Quality Management Systems for non-laboratory settings – Toolkit

QMS Training Curriculum

World Health Organization

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Training and continuing education are essential to ensure the quality of testing in all testing sites (including non-laboratory settings). It is also crucial to assess testing provider competencies to ensure they are competent before conducting client testing, regular competency-based assessments are also recommended to ensure continuity (see Competency-based Assessment and testing provider authorization of practice (PDF, 200 kB)).

Several partners have developed training curricula and training modules for testing providers that can be used by countries and can be found here (see Testing provider's training and supervision (PDF, 235 kB))

In this chapter, an initial training curriculum composed of 12 modules is proposed. Although this list is not exhaustive, countries can use it as a basis to develop their training curriculum adapted to their context, resources, and needs. This package is organized in two sets: a general one for testing providers and supervisors/QA officers and a supplementary one specific to QA officers/site supervisors, who are responsible for supervising the testing activities and supporting QMS implementation in testing sites. This training curriculum is focused on non-laboratory testing sites and is disease-agnostic.

This training package has been developed for non-laboratory settings and, therefore, is simplified to be used in contexts with low resources and external support. Countries are advised to adapt these training materials to their needs.

Below are a few essentials to consider:

- Training curricula and packages should be **adapted to the national context**, and the target audience(s), and be linked to job descriptions and competency-based assessment requirements.
- Training curricula and packages should be **validated by the national authority** before rollout.
- Authorities should consider developing or **delegating** the development of nationally tailored training curricula and packages **to external partners**.
- Training should contain a **mix of theoretical and practical sessions** (hands-on, case studies...) **and be validated** through a competency-based assessment, which, if successful, will be used to provide the authorization of practice/work letter to the testing provider before the test clients (see Competency-based Assessment and testing provider authorization of practice (PDF, 200 kB) and Competency Assessment tool (PDF, 375 kB)). Depending on the context, certification programs should also be considered.
- A **national training plan** should be developed: it should include Training of trainers (TOT) to set up a pool of trainers who are going to ensure national coverage.
- It is important to plan for both **initial training and ongoing continuing education**/refresher training to keep staff updated on new techniques and methodologies. This includes cross-training for staff with different responsibilities to

make sure there are backup human resources, which allows personnel to acquire skills outside their primary discipline, promoting flexibility.

- It is important to **evaluate the training**. It will help improve training packages. All training efforts should be documented, including the contents of training sessions and participant attendance, to ensure accountability and facilitate continuous improvement.

Audience	Training module	Purpose	Duration
Testing providers, QA officers/site supervisors	00-Introduction to the training package	General presentation of the content of the training package	20 mins.
	01- Introduction rapid serology testing and national testing strategy/algorithm	explain importance of accurate diagnosis, understand what serological testing is and RDTs, understand AB/Ag reaction principle, know what are testing strategies and algorithms	30 mins
	02- Introduction to QMS	understand what means quality and explain why it is important, describe QMS, list important QMS elements/pillars, list key factors that may affect quality of testing	45 minutes
	03- Testing environment: Safety and IPC measures	Know and follow adequate personal health and safety practices; Maintain a clean and organized workspace; Segregate and dispose of wastes properly; Describe what to do in the case of an accident; Follow safety procedures and keep safety records	45 mins
	04- Testing procedure and interpreting the results using the IFU and SOP/bench aids	Know the different steps of the testing process; Understand what are RDTs; Know what is needed to perform the testing procedure; Understand the importance of adequate RDT storage conditions and know where to find the information; Understand the importance of IFU, SOP, and bench aid and know what information is included in those; Know how to perform the finger prick procedure; Know how to perform RDT procedure; Know the main cause of errors	40 minutes of theory and 120 minutes hands-on practice and restitution

	05- Site Inventory, stock management and ordering process	Identify the principles and importance of good supply chain management; Identify and implement adequate storage conditions; Define testing site needs; Define order parameters: Average Monthly Consumption, Buffer and alert stock, lead time… Calculate quantity to order; Describe how to inspect the delivery of supplies before acceptance; Know good inventory practices and procedure	45 mins for theory and 45 min exercise (how to calculate order quantities?)
	06- Testing provider professional ethics and code of conduct	Explain the importance of professional ethics; Describe the appropriate testing provider code of conduct; Understand the importance of confidentiality and implement it in the testing site; Know major unethical behaviors; Understand the consequences of recurrent unethical behaviors; Know what to do in case of client complaint	20 mins
	07- Documents, records and information management	Explain why testing site need to manage document, records; List the important documents and records needed in a testing site; Explain why it is important to collect information; Describe different information systems solutions	40 mins
	08- M&E: collect, analyze and use of routine data	Explain why collecting, analyze and use the data are important; understand and now how to fill the testing register implemented in testing site; know how to calculate routine testing indicators; know the expected values and how to use those values	30 mins
	09- Process control and assessment: IQC, EQC and PT/EQA scheme	Describe the different process control activities (QC and EQA); describe the importance and objectives of internal and external quality control (QC) specimens; Understand the EQA/PT program/scheme process; Describe the dried tube specimen (DTS) technique/Understand the DTS reconstitution process; Describe the tester's responsibility in the PT program	45 mins

Additional training for Quality officers/site supervisors and instructors	10- Site supportive supervision visits	Explain the supervision visit process; know the different steps for conducting a supervision visit; Know the supervision visit tools that need to be used	40 mins
	11- Testing provider competency-based assessment for authorization to work/practice	Understand the importance and objectives of a testing provider competency-based assessment program; Describe the national competency-based assessment program cycle: initial and regular/ongoing; List the different components of competency-based assessment at initial and ongoing: theoretical exams (questionnaire) and practical (observation checklist +/- proficiency testing using known samples)	30 mins theory + 1hr mins practical competency assessment

Additional considerations

- **Competency-based assessment**: at least implement assessments to evaluate competency after training for testers who complete the curriculum and consider certification programs. For, a competency-based post-training evaluation should be done for each participant to validate their competencies and provide the "authorization of practice." The assessment could include passing both a written test (80%) and a practical exam (100%).
- **Refresher courses**: Offer periodic refresher courses to ensure testers stay updated with new developments and maintain high standards.
- **Instructors/trainers**: nationally recognized medical professionals, and laboratory technicians who receive and validate training of trainers (TOT) training should conduct the training and provide the authorization of practice letters.

Training delivery

- **Format**: training should contain a combination of theoretical and hands-on sessions. Depending on context and resources, ideally, in-person training but a combination of online (e.g., for theoretical modules) and in person sessions (for hands-on sessions) is another option (See training modules and spreadsheet "Supportive site supervision visit"). This mixed approach could decrease costs and increase training efficiency.
- **Duration**: Depending on the complexity and number of tests being taught, the training duration could be modified.