MINISTRY OF HEALTH

National Public Health Laboratory Services

NATIONAL INTEGRATED EXTERNAL QUALITY ASSESSMENT STRATEGY FOR MEDICAL LABORATORY SERVICES

FOREWORD

The Ministry of Health has established programmes, policies and strategies to ensure that the health laboratory sub-sector vision of an efficient and high quality health care system that is accessible, equitable and affordable for all is realised. Medical laboratory services are vital for effective disease prevention, control, and patient management. Laboratories need to produce accurate, reliable, timely and clinically appropriate laboratory results at all times, necessitating appropriate quality assurance programmes. This has led to a heightened focus on strengthening and streamlining quality assurance systems within national and county laboratory management systems. The purpose of this National Integrated External Quality Assessment (EQA) Strategy is to strengthen laboratory quality assurance systems in the health sector. This strategy will establish a well-coordinated, standardised, sustainable and integrated EQA system that will promote the quality of laboratory services. It shall cover all medical laboratories listed in the Health Care Strategic Plans and Vision 2030. This strategy shall integrate Proficiency Testing (PT) and support supervision to ensure a comprehensive quality assurance programme exists

The National Integrated EQA Strategy has been developed in line with the *Quality Policy Manual for Medical Laboratories in Kenya (2012)* which establishes overall policies for the national quality management system for the medical laboratory services in Kenya. These policies are harmonized with: ISO 15189:2012 – the international quality management system standards, for quality and competence of medical laboratories; the Clinical Laboratory Standards Institute (CLSI) based on the twelve quality system essentials; the Maputo Declaration of 2008 and the *National Policy Guidelines for the Medical Laboratory Services of Kenya (2006)*. The *strategy* is aligned with the National Strategic Plans of the Ministry of Health. National integrated EQA Strategy recommends integration of external quality assurance programmes to ensure the impact of these programmes are realized. This strategy is relevant to all health facilities in Kenya including public and private facilities. The *National Health Sector Strategic Plan* (NHSSP) III (2009 – 2015) also recommends registration, inspection and control of public and private health care providers as some of the efforts for improving quality assurance and standards. This strategy document clearly defines the integrated laboratory external quality assessment programme and documents the goals, objectives, strategies, activities, approaches, structures (administrative and functional) and procedures needed to implement continuous quality laboratory service for improved health outcomes of the population.

This document specifies the strategies, administrative and management structures required as well as the implementation plan to ensure the intended objectives are accomplished. It is anticipated that compliance with the National Integrated EQA Strategy will signify the availability of efficient EQA schemes, increased participation in these schemes, and improved performance for the participating health facilities hence improving the quality of laboratory services

The strategy aims to synergize the gains made in the HIV Proficiency Testing, Tuberculosis EQA and the East African Regional External Quality Assessment Scheme (EA-REQAS) to inform and enrich these processes as well as inform the establishment of an integrated well-coordinated national EQA programme. This will help build momentum on existing schemes and scale up replication to cover all laboratory disciplines at all tiers (National, Reference, County, and Facility levels).

The Government of Kenya is committed to enhancing quality assurance in all medical laboratories through the implementation of this strategy. It is hoped that the implementation of this Strategy will ensure delivery of quality laboratory services in line with the flagship Vision 2030.

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Director of Medical Services

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ACRONYMS

AFB	Acid Fast Bacilli
APHL	Association of Public Health Laboratories.
CDC	Centers of Disease Control and Prevention
CQI	Continuous Quality Improvement
DDPC	Department of Disease Prevention and Control
EA-REQAS	East African Regional External Quality Assessment Scheme
EA-REQAS	East Africa Regional External Quality Assessment Scheme
ECSA-LPT	East Central Southern Africa Laboratory Proficiency Testing
EQA	External Quality Assessment
HIV	Human Immunodeficiency Virus
HR	Human Resource
HTC	HIV Testing and Counselling
HuQAS	Human Quality Assessment Service
IQC	Internal Quality Control
KEMRI	Kenya Medical Research Institute
KNH	Kenyatta National Hospital
LQAS	Local Quality Assurance Scheme
M & E	Monitoring and Evaluation
MOH	Ministry of Health
NGO	Non-Governmental Organisation
NHRL	National HIV Reference Laboratory
NMRL	National Microbiology Reference Laboratory
NPHLS	National Public Health Laboratory Services
NTRL	National Tuberculosis Reference Laboratory
PITC	Provider Initiated Testing and Counselling
PMTCT	Prevention of Mother to Child Transmission
PT	Proficiency Testing
QA	Quality Assurance
QASI	Quality Assurance Scheme International
QC	Quality Control
TAT	Turn Around Time
TB	Tuberculosis
USAID	United States Aid Agency for International Development

DEFINITION OF TERMS

Term	Definition
Accreditation	Process by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks
Systematic Investigation	Independent and documented process for obtaining and evaluating objective data to determine the extent to which set criteria are fulfilled
Client	Person or organization using the medical laboratory services
Complaint	User dissatisfaction or opinion addressing an area in which the service provided has failed to meet their requirements
Corrective action	Steps taken to eliminate the cause of a detected non-conformity or other undesirable situation. Note: Corrective action is taken to p revent recurrence of a non-conformity whereas preventive action is taken to prevent occurrence of a non-conformity
Unsatisfactory performance	Non-fulfillment of a requirement for specific targets
Management structure	Arrangement of responsibilities, authorities and relationships between offices and personnel in an organization
Post-analytical phase	All the steps following the examination of a specimen including systematic review, interpretation, authorization for release, reporting and transmission of results, and storage of samples and data
Pre-analytical phase (pre-examination process)	All the steps starting from the clinician's request, including examination requisition, preparation of the patient, collection of the primary sample, transportation of the specimen to and within the laboratory, and ending when the specimen examination procedure starts
Premises	Physical environment in which an organization carries out particular functions
Preventive action	Action towards eliminating potential non-conformities or other undesirable potential situations. Note: Preventive action is taken to prevent occurrence of a non-conformity whereas corrective action is taken to prevent recurrence
Procedure	Specified systematic actions to carry out an activity or process. Note: When the term 'procedure' is used in this document a written procedure is required that is subject to standardization, document control, regular review and revision

Quality assurance	A planned and systematic pattern of all actions necessary to provide adequate confidence that the product/services optimally fulfill customers' expectations.
Quality control	Quality control is a procedure or set of procedures intended to ensure that a product or performed service adheres to a defined set of quality criteria.
Quality improvement	Part of quality management focused on continually increasing accuracy, effectiveness and efficiency. Note: the term 'continuous quality improvement' is used when quality improvement is progressive and the organization actively seeks and pursues improvement opportunities
Quality management System	Management system to direct and control an organization with regard to quality services
Referral laboratory	External facility to which a sample is submitted for supplementary or confirmatory examination and reporting
Requirement	Need or expectation that is stated, generally implied or obligatory
Review	Activity undertaken to ensure the suitability, adequacy, effectiveness and efficiency of the subject matter to achieve established objectives
Work environment	Set of conditions under which work is performed

EXECUTIVE SUMMARY

The National Integrated EQA Strategy has outlined four objectives namely: a)establishment of a well-coordinated and integrated EQA system to deliver quality laboratory services; b) establishment of mechanisms to improve EQA performance; c)Establishment of an integrated laboratory M&E system for EQA; and d) Strengthening Operational Research to inform EQA schemes. The integration of EQA services will be pegged on the existing laboratory organizational structure of health service delivery in Kenya. The strategy shall be implemented at all levels. At the national level there shall be a National Quality Assurance Office which shall coordinate EQA services.

This will occur with assistance from or in consultation with a National EQA advisory body which will draw its membership from various key stakeholders. At the county level, there shall be a County EQA Coordinating Unit as well as an advisory body mainly focusing on implementation aspects of EQA. Implementation of the strategy will be monitored and evaluated periodically using key performance indicators. Coordination and integration of EQA programmes will leverage on quality improvement with the ultimate benefit of customer satisfaction. This Integrated EQA Strategy will enable all medical laboratories to improve quality of diagnostic services offered and also meet accreditation requirements.

CHAPTER 1

Introduction

1.1: Background

Laboratories are critical components of an efficient health system. In the era of evidence-based medicine, the use of laboratory test results to inform diagnosis and monitor treatment and management of patients cannot be overemphasized. In developed countries, an estimated 60% to 80% of patient management decisions are based on laboratory data (Forsman, 1996). In addition to the role of laboratory services in patient outcomes, laboratory data plays a pivotal role in disease surveillance and measurement of health system performance. Accurate, reliable, clinically relevant and timely laboratory results are therefore necessary to ensure the critical role of laboratory services is realized. For a laboratory to consistently produce reliable test results, it must implement an appropriate programme of quality assurance and performance monitoring procedures.

EQA in medical laboratory practice is an important component of a quality system. EQA is an external assessment of a laboratory's performance in testing samples of known, but undisclosed content and comparison with the performance of other laboratories. It is designed to raise standards of performance in medical laboratory services, reference laboratories, blood banks and other laboratories undertaking testing for diagnostic purposes including point of care testing. Information generated by EQA provides an opportunity for continuous quality improvement through the identification of laboratory errors and the implementation of measures to prevent their recurrence. Thus, EQA plays a vital role in ensuring generation of accurate and reliable results for disease diagnosis, treatment, and monitoring. Studies have shown that participation in EQA programmes leads to more accurate test results. Peter et al. (2010) showed that participation in just 3 rounds of an external CD4 EQA programme resulted in a 26% to 38% reduction in errors in the CD4 counting among laboratories in resource-limited settings.

For the benefits of EQA to be realized, there is need for a well-coordinated and integrated national EQA programme. This calls for the formation of structures and support systems to ensure provision of EQA materials that mimic patient samples, efficient delivery of EQA materials and utilization of EQA feedback reports for continuous quality improvement. In addition, other forms of EQA, e.g. rechecking and retesting, and support supervision need to be strengthened. Various strategies embedded in this document play an active role in advocacy to promote the establishment of integrated and coordinated EQA schemes and also encourage participation by medical laboratories in these schemes. Health authorities are urged to recognize the importance of EQA and support the implementation of schemes at national, county, and facility levels. Professional bodies are encouraged to endorse and support the establishment of EQA schemes.

This strategy describes the principles for establishing and operating an EQA scheme for medical laboratory practice. EQA schemes should be organized in accordance with these principles, although due consideration should also be given to any existing quality systems and regulatory mechanisms for medical laboratory practice.

1.2: Situation Analysis

EQA is a major component of a quality management system. Currently, access to quality l aboratory testing services in the country is faced with significant challenges that impede effective healthcare delivery. EQA programmes in Kenya are fragmented due to lack of a comprehensive national EQA programme. Participation in EQA schemes for public health laboratories are mostly donor supported and disease specific. Participation in EQA schemes is also skewed towards reference laboratories, private and high tier laboratories. HIV and TB Programmes, through their respective Reference Laboratories, have developed limited EQA Schemes (EQAS) targeting HIV, TB and related testing. These two national schemes have been running in parallel since inception. The TB programme runs a TB microscopy EQAS which involves quarterly blinded rechecking of TB slides at the National TB Reference Laboratory (NTRL) and at county level. From EQA participation data collected between 2010 and 2012 for 270 laboratories, the error rate in AFB microscopy reduced from 10.6% in 2010 to 2.4% in 2012. This translated to 97.6% improvement in reliability of AFB results hence increasing the confidence of AFB results for diagnosis and management of TB (Ruttoh, et al., 2012).

The HIV PT was started in 2007 by the National HIV Reference Laboratory (NHRL) with an initial enrollment of about 25 facilities. Currently, the PT has switched from site proficiency to individual proficiency testing. Individuals performing HIV testing receive panels prepared at NHRL, perform the tests, and return test results back to the NHRL. Analysis and feedback is prepared at NHRL. Currently over 7,000 testers are enrolled. Besides testing individuals working at medical laboratories, this PT covers other HIV programmes including HTC, HBTC, PITC and PMTCT. This PT involves 3 rounds per year. The Bacteriology and Parasitology schemes under the National Microbiology Reference Laboratory (NMRL) and National Malaria Reference Laboratory (NMARL) respectively are in their inception stages.

The East African Regional External Quality Assessment Scheme (EA-REQAS) was initiated in 2003 by the Ministries of Health of East Africa (Uganda, Tanzania, Zanzibar and Kenya); Burundi more recently joined the scheme. Amref Health Africa is the regional coordinating centre for the scheme. The scheme is integrated, presenting seven PT challenges in each survey of which four (Malaria, TB, HIV and HB estimation) are mandatory, while three of the challenges vary in each survey. The EQA materials are accompanied by four clinical scenarios with four questions each.

To encourage communication between health professionals ten questions are laboratory related, four are clinical and two are public health questions. By 2015, Kenya had 185 laboratories participating in the scheme most of which are health centres. These included government owned health facilities, faith-based and private health facilities. In East Africa there are a total of 513facilities enrolled in EA-REQAS (www.eareqas.org).

Through support from development partners, a number of laboratories undergoing accreditation are enrolled in EQA schemes operated by either commercial or not-for-profit organizations. The Human Quality Assessment Service (HuQAS) is a local NGO which provides EQA services to public, private, mission and research laboratories in Kenya. The NGO acts as the local agent for a collaboration of international EQA providers with a secretariat in Canada. Through this collaboration, HuQAS is able to provide EQA programmes covering the entire laboratory medicine spectrum.

Currently there are over 215 laboratories participating in the HuQAS EQA scheme with 70% from the private sector (www.huqas.org). QASI is a scheme operated from Canada and coordinated in the country by the National HIV reference laboratory since 2010 .Currently 120 laboratories enrolled; panels are shipped to the sites three times in a year. There are other ways of conducting EQA, for example, inter-laboratory comparison. This is through regional schemes for example Nyanza and western scheme (Nyawes) which rides on KEMRI CD4 sample split testing, covering majority of laboratories in the Western and Nyanza regions.

It also supports the labs in these regions in providing forums to discuss performance in all proficiency testing schemes, corrective actions and supportive supervisory visits. It is evident that coordination and integration of these EQA providers is lacking therefore denying the country a chance to leverage on the strength of each of the existing EQA providers. Monitoring EQA performance is critical to identify areas of improvement and institute effective corrective actions.

Follow up of performance is generally left to the participating health facilities which may lack the technical knowhow to utilize EQA feedback reports for continuous quality improvement. Failure to utilize EQA reports for continuous quality improvement renders the programmes ineffective and constitutes a burden to an already overburdened health system. This strategy seeks to integrate the existing EQA schemes and streamline their coordination therefore contributing to more efficient and effective national EQA programmes.

1.3 Approaches

There are three main approaches for implementing EQA programmes: Proficiency testing; blinded rechecking/ re-testing/validation; and on-site supervision. These three EQA approaches will be incorporated into a single unit to ensure a comprehensive national EQA programme.

1.3.1: Proficiency testing

This is the process of sending materials of known status from an EQA provider to participating laboratories to check their competency to perform particular tests and reporting results. This process can also be adapted to address individual testers. The results are returned to the EQA provider which evaluates them and provides feedback to the participating laboratories or individuals. Laboratory supervisors use panel testing results to plan and undertake appropriate corrective actions to improve performance.

1.3.2: Blinded re-testing/ rechecking

Is whereby a reference laboratory retests samples/slides that have been analyzed allowing for inter-laboratory comparison. This method can be applied to systematic sampling of malaria blood films and TB sputum smears from the peripheral laboratory for rechecking by a higher-level laboratory. For this method to be effective, there are a few important considerations:

- Rechecking must be blinded i.e. a supervisory laboratory or a technician responsible for rechecking slides must not know the results from the peripheral laboratory
- Selection of slides should be based on a local quality assurance scheme (LQAS) system. LQAS is a method to determine the optimum sample size of slides to be rechecked which, when applied properly, yields statistically acceptable samples to assess quality of work.
- Storage of routine samples in peripheral laboratories must be systematic to enable LQAS to take place.
- A procedure to resolve discrepancies must be established, usually a third independent examiner.
- Feedback with appropriate support.

This system is considered to be the best method for evaluating performance of some routine tests such as microscopy because it reveals the reality of the daily performance of the laboratory. However it cannot easily be applied to certain tests, such as hemoglobin or chemistry measurements, and cannot challenge laboratories with pathology they do not see. It is resource intensive to implement and constitutes a great deal of work for intermediate and central level; one of the challenges is returning results in good time.

It also requires a very high standard of microscopy skills by the rechecking technical personnel (at least as good as the laboratory staff they are checking), and refresher training programmes may be required for them.

Although the concept of rechecking smears may seem simple, expertise is needed to:

- calculate the proper sample size,
- set up a system for blinding samples,
- resolve discordant results, and
- Implement an equitable programme for different laboratories.

Blinded rechecking cannot be used when almost no positive results are detected.

1.3.3: On-site supervision

This is a systemic process of making periodic visits to testing laboratories to assess laboratory performance and obtain a realistic picture of laboratory practices with an aim of assisting with problem solving. This EQA method is especially helpful to resolve problem areas identified by other EQA methods (blinded rechecking and/or panel testing). It allows for provision of hands-on training and solving problems in the local context.On-site supervision includes regular visits by trained supervisors as well as visits by laboratory supervisors from a higher-level laboratory.

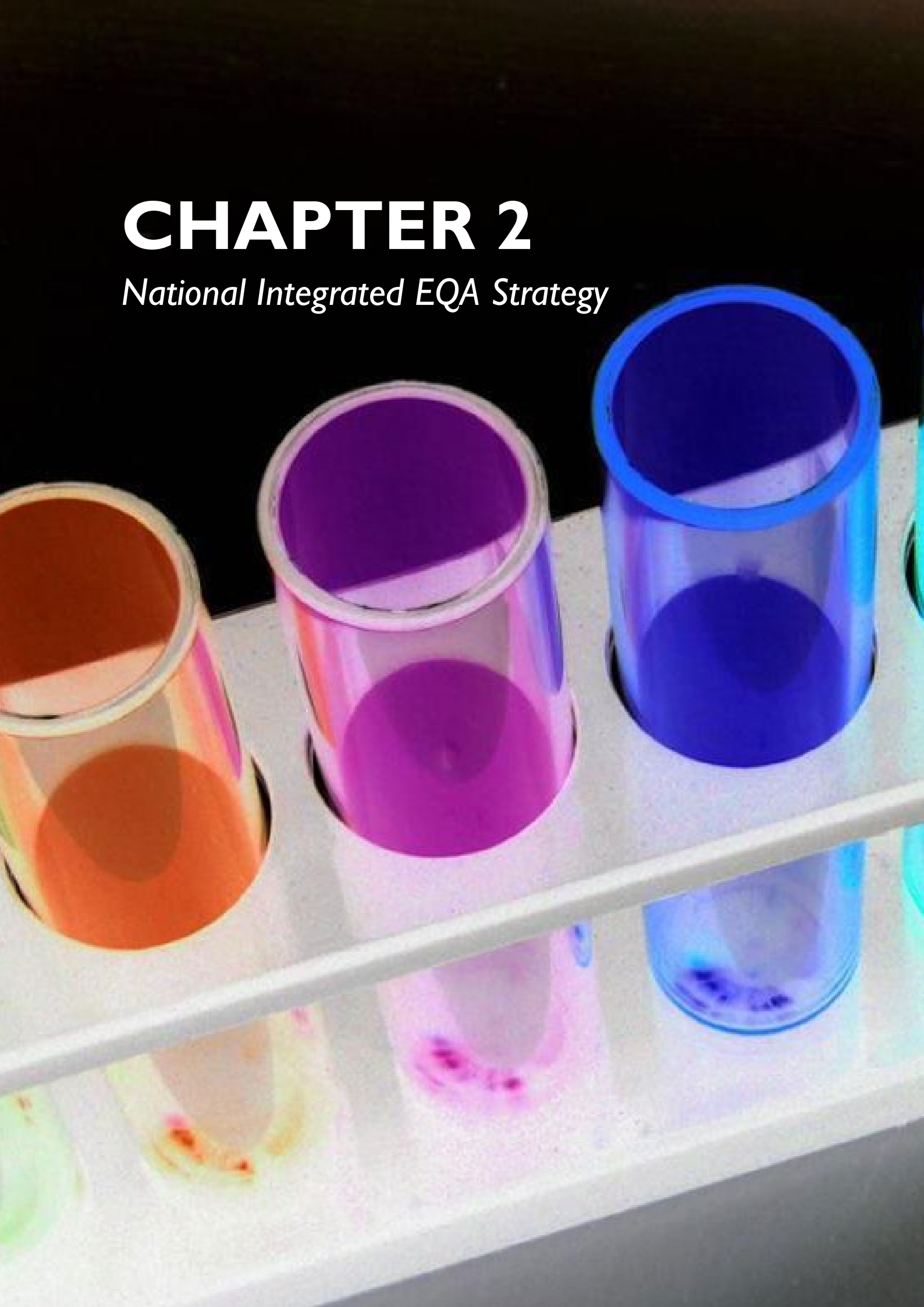
In order to ensure that on-site evaluations are carried out in a consistent and structured way and to be able to follow up on previous visits, standard checklists to assist laboratory supervisors during their field visits need to be used. Planning should also consider the need for follow-up visits to monitor corrective actions and provide additional training if needed.Although conducting on-site supervisory visits can be costly and time consuming it is an efficient use of time and resources, and a properly conducted visit provides motivation and support, and can assist with immediate problems such as shortages of reagents and equipment repair.

Benefits of EQA processes

- Motivating for staff
- A method of continuing education
- Properly executed, with attention to weak areas, are capable of gradually bringing the quality of the laboratory to a high level
- Bench marking-Laboratories compare their performance with their peers

CHAPTER 2

National Integrated EQA Strategy



2.1: Goal

To establish a well-coordinated, standardized, sustainable & integrated EQA system with the aim of improving the quality of laboratory services.

2.2: Scope

The integration of EQA schemes will be pegged to the existing laboratory organizational structure of health service delivery in Kenya. The strategy shall be implemented at all laboratory levels. At national level there shall be a National Quality Assurance Office which shall coordinate EQA services, with assistance from and in consultation with a National EQA advisory body which will draw its membership from key stakeholders. At the county level, there shall be a County EQA Coordinating Unit under the county laboratory coordinator.

Vision

Efficient EQA services that are accessible, equitable and affordable to all laboratories.

Mission

To provide a sustainable, integrated National EQA system that is effective, efficient, accessible, equitable and affordable that supports delivery of quality medical laboratory services.

Objectives

- Implement a well-coordinated and integrated national EQA system to support laboratory quality improvement processes
- Establish mechanisms to increase EQA participation ,response, and improve performance
- Establish an integrated laboratory M&E system for EQA
- Strengthen Operational Research to inform the national EQA programme

2.3.1: Summary of Objectives and Strategies

Objective 1: Implement a well-coordinated and integrated national EQA system to support laboratory quality improvement processes

Strategy 1: Strengthen existing administrative structures and systems to support national and county EQA programmes

Activities:

- Establish a national and county EQA coordinating units and committees
- Define the roles and responsibilities of the national office, county office and the participating laboratories
- Develop EQA enrolment criteria.
- Develop a database for participating laboratories and EQA providers

Strategy 2: Establish in-country capacity for PT panel production and or acquisition.

Activities:

- Develop a national database of available PT schemes.
- Train reference laboratories' technical staff on PT scheme establishment
- Support acquisition of PT production equipment, supplies and accessories
- Coordinate the Development of protocols for PT material production
- Strengthen the existing PT material production
- Set up an integrated PT Production Unit
- Recruit and capacity build laboratory personnel at the PT Production Unit
- Support PT providers and reference laboratories to meet appropriate international standards

Strategy 3: Delivery of PT panels to participating laboratories and return of reports

Activities:

- Coordinate delivery of PT panels from the national office and or EQA PT provider to participating laboratories.
- Establish EQA point of contact personnel to facilitate tracking of PT materials and feedback reports

Strategy 4: Provide coordination and networking of integrated EQA services at national and county levels

Activities:

- Stakeholders meetings
- Technical Working Group meetings

Objective 2: Establish mechanisms to increase EQA participation, response, and improve performance

Strategy 1: Institute measures to improve EQA response rate, turnaround time and performance

Activities:

- Establish an alert notification system for upcoming EQA activities and approaching deadlines
- Train laboratory personnel and supervisors on EQA feedback reports, systematic investigation of EQA failure and implementation of remedial actions
- Establish a process of offering technical assistance to participating facilities that experience challenges in utilization of EQA reports for continuous Quality Improvement.

Strategy 2: Institute measures to increase number of enrolled laboratories

Activities:

- Advocacy aimed at national and county governments
- Reduce cost of EQA participation by integrating logistics

Strategy 3: Conduct annual assessments to evaluate laboratory infrastructure, logistics and technical capabilities

Activities:

- Develop a laboratory EQA Quality Manual
- Conduct quality assessment
- Train National and County Laboratory Coordinators on EQA Scheme operations
- Train County QA Officers
- Conduct integrated Laboratory EQA Audits

Objective 3: Establish an integrated laboratory M&E system for EQA

Strategy 1: Strengthen reporting on EQA Performance

Activities:

- Develop EQA performance indicators
- Develop an EQA monitoring and evaluation plan
- Develop EQA data collection and reporting tools
- Develop EQA data analysis plan
- Support internet-based EQA results submission and feedback report provision
- Conduct EQA review meetings at national and county level
- To develop an integrated EQA data base at national level

Objective 4: Strengthen Operational Research to inform the national EQA programme

Strategy 1: Establish supportive mechanisms for operational research

Activities:

- Identify key research questions
- Develop operational research protocols
- Constitute a technical working group for EQA operational research
- Train personnel in scientific writing

Strategy 2: Develop a communication strategy guide to support EQA activities

Activities:

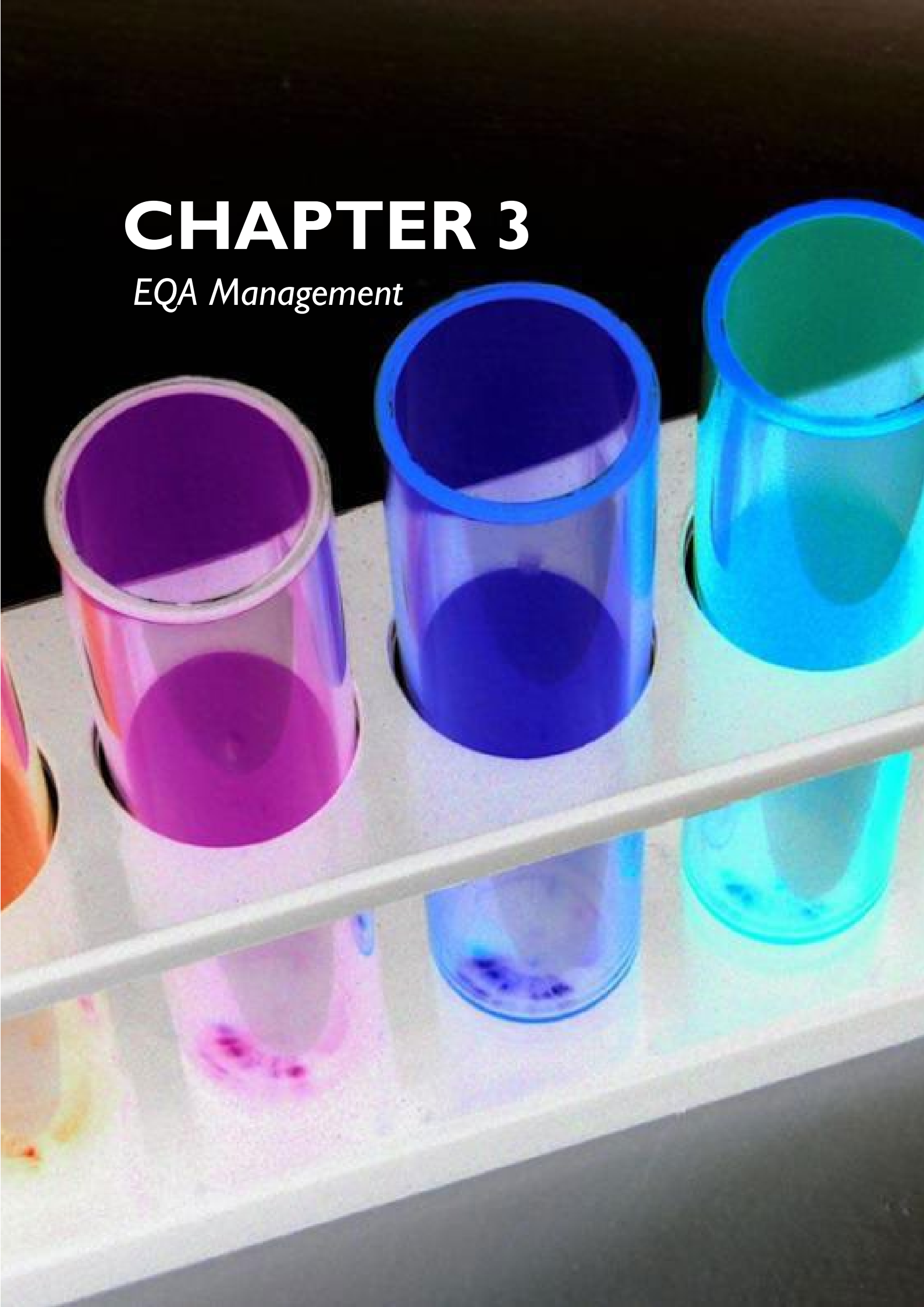
- Design a quarterly EQA bulletin/Newsletter
- Support for a for dissemination of EQA information to stakeholders
- Support professional bodies to offer advisory services in management of the EQA process
- Conduct EQA data utilisation through manuscript writing

Objective narratives

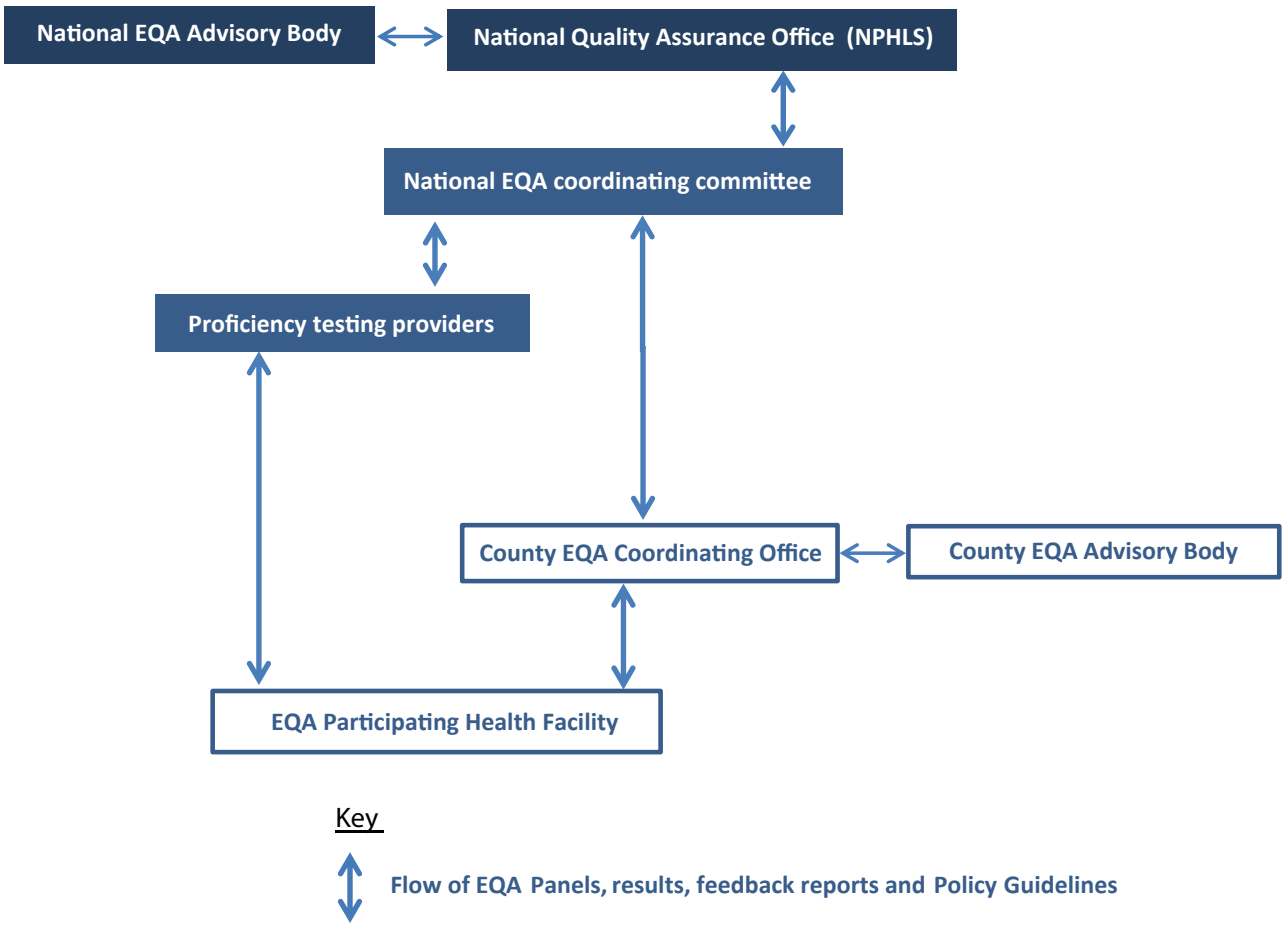
Objective 1. Implement a well-coordinated and integrated national EQA system to support laboratory quality improvement processes	The EQA Strategy will strengthen EQA management in the Country by establishing an effective, efficient and responsive mechanism for integration of EQA services to harness the sharing of resources to leverage cost effectiveness, coverage and efficiency at planning and execution levels. The strategy also will support establishment of in country capacity to produce panels. Taking into consideration the new constitutional dispensation the strategy emphasizes the creation of structures at the county level.
OBJECTIVE 2: Establish mechanisms to increase EQA participation, response, and improve performance	The EQA Strategy intends to harness resources through engagement with health management organs and developmental partners at all levels, to improve EQA response rate, turnaround time and performance. The number of laboratories enrolled into EQA will be increased to ensure equity and coverage for all laboratories. The strategy supports annual assessments to evaluate laboratory infrastructure, logistics and technical capabilities which will improve performance and response rates. Quality audits are an emerging trend that may change quality approaches among service providers. Benefits of audits designed to identify testing weaknesses have not been harnessed and turned into opportunities through systematic, well planned and monitored internal QI processes to impact on delivery of services. The EQA strategy intends to mainstream quality audits within laboratory management functions and sensitize both management and staff on the roles and benefits of audits. The competency and understanding of QA auditors and management will be improved through training and mentoring. Appropriate audit tools will be developed and made available to assess further change from the old practices and values of technical
Objective 3. Establish an integrated laboratory M&E system for EQA	The missing link in current practices and experience with some EQA Schemes operating in the country has been the lack of robust laboratory M&E. This has led to inadequacy in reporting systems among participating laboratories. This has led to lack of sufficient data to inform EQA Planning and resource allocation. Strengthening laboratory EQA M&E systems to support efficient services delivery and to inform planning and service uptake will be a key strategic initiative within this EQA Strategy. There is need to design performance indicators, and develop an EQA M&E plan to support quality assurance improvement and monitoring processes.
Objective 4. Strengthen Operational Research to inform the national EQA programme	Operational research is an area that has not been fully exploited and integrated into laboratory practice in the country. Most programmatic operational research is limited to collection and analysis of data to inform certain changes within specific areas. There is need therefore to invest resources in operational research to bring out practices, methods and important findings that may influence and revolutionize the way EQA Schemes will be managed. Accurate data capture, transmission, timeliness, accuracy and efficiency, new EQA innovations that are technologically versatile and can be adapted need to be explored to make meaningful service impacts in the future.

CHAPTER 3

EQA Management



3.1: EQA Management structure



Flow of EQA Panels, results, feedback reports and Policy Guidelines

3.2: Roles and responsibilities

3.2.1 Roles and responsibilities of the National Public Health Laboratory Service

- Develop and coordinate the implementation of policies, guidelines, procedures and standards relevant to EQA
- Resource mobilization
- Coordinate EQA collaborations, networks and partnerships
- Provide technical support to county governments and reference laboratories to establish and maintain a functional EQA process
- Conduct research, development and innovation in EQA in collaboration with academic institutions, participating health facilities and relevant government agencies

3.2.2 Roles and responsibilities of National EQA Advisory Body

The role of the advisory body will be to provide advisory services on the design, planning and implementation of an integrated EQA programme at national and county levels. In addition the body will: Advise and provide guidance and oversight on issues relating to implementation of national laboratory EQA programmes

- Review national policy guidelines on laboratory quality assurance and operational plans for approval
- Provide guidelines on complaint management
- Promoting the educational and training role of the scheme
- Liaise with ethical review boards and committees where approval of EQA research protocols is required
- Develop recognition mechanism for participating health facilities
- Safeguarding quality standards for PT providers
- Safeguarding PT users against poor quality EQA schemes.

The National EQA Advisory body should be composed of:

- National Quality Assurance Officer (Secretary)
- Representative from coordination committee
- Representatives from national reference laboratories
- Representatives from EQA providers
- Representatives from development partners
- Representative from private health sector
- Representatives from health academic institutions
- Representative from accreditation and regulatory bodies
- Representative from relevant professional bodies

The chair will be selected among the members and appointed by the head NPHLS

3.2.3 Roles and responsibilities of National EQA Coordination Unit

The national EQA coordination unit shall:

- Lobby for resources to support EQA activities
- Develop and maintain a database of participating health facilities in the country
- Ensure distribution of materials to participating laboratories
- Ensure submission of results to the EQA providers within the set timelines
- Ensure feedback reports are returned to the participating health facilities
- Provide mentorship and technical assistance to participating health facilities to improve EQA performance
- Identify training needs and coordinate training of personnel in the participating health facilities
- Monitor EQA performance indicators
- Conduct EQA review meetings
- Provide recommendations and feedback to the national EQA advisory body on the scheme activities

3.2.4 Roles and responsibilities of County EQA Advisory Body

The roles and responsibilities of the county EQA advisory body will be similar to the national EQA advisory body but more focus should be directed toward successful implementation of EQA in the participating health facilities and addressing remedial action.

The county EQA advisory body should be composed of:

- County Laboratory Coordinator
- County QA coordinators.
- Sub county laboratory coordinators
- Representative from CHMT(County Director)
- Representatives from County referral hospitals(Lab manager)
- Representative from development partners
- Representative from the Private health sector
- Representative from the FBO sector
- Representative from health academic institutions
- Representative from clinicians

3.2.4 Roles and Responsibilities of the National Quality Assurance Office

The National Quality Assurance Office will be the secretariat and the coordinating centre of the national EQA programme. The office will be housed at the NPHL.

Its key mandate will be:

- monitor production and acquisition of EQA panels with reference laboratories and EQA providers
- Monitor the distribution of EQA materials from the national level to the county
- Monitor the submission of EQA results to EQA providers to ensure improved response rate and turnaround time
- Collation of EQA feedback reports from EQA providers to generate summary performance reports
- Review EQA summary feedback reports and coordinate implementation of corrective actions in collaboration with county laboratory coordinators
- Facilitate use of EQA information to improve the EQA process
- Provide technical assistance to the county on EQA matters
- Provide linkage with regional and international EQA providers
- Oversee the implementation of national framework for integration of EQA
- Coordinate monitoring and evaluation the EQA systems
- Conduct national EQA dissemination for a
- Provide annual reports on EQA activities, laboratory performance and future plans.
- Provide linkages between the QA office and the EQA advisory body

3.2.5 Roles and responsibilities of PT providers

With regard to EQA, they will be mandated to:

- Produce and validate EQA materials and associated tools/forms
- Offer technical assistance to the national and county EQA coordination units
- Where reference laboratories act as EQA providers, they should ensure dispatch of EQA panels, analysis of results, generation of EQA reports and recommendations
- Participate in the development of EQA guidelines and operational plans for PT, blinded rechecking and onsite supervision
- Comply with ISO 17043
- Ensure the highest quality standards are maintained throughout the EQA production process (where reference laboratories act as EQA providers)

3.2.6: Roles and responsibilities of County EQA Coordination Unit

The County EQA coordination unit shall:

- Lobby for resources from the county government to support EQA activities
- Develop and maintain a database of participating health facilities in the county
- Ensure distribution of materials to participating laboratories
- Ensure submission of results to the EQA providers within the set timelines
- Ensure feedback reports are returned to the participating health facilities
- Ensure remedial actions are implemented for unsatisfactory EQA performance
- Provide mentorship and technical assistance to participating health facilities to improve EQA performance
- Identify training needs and coordinate training of personnel in the participating health facilities
- Monitor EQA performance indicators
- Conduct EQA review meetings
- Provide recommendations and feedback to the national level on the scheme activities

3.2.7 Roles and responsibilities of participants

- Ensure availability of standard operating procedures for EQA
- Receive EQA panels
- Analyse EQA panels within the set timelines
- Treat EQA panels as much as possible as the same way as patient samples
- Submit EQA results within the set timelines
- Review EQA feedback reports
- Investigate unsatisfactory EQA performance and implement appropriate remedial actions
- Monitor EQA performance over time to identify trends and take preventive measures
- Maintain EQA records
- Report on EQA performance indicators
- Accept/receive supervisory visits
- Provide recommendations and feedback to the county level on scheme activities

CHAPTER 4

Implementation

4.0: IMPLEMENTATION

A log frame will be utilized to guide the implementation of strategies to ensure the objectives are realized. Performance will be monitored using a set of indicators.

4.1 LOGFRAME

This strategy will provide an opportunity to establish a nationally integrated EQA system first by establishing a National EQA Coordinating Unit and then ensuring that each County government has an EQA coordinating unit to facilitate tracking of EQA materials, EQA results and EQA feedback results including using the information generated to guide evidence-based decision making on the quality of laboratory testing. This logical framework describes the key objectives, activities and the expected results with the aim of improving the quality of laboratory testing services.

Objective 1: Implement a well-coordinated and integrated EQA System to deliver quality laboratory services					
	Activities	Outputs	Outcomes		
Strategies			Immediate (2015/2016?)	Intermediate (2017/2018?)	Long term(/2019?)
Strengthen existing administrative structures and systems to support National and County EQA Services	Establish a national and county EQA coordinating units and committees	National and county EQA coordinating units established	Coordinating unit available	Improved coordination of EQA	Improved quality of laboratory services
	Develop a database for participating laboratories and EQA providers	EQA data base developed	Availability of EQA database	Coordinated EQA process	Efficient EQA Process
Establish an in country capacity for PT panel production and Acquisition	Develop a national list of available PT schemes	National List of PT schemes developed	Availability of a list of PT schemes	Availability of schemes covering all laboratory discipline	Increased number of laboratories participating in EQA to assure quality of laboratory services
	Training of Reference laboratories technical staff on PT production	Technical staff of reference laboratories trained	Laboratory staff competent of production of PT panels	Supporting structures for production of PT panels	In country production of PT panels
	Support acquisition of PT production equipment, supplies and accessories	PT panel production equipment and supplies provided	System, structures and resources available for production of PT panels	Initial production of PT Panels	Mass production of quality PT panels

	Support PT providers to meet appropriate international standards	PT providers implementing a quality management system	QMS implement-ed by EQA providers	EQA providers accredited to relevant international standards	Efficient, effective and customer oriented EQA services
Delivery of PT panels and performance reports to participating laboratories	Support delivery of PT panels from the national office through the county office to the participating laboratory	PT panels and reports delivered within specified timelines	Improved delivery of PT panels and reports	Improved TAT	Improved utilization of EQA information
	Establish EQA Point of Contact (POC) personnel to facilitate tracking of PT ma-terials and feedback reports	POC established at each level	Improved tracking of EQA activities	Improved efficiency of EQA process	
Objective 2 : Established mechanisms to improve EQA performance					
Institute measures to improve EQA response rate, turnaround time and performance	Establish a notification system to alert on upcoming EQA activ-ities and approaching deadlines	Notification and alert systems estab-lished	Improved TAT and response rate	Increased participation	Improved quality of laboratory services
	Training of personnel on EQA feedback reports, systematic investigation of EQA failure and implementation of remedial actions	Personnel trained on EQA feedback reports, systematic investigation of EQA failure and implementation of remedial actions	Increase knowledge on EQA process	Improved EQA practices	Increased competency on EQA and therefore assured quality of laboratory services
Objective 3: Establish an integrated laboratory M&E system for EQA					
Strengthen reporting on EQA Performance	Develop EQA performance indicators	EQA performance indicators developed	Increased reporting on EQA	Improved EQA performance monitoring	Increased utilization of EQA reports for continuous quality improvement
	Develop EQA monitoring and evaluation plan	EQA M&E developed	Availability of EQA information	Increased utilization of EQA information	Informed decision making on EQA activities
	Develop EQA data collection and reporting tools	EQA data collection & reporting tools developed	Availability of EQA data collection and reporting tools	Increased utilization of EQA data collection and reporting tools	Improved EQA data quality

	Develop EQA data analysis plan	Data analysis plan developed	Availability of data analysis plan	Increased EQA data utilization	Improved EQA decision making
	Conduct EQA review meetings at national and county level	EQA review meeting conducted	Increased support for EQA at all levels	Increased support for EQA at all levels	Increased Health facilities participating in EQA
Development of EQA database	Hiring of consultant	Consultant contract			
	Needs assessment	Needs assessment report			
	Technical gap analysis	Gap analysis report			
	Customization/ configuration of three modules- HIV	Malaria and microbiology and HIV modules			
Objective 4: Strengthen Operational Research to inform EQA scheme					
Establish supportive mechanisms for operational research	Develop operational research protocol	Operational research protocols developed	Increased operational research	Improved dissemina-tion of EQA activities	Improved EQA policy
	Train personnel in scientific writing	Personnel trained on scientific writing	Increased knowledge on scientific writing	Improved scientific writing practices	

4.2 Performance Measurement

This strategy will be monitored and evaluated periodically using key performance indicators to ensure timely corrective interventions are administered as part of continuous quality improvements.

Monitoring Question	**Indicators**	**Data source**	**Frequency of data collection**	**Data Use**
Has the Implementation of a well-coordinated and integrated EQA System resulted to improved quality of laboratory services?	• Availability of EQA database • List of PT schemes available • No of EQA providers accredited • No of technical staff in reference laboratory trained on PT panel production	NPHLS EQA Data base NPHLS training records	Quarterly Quarterly	Improve EQA programme

Has the quality laboratory services improved since the EQA performance mechanisms were established?	• Proportion of laboratories participating in EQA schemes • Proportion of participating laboratories analysis PT panels with the set TAT • Proportion of laboratories with successful PT performance (>80%) • Proportion of laboratories institution remedial actions for unsatisfactory PT performance	NPHLS EQA Data base County EQA data base	Quarterly	Improve EQA programme
Has the Strengthening of operational Research in EQA scheme s resulted to increased evidence based EQA policy decisions?	• No of research protocol developed and approved • Number of personnel trained in scientific writing and manu-script writing • Number of EQA manuscripts published • Number of EQA bulletins published	NPHLS and County EQA Database	Annually	Improve EQA programme

EQA Financing

Effective financing mechanisms shall be put in place at both national and county levels to ensure availability and accessibility of adequate resources for laboratory EQA activities. Sources of funding shall be through the Ministry of Health, development partners and private institutions either directly or in kind. Dedicated budget lines for EQA activities shall be established at national and county levels.

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