

Module 13: External Quality Assessment – On-site Evaluation and Re-testing

Purpose	To provide participants an overview of External Quality Assessment with focus on on-site evaluation and re-testing.
Pre-requisite Modules	<ul style="list-style-type: none"> Module 5: Assuring the Quality of HIV Rapid Testing
Module Time	1 hour 30 minutes
Learning Objectives	<p>At the end of this module, participants will be able to:</p> <ul style="list-style-type: none"> 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

Module Overview

Step	Time	Activity/Method	Content	Resources Needed
1	3 min	Presentation	Module introduction	Slides 1-4
2	7 min	Presentation Discussion	EQA: what, why, responsibilities	Slide 5-9
3	15 min	Presentation Discussion	EQA methods	Slides 10-18
4	20min	Presentation Discussion	Implementing on-site evaluation	Slides 19-30
5	30 min	Role play	On-site evaluation visit	Slides 31
6	10 min	Presentation Discussion	Implementing re-testing	Slides 32-40
7	5 min	Q&A	Summary	Slide 41

Material/Equipment Checklists

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline
- Handouts:
 - Corrective Action Form
 - On-site Evaluation Checklist
 - Example Specimen Transfer Log for Re-Testing

Teaching Guide

Slide Number	Teaching Points
 <i>Customization Notes</i>	<p>Customize the module according to the participants' job positions and responsibilities (management versus testing personnel). The icons at the bottom of each slide indicate suggested audiences.</p> <p>Other modifications are also required throughout the module to provide specific information on in-country EQA program</p>
1	<p><u>Module 13: EQA (On-site Evaluation and Re-Testing)</u></p> <p>DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module.</p>
2	<p><u>The Quality System</u></p> <p>REMIND participants that EQA is a component of the Laboratory Quality System.</p> <ul style="list-style-type: none"> ▪ This is a graphic illustrating the essential elements of a laboratory quality system. ▪ EQA methods comprise both Process Control and Assessment.
3	<p><u>Learning Objectives</u></p> <p>STATE the objectives on the slide.</p>
4	<p><u>Content Overview</u></p> <p>EXPLAIN the topics that will be covered in this module.</p>
Flipchart 	<p>WRITE the content outline on a flipchart prior to training.</p> <p>REFER to it frequently to orient participants to where they are in the module.</p>
5	<p><u>External Quality Assessment (EQA): Definition</u></p> <p>STATE the definition of EQA on the slide.</p>

Slide Number	Teaching Points
6	<p><u>Why EQA?</u></p> <p>EXPLAIN the points on the slide.</p> <ul style="list-style-type: none"> ▪ Results may be compared between laboratories offering not only an opportunity for performances checks, but an opportunity to systematically identify problems with kits or operations. ▪ Training needs may be identified and evaluated.
 <p><i>Customization Notes</i></p> <p>7-9</p>	<p>Modify the next three slides according to in –country EQA process, structure, roles and responsibilities.</p>
7	<p><u>EQA: Conducted at Three Levels</u></p> <p>PROVIDE the following points:</p> <ul style="list-style-type: none"> ▪ 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.

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8	<p><u>Management Responsibilities: An Overview</u></p> <p>PROVIDE the following explanations:</p> <ul style="list-style-type: none"> ▪ Someone of authority must take responsibility for EQA. If job titles are not the same as those on the slide, then tasks should be accomplished by designated individuals. ▪ Management must designate a staff member with the responsibility to establish and implement the EQA program. ▪ 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. ▪ 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.
9	<p><u>Testing Personnel's Responsibilities</u></p> <p>EXPLAIN the points on the slide.</p>
10	<p><u>EQA Methods</u></p> <p>STATE there are three main EQA methods:</p> <ul style="list-style-type: none"> ▪ Proficiency testing (PT) ▪ On-site evaluation, which is sometimes referred to as on-site monitoring visits or audits ▪ Rechecking or retesting of specimens <p>CLARIFY that:</p> <ul style="list-style-type: none"> ▪ This module will focus primarily on on-site evaluation and re-testing. ▪ Proficiency panel may be used during on-site visits.
11	<p><u>What is Proficiency Testing?</u></p> <p>EXPLAIN proficiency testing by STATING the points on the slide.</p>

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12	<p><u>What is On-site Evaluation?</u></p> <p>EXPLAIN on-site evaluation:</p> <ul style="list-style-type: none"> ▪ On-site evaluation provides a realistic picture of laboratory practices. ▪ It also provides a means for assisting with problem areas. <p>EMPHASIZE the point that these visits should be instructional rather than punitive.</p>
13	<p><u>What is On-site Evaluation? – Cont'd</u></p> <p>EXPLAIN further that 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.</p>
14	<p><u>What is Re-testing?</u></p> <p>EXPLAIN re-testing.</p>
15	<p><u>EQA Should Lead to Corrective Actions</u></p> <p>DEFINE corrective action as an action taken to correct a problem or non-conformance within the QMS.</p> <p>PROVIDE examples of a non-conformance:</p> <ul style="list-style-type: none"> ▪ 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

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16	<p><u>Problems May Occur Throughout the Testing Process</u></p> <p>EXPLAIN the following points:</p> <ul style="list-style-type: none"> ▪ The problems may lie anywhere in the testing process. ▪ The integrity of the specimen may have been compromised during preparation, shipping or after receipt by improper storage or handling <p>EMPHASIZE the following points:</p> <ul style="list-style-type: none"> ▪ Most problems occur in the pre and post analytic phase of 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
17	<p><u>Take Corrective Actions</u></p> <p>EXPLAIN the points on the slide.</p>
18	<p><u>Sample Corrective Action Form</u></p> <p>REFER participants to the form in the participant manual.</p>
19	<p><u>How To Implement EQA</u></p> <p>STATE:</p> <ul style="list-style-type: none"> ▪ This module focuses on on-site evaluation and re-testing processes. ▪ We will discuss implementation of on-site evaluation next.
20	<p><u>On-Site Evaluation Process</u></p> <p>PROVIDE an overview of the on-site evaluation process.</p> <p>NOTE: For testers – EMPHASIZE they should understand the process for how the visits will be conducted. This will assist them in preparing for a productive visit.</p>
 <i>Customization Notes</i> 21	<p>The form on the slide is an example of a checklist that can be used to assess the site's quality system. Countries may need to adapt this checklist to include specific country requirements reflecting national policy.</p>

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21	<p><u>On-Site Evaluation Checklist</u></p> <p>REFER participants to the form in the participant manual.</p> <p>DISCUSS each section of the form.</p>
 <p><i>Customization Notes</i> 22</p>	<p>Customize the slide to reflect standard operating procedures, or additional tasks that are site-specific for ensuring a productive visit.</p>
22	<p><u>Tester Responsibilities: Ensuring a Productive Site Visit</u></p> <p>EMPHASIZE testers play an important role in ensuring a productive site visit.</p> <p>HIGHLIGHT the tasks the testers should perform before, during and after the visit.</p> <p>EMPHASIZE the need to take corrective actions, immediately, if any are identified. This will help ensure the continued quality of testing.</p>
23	<p><u>On-site Evaluation: 1 Pre-Evaluation Preparation</u></p> <p>EXPLAIN the points on the slide:</p> <ul style="list-style-type: none"> ▪ Someone should take responsibility for preparing for onsite 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.

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24	<p><u>On-site Evaluation: ① Pre-Evaluation Preparation</u></p> <p>STATE the recommended frequency for site visits are referenced in the Guidelines for Applying Quality Systems to HIV Rapid Testing developed through a consensus process in Johannesburg, May 2004.</p> <p>EXPLAIN frequency of the visit may be determined by a number of factors:</p> <ul style="list-style-type: none"> ▪ 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 <p>EXPLAIN advantages and disadvantages for unannounced visits.</p> <ul style="list-style-type: none"> ▪ 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. <p>STATE evaluation visits may be conducted in response to a problem within the system. Schedule evaluation visits during a time that will minimize disruption of services</p>
25	<p><u>On-site Evaluation: ② Entrance Interview</u></p> <p>EXPLAIN the points on the slide.</p>

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26	<p><u>On-site Evaluation: ③ Information Gathering</u></p> <p>PROIVDE the following points:</p> <ul style="list-style-type: none"> ▪ It is important to gather information in an organized, consistent manner to make decisions about the site's quality system. ▪ Try to minimize disruption to the work flow of testing site for your information gathering effort. ▪ Observation of test performance. This 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
27	<p><u>On-site Evaluation: ④ Outcome Assessment</u></p> <p>EXPLAIN the decision algorithm in the slide.</p> <p>Further EXPLAIN if problems are detected, the assessor should determine the impact of the problem in relation to patient test outcome.</p> <ul style="list-style-type: none"> ▪ 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?
28	<p><u>On-Site Evaluation: ⑤ Exit Conference</u></p> <p>EXPLAIN the procedure in conducting an exit conference.</p>
29	<p><u>On-site Evaluation: ⑥ Reporting</u></p> <p>EXPLAIN the points on the slide.</p> <p>ADD each country should determine who should receive the report. It is recommended that the report be submitted to Quality Manager, Site Manager, Program Manger, or MoH.</p>
 <i>Customization Notes</i> 30	<p>Provide a real assessment report from a visit actually performed in your country.</p>

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30	<p><u>Sample Assessment Report</u></p> <p>REFER participants to the Sample Assessment Report in the participant manual.</p> <p>DISCUSS each section of the report, including subsequent actions required by the tester.</p>
<p>31</p> <p>Role Play</p> <p>30 minutes</p>	<p><u>Role Play: On-site Evaluation Visit</u></p> <p>FOLLOW the procedure below when conducting the role play:</p> <p> INFORM participants that they are going to have a role play.</p> <p> POINT OUT the instructions on the slide.</p> <p> ASSIGN roles to four volunteers (or pre-selected prior to the role play).</p> <p>DEBRIEF the role play by asking:</p> <ul style="list-style-type: none"> • What did you observe? • What did you learn?
 <p><i>Customization Notes</i></p> <p>31</p>	<p>Role Play Scenarios</p> <p>These are examples of the kinds of situations that may be observed. Edit this list to reflect actual situations that have been encountered within country.</p> <ul style="list-style-type: none"> • Improper workstation setup • Possible things to observe leading to problem areas: • Cell phone ringing while conducting testing • Used lancet on floor – missed placing in discard bin • Time for test cut short...in hurry to go home • Missing or incomplete test records • Missing temperature logs • Improper performance of test • Breaching confidentiality
32	<p><u>How To Implement EQA</u></p> <p>TRANSITION to discussion of re-testing.</p>
33	<p><u>Issues to Consider Prior to Implementing a Re-testing Program</u></p> <p>STATE the points on the slide.</p>

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34	<p><u>Statistical Basis for Re-testing: Error Detection</u></p> <p>PROVIDE the following points:</p> <ul style="list-style-type: none"> ▪ This chart is an excerpt from the CDC/WHO Guidelines for applying quality systems to HIV rapid testing. The purpose here is to illustrate the number of specimens that will need to be re-tested to statistically detect 1 or 5% error at the 95% confidence level. ▪ If re-testing is to be one of the EQA methods, it must be based upon statistical considerations. ▪ Countries must realize the numbers of specimens for re-testing will quickly overwhelm the reference laboratory. ▪ Outcome of re-testing must be analyzed for effective and timely feedback.
35	<p><u>Re-testing: Example Sampling Plan</u></p> <p>STATE the following:</p> <p>This slide provides an example of how to determine your sampling plan, given a specified time period.</p> <ol style="list-style-type: none"> 1. Determine number of specimens required to detect specific error detection rate over a one month time period 2. For 1% error detection rate, 225 specimens will need to be re-tested. 3. How many specimens must then be collected per week and per day? Approximately 50 specimens per week, or approximately 11 specimens per day <p>EMPHASIZE specimens MUST be collected randomly. Every effort should be made to avoid systematic sampling bias.</p>
36	<p><u>Re-testing Process</u></p> <p>STATE the re-testing process on the slide.</p>
37	<p><u>Tester Responsibilities: Re-Testing</u></p> <p>EMPHASIZE the points on the slide.</p>

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38	<p><u>Specimen Requirements</u></p> <p>STATE the points on the slide.</p> <p>EMPHASIZE all specimens should be properly labeled. At a minimum, include specimen identification number and date of collection.</p>
 <i>Customization Notes</i> 39	<p>This form is an example of information that needs to be captured for transferring EQA specimens to a reference laboratory. Replace this form, if necessary, to reflect standard operating procedures.</p>
39	<p><u>EQA Specimen Transfer Log</u></p> <p>REFER participants to EQA Specimen Transfer Log in the participant manual.</p> <p>INSTRUCT participants on how to complete the form.</p>
40	<p><u>Specimen Management : Common Problems</u></p> <p>EXPLAIN the points on the slide.</p> <p>ADD:</p> <ul style="list-style-type: none"> ▪ 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. ▪ Remember – a test result is only as good as the specimen received for testing.
	<p>MENTION the next module will cover the skills of collecting and handling Dry Blood Spots (DBS) as part of the re-testing process.</p>
41	<p><u>Summary</u></p> <p>ASK participants to answer the questions on the slide.</p> <p>ANSWER any questions participants may have.</p>