Module 13

External Quality Assessment –

On-site Evaluation and Re-testing

Purpose	To provide you an overview of External Quality Assessment with focus on on-site evaluation and re-testing.
Pre-requisite Modules	Module 5: Assuring the Quality of HIV Rapid Testing
Learning Objectives	At the end of this module, you will be able to: ▪ Assess operations at test site to determine if quality requirements are met ▪ Take corrective actions following External Quality Assessment (EQA) ▪ Keep appropriate records related to EQA ▪ Avoid common problems associated with EQA specimen management
Content Outline	What is EQA and why is it important? EQA Responsibilities EQA Methods – Proficiency Testing, On-Site Evaluation, Re-testing How to implement EQA
Handouts	Corrective Action Form On-site Evaluation Checklist Example Specimen Transfer Log for Re-testing
Notes on Customization	Customize the module according to the participants' job positions and responsibilities (management versus testing personnel). Other modifications are also required throughout the module to provide specific information on in-country EQA program.

External Quality Assessment (EQA): Definition	External Quality Assessment (EQA) is the objective assessment of a test site's operations and performance by an external agency or personnel.
Why EQA?	EQA allows comparison of performance and results among different test sites offering not only an opportunity for performances checks, but an opportunity to systematically identify problems with kits or operations. Additionally, EQA also provides objective evidence of testing quality, indicates areas that need improvement, and identifies training needs.
EQA: Conducted at Three Levels	EQA should be conducted at all levels of testing service. These include national reference lab, provincial or intermediate lab, and test site (point of service). For EQA program to be effective, the Ministry of Health must establish an organizational structure and assign responsibility to assure that on-site monitoring occurs in all locations. In most countries, the National Reference Laboratory (NRL) has overall oversight responsibility. However, to have better reach in meeting the needs of rural test sites or points of service, this may be best accomplished with oversight by provincial labs.
Management Responsibilities: An Overview	Someone of authority must take responsibility for EQA. First of all, they must determine policies for EQA (WHO, WHAT, WHEN, HOW) and designate a staff member with the responsibility to establish and implement the EQA program. They are also responsible for establishing and maintaining a system for assessment visits – this includes scheduling visits and conducting evaluation. Ideally the person conducting the on-site visit should have an understanding of the Quality Management System, knowledge of testing technologies, ability to analyze situations and good communication skills. Furthermore, it is management's job to receive EQA results and support corrective action measures. Management will determine how and when they are advised of the outcomes of the EQA program. The best way to ensure EQA reports are reviewed by management is by including them as an agenda item in management review meetings. Finally, management must monitor and maintains records, investigate deficiencies, manage corrective action efforts, and communicate outcomes.

Testing Personnel's Responsibilities

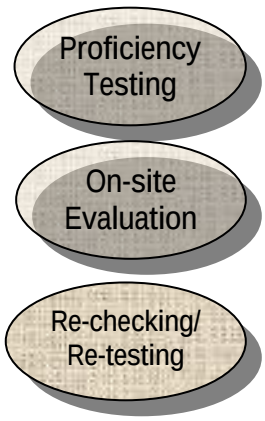
Test providers' EQA responsibilities include:

- Participating in the EQA program
- Taking corrective actions
- Maintaining EQA records
- Communicating outcomes to supervisors

EQA Methods

There are three main EQA methods:

- Proficiency testing (PT) – Proficiency panel may be used during on-site visits.
- On-site evaluation, which is sometimes referred to as on-site monitoring visits or audits
- Rechecking or retesting of specimens



What is Proficiency Testing?

In proficiency testing (PT), a reference laboratory sends out panels of specimens to multiple test sites, who in turn perform tests on these panels and report results. The reported results indicate quality of personnel performance and test site operations. Results are often compared across several testing sites.

What is On-site Evaluation?

On-site evaluation is periodic site visits to systematic assessment of lab practices. These visits focus on how the lab monitors its operations and ensures testing quality. They provide information for internal process improvement. On-site evaluation is also referred to as audits, assessments, or supervisory visits.

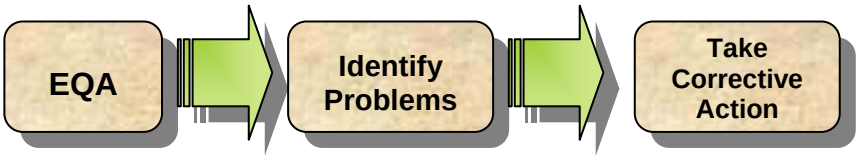
These site visits enable us to learn "where we are" so we may measure gaps or deficiency. From the visits we can collect information for planning & implementation, monitoring, and continuous improvement. They are part of every lab quality system.

These visits should be instructional rather than punitive. The main purpose of on-site visits is to observe the testing site under routine conditions in order to check that it is meeting quality requirements.

What is Re-testing?

Re-testing is the process by which a random selection of specimens are collected from the routine workload at the test site and sent to the reference laboratory for validation. It is used to detect errors.

EQA Should Lead to Corrective Actions



A Corrective action is an action taken to correct a problem or non-conformance / deficiency within the Quality Management System. Examples of a non-conformance include:

- Production of an incorrect result
- Any step within a process which contributed to an incorrect result
- When the documented quality system is not followed exactly as intended
- When the quality system does not meet the requirements of quality standards or requirements

Problems May Occur Throughout the Testing Process

Problems may lie anywhere in the testing process: pre-testing, testing, and post-testing. Most problems occur in the pre and post analytic phase of testing. The integrity of the specimen may have been compromised during preparation, shipping or after receipt by improper storage or handling

Problems such as with reagents, test methods, quality control, or competency of staff may occur during testing. Due to the numbers of specimens collected and transported by various test sites, care must be taken to ensure proper transcription of data throughout the testing process

Take Corrective Actions

Whenever problems are detected, corrective actions must be taken.

- Use problem-solving team
- Investigate root causes and develop appropriate corrective actions
- Implement corrective actions
- Examine effectiveness
- Record all actions and findings

On-Site Evaluation Process

As a tester, you should understand the process for how the visits will be conducted. This will assist you in preparing for a productive visit. Refer to handout "On-site Evaluation Checklist" at the end of this module.

The on-site evaluation process includes the following steps:

1. Pre-Evaluation Preparation
2. Entrance Interview
3. Information Gathering
4. Outcome Assessment
5. Exit Conference
6. Reporting

Tester Responsibilities: Ensuring a Productive Site Visit

You as a tester play an important role in ensuring a productive site visit. Review the table below for tasks that should be performed before, during, and after a site visit.

Before Visit	Record keeping is essential. Get organized Confirm date of visit Review written policies and procedures Conduct internal assessment in preparation of site visit
During Visit	Participate in visits – cooperate Ask questions of site assessors
After Visit	Take corrective actions, where necessary. These corrective actions should be taken immediately to help ensure the continued quality of testing.

On-site Evaluation: ❶ Pre-Evaluation Preparation

Someone should take responsibility for preparing for on-site visits. A team consisting of both program and laboratory staff should collectively plan for and conduct the on-site visit. Doing so will provide a comprehensive view of the testing site, and will prevent vertical assessments. Appropriate training should be provided for those who will serve as assessors.

A schedule of when the visits will occur should be developed and communicated to the test site. The frequency of the visit may be determined by a number of factors:

- Previous results where problems or deficiencies have been noted, due to complaint or follow-up
- Number of trained assessors
- Minimum frequency 2x year for established sites
- Quarterly for new sites

There are both advantages and disadvantages for unannounced visits.

- Announcing the date of the visit will ensure that relevant staff will be present during the visit.
- Unannounced visits will most likely give you a true picture of routine practice. These unscheduled visits aim to fix the problem and improve the system to prevent recurrence.

Evaluation visits may also be conducted in response to a problem within the system. Schedule evaluation visits during a time that will minimize disruption of services.

On-site Evaluation: ❷ Entrance Interview

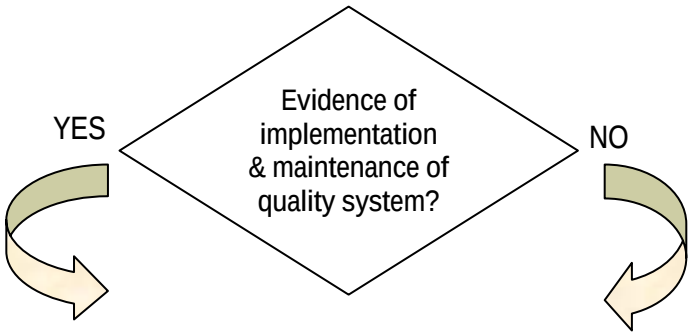
The entrance interview sets the tone for the entire visit. Individuals conducting the visit should be prepared, positive and courteous. They should first introduce the evaluation team and show identification before entering the facility. Part of this entrance interview also includes an overview of the process in terms of what will be done. This may include review of facility, record review, observation, interview with testing staff, use of proficiency panel, and exit interview.

On-site Evaluation: ❸ Information Gathering

Individuals conducting the onsite visit will need to gather information in an organized, consistent manner to make decisions about the site's quality system. They should try to minimize disruption to the work flow of testing site during the information gathering effort.

Observation of test performance may be accomplished by observing staff performing actual patient/client testing, or by use of proficiency panel comprised of 5-10 specimens. Site assessors should plan in advance to arrive at site with proficiency panel. Provision of proficiency panel is the responsibility of reference labs. At all times, respect patient privacy and confidentiality

On-site Evaluation: ❹ Outcome Assessment



If problems are detected, the assessor should determine the impact of the problem in relation to patient test outcome. Ask the following questions:

- Does the problem result in inaccurate test results?
- Does the problem result in a high probability of inaccurate test results?
- Is immediate corrective action necessary?

On-Site Evaluation: ❺ Exit Conference

Findings from the on-site visit should be reviewed with supervisory and testing staff. When reviewing findings, try to make positive statements first and acknowledge staff cooperation and support. When addressing negative findings, allow test site to discuss findings and provide additional information. Provide instructions and timeframe for the test sites to submit plans for correcting problems.

On-site Evaluation: ❻ Reporting

An on-site evaluation report should include the following information:

- Site Name & Location
- Date of Visit
- Assessment Team Members
- Major Findings
- Recommendations for corrective actions

Completed checklist and report should be submitted to relevant authorities, e.g., Quality Manager, Site Manager, Program Manger, or MOH.

Issues to Consider Prior to Implementing a Re-testing Program

Implementation of a re-testing program requires consideration of the following issues:

- What is the purpose of re-testing?
- Is re-testing feasible?
- Does technical capacity exist at reference lab?
- Can turnaround of re-testing be accomplished in a timely manner allowing for immediate corrective actions?
- What type of specimen should be collected for re-testing?
- How should EQA specimens be labeled and recorded?
- When should specimens be shipped / transported to reference laboratory?
- Which laboratory should re-test specimens submitted by test sites?

Statistical Basis for Re-testing: Error Detection

If re-testing is to be one of the EQA methods, it must be based upon statistical considerations. Specimens MUST be collected randomly. Every effort should be made to avoid systematic sampling bias. Outcome of re-testing must be analyzed for effective and timely feedback.

Re-testing Process

The process for re-testing includes the following steps:

1. Determine specimen type
2. Determine sampling plan and time interval
3. Collect specimens
4. Store specimens until transport
5. Package and transport specimens along with paperwork to designated laboratory
6. Compare re-test results with site results
7. Take Corrective actions, if needed

Tester Responsibilities: Re-Testing

Your responsibilities in a re-testing program is to:

- Follow written policies and procedures
- Collect appropriate specimen
- Record keeping is essential
- Take necessary precautions to avoid transcription errors
- Package and transport EQA specimens to designated reference laboratory
- Take necessary corrective actions

Specimen Requirements

Specimens for re-testing can be either Dried Blood Spots (DBS) or serum/plasma.

- If using Dried Blood Spots (DBS), collect 100 µl on labeled filter paper and store the samples refrigerated in appropriately packaged re-sealable plastic bag.
- If using serum or plasma, collect 0.5 ml aliquot in labeled cryovial, and store at 2-8ºC for up to 1 week or at -20ºC or below if longer than 1 week.

All specimens should be properly labeled. At a minimum, include specimen identification number and date of collection. This information needs to be captured on a form that is submitted along with specimen to a reference laboratory.

Refer to Module 14 for details on the use of Dried Blood Spots for re-testing.

EQA Specimen Transfer Log

You can find an example of EQA specimen transfer log at the end of this module.

Specimen Management : Common Problems

Given the volume of specimens that may be required for re-testing, care must be taken to avoid errors that may occur in the pre-analytic and post-analytic phase of testing.

Common problems include:

- Transcription errors, such as mislabeling cryovial or DBS card, from Lab register to specimen transfer log, and from reference lab to testing site
- Inadequate specimens

Remember – a test result is only as good as the specimen received for testing.

Key message

- EQA provides early warning for systematic problems associated with kits or operations
- Problems may occur throughout the testing process
- On-site visits are designed to be instructive, not punitive
- Corrective actions should be implemented and recorded for any problems identified.
- A test result is only as good as the specimen received for testing.

On-Site Evaluation Visit Role Play

Observe the scenario of a on-site evaluation visit. Answer the following questions..

What did you observe?

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What did you learn?

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Module Review

Find out how much you have learned by answering these questions.

Describe your responsibilities in EQA.

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What is proficiency testing?

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What is On-site evaluation?

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What is Re-testing?

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Module Review

Find out how much you have learned by answering these questions.

Explain the process for on-site evaluation.

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What are some issues that are considered prior to implementing a re-testing program?

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Explain the process for re-testing.

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What are some common problems associated with specimen management?

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CORRECTIVE ACTION FORM

This Corrective Action is a result of:

_____Occurrence Date_____ Time: _____

_____Internal Assessment Date_____ Time: _____

_____External Assessment: Date_____ Time: _____

Description of Problem or Finding: *(What happened and Why)*

_____

_____

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Reported by: (Staff Name) _____

Corrective Action Taken: *(What was done to prevent re-occurrence?)*

_____

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_____

Staff Name: _____ Date:_____

Reviewed by: (Test Site Manager / Quality Officer) _____

Date Reviewed:_____

On-site Evaluation Checklist – Assessment of Quality System

Quality System Essential		Yes	No	Assessor's comments
Organization	▪ Is there a quality policy manual present and accessible? o Does the policy manual address all elements of the quality system?			
	▪ Does the site have a designated quality officer?			
	▪ Is the site manager aware of all quality system components?			
Personnel	▪ Does testing staff possess certificate indicating successful participation in HIV rapid test training?			
	▪ Has the staff been oriented to the patient/client flow at the test site?			
	▪ Does staff demonstrate professionalism?			
	▪ Is number of staff adequate for the site workload? o Approximately how many tests does each staff member perform per month?			
Documents and Records	▪ Are standard operating procedures for all aspects of the testing process written, up-to-date, and accessible to staff?			
	▪ Is the handwriting legible?			
	▪ Do worksheets include appropriate information?			
	▪ Are external quality control records up-to-date, easily reviewed?			
	▪ Are corrective actions recorded?			
	▪ Are results interpreted and recorded according to the SOP and site protocol?			
Purchasing and Inventory	▪ Are kits and reagents stored properly?			
	▪ Is staff following "first in, first out" method when managing inventory stock?			
	▪ Is there a policy for re-ordering kits and supplies?			
	▪ Is minimum stock on hand? (Look at re-order levels)			
	▪ Is the site ever unable to perform testing because there are no kits or supplies on hand? o How frequently does this occur?			
	▪ If unable to test, how is this information provided to clients?			

Quality System Essential		Yes	No	Assessor's comments
	▪ Does testing site have adequate space for storage of specimens?			
Equipment	▪ Is refrigerator clean and organized?			
	▪ Are refrigerator temperatures monitored and recorded?			
	▪ Are freezer temps monitored and recorded, if present?			
	▪ If centrifuge is used, are function checks routinely performed?			
	▪ If non-disposable pipettes are used, are calibration records available?			
Process Control *Specimen Management*	▪ Is there a written procedure for collecting, processing and storing specimens?			
	▪ Are specimens appropriately labeled and packaged for transport to reference laboratory?			
	▪ Does staff follow universal or standard precautions when collecting or handling patient/client specimens?			
	▪ Do DBS or other collected specimens meet acceptance criteria?			
	▪ Observe staff perform rapid test using client specimen. All steps should follow SOP.			
Quality Control	▪ Are both internal and external quality control samples analyzed? o How often? o What is the source of QC material?			
	▪ Are external quality control results recorded and reviewed?			
	▪ Are appropriate corrective actions taken when controls results do not produce expected results?			
	▪ Is HIV status reported only when internal and external control is acceptable?			
Information Management	▪ Are test results properly maintained and accessible?			
	▪ Is a computer used in recording information and data? If yes, are there procedures to assure accuracy?			
	▪ Is patient/client confidentiality maintained? o If yes, is there adequate back-up to assure integrity of data in case of equipment (computer) failure?			
	▪ Is the testing site meeting program reporting requirements?			

Quality System Essential		Yes	No	Assessor's comments
Occurrence Management	▪ Is there a written policy for investigating errors?			
	▪ How is communication with affected customers handled?			
	▪ Are all errors, with any corrective action and communication, recorded?			
Assessment	▪ What EQA method(s) is used?			
	▪ Are results of re-testing submitted to testing site in timely manner?			
	▪ Are appropriate actions taken when re-testing results differ from initial results?			
	▪ Has the testing site been monitored within last 6 month?			
	▪ Have corrective actions been taken for previously identified problems?			
	▪ Are corrective actions taken and recorded?			
	▪ Are the results of on-site monitoring communicated to staff?			
	▪ Observe staff perform rapid tests using proficiency panel. (record results for each individual). All steps should follow SOP.			
Process Improvement	▪ Have any projects been undertaken for process improvement?			
Service and Satisfaction	▪ Is staff courteous to clients?			
	▪ Are there efforts to reassure client and/or alleviate client's fear of needle or sight of blood?			
	▪ When reporting to outside providers, is turnaround time appropriate?			
	▪ Does the site solicit input and advice from clients?			
	▪ Are program needs and expectations being met?			
	▪ Is the testing space adequate in size; clean and well organized?			
	▪ Is the environment suitable for patient testing (e.g. temperature, electrical supply)?			
Facilities and Safety	▪ Is storage space adequate, clean and maintained?			
	▪ Are gloves available and used routinely?			
	▪ Are hand washing supplies and facilities available in a convenient area?			
	▪ Are work areas disinfected?			

Quality System Essential		Yes	No	Assessor's comments
	▪ Is biohazard waste disposed of safely?			
	▪ Does the laboratory have policy and procedure for addressing accidental exposure to infectious material?			
	▪ Are emergency contacts located in visible area at test site?			
	▪ Is staff aware of policy for post exposure prophylaxis?			

Example Specimen Transfer Log for Re-testing

[Insert Name of Referring Testing Site,
Contact Name
Address and Phone Number]

Date: _____ **Referring Testing Site _____**

Specimen Tracking Number	Test Subject ID*	Final Result (Testing Site)	Date Specimen Collected	Specimen Type (DBS or Serum)	Collected by	Referral Lab Req† Completed (✓)	Date to referral lab	Date Conf Result Received	Result of Re-test

*ID = Identification
†Lab Req = Laboratory Requisition