National Health Insurance Authority

SPECIMEN COLLECTION CENTER QUALITY AND SAFETY STANDARDS MANUAL

1st Edition

Created: February 2023

INTRODUCTION

The Specimen Collection Center 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 Collection Centers can operate.

In developing the Specimen Collection Center 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 Specimen Collection Center Quality Management Systems and the Hospitals & Healthcare Facilities 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 Laboratory Director/designee of a Specimen Collection Center is notified in advance of an inspection. The idea of unannounced inspections is for the team to be able to see how the Specimen Collection Center operates on a daily basis.

AIM

These standards aim to improve the quality of Specimen Collection Center services delivered by describing a nationally consistent framework, which all NHI Specimen Collection Center 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 Specimen Collection Center services in the The Bahamas to be achieved.

ORGANIZATION OF THE STANDARDS MANUAL

The standards will provide NHI Specimen Collection Center 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 thirteen categories:

- **Responsibilities of Management (ROM)**
- **Staffing (STAFF)**
- **Quality Control Processes (QCP)**
- **Beneficiary Safety Criteria (BSC)**
- **Infection Prevention and Control (IPC)**
- **Specimen Processing (SP)**
- **Specimen Collection Center 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)**

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CHAPTER 1: Responsibilities of Management (ROM)

Purpose

The management of the Specimen Collection Center 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), and for meeting the organization's responsibility to the beneficiary population served.

Standards

ROM.1 **The Specimen Collection Center Medical Director/Specimen Collection Center Director/Designee is present for the inspection.**

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

ROM.3 **All personnel providing Specimen Collection Center services are appropriately registered/licensed as required by local laws.**

ROM.4 **The Specimen Collection Center has legible signage posted on the exterior or door indicating the type of services offered.**

ROM.4.1 There are "Authorized Personnel Only" signage in places where appropriate.

ROM.4.2 There is a list of all procedures/tests that are carried out by the Specimen Collection Center that is available for the client or Inspector, when requested.

ROM.5 **The Specimen Collection Center's infrastructure includes a functional telephone system. Land line, cell phone or fax machine.**

ROM.5.1 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.6 **The Specimen Collection Center's infrastructure has designated specimen collection area(s). Centers must be in an enclosed space, no tents, or outdoor cubicles.**

ROM.7 **The Specimen Collection Center's infrastructure has a designated waiting area(s).**

ROM.7.1 No Smoking signs are posted in waiting area or in an area where it is visible.

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

ROM.8 **The Specimen Collection Center has emergency power (generator) and UPS during a power outage to provide for required refrigeration and equipment. All major equipment should be on an Uninterruptible Power Supply (UPS).**

ROM.9 **The Specimen Collection Center 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 Specimen Collection Center Director/designee identifies the appropriate headcount and skill sets of staff required to render safe care to the beneficiaries. The Specimen Collection Center must orient the staff to its environment and orient them to specific duties and responsibilities related to their position.

Standards

STAFF.1 **The Specimen Collection Center is under the direction of a competent Laboratory Director/Designee with medical/scientific and technical background. She/he must be registered and licensed by the Health Professions Council of the Bahamas and poses a minimum of two (2) years technical experience in a clinical Laboratory. (Health Professions Act 1998).**

STAFF.2 **The name and credentials of the Laboratory Director shall be posted in a clear & visible location.**

STAFF.2.1 The names & credentials of all professional staff shall be available for review by the Inspector(s).

STAFF.3 **The Specimen Collection Center 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 Specimen Collection Centers to provide guidance to its staff through written policies and procedures that support their quality management system. The aim is to ensure that the Centers are committed to providing quality services in terms of adequate beneficiary preparation, specimen collection and specimen handling techniques. The chapter standards highlight the activities that would control the quality of service so that it meets the needs of the beneficiaries and ensure accurate test results.

Standards

QCP.1 The Specimen Collection Center 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 (Specimen Collection Center overview, mission, vision, objectives & scope).
- Facilities and safety (security, working environment, waste disposal).
- Purchasing and inventory (reagents & supplies management, stock management).
- Process management (specimen collection & transport, specimen/sample receiving, specimen/sample handling, preparation, storage, sample retention and disposal).
- Customer satisfaction & complaints management.
- Incident reporting and management.
- Information management (information security, confidentiality).

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 a problematic area and describes evidence-based solutions to this problem. The standard 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 Specimen Collection Center 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.

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, and the community. Infection Prevention and Control activities can differ from Specimen Collection Center to Specimen Collection Center 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 Specimen Collection Center 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 Specimen Collection Center 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 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 Specimen Collection Center 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 Specimen Collection Center ensures effective environmental cleaning and disinfection practices to maintain environmental cleanliness.

- 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 Specimen Collection Center Associated Infections

- Implement hand hygiene guidelines to reduce the risk of infections. Use Centers for Disease Control and Prevention (CDC) guideline found on their website. **See reference list at the back with link containing free handwashing posters.**
- 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

Specimen Collection Center services 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 test result. Specimens must be obtained in the proper tubes or containers, correctly labelled, and then promptly transported to the main Laboratory. It is also essential that specimen is processed and stored correctly prior to 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. (Health Professional Act 1998, Part X General Medical Laboratory 47:2).

SP.2 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.3 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.4 All urine specimen containers are labelled with the beneficiary's name, DOB, and the date of specimen collection.

SP.5 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.6 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: Specimen Collection Center Environment (ENVN)

Purpose

These standards guide the provision of a safe and secure environment for beneficiaries, their families and staff. 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 Specimen Collection Center.

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

ENVN.2 Safe flooring and walkways exist throughout the Specimen Collection Center.

- Aisles and passageways are clear and free from obstruction.

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 Specimen Collection Center 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 Specimen Collection Center, and staff are properly trained on how to use them if needed.

Standards

EQUP.1 **The Specimen Collection Center 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 Specimen Collection Center.
- Smoke detectors are checked at least once a year. **E.g., check batteries and change, as necessary.**

EQUP.2 **The Specimen Collection Center has a process for responding to spills of hazardous materials emergencies.**

- Portable or stationary eyewash unit within 10 seconds of hazard.
- Stationary eyewash unit and safety shower inspection up-to-date, if applicable. **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, noses and mouth splashes.**

EQUP.3 **The Specimen Collection Center ensures that the appropriate equipment/supplies are available for specimen taking.**

- Holder/adapter with evacuated collection system.
- Tourniquet.
- 70% isopropyl alcohol wipes.
- Povidone-iodine if taking blood cultures.
- Cotton and/or gauze, band aids for application on site.
- Syringes (maybe used in place of evacuated collection).
- Needles.
- Blood tubes

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

- The Specimen Collection Center 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 shall be done at least annually.**
- Maintain a "sign in" sheet to document who was present during fire training.
- All staff are trained on how to handle/control hazardous spills. **Should be done annually.**
- Maintain a training record/sign in sheet to document who completed hazardous spill training.

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, gowns, aprons or any other PPEs needed to perform hazardous procedures should be provided by the Specimen Collection Center.

Standards

PPE.1 **Gloves, masks, eye protection and other protective equipment are available and used correctly when required.**

- Personnel are wearing appropriate eye and face protection, when applicable.
- Appropriate eye & face protection available in the Specimen Collection Center.
- Personnel are wearing appropriate gloves.
- Appropriate gloves are available in the Specimen Collection Center.

PPE.2 **The Specimen Collection Center ensures appropriate footwear and clothing is worn by all staff.**

- Shoes are appropriate for the Specimen Collection Center. **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 Specimen Collection Center.

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

Purpose

The standards guide the Specimen Collection Center 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 Specimen Collection Center reagents or supplies is also required to ensure that they are used for their intended purpose.

Standards

SIGN.1 **All refrigerators and freezers located in the Specimen Collection Center are clearly labeled for their intended purpose.**

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

SIGN.2 **General information signage to assist staff in emergencies and to identify potential hazards are posted throughout the Specimen Collection Center.**

- Biohazard signs are posted in the areas handling infectious materials.

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 and staff. 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 on surfaces where flammable liquids may pool.
- Cover plates on 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 labeled and have functional latches and power switches (on/off).
- Staff knows where electrical panels are located.

CHAPTER 12: Chemical/Hazardous Storage (STOR)

Purpose

Specimen Collection Centers 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 Specimen Collection Center. Proper storage of chemicals and supplies in the Center also helps utilize limited space in a more efficient manner.

Standards

STOR.1 The Specimen Collection Center 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.

- Cleaning supplies/chemicals are stored separately.
- Supplies are stored in a separate or designated area.

STOR.3 Safe storage of hazardous waste is implemented.

- Waste containers are sealed during transfers.
- Waste containers labeled 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 Specimen Collection Center maintains complete and accurate records for every beneficiary.

Standards

IMS.1 **The Specimen Collection Center maintains records of all requisitions for tests undertaken at the Specimen Collection Center as well as samples received externally. Kept for 7 years.**

IMS.2 **The Specimen Collection Center maintains confidentiality, privacy and security of records, data, & information to protect against loss, theft, damage, and destruction and facilitates easy retrieval. Policies shall be available to guide these processes, including retention of documents. Process covers paper/electronic records.**

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

IMS.3 **The Specimen Collection Center develops downtime policies and procedures exists to ensure data integrity and timely reporting of results.**

- Policies define the activities for the collection process. Downtime records should be available for all equipment used in the specimen collection process, e.g., analyzers, computers, etc.
- Should another Specimen Collection Center/Laboratory be used during downtime, the Specimen Collection Center/Laboratory should either be accredited or an NHI approved Specimen Collection Center/Laboratory.

Reference List

1) **Joint Commission International Accreditation Standards for Laboratories – 4th Edition.**
https://www.jointcommissioninternational.org/-/media/jci/jci-documents/accreditation/Specimen Collection Center/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 Specimen Collection Center 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 Specimen Collection Center 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 Specimen Collection Center 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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