Republic of Botswana

BOTSWANA NATIONAL HEALTH QUALITY STANDARDS FOR HOSPITALS

19.Laboratory Service

These forms are designed to be used by both hospital personnel and external surveyors. The following information must be provided after each survey, before submitting the completed survey forms.

1.NAME OF HOSPITAL/CLINIC/FACILITY:_____

2. BASELINE/INTERNAL SURVEY INFORMATION:

Title and name of person who completed this document: _____

Post and position held: _____

Date of survey: _____

3. EXTERNAL SURVEY INFORMATION:

Name of external surveyor: _____

Date of external survey: _____

GUIDE TO COMPLETION OF FORM

N.B. Hospital staff are please to use BLACK ink at all times. The external surveyors are requested to use RED ink at all times.

Please circle the rated compliance with the criterion, e.g. NA (Not applicable), NC (Non-compliant), PC (Partially compliant), C (Compliant).

The default category affected is designated on the form for each criterion as follows:

1. patient and staff safety
2. legality
3. patient care
4. efficiency
5. structure
6. basic management
7. basic process
8. evaluation

The seriousness of the default is designated on the form for each criterion as follows:

1. mild
2. moderate
3. serious
4. very serious

Documents Checked

Surveyor: .....

Surveyor: .....

19.1 Management of the Service

19.1.1 Standard

Laboratory services are available to meet the needs of patients in compliance with local and national laws, regulations and standards.

Standard Intent: The organisation has a system for providing the laboratory services, including clinical pathology services, required by its patient population, clinical services offered and health providers' needs.

The laboratory services are organised and provided in a manner that meet applicable local and national standards, laws and regulations.

Laboratory services, including those required for emergencies and after-hours, may be provided within the organisation, by agreement with another organisation or both if outside sources are convenient for the patient to access. The organisation selects outside sources based on the recommendations of the director or other individual responsible for laboratory services. Outside sources of laboratory services have an acceptable record of accurate, timely services. Patients are informed when an outside source of laboratory services is owned by the referring physician.

	Criterion	Comments Recommendations
Criterion 19.1.1.1 Critical: .. Catg: Basic Management + Patient Care **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Adequate, convenient and regular laboratory services are available to meet the organisation's needs.	
Criterion 19.1.1.2 Critical: .. Catg: Basic Management + Legality **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The laboratory services are organised and provided in a manner that meets applicable national standards, laws and regulations.	
Criterion 19.1.1.3 Critical: .. Catg: Basic Management + Patient Care **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Emergency laboratory services are available, including after-hours services.	

Criterion 19.1.1.4 Critical: .. Catg: Basic Management + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	A list of referral laboratories is available for tests not performed on site.	

19.1.2 Standard

A qualified individual is responsible for managing the laboratory service.

Standard Intent: The laboratory service is under the direction of a qualified person who has documented evidence of training, expertise and experience and who is registered by the Health Professions Council in accordance with applicable laws and regulations. This qualified person assumes professional responsibility for the laboratory facility and for the services provided. When this individual provides clinical consultations or medical opinions, he or she is a physician, preferably a pathologist. Speciality and subspecialty laboratory services are under the direction of appropriately qualified individuals. Responsibilities of the laboratory director/manager include the:

- ordering of tests
- collecting and identifying of specimens
- transporting, storing and preserving of specimens
- receiving, logging in and tracking of specimens.

These procedures are also observed for specimens sent to outside sources for testing.

	Criterion	Comments Recommendations
Criterion 19.1.2.1 Critical: .. Catg: Basic Management + Legality **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The laboratory is under the direction of a qualified individual.	
Criterion 19.1.2.2 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The responsibilities of this person include maintaining quality control programmes.	

Criterion 19.1.2.3 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The responsibilities of this person include administrative supervision.	
Criterion 19.1.2.4 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The responsibilities of this person include the monitoring and reviewing of all laboratory services.	
Criterion 19.1.2.5 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The responsibilities of this person include ordering and monitoring tests from outsourced laboratories.	
Criterion 19.1.2.6 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The responsibilities of this person include the ordering of equipment and the development of an equipment maintenance plan.	

19.1.3 Standard

Individuals with adequate training, skills, orientation and experience administer tests and interpret the results.

Standard Intent: The organisation identifies which laboratory personnel may perform testing and who may direct or supervise testing. Supervisory and technical personnel have appropriate and adequate training, experience and skills and are oriented to their work. Technical personnel are given work assignments consistent with their training and experience. In addition, there are a sufficient number of personnel to perform tests promptly and to provide the necessary laboratory staffing during all hours of operation and for emergencies.

The organisation is able to identify and contact experts in specialised diagnostic areas such as parasitology, cytology or virology, when needed.

	Criterion	Comments Recommendations
Criterion 19.1.3.1 Critical: .. Catg: Basic Management + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Those individuals who may perform testing and those who may direct or supervise testing are identified.	
Criterion 19.1.3.2 Critical: þ Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Appropriately trained and experienced personnel perform tests.	
Criterion 19.1.3.3 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Appropriately trained and experienced personnel interpret tests.	

Criterion 19.1.3.4 Critical: .. Catg: Basic Management + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	There is an adequate number of personnel to meet patient needs.	
Criterion 19.1.3.5 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	A roster of experts for specialised diagnostic areas is maintained.	

19.1.4 Standard

All laboratory equipment is regularly inspected, maintained and calibrated, and appropriate records are maintained for those activities.

Standard Intent: Laboratory personnel work to ensure that all equipment functions at acceptable levels and in a manner that is safe to the operator(s). A laboratory equipment management programme provides for:

- selecting, acquiring and replacing equipment
- identifying and taking an inventory of equipment
- assessing equipment use through inspection, testing, calibration and maintenance
- the monitoring of and acting on equipment hazard notices, recalls, reportable incidents, problems and failures, and
- documenting the management programme.

Testing, maintenance and calibration frequency are related to the laboratory's use of equipment and its documented history of service.

An individual is assigned responsibility for monitoring the temperature of the specimen refrigerator, which must be maintained between 2°C and 6°C, and other refrigerators in the laboratory.

	Criterion	Comments Recommendations
Criterion 19.1.4.1 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	There is a laboratory equipment management process.	

Criterion 19.1.4.2 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The process includes selecting, acquiring and replacing of equipment.	
Criterion 19.1.4.3 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The process includes taking an inventory of the equipment.	
Criterion 19.1.4.4 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The process includes the monitoring of environmental temperature at the prescribed level.	
Criterion 19.1.4.5 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The process includes inspecting and testing the equipment.	
Criterion 19.1.4.6 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The process includes calibrating and maintaining the equipment.	

Criterion 19.1.4.7 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	The process includes monitoring and follow-up of equipment maintenance.	
Criterion 19.1.4.8 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	There is adequate documentation of all testing, maintenance and calibration of equipment.	
Criterion 19.1.4.9 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	A named person is responsible for the specimen and reagent refrigerators.	

19.1.5 Standard

Essential reagents and other supplies are regularly available.

Standard Intent: The organisation has identified those reagents and supplies necessary to regularly provide laboratory services to its patients. A process to order or secure those essential reagents and other supplies is effective. All reagents are stored and dispensed according to defined procedures. The periodic evaluation of all reagents ensures accuracy and precision of results. Written guidelines ensure the complete and accurate labeling of reagents and solutions.

	Criterion	Comments Recommendations
Criterion 19.1.5.1 Critical: .. Catg: Basic Management + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	Essential reagents and supplies are identified.	

Criterion 19.1.5.2 Critical: .. Catg: Basic Management + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Essential reagents and supplies are available.	
Criterion 19.1.5.3 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	All reagents are stored and disposed of according to guidelines.	
Criterion 19.1.5.4 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	All reagents are periodically evaluated for accuracy and precision of results.	
Criterion 19.1.5.5 Critical: .. Catg: Basic Process + Legality **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	All reagents and solutions are completely and accurately labelled.	

19.2 Management of Specimens and Results

19.2.1 Standard

Procedures for collecting, identifying, safely transporting and disposing of specimens are followed.

Standard Intent: Procedures are developed and implemented for the:

- ordering of tests
- collecting and identifying of specimens
- transporting, storing and preserving of specimens, and
- receiving, logging in and tracking of specimens.

The procedures are observed for specimens sent to outside sources for testing as well as for on-site laboratories.

Records are kept of when results have been telephoned, at what time and to whom.

	Criterion	Comments Recommendations
Criterion 19.2.1.1 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Request forms and specimen labels include unique patient identification and adequate supporting information.	
Criterion 19.2.1.2 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	There is a daily collection and delivery service for specimens from the organisation.	
Criterion 19.2.1.3 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Specimens are given a laboratory specimen number.	

Criterion 19.2.1.4 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Procedures guide the ordering of tests.	
Criterion 19.2.1.5 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Procedures guide the collection and identification of specimens.	
Criterion 19.2.1.6 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Procedures guide the transport, storage and preservation of specimens.	
Criterion 19.2.1.7 Critical: b Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Procedures guide receiving, logging-in and tracking specimens.	

19.2.2 Standard

Established reference ranges are used to interpret and report clinical laboratory results.

Standard Intent: The laboratory establishes reference intervals or "normal" ranges for each test performed according to national/international standards. The range is included in the clinical record, either as part of the report or by including a current listing of such values, approved by the laboratory director/manager. Ranges are furnished when an outside source performs the test. The reference ranges are appropriate to the organisation's patient population and are reviewed and updated when methods change.

	Criterion	Comments Recommendations
Criterion 19.2.2.1 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The laboratory has national reference ranges for each test performed.	
Criterion 19.2.2.2 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The range is included in the clinical record at the time test results are reported.	
Criterion 19.2.2.3 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Ranges are furnished when tests are performed by outside sources.	
Criterion 19.2.2.4 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Ranges are reviewed and updated, as needed.	

19.2.3 Standard

Policies and procedures regarding the reporting and reviewing of results are implemented.

	Criterion	Comments Recommendations
Criterion 19.2.3.1 Critical: .. Catg: Basic Management + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	The organisation has established the expected turnaround time for results.	
Criterion 19.2.3.2 Critical: .. Catg: Basic Process + Patient Care **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	Laboratory results are reported within a time frame to meet patient needs.	
Criterion 19.2.3.3 Critical: .. Catg: Basic Process + Patient Care **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	Emergency results may be obtained by telephone.	
Criterion 19.2.3.4 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	Laboratory results are validated and include unique patient identity, date of testing/reporting and name and location of requesting physician.	
Criterion 19.2.3.5 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	The validating officer is identified and recorded.	

Criterion 19.2.3.6 Critical: b Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	There is a record of each test done, by whom, the result thereof and a monthly summary.	

19.3 Quality Improvement

19.3.1 Standard

A formalised proactive quality improvement approach is maintained in the service.

Standard Intent: This refers to the implementation of organisational quality improvement processes (Service Element 8).

It is the responsibility of management of the organisation to ensure that standards are set throughout the organisation. Within each department or service, it is the responsibility of managers to ensure that standards are set for the particular department. This requires coordination with the organisation's central/management/coordinating quality improvement structures or systems. Departmental managers use available data and information to identify priority areas for quality monitoring and improvement.

The following will be evaluated:

- problems identified in this service for which quality improvement activities were initiated
- the processes put in place to resolve the problems
- the identification of indicators to measure improvement
- the tool(s) used to evaluate these indicators
- the monitoring of these indicators and corrective steps taken when goals were not achieved
- graphed and/or tabled results, as appropriate.

A once-off project such as acquiring a specific item of equipment will be scored NC. Quality improvement processes not related to the clinical quality of patient care but to the environment within which care is provided, for example monitoring the temperature of the refrigerator over time, will be scored PC.

	Criterion	Comments Recommendations
Criterion 19.3.1.1 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	There are formalised quality improvement processes for the service that have been developed and agreed upon by the personnel of the service.	

Criterion 19.3.1.2 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Indicators of performance are identified to evaluate the quality of treatment and patient care.	
Criterion 19.3.1.3 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The quality improvement cycle includes the monitoring and evaluation of the standards set and the remedial action implemented.	
Criterion 19.3.1.4 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	A documentation audit system is in place.	
Criterion 19.3.1.5 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	An internal audit process for the laboratory services is implemented.	
Criterion 19.3.1.6 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	An external audit process for the laboratory services is implemented.	

19.3.2 Standard

There is a quality management plan for the execution of all laboratory quality control processes.

Standard Intent: Sound quality control systems are essential to providing excellent pathology and clinical laboratory services. Quality control procedures include:
a) validation of the test methods used for accuracy, precision and reportable range
b) daily surveillance of results by qualified laboratory personnel
c) rapid corrective action when a deficiency is identified
d) testing of reagents
e) documentation of results and corrective actions.

Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methodologies. Such testing can identify performance problems not recognised by internal mechanisms. Thus, the laboratory participates in an approved proficiency testing programme when available. Alternatively, when approved programmes are not available, the laboratory exchanges samples with a laboratory in another organisation for purposes of peer comparison testing. The laboratory maintains a cumulative record of participation in a proficiency testing process. Proficiency testing, or an alternative, is carried out for all speciality laboratory programmes, when available.

	Criterion	Comments Recommendations
Criterion 19.3.2.1 Critical: .. Catg: Evaluation + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	There is a quality control process for the clinical laboratory.	
Criterion 19.3.2.2 Critical: .. Catg: Evaluation + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	The processes include the validation of test methods.	
Criterion 19.3.2.3 Critical: .. Catg: Evaluation + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	The processes include the daily monitoring of test results.	

Criterion 19.3.2.4 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The processes include the rapid correction of deficiencies.	
Criterion 19.3.2.5 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The processes include the documentation of results, plus preventive and corrective actions.	
Criterion 19.3.2.6 Critical: þ Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The laboratory participates in a proficiency testing programme, or an alternative, for all speciality laboratory services and tests.	
Criterion 19.3.2.7 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	A cumulative record of participation is maintained.	
Criterion 19.3.2.8 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The organisation regularly reviews quality control results from all outside sources of laboratory services.	

19.4 Patient Rights

19.4.1 Standard

The department/service implements processes that support patient and family rights during care.

Standard Intent: This refers to the implementation of organisational policies on patient and family rights (Service Element 5).

Compliance will be verified during observation of patient care processes, patient record audits and patient interviews.

	Criterion	Comments Recommendations
Criterion 19.4.1.1 Critical: .. Catg: Basic Management + Patient Care **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	There are processes that support patient and family rights during care.	
Criterion 19.4.1.2 Critical: .. Catg: Basic Process + Patient Care **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	Measures are taken to protect the patient's privacy, person and possessions.	
Criterion 19.4.1.3 Critical: .. Catg: Basic Process + Patient Care **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	The personnel respect the rights of patients and families to treatment and to refuse treatment.	

19.5 Prevention and Control of Infection

19.5.1 Standard

The department/service implements infection prevention and control processes.

Standard Intent: This refers to the implementation of organisational processes for infection prevention and control (Service Element 9).

	Criterion	Comments Recommendations
Criterion 19.5.1.1 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The department identifies the procedures and processes associated with the risk of infection and implements strategies to reduce risk.	
Criterion 19.5.1.2 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Individuals who handle specimens are trained in the proper handling of dangerous specimens.	

19.6 Risk Management

19.6.1 Standard

The department/service implements risk management processes.

Standard Intent: This refers to the implementation of organisational risk management processes (Service Element 7).

	Criterion	Comments Recommendations
Criterion 19.6.1.1 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The department conducts on-going monitoring of risks through documented assessments as part of organisational risk management processes.	

Criterion 19.6.1.2 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	A system for monitoring incidents/near misses/sentinel/adverse events is available and includes the documentation of interventions and responses to recorded incidents.	
Criterion 19.6.1.3 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Security measures are in place and are implemented to ensure the safety of patients, personnel and visitors.	
Criterion 19.6.1.4 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Fire safety measures are implemented.	
Criterion 19.6.1.5 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The organisation's policy on handling, storing and disposing of health waste is implemented.	