

SAMPLECOUNTRY

**Laboratory Services
National Strategic Plan**

MISSION

To improve the health status of (SampleCountry) through the provision of quality services by advancing the capabilities of all laboratories in laboratory technology, related public health disciplines, training, research and well motivated staff.

National Strategic Plan for Laboratories 2008-2012 (Version 2) (Feb 2007)

Introduction

The Role of medical laboratories

ISO 15189:2003 defines the medical laboratory (clinical laboratory) as a “laboratory for biological, microbiological, immunological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological or other examinations of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.”

Information provided by the medical laboratory underpins the practice of modern medicine and by defining the incidence and prevalence of disease it allows government and other agencies to plan the provision of health care services and monitor their effectiveness.

Over the years the practice of medicine and surgery has become increasingly complex and so have the demands that are placed on laboratories. The direct impact of diseases on the population reinforces the recognition that disease prevention and control are critical to sustainable human development. Laboratories are often the first sites for the detection of disease outbreaks and also serve as a major source for health information. They produce critical and relevant information for patient care and treatment, epidemiology and surveillance. Strong laboratory facilities are therefore essential to health as well as to the national well-being and maintenance of health and economic development.

Background

The Government of SampleCountry is currently engaged in a programme of significant restructuring /reform of the nation’s health services and the health sector. Over the years, the Ministry of Health (MOH) has remained committed to improving the institutional capacity of the health sector to be able to respond in an adequate and timely manner to the public health care needs of the country within a resource constrained environment. Within this context the Ministry of Health is developing a series of sector specific reform plans such as this for the medical laboratory services.

In March 2003 the Ministry of Health published the **National Health Plan 2003- 2007** (NHP) document which provided a strategic framework for the health sector over that period. This reform strategic plan focuses on the health priorities of the government and is premised on the millennium development goals, the poverty reduction paper and the national development strategy. The NHP provides the overall framework and the overarching frame of reference for the National Strategic Plan for Laboratories 2008-2012. In addition, this Plan is consistent with the findings and recommendations of the following:

- Strengthening of Medical Laboratory Services in the Region – A European Union Funded Project.
- SampleCountry’s National Laboratory Strategic Planning Workshop Draft Report – January 2005.

- Consultation with key stakeholders in the public and private medical laboratory services through the National Laboratory Advisory Steering Committee now referred to as the National Laboratory Oversight Committee.

The central purpose of this Plan is to provide a chartered course or road map for improvement and strengthening the provision and delivery of laboratory services to ensure equitable access to quality services based on the adequacy and availability of skilled human and other resource inputs – financial and material. The objective is to improve, strengthen and promote the institutional and operational capacities of laboratories that will improve their diagnostic and monitoring capabilities.

Situational Analysis – Strategic Assessment of the Laboratory Sector

The Public Health Laboratory services in SampleCountry consist of a network of diverse institutions and public laboratories that work in undefined collaboration with private clinical laboratories. Since the 1980s, the HIV epidemic has emphasized the Public Health Laboratory's critical role in assessing, leading, and developing health policies. The Public laboratory system has recognized the need for established laboratory priorities for bio-terrorism, emerging and re-emerging pathogens e.g. anthrax (2001), SARS (2003), avian influenza (2005).

The Existing Laboratory Services

Public Facilities

Clinical laboratory Services within the public system are provided through the Central Medical Laboratory (CML) of the Sample Public Hospital Corporation (SPHC), four Regional Hospitals with functioning medical laboratories and nine (9) district hospitals

The SPHC provides anatomical and clinical laboratory services. The SPHC is the only Tertiary Care facility where the highest level of specialization in Clinical Medicine is practiced. The CML is the main referral hospital laboratory. The Medical Technologist, who works in specialized areas, is the mainstay in respect of staffing at this facility. However, there is great scope for scientific officers as well as several categories of support staff. This laboratory possesses the highest level of medical technology available in the Public Health system for clinical care.

The CML provides a range of services in biochemistry, hematology, serology/immunology and microbiology. Histo-and cytopathology laboratory services are offered by the anatomical pathology laboratory.

The main focus of the Regional Hospital is to provide secondary health care to the population. They operate on a 24hour basis and the laboratory service is available at all times. This category of laboratory provides the highest level of service in the region. They are served by Medical Technologists, Multi Purpose technicians and Phlebotomists. The following services are offered:

- basic Biochemistry
- TB diagnosis
- Malaria
- basic Haematology
- Urinalysis

- basic serology (VDRL, HepB, HIV)

There are also seven (7) district hospitals, which offer varying degrees of testing in their laboratory departments; these are Sample Hospital 1 (Region 8), Sample Hospital 2 (Region 5), Sample Hospital 3 (Region 9), Sample Hospital 4 (Region 2), Sample Hospital 5 (Region 7) and Sample Hospital 6 and Sample Hospital 7 (Region 10). These hospitals provide the following services

- TB diagnosis
- limited Biochemistry and Hematology
- Malaria
- basic serology (HIV, VDRL)

There are a seven (7) other district hospitals, A, B, C, D (Region 1), E (Region 9), F (Region 3) and G (Region 6) that have infrastructure to house laboratory facilities. However, there is need for structural alterations to make them more suitable for fulfilling their laboratory functions.

Point- of- care testing is done in some Health Centers, e.g. HIV testing and blood sugar tests.

The National Blood Transfusion Service (NBTS)

There is one specialized laboratory; the National Blood Transfusion Service. It is the only free-standing blood collection facility in the country and was established in 1989. Blood collection facilities in the Regions are located within the Regional Hospital facility. In addition to providing specifically for the blood transfusion service the laboratory also provides infectious disease testing for private and public health facilities.

Testing: All blood collected by Blood Transfusion Centres in SampleCountry is screened for HIV, Hepatitis B (HBV), HCV, syphilis and malaria. In August 2006 testing became available for HTLV 1 & 2. At NBTS screening for HIV, HBV and HCV is done by use of commercially available enzyme linked immuno-sorbent-assay (ELISA) kits. All testing is conducted in accordance with manufacturer's protocols and international guidelines for quality assurance. Screening for malaria and filaria is done by smear-microscopy and that for syphilis by RPR and TPHA.

Regional Centres screen blood for HIV HBV and syphilis using rapid tests. Testing for HCV and other confirmatory ELISA testing is carried out at the NBTS. This arrangement has created an informal programme of Quality Assurance among the Regional Centres in SampleCountry. Discordant test results found between the rapid tests and the ELISA tests have been statistically insignificant.

NBTS also provides proficiency test (PT) samples to the Regional Centres on a regular basis. The laboratory staff participates in external PT programmes for immuno-haematology (NEQAS), syphilis (Health Canada) and ELISA-based testing (Q-panel). They also participate in the Model Performance Evaluation Programme (MPEP) from the Centres for Disease Control and Prevention (CDC).

Private Facilities

Laboratory services are also provided within the private sector. There are currently 15 known private laboratories in operation of which two are certified by the SampleCountry NBS. They provide a range of general clinical laboratory services.

Private/Public Collaborative Efforts

The quality of both public and private sector laboratory services vary widely. This requires an established mechanism for standardising, monitoring and controlling the quality of medical laboratory services available to the public. Important advances have already been made in this regard in recent years. They include:

- Establishment of a National Laboratory Advisory Committee through the EU Lab Strengthening Project in 2003. The Minister of Health is the Chairman with stakeholders from both private and public sectors.
- Establishment of a national certification system for laboratory operations by the SampleCountry National Bureau of Standards, fulfilling the requirements of the SYS 170:2003.
- Adoption of the Southern Regional Standards for Blood Banks.
- Adoption of the ISO 15189 International Standards for Clinical Laboratories.
- Donor support for several aspects of laboratory service development, particularly in the areas of HIV/AIDS and TB care, treatment and support.
- Establishment of a network of public and private laboratories such as the SampleCountry Lab Link founded in 2004 (through the EU Project) and the SampleCountry NBS Clinical Subcommittee.
- Implementation of a number of training initiatives which started through Southern Region and was strengthened by the EU Project.
- Implementation of a proficiency testing programme for monitoring laboratory quality nationally.
- Development of a Health Facilities Act which is currently under parliamentary review.

Strengths and Challenges to Service Delivery.

Overview: Delivery of high-quality laboratory services is essential in our health-care system both for providing the foundation for clinical decisions and as an objective means to measure and monitor biological and environmental markers. Accurate and timely laboratory analyses are critical to identify, track, and limit public health threats which ultimately will reduce rates of preventable morbidity and mortality. Optimal functioning of the public health system to meet these threats is dependent on uniform and high-quality laboratory testing.

A key precept for public health is recognizing that a significant amount of testing for public health is either performed in private laboratories or is dependent on private laboratories for referral and reporting. Therefore, a function of public health and specifically of the Public Health Laboratory system is to ensure the availability, quality, and reporting of laboratory testing performed in the private sector.

A minimal association exists between public and private (i.e., hospital and independent) laboratories, and this limited association has led to limited communication and coordination of the laboratory testing that is necessary to support public health interventions.

Strengths:

A guaranteed package of services to be delivered at each level of Laboratory service has been defined (see Appendix ...) and a strategic plan for the strengthening of the National Blood Transfusion Services and improvement of blood safety has been developed and accepted. (See Appendix ...)

The National Certification of laboratories programme is coordinated by the SNBS and was implemented in 1995.

A number of training opportunities for laboratory personnel have been utilized in the following areas: Laboratory Quality Management, STIs and OIs, TB, Flow Cytometry and CD4 Testing.

Closer collaboration between the laboratories and the Ministry of Health in the following areas –

- Increased awareness of the laboratory profession by other health care providers
- Creation of the Network of Medical Laboratory Professionals and the increased participation of laboratory personnel in this network
- The acquisition of new technologies for use in both public and private laboratories
- The proficiency testing scheme available to all medical laboratories
- Open door management style that exists in some medical laboratories.

Challenges

Internal

Each member of staff should have the opportunity to update his or her knowledge on laboratory testing. However, opportunities for laboratory technologists to obtain additional education in some areas of laboratory technology are urgently needed. Standardised training for other levels of staff is almost non-existent. Currently the NBTS offers one blood safety training module routinely to donor nurses employed there or at regional centres. The only other training provided regularly by NBTS or SOUTHERN REGION covers testing procedures for HIV, HBV, HCV, syphilis and quality assurance. This training is limited to laboratory personnel. Current resources do not permit external training opportunities for medical or administrative personnel.

The Ministry of Health facilitates and coordinates with other international organisations to convene workshops and training sessions for lab personnel country-wide:

- laboratory quality assurance
- General lab services

Other challenges include:

- Balancing the capacity of new technology with current needs.
- Unreliable supply of reagents
- Preventive maintenance and repair of biomedical equipment.
- Rapid staff turn-over and shortage of qualified/specialised staff.
- Lack of updated and enforced regulations.
- Poor remuneration of staff.

External

- Non availability of a constant supply of the utilities (water, electricity)
- Meeting the demands of international standards.
- Utilising donor resources for the maximum benefits of the Medical Laboratory Services Network

Opportunities

Significant technical and financial support for laboratory services is being provided by our development partners – PAHO/WHO, CDC, CIDA/CSIH, EU, Global Fund, USAID, World Bank, and SOUTHERN REGION. Many of the technical and financial inputs are already en train and it is hoped that the strategic plan – NSLP – will further streamline and strengthen these collaborative links.

Consistent with the policy of the Government to stimulate and encourage private sector involvement in health development, it is envisaged that there will be increased public/private sector partnership and collaboration in the provision of quality laboratory services. Such a partnership will assist in maximizing the use of resources.

Health sector reform activities will provide the environment for improving efficient and effective delivery of the laboratory services.

The implementation of national standards will improve the quality of laboratory testing and the level of performance by all stakeholders. The introduction of new and revised health legislation will provide a regulatory framework within which both public and private laboratories can operate while maintaining the same standard. The development of the National Public Health Reference Laboratory (NPHRL) will provide a nucleus for the defined functions of the National Laboratory System.

National Laboratory Services: Vision and Mission

The Vision

A network of highly efficient laboratories, public and private, functioning according to national standards and guidelines, well staffed with appropriately trained personnel, technically and financially sound. This will require the expansion of the range of services – diagnostic and confirmatory tests. Such a network will be supported by a centralized management information system (MIS).

In the past certain diseases were managed based on clinical diagnosis because of the lack of laboratory diagnostic capability to carry out confirmatory testing. Such testing had to be accessed overseas. The time is now right for such capabilities to be developed in SampleCountry. Thus the vision includes the establishment of a Centre of Excellence for Laboratory Performance in the form of a National Public Health Reference Laboratory (NPHRL). This laboratory will serve as the nucleus of the National Laboratory Services and provide a combination of selected laboratory services that support specific programs such as HIV, TB, STIs, and Malaria. This laboratory will have the flexibility and capability to assist with the management of disease outbreaks such as leptospirosis; special investigations and surveys related to specific issues of concern for example filariasis, anemia, avian influenza, and West Nile virus and drug resistance. In addition, the NPHRL, certified in accordance with current international standards, will be the centre for many of the National Laboratory Services core functions.

It will play a key role in ensuring private laboratories meet a minimal standard of quality and reporting. This will guarantee that information used for the management of individual patient care and treatment is both accurate and reported to the Ministry of Health when it is of ‘public health importance.’

Mission of the Laboratory Services

To improve the health status of Sample Country through providing quality service by advancing the capabilities of all laboratories in laboratory technology, related public health disciplines, training, research and well motivated staff.

Core Functions

In the next five years the Ministry of Health projects that its National Laboratory Service will execute the listed core functions with the NPHRL providing leadership and specialized services, as well as having all laboratories and testing sites certified and licensed to the National Standard (GYS:170:2003):

- disease prevention, control, and surveillance;
- integrated data management;
- reference and specialized testing;
- environmental health and protection;
- food safety;
- laboratory improvement and regulation;
- policy development;
- emergency response;
- public health-related research;
- training and education; and
- Partnerships and communication.

Disease Prevention, Control, and Surveillance

- Provide timely, accurate and precise analytical results for different diagnostic and analytical functions for the assessment and surveillance of infectious, communicable, genetic, and chronic diseases, and environmental exposures.
- Serve as a first line of defense by rapidly recognizing and preventing the spread of communicable diseases by
 - examining specimens for identifying disease outbreaks;
 - isolating and identifying the causative agents;
 - determining the sources of infection;
 - identifying carriers; and
 - locating sources of infection in the environment.
- Serve as a centre of expertise for the detection and identification of biologic agents of significance in human disease; as such, ensure access to laboratory expertise and capabilities in the disciplines of
 - bacteriology;
 - virology;
 - parasitology;

- molecular microbiology;
- immunology and serology;

- Chemistry

- Mycology; and
- hematology and Immuno-hematology

- Provide specialized tests for low-incidence, high-risk diseases, detect epidemiologic shifts; and detect newly emerging pathogens, including but not limited to
 - testing specimens from suspect cases of tuberculosis to identify *Mycobacterium tuberculosis* infections and determine effective antibiotic treatment;
 - assisting public and private health-care providers in investigating and controlling communicable or environmental related health conditions.

- Provide population surveillance for conditions of interest to the public health community, including screening for inherited neonatal metabolic disorders, environmental toxins, immune status, risk factors, chronic blood diseases, blood lead, and antibiotic resistance.
- Perform tests to meet specific program needs of public health agencies.

Integrated Data Management

- The NHPRL will serve as the focal point for accumulating, blending, and disseminating scientific information in support of public health programs, including
 - capturing laboratory data essential for public health analysis and decision-making;
 - ensuring the ability to maintain and communicate laboratory data by using standardized data formats;
 - ensuring rapid dissemination of laboratory information to assist in identification, understanding, and controlling disease outbreaks;
 - providing primary data necessary to provide information for and implement policy and planning; and
 - providing a countrywide disease reporting network, with centralized facilities for receipt, storage, retrieval, and analysis of data.
- The NPHRL will serve as nucleus in the national database system to collect, monitor, and analyze laboratory data, as the primary data link with SOUTHERN REGION and CDC for surveillance of diseases of national, regional and global concern.
- Serve the data needs of country epidemiologists, laboratories, and practitioners in identifying trends and sentinel events which indicate emerging health problems.

Reference and Specialized Testing

- The NPHRL will serve as the country's primary reference to
 - test for, and aid in the diagnosis of unusual pathogens;
 - confirm atypical laboratory test results;
 - verify results of other laboratory tests;
 - provide oversight for quality assurance;
 - test epidemiologically significant specimens with potential public health implications;

- provide reference diagnostic testing to private sector laboratories that might not have the capability to fully identify disease agents of public health significance;
- test for diseases of public health consequence that are rare or unusual for other laboratories to maintain capacity for testing, including human genetic markers of disease; and
- provide toxicology testing, including drug, alcohol, poison, and trace metal analyses.

Environmental Health and Protection

- Conduct scientific analyses of environmental samples (air, water, and soil) to identify and monitor potential threats to human health and ensure compliance with environmental regulations.
- Analyze environmental and biological specimens and detect, identify, and quantify toxic contaminants (e.g., lead, pesticide residues, and heavy metals).
- Ensure laboratory services that support assurance of clean water in the county by analysing water for synthetic organic chemicals, pesticides, inorganic chemicals, and micro-organisms.

Food Safety

In collaboration with the food and drug department, the NPHRL will:

- Test specimens from persons, food, and beverages implicated in food borne illness outbreaks to identify causes and sources. Testing might include assays to identify organisms (e.g., staphylococcus, bacillus, salmonella, shigella, vibrio, listeria, and clostridium).
- Analyze food specimens to detect, identify, and quantify toxic contaminants e.g., pesticide residues, and heavy metals.

Laboratory Improvement and Regulation

- Coordinate and promote quality assurance programs for private clinical and environmental laboratories through training, consultation, certification, and proficiency testing.
- Serve as the standard of excellence for local and private laboratory performance.
- Exercise leadership and authority as the agency responsible for laboratory regulation and training in the clinical and environmental areas.
- Develop and oversee countrywide quality assurance and laboratory improvement programs to ensure the reliability of laboratory data used for communicable disease control and environmental monitoring.
- Oversee the licensure, certification, and accreditation of laboratories to ensure medical, environmental, and food safety, laboratories fulfill national and legal mandates.

Policy Development

- Provide scientific and managerial leadership in developing public health policy and in developing, promoting, and integrating public health laboratory science into practice.
- Participate in developing standards for all health-related laboratories, including food, environmental, clinical, and research standards.

Emergency Response

- Provide laboratory support as part of national disaster preparedness plans for environmental or health emergencies, including
 - rapidly identifying and investigating analyses of biological, chemical, and radiological agents, regardless of the source of exposure (i.e., unintentional, terrorist, or natural disaster);
 - ensuring the capacity to quickly and accurately handle a substantial volume of tests during an emergency situation; and
 - providing a rapid response system for hazardous contaminants waste spills (air, water, and soil) and in food borne disease outbreaks.

Public Health-Related Research

- Evaluate and implement new technologies and analytical methodologies to ensure laboratories provide state-of-the-art, cost-effective, and timely analytical diagnostic services and support the public health care professionals in the country by
 - identifying the need for new laboratory methodologies for disease detection and prevention;
 - conducting research to improve laboratory tests for more effective disease surveillance; and
 - conducting research to develop rapid methods for laboratory diagnosis.
- Collaborate with academic, private sector researchers and other government agencies to adapt emerging technologies in public health laboratory techniques and information systems.
- Conduct applied studies into new and improved analytical methods and services which are necessary to meet changing public health surveillance and environmental regulatory requirements.
- Provide advice to the private sector regarding newly marketed and validated tests.

Training and Education

- Sponsor training opportunities to improve scientific and technical skills of public health laboratory staff.
- Provide, or facilitate, training courses and workshops for laboratory staff in private and public sectors to continually upgrade the knowledge and skills essential for providing quality services in medical, environmental, and public health laboratories.
- Provide short- and long-term training opportunities to prepare scientists for careers in public health laboratory practice.
- Provide continuing education in management and leadership development for those in administrative positions.
- Participate in training of medical scientists.

Partnerships and Communication

- Develop and strengthen partnerships among countrywide public health leaders, academia, and private industry to advance understanding of the critical role played by public health laboratories in supporting the core functions of public health.
- Emphasize the role and value of the public health laboratory to national public health programs.
- Participate in strategic policy planning and development processes.

- Maintain strong communication networks among
 - public health doctors/private doctors;
 - city council officials;
 - epidemiologists;
 - directors of various public health programmes
 - legislators;
 - state health budget personnel;
 - other laboratory management staff;

The definition of laboratory core functions provides a basis for assessment of laboratories against appropriate standards and guidelines for the improvement of laboratory activities, followed by policy development and quality assurance.

Another key continuation of the definition of laboratory services core functions is the need to develop performance standards. Performance standards are critical for public health by providing potential benefits of improved accountability; better resource deployment; enhanced capacity building for community, and national public health systems; widespread use of best practices; and increased focus on mission and goals. The same premise is true for benefits of performance standards for laboratories. Work is in progress to create performance standards for the nation's laboratories through collaborative efforts with SOUTHERN REGION and CDC.

The Plan

Over-arching Goal:

A coordinated Public Health Laboratory Service established and functioning according to agreed upon standards.

Specific Objective:

To strengthen and enhance the planning, management and operational/service capacity of the Laboratory Services – including Blood Transfusion Services and the NPHRL for the provision of efficient and quality services.

General Strategic Objectives of the Laboratory Services over the next

Five years:

1. Network laboratory structure, system, roles and responsibilities defined and operational.
2. A framework within which planning and development of an integrated Laboratory Services Delivery System will occur and be established.
3. Operational standards and guidelines established and implemented.
4. Laboratory services well staffed and managed.
5. Quality Assurance (QA) and Continuous Quality Improvement (CQI) Programmes for laboratory services developed and implemented.
6. A centralised management information system (MIS) for the laboratory service network established.
7. To advocate for an efficient and effective procurement and maintenance system to be established and implemented.

8. A marketing, advocacy and promotional programme designed and implemented to ensure quality laboratory services nationally.
9. New/revised legislation and regulations in support of laboratory service reform and accreditation of laboratories developed.

Management of the Network of Laboratory Services

The efficient and effective management of the network of laboratories requires that there be a clearly defined technical and administrative relationship between the Ministry, the Regions, the public facility level and the private sector. The main areas for consideration in the public sector are appointment, training and supervision of staff, procurement of equipment, supplies and maintenance of equipment.

In general the Ministry will be responsible for defining policy and determining standards for the entire system - procurement of equipment and reagents; assessing and evaluating the need for new technologies; advising on the types of service contracts required on the purchase of equipment, investment in a biomedical equipment maintenance unit and overall monitoring and evaluation of the services.

In terms of biomedical equipment maintenance it is felt that service contracts need to be established with the suppliers, maintenance manuals must be provided and training in day to day maintenance provided to the users. Given the paucity of biomedical equipment maintenance services available in the public domain the Ministry should invest in the training of biomedical equipment maintenance personnel.

The Regional level should be responsible for ensuring policies are carried out, standards enforced, and for general supervision of all staff working in the regional facilities. In the case of vertical programmes such as Malaria and TB technical oversight should be carried out by the vertical program but day to day supervision by the relevant senior officer within the regional services of the laboratory in which the technician works. Issues related to program management will be dealt with at the level of the Medical Superintendent and the (vertical) Program Director.

At the Regional level the Chief Technologist will be responsible for the hospital laboratory management and technical supervision of staff of the lower level laboratory services and will report to the Medical Superintendent of the hospital. All staff working within the laboratory will report to and be supervised by the Chief Technologist.

Objective: *Network laboratory structure, system, roles and responsibilities for laboratories defined and operational*

Indicators:

- i) *An efficient and effective procurement and maintenance system established and implemented as demonstrated by uninterrupted quality services to all users by the end of 2010.*
- ii) *Legislation and regulations in support of laboratory service reform and accreditation of laboratories developed by 2009.*

Activities:

- Develop a document detailing the roles and responsibilities of each level of the network, central, regional, district and facility.
- Conduct training programmes for regional laboratory and administrative staff on roles, responsibilities and collaboration in the efficient functioning of the service.
- Conduct training in the use of information systems in laboratory service management

- Ongoing monitoring and evaluation of the various programmes and activities.

Objective: *Laboratory services reformed and facilities equipped, staffed and functioning at a level that provides accurate, reliable results in a timely fashion.*

Indicators:

1. *75% of laboratories at all levels equipped as defined in the levels of care by the end of 2009.*
2. *75% of laboratories with the categories and number of each category of personnel defined for their level of care by the end of 2009.*
3. *All public laboratories (Levels 1-4) certified to GYS 170:2003 by the end of 2009.*
4. *All level 5 laboratories (SPHC, NBTS and NPHRL) accredited to the ISO 15189 by the end of 2009.*
5. *Quality Assurance (QA) and Continuous Quality Improvement (CQI) Programmes for laboratory services validated by the number of laboratories in compliance with the relevant standards for operation.*

Activities:

- Survey all laboratory facilities to determine space, equipment and staffing needs on a quarterly basis.
- Prepare a five-year programme based on a yearly budget for filling these needs.
- Conduct a gap analysis followed by a work plan to prepare laboratories for the certification and accreditation processes.

Human Resources:

Human resources for the provision of laboratory services are comprised of Medical Technologists, Multi-Purpose Technicians, Laboratory Aides and Phlebotomists. The medical technologist has undergone a three year university programme, the multipurpose technician an eighteen month programme sponsored by the Ministry of Health, which includes pharmacy and X-Ray technology, and the phlebotomist in-service training in withdrawing blood. The Laboratory aide is not required to undergo any defined training programme.

There is almost a crisis situation in relation to the categories of staff. The current situation is that the National Health Service is not benefiting from the training of laboratory technologist at the University of SampleCountry. Graduates either enter the private sector or migrate. Furthermore with the advent of the National Public Health Reference Laboratory technologists with higher levels of training will be required.

Specialized training of technologists in the field of microbiology and chemical pathology is available at the University of SampleCountry. However, the un-availability of lecturers has curtailed the training of Medical Technologists in the specific areas of haematology and blood banking. As such, there have been no graduates in the programme of the University for the past three years. This has resulted in a chronic shortage of specialised staff in this area.

The NBTS conducts limited in-service training but does not have enough staff to meet current training requests from other laboratories. The Ministry of Health currently provides training in all areas with emphasis on quality management systems whilst the CML, SPHC offers regular in service training.

The degree programme in laboratory technology is to be instituted at the start of the 2007-2008 academic year. This programme will be offered instead of the current Associate degree programme. It is necessary that links with training institutions be formalized to ensure the provision of appropriately trained personnel. For

example the tri-partite forum on training matters – MOH, SPHC and UG – should be reinstated to ensure that the curriculum meets the needs of the health services and that the appropriate ‘hands on’ experience is being provided.

The solution to the shortage of human resources would be to establish a proactive, innovative and appropriate mechanism to encourage technologists to enter the public service, provide incentives to retain them and in the interim make use of other levels of personnel according to the needs of the service.

In terms of recruitment this may include offering scholarships to and contracting an agreed upon number of technologists every year and establishing training programme for medical laboratory technicians (with students coming from all regions especially the rural areas).

In terms of retention it is recommended that well defined career paths be developed for all categories of staff through the introduction of standardized continuing education. Opportunities must be created for technologists to specialize in different fields– hematology and blood banking, microbiology and chemical pathology since level 4 and 5 services require these three (3) specialties. A technologist should have at least a BSc degree and be certified to become a Head of Department or a Chief Technologist so that post graduate training should be made available.

It is necessary that the various curricula and job descriptions be reviewed. There is also need to institute basic training for laboratory attendants. Senior laboratory personnel including management must be involved in this exercise.

Human resource policies will also need to be reviewed to define the categories of staff required in light of the redefined laboratory services, to redefine the requirements for personnel to move from one level to the next in the system, and the new categories of staff to be added to the establishment.

Objective: *To provide and retain appropriately trained personnel in adequate quantities to staff the laboratory network within the framework of the Workforce Development Strategy*

Indicators:

- i) *Five year training plan for pre service and in-service training for all categories of laboratory technical staff developed*
- ii) *80% of target reached in the number of persons of each category of staff to be trained annually*

Activities

- The NLOC will address the requirement of human resources necessary to provide quality laboratory services.
- Conduct a skills-needs analysis in relation to the defined network functions.
- Develop a training plan based on the human resource needs/skills ensuring that sustainability strategies are a major focus.
- Design an appropriate common approach for the delivery of training, both pre-service and in-service, and the monitoring of the training outcomes and impact.
- Conduct internal and external evaluation of all training programmes to ensure that they remain relevant to the services being provided.
- Develop criteria for:
 - iii) recruitment that reflect the skills appropriate to the organizational structure and function, develop targeted recruitment strategies; and
 - iv) Promotion from one level to the next.

- Develop a tool for the evaluation of staff in terms of proficiency and readiness for promotion or in grade increases in salary;
- Develop and implement relevant and effective orientation programmes for recruits in terms of their role, their reporting relationships, functioning of the facility.
- Design and conduct a series of in-service training modules to prepare each category/level of personnel to enter the programme of the level above.
- Reconstitute the tri-partite forum on training (MOH, SPHC and UG)

Data Management

The National Laboratory Services of the Ministry of Health will be the central repository for management data and will be linked to the Ministry of Health MIS unit. This unit will be responsible for design, acquisition and storage of all forms required for data collection, analysis and for utilizing the data for decision making.

Objective: *To establish a centralized interactive database and electronic communication links for the laboratory service network*

Indicators:

- i) *Data management system developed to address the type of data to be collected, frequency, flow, analysis, and use designed, for both disease surveillance and programme management by the end of 2009.*
- ii) *75% of laboratory facilities utilizing and reporting according to agree upon data needs, flow and timelines by the end of 2010.*
- iii) *All laboratories at level 3 and higher equipped with computers by the end of 2008.*

Activities:

- Convene meeting of all stakeholders to determine data needs, reason needed, utilization frequency etc.
- Design information system, including standardized data formats and user manuals.
- Conduct training programmes for relevant staff in data collection, compilation, utilization and reporting.
- Conduct training in data entry and the use of relevant software
- Issue contract for printing of data forms and manuals.
- Procure IT equipment and service contracts.

Monitoring and Evaluation

The functioning of the entire system of laboratories needs to be carefully monitored so as to maintain a high level of service. This includes evaluation (internal and external) of all training programmes to ensure that they remain relevant to the services being provided -

- evaluation of services in relation to certification
- evaluation of staff in terms of proficiency and readiness for promotion or in grade increases in salary

- development of instruments to carry out the evaluation of laboratories
- services and staff

Chapter 1

Laboratory Institutional and Management Framework

- 1.1 Strategic Objective**
Develop the administrative and technical management structure of the National Public Health, Regional and District Laboratories
- 1.2 Challenges**
- No organizational or coordinating structure
 - Weak national management system
 - Lack of strong national reference laboratory
 - Lack of qualified human resource
- 1.3 Planned activities**
- 1.3..1 Establish linkages between the National Public Health, Regional and District Laboratories to the Ministry of Health
- 1.3..2a Designate the following positions at:
 NPHL – Director , Head of Sections, Administrative Officer, executive Secretary, Senior Medical Technologist, Medical Technologist, Medical Laboratory Technician
 Regional Laboratory – Supervisor, Senior Medical Technologist, Medical Technologist, Multi Purpose Technician and Phlebotomist
 District Laboratory – Medical Technologist, Multi Purpose Technician
- 1.3.2b Develop and organizational chart for the NPHL, regional and District Laboratories
- 1.3..3 Establish the location and physical offices of the:
 Director, Respective Head of Departments, Administrative Officers – NPHL and the Supervisor and Medical Technologist for the Regional and District Laboratories respectively
- 1.3..4 Revise the roles and responsibilities of the Regional and District Laboratories and implement the defined roles and responsibilities of the NPHL
- 1.3.5 Revive the National Laboratory Oversight Committee (NLOC) to provide linkages to programs and partners to support the National Strategic Plan for laboratories
- 1.3.6 Appoint standing Technical Advisory Committee(s) as required supporting the functions of the NLOC.
- 1.3.7 Include representatives from the regional and district laboratories at the NLOC meetings

Table 1: Laboratory Institutional and Management Framework

Strategic objective Planned interventions		Time Frame (Year 2000)					Responsible partners	Outcomes and planned results
		08	09	10	11	12		
1.1.	Strategic Objective Develop the administrative and technical management structure of the National Public Health, Regional and District Laboratories	X	X	X	X	X		
1.2	Challenges <ul style="list-style-type: none"> ▪ No organizational or coordinating structure ▪ Weak national management system ▪ Lack of strong national reference laboratory Lack of qualified human resource	X					MOH Regional Health Services and partners	Organogram developed
1.3.1	Establish linkages between the National Public Health, Regional and District Laboratories to the Ministry of Health	X	X				MOH CDC RHS	Organogram Job Descriptions developed/ reviewed
1.3.2a	Designate the following positions at: NPHL – Director , Head of Sections, Administrative Officer, executive Secretary, Senior Medical Technologist, Medical Technologist, Medical Laboratory Technician Regional Laboratory – Supervisor, Senior Medical Technologist, Medical Technologist, Multi Purpose Technician and Phlebotomist District Laboratory – Medical Technologist, Multi Purpose Technician	X	X				MOH CDC RHS	Completed Organogram
1.3.2b	Develop and organizational chart for the NPHL, regional and District Laboratories	X	X				MOH CDC RHS	Package of services used at the various levels
1.3.3	Establish the location and physical offices of the: Director, Respective Head of Departments, Administrative Officers – NPHL and the			X	X		MOH Partners Stakeholders	Functional committee to strengthen linkages and partnerships

	Supervisor and Medical Technologist for the Regional and District Laboratories respectively							
1.3.4	Revise the roles and responsibilities of the Regional and District Laboratories and implement the defined roles and responsibilities of the NPHL		X	x				
1.3.5	Revive the National Laboratory Oversight Committee (NLOC) to provide linkages to programs and partners to support the National Strategic Plan for laboratories	X	X	X				
1.3.6	Appoint standing Technical Advisory Committee(s) as required supporting the functions of the NLOC.	X	X	X				
1.3.7	Include representatives from the regional and district laboratories at the NLOC meetings	X	X	X				

Chapter 2

Laboratory Services

2.1 Strategic Objective

To strengthen and enhance the planning, management and operational/service capacity of the Laboratory services - including Blood Transfusion Services and the NPHRL for the provision of efficient and quality service

2.2 Challenges

- Balancing the capacity of new technology with current needs
- Unreliable supply of reagents
- Preventative Maintenance
- Rapid staff turn-over and shortage of qualified/specialist staff

2.3 Planned activities

2.3.X Develop a network laboratory structure with systems, roles, and responsibilities defined and established

Establish a comprehensive surveillance, preparedness and disease outbreak response system: Develop guidelines for capabilities, planning and SOP's for disaster/outbreak response in the lab at each health care level.

2.3.X Establish and implement national operational standards and guidelines for laboratory services

Ensure Laboratory facilities are well staffed and managed

2.3.X Develop and implement a quality assurance programme for the laboratory service

Establish a centralized management information system within the Laboratory network

2.3.X Advocate for an efficient and effective procurement and maintenance system to be established and implemented

Revise existing legislation and regulations in support of laboratory service reform.

2.3.X Campaign for Laboratory Certification and Accreditation

Use audit results to identify current gaps within the laboratory services and develop strategies for closing these gaps

2.3.X Create a National Public Health Reference Laboratory (NPHRL) within the MOH Laboratory network

Establish an External Quality Assessment Scheme (EQAS) within the National Laboratory Network

2.3.X Revise and possibly increase the scope of testing at the different levels of care

Table 2: Laboratory Services

Strategic objective Planned interventions		Time Frame (Year 2000)					Responsible partners	Outcomes and planned results
		08	09	10	11	12		
2.1.	Develop a network laboratory structure with systems, roles, and responsibilities defined and established	X	X				M.O.H R.H.S Partners	A developed Laboratory network, with its system, roles and responsibilities clearly defined and established reflecting the levels of care.
2.	Establish a comprehensive surveillance, preparedness and disease outbreak response system: Develop guidelines for capabilities, planning and SOP's for disaster/outbreak response in the lab at each health care level.	X	X	X	X	X	M.O.H CML R.H.S PARTNERS	A developed and functioning surveillance, preparedness and outbreak response system
2.	Implement national operational standards and guidelines for laboratory services	X	X	X	X	X	M.O.H R.H.S Partners	Clearly defined guidelines and standards for Laboratory operation
2.	Ensure Laboratory facilities are well staffed and managed	X	X	X	X	X	M.O.H R.H.S Partners	Lab facilities well staffed and managed
2.	Develop and implement a quality assurance programme for the laboratory service	X	X	X	X	X	M.O.H R.H.S PARTNERS	A functional quality assurance system in laboratories
2.	Establish a centralized management information system within the Laboratory network	X	x				M.O.H	A M.I.S that is developed and functional
2.	Advocate for an efficient and effective procurement and maintenance system to be established and implemented	X	X	X	X	X	M.O.H R.H.S Partners	A procurement and maintenance system that is efficient and effective
2.	Revise regulations in support of laboratory service reform	X					M.O.H	Laboratory regulations mandatory
2.	Promote Laboratory Certification and Accreditation	X	X	X	X	X	M.O.H GSCP Partners	Labs certified and accredited

2.	Establish an External Quality Assessment Scheme (EQAS) within the National Laboratory Network	X	X	X	X	X	M.O.H RHS Partners	Scheme established and revised
2.	Revise scope of testing to reflect the levels of care	X	X				M.O.H R.H.S	A revised level of care document with an increased scope of service

Chapter 3 **Human Resources**

3.1 Strategic Objective

To provide and retain appropriately trained personnel in adequate quantities of staff the laboratory network within the framework of the Workforce Development Strategy

3.2 Challenges

- Poor retention of qualified staff resulting from migration or move to private sector
- Unavailability of specialist training in hematology & blood banking at the University of SampleCountry
- Limited in-service training at NBTS and other institutions
- Absence or poorly defined job descriptions along with staff development framework with predictable staff progression

3.3 Planned activities

3.3.1 NLOC to address the requirement of human resources necessary to provide quality laboratory services

3.3.2 Conduct a skills/needs analysis in relation to the defined network functions

3.3.3 Development of a human resource skills/needs training plan with major focus on sustainability strategies

3.3.4 Design and conduct a series of in-service training modules to prepare each category/level of personnel to enter the next level in the organization

3.3.5 Design an appropriate pre-service and in-service delivery of training including the monitoring of the training outcomes and impact

3.3.6 Conduct internal and external evaluation of all training programmes to ensure that they remain relevant to the services provided

- 3.3.7 Develop Criteria for;
- i) recruitment that reflect the skills appropriate to the organizational structure & function, develop targeted recruitment strategies, and
 - ii) evaluation of staff in terms of proficiency and readiness for promotion or in grade increases in salary
- 3.3.8 Develop and implement relevant and effective orientation programmes for recruits in terms of their role, their reporting relationships and functioning of the facility
- 3.3.9 Reinstitute the tri-partite forum on training (MOH, SPHC and UG)
- 3.3.10 Development of Medical Laboratory Technician Training Programme
- 3.3.11 Development of Training Committee within the department of Standards & Technical Services
- 3.3.12 Develop a Human Resources database

Table 3: Human Resources

Strategic objective Planned interventions		Time Frame (Year 2000)					Responsible partners	Outcomes and planned results
		08	09	10	11	12		
3.1	NLOC to address the requirement of human resources necessary to provide quality laboratory services	X	X	X	X	X	NLOC MOH – Standards & Technical Services	Regular updates of Laboratory Services
3.2	Conduct a skills/needs analysis in relation to the defined network functions	X		X		X	MOH-HRD, HSE, DSTS UG	Level of skills available
3.3	Development of a human resource skills/needs training plan with major focus on sustainability strategies	X	X				MOH, HSDU, HSE, HRD, SPHC, UG	Availability of training plan Implementation of training programs
3.4	Design and conduct a series of in-service training modules to prepare each category/level of personnel to enter the next level in the organization i.e. career path	X	X	X	X	X	MOH, HSDU, HSE, HRD, Partners	Provision of Training Modules
3.5	Design an appropriate pre-service and in-service delivery of training including the monitoring of the training outcomes and impact	X					MOH, HSDU, HSE, HRD, SPHC	Five year training plan for all categories of laboratory technical staff developed
3.6	Conduct internal and external evaluation of all training programmes to ensure that they remain relevant to the services provided	X	X	X	X	X	MOH, DSTS,HSDU HSE, HRD, SPHC	80 % of target reached in the number of persons in each category of staff to be trained annually
3.7	Develop Criteria for; i) recruitment that reflect the skills appropriate to the organizational structure & function, develop targeted recruitment strategies, and ii) evaluation of staff in terms of proficiency and readiness for promotion or in grade increases in salary	X		X		X	MOH, DSTS,HSDU HRD, SPHC	Recruitment plan developed Evaluation & Promotion scheme designed and developed

3.8	Develop and implement relevant and effective orientation programmes for recruits in terms of their role, their reporting relationships and functioning of the facility	X	X	X	X	X	HRD, DSTS	All staff correctly indoctrinated to the organization
3.9	Reinstitute the tri-partite forum on training (MOH, SPHC and UG)	X					MOH, SPHC, UG	Reformation of the training forum
3.10	Development of Medical Laboratory Technician Training Programme	X		X		X	HRD, DSTS, HSE	Train an agreed-upon number of MLTs in every batch
3.11	Development of Training Committee within the department of Standards & Technical Services	X					DSTS	* Formation of committee * Development of Training Schemes
3.12	Develop a Laboratory Human Resources database	X					HRD	Generation of personnel capacity

Chapter 4

Laboratory Support Systems

4.1 Strategic Objective

Ensure each level of lab service is submitting regular standardized reports to the Ministry of Health

4.2 Challenges

- Absence of accurate and regular reports from decentralized labs
- Inadequate or inappropriate laboratory infrastructure
- Lack of or non-functional laboratory equipment
- Non-functional procurement procedure
- Non-standardized equipment and reagents at all levels of service

4.3 Planned activities

4.3.1 Establish and implement a National Laboratory Information System (NLIS)

4.3.1a1 Determine information needs of NLIS

4.3.1a2 Procure IT equipment and service contracts

4.3.1a3 Printing of data forms and manuals

4.3.1b Develop and implement manual laboratory data procedure and tools

4.3.1c Conduct training in the use of the laboratory information tools and relevant software

4.3.1d Pilot an electronic NLIS in selected sites and roll on a national scale

4.3.2 Improve the physical infrastructure at prioritized laboratories at all health care levels

- 4.3.2a Develop an implementation plan for laboratory physical structure upgrading and maintenance
- 4.3.3 Provide essential equipment, reagents and supplies according to the needs assessment
- 4.3.3a Develop mechanisms for procurement of standard equipment
- 4.3.3b Develop regular laboratory equipment maintenance schedules
- 4.3.3c Develop a procurement and supply plan for laboratory supplies and reagents integrated with the NLIS.

Table 4: Laboratory Support Systems

Strategic objective Planned interventions		Time Frame (Year 2000)					Responsible partners	Outcomes and planned results
		08	09	10	11	12		
4.1.	Ensure each level of service is submitting regular standardized reports to the M.O.H							

4.3.1	Establish and implement a National Laboratory Information System (NLIS)	x	x	x	x	x	MOH,RHS, Partners	NLIS
4.3.1a	Determine information needs of NLIS	x	x				MOH,RHS, Partners	NLIS requirement equipment installed. Forms and manuals printed
4.3.1a1	Procure IT equipment and service contracts		x	x			MOH,RHS, Partners	NLIS requirement equipment installed. Forms and manuals printed
4.3.1a2	Printing of data forms and manuals		x	x			MOH,RHS, Partners	NLIS requirement equipment installed. Forms and manuals printed
4.3.1b	Develop and implement manual laboratory data procedure and tools		x	x			MOH,RHS, Partners	Efficient management of laboratory data
4.3.1c	Conduct training in the use of the laboratory information tools and relevant software		x	x	x		MOH,RHS, Partners	Efficient management of laboratory data
4.3.1d	Pilot an electronic NLIS in selected sites and roll on a national scale		x	x	x	x	MOH,RHS, Partners	Electronic NLIS piloted and extended according to national plan
4.3.2	Improve the physical infrastructure at prioritized laboratories at all health care levels	x	x	x	X	x	MOH,RHS, Partners	Improved quality of lab testing, improved safety, moral and productivity of lab staff
4.3.2a	Develop an implementation plan for laboratory physical structure upgrading and maintenance	x	x	x			MOH,RHS,	Annual planning for facility improvements , time lines and progress made in lab upgrading and maintenance

									plan schedules
4.3.3	Provide essential equipment, reagents and supplies according to the needs assessment	x	x	x	x	x	MOH,RHS, Partners		Strengthen provision of quality and standardized lab services
4.3.3a	Develop mechanisms for procurement of standard equipment	x	x	x	x	x	MOH,RHS, Partners		Establishment of priorities and obtaining commitments form MOH and partners for funding lab services
4.3.3b	Develop regular laboratory equipment maintenance schedules	x	x	x	x	x	MOH,RHS, Partners		Proper function and maintenance of equipment
4.3.3c	Develop a procurement and supply plan for laboratory supplies and reagents Integrated with the NLIS.	x	x	x	x	x	MOH, SCMS, Partners		National system for procurement and distribution, inventory reports, NLIS data on tests performed

Chapter 5

Laboratory Quality Systems

5.1 Strategic Objective

Provide accurate, precise and reliable medical laboratory data for the SampleCountry population

5.2 Challenges

- Lack of trained staff
- Absence of legislation
- Staff attitudes to implementation of QMS
- Lack of supporting infrastructure and equipment
- Absence of inbuilt quality culture within the national laboratory system
- Lack of support from top management
-

5.3 Planned activities

5.3.1 Develop and implement standard training program for Laboratory Quality Management

- 5.3.1.a. Develop training module and conduct TOT
- 5.3.1.b. Establish training Committee/Group
- 5.3.1.c. Develop national roll out plan
- 5.3.1.d. Develop and manage national QA guidelines (including safety) for different levels, scope of testing supporting program needs
- 5.3.1.e. Implement National Lab QA guidelines and enroll labs in Certification program
- 5.3.1.f. Employ and train Lab QA Managers
- 5.3.1.g. Monitor and evaluate Nat. Lab QA service
- 5.3.1. h. Develop and manage an EQA program nationally

5.3.2. Advocate for legislation promulgation

- 5.3.2.a Provide regulatory framework for both public and private lab operation

5.3.3. Create and establish quality circles within lab system and include QA indicators in job descriptions and performance evaluations

- 5.3.3.a. Revise JDs to include quality component and performance management
- 5.3.3.b. Develop and implement staff advancement program

5.3.4. Develop lab infrastructure improvement program

- 5.3.4.a. Refurbish and construct suitable laboratory facilities
- 5.3.4. b. Develop policy and guidelines for procurement and maintenance of equipment

5.3.5 **Strengthen National Laboratory Oversight Committee**

5.3.5.a Market and promote quality lab services nationally

Table 5: Laboratory Quality Systems

Strategic objective Planned interventions		Time Frame (Year 2000)					Responsible partners	Outcomes and planned results
		07	08	09	10	11		
5.1.	Provide accurate, precise and reliable medical laboratory data for the SampleCountry population	x	x	x	x	x		
5.3.1	Develop and implement standard training program for Laboratory Quality Management	x	x	x	x	x	MOH,UG, Donors, Partners	All public and private lab staff and University students trained in LQM
5.3.1.a.	Develop training module and conduct TOT	x	x				MOH,UG, Donors, Partners	LQM Module established and used at the University and by the MOH Trainers available nationally
5.3.1.b.	Establish training Committee/Group	x	x				MOH,UG,	Committee responsible for LQM training nationally
5.3.1.c.	Develop national QM training roll out plan		x	x			MOH, UG Partners Donors	One year training plan developed
5.3.1.d	Develop and national QA guidelines (including safety) for different levels, scope of testing supporting program needs	x	x				MOH, Partners Consultant Donors	National QA guidelines developed and approved
5.3.1.e.	Implement National Lab QA guidelines and enroll labs in Certification program		x	x	x		MOH, Partners Lab Staff Donors	QA guidelines implemented at all levels of testing and labs enrolled in the SNBS certification program
5.3.1.f.	Employ and train Lab QA Managers			x	x	x	MOH, Partners Donors Consultant	QA managers employed and working with all labs

5.3.1.g.	Monitor and evaluate Nat. Lab QA service			x	x	x	MOH, SNBS QA Managers	Checklists used for QI in lab service
5.3.1.h.	Develop and manage an EQA program nationally	x	x	x	x	x	MOH, Donors	EQA Scheme implemented nationally and labs participating
5.3.2.	Advocate for legislation promulgation	x	x	x			MOH,SNBS	Legislation approved and published
5.3.2.a.	Provide regulatory framework for both public and private lab operation	x	x	x	x	x	MOH, SNBS	National and International standards developed or adopted/adapted
5.3.3.	Create and establish quality circles within lab system and include QA indicators in job descriptions and performance evaluations	x	x	x	x	x	MOH, RHA	Lab staff supporting each other QA indicators identified to be used
5.3.3.a.	Revise JDs to include quality component and performance management	x	x				MOH, RHA	JDs revised and used in lab system
5.3.3.b.	Develop and implement staff advancement program	x	x	x	x	x	MOH, RHA, Partners, Donors	Staff development /advancement program developed and implemented Staff Motivation
5.3.4.	Develop lab infrastructure improvement program	x	x	x	x	x	MOH, RHA Partners, Donors	Improvement in lab infrastructure nationally
5.3.4.a.	Refurbish and construct suitable laboratory facilities	x	x	x	x	x	MOH, RHA, Partners, Donors	Laboratory facilities refurbished and modernized to support

									testing needs
5.3.4.b.	Develop policy and guidelines for procurement and maintenance of equipment and consumables	x	x	x	x	x	MOH, Partners Donors Consultant		Policy and guidelines developed and implemented Decrease in stock outs
5.3.5.	Strengthen National Laboratory Oversight Committee	x	x	x	x	x	MOH PARTNERS DONORS Stakeholders		Improved networking of public and private labs Consensus decision making for national lab services
5.3.5.a.	Market and promote quality lab services nationally	x	x	x	x	x	MOH Partners Donors		

Chapter 6

Monitoring and Evaluation of the Laboratory Services

6.1 Strategic Objective

Establish a monitoring and evaluation system to measure the delivery of quality Laboratory Services from Regional and District Laboratories as well as the National Public Health Laboratory and provide the means for continual quality Improvement.

6.2 Challenges

- Lack of M&E tools specific to the Laboratory.
- Weak supervision and lack of commitment at the lower level health Facilities.
- Lack of qualified M&E personnel specific to the Laboratories.
- Lack of a relevant Laboratory Monitoring Policy.

6.3 Planned activities

6.3.X Establish a monitoring and evaluation system

- 6.3.X Develop monitoring and evaluation tools to assess Laboratory Services
- 6.3.X Develop an M&E training programme
- 6.3.X Establish a Laboratory Monitoring and Evaluation Training Advisory Committee
- 6.3.X Develop an effective support supervisory system
- 6.3.X Review supervisors job responsibilities in line with the revised scheme of service and establish a clear supervisory chain of command.
- 6.3.X Establish and Implement detailed M&E procedures.
- 6.3.X Provide applied public health laboratory documentation and collaboration of data.
- 6.3.X Promote collaboration of laboratory personnel in documentation of data.
- 6.3 Procurement of tools needed for the implementation of Monitoring and Evaluation system

Table 6: Monitoring and Evaluation of the Laboratory Services

Strategic objective Planned interventions		Time Frame (Year 2000)					Responsible partners	Outcomes and planned results
		08	09	10	11	12		
6.1.	Establish a monitoring and evaluation system							
6.	Develop monitoring and evaluation tools to assess Laboratory Services							
6.	Develop an M&E training programme							
6.	Establish a Laboratory Monitoring and Evaluation Training Advisory Committee							
6.	Develop an effective support supervisory system							
6.	Review supervisors job responsibilities in line with the revised scheme of service and establish a clear supervisory chain of command.							
6.	Establish and Implement detailed M&E procedures							
6.	Provide applied public health laboratory documentation and collaboration of data.							

6.	Promote collaboration of laboratory personnel in documentation of data							
6.	Procurement of tools needed for the implementation of Monitoring and Evaluation system							

Chapter 7
Policy, Legal and Regulatory Framework

7.1 Strategic Objective

Strengthen the legal and regulatory framework to support implementation of national laboratory policy

7.2 Challenges

- Weak regulatory and enforcement systems
- Various agencies engaged in separate training programmes
- Efficient dissemination of information

7.3 **Planned activities**

- 7.3.1 Strengthen the capacity of laboratories to certify institutions in accordance to GYS170:2003

- 7.3.2 Strengthen the capacity of laboratories to accredit institutions in accordance to ISO 15189

- 7.3.3 Develop scheme to evaluate, certify and register laboratory personnel

- 7.3.4 Establish and disseminate national standards for laboratory equipment & reagents

- 7.3.5 Develop a monitoring system to ensure laboratory equipment, reagents & kits confirm to nationally established standards

- 7.3.6 Develop standards for the relevant areas engaged in clinical and surveillance services such as environmental health, food safety and research

- 7.3.7 Adoption of any relevant standards by the SNBS in relation to laboratory services

- 7.3.8 Develop Quality Assurance (QA) and Continuous Quality Improvement (CQI) programmes for laboratory services validated by a number of laboratories in compliance with the relevant standards for operation

Table 7: Policy, Legal and Regulatory Framework

Strategic objective Planned interventions		Time Frame (Year 2000)					Responsible partners	Outcomes and planned results
		08	09	10	11	12		
7.3.1	Strengthen the capacity of laboratories to certify institutions in accordance to GYS170:2003	X	X	X	X	X	MOH-DSTS NPHRL SNBS	All public & private laboratories certified by the end of 2009
7.3.2	Strengthen the capacity of laboratories to accredit institutions in accordance to ISO 15189	X	X				MOH-DSTS NPHRL NLOC	The following laboratories - SPHC, NBTS, GDF, MultiTech, Balwant Singh, Eureka, St. Joseph Mercy - accredited to ISO 15189 by the end of 2009
7.3.3	Develop scheme to evaluate, certify and register laboratory personnel	X	X				MOH-DSTS NPHRL	All staff certified and registered by the end of 2008
7.3.4	Establish and disseminate national standards for laboratory equipment & reagents	X			X		MOH-DSTS NPHRL	Published standards approved by MOH
7.3.5	Develop a monitoring system to ensure laboratory equipment, reagents & kits conform to nationally established standards	X	X	X	X	X	MOH-DSTS NPHRL Hospital Inspectorate	Inspection of laboratories & means to address non-conformances
7.3.6	Develop standards for the relevant areas engaged in clinical and surveillance services such as environmental health, food safety and research	X		X		X	MOH-DSTS NPHRL Food & Drug Department	Standards developed, published and available to the national institutions
7.3.7	Adoption of any relevant standards by the SNBS in relation to laboratory services	X	X	X	X	X	SNBS	Availability of any new standards
7.3.8	Develop Quality Assurance (QA) and Continuous Quality Improvement (CQI) programmes for laboratory services validated by a number of laboratories in compliance with the relevant standards for operation	X	X	X			MOH-DSTS NPHRL SNBS Relevant Laboratories	QA & CQI programmes established & implemented in all labs by the end of 2009