

Module 15: Documents and Records

Purpose	To help participants understand the role documents and records play in the quality system and the monitoring of programs.
Pre-requisite Modules	<ul style="list-style-type: none">▪ Module 5: Assuring the Quality of HIV Rapid Testing
Module Time	30 minutes
Learning Objectives	<p>At the end of this module, participants will be able to:</p> <ul style="list-style-type: none">▪ Tell the difference between a document and a record▪ Explain the rationale for following documents and keeping records▪ Provide examples of documents and records kept at a test site▪ Follow the procedures as prescribed in SOPs▪ Describe how to properly keep and maintain test site documents and records▪ Describe the types of information typically <u>not</u> found in a manufacturer's product insert

Module Overview

Step	Time	Activity/Method	Content	Resources Needed
1	3 min	Presentation	Module introduction	Slides 1-4
2	4 min	Presentation Exercise	Documents vs. records	Slide 5-7
3	10 min	Presentation Discussion	Documents	Slides 8-14; manufacturer product inserts
4	10 min	Presentation	Records	Slides 15-22
5	3 min	Presentation Q&A	Summary Key messages	Slide 23-24

Material/Equipment Checklists

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline

- Handout: Client Test Record (please be prepared to show a form used locally)
- Manufacturer product inserts from test kits (enough copies to pass around)

Teaching Guide

Slide Number	Teaching Points
 <i>Customization Notes</i>	In general, this module must be customized with in-country examples of documents and records and site-specific information on how to keep and maintain records.
1	<p><u>Module 15: Documents and Records</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 Documents and Records is a component of the Lab Quality System.</p> <ul style="list-style-type: none"> • Documents and Records is an essential component of the Quality System. As a matter of fact, it is the backbone of the quality system. • Documents communicate the policies and procedures that should be followed at each test site. This is important for assuring consistency and accuracy at the test site.
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>
<p>Flipchart</p> 	<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>

Slide Number	Teaching Points
5	<p><u>What Are Documents and Records?</u></p> <p>STATE the points on the slide and ADD the following information:</p> <ul style="list-style-type: none"> • Documents are written instructions for HOW TO do a specific task • Blank forms are also considered documents. Forms are used to capture data or information from performing a procedure. • Records are generated when written instructions are followed. In other words, after data, information, or results are recorded onto a form, label, etc, then it becomes a record. • Documents and records may be paper or electronic.
<p>Exercise</p> <p>6-7</p> <p>3 minutes</p>	<p><u>Exercise: Differentiate Between Documents and Records</u></p> <p>DISPLAY slide 6.</p> <p>ASK participants to look at the list on the slide for a minute and think about which item is an example of documents versus records.</p> <p>Go through each item as a group soliciting answers.</p> <p>DISPLAY slide 7 to show the correct answers (items in yellow are examples of documents and items in white are records).</p> <p>ANSWER any questions participants may have before moving on.</p>
8	<p><u>Documents Are the Backbone of the Quality System</u></p> <p>STATE the points on the slide.</p>
9	<p><u>Standard Operating Procedures (SOPs) Are Documents that...</u></p> <p>EXPLAIN SOPs are one type of document. Using SOPs results in reliable and consistent results.</p>
 <p><i>Customization Notes</i></p> <p>10</p>	<p>Customize slide #10 by replacing the sample SOP page on the slide with a page from a real in-country SOP.</p>

Slide Number	Teaching Points
10	<p><u>SOPs Are Controlled Documents</u></p> <p>DESCRIBE “controlled documents.”</p> <p>EXPLAIN that key features of SOPs include:</p> <ul style="list-style-type: none"> • Cover page • Descriptive Title • SOP number • Version Number • Date when SOP become effective • Signature of person responsible for writing the SOP • Signature of person authorizing the SOP
 <i>Customization Notes</i> 11-12	<p>ADD the following in-country information about SOPs:</p> <ul style="list-style-type: none"> • Who develops • How distributed • Process for updating
11	<p><u>What SOPs Should You Keep at a Test Site?</u></p> <p>EXPLAIN each test site should have on hand current/approved SOPs. These are typical SOPs kept at a test site.</p> <p>READ the examples on the slide.</p>
12	<p><u>What SOPs Should You Keep at a Test Site?– Cont’d</u></p> <p>READ the examples on the slide.</p>
13	<p><u>SOPs Must Be Followed</u></p> <p>PROVIDE examples of consequences of not following SOPs.</p> <ul style="list-style-type: none"> ▪ Not following safety precautions poses unnecessary risk to self, client and the environment ▪ Reporting inaccurate results – negative impact on client and family ▪ Breach of ethical conduct
<p>Activity 2 minutes</p>	<p>PASS AROUND manufacturer product inserts (from test kits) for participants to examine.</p> <p>DISCUSS what information is included in the inserts and what is not.</p>
14	<p><u>Do Not Rely Solely on Manufacturer Product Inserts</u></p> <p>CONCLUDE the activity by pointing out the information on the slide.</p>

Slide Number	Teaching Points
15	<p><u>Proper Record-Keeping Makes Quality Management Possible</u></p> <p>EXPLAIN the points on the slide.</p> <ul style="list-style-type: none"> ▪ Communicate accurately and effectively - Record keeping enables sites to be timely in reporting to program managers and site supervisors ▪ Minimize error – All records must be written. ▪ Monitor quality system – Records allow for periodic review of testing operations. Only through the review of records can improvements be identified.
16	<p><u>What Records Should You Keep at a Test Site?</u></p> <p>STATE the list on the slide.</p>
17	<p><u>Tips for Good Record Keeping</u></p> <p>STATE the points on the slide.</p> <ul style="list-style-type: none"> ▪ Understand the information to be collected. Before you record any information, make sure that you understand what is to be collected ▪ Record the information every time. Record on the appropriate form each time you perform a procedure. ▪ Record all the information. Make sure you have provided all the information requested on a form. ▪ Record the information the same way every time. Be consistent in how you record information.
 <i>Customization Notes</i> 18	<p>Customize slide #18 by replacing the sample client test record on the slide with a real in-country one.</p>

Slide Number	Teaching Points
18	<p><u>Client Test Records</u></p> <p>POINT OUT types of information captured on test records and the proper way to complete the information:</p> <ul style="list-style-type: none"> • Client/Patient ID # • Date of test • Test 1 result • Test 2 result • Test 3 result • Repeat results • HIV Status • Kit Name & Lot # • Person performing test <p>MENTION any commonly made mistakes</p>
 <i>Customization Notes</i> 19	<p>Customize slide #19 with in-country policy and information regarding record retention.</p>
19	<p><u>How Long Should You Retain Client Records?</u></p> <p>STATE points on the slide</p> <p>DISCUSS importance of maintaining secure storage for all records</p>
20	<p><u>Logbooks Are Cumulative Records of Test Site Operations</u></p> <p>EXPAND the points on the slide:</p> <ul style="list-style-type: none"> • These photos of logbooks are common. Storage of logbooks and records should be kept in a manner that will minimize deterioration. • Note also that although many sites used paper-based logbooks and records, they should be indexed so to allow for easy retrieval. • Note the From and To Dates.
21	<p><u>Records Should be Permanent, Secure, Traceable</u></p> <p>STATE facilities where records are kept should be secure to maintain patient/client confidentiality. Procedures and mechanisms should be that prevents unauthorized access.</p>

Slide Number	Teaching Points
 <p><i>Customization Notes</i></p> <p>22</p>	<p>Customize slide #22 with specific in-country information related to the reporting processes:</p> <ul style="list-style-type: none"> • What will be reported? • When will it be reported? • How will it be reported? • Whom will it be reported to? • How will the data be used?
<p>22</p>	<p><u>Information Recorded will Feed Into Monitoring and Evaluation Systems</u></p> <p>EXPLAIN records must be kept permanent, secure, and traceable because they will be used for reporting and monitoring purposes.</p> <ul style="list-style-type: none"> • Monitoring is the routine tracking of program information • Accurate facility records provide essential information for providing quality health care and monitoring PMTCT programs. • It is recommended that you analyze on a monthly basis the number of clients served and summarize the test results.
<p>23</p>	<p><u>Summary</u></p> <p>ASK participants to answer the questions on the slide.</p>
<p>24</p>	<p><u>Key Messages</u></p> <p>STATE the key messages on the slide.</p> <p>ANSWER any questions participants may have.</p>