCE

This framework document is intended for use in policy development, planning, and implementation by the Ministry of Health (MOH) technical officers and policy makers, in collaboration with other governing entities, program managers and implementing partners. This document is also applicable to POCT site supervisors, managers and quality officers involved in the oversight and execution of HIV related POCT services.

3. SCOPE

This framework is applicable to programs and organizations which oversee or incorporate HIV related POCT for patient care management and public health practices, in low- and middle-income countries though certification of POCT sites and testers. This document is applicable to POCT conducted in both laboratory and non-laboratory settings and targets primarily HIV rapid testing. However, the quality assurance principles and the certification requirements equally apply to current as well as future POC technology including HIV and other POC testing across the tiered national health systems (Figure 1).

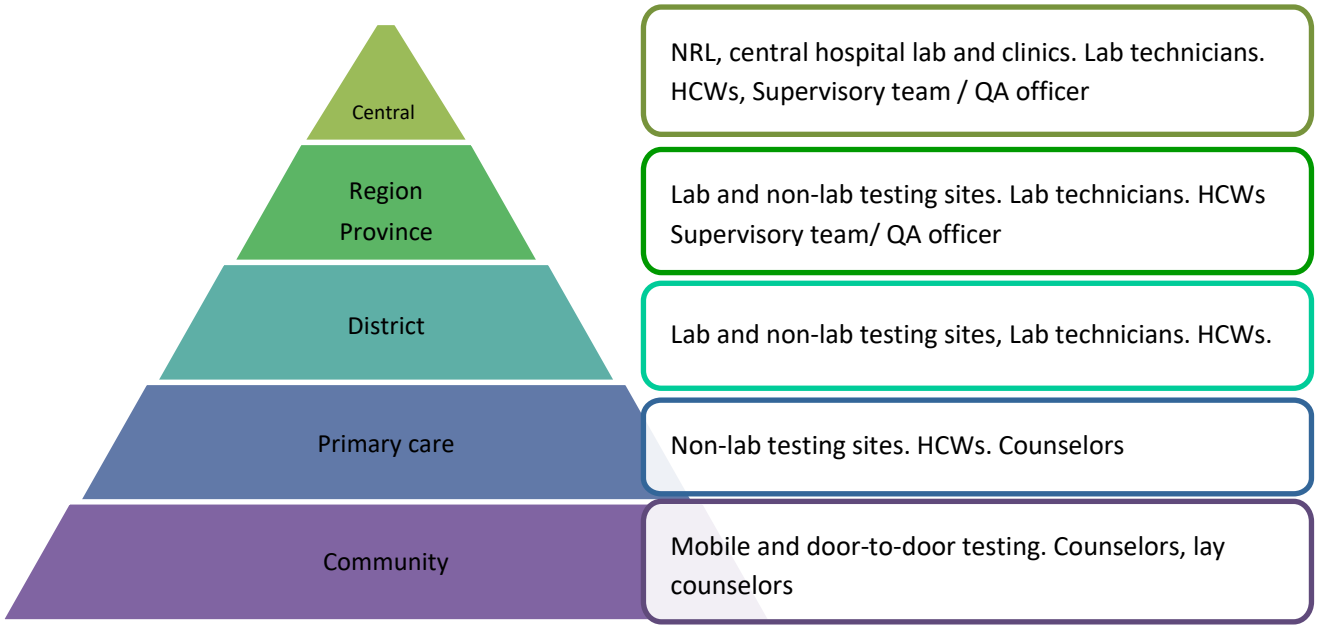

Figure 1. POCT across the tiered national health system

4. INTRODUCTION

Rapid diagnostic and recently POC technologies have become widely available in last the 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 related POCT. The limited human resources, the unavailability of testing supplies, the under-utilization of testing data for timely corrective action in most

resource-limited settings have hindered the complete and seamless implementation for certification-related monitors for quality systems.

Although, concerns may be raised about cost of implementing quality assurance programs for HIV related POCT, the costs associated with both attaining and failing to attain accurate and reliable test results are inestimable. These include the cost of preventing problems, the cost of initiating treatment for patients who do not otherwise require any and essentially, any cost that would not have been expended if quality measures were adequately and consistently implemented. Ample evidence exists in the business and manufacturing sectors that when companies adopt a cost of quality concept, they are successful in reducing failure cost and improving quality for customers. There is a lot to be learned from these sectors; adoption of a business model that incorporates cost of quality as a means to reduce overall operational and programmatic costs to the laboratory and healthcare system will reduce waste and improve quality to patients and other customers at a reasonable cost. An investment in a national certification program for POCT may prove to be not only a healthcare cost savings, but an expansion of quality of care.

There is now a growing need for innovative methods and practices to assist testing sites and tester with the improvement and maintenance of quality, while leveraging existing resources. Thus, national certification programs for POCT sites and testers would be an innovation by providing clinical governance to support health care providers involved in testing. The clinical governance would allow health-care providers to be accountable for continuing to improve the quality of the POCT service and safeguarding high standards of care by creating an environment in which excellence in clinical care can flourish. The implementation and the maintenance of a POCT site and tester certification will add credibility to any testing site, provides means to ensure and monitor adherence to quality standards and instill confidence in the results for patient care.

National certification programs for POCT sites and testers would provide an umbrella under which all aspects of quality can be gathered and continuously monitored. Site certification, including regular on-site supervision, mentoring and site audit, has been identified as an important method to meet and maintain quality in countries with growing numbers of rapid diagnostic and POCT sites. Likewise, provider certification along with standardized hands-on training and ongoing supervision and reassessment to ensure competency are critical to ensure accurate and reliable rapid diagnostic and POCT results. National site and tester certification can be used to verify that the site is equipped and personnel are competent to conduct testing per national and/or international established guidelines.

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. Therefore, a systematic approach that includes development of appropriate policies, processes, and procedures around the quality of POCT should be adopted and a stepwise process including proper planning, implementation should be considered at all levels by national programs.
Similarly to the WHO handbook on *HIV Diagnostics: Improving the Quality of HIV-Related Point-of-Care Testing: Ensuring the Reliability and Accuracy of Test Results*, 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. Moreover, it pprovides the technical requirements necessary to establish national certification programs for HIV related POCT sites and testers that will result in increased uptake and coverage of quality practices and access to accurate and reliable diagnostics.

5. STRUCTURE OF THIS FRAMEWORK

This framework is divided in four distinct sections:

1. **Section 1. National certification program** describes the managerial activities at national, sub-national and facility levels which are considered to be essential for the smooth implementation of the certification program, the steps for the establishing a certification program, the resources required and the monitoring and evaluation process.
2. **Section 2. POCT Tester certification program** describes the technical considerations which include the roles and responsibilities of each stakeholders, the training and competency maintenance requirements, certification examinations, scoring, reporting and documentation, corrective actions and remediation plan , POCT tester, certification process and key program indicators
3. **Section 3. POCT sites certification program** describes the technical considerations which include training requirements, auditors' selection criteria, elements of an effective audit, scoring, audit process and frequency, reporting mechanism, remediation plan and key program indicators.
4. **Section 4** contains the references, the glossary of terms and annexes which includes useful tools.

6. SECTION 1. NATIONAL CERTIFICATION PROGRAM

Certification is the process by which an independent and authorized agency assess the quality system of a facility/site and/or competency of a tester 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 tasks, such as HIV rapid testing for diagnosing HIV infections, or a specific test such as POCT for CD4 quantification (i.e. PIMA).

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

- Facilitates the implementation and maintenance of an effective quality management system
- Gives confidence to users in availing the services
- Gives confidence to the site and user for the results generated
- Provides recognition of technical competence
- Helps in defending site while dealing with legal disputes pertaining to results
- Reduces the operating costs of POCT by getting results right the first time and every time.

Certification is done at regular intervals to ensure maintenance of standards and reliability of results generated to support clinical and public health activities by the POCT site and tester. Both site and tester certification provides confidence in the POCT results for both the user (site and tester) and end-user (health care provider and patient).

- Site certification verifies that testing procedures are in place and follow, results are technically valid, only competent staff performs testing, and confirms that the site conforms to a quality management system.
- Tester certification verifies that the provider performing POCT is adequately trained, is authorized to do so and there is evidence of demonstrated competency.

6.1 PROCESS FOR ESTABLISHING A POCT CERTIFICATION PROGRAM

Establishing a National POCT Certification Program requires the following processes:

- Establishing the governance structure
- Adoption of standards
- Institution of a mechanism of assessment to certify compliance with HIV related POCT quality standards

The following are recommended steps for establishing a fully functioning site certification system.

1. Endorsement of the certification program. It is recommended that the appropriate government authority establishes a national quality system, extend the system to all levels and to all POCT sites. The country should establish a national and sub-national team that will:
    - Set/Review ensuring reliability and accuracy of tests for POCT sites
    - Define how the program will be integrated within the current QA/QI framework (i.e. existing programs if available)
    - Identify or leverage human and financial resources needed to start such a program
2. Set national certification requirements focused on measurable quality goals. Develop and/or evaluate existing standards that will meet national quality goals by tailoring the requirements to POCT sites. Once developed, guidelines must be approved by the relevant authorities before the implementation.
3. Define requirements for site certification auditing and tester certification assessment (e.g., frequencies, tools, auditors, reporting mechanism, and structure)
4. Establish authority that will implement policies, procedures, and oversee the evaluation process including scoring and certification decisions (See section 8.1.2 b)
5. Define process for recognizing testers and testing sites once certified (e.g., National Certificate Document signed and approved by appropriate authorities).
6. Establish mechanism for gathering, analyzing, and reporting program data
7. Identify resources to strengthen or build capacity for a sustainable monitoring and evaluation program.

6.1.1 GOVERNANCE STRUCTURE

National Certification Programs are an effective way to ensure the reliability and accuracy of test results and encourage continuous improvement for both POCT tester and sites. Successful certification program requires the involvement of stakeholders with specific roles at all levels (Figure 2).

1. National level: Ownership and capacity building (stage 1)
2. Certifying body: Oversee the implementation of the certification process (stage 2)
3. Sub-national level: Support the implementation of the certification process (stage 3)

Figure 2. Stages of successful National POCT Certification Program

6.1.2 ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

The WHO Handbook describes the roles and responsibilities key stakeholders to be considered for the certification program (Table 1). This program is a multi-level activity which involves various stakeholders with different roles as outlined in Figure 5. To ensure a successful program, it is of paramount importance to involve and link all stakeholders in a meaningful manner, to carefully develop a coordination strategy and lay down the terms of reference for the collaboration.

a. **National Government Institution**

This section discusses the responsibility of countries governments at the national level and their role in establishing a fully functioning certification program. At the national level, the governments are recommended to develop guidelines, allocate the necessary funding, and mandate the certification for testers and POC testing sites.

Government entities will be considered the Program Administrator and will be responsible of:

- developing roll out plans,
- providing guidance on implementation,
- setting certification standards and audit and evaluation criteria,
- overseeing auditors and evaluators training, and
- issuing certificates to sites and providers.

The quality assurance planning tool developed by FIND is an automated calculation tool that can be used to compute the approximate budget required to conduct audit activities in local or donor currencies: http://www.finddiagnostics.org/programs/scaling_up/lab-strength/slmta/tb-slmta/

Table 1. WHO Proposed Roles and Responsibilities for HIV related POCT site and testers certification programs

Task	Who	What	How
Site supervision and certification	Donors	Support staff positions and site supervision	Funding of human resources (quality officers) for regular supervisory visits to all testing sites
	Health ministry and partners	Develop method and plan for assessing point-of-care sites	Coordinate supervisory site visits
			Train and certify quality officers (reference laboratories)
		Analyse findings from assessments	Collate data centrally from assessments
			Coordinate accreditation of all point-of-care testing sites (Annex 1)
		Provide certification and guidance on improvements	Work with programme managers to provide quality improvement activities (modules pending)
			Develop summary report and disseminate
			Use data for monitoring and evaluation purposes
			Provide feedback to sites
			Consider combining site certification visits with external quality assessment panel distribution and site supervision
	Programme managers	Ensure that sites are ready for certification and implement quality improvement activities	Use rapid diagnostic testing and point-of-care testing checklists for all sites currently performing or planned for point-of-care testing
			Ensure that sites receive feedback and follow-up for corrective action

Task	Who	What	How
Quality-assured training and certification	Donors	Support the development of training materials	Funding of technical working group and technical assistance to develop and produce high-quality training tools
		Support training and certification of point-of-care testing	Funding for training activities
	Health ministry and partners	Develop and approve training materials	Through point-of-care testing working group and technical assistance using tools developed by other organizations and manufacturers as a starting-point
		Coordinate the training of sites in a phased approach	Assess what country-specific changes need to be made
			Develop train-the-trainer programmes
		Coordinate the supervision of sites	Set assessment and proficiency criteria for certification and site accreditation
			Coordinate an annual plan for training and execute the plan
			Collect data from training for monitoring and evaluation
			Develop and execute supervisory plan with appropriate human resources dedicated for point-of-care testing
	Programme managers	Assist in developing training materials	Programme managers should be part of the technical working group for point-of-care testing and contribute to developing training materials
		Deliver training to sites	As appropriate, become certified as a trainer and deliver training
			Develop a checklist for certifying trainees (Annex 6)

b. Certifying Body

In establishing a POCT certification program national, the Program Administrator should consider identifying of a certifying body and allocate adequate resources, infrastructure and personnel for the implementation of the certification programs. The Program Administrator (Government Entity) should establish a partnership with an independent organization with deemed status (e.g., Laboratory professional association, academic partner, or public health institute) to act as the POCT authoritative or certifying body or should appoint a steering committee comprising all stakeholders of the tiered health system and define the roles and responsibilities.

The authoritative or certifying body will serve as the program implementer and should conduct audit, assess competency of testers, collect data, and provide reports the Program Administrator (Figure 3). This body's duties could include but are not limited to the following:

- Identify the quality standards for the participating POCT site and testers
- Establish the developmental steps and preparation of the scoring system
- Establish the implementation approach for self-evaluation and development
- Coordinate project implementation within a defined roll out plan (e.g., geographical approach) and clear timelines
- Monitor submission by each region of the appropriate detailed activities for budget request
- Analyze and plan adjustment for subsequent year
- Maintain database of national auditors
- Audit site eligible for certification
- Issue certificate for eligible site and providers
- Maintain the certification databases
- Develop corrective actions for remediation
- Submit progress reports every six months to program administrator
- Coordinate stakeholders meeting for appraisal of the evaluations reported by the committee (i.e., annual meetings).

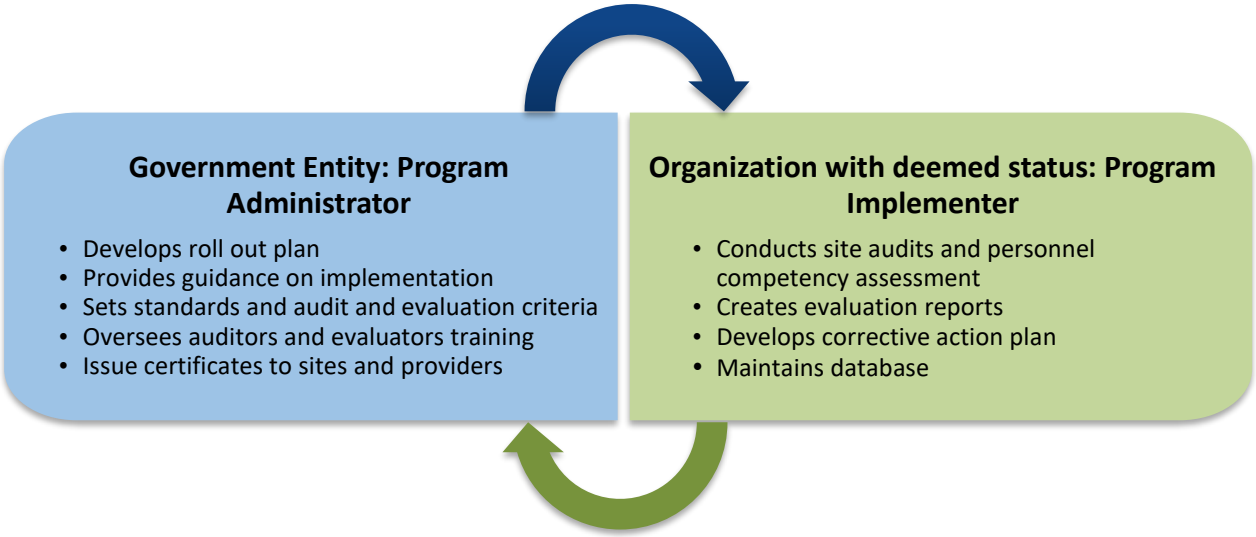

Figure 3. Relationship of POCT Certification Program Administrator and Program Implementer

c. Sub-National

Mid-level government management and implementing partners should assist as program implementers and reinforce the implementation of the policies and guidelines established by the national government. The sub-national should support training efforts for auditors' capacity building, provide mentorship to sites, and conducting baseline line audits of sites (Figure 4).

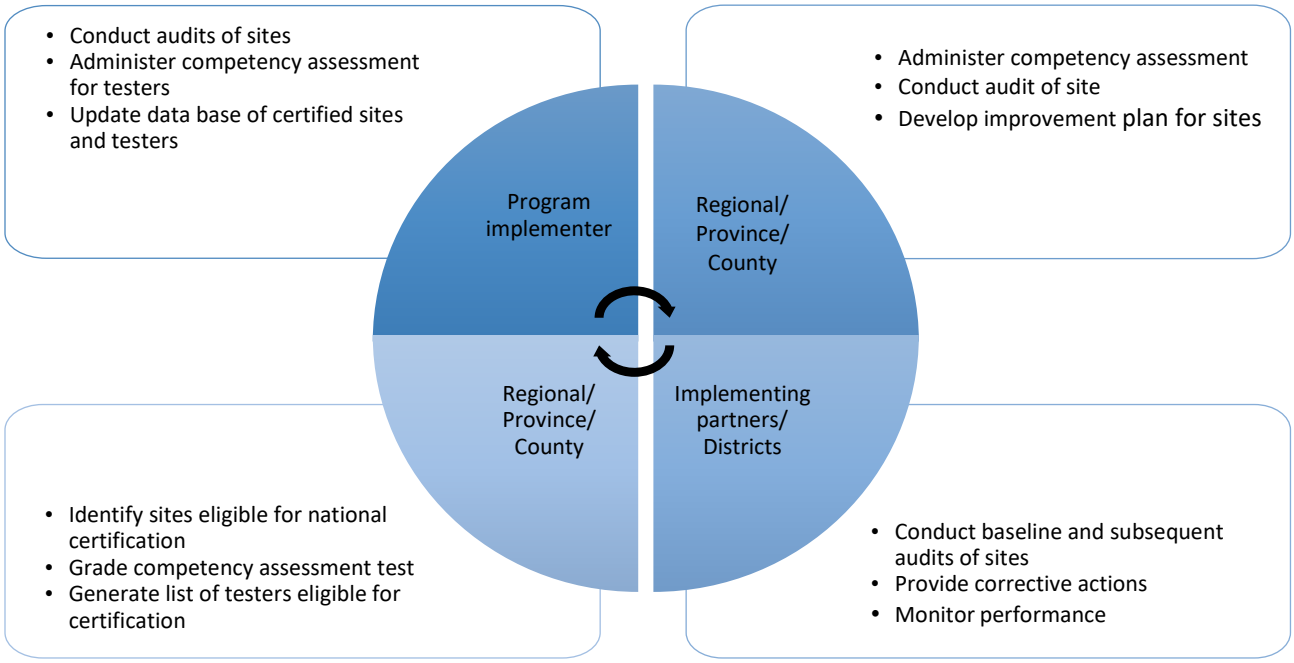

Figure 4. Stages of successful National POCT Certification Program

d. Management and Personnel at POCT Site

Site management and POCT site personnel, as the primary recipients of the certification programs, play a critical role for a successful program, should be engaged at all time and their roles and responsibilities in the process clearly outlined.

Management should:

- Ensure all POCT sites are implementing comprehensive CQI and prioritize sites to be enrolled in the certification program.
- Head of POCT sites should promote and discuss the benefits of CQI towards site certification and the set national requirements for certification.
- Educate site personnel on site certification requirements.
- Ensure sites meet minimum requirements for site certification.
- Select and train teams to conduct internal audits using appropriate tools, address all gaps through training of staff and development of necessary corrective actions.
- Apply for external audit for certification to validate the site's internal self-audit.
- Develop Internal Audit Procedures.
- Develop a contingency plan for situations that may arise during the audit internal audits that need immediate attention, such as conditions that may present an immediate risk to patient care or employee safety.

Personnel at POCT site level should:

- demonstrate commitment to ensuring reliability and accuracy of tests at POCT site,
- have an understanding of applicable national, sub-national, and facility guidelines, policies and regulations and how to comply,
- have an understanding of the appropriate tools available to perform internal audit as well as external audits and know how to use them (e.g., SPI-RT, SPI-POCT),
- summarize audit findings and performed corrective actions in a report to laboratory leadership,
- should be fully qualified and registered with a professional registration/licensing body or per country regulations.

What to consider:
Written standards should follow the rules below:

- No jargon. Written in simple language for target audience
- Sets specific expectations. Unlike recommendations which use terms such as "should" or "may", implying a suggestion, standards are written using active verbs and are required expectations (e.g., The healthcare site supports….)
- Identifies a person responsible for implementing the standards and ensure their implementations
- Knowledge and evidence based
- Measurable, credible by self-audit and external audits
- Each standard identifies one major criteria required to meet compliance
- Reflect and support quality principles

6.1.3 STANDARDS FOR POCT CERTIFICATION PROGRAMS

Standards implemented result from combined national statutes, governmental guidance, independent reports, and standards from other countries. In order to develop or review the standards that have been drafted or will be developed need to adhere to certain criteria.
The result of a laboratory test, performed in both the laboratory or outside of 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 for patient care management. International standards are now widely used in implementing quality in developed countries as well as resource limited countries. Among these standards the ISO/IEC 17025:2005 pertains to general requirements for the competence of Testing and Calibration Laboratories while the ISO 15189:2003 specifically addresses Quality Management for the Medical Laboratories. Similarly, the ISO 22870:2006 provides standard for POCT in regards to quality testing and competency of testers.

In developing countries, national standards from POCT site and tester certification need to be developed and implemented based on the above international standards. The process requires the following step-wise approach for sustainability:

- Identify a national focal point for POCT sites and testers
- Develop national quality standards through a core group
- Build national consensus by peer review
- Ensure ratification/notification by the national authorities
- Identify and strengthen the capacity of an independent organization
- Sensitize and train the participating organizations and bodies
- Facilitate the adoption of national standards
- Monitor and evaluate the process.

Once the national standards are implemented, POCT sites and testers are in a better position to meet the requirements of international standards.

When establishing standards for POCT certification, it is important to ensure that they can be assessed for compliance. Many auditing and assessment tools and checklist are based on the agreed upon standards. *An example of an auditing checklist with standards is the WHO Stepwise Process for Improving the Quality of Instrument based Point-of-Care Testing (SPI-POCT) as presented in Table 2.*

Table 2. SPI-instrument based POCT Checklist Sections and Standards

Section	Standard
1.0 Integration of POCT service for Patient Care	POCT services should be offered so results are interpreted and utilized to support patient care, in accordance with national/sub-national/facility guidelines, policy and regulations
2.0 Personnel Training, Competency, and Certification	POCT services should be offered so results are interpreted and utilized to support patient care, in accordance with national/sub-national/facility guidelines, policy and regulations.
3.0 Physical Facilities	The POCT facility/site should be adequate to provide safe and effective POCT services.
4.0 Safety	The POCT facility/site should be 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 should provide for a standardize system for patient handling and identification, specimen collection and processing, and recording of patient/specimen information.
6.0 Testing Phase	The POCT facility/site should provide for a standardize system to perform POCT and included QC testing and troubleshooting guides
7.0 Post-Testing Phase	The POCT facility/site should provide for a standardize system for POCT results to be recorded and reported and include a system for recording QC results
8.0 Supplies, Reagents, and Equipment	The POCT facility/site should provide for adequate and reliable stocks of supplies and reagents, and functional equipment and instruments.

9.0 Monitoring Quality	The POCT facility should provide for a quality monitoring system to ensure accurate and reliable POCT results.

6.1.4 AUDITING AND ASSESSMENT FOR COMPLIANCE TO STANDARDS

a. Introduction to POCT certification programs

For a certification program for POCT to self-sustain, the governing body or Program Administrator should create an enabling environment which will allow for increasing demands by POCT sites and testers. Therefore, as a part of advocacy, the Program Administrator should inform all stakeholders about the standards and requirements used for both POCT sites and testers certification. This process should be done while setting up of the certifying body. To prepare the sites and testers for audits or national certification examination, it will be critical for the certifying body to engage the sub-national management and the local implementing partners for the implementation of national standards and quality systems.

Clear and tangible objectives should be outlined out for everyone to know and understand that POCT certification is a process to ensure compliance to quality practices and maintaining competency of testers. Certification is not a one-time activity but rather a continuous process of improvement. Therefore, granting certification to a POCT site or tester means they have met the standard and requirements for a certain period of time (i.e., maximum 2 years). Subsequent audits and examinations aim to improve performance and ensure competency is maintained. Certification should not be used for punitive or disciplinary actions.

It is recognized that sites and or testers may not achieve certification upon initial audit or competency assessment, recognizing that the accuracy and quality of the testing should not be compromised, corrective actions should be taken and achieving certification should be prioritized as a goal to be achieved in an expedited timeframe.

b. **Objectivity of the certification process**

The Certifying Body should operate with impartiality irrespective of the settings (lab vs. non-lab), the testers training background and the organization affiliation (government, private, NGO, etc.). This may sound simple but the certifying body must demonstrate objectivity and not merely by declaring policy. *For example, all requirements must be made transparent and any request for site assess for certification should not be refused without providing valid reasons.*

c. Addressing conflict of interest

Conflict of interest of the certifying body and related bodies needs to be addressed, especially if the certifying body is a part of government department. The certification process should be totally free from interference by the top management as this can adversely affect the credibility of the program. Conflict of interest can be minimized or eliminated by designing an appropriate certification system, thus the need for identifying an independent entity.

For example, the certification committee should be diverse and include various stakeholders (i.e. representatives from the following groups: government, testers, professional associations, other certifying bodies or regulatory bodies if any, NGOs, etc.) to make decisions for certification.

d. Addressing complaints from POCT sites and testers

Accessible complaint and appeal mechanisms are good ways to find out if there are any conflicts of interest. Allowing POCT sites and testers the chance to accept or reject personnel involved in the certification process is also important for avoiding conflicts of interest. However, the certification body should take action only if the POCT site or tester can provide valid reasons and not merely express subjective feelings or personal reasons for not accepting a particular person.

The top management should not have any power over the certification process, including the decision-making process. The certification committee should take full responsibility for the decision to offer or refuse certification. This process will help avoid any external influence or pressure.

In all types of quality systems, traceability of all actions and documents is a must. As a certifying body, the process of establishing a quality system must be implemented in such a way that it is readily accessible for verification by any party. The question of who, when, where, why and how shall be recorded in all processes. This also supports the transparency criterion for the certification body.

6.2 MONITORING AND EVALUATING POCT CERTIFICATION PROGRAM

Assessing the impact of both tester and site certification programs are one of the most crucial steps, but also it can be the most difficult. A country must define the programs outcomes, connect these outcomes to the goals or impact and measure them with suitable indicators. Establishing an effective monitoring and evaluation process is recommended in order to ensure that the tester and site certification programs are meeting its goals and also to evaluate the outcomes of each of the programs. Monitoring and evaluation does not need to be expensive or complicated, nor require a specialist. An effective monitoring and evaluation design should include:

- Measurable program objectives
- Structured set of indicators
- Provisions for collecting data and managing program records
  - *Note: Data required for indicators must be compatible with existing statistics and available at reasonable cost*
- An institution to gather, analyze, and report program data, and also build capacity to sustain the M&E
- Means for M&E findings to be fed back into decision making processes

In countries where M&E tools and mechanisms are already available in country, it is strongly recommended to consider utilizing these resources to fit the M&E design for tester and site certification programs. This will not only allow for easier data capture and analysis, but it will be a cost effective resource to leverage to strengthen M&E programs countrywide for certification program. Additionally, innovative ways of capturing the data noted above can be made through the use of cell phones, tablets, portable electronic scanners, etc., which would link back to database management servers typically housed within the national and sub-national levels.

7. SECTION 2. POCT TESTER CERTIFICATION PROGRAM

7.1. BENEFITS

National tester certification programs ensure all testing personnel are properly trained and competent to conduct POCT and produce accurate and reliable test results. When a POCT tester successfully completes training as well as passes the examination process within the certification process, this cultivates both personal achievement and also professional recognition. Furthermore, participation in tester certification maintenance programs shows continued demonstration of competence in theoretical and practical testing skills.

7.2. KEY CONSIDERATIONS FOR POCT TESTER CERTIFICATION

Countries should consider a stepwise approach for rolling out the POCT tester certification program. Because of the sheer number of health care providers conducting laboratory testing to address staff shortage, countries should think outside of the box and establish partnership with professional associations, they should involve Q-corps volunteers who can serve as proctors during the examination and explore innovative training platforms for mentoring, networking and best practice sharing.

In this section key considerations such as government's endorsement, human resources, establishing standards, maintaining databases, developing functioning feedback mechanism and low cost remediation plans and a well-designed M&E plan for sustainability will be described (Figure 5).

Figure 5. Essentials Components of National POCT Testers Certification program

7.3. ROLES AND RESPONSIBILITIES OF TESTING

Management and testing site personnel play key roles in ensuring all components of national tester certification programs are implemented successfully, especially at the site level. Examples of possible roles and responsibilities for each cadre are listed below.

7.3.1. Management

- Supervise testing personnel and provide annual performance feedback to testing personnel
- Promote annual competency assessments for all testing personnel
- Maintain training files/documentation for all testing staff, which can contain the following:
    - Initial training completed on POCT and related quality assurance
    - Initial certification documentation
    - Refresher trainings and continuing education completed
    - Recertification status and documentation
    - Annual competency assessment results
    - Corrective action and remediation plan, if necessary
- Serve as proctors during written and practical examinations
- Serve as site points-of-contact for both the Program Administrator and the Program Implementer (including sub-national technical teams) during certification, mentoring, and recertification activities
- Recognize testing personnel who successfully complete national tester certification and recertification processes

7.3.2 Testing Site Personnel

- Complete national certification processes including standardized training, examinations, and clinical supervision components
- Track recertification progress (e.g., continuing education completed, refresher trainings attended, etc.)
- Complete national recertification requirements including refresher trainings, continuing education, and/or competency assessments

7.4. TRAINING AND MAINTENANCE OF CERTIFICATION

7.4.1 National Training Program and Refresher Training

- Nationally approved standardized training program
- Refresher training program on HIV rapid testing and related quality assurance topics
- Training formats such as
    - Formal training including classroom didactic and practical sessions
    - Innovative approaches (i.e., Distance learning, SIEMENS personalized education plan, etc..)
    - Direct observation during testing process

7.4.2 Mentoring

- Essential to recertification process, remediation, and investment in certification process
- Mentoring may be provided on site by:
    - Management
    - Supportive supervision team
    - Quality officers
    - Experienced POCT testers
- Innovative approaches may also be explored for cost effectiveness (i.e. TeleECHO platform - http://echo.unm.edu/about-echo/)

7.4.3 Continuing Education

What to Consider :
Experienced and certified testers can perform the following functions for fellow testers:

- Serve as trainers for national standardized training programs
- Serve as mentors during certification and recertification processes
- Serve as evaluators during written and practical examinations as well as competency assessments and direct observation.

- Refresher training: should cover previously toughed topics to ensure POCT testers maintain their skills, knowledge and competency. Only training content specifically covering POCT and related quality assurance issues for which tester will be certified, will be considered refresher training. New topics introduced during refresher training sessions should be assessed as if it is an initial training. *Note: Length of the refresher training will vary based on the topic to be covered and the resources available. Refresher training may be provided on site or in a formal training setting*.

- Seminar/Workshops and Conferences, if available (i.e. POCT and quality assurance related POCT teleECHO sessions)

What to consider:
POCT testers can maintain their competency through:

- Refresher training
- Continuing education (e.g., seminar, workshops/conferences, etc.).

7.5. CERTIFICATION EXAMINATIONS

7.5.1 Format

All certification examinations will include both written and practical sessions.

- Written: 20-25 multiple-choice questions
- Practical: Minimum of 5 unknown specimens

7.5.2 Development

- Standardized job descriptions for all POCT providers to delineate the essential skills, tasks, and background requirements to meet necessary competencies and be deemed proficient

- Ensure training guidelines contain the following:
    - how written and practical training content will be derived to mirror standardized job descriptions,
    - how and how often training content will be continuously revised to reflect current practice,
    - how training content will be given
        - (e.g., length of each component, time requirements for trainees, trainer requirements, etc.)
    - where training will be given
        - (e.g., in-person, distance learning approach, etc.),
    - how training content will be monitored to ensure efficacy,
    - how in-training assessment content will be kept confidential and
    - how training content will be stored and tracked within a database system

- Standardized theoretical and practical skills training content (including in-training assessment tools for both theoretical and practical components) to measure both theoretical knowledge and hands-on skills content, respectively, to mirror standardized job descriptions for all testers

- Established certification guidelines to indicate the following:
    - how written and practical examination content will be derived to mirror standardized job descriptions,
    - how and how often examination content will be continuously revised to reflect current practice,
    - how examination content will be given
        - (e.g., length of each examination part, time requirements for examinees, proctor requirements, etc.)
    - where examinations will be administered
        - (e.g., paper form, hand held device, web-based, etc.)
    - how examination content will be monitored to ensure efficacy,
    - how examination content will be kept confidential
    - how examination content will be stored and tracked within a secure database system

- Standardized written examination content (e.g. multiple-choice questions) and practical skills assessment content (e.g. checklist items) for the formation of a two-part certification examination to measure both theoretical knowledge and hands-on skills content, respectively, to mirror standardized job descriptions for all HIV testing providers

- Established certification examination guidelines to indicate the minimum requirements to take and successfully pass the two-part examination to be nationally recognized as a certified POCT provider. For example:
    - minimum passing percentage for written examination,
    - minimum passing percentage for practical examination,
    - number of times allowed to sit for the two-part certification examination and within what timeframe,

- eligibility time window between education/training/experience and certification examination, etc.

- Eligibility requirements to determine the formal education, training, and/or work experience needed for candidates to sit for the certification examination
- Established certification guidelines to indicate the following:
  - how certification numbers will be assigned to successful examinees,
  - how these numbers will be tracked in a database system,
  - what credential (if any) will be given to successful examinees to indicate their certification,
  - how certified POCT providers will maintain their certification. For example:
    - number of continuing education courses,
    - minimum passing score for reassessments,
    - validity period for certification,
    - remediation action plans for lapsed certification and etc.
  - how certification maintenance will be tracked for all certified HIV testing providers

7.5.3 Examinee Preparation and Study Tools

- Exam topic outlines
- Exam reading lists
- Exam administration guidelines

7.6. SCORING

All POCT personnel must pass both certification exam types (written and practical) to be considered certified or eligible for recertification. In case of unsatisfactory score at any of the examination type, POCT personnel should be mentored/coached to ensure all POCT and related quality components are well understood before attempting to retake the examination within a three month period following the previous examination.

Table 3. Minimum passing score for tester certification examinations

Test Type	Tester Certification		Tester Recertification	
	Examination Type	Suggested Minimum Passing Score (MPS)	Examination Type	Suggested Minimum Passing Score (MPS)
HIV related POCT (including rapid testing)	Written	80%	Written	80%
	Practical	100%	Practical	100%
HIV instrument based POCT	Written	80%	Written	80%
	Practical	100%	Practical	100%
Non-HIV POCT	Written	80%	Written	80%
	Practical	80%	Practical	80%

7.7. REPORTING MECHANISM AND DOCUMENTATION

- Examinee feedback

Establishing and maintaining a certification program requires an effective information flow include a good examinee feedback mechanism. This may include but are not limited to the following:

- Examination score letter
  - Written
  - Practical
  - Subtest scores, if fail
- Direct observation feedback. *Note countries may develop a checklist to accurately assess all three phases of a testing process during the direct observation. This will allow examiner or protocol to provide timely feedback on POCT provider performance and highlight mistakes observed during the practical examination.*

- Importance of timely feedback to examinee. Feedback on overall performance should be provided within 90 days of the examination to be meaningful.
- Assignment of POCT Provider certification number for successful passing score. The certificate issued by the Certifying body should include the certification number, the date issued and the validity period. It should specify the POCT for which the provider was granted the certification.

7.8. CORRECTIVE ACTION AND REMEDIATION PLAN

It is recommended that the tester reviews the findings of the examinations and work with manager and/or mentor to begin the process of corrective actions to address the deficiencies within 30 days of the poor performance results.

A written procedure on the competency remediation plans should be available at the site and include information on frequency of competency assessments and/or direct observations as well as time allotted to perform and complete corrective actions.

7.9. TESTER CERTIFICATION PROCESS

7.9.1 Initial Certification

- Begins with national standardized tester training
- Written and practical examination completed during initial training
- Direct observation component required (minimum 2-3 days placement or per country training guidelines)

7.9.2 *R*ecertification

- Valid for one-two years
- Granted upon completion of specific recertification requirements, which can include any of the following:
  - Recertification examination (two-parts: written and practical)
  - Annual competency assessments (two-parts: written and practical)
- May also be granted upon completion of the following recertification requirements, which can include any of the following in combination with the written examination:
  - Direct observation by site/testing supervisor or CQI member
  - Proficiency testing (minimum of five samples).

7.9.3 Remediation Plan

- In the event of poor performance on any of the following:

    - Initial certification process
    - Recertification process
- Remediation plans can involve any of the following components:
    - Mentoring
    - Annual competency assessments (two-parts: written and practical)
    - Direct observation by site/testing supervisor or CQI member
    - Proficiency testing (minimum of five samples)
    - Refresher training
    - Continuing education (e.g., seminar, workshops/conferences, etc.)

7.9.4 Withdrawal

The certification body should develop and document the procedures for withdrawing certification from tester personnel. Some circumstances warranting withdrawal of tester certification are listed below:

- Repeated, poor performance during national certification examination process
- Lack of participation in national recertification process
- Lack of successful completion in national recertification process

International best practices suggest testing personnel who are not able to demonstrate required competencies should not be allowed to perform patient testing (e.g., individuals not able to successfully complete certification requirements and/or continue to participate/complete recertification requirements). However, the enforcement of this best practice may be challenging, especially in settings where human resources may be limited.

What to consider:
POCT testers with repeated low performance during national certification examination process, it is strongly recommended to place them in job tasks, which do not involve patient testing.

7.10. MONITORING AND EVALUATION

The main driving force to determine the efficacy of a national tester certification program is the implementation of M&E practices at all levels of the process as mentioned above. The M&E practices include the following:

- training and its assessment tools,
- written and practical certification examinations,
- certified workforce tracking,
- continuing education,
- competency reassessments, and
- remediation action plans.

Some of the program specific metrics to track and that help monitoring tester efficacy and impact are highlighted below:

- Number of testers enrolled in program during a specific time period (i.e., past 6 months, in a year, etc..)
- Number of testers evaluated during a specific time period (i.e., past 6 months, in a year, etc..)
- Number of testers national certified during a specific time period (i.e., past 6 months, in a year, etc..)
- Percent of testers nationally certified during a specific time period (i.e., past 6 months, in a year, etc..)
- Number of testers national recertified during a specific time period (i.e., past 6 months, in a year, etc..)
- Percent of testers nationally recertified during a specific time period (i.e., past 6 months, in a year, etc..)
- Distribution of testing/quality components with low scores
- Percent of testers with low scores by testing/quality components

8. SECTION 3. POCT SITE CERTIFICATION PROGRAM

8.1 BENEFITS

Certification programs are an effective way to ensure compliance with standards and quality improvement processes are continuously implemented in POCT sites. Achieving certification offers the opportunity to recognize POCT site as a site that has the ability to offer POCT in a certain area.

8.2 KEY CONSIDERATIONS FOR SITE CERTIFICATION

The transition from laboratory based testing to point of care and near point care testing requires that countries establish a systematic approach to verify that testing processes and procedures are in place, adhered to and properly documented. Countries should consider establishing partnership with laboratory professional associations to oversee the implementation of the process in a phased manner. This program will require a systematic training program to certify the POCT sites auditors and allow them to maintain their competency overtime. A tiered approach should be considered to mentor POCT sites to address deficiencies. The certifying body should maintain and update databases of certified auditors and POCT sites.

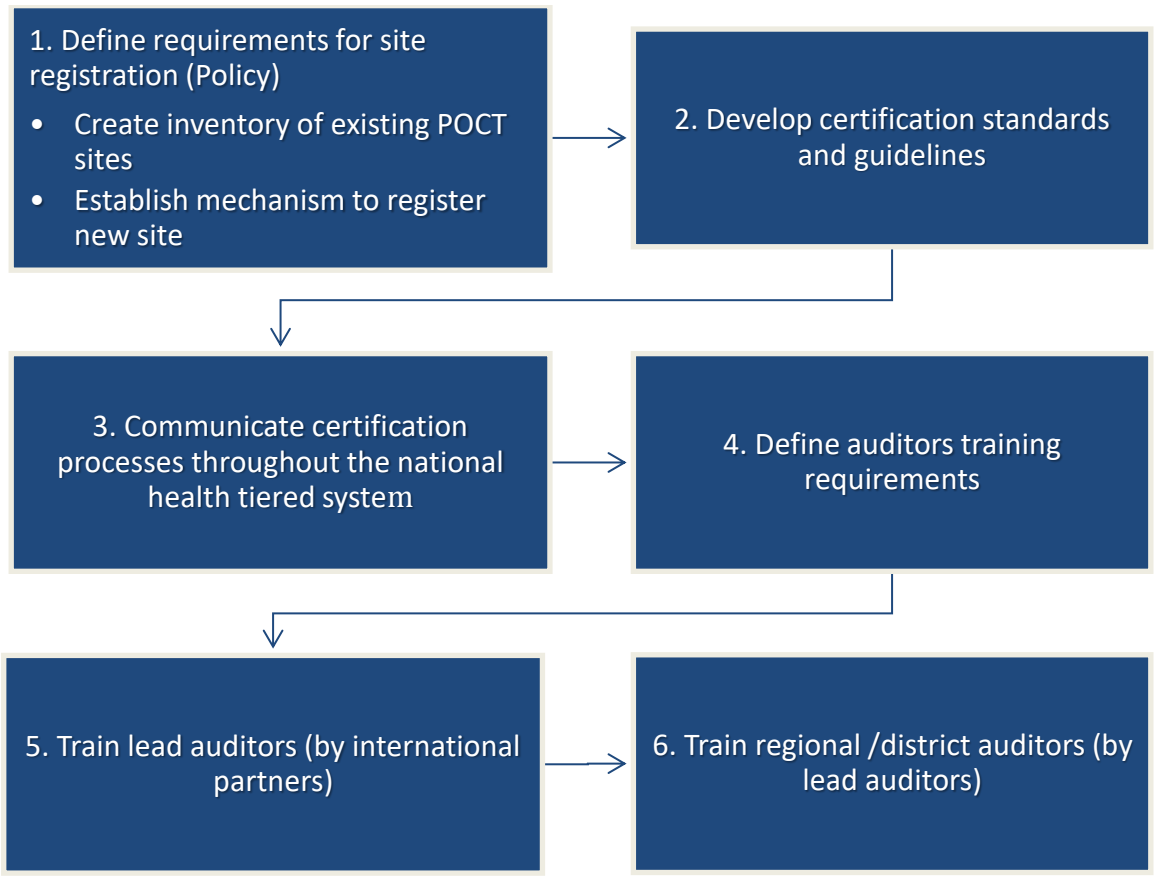

Figure 6. Multi-step for establishing a POCT site certification program

8.3 POCT SITE CERTIFICATION STAKEHOLDERS AND ROLES

As outlined in Section 1, under Roles and Responsibilities, the POCT site certification calls for a commitment from all stakeholders. These include the POCT sites management and staff, the sub-national teams (e.g. MOH, implementing partners, etc.), Certifying Body and government entity (e.g. National Reference laboratory, National AIDS Control program, Registrar, etc…). Each one of them plays a critical role that should be clearly defined and widely communicated (Figure. 7)

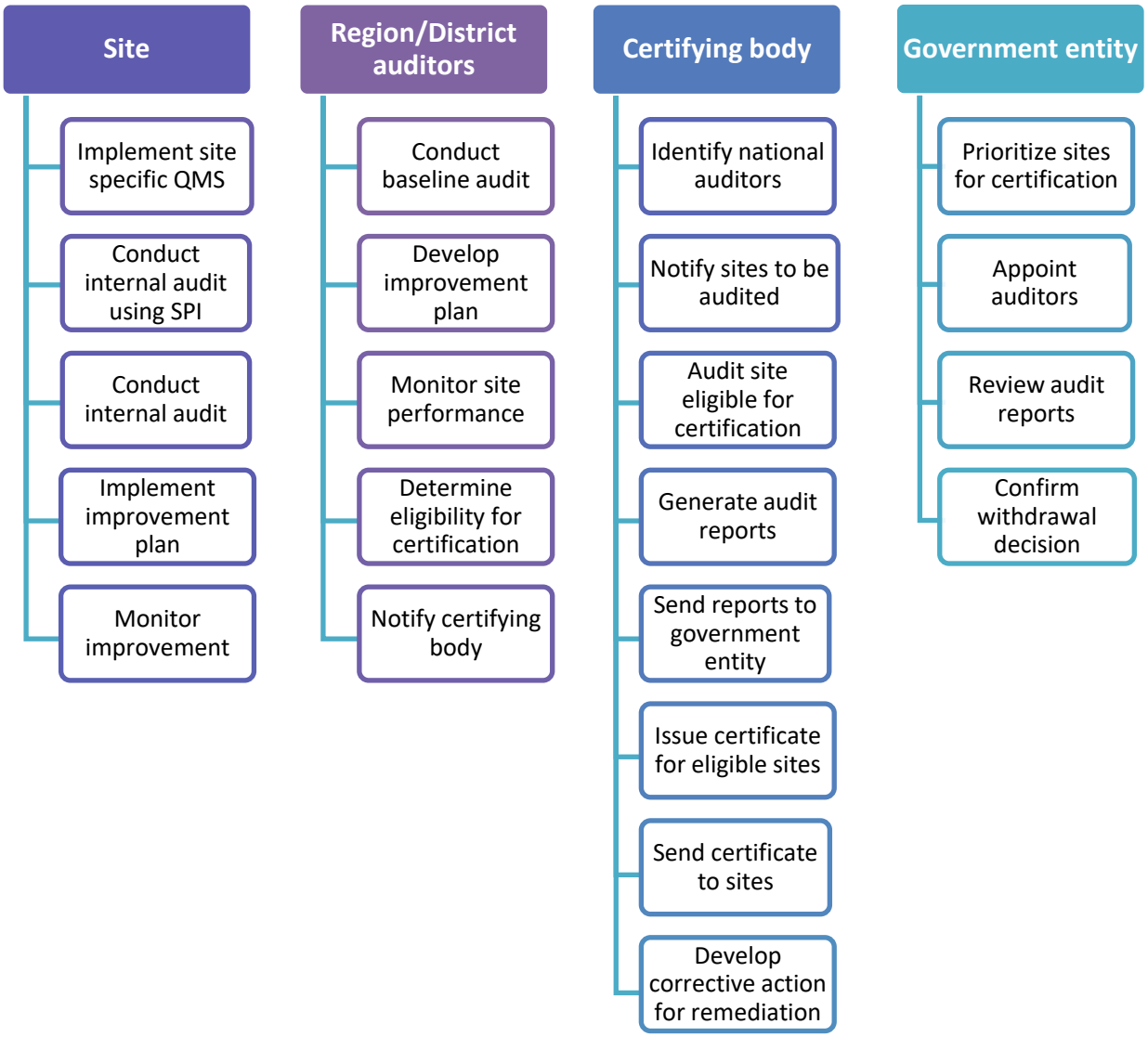

Figure 7. Role of POCT Site certification stakeholders

8.4 STANDARDIZED AUDITORS TRAINING

8.4.1 Categories of Auditors and Roles

In the POCT site certification program, auditors lay a key role in measuring the level on implementation of quality system at POCT sites. There are commonly two categories of auditors:

- System auditors: These may act as lead auditors. These groups of auditors are very familiar with the quality systems and standards. Most often system auditors operate alone. It is preferable for them to have a technical background in laboratory methods, but this is not essential. *Note: It is more likely that rapid testing sites (e.g. HIV, malaria, etc.) auditors will be drawn from this category of auditors because of the sheer number of testing sites, the limited number of laboratory professionals and the need to urgently address quality issues.*

- Technical auditors: In general, technical assessors are not members of the certifying body; instead they are experts working in specific laboratory area (serology, molecular biology, etc..). This is to ensure that technical auditors always keep up-to-date with technology and know-how. The selection criteria of technical auditors, for POCT sites potentially eligible for audits, should be based on their experience and the knowledge of the particular field. The procedures and forms for the selection and monitoring of auditors should be well defined. *Note: The group of auditors is more likely to be considered for instrument-based POCT.*

8.4.2 POCT Site Auditors Training Requirements

A successful POCT site certification program require intensive training sessions of both types of auditors. The certifying body should review and agree upon required course load for auditor training. Only auditor training that includes the approved training curriculum will be recognized by the certifying body. At minimum POCT site auditors should be required to:

- participate in a standardized course for POCT sites auditors (including professionalism, ethics, practical session using checklists and tools, case studies and group exercises applying the requirements, etc.),
- observe on-site audits, initially with experienced auditors after a formal training has proven to be very satisfactory.
- conduct audits under the mentorship of a trainer or an experienced auditor before they are determined to be sufficiently knowledgeable in interpreting the standards, determining compliance with the standards and capable of accurately summarizing audits findings and providing recommendations accordingly, and
- maintain competency by participating in continuing education to ensure that their knowledge is current (e.g. Refresher training, minimum of 10 sites audits every 3 months).

For many countries, identifying trained and skilled personnel to conduct the audits may prove to be challenging. Country should consider using auditors with prior audit skills and/or audit training (e.g. SPI-RT, SPI-POCT or SLIPTA auditors, SLMTA mentors, trained quality assurance officers, etc.).
There are several ways of enabling POCT site auditors to perform successfully site audits, besides the formal training in standards, requirements and audits techniques. These include the following:

- audit checklists and tools
- case studies and group exercises and actual site audits
- professionalism and effective communication
- professional ethics during POCT site audit
- actual site audit
- Summary of findings, etc.

8.4.3 Managing POCT site auditors database

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

- Auditors 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 should be updated periodically.

8.5 SELECTION CRITERIA FOR AUDITORS

The Certifying body should develop the POCT site auditors their terms of reference. These should include the essential background requirements, the essentials skills to meet the requirements for POCT site auditors and outline the auditors' tasks and resources necessary to conduct the audits. The Certifying body should be responsible of maintaining the trained and certified POCT auditors' database. Trained auditors are an integral part of the certification program process. They are responsible for conducting audits and investigating whether the POCT sites are compliant to the national requirements. It is therefore recommended that selected auditor should have specific attributes in order to fulfil their tasks. Table 4 below outlines some of the eligibility criteria for auditors

Table 4. Eligibility criteria for POCT sites auditors

Attributes	Required	Recommended
Understanding of the POCT site audit tools *(e.g. SPI-Checklists)*	✓	
Knowledge of national recommendations and requirements of POCT sites	✓	
Understanding of POCT program specific guidelines and policies *(e.g. National HIV Testing Services guideline, etc.)*	✓	
Knowledge of all three testing phases requirements for certification	✓	
Understanding risk specific audit		✓
Communication skills *(to include interviews with staff involved in testing, janitorial and clerical activities, stock management and other relevant activities).*		✓
Knowledge of safety and waste management practices as recommended by national safety manuals	✓	
Ethics responsibility and conflict of interest		✓
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		✓

8.6 ELEMENTS OF AN EFFECTIVE AUDIT PROGRAM

As countries develop guidelines or implementation plan for POCT sites certification, there is a need to consider the following elements to ensure the audit process is effective and efficient.

- Risk-based audit: This type of audit focuses on elements that pose greater risk to the safety of testing site personnel, may affect the quality of service rendered and the accuracy of test results. The timeframe for addressing the deficiencies identified during an audit is dependent on the

'criticality' of the findings and the level of risk they pose to the staff and to the client. It is recommended to address the deficiencies within 3-6 months of the audit.

- Adequate Human Resources: Available human resources such as, facility laboratory technologists, implementing partners, facility or district level quality improvement teams (including Q-Corps teams) can serve as mentors to support the POCT sites and assist with troubleshooting and addressing quality related deficiencies.
- Written guidelines and procedures: written documentation describing the process of conducting the audits should be available to, understood and used by all certified auditors.
- Verification of compliance: At the end of the audit, the certifying authority should ensure that there is documentation the testing site is compliant and meets the requirement for national certification.
- Complaint Resolution: POCT site audited should be given the opportunity to dispute an audit report that negatively impacts the site. It is recommended that a system be put in place to resolve such complaints in a timely manner.
- Audit schedule: In order to better coordinate the POCT audits process and adequately allocate the resources, countries should consider establishing an audit schedule for a 6-12 month period.

8.7 POCT SITE AUDITOR TOOL – STEPWISE PROCESS FOR IMPROVING THE QUALITY OF TESTING CHECKLISTS

To standardize the POCT site audits, WHO in collaboration with partners developed checklists for a Stepwise Process for Improving the Quality of HIV rapid testing (SPI-RT) and SPI- instrument based POCT. (Annex). The checklists provide guidance on quality assurance (QA) practices for sites using HIV rapid tests to diagnose HIV infection and other POCT. The SPI checklists set minimum standards for POCT and provides guidelines for continuous quality improvement. The SPI checklists scoring is based on 70 points representing the maximum points that a POCT site can obtain. The 70 points are divided into five steps that correspond to quality compliance levels. The sites audited are recognized as operating at one of the levels of compliance (Table 6).

Table 6. Five-point level for compliance with quality standards for POCT sites certification using the SPI 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

8.8 PREPARING FOR SITE CERTIFICATION

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 5). Under the mentorship of laboratory

personnel at facility or district level, or MOH or partners QA officers (e.g. Q-corps volunteers), POCT sites should implement quality management system (QMS) and perform continuous (e.g. quarterly) internal audits using the audit tools (e.g. SPI- checklists) to document and address deficiencies identified when until eligible for national certification.

Note. In many resource constrained countries, third party audits may not occur as often as it is recommended. In such cases, it is advisable for the POCT sites to opt to establish Core Quality Improvement (CQI) teams and to use standardized tools to perform internal audits on regular basis in order to maintain compliance with certification requirements until the third party audit (national certifying body).

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

- Completed Audit Checklists and/or marked up procedures
- Notes on the evidence observed, if applicable
- Audit findings documented (e.g. Auditor's Summation Report for SPI-RT Audit)

8.9 SCORING

The scoring and decision process for certification is based on compliance to national requirements. These decisions should be transparent and easily understood by the auditors and the auditees.

Using the SPI checklists the POCT site can gage its level of compliance to national requirements and thus determine its level of eligibility for certification. The higher the number of points obtained, the level and the closer to certification the site will be (Table 6).

Note: For POCT sites that attain the highest level (level 4), the sub-national team should notify the certifying body to schedule an auditor.

8.10 TYPES OF AUDITS, FREQUENCY AND CERTIFICATION LEVEL

Establishing reasonable timelines for site audits is important for planning and resource allocations. The table below outlines the minimum 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.

Note: Countries can choose to allocate more resources and increase the frequency of the audits.

Table 7. Types of Audits, Frequency and Certification Interval

Quarterly	Semi-annually	Annually	Bi-Annually
SPI Checklist Level 0 & 1 • Internal audits by POCT site personnel • Mentoring by facility lab staff, implementing partners or CQI team	**SPI Checklist Level 2 & 3** • Audits by sub-national team • Mentoring by sub-national team, including Q-corps **Certified POCT sites** • Internal audit by POCT site to ensure compliance and meet recertification eligibility requirements	**SPI Checklist Level 4** • Audits by certifying body • Initial certification	**Certified POCT site** • Audits by certifying body • Recertification

What to Consider:
First party audits (Internal) : Site audit its own systems and operation ; to measure the strengths and weaknesses of site against facility requirements.
Second Party Audit (External) : Inter-site audits within the same facility for compliance with the requirements.
Third Party Audit (External) : Independent outside organization (e.g. Certifying body) performs the audit of the POCT site.

8.10.1 Managing POCT Sites Certification Database

The Certifying Body should develop a database to track the POCT site certification data. The information captured includes but are not limited to the following:

- Site general characteristics information as outlined in the SPI 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 certification)
- Expiration date of sites certified
- Resubmission of audit request (including date – should not exceed 90 days following the previous audit)

Guidelines should be develop to describe how the certification data will be maintain secured, whether the country would host the data on governing body server or a third party server.

8.11 REPORTING AND DOCUMENTING MECHANISM

Any audit performed should be documented in a report and shared with the POCT site staff. Formal written report on the audit findings be 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

Note: In circumstances when there is no clear course of action, the auditor is encouraged to consider alternative ways to address deficiencies.

8.12 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 (internal and external) audit 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.

8.13 CERTIFICATION PROCESS

Site certification should be endorsed by governmental and granted by independent entities entity such as medical laboratory council, laboratory professional associations mandated to do so. The site certification process as proposed in this framework is a multi-step approach.

Issues to Consider

- Minimum requirements for site certification
- Audit requirements
- Validity of the certification

8.13.1 Initial Certification

Once notified by the sub-national team, the certifying authority should identify the team of certified auditors to audit the POCT sites which have obtained 90% score in the SPI-RT audit.
Certifying authority should schedule the audit and notify the facility management and testing sites. Certified auditors acting for the certification body should perform the audit of the sites, review internal audit reports and previous certification audit reports, and document audit findings. If all documentation and requirements are in compliance with national requirement the site is awarded a certificate

Note: for efficiency, pre-established timetable by geographic location may ensure appropriate resource allocation. It is recommended that certification not be granted if the site unduly delays, limits, or denies the certification body or any auditors acting on its behalf, access to the testing site facility, processes, or records needed to verify conformance with certification requirements.

8.13.2 Recertification

In order to maintain continued conformity with certification criteria, the POCT sites should seek recertification through the sub-national team. While recertification interval should be defined by the policy of certification authority, it should occur at minimum every two years, as recommended by most international certifying bodies. The frequency of recertification would be dependent on the risk posed by the processes used at the POCT site an. The greater the risk the more frequent the recertification.

8.13.3 Remediation Plan

It is recommended that the site personnel review the findings of the audit and begin the process of implementing the recommended corrective actions to address the deficiencies within 30 days of the audit. A written procedure on (internal and external) the audit process 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.

8.13.4 Withdrawal

The certification body should develop and document the procedures for withdrawing certification. Some circumstances on when to withdraw certification are listed below:

- Major deviations on one or more certification requirements that are not resolved by site in a timely and acceptable manner.
- Site delays, limits, or denies access to records, documentation, or facility to certifying authority or its auditors thus they are unable to verify and confirm compliance to certification requirements

8.14 MONITORING AND EVALUATION

Examples of potential specific indicators to track and monitor site certification program efficacy and impact are highlighted in the box to the right.

- Number of sites enrolled in program during a specific timeframe
- Number sites audited
- Number nationally sites certified
- Percentage of sites with improved performance
- Percent of sites nationally recertified
- Distribution of QSEs with low scores

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10. GLOSSARY OF TERMS

Accreditation

Procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks (modified from ISO/IEC 17000)

Assessment

The systematic process of collecting and analyzing data to determine the current, historical, 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 and provide written evidence of its compliance with regards to a standard

Certification Maintenance

The process by which individuals possessing a professional certification perform certain specified requirements in order to maintain their certification to demonstrate continued competence

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)

Assessment that includes pre-examination, examination, and post-examination phases. Proficiency testing is considered equivalent to examination phase of EQA – also see **Proficiency Testing**

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

Experienced individual teaching or giving help and advice to a less experienced person.

Mentoring

The process of teaching or giving help and advice to a less experienced person (Merriam-Webster Dictionary)

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 that 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

(*verb*) To watch examinees taking an exam in order to check that they do not cheat nor violate other exam administrative procedures (Cambridge Dictionaries)

(noun) A person whose job is to watch examinees taking an exam in order to check that they do not cheat nor violate other exam administrative procedures (Cambridge Dictionaries)

Proficiency Testing (PT)

Evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons (ISO 17043)[31]. In the context of HIV rapid testing and related POCT, the inter-laboratory comparison may include both laboratory and non-laboratory settings

For the purposes of ISO 17043,[31] the term "proficiency testing" (PT) is taken in its widest sense and includes, but is not limited to: a) quantitative scheme – in which the objective is to quantify one or more measures of the proficiency test item; b) qualitative scheme – in which the objective is to identify or describe one or more characteristics of the proficiency test item; c) sequential scheme – in which one or more proficiency test items are distributed sequentially for testing or measurement and returned to the PT provider at intervals; d) simultaneous scheme – in which proficiency test items are distributed for concurrent testing or measurement within a defined time period; e) single occasion exercise – in which proficiency test items are provided on a single occasion. It may be advantageous to pilot the change to evaluate its effectiveness before implementing a full-scale change; f) continuous scheme – in which proficiency test items are provided at regular intervals; g) sampling – in which samples are taken for subsequent analysis; and h) data transformation and interpretation – in which sets of data or other information are furnished and the informationon is processed to provide an interpretation (or other outcome);

Some providers of PT in the medical area use the term "External Quality Assessment (EQA)" for their PT schemes, or for their broader programs, or both. The requirements of ISO 17043[31] cover only those EQA activities that meet the definition of PT.

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

Part of quality management focused on increasing the ability to fulfill quality requirements (ISO 9000 [3.2.12]).

Quality Management System (QMS)

The management to direct and control an organization with regard to quality (ISO 9000[3.2.3]).

Note: Systematic and process-oriented efforts are essential to meet quality objectives

Quality System Essential (QSE)

The management infrastructure necessary to support any health care organization or service's 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.

Site

A location where point-of-care testing is performed with rapid diagnostic devices within laboratory or non-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 standard is an authoritative "document" setting forth criteria for performance and characteristics (RHuD1.7CD/CLSI). Standards may be issued by national, regional, or international standards bodies. The most widely accepted international standards are issued by the International Organization for Standardization (ISO), a federation of national standards bodies from more than 140 countries. ISO standards are formulated by technical committees.

Standards Development Organization

Standardization bodies have the authority to develop standards. They can be national or international. The ISO is the world's largest developer of international standards, including the most common standard used by medical laboratories (i.e. ISO 15189), as well as ISO 17025 widely used by food safety or environmental laboratories. ISO is used to compose national standardization bodies.

National standardization bodies can develop national standards or adopt international standards with or without modifications. The European Committee for Standardization (CEN) is an example of a regional standardization body with a technical cooperation agreement with ISO.

Supervisory

The action of watching and direction someone or something – also see **Supervisor.**

Supervisor (e.g. Site Supervisor)

Individual who is in charge of (someone or something): to watch and direct (someone or something) (Merriam-Webster Dictionary)

Tester

A person who tests something or performs testing (Merriam-Webster Dictionary) *e.g., performing point of care testing including within laboratory and non-laboratory settings*

Tester Certification

The procedure by which a third party gives written assurance that an individual performing point-of-care testing conforms to specified requirements within laboratory and non-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

Testing Sites

The health care environment immediately surrounding a patient. Examples include bedside on a medical unit, the operating room, ambulance or mobile transport vehicle, and physician's office.

Training

A process by which someone is taught the skills that are needed for an art, profession, or job.

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APPENDICES

Annex 1: Simplifying Management of Non-Instrumented Testing- A Checklist

Before Conducting Testing	
	Check when completed
Facility:	
Review requirements and ensure compliance:	
Facility qualifications (state/local requirements and/or regulations)	☐
Safety requirements	
Adequate facility and testing space	☐
Infection control requirements	☐
Record requirements	
Records access, retention, storage, privacy, and security procedures	☐
Personnel:	
Identify person or persons to oversee testing	☐
Ensure adequate personnel to conduct testing	☐
Verify personnel qualifications	☐
Train testing personnel and conduct competency checks	☐
Equipment and Supplies:	
Order and receive supplies as applicable:	
Storage: Refrigerator, freezer	☐
Collection supplies: Swabs, slides, lancets, capillary tubes	☐
QC materials	☐
Test kits	☐
Testing:	
Determine if the test is appropriate for the patient population	☐
Develop, write, and/or review testing instructions: policy, procedure, manufacturer's instructions	☐

Develop a system to maintain documents/records/results	□
Establish methods and frequency to check all steps of the testing processes for accuracy and completeness	□
Establish processes for identifying and correcting errors/issues/concerns	□

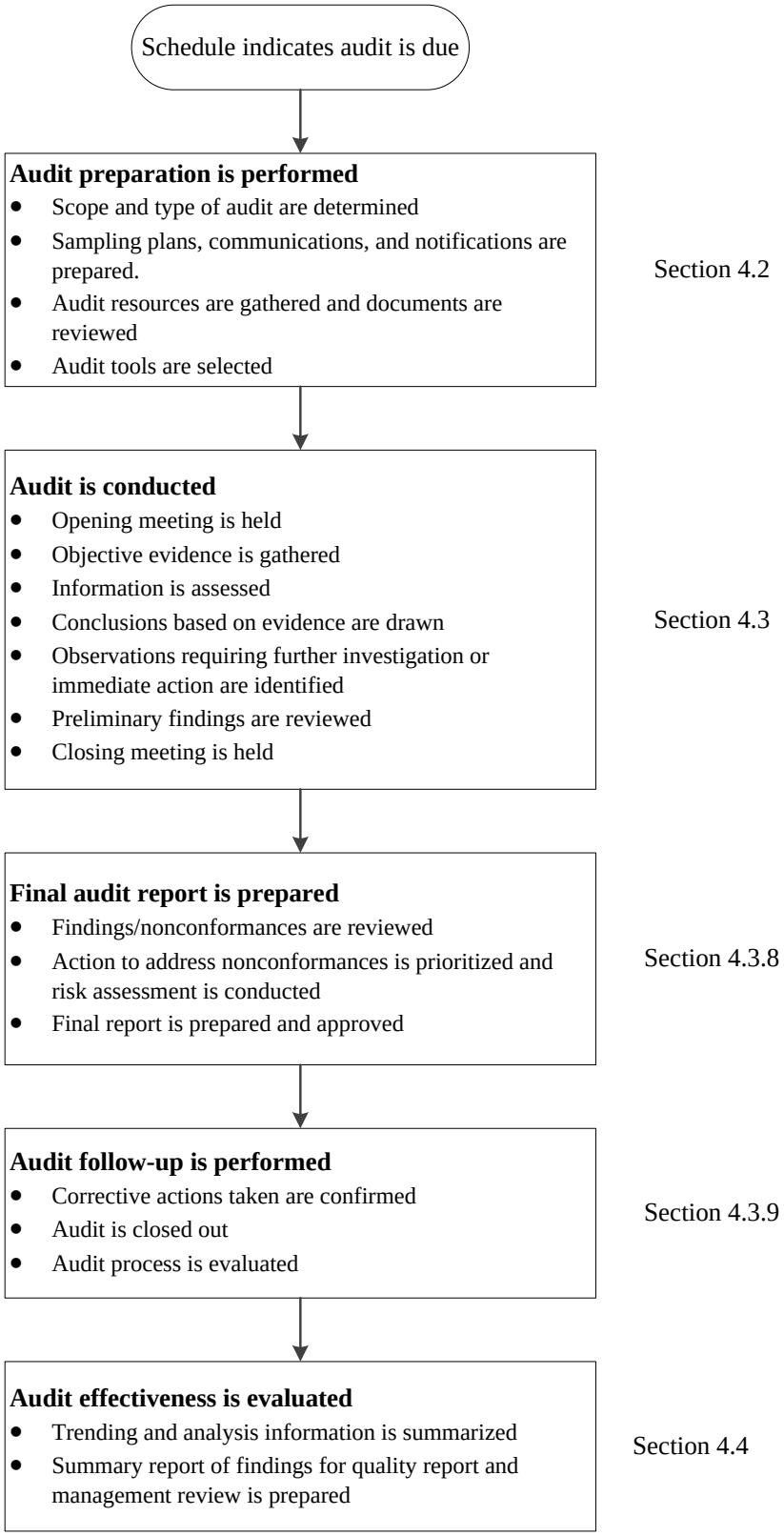
Immediate Pretesting Activities	
	Check when completed
Personnel:	
Verify personnel are completely trained	□
Testing:	
Ensure testing reagents and supplies are within expiration dates	□
Review polices/procedures/written test instructions	□
Know the collection requirements for each procedure	□
Know the limitations of procedures	□
Know the interfering substances for each test procedure	□
Know the QC procedures and frequency	□
Review sequence of testing processes	□
Verify environmental conditions (space, temperature, humidity) are appropriate for testing	□
Perform any required validation or verifications of test kits, if needed	□

Testing Activities	
	Check when completed
Perform QC and document results per policy	□
Follow manufacturer's instructions or written policy/procedure	□
Ensure workflow enables timely reporting of results	□

Verifying and Reporting Results	
	Check when completed
Compare patient test results against reportable ranges/measuring intervals	☐
Communicate values to appropriate personnel who can take action	☐
Evaluate results against clinical data and previous test results	☐
Determine if repeat testing is required	☐
Record results in medical record	☐
Record testing personnel ID with each test result	☐

Post-testing Management Activities	
	Check when completed
Review testing trends or alerts and flags that may need attention	☐
Initiate corrective and preventive actions as appropriate	☐
Maintain test and quality management–related records	☐

Annex 2: Example of an Audit Schedule Process Map



Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Checklist

SPI-RT Checklist

Version 3.0

PART A: CHARACTERISTICS OF THE FACILITY OR TESTING POINT AUDITED

Before completing the checklist, it is important to characterize the testing point to be audited. Please provide relevant information in the summary table below.

Date of Audit (dd/mm/yyyy)**:**	**Audit Round No:**
Testing Facility Name:	**Testing Facility ID** (if applicable)
Testing Point Name:	**Type of testing point** (Circle One) **VCT/HTC PITC PMTCT TB clinic Laboratory Treatment Center Other** (Specify)
Location/Address:	
Level (Circle One and specify name) **Region/Province/Zone:** **District:** **Referral center:** **Health center:** **Dispensary:** **Health Post:** **Other** (Please specify to reflect country context):	**Affiliation** (Circle One) **Government** **Private** **Faith-based Organization** **Non-governmental organization** **Other:**
Number of Testers:	**Average tested per month:**
Name of the Auditor 1:	**Name of the Auditor 2:**

PART B. SPI- RT Checklist

For each of the sections listed below, please check **Yes, Partial or No**, where applicable. Indicate "**Yes**" only when all elements are satisfactorily present. Provide comments for each "**Partial**" or "**No**" response. State N/A in the comments section if "not applicable" where appropriate (*).

SECTION		YES	Partial	NO	Comments	Score
1.0	**PERSONNEL TRAINING AND CERTIFICATION**					**10**
1.1	Have all testers received a comprehensive training on HIV rapid testing using the nationally approved curriculum?					
1.2	Are the testers trained on the use of standardized HIV testing registers/logbooks?					
1.3	Are the testers trained on external quality assessment (EQA) or proficiency testing (PT) process?					
1.4	Are the testers trained on quality control (QC) process?					
1.5	Are the testers trained on safety and waste management procedures and practices?					
1.6	Have all testers received a refresher training within the last two years?					
1.7	Are there records indicating all testers have demonstrated competency in HIV rapid testing prior to client testing?					
1.8	Have all testers been certified through a national certification program?					
1.9	Are only certified testers allowed to perform HIV testing?					
1.10	Are all testers required to be re-certified periodically (e.g., every two years)?					

1.0 PERSONNEL TRAINING AND CERTIFICATION SCORE						
2.0 PHYSICAL FACILITY						**5**
2.1	Is there a designated area for HIV testing?					
2.2	Is the testing area clean and organized for HIV rapid testing?					
2.3	Is sufficient lighting available in the designated testing area?					
2.4	Are the test kits kept in a temperature controlled environment based on the manufacturers' instructions?					
2.5	Is there sufficient and secure storage space for test kits and other consumables?					
2.0 PHYSICAL FACILITY SCORE						
3.0 SAFETY						**11**
3.1	Are there SOPs and/or job aides in place to implement safety practices?					
3.2	Are there SOPs and/or job aides in place on how to dispose of infectious and non-infectious waste?					
3.3	Are there SOPs and/or job aides in place to manage spills of blood and other body fluids?					
3.4	Are there SOPs and/or job aides in place to address accidental exposure to potentially infectious body fluids through a needle stick injury, splash or other sharps injury?					
3.5	Is personal protective equipment (PPE) always available to testers?					
3.6	Is PPE consistently used by all testers?					
3.7	Is PPE properly used by all testers through the testing process?					

3.8	Is there clean water and soap available for hand washing?					
3.9	Is there an appropriate disinfectant to clean the work area available?					
3.10	Are sharps, infectious, and non-infectious waste handled properly?					
3.11	Are infectious and non-infectious waste containers emptied regularly per the SOP and/or job aides?					
3.0 SAFETY SCORE						
4.0 PRE-TESTING PHASE						**12**
4.1	Are there national testing guidelines specific to the program (e.g. HTS, PMTCT, TB, etc.) available at the testing point?					
4.2	Is the national HIV testing algorithm being used?					
4.3	Is there a process in place for an alternative HIV testing algorithm in case of expired or shortage of test kit(s)?					
4.4	Are there SOPs and/or job aides in place for each HIV rapid test used in the testing algorithm?					
4.5	Are only nationally approved HIV rapid kits available for use currently?					
4.6	Are all the test kits currently in use within the expiration date?					
4.7	Are test kits labeled with date received and initials?					
4.8	Is there a process in place for stock management?					
4.9	Are job aides on client sample collection available and posted at the testing point?					
4.10	Are there sufficient supplies available for client sample collection?					

4.11	Are there national guidelines describing how client identification should be recorded in the HIV testing register?					
4.12	Are client identifiers recorded in the HIV testing register per national guidelines and on test devices?					
4.0 PRE-TESTING PHASE SCORE						
5.0 TESTING PHASE						9
5.1	Are SOPs and/or job aides on HIV testing procedures available and posted at the testing point?					
5.2	Are timers available and used routinely for HIV rapid testing?					
5.3	Are sample collection devices (e.g., capillary tube, loop, disposable pipettes, etc.) used accurately?					
5.4	Are testing procedures adequately followed?					
5.5	Are positive and negative quality control (QC) specimens routinely used (e.g., daily or weekly) according to country guidelines?					
5.6	Are QC results properly recorded?					
5.7	Are incorrect/invalid QC results properly recorded?					
5.8	Are appropriate steps taken and documented when QC results are incorrect and/or invalid?					
5.9	Are QC records reviewed by the person in charge routinely?					
5.0 TESTING PHASE SCORE						
6.0 POST TESTING PHASE - DOCUMENTS AND RECORDS						9
6.1	Is there a national standardized HIV rapid testing register/logbook available and in use?					
6.2	Does the HIV testing register/logbook include all of the key quality elements?					

6.3	Are all the elements in the register/ logbook recorded/captured correctly? (e.g., client demographics, kit names, lot numbers, expiration dates, tester name, individual and final HIV results, etc.)?					
6.4	Is the total summary at the end of each page of the register/logbooks complied accurately?					
6.5	Are invalid test results recorded in the register/logbook?					
6.6	Are invalid tests repeated and results properly recorded in the register/logbook?					
6.7	Are all client documents and records securely kept throughout all phases of the testing process?					
6.8	Are all registers/logbooks and other documents kept in a secure location when not in use?					
6.9	Are registers/logbooks properly labeled and archived when full?					
6.0 POST TESTING PHASE - DOCUMENTS AND RECORDS SCORE						
7.0 EXTERNAL QUALITY AUDIT (PT, SUPERVISION AND RETESTING)						**8/14**
7.1	Is the testing point enrolled in an EQA/PT program?					
7.2	Do all testers at the testing point test the EQA/PT samples?					
7.3	Does the person in charge at the testing point review the /PT results before submission to NRL or designee?					
7.4	Is an EQA/PT report received from NRL and reviewed by testers and/or the person in charge at the testing point?					
7.5	Does the testing point implement corrective action in case of unsatisfactory results?					
7.6	Does the testing point receive periodic supervisory visits?					

7.7	Is feedback provided during supervisory visit and documented?					
7.8	If testers need to be retrained, are they being retrained during the supervisory visit?					
If the country external quality assessment program includes retesting of serum or DBS, proceed with questions 7.9 – 7.14. Otherwise, STOP here.						
7.9*	Does the site collect samples for retesting according to country guidelines (e.g., collection of every 20th client serum or DBS sample)?					
7.10*	Are the serum or DBS samples collected for retesting properly documented?					
7.11*	Are serum or DBS samples collected properly (e.g., at least 3 complete circles or correct volume and correct tubes, etc.)?					
7.12*	Are serum or DBS samples stored properly (e.g., away from sunlight, separated by glassine paper, desiccant, or at 4oC or 20oC, etc.)?					
7.13*	Are the identifiers of serum or DBS samples sent for retesting properly recorded?					
7.14*	Are the serum or DBS results received from the referral lab properly documented and recorded in the HIV testing register/logbook?					
7.0 EXTERNAL QUALITY AUDIT (PT, SUPERVISION AND RETESTING) SCORE						

*Those marked with an asterisk are only applicable to sites where sample retesting is performed.

PART C: SCORING CRITERIA

Each element marked will be assigned a point value:

- Items marked “Yes” receive 1 point each.
- Items marked “Partial” receive 0.5 point each.
- Items marked “No” receive 0 point each.

Total points scored for each section should be tallied and recorded at the end of the section.

The overall total points obtained by each HIV testing point audited will be weighed to correspond to a specific performance level.

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

Part D. Auditor's Summation Report for SPI-RT Audit

Facility Name: Site Name: Site Type: Staff Audited Name:	No. of Tester(s): Duration of Audit:	Total points scored (exclude N/A) = a Total score expected = b % Score = (a/b) x 100 Level 0 ☐ Level 1 ☐ Level 2 ☐ Level 3 ☐ Level 4 ☐

Section No.	Deficiency/Issue observed	Correction Actions		Auditor's Comments	Recommendations	
		Immediate	Follow up		Actions	Timeline / Person responsible

Staff Audited Signature: Person in Charge Name and Signature:	Auditor Name and Signature: Date (dd/mm/yyyy):

Stepwise Process for Improving the HIV related Quality of Point of Care Testing (SPI-POCT) Checklist

SPI-POCT (Instrument based) Checklist

Version 2.0

Level (Specify all appropriate names) **Region/Province:** **District:** **Referral center:** **Health center:** **Dispensary:** **Health Post:** **Other:**	**Affiliation (Circle One)** **Government** **Private** **Faith-based Organization** **Non-governmental organization** **Other:**
Name of POCT Facility/ Site:	
Location/Address of POCT Facility/ Site:	
Location of Point-of-care Testing Service:	
Point-of-care Test offered (list all):	
POCT Facility/Site Supervisor or point of contact:	
Name of the Auditor:	

Signature of Auditor:	Date of Audit:

Levels	% Score	
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 site certification)**
Level 4 =	**90% or higher**	**(Eligible for certification)**

For each of the sections listed below, please check **Yes, Partial or No**, where applicable. Indicate "Yes" only when all elements are satisfactorily present. Provide comments for each "Partial" or "No" response. State N/A in the comments section if "not applicable" where appropriate (*).

	SECTION	YES	Partial	NO	Comments	Score
2.0	**Integration of POCT service for Patient Care** ***POCT services should be offered so results are interpreted and utilized to support HIV+ patient care, in accordance with national/sub-national/facility guidelines, policy and regulations***					6
1.1.	Is there a testing algorithm/guideline at the facility/site for using POCT results for Patient Care?					
1.2.	Does the testing algorithm/guideline specify on which patients and when POCT should be performed?					
1.3.	Does the testing algorithm/guideline include steps for result interpretation?					
1.4.	Does the testing algorithm/guideline specify when to provide results to patient for medical review?					
1.5.	Is there a plan or policy for an alternative algorithm or testing facility in case the POCT facility/site is unable					

	to provide POCT? (ie stockouts, expired reagent, equipment failures, etc.)					
1.6.	Are the testing algorithm/guidelines current? Have they been reviewed and/or approved within the last 2 years?					
3.0 Personnel Training, Competency, and Certification ***POCT services should be offered so results are interpreted and utilized to support HIV+ patient care, in accordance with national/sub-national/facility guidelines, policy and regulations.***						**9***
2.1.	Does the POCT facility/site have a policy specifying which cadre may perform POCT?					
2.2.	Does the POCT facility/site have a policy specifying the qualification of the POCT personnel?					
2.3.	Have all POCT personnel received training on specimen collection and processing for each POC test? Has the training been documented?					
2.4.	Have all POCT personnel received training on the POC test procedure? Has the training been documented?					
2.5.	Have all POCT personnel received training on results recording and interpretation? Has the training been documented?					
2.6.	Have all POCT personnel received training on QC testing and QC results interpretation? EQA/PT testing? Has the training been documented?					
2.7.	Does the POCT facility/site have a documentation to ensure that each POCT personnel annually maintain a satisfactory level of competency?					
2.8.	For competency assessment is direct observation of routine test performance, including, as applicable, patient identification and preparation, specimen collection and processing, testing procedure, and result recording?					
2.9.	For competency assessment is there a review of POCT personnel performance with results reporting and					

	interpretation, QC testing, EQA result, and/or equipment maintenance?					
2.10.	*If available, are all POCT personnel certified to perform each specific POCT?					
4.0 Physical Facilities ***The POCT facility/site should be adequate to provide safe and effective POCT services.***						**5**
3.1	Are there designated areas for POCT?					
3.2	Are the designated POCT areas clean and organized for POCT?					
3.3	Are each of designated areas of adequate space, lighting and environmental control to perform POCT?					
3.4	Is there sufficient and secure storage for POCT reagent, supplies, and equipment?					
3.5	Is there environmental monitoring of temperatures at the POCT area and reagent storage?					
5.0 Safety ***The POCT facility/site should have organization and processes in place providing for safety of staff, patients, and community.***						**6**
4.1	Does the POCT facility/site have documented procedures for handling and disposable of biohazardous material?					
4.2	Does the POCT facility/site have documented procedures and/or policies for safety in the work place?					
4.3	Are there SOPs and/or job aides in place to manage spills of blood and other body fluids?					
4.4	Are all POCT personnel trained on handling biohazardous material, workplace safety, and spill management? Is there documentation of these trainings?					

4.5	Is Personnel Protective Equipment always available? Gloves or other PPE, as appropriate, must be available.					
4.6	Are biohazardous waste and sharps containers available and appropriately labeled?					
6.0 PRE-TESTING PHASE ***The POCT facility/site should provide for a standardize system for patient handling and identification, specimen collection and processing, and recording of patient/specimen information.***						6
5.1	Are SOPs and/or job-aids available for patient handling and patient identification?					
5.2	Are SOPs and /or job-aids for specimen collection and processing, including specimen storage conditions?					
5.3	Are there SOPs and / or job-aids for recording of patient/specimens? Including specimen identification?					
5.4	Are there standardized forms/registers/logbooks or /electronic files available for recording patient/specimen information?					
5.5	Are all standardized forms/registers/logbooks or /electronic files complete and legible?					
5.6	Are pre-testing procedures being adequately followed? Included safety practices and biohazardous disposable? (direct observation)					
7.0 TESTING PHASE ***The POCT facility/site should provide for a standardize system to perform POCT and included QC testing and troubleshooting guides***						**5**
5.1	Are SOPs and/or job-aids available for the POC testing procedures?					
5.2	Does the testing SOPs and/or job-aids specify how each sample is identified during the testing procedure and linked to patient/specimen?					
5.3	Does the testing SOPs and /or job-aids specify when and how to preform QC testing? Does the SOPs and /or job-aids include interpretation QC results and troubleshooting sets for failed QC results?					

5.4	Does the SOPs and or jo-aids include interpretation of patient results and troubleshooting sets for failed/invalid results?					
5.5	Are testing procedures adequately followed (direct observation)?					
8.0	**POST-TESTING PHASE** ***The POCT facility/site should provide for a standardize system for POCT results to be recorded and reported and include a system for recording QC results***					**5**
7.1	Are SOPs and/or job-aids available for recording and reporting of POCT results?					
7.2	Are there standardized forms/registers/logbooks or /electronic files available for recording POCT patient and QC results?					
7.3	Are all standardized forms/registers/logbooks or /electronic files for recording of POCT results complete and legible?					
7.4	Are SOPs and/or job-aids available or recording POCT QC results? Are the QC results recorded?					
7.5	Are all standardized forms/registers/logbooks or /electronic files properly labeled and kept in a secure location?					
9.0	**Supplies, Reagents, and Equipment** ***The POCT facility/site should provide for adequate and reliable stocks of supplies and reagents, and functional equipment and instruments.***					**5/8***
8.1	Are supplies available and in date for specimen collection? (ie.lancets, gauze, alcohol swabs, plasters, tubes, etc)					
8.2	Are POCT reagents and supplies available and in date?					
8.3	Are all POCT and specimen collection supplies and reagents stored as recommended by manufacturer?					

8.4	Are all POCT and specimen collection supplies and reagents inventoried monthly?					
8.5	Are there procedures and / or policies for ordering and receiving supplies and reagents?					
8.6*	Are all equipment and instruments functional?					
8.7*	Are there SOPs and job / aids available for maintaining of equipment and instruments? Including troubleshooting steps and procedures?					
8.8*	Is there document of equipment and instrument routine maintenance and troubleshooting /repairs?					
10.0 Monitoring Quality ***The POCT facility should provide for a quality monitoring system to ensure accurate and reliable POCT results.***						**6**
9.1	Are all POCT results regularly reviewed by a site supervisor or external monitor? Does this review included completeness and timing of patient result reporting, error/invalid test rates, interruption in testing, and individual POCT personnel performance?					
9.2	Does the POCT facility/sites verify the QC results for acceptability before reporting results?					
9.3	Are QC results regularly reviewed by a site supervisor or external monitor?					
9.4	Is the POCT facility/site enrolled in an EQA/PT program?					
9.5	Does the POCT facility/site report EQA/PT results to the program provider within the set timeframe?					
9.6	Is EQA/PT feedback report received and reviewed? Does the POCT facility/site implement corrective action in case of unsatisfactory results?					

*Those marked with an asterisk may be optional questions; please indicate N/A in the comments section if not applicable.

Auditor's Summation Report for SPI-POCT Assessment

POCT Facility Name: POCT Site Name: Number of POCT Personnel:	Date of Audit Audit Number Lenght of Audit:	Total points scored (exclude N/A) = a Total score expected = b % Score = (a/b) x 100 Level 0 ☐ Level 1 ☐ Level 2 ☐ Level 3 ☐ Level 4 ☐

Section No.	Score	Possible Score exclude NA	Auditor's Comments	Recommendations
1. Integration of POCT service for Patient Care		6		
2. Personnel Training, Compet and Certification		9-10		
3. Physical Facilities		5		
4. Safety		6		
5. Pre-Testing Phase		6		
6. Testing Phase		5		
7. Post-Testing Phase		5		

8. Supplies, Reagents and Equipment		5-8		
9. Quality Monitoring		6		

Annex 5. Examinee Performance Report – Pass Letter Example

33 West Monroe Street, Suite 1600
Chicago, Illinois 60603-5617

T 312.541.4999
F 312.541.4998
www.ascp.org

EXAMINEE PERFORMANCE REPORT
INTERNATIONAL MEDICAL TECHNOLOGIST

[redacted]

ASCP [redacted]
CUSTOMER ID: [redacted]
MT(ASCP[i]) [redacted]

[redacted]

THIS REPORT PROVIDES INFORMATION CONCERNING YOUR EXAMINATION PERFORMANCE. A SCALED MINIMUM PASS SCORE (MPS) OF 400 ON THE TOTAL TEST WAS REQUIRED TO PASS.

YOUR PERFORMANCE SUMMARY FOR THE TOTAL IMT EXAMINATION TAKEN ON [redacted]

MPS	YOUR SCORE	STATUS
400	438	PASS

Please retain this examination score report for your records. This report is the only document from the ASCP/Board of Registry that will contain your Certification Number.

Annex 6. Examinee Performance Report – Fail Letter Example

EXAMINEE PERFORMANCE REPORT
INTERNATIONAL MEDICAL TECHNOLOGIST

ASCP [redacted]
CUSTOMER ID: [redacted]

[redacted]

[redacted]

THIS REPORT PROVIDES INFORMATION CONCERNING YOUR EXAMINATION PERFORMANCE. A SCALED MINIMUM PASS SCORE (MPS) OF 400 ON THE TOTAL TEST WAS REQUIRED TO PASS.

YOUR PERFORMANCE SUMMARY FOR THE TOTAL IMT EXAMINATION TAKEN ON [redacted]

MPS	YOUR SCORE	STATUS
400	244	FAIL

SUBTEST PERFORMANCE SUMMARY

SUBTESTS	[PERCENT OF TOTAL TEST]	SCALED SCORES
BLOOD BANKING	[21%]	133
CHEMISTRY	[21%]	308
HEMATOLOGY	[21%]	303
IMMUNOLOGY	[8%]	458
MICROBIOLOGY	[21%]	212
URINALYSIS AND BODY FLUIDS	[8%]	144

Pass/fail decisions are based on your total test score. Subtests scores are reported to failing candidates to assist in determining their relative strengths and weaknesses so that they can better prepare to retake the test. All scores are transformed to a standard scale, with 400 as the MPS. Subtests scores do NOT add up to the total score. They are independently calculated for each subtest.