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BOTSWANA HARVARD AIDS INSTITUTE PARTNERSHIP FOR HIV RESEARCH AND EDUCATION

Quality Manual

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Authorized by

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Name, Title, Signature, Date

Copy Number: _____

I. Document Control

The Master Copy of the Quality Manual and SOPs will be filed in the Quality Management Office. Controlled copies are numbered and stamped "Controlled" in red ink. Uncontrolled copies are marked "Uncontrolled" in black ink, and may only be issued under special circumstances, for example; to assessment bodies, study sponsors and potential clients upon request

If this SOP appears inadequate or outdated it is the responsibility of all staff to bring this to the attention of their Supervisor immediately.

II. Training Record

The training record for this manual is filed with the master copy of the manual in the Quality Assurance Manager's Office.

III. Security Statement

This SOP is the intellectual property of the BHHRL Quality Assurance Unit within BHP and as such, must not be circulated outside of BHHRL without written approval from the Director, Quality Assurance Manager, Laboratory Manager and the Author of this procedure.

Purpose and Scope

This Quality Manual (QM) communicates the policies, processes, and practices of Botswana-Harvard HIV Reference (BHHRL). It has been established to provide guidance to the laboratory and other stakeholders on the laboratory's endeavours to attain consistently accurate and timely results, meet customer/stakeholder needs and expectations, as well as efficiently and effectively execute its functions.

The Manual includes the history of BHHRL and the scope of its operations, the scope of Quality Management System (QMS). It also gives an overview of initiatives undertaken by BHHRL to meet the requirements of the ISO/IEC 15189: 2012 international standard, GCLP and other local/international requirements in a bid to consistently meet the requirements of its customers/stakeholders and fulfil its stated mission and vision. The documented supporting procedures established for the QMS are referenced in this Manual.

Normative References

ISO 15189, Medical laboratories – Requirements for quality and competence

ISO/IEC 17000, Conformity assessment – Vocabulary and general principles

ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories

BOTSWANA HARVARD AIDS INSTITUTE PARTNERSHIP FOR HIV RESEARCH AND EDUCATION

1. TABLE OF CONTENTS

2. OVERVIEW OF THE ORGANIZATION

2.1. Background of the BHHRL

The BHHRL was formed following a 1996 collaborative partnership agreement between the Harvard AIDS Institute (HAI) and the Ministry of Health & Wellness (MOH); established as part of the national response to the HIV epidemic, forming the Botswana-Harvard AIDS Institute Partnership (BHP). BHHRL was officially opened on December 1, 2001, and functions as the HIV Reference Laboratory for the Ministry of Health, and also conducting collaborative research through the framework of memorandum of agreement with BHP that is renewed every 5 years.

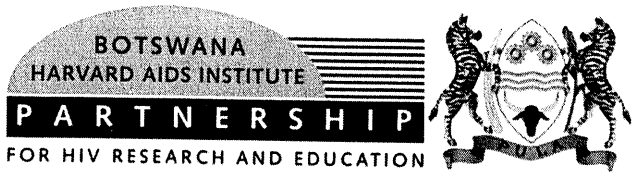
The BHHRL is located at Plot 1836 North Ring Road, Gaborone, Botswana, on the grounds of the main public referral hospital in Botswana, Princess Marina Hospital. It is one the largest HIV reference and research laboratory of its kind in Sub Saharan Africa, capable of undertaking sophisticated HIV related research and training. The building is a three-floor, 25,000 square foot facility consisting of laboratory and office space, conference rooms, and storage and service areas. The laboratory area consists of 18 rooms with different functions.

2.2. Laboratory services

The BHHRL provides medical laboratory testing services mainly to BHP study clinics and MOH IDCC Clinics in Gaborone and surrounding areas. The laboratory provides testing in the following specialties: Molecular Virology (Quantitative PCR & Qualitative PCR), HIV genotyping (Drug Resistance), Flow Cytometry (CD4), Haematology, Clinical Chemistry, Serology, Epidemiological Surveillance, SARS CoV-2 and Research specialties (including clinical trials processing, biorepository, Peripheral Blood Mononuclear Cell Isolations (PBMC). The laboratory also participates in National Public Health activities such surveillance programs, methods development, verification and evaluation of equipment and methods.

2.3. History of the Quality Management System

The BHHRL was in the forefront of the fight against HIV since its establishment and official opening in December 1, 2001. In 2002, BHHRL offered its services to the first HIV adult treatment study, that began a pilot and launching site for the National ARV program, called MASA ("dawn"). BHHRL began to implement Good Clinical Laboratory Practice (GCLP) in 2002 to provide international standards for both patients in the ARV program and participants enrolled in the studies. In 2003, BHHRL adopted GCLP & the ISO 17025 standard as interpreted for medical laboratories. At the time ISO 15189 was not yet developed as clinical laboratories were using this standard to design and implement quality management systems. Under this framework, BHHRL received annual sponsor and regulatory audits since 2003 and was recognised by international clinical trials bodies for competency to conduct regulated clinical trials. In December 2010, BHHRL received International Accreditation to ISO 17025 and continues to participates in regulated clinical trials, surveillance studies, reference testing and clinical care testing for national ARV program. BHHRL thereafter transitioned to ISO 15189 ,initial assessment was conducted October 2018 and the laboratory has been accredited by SADCAS. Over the years BHHRL has participated built a vibrant basic science research program for training scientists from undergraduate, masters and PhD degrees while participating in various programs of national interests and has become a regional centre for HIV laboratory medicine.



2.4. Our vision, mission and core values

The BHHRL operates within a broader mandate of the collaborative agreement between The Harvard School of Public Health(HSPH), The Government of Botswana (GoB) through the Ministry of Health and Wellness (MoH) and the Botswana Harvard Partnership (BHP). The Vision, Mission and Core Values of BHHRL represent the strategic foundations of the collaborating institutions.

Our Vision
To be a world renowned HIV Reference Laboratory

Our Mission
BHHRL is dedicated to provide accurate, reliable and timely laboratory results to all its customers – through innovative diagnostics, research and training, and internationally recognised good clinical laboratory practices, and contributing to the national health care strategy.

Our Core values
BHHRL is committed to the principles of openness, integrity and accountability in its dealings with all its customers. Management affirms that the laboratory has applied and complied with the outlined principles and ethics, which are in line with the Ministry of Health & BHP core values.

BOTHO

An encompassing Setswana word which means, amongst others, integrity, respect, honesty and compassion. We are committed to adhering to moral and ethical principles, treating all our customers, including patients and research participants, with respect, dignity and compassion. All information collected by BHHRL will be handled with utmost confidentiality. We shall be guided by the principle of "Do Not Harm" in our diagnostic, research and related activities.

EXCELLENCE

To achieve our vision of being a "world HIV reference laboratory" we at BHHRL commit to quality driven laboratory processes, research and training programmes. We will be second to none in our drive to attain sustainable quality in all our processes.

2.5. Our Strategic Objectives

As of January 2018, the BHHRL is in the process of drawing up a five year strategic plan to run from April 2018 to March 2023. The plan is driven by a set of strategic objectives that are derived from and are consistent with the thematic areas of the BHP Strategic Plan 2017-2022 and the MoH Strategic Plan being:

a) Customer Service Excellence

b) Research Excellence

c) Quality Assurance

d) Financial Sustainability

e) Organizational Efficiency

f) Learning and growth.

3. ABBREVIATIONS, TERMS AND DEFINITIONS

3.1. Abbreviations

a)	BHP	Botswana Harvard Partnership
b)	BHPC	Botswana Health Professions Council
c)	BMLPS	Botswana Medical Laboratory Practice Standards
d)	CMS	Central Medical Stores
e)	EQA	External Quality Assessment
f)	HAI	Harvard AIDS Institute
g)	IPMS	Integrated Patient Management System
h)	ISO	International Organization for Standardization
i)	LIMS	Laboratory Information Management System
j)	MoH	Ministry of Health
k)	QMS	Quality Management System
l)	SADCAS	Southern African Development Community Accreditation Services
m)	SOPs	Standard Operating Procedures
n)	TAT	Turn-around time

3.2. Terms and Definitions

a) Accreditation – Procedure by which an authoritative body gives formal recognition that a body is competent to carry out specific tasks.

b) Alert interval – Interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death

c) Biological reference interval – Specified interval of the distrbution of the values taken from a biological reference population

d) Calibration - The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system or values represented by a material measure, and the corresponding known values of a reference standard.

e) Clinical decision value – is a flag or warning, which indicates that it is time to take some action (investigate, perform maintenance, etc.).

f) Competence - Demonstrated ability to apply knowledge and skill.

g) Continual Improvement - The measures taken to assess the effectiveness of the laboratory's management system is improving by using the following activities: internal audits; management reviews; analysis of quality control data; corrective actions; preventive actions; the quality policy; and the quality objectives.

h) Corrective action - Action taken to eliminate the root cause of an identified nonconformity or other undesirable situation

i) Customer – Clinicians and patients

j) Downtime - The period when the services are interrupted

k) Examination Procedures - Activities and steps related to performing laboratory tests.

l) External Quality Assessment - A program that allows laboratories to assess the quality of their performance by comparison of their results with other laboratories through analyzing proficiency panels, or blind rechecking.

m) Lab director – Person(s) with resposibility for, and authority over, a laboratory(defined in the lab organogram)

n) Lab management – Person(s) who direct and manage the activities of a laborator (defined in the lab organogram)

o) Laboratory access control system – A method for preventing unauthorized access to a laboratory facility, e.g. visitors book, locked doors, signage, etc.

p) Non-Conformity - The non fulfillment of specified requirements.

q) Performance characteristics: include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity, including interfering substances, analytical sensitivity, detection limit and quantization limit, measuring interval, diagnostic specificity and diagnostic sensitivity.

r) Post-examination Procedures - All processes following laboratory testing including interpretation, authorization for release, reporting of results, transmission of results, and storage of samples

s) Post-examination processes (Post-analytical phase) - Processes that follow the examination, including: review of results, retention and storage of clinical material, sample (and waste) disposal, formatting, releasing, reporting and retention of examination results.

t) Pre-examination procedures - Steps starting from clinician's request, patient preparation, Specimen collection, transportation to and within the laboratory and ending when analytical process starts

u) Pre-examination processes (Pre-analytical phase) - Processes that start, in chronological order, from the clinician's request and include: the examination request, preparation and identification of the patient, collection of the primary sample(s), transportation to and within the laboratory, and end when the analytical examination begins.

v) Preventive Action - This is an endeavor taken to eliminate the cause of a potential nonconformity or other potentially undesirable situation to prevent occurrence. This is a proactive process.

w) Primary sample (specimen) - Discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole.

x) Procedure – specified way to carry out an activity or a process

y) Process – set of interalated or interacting activities which tranforms input into outputs. An output of one process can be an input of another process.

z) Quality – A degree to which a set of inherent characteristics fulfills requirements.

aa) Quality Assurance - Part of quality management focused on providing confidence that quality requirements will be fullfilled.

bb) Quality Audit - A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. Audit criteria are a set of policies, procedures or requirements.

cc) Quality Control - The operational techniques and activities that are used to fulfill requirements for quality

dd) Quality indicator – Measure of the degree to which a set of inherent characteristics fulfils the requirement

ee) Quality Management - Coordinated activities to direct and control an organization with regard to quality

ff) Quality Management System - Management system to direct and control an organization with regard to quality.

gg) Quality Manager - An individual with delegated responsibility and authority to ensure compliance with the quality management system.

hh) Quality Manual - Describes the quality management system in use by an organization.

ii) Quality Policy Statement - Overall intentions and direction of an organization related to quality as formally expressed and authorized by top management.

jj) Record - Any information that produces evidence (e.g. requests, examination results and reports, instrument printouts, laboratory workbooks and worksheets, accession records, calibration records, quality control records, audit records, complaints and action taken, external quality assessment records, instrument maintenance records, incident / accident reports, staff training and competency records, personnel records).

kk) Referral lab – external laboratory to which a sample is submitted for examination (Another MoH Lab is regarded as a referral)

ll) Specification - Document that states the requirements to which the product, service, or test method has to conform.

mm) Standard Operating Procedures - Detailed explanation of how a policy is to be implemented in order to achieve uniformity of the performance of a specific function (Who, What, Where, When, and Why).

nn) Support Staff – Non technical staff involved in laboratory processes (such as Cleaners, Lab Aide, Health Care Auxiliary, Data Clerk, hospital orderly and Phlebotomist)

oo) Technical staff – Analyst

pp) Top management – Senior most staff members who direct and manage the activities of a laboratory services (defined in the lab organogram)

qq) Traceability - Ability to trace the history, application or location of an item, activity or result by means of documented records.

rr) Turn Around Time - The interval between specimen receipt by the laboratory personnel and releasing of results.

ss) Validation - The act of confirming that a product, service, or test method meets the requirements for which it was intended.

tt) Verification – Confirmation ,though provision of objective evidence, that the requirements have been fulfilled

uu) Work Instructions - Actions or operations which have to be executed in the same manner in order to achieve intended results under the same circumstances (How).

4. MANAGEMENT REQUIREMENTS

4.1. Organization and management responsibility

4.1.1.Organization

4.1.1.1. General

The BHHRL complies with the requirements of BOS ISO15189:2012 and DAIDS GCLP standards and applies this Quality Management System when carrying out work at its permanent facilities, or in associated or mobile facilities.

4.1.1.1. Legal entity

The BHHRL was formed out a collaborative agreement between the Harvard AIDS Institute (HAI) and the Government of Botswana (GoB).

The Harvard AIDS Institute (HAI), the Botswana Harvard Partnership (BHP) and the Government of Botswana are jointly responsible for the activities of the BHHRL.

The specific obligations of each party to the partnership are outlined in the memorandum of agreement.

Supporting Document(s)
Memorandum of Agreement, BHP company registration, BHHRL Governance Document

4.1.1.2. Ethical conduct

The BHHRL is committed to ethical conduct. Special arrangements have been put in place to protect the BHHRL from any involvement in activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity.

Laboratory personnel are protected from any undue commercial, financial, or other pressures and influences that could adversely affect the quality of their work and independence of professional judgement. Where potential conflict in competing interests exists, they are openly declared through the appropriate channels, and then measures are put in place to maintain the integrity of work processes involved.

All personnel are required to undergo training and maintain competence in Good Clinical Practice and the Protection of Human Subjects in Research.

All personnel understand that they have an individual responsibility to access, read, understand, and comply with the following country laws, professional regulations, guidelines and codes of ethics governing medical laboratory practice:

i. Health Professions Council Act

ii. Botswana Health Professions Council (BHPC) Code of Conduct/Ethics

iii. Botswana Medical Laboratory Practice Standards (BMLPS)

To ensure confidentiality of information, personnel access to confidential information is limited to that which is within their scope work, and only to an extent necessary for the effective performance of their duties. All staff are required to sign a declaration of confidentiality on employment, which prohibits the unauthorized distribution, sharing or disclosure of confidential information.

Supporting Document(s)
FR01 Declaration of Confidentiality

4.1.1.3. Laboratory Director

The BHP Executive Management appoints a Laboratory Director (hereinafter "the Director"), who has the qualifications, experience, competence and delegated responsibility for the services provided by the BHHRL.

The responsibilities of the Director include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.

The Director may delegate selected duties and/or responsibilities to qualified personnel; however, he/she maintains ultimate responsibility and accountability for the overall operation and administration of the laboratory.

The duties and responsibilities of Director are documented in the Laboratory Director Job Profile.

The Director (or designates for delegated duties) have the necessary competence, authority and resources to fulfil the requirement of this Quality Management System.

Supporting Document(s)
FR02 Laboratory Director Job Profile

4.1.2.Management responsibility

4.1.2.1. Management commitment

The BHHRL Management demonstrates commitment to the development and implementation of the quality management system; and to continually improve its effectiveness by:

a) Communicating and taking reasonable steps to ensuring compliance with statutory, regulatory and accreditation requirements for quality

b) Ensuring that all personnel are aware of and comply with the needs and requirements of users of laboratory services.

c) Establishing and periodically reviewing of the laboratory quality policy and objectives.

d) Defining the responsibilities, authorities and interrelationships of all personnel.

e) Establishing effective communication processes; and taking reasonable steps to remove any barriers to effective communication

f) Appointing a Quality Assurance Manager

g) Conducting annual review of quality management system

h) Ensuring that qualified, trained and competent personnel are assigned to specific positions or activities.

i) Ensuring adequate resources are availed to enable the proper conduct and monitoring of pre-examination, examination and post-examination activities.

4.1.2.2. Needs of users

The BHHRL understands the value and contribution of users and customers to organizational success. Management therefore strives to systematically identify current and future customer needs; to understand and meet customer requirements; and to exceed customer expectations. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate officers within the laboratory. Further to this, the laboratory undertakes customer and employee satisfaction activities and the Laboratory Managers formally avail information on customer and employee perception through Management Review meetings.

4.1.2.3. Quality policy statement

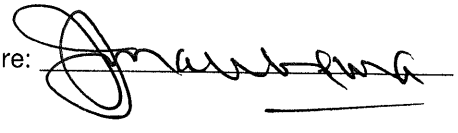
The intent of the BHHRL Quality Management System is outlined in the Quality Policy Statement:

Quality Policy Statement

BHHRL Management is committed to the provision of medical laboratory services of a high international standard which are in line with the principles of good professional medical laboratory practice. We commit to continuously improve our services whilst complying with the quality management system requirements of ISO15189:2012, DAIDS GCLP and all applicable statutory requirements and regulations that govern medical laboratory practice. We only use test methods that have been verified as fit for intended use, and we do not deviate from our documented procedures. We value employee satisfaction, and recognize it as an antecedent to customer satisfaction and organizational growth. Our path to excellence is guided by this quality policy and quality system objectives, which are reviewed periodically for continued suitability. This quality policy is communicated, understood and applied throughout, and at all levels within the organization.

Dr. Joseph. M. Makhema

Chief Executive Officer

Signature:  Date: 16 Dec 2021

4.1.2.4. Quality Objectives and Planning

The BHHRL has established a balanced set of measurable quality management system objectives that are consistent with, and support the quality policy. The quality objectives form a critical part of the laboratory's performance management.

The objectives, and the extent to which they are achieved is continually monitored, reviewed and where necessary, revised on an annual basis.

Any proposed changes to the quality management system are discussed and agreed to by the quality management to ensure the integrity of the system is not compromised.

Supporting Document(s)
FR03 Quality Management System Objectives

4.1.2.5. Responsibility, authority and interrelationships

a) Personnel responsibilities, authorities and interrelationships are defined and communicated within the organization through the organogram, position profiles and within standard operating procedures.

b) The BHHRL Management ensures that an up-to-date organogram is in place, that defines the organization and management structure of the laboratory as well as the relationship between Quality Management, Technical operations and Support services.

c) BHHRL Executive Management has appoints a technical manager, known as the Laboratory Manager who has the overall responsibility for the technical operations and provision of the resources needed to ensure the required quality of laboratory operations. The Laboratory Manager ensures that section 4 of the Quality Manual is implemented and maintained

d) The BHP Executive Management appoints a Quality Manager who has the defined responsibility and authority for ensuring the that the Quality Management System is understood, implemented and followed at all times by all personnel and has direct access to the highest level of management at which decisions are made on laboratory policies and resources. Working with the Quality Assurance Unit (QAU), The Quality Manager ensures that section 3 of the Quality Manual is implemented and maintained.

e) To ensure that activities flow in an uninterrupted manner, BHHRL management appoints deputies for key managerial personnel as shown in the Laboratory Roster. Management is committed to provision of adequate supervision for testing staff including those on training, by personnel familiar with methods and procedures, purpose of the test and with assessment of the test.

Supporting Document(s)
FR04 Organizational Structure, FR05 Laboratory Roster, FR06 Laboratory Manager Position Profile, FR07 Quality Assurance Manager Position Profile

4.1.2.6. Communication

a) General

Management is aware of the importance of efficient and effective communication within the laboratory, and is therefore committed to ensuring:

1) that communication channels are available to staff, that include, but are not limited to, meetings, memos, email, notices on boards, staff surveys, and confidential suggestion box.

2) that communication takes place regarding the effectiveness of the quality management system. Staff are also encouraged to communicate to their supervisors all matters that impact adversely on the quality management process.

3) that all communication critical to quality is documented and records are maintained.

4) continually review of the effectiveness of communication channels within the laboratory; and taking reasonable steps to remove any barriers to effective communication

5) that personnel are aware of the relevance and importance of their activities; and how they contribute to the achievement of Quality Management System Objectives.

All staff are issued with a bhp.org.bw e-mail address on appointment, and are expected to check their mail at least twice a day, once in the morning and once in the afternoon.

To ensure that the laboratory designs, implements and maintains an effective management system that exhibits staff ownership, the management is committed to involving the staff as widely as possible in all the different development and maintenance phases of the QMS.

b) Communication with External Stakeholders

Laboratory staff is authorised to communicate with clients by phone on technical matters pertaining to work-in-progress, the information which should be within the scope of their responsibility.

Telephonic communication pertaining to managerial matters with stakeholders and customers is exclusively, depending on specific issue and source, by the Laboratory Director/Designee, Laboratory Manager, Technical Supervisors/Coordinators, and the Quality Manager/Designee.

All staff are forbidden from speaking in their capacity as BHHRL staff to members of the media or the press.

All staff are strictly forbidden from publishing on social media any material or opinion purporting to be, or that can be wrongly construed as representing the opinion or position of BHHRL on any matters unless specifically authorised to do so.

Communication of test results is governed by the Release of Results SOP (**PR19**)

4.1.2.7. Quality Manager

The BHP Executive Management has appointed a Quality Assurance Manager who has direct access to the highest executive level; who is head of the QAU; whose responsibilities and authorities include, but not limited to:

a) Ensuring that processes and procedures needed for the quality management system are established, effectively implemented and maintained.

b) Advising laboratory management and reporting to executive management on the performance of the laboratory quality management system and on any need for improvement.

c) Appointing and supervising members of the Quality Assurance Unit (Quality Officers, Safety Officers, Internal Auditors) to ensure specific QAU activities are effectively implemented.

To ensure objectivity and independence of professional judgement, the Quality Assurance Manager and the Quality Assurance Unit work independent of laboratory technical operations.

Supporting Document(s)
FR07 Quality Assurance Manager Job Profile, FR08 Safety Officer Job Profile

4.2. Quality Management System (QMS)

4.2.1. General requirements

The BHHRL has established and continuously reviews the sequence and interaction of Quality Management System processes; and the criteria and methods needed to ensure that both the operation and control of these processes are effective.

4.2.2. Documentation requirements

4.2.2.1. General

The Quality Management System operates with, and through several documents which support one another to fulfil the different sets of standards. The hierarchy of the documentation of the system is as shown in the four tier pyramid in figure 1 below, consisting of normative documents, laboratory quality manual, standard operating procedures, work instructions, and forms, reports, records, etc.

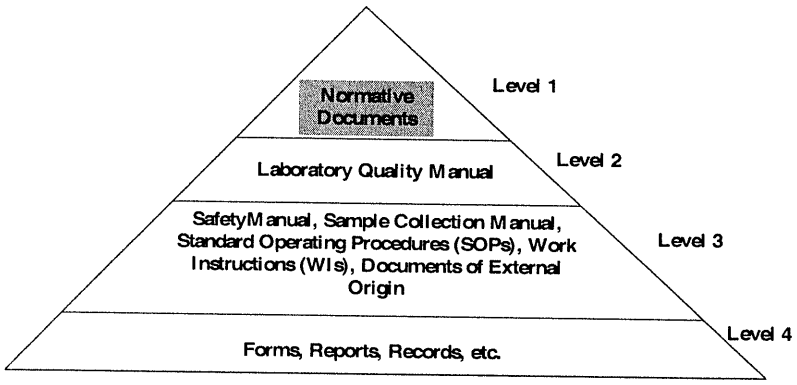


Figure 1: Laboratory quality management system documentation structure

Level 1: These are normative documents, i.e. those pertaining to, or prescribing a law, standard, or norm.

Level 2: The laboratory quality manual describes the quality management system through a series of policy statements and is the primary documentation of a quality management system. Related documents are referenced as appropriate.

Level 3: Includes safety manual, sample collection manual, standard operating procedures, work instructions and documents of external origin. These are documents which provide detailed explanation of how a policy, in the laboratory quality manual is to be implemented in order to achieve

uniformity of the performance of a specific function. They specify the Who, What, Where, When, and Why.

Level 4: Is made up or forms, reports, records, etc. These documents provide current and historic evidence of the status activities and processes within the QMS. They include, but are not limited to worksheets, computer printouts, labels, record books and tags that provide evidence of activities performed.

4.2.2.2. Quality manual

The Quality Manual is the principal document that defines the Quality Management System of BHHRL. It contains

a) documented statements of the laboratory's Quality Policy and Quality Objectives,

b) a description of the scope of the Quality Management System

c) a description of the organizational structure of the BHHRL

d) a description of the roles and responsibilities of the laboratory management (including the laboratory director and quality assurance manager)

e) Quality Management System policies with references to management and technical activities and procedures to support them

All BHHRL staff have access to, and are instructed on the use and application of the Quality Manual and referenced documents.

Laboratory management and staff have a shared responsibility to ensure that all staff are trained on the Quality Manual and apply it in their work processes.

The Quality Manual is reviewed at every two (2) years, or earlier as necessary.

4.3. Document control

The laboratory controls the development, distribution, review, and revision of the documents that make up its Quality Management System to ensure that only current, authorized editions of applicable documents are available at points of use.

The Quality Assurance Manager is responsible for all aspects of the document control system.

Supporting Document(s)
PR01 Document Control

4.4. Service agreements

4.4.1.Establishment of service agreements

The BHHRL may enter into a formal service agreement with a user or client to provide laboratory services under specified terms and conditions, for example, to support a clinical trial.

An informal agreement with a user or client is established when a requisition placed using a manual requisition form or electronic order is accepted for testing at the BHHRL. The BHHRL does not accept verbal requisitions or third party requisition forms.

The BHHRL only enters into service agreements where it has determined that it has the capability and resources to deliver on its obligations under the contract; and to meet the customer's and any other requirements for quality.

The BHHRL immediately informs customers and users of any deviations from an agreement that may impact on any aspect of examination results, e.g. test method, analytical quality, referral to ther lab, turnaround time etc.

The testing services offered by the BHHRL are defined in the Laboratory Test Menu (**FR18**) which has been made available to all users.

A documented procedure for the establishment and review of service agreements is maintained.

Supporting document(s)
PR02 Service Agreements, FR18 Test Menu & Back-Up Plan Laboratory Requisition Forms

4.4.2. Review of service agreements

All service agreements are subject to continual review. Reviews include all aspects of the agreement. Records of review are maintained, including a record of any changes to the agreement, any pertinent discussions or actions arising from these reviews.

All requisitions for medical laboratory services are reviewed upon receipt.

When an agreement needs to be amended after laboratory services are commenced, the same review process is repeated and any amendments is communicated in writing to all affected parties.

4.5. Examination by referral laboratories

4.5.1. Selecting and evaluating referral laboratories and consultants

Any work that is referred is placed with competent laboratories that are compliant with the requirements of this Quality Management System, ISO/IEC 17025:2017, ISO/IEC 15189:2012 or some other recognized quality management system. Referral Laboratories are listed on the Approved Supplier List (**FR14**).

In addition, all clinical trials work may only be referred to laboratories that are compliant with the quality management system requirements of DAIDS GCLP.

Referral laboratories are evaluated, selected and monitored by BHHRL management except in cases where the client or regulatory agency specifies which referral laboratory is to be used.

The general requirements and responsibilities for selecting and evaluating referral laboratories and consultants are described in the Examination by Referral Laboratories procedure.

Supporting Document(s)
PR03 Examination by Referral Laboratories

4.5.2. Provision of examination results

The BHHRL retains responsibility for ensuring that the results of tests undertaken by referral laboratories are provided to the test requester.

Any referral tests undertaken are clearly identified as having been generated by the referral laboratory on the report issued to the test requester. The BHHRL does not under any circumstances report or give an impression that the work has been carried out by itself.

4.6. External services and supplies

The BHHRL uses only such services and supplies that are of the quality needed to sustain confidence in the results of tests carried out. To assure this, the BHHRL selects and approves suppliers based only on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory requirements. The performance of suppliers is monitored to ensure that purchased services or items consistently meet the stated criteria.

Specific requirements for manging external services and supplies are described in the External Services and Supplies SOP.

For purposes of this clause, the Central Medical Stores (CMS) is considered a supplier specially appointed by the Ministry of Health and the same requirements for evaluation of performance and accepting goods and services are apply.

Supporting Document(s)
PR04 External Services and Supplies, FR14 Approved Supplier List

4.7. Advisory services

Customers and users of laboratory services are issued with the a collection of documents that include Test Menu & Back Up Plan, specimen collection and transport requirements, specimen rejection criteria, and test turnaround times.

Laboratory staff with the appropriate professional qualifications and licensure are authorized to advise on individual clinical cases; and making professional judgements on the interpretation of the results of examinations.

The BHHRL participates in regular meetings with clients to promote the effective utilization of laboratory services; to discuss logistical issues or scientific matters. These meetings ensure the best possible delivery of service.

The Laboratory ensures its representation in the following strategic platforms and uses these to provide any advisory services that may be required:

- ARV Program Managers
- Equipment Management Committee
- National Laboratory Services Committees (such as Reagent Distribution, Equipment, Reference Ranges)
- Public Health Surveillance Studies & Strategic Information

- Study Specific Meetings & Conference Calls
- Study Specific Trainings & Planning Meetings
- National Health Laboratory (for strategic laboratory services issues)
- Technical Working Groups that require BHHRL services

The Laboratory Manager(s) or designated technical heads/coordinators are the points of contact for with clients; providing advice and guidance on technical matters; giving opinions and interpretations based on results. The Laboratory Manager(s) also informs the client of any delays or major deviations in the performance of tests.

The Quality Assurance Manager provides guidance, advises and communicates on any matters related to the quality of test results, quality of services and the safety and wellbeing of patients and study participants.

4.8. Resolution of complaints

The BHHRL is committed to ensuring that all complaints raised by clinicians, patients, laboratory staff or other parties concerning any aspect of laboratory services are taken seriously regardless of perceived magnitude, are appropriately documented, thoroughly investigated and resolved to such an extent as is reasonable to bring satisfaction to the complainant.

The Quality Assurance Manager is the primary point of contact for receiving and ensuring resolution of employee and customer complaints.

Specific requirements and procedures for managing customer complaints and other feedback are described in the Resolution of Complaints SOP.

Supporting Document(s)
PR05 Resolution of Complaints

4.9. Identification and control of nonconformities

All non-conformities with respect to any aspect of the quality management system are identified, documented, investigated and promptly resolved. The level of effort in response to an identified or suspected non-conformity is commensurate to the risk.

Where a non-conformity creates doubt or lack of confidence in the integrity of a testing process or the quality of test results:

a) The Laboratory Manager or any competent medical laboratory personnel performing the affected procedure has the responsibility and authority to halt any testing or procedures or withhold reports related to the non-conformance; and to invalidate test results that are affected.

a) The Laboratory Manager or Quality Assurance Manager has the responsibility and authority to recall, or appropriately identify, as necessary, the results of any nonconforming or potentially nonconforming examinations already released

b) With the approval of the Quality Assurance Manager, the Laboratory Director or Laboratory Manager may authorize resumption of work after a non-conformity has been satisfactorily corrected.

The BHHRL fully recognizes the legal and ethical responsibility of the medical laboratory professional to protect the interests and safety of patients; and the health professions pledge to "do no harm". To that effect, no medical laboratory professional shall be forced, pressured, coerced or otherwise threatened to issue or release medical laboratory results against their independent professional judgement.

Supporting Documents(s)
PR06 Identification and Control of Nonconformities

4.10. Corrective action

The BHHRL undertakes corrective action to eliminate the root cause(s) of nonconformities. Corrective action implemented is appropriate to the effects of the non-conformities encountered.

The corrective action process is described in the Corrective Action SOP

Supporting Document(s)
PR07 Corrective action procedure

4.11. Preventive action

The BHHRL undertakes preventive action to eliminate the cause(s) of potential nonconformities. Preventive action implemented is appropriate to the effects of the potential problems.

The preventive action process is outlined in the Corrective Action SOP

Supporting Document(s)
PR08 Preventive action procedure

4.12. Continual improvement

Continual improvement of the effectiveness of the Quality Management System is achieved through a systematic comparative review of the laboratory's performance against its intentions as defined in the quality policy, quality objectives and standard operating procedures.

Improvement activities are then directed at areas of highest priority based on risk assessments. All action plans for improvement are documented. The effectiveness of actions taken are determined through a focused review of area concerned.

Periodic review of standard operating procedures as per the requirements of the document control system help to identify potential sources of improvement in the Quality Management System.

Laboratory management is committed to continual improvement, and will provide the necessary resources, including suitable education and training opportunities to Laboratory personnel.

4.13. Control of records

The BHHRL follows established procedures for identification, collection, indexing, access, storage, amendment, maintenance and safe disposal of quality and technical records.

Records are created concurrently with the performance of each activity that affects the quality of the examination.

The BHHRL has adequate facilities with a suitable environment for the safe storage of records to prevent damage, deterioration, loss or unauthorized access.

Record retention periods are predetermined. Where the retention periods are governed by multiple authorities, the most stringent requirements apply.

All quality and technical records shall be made available and presented within a reasonable time for purposes of Management Review or Audit.

Supporting Document(s)
PR09 Control of Records

4.14. Evaluation and audits

4.14.1. General

The Laboratory has established and maintains a documented program for Quality Management System evaluation and audit. The purpose is

a) to demonstrate that pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users;

b) to determine whether the Quality Management System conforms to the requirements of DAIDS GCLP, ISO 15189, national regulations and statutory requirements,

c) to determine whether Quality Management System processes have been effectively implemented and maintained; and

d) to identify opportunities for improvement.

Information gathered from evaluation and audit activities forms part of the input to management review.

Supporting document(s)
PR10 Evaluation and Audits

4.14.2. Periodic review of requests, and suitability of procedures and sample requirements

The Laboratory Manager periodically reviews:

a) the suitability of the testing procedures to ensure that they are clinically appropriate for the requests received.

b) the requirements (sample volume, collection device, specimen preservatives etc) required for examinations/tests provided to ensure that all sample types are properly collected to preserve analytes.

4.14.3. Assessment of user feedback

The BHHRL actively solicits and receives user opinion and any other feedback on the quality of laboratory services.

The Quality Assurance Manager conducts an annual customer satisfaction survey that targets all, or a representative sample of all users of laboratory services.

Following predetermined schedules, or as and when need arises, the BHHRL participates in discussion fora with users of laboratory services to determine whether or not their needs and requirements are being met.

User feedback and actions taken by management is documented and records are maintained.

4.14.4. Staff suggestions

BHHRL staff are encouraged to make suggestions for the improvement of any aspect of the quality management system.

Staff suggestions can be made through departmental, management or general staff meetings, suggestion box, biannual employee satisfaction surveys, or through on one to one discussions with senior staff.

All staff suggestions and actions taken by laboratory management are documented and records are maintained. BHHRL management commits to ensuring that all staff suggestions are evaluated, implemented as appropriate and feedback is given to staff.

4.14.5. Internal audit

An internal quality audit is conducted at least once annually to ensure the continuing suitability, adequacy, and effectiveness of the Quality Management System. The Schedule, Objectives and Scope of internal audits are determined by the Quality Assurance Manager as defined in the Internal Audit SOP.

The Quality Assurance Manager has overall responsibility for managing the Internal Audit process.

Output from the internal audit is reviewed as a standard agenda item at the Management Review meeting.

Nonconformities identified from these audits are resolved within 25 working days of issue of report.

4.14.6. Risk management

The Laboratory identifies risk of failure in work processes and their potential impact on patient safety. Management is committed to taking action to avoid or mitigate identified risk. Records of risk assessment and actions taken by management are maintained.

4.14.7. Quality indicators

The Laboratory has an established set of Quality Indicators to monitor and evaluate critical aspects throughout the pre-examination, examination and post-examination processes. At prescribed intervals, laboratory performance is compared against a stated benchmark or an established guideline or standard.

Quality Indicators are periodically reviewed to ensure continued appropriateness.

Supporting document(s)
FR27 Quality Indicators

4.14.8. Reviews by external organizations

The BHHRL shall facilitate review of the quality management system by external organizations, such as accreditation bodies, regulatory agencies/inspections, health.

When such reviews or inspections, raise nonconformities or identify a potential nonconformity, the BHHRL shall take appropriate immediate, corrective or preventive actions to ensure continual compliance with the standard or regulating body. The records of reviews and of the corrective and preventive actions taken are retained as per the records retention schedule.

4.15. Management review

The BHHRL management periodically, and in accordance with a predetermined schedule and procedure, conducts a review of the laboratory's Quality Management System and testing activities to ensure their continuing suitability and effectiveness and to introduce necessary changes and improvements. At a minimum, these reviews are held once annually.

In response to changing work conditions or performance data, the Quality Assurance Manager may, at his or her discretion, call for unscheduled reviews.

Attendance is mandatory for all directors, coordinators and managers. In the event that someone cannot attend he or she must send a representative. After reviewing the minutes of the meeting, the absent person must submit written input within two weeks of receiving the meeting minutes. Only one individual per meeting may be absent. In the event that the Laboratory Director cannot attend, the meeting should be rescheduled to a time that is convenient to him/her.

The Quality Assurance Manager is prepares the meeting agenda. The Director is responsible for approving the agenda and this must be distributed to the concerned people no less than two weeks prior to the meeting.

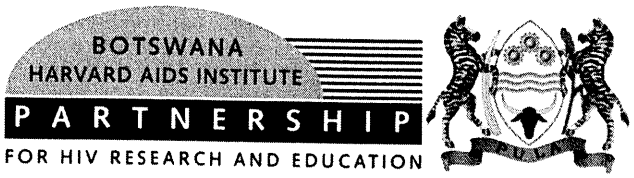
The Quality Assurance Manager coordinates and collects the information for the management review; assembles summary report and documents action items/plans; monitors implementation of system changes approved as a result of action items/plans; and maintains management review reports.

The review meeting is facilitated by the Quality Assurance Manager and is chaired by a nominated member of laboratory management.

Specific requirements for management review, the review input, review activities and review output are as defined in the Management Review SOP.

Records of management reviews are maintained and actions are carried out within an appropriate and agreed time period

Supporting document(s)
PR11 Management Review



5. TECHNICAL REQUIREMENTS

5.1. Personnel

5.1.1. General

The BHHRL maintains a procedure for personnel management and keeps records of all personnel and activities to demonstrate compliance with requirements.

The Laboratory Director continuously reviews staffing needs and takes the necessary action to ensure that adequate and sufficiently competent staff are available to meet the needs of users and the requirements of the quality management system.

Supporting document(s)
PR12 Personnel Management

5.1.2. Personnel qualifications

The laboratory documents personnel qualifications for each position. The qualifications reflect the appropriate education; training, experience and demonstrated skills needed and are appropriate to tasks and responsibilities.

All personnel making professional judgements with reference to examinations have the applicable theoretical and practical background and experience, and hold valid registration by the Botswana Health Council.

For purposes of this clause, professional judgements can be expressed as opinions, interpretations, predictions, simulations and models and values based on the laboratory examination of biological specimens from patients, study participants, calibration or quality control material for the purposes of diagnosis, monitoring of medical interventions, clinical research, or for the assessment of test method performance.

5.1.3. Job descriptions

All personnel are issued with job descriptions that describe their responsibilities, authorities and tasks on assumption of duty.

5.1.4. Personnel introduction to the organizational environment

All new staff undergo a standard induction program that introduces them to the organization, facilities, terms and conditions of employment, health and safety and the laboratory quality management system

5.1.5. Training

The laboratory maintains a training program that covers all technical and management aspects of the quality management system.

All students, interns and staff undergoing training at all times work under the direct supervision of a competent member of staff.

The duration of any training is as long as is necessary to ensure a minimum level of understanding and a degree of skill leading to a successful competency assessment. There shall be no expedited training programs implemented in response to staffing shortages.

The effectiveness of the training program is reviewed at the annual management review.

5.1.6. Competence assessment

The laboratory assesses the competency of all staff assigned to perform managerial or technical tasks in accordance to established criteria to provide evidence that such staff have received suitable instruction and are suitably knowledgeable and skilled in the performance of procedures.

Competency assessment shall be conducted every six months in the first 12 months following appointment and annually thereafter.

5.1.7. Reviews of staff performance

The BHHRL implements performance appraisals for all staff, as prescribed by the GoB and the BHP for GoB and BHP employees respectively.

Records of these reviews are maintained in personnel files.

Performance appraisals are conducted by staff with the appropriate training. Records of such training are maintained.

5.1.8. Continuing education and professional development

The laboratory provides and facilitates continual education and professional development of all staff through workshops, seminars, conferences etc. A review of the effectiveness of these programmes is considered at management reviews.

5.1.9. Personnel records

The Laboratory Manager ensures that all necessary personnel records are maintained to ensure full compliance with the quality management system's minimum requirements for personnel management

5.2. Accommodation and environmental conditions

5.2.1. General

It is the responsibility of laboratory management to ensure that the laboratory environment is appropriate and adequate for the type of work performed without compromising the quality of test results or the safety of staff, visitors and patients.

The laboratory and any point of care testing sites are organised to provide a safe working environment and to comply with appropriate health and safety legislation. Laboratory testing and reagent holding areas receive conditioned air as provided by the building management system in order to facilitate the correct operation of equipment and maintain reagent integrity. These conditions are monitored regularly.

5.2.2. Laboratory and office facilities

The facilities have been created with the express purpose of providing a suitable environment for the receipt, testing and reporting of patient results.

The laboratory access control system is designed to ensure that only staff with suitable authorisation is permitted access to laboratory areas. This ensures confidentiality of patient information.

The physical laboratory has been designed to provide the correct environment for sample testing to take place and is compliant with the requirements of ISO 15189:2012 standard and those of specific tests.

The facilities have been designed to ensure provision of the following:

a) Adequate lighting,

b) Adequate power supply (including contingency),

c) Adequate ventilation,

d) Adequate water supply,

e) Adequate waste disposal,

f) Adequate communication systems,

g) Suitable and regularly verified safety systems (such as fire detection and alarm systems, fire-fighting equipment, emergency release door-mechanisms for cold-rooms, emergency drench showers and eyewash facilities)..

5.2.3. Storage facilities

The BHHRL has appropriate storage space and conditions to ensure continuing integrity of samples, documents, files, manuals, equipment, reagents, laboratory supplies, records, results and any other item that could affect the quality of test.

Clinical samples and materials used in examination processes are stored in a manner to prevent cross-contamination.

All temperature controlled storage areas are monitored and records retained. Dangerous materials are stored and disposed of as specified by applicable requirements.

Supporting document(s)
PR13 Temperature Monitoring

5.2.4. Staff facilities

The laboratory sites provide adequate staff washrooms, supply of drinking water and facilities for storage of personal protective equipment and clothing.

5.2.5. Patient sample collection facilities

Sample collection facilities have separate reception/waiting and collection areas. Consideration has been given to the accommodation of patient privacy, comfort and needs and accommodation of appropriate accompanying person during collection.

The facilities provided for patient sample collection ensures that sample collection is carried out in a manner that does not invalidate results or affect quality of the examination.

Sample collection facilities maintain appropriate first aid materials for both patient and staff needs

5.2.6. Facility maintenance and environmental conditions

The laboratory premises are maintained in a functional and reliable condition. The work areas are kept clean, tidy and well maintained.

The BHHRL monitors, records and controls environmental conditions wherever they may impact upon the quality of the result and/or the health of staff. The laboratory management define conditions to be monitored at their respective laboratories considering the level of service provided.

The BHHRL defines work areas for all activities and ensures incompatible activities are effectively separated from one another. Where separation of incompatible activities is not possible, procedures are in place to prevent cross contamination.

Quiet and uninterrupted work environments are provided in certain laboratory areas so that the quality of work generated within these areas is not unduly affected by background noise or frequent interruptions.

5.3. Laboratory equipment, reagents and consumables

5.3.1. Equipment

5.3.1.1. General

BHHRL Management provides all items of equipment required for provision of services and efficient operation of the laboratory.

The Laboratory follows established policies for selection, procurement and management of equipment.

The Laboratory Manager maintains an updated master list of all Laboratory Equipment.

Supporting document(s)
PR14 Laboratory equipment, reagents and consumables, FR40 Equipment Inventory

5.3.1.2. Equipment acceptance testing

All equipment are subjected to verification and/or validation process upon installation and prior to be put into use. Individual equipment is uniquely labelled with the supplier's serial number and/ or lab unique identification number so that each can be definitively identified.

Before new equipment is put into routine use, it must have demonstrated its performance capability with respect to stated user requirements. All analysers undergo installation and performance verification, see Examination Processes (**PR15**)

Methods for test including methods for sampling, are selected and used to meet the needs of the client and are appropriate for the test undertaken. Methods published as international, regional or other national standards are used whenever possible. The latest valid edition of a standard is used unless it is not appropriate or possible to do so. When necessary, the standards are supplemented with additional details to ensure consistent application

If the method to be used in not specified by the client, the laboratory selects appropriate methods published either in international, regional, or national standards or by reputable technical organizations or in relevant scientific texts or journals or as specified by the manufacturer. Laboratory developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client is informed as to the method chosen. The laboratory confirms that it can properly operate standard methods before introducing the tests. If the standard method changes, the confirmation is repeated.

When it is necessary to employ non-standardized methods, these are subject to agreement with the client's requirement and the purpose of the test. The methods developed are validated appropriately before use and are available for examination by the client and other authorized recipients.

All standard test methods and procedures are verified to ensure that such methods and procedures are fit for the intended use and are relevant to the requirements of ISO/IEC 15189:2012 as well as the client.

All non-standard test methods and procedures are validated to ensure that such methods and procedures are fit for the intended use and are relevant to the requirements of ISO/IEC 15189:2012 as well as the client.

5.3.1.3. Equipment instructions for use

Manufacturer equipment operation manuals are held within the laboratory and controlled as per document control procedure. Laboratory staff will be authorized to use equipment unsupervised only after they have been trained and deemed competent.

Personnel from external laboratories are not authorized to operate BHHRL equipment.

Information on safe handling, transport, storage and use of equipment to prevent contamination or deterioration is available in the relevant equipment user manual.

5.3.1.4. Equipment calibration and metrological traceability

The BHHRL has an established procedure for the calibration of equipment that directly or indirectly affects examination results.

Metrological traceability shall be to a reference material or reference procedure of higher metrological order available.

5.3.1.5. Equipment maintenance and repair

The BHHRL has an established programme of preventive maintenance for all equipment, which, at a minimum, follows the manufacturer's instructions. Records of maintenance and equipment failure are kept in the equipment file kept at the point of use of the equipment.

Defective equipment is immediately taken out of service and clearly labelled "NOT IN USE". Checks are made to assess if the defective equipment has had any impact upon examinations undertaken prior to the defect being discovered. If so, suitable remedial and corrective actions are undertaken.

Upon suitable repair of the equipment, verification checks are made to ensure that it is working within the specified acceptance criteria prior to return to routine use.

The laboratory takes reasonable steps to decontaminate equipment prior to service, repair or decommissioning; to provide suitable space for repair; and to provide appropriate personal protective equipment (PPE) to the engineers.

Equipment that has been outside laboratory's direct control is verified before being returned to laboratory use.

5.3.1.6. Equipment adverse incident reporting

Adverse incidents associated with the use of equipment are recorded as nonconformities and these are assessed periodically for trends. In addition, any equipment failures which have resulted in the generation of incorrect results will also be investigated. A serious equipment failure or trends that indicate persistent quality issues will be alerted to the supplier as required.

5.3.1.7. Equipment records

Records for equipment that contributes to the performance of examinations are maintained in equipment files kept at the point of use.

5.3.2.Reagents and consumables

5.3.2.1. General

The BHHRL has an established procedure for the receipt, storage, acceptance testing (where relevant), inventory management of reagents and consumables.

5.3.2.2. Reagents and consumables – Reception and storage

There is adequate space for the receiving and storage of reagents and consumables in a manner that prevents damage and deterioration.

All reagents and consumables are stored as per manufacturer's recommendations.

5.3.2.3. Reagents and consumables – Acceptance testing

New lots or shipments of examination kits or new formulations of kits which have a change in reagent or procedure are verified for performance before they are used for testing. A similar approach is adopted for changes in consumables that may affect the quality of examinations.

5.3.2.4. Reagents and consumables – Inventory management

The laboratory has an established inventory control system for reagents and consumables. Any uninspected and unacceptable items are kept separately from those that have been deemed acceptable for use.

5.3.2.5. Reagents and consumables – Instructions for use

Instructions for the use of reagents and consumables are available, including those provided by the manufacturers are readily available.

5.3.2.6. Reagents and consumables – Adverse incident reporting

Adverse incidents associated with the use of specific reagents or consumables are recorded as nonconformities and these are assessed periodically for trends. In addition, any reagents or consumables failures which have resulted in the generation of incorrect results will also be investigated. A serious reagents or consumables failure or trends that indicate persistent quality issues will be alerted to the supplier and appropriate authority, as applicable.

5.3.2.7. Reagents and consumables – Records

Records of reagents, including those prepared in – house, and consumables that contribute to the performance of examinations are kept within the individual laboratories.

Supporting document(s)
PR14 Laboratory equipment, reagents and consumables

5.4. Pre-examination process

5.4.1.General

The BHHRL has documented procedures with all information required for pre-examination activities to ensure the validity of the results of examinations.

5.4.2.Information for patients and users

The laboratory provides all the information necessary for patients and users of laboratory services.

5.4.3.Request form information

The information of requisition forms is standard, the details of which are included in the procedure Pre-examination processes.

The BHHRL does not accept verbal requests for tests. The laboratory however cooperates with users or their representatives in clarifying any users requests.

5.4.4.Primary sample collection and handling

5.4.4.1. General

Instructions for sample collection, patient preparation and specimen transport criteria are available in specimen management SOPs, which are issued to the users.

Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these are recorded and included in all documents containing examination results are communicated to the appropriate personnel.

Informed consent is obtained from the patient for all examinations and this is in the form of a request.

Detailed explanation is given to the patient on special procedures, including invasive ones, and in some cases, the relevant consent form is used for obtaining patient consent.

5.4.4.2. Instructions for pre-collection activities

The laboratory maintains documented instructions for all pre-collection activities.

5.4.5.Sample transportation

The Specimen Transport SOP includes instructions for packaging samples for transportation and also has procedures for monitoring the transportation of samples to ensure the following conditions are met:

a) Within the time frame appropriate to the nature of the requested examination and the laboratory discipline concerned.

b) Within the temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples.

c) In a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.

5.4.6.Sample reception

The procedure for sample reception is detailed in the Specimen Reception procedure.

Where necessary, study specific procedure for sample reception and handling is available.

5.4.7.Pre-examination handling, preparation and storage

The pre-examination handling, preparation and storage activities are detailed in the specimen reception and respective test procedures. Time limits for requesting additional or further examinations on already received samples are documented.

5.5. Examination processes

5.5.1.Selection, verification and validation of examination procedures

5.5.1.1. General

The laboratory only uses examination procedures which have been validated for their intended use. Performance specifications for each examination procedure relate to the intended use of the examination.

The identity of persons performing activities in examination processes is recorded.

Supporting Document(s)
PR15 Examination Procedures

5.5.1.2. Verification of examination procedures

Examination procedures that have been validated by the manufacturer without modification, these examinations are subject to independent verification by the laboratory before being introduced into routine use.

The laboratory obtains information from the manufacturer/method developer for confirming the performance characteristics of the procedure as part of the verification.

The independent verification by the laboratory confirms, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met. The performance claims for the examination procedure confirmed during the verification process are those relevant to the intended use of the examination results.

The procedure used for the verification and the results obtained are documented. Staff with the appropriate authority reviews the verification results and record the review. Supporting Document(s)

5.5.1.3. Validation of examination procedures

The laboratories validate examination procedures derived from the following sources:

a) Non-standard methods;

b) Laboratory designed or developed methods;

c) Standard methods used outside their intended scope;

d) Validated methods subsequently modified.

The validation is as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of examination have been fulfilled. The laboratory document the procedure used for the validation and record the results obtained. Staff with the appropriate authority reviews the validation results and record the review.

When changes are made to a validated examination procedure, the influence of such changes is documented and, when appropriate, a new validation is carried out.

5.5.1.4. Measurement uncertainty of measured quantity values

The Laboratory determines the measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory defines the performance requirements for the measurement uncertainty of each measurement procedure and regularly reviews the estimates of measurement uncertainty.

Measurement uncertainty is considered when interpreting measured quantity values. The laboratory's estimates of measurement uncertainty are made available to service users upon direct request.

Unless otherwise specified by the customer, the uncertainly of measurement is expressed as a standard measurement uncertainty, equivalent to imprecision as determined through a replication experiment at method verification/validation.

Where examinations include a measurement step and measured quantity value is not reported, the Laboratory calculates the uncertainty of the measurement step where it has influence on the reported results.

5.5.2. Biological reference intervals or clinical decision values

The biological reference intervals or clinical decision values have been defined, their basis documented available to service users. These are periodically reviewed as required with respect to:

a) Appropriateness to the population being served.

b) Changes in examination procedures.

c) Changes in pre-examination procedures.

When a particular biological reference interval or decision value is changed, this is communicated to the users.

5.5.3. Documentation of examination procedures

All BHHRL has documented examination procedures for all tests within the scope of service. The

Instrument manuals and package inserts from test kits may be incorporated into examination procedures by reference.

All these documents comply with the document control procedure.

When a particular examination procedure is changed, this is communicated to the users.

The Laboratory informs clinical users in advance of change to an examination procedure, where the change has an impact on interpretation. The notification should be in writing and can be by hard copy or electronic methods. Records of each notification are maintained.

5.6. Ensuring quality of examination results

5.6.1. General

The BHHRL aims to ensure the quality of examinations are performed under suitably controlled conditions.

The BHHRL does not fabricate results.

Supporting Document(s)
PR16 Ensuring quality of examination results

5.6.2.Quality control

5.6.2.1. General

To assure the quality of examinations, the BHHRL has Quality Control (QC) procedures for monitoring the validity of tests results.

5.6.2.2. Quality control material

The laboratories use quality control materials that react in a manner as close as possible to patient samples.

Whenever possible, the laboratory chooses

concentrations of control materials, especially at or near clinical decision values, which ensure the validity of decisions made.

QC materials are periodically examined at a frequency that is based on the stability of the procedure and the risk of harm to the patient due to erroneous results. Wherever possible, independently sourced third-party QC materials are used in order to reduce the possibility of bias associated with the use of reagents supplied by the system manufacturer.

5.6.2.3. Quality control data

The procedure exists to indicate actions to take to prevent the release of patient results following a failure of QC. When QC rules are violated and indicate that examination results are likely to contain clinically significant errors, the results are rejected and relevant patient samples re-examined after the error condition has been corrected and within specification performance is verified. The laboratory also assesses results of patient samples that have been examined since the last successful QC event.

QC data are reviewed regularly in order to identify trends that may indicate deterioration in the performance of examination procedure so that suitable action can be initiated. Trends noted in this way and the subsequent actions are recorded.

5.6.3.Interlaboratory comparison

5.6.3.1. Participation

The BHHRL participates in inter laboratory comparison programme(s), such as external quality assessment (EQA) programme or proficiency testing programme, appropriate to the examination and interpretation of examination results.

Results of inter laboratory comparison programme(s) are monitored and take corrective action is undertaken when the pre-determined performance criteria are not fulfilled.

5.6.3.2. Alternative approaches

Where inter-laboratory comparison programme(s) are not available then the laboratory aims to provide objective evidence for the acceptability of examination results via a number of means, including, but not limited to the use of certified reference material, re-assessment of samples previously examined and exchange of samples with other laboratories.

5.6.3.3. Analysis of Interlaboratory comparison samples

Analysis of inter laboratory comparison samples is in accordance with the procedure for ensuring quality of examination results.

5.6.3.4. Evaluation of laboratory performance

Interlaboratory comparison results are reviewed and discussed with relevant staff.

When predetermined performance criteria are not fulfilled, members of staff participate in the implementation and recording of corrective action. Results are evaluated for trends that indicate potential nonconformities and preventive action taken.

5.6.4.Comparability of examination results

Comparability of examination results is in accordance with the procedure for ensuring quality of examination results. This includes different procedures, equipment, methods and different sites.

The BHHRL has a documented procedure for ensuring comparability of examination results.

The quality of examination results is assured with reference to a comprehensive quality control approach to pre-testing, testing and post-testing processes. The approach to quality control is based on principles of in-process quality control checks. It is policy of the Laboratory to focus on elimination or reduction of errors in the following critical areas of activities:

a) Specimen collection, inspection and registration

b) Primary processing including centrifugation and aliquoting.

c) Testing processes (using Quality Control samples, equipment maintenance, competent personnel and reagents).

d) Results Reporting.

Equipment calibration programs are in place for measuring systems in order to verify the correctness of results. Where it is not possible to verify the correctness of results by calibration of equipment the laboratory may use the following methods to provide confidence in the results:

a) Participate in available and suitable inter-laboratory comparison programs

b) Using reference materials which are certified to indicate the characterization of material.

c) Regular use of internal quality control using secondary reference materials.

d) Internal quality control schemes using statistical techniques.

e) Methods which are clearly established specified and characterized.

f) Use of certificates of analysis or conformance provided by the manufacturers or agent of same as a method of verifying reagents, test procedures or analytical system.

g) Resulting data is recorded in such a way to detect trends and where practicable, statistical techniques are applied to the reviewing of the results.

Failures in external quality assessment schemes or inter-laboratory comparisons and internal quality control methods are documented and investigated using root cause analysis.

It is policy of the Laboratory and the responsibility of the Quality Manager to ensure that external quality assessment specimens, in so far as possible are treated as routine specimen. External quality assessment specimen goes through the normal pre-examination and post examination process.

The Quality Assurance Manager or designee is responsible for monitoring and updating records traceable to third party assessment schemes. These records include the documented corrective action, reports and non-conformances.

5.7. Post-examination processes

5.7.1. Review of results

Competent or authorized personnel review the results of examinations and evaluate them against internal quality control and available clinical information, previous results or other criteria before release of results.

Staff that has been deemed competent will provide secondary review of results.

In cases where samples are processed outside normal working hours (Night shift, weekends and public holidays) with limited staff or urgent requests, results will be released by the testing personnel. Secondary review of results is then done by appropriate competent personnel during the normal working day. Results will be recalled in instances where transcriptional errors or inconsistences are noted.

The BHHRL does not use automated selection and reporting of results.

5.7.2. Storage, retention and disposal of clinical samples

A procedure to ensure that all clinical samples are effectively identified, collected, indexed, accessed, stored, maintained and disposed where necessary, has been developed and implemented. The laboratory management has defined retention times for clinical samples.

After testing the primary sample and portions of samples are stored in accordance with specified times. Primary samples, portions of samples and material used in the testing processes but no longer required are disposed of safely. Specifics of handling specimens are testing are specified in the relevant test specific procedures, where appropriate.

5.8. Reporting of results

5.8.1. General

The results of each test or series of tests carried out by the laboratory are reported accurately, clearly, unambiguously and objectively and in accordance with any specific instructions in the test methods.

The Laboratory has an established procedure for to ensure correct transcription of laboratory results.

The results are reported in a test report that includes all the information requested by the client and necessary for the interpretation of the test results and all information required by the method used. Test reports can be on electronic or paper media.

Where a report delay is thought likely to potentially compromise patient care, the laboratory notifies the requester.

5.8.2.Report attributes

The Laboratory ensures that the following report attributes effectively communicate laboratory results and meet the users' needs.

a) Comments on sample quality that might compromise examination results;

b) Comments regarding sample suitability with respect to acceptance/rejection criteria

c) Critical results, where applicable;

d) Interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results in the final report

5.8.3.Report content

All BHHRL test reports follow a standard format consistent with the requirements of ISO 15189.

The Laboratory Directors or authorised designees are responsible for approving the format of the laboratory test reports. The format review is cognisant of the view and opinions of laboratory personnel and users of the Laboratory services.

The laboratory has a procedure for reporting of results is in place Reporting of Results (**PR18**)

Results are reported into the electronic patient records and copies of machine printouts and results sheets are retained according to the document retentions times (Control of Quality and Technical Records).

Urgent or Critical results must be reported according to the Release of Results SOP, **(PR19)**

Turnaround times are documented and communicated to the clients.

Turnaround times are monitored, recorded and reviewed during management reviews, whichever comes first.

In case the test is performed for internal clients, or in the case of a written agreement with the client, the results may be reported in a simplified way and may not require the formalized test report but all data is readily available and kept permanently on file.

When opinions and interpretations are included in the test report, the basis upon which the opinions and interpretations have been made is documented. Opinions and interpretations are clearly marked as such in the test report. If such opinions/interpretations are verbally communicated to the client, the appropriate dialogue is recorded in writing. Opinions and interpretations included in a test report may comprise, but not be limited to the following:

a) Opinion on the statement of compliance/non-compliance of the results with requirements

b) Fulfillment of contractual requirements

c) Recommendations on how to use the results

d) Guidance on how to use the results.

When the test report contains reports of tests performed by referral laboratory, these results are clearly identified.

The format is designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse. Attention is given to the layout of the test report especially with regard to the presentation of the test data and ease of assimilation by the reader.

Material amendments to a test report after issue are made only in the form of a further document or data transfer, which includes the statement "Supplement to Test Report....." or an equivalent form of wording. Such amendments meet all the requirements of ISO/IEC 15189:2012. When it is necessary to issue a complete new report, it is uniquely identified and contains a reference to the original that it replaces.

Supporting Document
PR18 Reporting of Results

5.9. Release of results

5.9.1.General

The BHHRL has an established procedure for release of results.

Test results are not conveyed directly to patients or relatives. Nurses/ Ward staff or other designated persons may receive the test results.

Only competent laboratory scientists are authorised to release results. Results are be checked for any transcription errors prior to release. In the event that only one scientist is on duty results may be released, however, such results are checked during normal shifts and if there are any mistakes noted the clinician shall be informed and a correct report re-issued. Hard copies can only be issued to authorised personnel and they shall sign an acknowledgement of receipt log.

Supporting Document(s)
PR19 Release of Results

5.9.2.Automated Selection and Reporting of Results

For instruments that are interfaced to the laboratory information system, a Laboratory Scientist shall review and validate results prior to transmission. Only authorised results are accessible to clinicians.

5.9.3. Revised Reports

In the event that a report has been revised the clinician shall be made aware of any changes that have been made to the original report. Such results shall be clearly marked appropriately as revised or amended reports.

Supporting Document
PR19 Release of Results

5.10. Laboratory information management

5.10.1. General

The Laboratory uses both computer-based (and paper-based) laboratory information management systems that are designed to ensure traceability, retrievability, accuracy and completeness, timeliness, security, confidentiality and privacy of patient information or test results.

The BHHRL uses unique patient and sample identifiers, standardized request forms, standardised electronic ordering, logsheets/results sheets, review and verification processes that assure accuracy of data recording and transmission, protection against loss of data, protection of patient confidentiality and privacy as well as effective and timely reporting and communication systems.

The Integrated Patient Management System (IPMS) & BHP LIS (DMIS) are computerised systems that enable stored patient results and archival information to be easily and readily retrievable within timeframe consistent with client needs.

Supporting Document(s)
PR20 Laboratory Information Management

5.10.2. Authorities and responsibilities

Authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care.

5.10.3. Information system management

The LIMS has been validated by the supplier and verified upon installation and before use by the laboratory. Any changes to the system are documented, verified and approved for use prior to introduction in the laboratory. All verification data associated with the testing (including any simultaneous screen shot evidence etc.) are retained within the individual laboratory records.

User Manuals for the computerised Lab Information Systems are available at the points of use.

Data storage media e.g. files and disks are properly labelled, stored and protected from damage or unauthorized use. Back-up media are also stored off-site in case of fire or natural disaster. Patient results, technical and non-technical records have backup to prevent loss of data.

Computer hardware and software preventative and corrective maintenance, verification and validation are coordinated through the Information Technology Departments (IPMS) & Data Management Centre (DMIS) in order to keep scheduled and unscheduled system downtime minimal.

Manual downtime procedures are available in case of failure or downtime of the information system. In cases where laboratories utilize non – computerized systems, conditions for safeguarding the accuracy of manual recording and transcriptions are provided.

5.11. Occupational Health and Safety

Lab maintains an Occupational Health and Safety (OHS) programme described in the Health and Safety Manual (**LM03**). The programme is designed to protect patients and study participants, lab personnel, other hospital personnel, the community and the environment from physical, chemical and biological hazards.

The programme enables identification and assessment of OHS risks and incidents resulting in appropriate remedial actions and preventive/corrective actions. Periodic safety audits conducted by the Safety Officers and Quality Assurance Unit.

Analysis of data obtained through monitoring of safety indicators provides important information on the effectiveness of the program. Safety indicators monitored include number of safety incidents, number of accidents resulting in serious injury per quarter, number of needle stick injuries per month.

Designated Safety officers are responsible for ensuring implementation, monitoring and improvement of the Health and Safety programme and ensuring that staff and patients are familiar with the relevant safety procedures and regulations.

All staff are required to adhere to Universal Safety Precautions, Post- Exposure Prophylaxis procedure, use appropriate Personal Protective Equipment and follow specified Waste Management procedures as well as the Laboratory Safety Manual.

All staff are required to familiarise themselves with the contents of the Health and Safety Manual.

Supporting Documents:
LM03 Health and Safety Manual

6. CONCLUSION

This Quality Manual together with the supporting QMS procedures, SOPs and related forms and records, form the Quality Management System for BHHRL. The quality policy statement contained in this manual provides direction and intent to the QMS activities and is in line with strategic and operational goals of the laboratory and its stakeholders.. Therefore, effective implementation of the requirements set out in this ISO 15189:2012 aligned Quality Manual is expected to enable BHHRL Laboratory to effectively and efficiently achieve its Mission and Vision resulting in exemplary customer satisfaction and ultimately, be recognised through accreditation to the ISO 15189:2012 international standard.

7. CO-APPLICABLE DOCUMENTS

a) Health and Safety Manual

b) Laboratory Services Manual

c) Study Specific Manual of Operations

d) Study Specific Laboratory Processing Charts

e) Laboratory Data Management System (LDMS)

f) National ARV Treatment Guidelines

8. REFERENCES

ISO 15189:2012 Medical Laboratories – Requirements for Quality and Competence

BOS ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories. Geneva, Switzerland: The International Organization for Standardization and the International Electro technical Commission.

ISO 9000 - Quality Management Systems -- Fundamentals and Vocabulary. Geneva, Switzerland: The International Organization for Standardization and the International Electro technical Commission

BOTSWANA HARVARD AIDS INSTITUTE PARTNERSHIP FOR HIV RESEARCH AND EDUCATION

SOP Review Form

Document Title: Quality Manual

Document ID: LM01 Version: 2.0 Effective Date: 09/11/2021

Review Date	Reviewed By	Summary of Changes	Proof-read by	QA Manager Review	Lab Manager Review	Lab Director Review
16/12/2021	T.Ntsipe	Change clause 4.5.1: from ISO/IEC 17025:2005 to ISO/IEC 17025:2017.	C.Boleo	T.Ntsipe 16 DEC 2021	16 DEC 2021	16 DEC 2021

BOTSWANA HARVARD AIDS INSTITUTE PARTNERSHIP FOR HIV RESEARCH AND EDUCATION

SOP Acknowledgement Log

Document Title: Quality Manual

Document ID: LM01 Version: 2.1 Effective Date: **21/12/2021**

I, the undersigned, certify that I have read and understood this SOP. I hereby acknowledge my responsibility for compliance and for ensuring the effective implementation & improvement of this and any related policies & procedures.

Name of Personnel	Signature	Date
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