National Health Insurance Authority

LABORATORY QUALITY AND SAFETY STANDARDS MANUAL

1st Edition

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INTRODUCTION

The Laboratory Quality and Safety Standards Manual was developed to ensure that NHIA approved facilities provide services that are safe, effective, and responsive to the needs of the community. This manual provides an operational framework in which the NHIA approved laboratories can operate.

In developing the Laboratory Quality and Safety Standards Manual, NHIA has aligned the structure and format to other best practice standards and local laws such as Joint Commission International, International Organization for Standards, Pan American Health Organization/World Health Organization & US Centers for Disease Control and Prevention/Department and Human Services Joint Initiative for Laboratory Quality Management Systems and the Hospitals & Healthcare Facility Act and Regulations.

To ensure that our facilities consistently remain focused on providing safe, high-quality care, NHIA will from time-to-time conduct unannounced inspections. Unannounced inspections do not require that the medical director of a facility is notified in advance of an inspection. The idea of unannounced inspections is for the team to be able to see how the facility operates on a daily basis.

AIM

These standards aim to improve the quality of laboratory services delivered by describing a nationally consistent framework, which all NHI laboratory practices can apply when delivering services. The standards are designed to mitigate risk relating to the delivery of services thus allowing our goal to standardize, modernize and optimize laboratory services in the The Bahamas to be achieved.

ORGANIZATION OF THE STANDARDS MANUAL

The standards will provide NHI Laboratory practices with a framework that describes the processes and structures that are needed to deliver safe and quality care. This manual cover standards that fall under the following fourteen categories:

- **Responsibilities of Management (ROM)**
- **Staffing (STAFF)**
- **Quality Control Processes (QCP)**
- **Beneficiary Safety Criteria (BSC)**
- **Infection Prevention and Control (IPC)**
- **Specimen Processing (SP)**
- **Laboratory Environment (ENVN)**
- **Emergency Equipment and Planning (EQUP)**
- **Personal Protective Equipment (PPE)**
- **Required Information and Posting/Signage (SIGN)**
- **Electrical Hazards (HAZD)**
- **Chemical/Hazardous Storage (STOR)**
- **Information Management System (IMS)**
- **Result Reporting (RPT)**

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CHAPTER 1: Responsibilities of Management (ROM)

Purpose

The management of the facility is aware of and understands the various responsibilities and authority of individuals in the organization and how these individuals work together. The standards require that one or more individuals be accountable for the expectation(s) found in this chapter. The responsibilities of management are defined. Collectively and individually, they are responsible for complying with local laws and regulations (*Hospitals and Health Care Facilities (General) Regulations, 2000*. *Retrieved from* http://laws.bahamas.gov.bs/cms/images/LEGISLATION/SUBORDINATE/2000/2000-0098/HospitalsandHealthCareFacilitiesGeneralRegulations_1.pdf) and for meeting the organization's responsibility to the beneficiary population served.

Standards

ROM.1 **The facility Medical Director/Laboratory Director/Designee is to be present for the inspection.**

ROM.2 **The facility has a certificate to prove compliance with The Bahamas building code regulation (business license, healthcare facilities license).**

ROM.3 **The facility infrastructure includes an emergency vehicle access (ramp) that is not obstructed to transport wheelchair and stretcher bound beneficiaries, if applicable.**

ROM.4 **All personnel providing Laboratory services are appropriately registered and licensed as required by local laws.**

ROM.5 **The facility has "Authorized Personnel Only" signage in places where appropriate.**

ROM.6 **There is a list of all procedures/tests that are carried out by the facility that is available for the inspector or client when requested.**

ROM.7 **There is a registration system in place for beneficiaries. System can be electronic or manual (paper).**

ROM.8 **The facility's infrastructure includes a functional telephone system**

ROM.8.1 Interim measures are implemented when telephone system is damaged, nonfunctional or in need of repair.

- Provide emergency/alternative telephone contact(s) to beneficiaries and staff

ROM.9 **The facility's infrastructure has a designated waiting area(s).**

ROM.9.1 No Smoking signs are posted in waiting area or in an area where it is noticeable.

- No smoking includes vapes/vaporizers and e-cigarettes that is used for vaping.

ROM.10 **The facility has a system in place to accommodate ambulatory beneficiaries to meet their needs.**

- There are wheelchair(s) readily available for beneficiaries.

ROM.11 **The facility has emergency power (generator) and UPS during a power outage to provide for required refrigeration and equipment. (All major equipment should be on a UPS).**

ROM.12 **The facility shall ensure that the Quality Action Plan, listing opportunities for improvement identified during the inspection/reinspection process, is updated within 2 weeks of the inspection/reinspection date.**

CHAPTER 2: Staffing (STAFF)

Purpose

The most important resource of the organisation is its human resource. Human resources are an asset for the effective and efficient functioning of the organisation. The facility provider identifies the appropriate headcount and skill-sets of staff required to render safe care to the beneficiaries. The facility must orient the staff to its environment and orient them to specific duties and responsibilities related to their position.

Standards

STAFF.1 **The facility is under the direction of a competent Laboratory Director/Designee with medical/scientific and technical background who is registered and licensed by the Health Professions Council or Bahamas Medical Council. The Laboratory Director/Designee must have a minimum of five (5) years technical experience in a clinical laboratory.**

STAFF.2 **The names & credentials of all professional staff shall be available for the inspectors.**

STAFF.3 **The facility has an orientation program for new staff. Orientation process includes information technology requirements for professional and clerical staff and NHIA program benefits for staff who deal with beneficiaries.**

CHAPTER 3: Quality Control Processes (QCP)

Purpose

The goal of this chapter is for NHIA approved Laboratories to provide guidance to its staff through written policies and procedures that support their quality management system. The aim is to ensure that the laboratories are committed to providing quality services in term of generating reliable patient test reports/results, on time, using appropriate technology. The chapter standards highlight the activities that would control the quality of service so that it meets the needs of the beneficiaries.

Standards

QCP.1 The facility has a documented quality manual of policies and procedures and other documents that is accessible to and used by staff. The manual includes the following: -

- Introduction to quality manual (facility overview, mission, vision, objectives & scope).
- Quality policy (facility commitment to continual improvement, establishment of quality indicators).
- Governance structure (organization chart, role of management, internal communication, staff responsibilities/roles, meeting frequency, etc.)
- Facilities and safety (security, working environment, waste disposal).
- Equipment management (selection, installation & acceptance, inventory, validation, verification, preventative maintenance & repair, decommissioning).
- Purchasing and inventory (reagents & supplies management, equipment procurement, stock management, referral lab/subcontracting).
- Process management (specimen collection & transport, specimen/sample receiving, specimen/sample handling, preparation, and storage, validation, verification, quality control, reporting, sample retention & disposal).
- Quality assessments (internal audits, quality indicators, proficiency testing, external audits (benchmarking).

- Staffing (recruitment, personnel file, training, competency, continuous education, orientation, performance appraisal).
- Customer satisfaction & complaints management.
- Incident reporting and management.
- Documentation management (review and approval of policies and other documents, documents and records control, retention of records and disposal).
- Information management (information security, confidentiality).

QCP.2 **The facility establishes acceptable parameters for quality control for each test method, and quality control data is available and used to monitor and ensure the stability of test systems.**

QCP.3 **The facility establishes a program of externally graded inter-laboratory comparison testing, or proficiency testing for all tests available.**

QCP.4 **The facility performs initial validation/verification for new instruments and analytic systems to ensure that the method(s) will produce accurate and reliable results. Appropriately signed validation/verification records shall be available. Reference made to ISO15189:2012, clause 5.5.1.2 & 5.5.1.3.**

QCP.5 **The facility performs calibration, calibration verification, and function checks of instruments and analytic systems used for testing based on established standards.**

QCP.6 **The facility identifies a qualified individual who is responsible for the oversight and supervision of the point-of-care testing (POCT) program. Oversight and supervision of the POCT program should be by a licensed and experienced Medical Technologist.**

CHAPTER 4: Beneficiary Safety Criteria (BSC)

Purpose

The purpose of the Beneficiary Safety Criteria is to continuously improve beneficiary safety thus affording our beneficiaries the best care possible. This chapter highlights problematic areas and describes evidence-based solutions to these problems. The standards covered under this chapter aim to prevent and reduce risks, errors and harm that occur to beneficiaries during provision of care.

Standards

BSC.1 The facility improves accuracy of beneficiary identification.

- Unique beneficiary identifier is used to standardize beneficiary identification.
- Use a minimum of three approved beneficiary identifiers to correctly identify beneficiaries. **Example full name, date of birth and NIB or passport or driver's license number.**
- Staff must ask the beneficiary to state at least two identifiers **(e.g., their full name and date of birth)**, while remaining mindful of privacy and confidentiality issues. Staff must proactively ask the beneficiary for the information, rather than providing the identifying information and subsequently asking the beneficiary to confirm the information.
- Beneficiary identifiers are required before providing services such as taking blood and other specimens for testing.

BSC.2 A documented process exists to improve the effectiveness of verbal/telephone communication.

- Verbal/telephone communications are documented immediately by the individual receiving order(s) and should be followed by a written/electronic request within 24 hours.

BSC.3 A documented process exists that clearly defines how critical results of diagnostic tests are communicated to providers and how the information is documented.

- Define what critical results may represent urgent or emergent life-threatening values, critical results shall be reported/ communicated immediately, information documented shall include the critical result, the lab personnel that called, the person notified, the date and time called and if there were any difficulties in contacting the Clinician**.** Critical values need to be accessible.

CHAPTER 5: Infection Prevention and Control (IPC)

Purpose

The goal is to identify and to reduce or eliminate the risks of acquiring and transmitting infections among beneficiaries, staff, providers, and the community. Infection prevention and control activities can differ from facility to facility but should address infection risks in persons and the environment.

Standards

IPC.1 There is Evidence of at least one sink with running water for hand washing that is connected to the internal drainage system per testing room.

IPC.2 There is Evidence that reagents and supplies are stored safely to ensure proper cold chain management.

- Evidence that no food or staff personal items are stored in fridge.
- Evidence that no food or drink in active laboratory areas.
- Daily monitoring of room temperature, freezer, refrigerator is required. Can use digital or manual thermometer that has been calibrated and verified.
- Maintain temperature log/checklist to demonstrate temperature recording.
- Documentation of corrective action plan when temperatures are out of range or refrigerator is not operational.
- Evidence of defined contingency plan when fridge/freezer is not operational.

IPC.3 Reagents and supplies are removed from cardboard boxes and boxes removed from the facility to avoid clutter and rodent/insect infestation.

IPC.4 Supplies used in the care of beneficiaries are not to be stored directly on the floor. E.g., on a raised platform. They should be stored according to the manufacturer's instructions.

IPC.5 Shelves used for storage of clean/sterile medical supplies and devices are at least 25 cm (10 inches) off the floor and 45 cm (18 inches) from the ceiling and sprinkler head.

- Example, you can measure 18 inches from the ceiling and place colored (red, blue) tape to mark the point where items are not be stored above that marker.

IPC.6 The facility has a process of managing expired reagents and supplies.

- Expired reagents or supplies found on site.
- Evidence of defined process for destruction of expired reagents or supplies.

IPC.7 The facility ensures effective environmental cleaning and disinfection practices to maintain environmental cleanliness. Records should be available.

- Environment to be cleaned at least daily.
- Ceiling tiles are intact, none missing or stained.
- Fans are clean and dust free.
- Air condition filters/vents are cleaned at least twice a year.
- Trash should be removed daily or as needed.
- Disinfectants are on hand for sanitizing benchtops.

IPC.8 Reduce the risk of facility associated infections

- Implement hand hygiene guidelines to reduce the risk of infections.
- **For example**, Centers for Disease Control and Prevention (CDC) guideline found on their website.
- Educate staff on proper hand washing techniques outlined on CDC website.
    - Wash hand for at least 20 seconds. **E.g., to time washing count to 20, sing happy birthday song from beginning to end twice.**
- Post hand hygiene guidelines near washing stations/sinks.
- Ensure supplies such as soap, disinfectant, hand towels, etc. are available and located in areas where hand washing is required.

CHAPTER 6: Specimen Processing (SP)

Purpose

Laboratory testing provides information about a beneficiary's health to assist providers in diagnostic and therapeutic decisions. Proper specimen collection and handling is an integral part of obtaining a valid and timely laboratory test result. Specimens must be obtained in the proper tubes or containers, correctly labelled, and then promptly transported to the laboratory. It is also essential that specimen is processed and stored correctly prior to and during the testing process. The standards falling under this chapter will ensure that NHIA approved laboratories have written policies and procedures to describe the methods used for specimen collection, handling, preservation, transportation, storage, retention and disposal.

Standards

SP.1 There is a process established and implemented for collecting, handling, preserving, transporting, storing, retaining and disposal of specimens.

SP.1.1 All venipuncture specimens are labelled by personnel performing Phlebotomy procedure with the beneficiary's name, DOB, date, and time of collection and the personnel's initials before leaving the beneficiary.

SP.1.2 All capillary tubes are placed in a test tube, which is then labelled with the beneficiary's name, DOB, date of collection and the personnel's initials before leaving the beneficiary.

SP.1.3 All urine specimen containers are labelled with the beneficiary's name, DOB, and the date of specimen collection.

SP.1.4 All miscellaneous specimens collected are labelled with the beneficiary's name, DOB, date of collection and type of specimen with additional labelling, if required.

SP.1.5 Written instructions exist for the collection, handling, preservation, storage, transportation, retention and disposal of specimens.

- Policies exists that define the process for each area listed above. **Reference made to ISO15189:2012 standard Primary Sample collection and handling (Clause 5.4.4), Sample Transportation (Clause 5.4.5), Sample Reception (Clause 5.4.6), Pre-examination handling, preparation and storage (Clause 5.4.7).**

CHAPTER 7: Laboratory Environment (ENVN)

Purpose

The standards guide the provision of a safe and secure environment for beneficiaries, their families, staff, and providers. The focus is on the internal physical environment for the purpose of 1) preventing accidents and injuries and 2) maintaining safe conditions.

Standards

ENVN.1 Adequate lighting installed throughout the facility.

- Work areas illuminated. **E.g., adequate lighting provided.**

ENVN.2 Safe flooring and walkways exist throughout the facility.

- Aisles and passageways are clear and unobstructed.

ENVN.3 A process exists to ensure safe exit when fire and non-fire (smoke) emergencies occur.

- Exit/emergency illuminated signs/lights working.
- Exit/emergency paths free from obstruction.
- Exit/emergency door(s) free from obstruction.
- Exit/emergency door(s) are unlocked from the inside.

ENVN.4 The facility reduces the risk of infections by ensuring proper waste disposal and safe handling of needles.

- Waste container(s) are closed unless actively adding or removing waste.
- Waste container(s) are marked with words “Hazardous Waste.”
- Sharps waste (needles, syringes, etc.) are immediately discarded into proper sharp container.
- Sharps containers closed and secured for disposal once three-quarters full (¾).

CHAPTER 8: Emergency Equipment and Planning (EQUP)

Purpose

This chapter focuses on best practice standards that outline processes and procedures associated with ensuring that emergency safety equipment exist within the facility, and staff are properly trained on how to use them if needed.

Standards

EQUP.1 The facility has a process for fire and non-fire (smoke) emergencies. Fire extinguisher safety measures implemented. Records should be available.

- Appropriate fire extinguishers are available, **E.g., Class ABC or BC fire extinguisher(s) available.**
- Fire extinguisher(s) mounted or visible.
- Fire extinguisher(s) unobstructed (nothing blocking extinguisher).
- Evidence that fire extinguisher is inspected annually. **E.g., sticker affixed indicating month and year of check.**
- Adequate number of smoke detectors are installed throughout the facility.
- Smoke detectors are checked at least once a year. **E.g., check batteries and change, as necessary.**

EQUP.2 The facility has a process for responding to spills of hazardous materials emergencies.

- Eyewash unit and safety shower within 10 seconds of hazard.
- Eyewash unit and safety shower inspection up to date. Checked weekly and results recorded on inspection card. An inspection card shall be available upon request.
- In the absence of an eyewash unit/station, a procedure exists that defines how a mishap in which blood and blood products splashes are handled. E.g., procedure outlines the process for eyes, nose, and mouth splashes.
    - Eyes: tilt head sideways and place eyes directly beneath running water. Let rinse for 30-60 seconds.

- Nose: do not inhale, splash water upwards into nasal cavity and let drain downward. Ensure no water drains into mouth and conduct shallow breathing. Repeat process for 30-60 seconds.
- Mouth: do not swallow, place mouth directly under running water and let drain. Water can also be splashed upwards into the mouth. Repeat process for 30-60 seconds.

EQUP.3 The facility establishes and implements a program for inspecting, testing, and maintaining laboratory equipment and documenting results.

- Maintain an equipment inventory list of all equipment used for the delivery of care to beneficiaries. Inventory equipment list includes date of purchase, brand, serial numbers, and date of last service, location, date of arrival, date of entering into service, condition when received and vendor's contact.
- Evidence that equipment/devices were checked twice a year or according to manufacturer's requirements. Affix PM sticker indicating month and year maintenance was done and signature of person completing same.

EQUP.4 Staff are educated/orientated on fire and non-fire (smoke) safety practices and how to appropriately respond to a hazardous spill.

- The facility involves staff in regular exercises to evaluate fire safety process. **E. g. conduct fire drills or simulate drill process, determine frequency of drills/simulation. Online fire training course can be completed. Fire training is to be done at least annually.**
- Maintain a "sign in" sheet to document who was present during drill/simulation.

CHAPTER 9: Personal Protective Equipment (PPE)

Purpose

The aim of this chapter is to ensure that all staff are protected against specific toxic and hazardous materials in the working environment. PPE is a gear or clothing to protect the wearer and is the final protection system to be used to reduce the risk associated with the hazard or hazardous material(s). PPEs such as gloves, eye and face protection, isolation gowns, aprons or any other PPEs needed to perform hazardous procedures should be provided by the facility.

Standards

PPE.1 **Gloves, masks, eye protection and other protective equipment are available and used correctly when required. Evidence of staff training should be available.**

- Appropriate eye & face protection available for all hazards in the laboratory.
- Personnel are wearing appropriate gloves. **Specific to specialty labs or hospital labs that use harsh chemicals or autoclaves requiring gloves for these purposes.**
- Appropriate gloves are available for all hazards in the laboratory.

PPE.2 **The facility ensures appropriate footwear and clothing is worn by all staff.**

- Shoes are appropriate for the laboratory. **E.g., closed-toe, closed-heel shoes with non-slip soles. Shoes must cover the entire foot. Shoes with holes should not be worn.**
- Clothing (lab coats, gowns, scrubs) is appropriate to the hazards posed in the laboratory.

CHAPTER 10: Required Information and Posting/Signage (SIGN)

Purpose

The standards guide the facility on the required information that is to be posted with respect to hazard and general information signage. Signage must be posted as necessary to inform staff of potential environmental and chemical hazards. General information signage can assist staff in emergencies to fire exits and emergency egress routes. Labeling of equipment used for storing laboratory reagents or supplies is also required to ensure that they are used for their intended purpose.

Standards

SIGN.1 All refrigerators, freezers and ice machines located in the facility are clearly labeled for their intended purpose.

- Chemical (reagents) refrigerators labelled “No food.”
- Food refrigerators labelled “Food only–no chemicals/ reagents.”

SIGN.2 General information signage to assist staff in emergencies and to identify potential hazards are posted throughout the facility.

- Biohazard signs are posted in the lab areas handling infectious materials.
- Biosafety cabinets shall be appropriately labelled according to the usage, e.g., “Flammable.”

SIGN.3 Equipment should be uniquely labelled and identifiable.

- Shall be uniquely labelled using any of the following:-
    - Manufacturer’s name, serial number or other unique identifier.
- When there are two of the same equipment, the serial number can be used as a unique identifier.

CHAPTER 11: Electrical Hazards (HAZD)

Purpose

The goal is to identify and reduce or eliminate electrical hazards that may create an unsafe environment for beneficiaries, their families, staff, and providers. The standards define the framework for reducing and controlling hazards and risks, preventing accidents and injuries, and maintaining safe conditions.

Standards

HAZD.1 Electrical safety hazard measures are implemented.

- Flexible cords in good condition.
- Cords are not on surfaces where flammable liquids may splash.
- Cover plates in place for outlets and switches to prevent accidental contact with electrical wires.
- Extension cords used. No extension cords should be used.

HAZD.2 Electrical Panel safety hazard measures are implemented.

- Electrical panel(s) are obstructed (blocked).
- Electrical panel(s) are labelled and have functional latches and power switches (on/off).
- Staff knows where electrical panels are located.

CHAPTER 12: Chemical/Hazardous Storage (STOR)

Purpose

Laboratories should have standards to define the guidelines for the proper and safe storage of chemicals. Therefore, this chapter highlights standards that establishes requirement as well as recommended best practices for storing chemicals. By implementing these standards, laboratories can ensure safer storage of chemicals and enhance housekeeping and organization of the lab. Proper storage of chemicals and supplies in the lab also helps utilize limited space in a more efficient manner.

Standards

STOR.1 The facility is designed with adequate shelving to store chemicals safely.

- Heavy items on lower shelves.
- Storage at least 18 inches below ceiling.

STOR.2 Safe chemical storage measures are implemented.

- Chemicals stored by compatibility and hazard class.
- Chemical containers clearly labelled with contents.
- Safety data sheets (SDS) accessible. SDS comes with chemical shipment & must be retained by laboratory.

STOR.3 Safe storage of hazardous waste is implemented.

- Waste containers are sealed during transfers.
- Waste containers labelled with the contents, “Hazardous Waste.”

CHAPTER 13: Information Management System (IMS)

Purpose

The goal of this information management system chapter is to ensure that the right information is available to the right person at the right time. The facility maintains complete and accurate records and reports for every beneficiary. Various aspects of the record and reports, like staff authorised to make entries and retention of records/reports are addressed effectively by the facility.

Standards

IMS.1 **The facility maintains records and reports of all tests undertaken at the facility. The facility also maintains records and reports of tests carried out by another facility on behalf of the facility.**

IMS.2 **The facility determines the retention time of records and reports to comply with local laws and regulations. Reference is made to** *Hospitals and Health Care Facilities (General) Regulations, 2000*. *Retrieved from* http://laws.bahamas.gov.bs/cms/images/LEGISLATION/SUBORDINATE /2000/2000-0098/HospitalsandHealthCareFacilitiesGeneralRegulations_1.pdf, page CH.235-25, 48.(2).

- Retention time based on local law cited above that states a beneficiary's records and reports or a copy shall be retained for at least 7 years.
- Retention time applies to records and reports from another Laboratory.

IMS.3 **The facility identifies those authorized to access data and information and those who are authorized to enter results and change results.**

- Data/information access restricted to "authorized" personnel only. For CLIA-waived tests, results can be entered by authorized non-testing personnel trained in this procedure. For CLIA non-waived tests, results should be entered by trained and competent testing personnel.
- Those authorized to enter results and change results are identified.

IMS.4 **The facility maintains confidentiality, privacy and security of records, data, and information to protect against loss, theft, damage, and destruction and facilitates easy retrieval. Policies/procedures should be available to guide these processes, including retention of documents. Process covers paper and/or electronic records.**

- Paper records are kept in a secure area where only authorized agents have access to them.
- Electronic records shall have a backup system.
- With electronic medical records, computer screens are minimized as appropriate.
- Beneficiary records, data, information are destroyed in a manner that does not compromise confidentiality. **E.g., utilizing a shredder machine.**

IMS.5 **The facility develops downtime policies and procedures to ensure data integrity and timely reporting of results.**

- Policies define the activities for all phases of testing (pre-analytic, analytic and post analytic). Downtime records should be available for all equipment, e.g., analyzers, computers, etc. Should another laboratory be used during downtime, the laboratory should either be accredited or an NHI approved laboratory.

IMS.6 **The facility has a process for proper authorization and release of information, reports and/or images.**

IMS.7 **The facility develops and maintains policies and procedures to provide uniform knowledge on their clinical and non-clinical functions/processes.**

CHAPTER 14: Result Reporting (RPT)

Purpose

The goal of this chapter is to ensure that the facility has established procedures for the reporting, release and amendment of results. Reference made to ISO15189:2012, clause 5.8.1. Reporting of Results.

Standards

RPT.1 **The facility establish procedure(s) to ensure that results are not misinterpreted. Result reporting is critical to the diagnosis and treatment of the beneficiary. It is important that lab results are not misinterpreted. Clear, legible results are to be released and there is an indication of any interfering substances that may cause a deviation in reported results.**

- Results are legible and easily understood.
- The presence of sample interference is mentioned in the report, e.g., lipemia, hemolysis, etc.

RPT.2 **The facility ensures that all results are traceable. When there is a revision or amendment to a result, the original record of the result is accessible.**

- The date, time and personnel amending the report is captured.
- The reason for the change is clearly stated.
- Results that are verbally communicated are to be documented.
- Manually amended results (e.g., in workbooks/log) are neatly crossed-out, initialed and dated with the correct result clearly stated. There is to be no use of white-out and no coverups.
- The Clinician is informed when there is a correction or revision of results.

Reference List

1) **Joint Commission International Accreditation Standards for Laboratories – 4th Edition.**
   https://www.jointcommissioninternational.org/-/media/jci/jci-documents/accreditation/laboratory/jci_standards_for_laboratories_standards-onlypdf.pdf

2) **International Organization for Standardization.**
   ISO 15189:2012. Medical laboratories - Requirements for quality and competence in medical laboratories. https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-3:en

3) **Pan American Health Organization/World Health Organization & US Centers for Disease Control and Prevention/Department and Human Services Joint Initiative for Laboratory Quality Management Systems – Step-Wise Improvement Process (LQMS-SIP) Checklist.**
   https://www.cmedlabsfoundation.com/wp-content/uploads/2020/11/Guidance-Stepwise-Final-04-10-2012.pdf

4) **Hospitals and Health Care Facilities (General) Regulations, 2000**
   http://laws.bahamas.gov.bs/cms/images/LEGISLATION/SUBORDINATE/2000/2000-0098/HospitalsandHealthCareFacilitiesGeneralRegulations_1.pdf

5) **CLIA 2013 Laboratory Record Retention Requirements 493.1105 Standard**
   https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-J/section-493.1105

6) **CLIA 2013 Laboratory Record Retention Requirements 606.160(d) Standard**
   https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-606/subpart-I/section-606.160

Manual Tracking Sheet

	Title	**Institution**	**Date**
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