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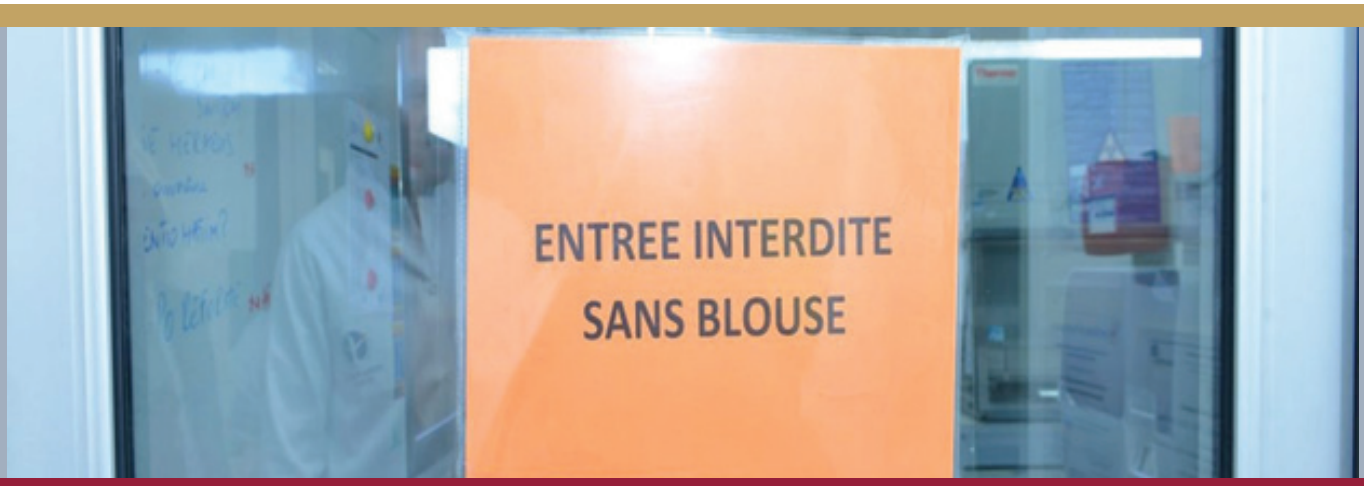
Safeguarding Africa's Health




# REGULATORY AND CERTIFICATION FRAMEWORK

## FOR INSTITUTIONS HANDLING HIGH RISK PATHOGENS

July 2022

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# Acronyms

| | |
|---|---|
| **Africa CDC** | Africa Centres for Disease Control and Prevention |
| **AfSME** | Africa Region Subject Matter Expert |
| **ANSI** | American National Standards Institute |
| **ASLM** | African Society for Laboratory Medicine |
| **BBI** | Biosafety and Biosecurity Initiative |
| **BRM** | Biorisk Management |
| **BSBS** | The Regional Biosafety and Biosecurity Legal Framework for the African Union Member States |
| **BSC** | Biological Safety Cabinet |
| **BSL** | Biosafety Level |
| **GHSI** | Global Health Security Index |
| **HCAT** | High Consequence Agents and Toxins |
| **HEPA** | High Efficiency Particulate Air |
| **HVAC** | Heating, ventilation and air-conditioning |
| **JEE** | Joint External Evaluation |
| **WHO** | World Health Organisation |

# Relevant Terms and Definitions[1]

The following terms and definitions are noted for the purposes of this document.

**Accreditation:** Written confirmation that an organization had demonstrated the competency to perform specified tasks. The tasks are performed following set standards. In the case of this certification framework, accreditation is conferred as prescribed in the Regional Biosafety and Biosecurity Legal Framework for the African Union Member States (BSBS).

**Biological agent:** A microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, animals, or plants.

**Biological safety cabinet (BSC):** An enclosed, ventilated working space designed to provide protection to the operator, the laboratory environment and/or the work materials for activities where there is an aerosol hazard. Containment is achieved by segregation of the work from the main area of the laboratory and/or through the use of controlled, directional airflow mechanisms. Exhaust air is passed through a high efficiency particulate air (HEPA) filter before recirculating into the laboratory or into the building's heating, ventilation and air conditioning system. There are different classes (I, II and III) of BSCs that provide different levels of containment.

**Biosafety:** Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

**Biosecurity:** Principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion or release.

**Commissioning:** Process of bringing an item into operation and ensuring that it is in good working order.

**Containment:** The combination of physical design parameters and operational practices that protect personnel, the immediate work environment and the community from exposure to biological agents. The term "biocontainment" is also used in this context.

**Certification:** Written confirmation that a person, product, or process conforms to specified requirements and standards. In the case of this certification framework, certification is conferred as prescribed in the BSBS Legal Framework.

**Decommissioning:** Process of stopping work, decontaminating and making safe a facility such that residual risk in the facility is reduced to an acceptable risk. Decommissioning may be followed by re-commissioning, repurposing or demolition.

**Decontamination:** Reduction of viable biological agents or other hazardous materials on a surface or object(s) to a pre-defined level by chemical and/or physical means.

**Design requirements:** Stated features required by a needs assessment which must be included in the design and which are set out in the user requirement specification.

**Directional airflow:** Air moving from an active (caused by an intentional force) or passive (air movement as a secondary effect) air source to an active extraction location.

**Engineering controls:** Risk control measures that are built into the design of a laboratory or laboratory equipment to contain the hazards. Biological safety cabinets (BSCs) and isolators are forms of engineering control in order to minimize the risk of exposure to and/or unintended release of biological agents.

**Expert:** An individual who has mastered the principles, concepts and/or methodologies related to the competency and has had significant success in performing the most demanding assignments requiring the competency. Within the context of the competency, able to apply innovations to problem-solving and task completion. Individuals are able to synthesize, critique or teach the competency and are able to provide

[1] World Health Organization. Laboratory Biosafety Manual Monograph: Laboratory design and maintenance, 2020. https://www.who.int/publications/i/item/9789240011397

coaching and mentoring. (Defined by its specific use in the description for an AfSME in the Regional Training and Certification Program for Biosafety and Biosecurity Professionals program).

**Exposure -** a situation or condition that makes someone likely to be harmed, especially when the person has not been protected from a hazard.

**High Consequence Agents and Toxins** - These are biological agents and toxins that have been determined to have the potential to pose a severe threat to both human, animal, and plant health.

**Infectious substances:** The term applied for the purposes of transport to any material, solid or liquid, which contains biological agents capable of causing infection in either humans, animals or both. Infectious substances can include patient specimens, biological cultures, medical or clinical wastes and/or biological products such as vaccines.

**Inward airflow:** Passive or active airflow that comes from outside a room or device.

**Pathogen:** A biological agent capable of causing disease in humans, animals or plants.

**Personal protective equipment (PPE):** Equipment and/or clothing worn by personnel to provide a barrier against biological agents, thereby minimizing the likelihood of exposure. PPE includes, but is not limited to, laboratory coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks and respirators.

**Primary containment:** The protection of the worker and immediate environment through a combination of good microbiological practices or techniques and the use of appropriate primary containment devices, e.g. BSCs

**Primary containment device (equipment):** A contained workspace designed to provide protection to its operator, the laboratory environment and/or the work materials for activities where there is an aerosol hazard. Protection is achieved by segregation of the work from the main area of the laboratory and/or through the use of controlled, directional airflow mechanisms. Primary containment devices include biological safety cabinets (BSCs), isolators, local exhaust ventilators and ventilated working spaces.

**Risk:** A combination of the likelihood of an incident and the severity of the harm (consequences) if that incident were to occur.

**Risk assessment:** A systematic process of gathering information and evaluating the likelihood and consequences of exposure to or release of workplace hazard(s) and determining the appropriate risk control measures to reduce the risk to an acceptable risk.

**Secondary containment:** The protection of people and the environment outside the laboratory by combining appropriate laboratory design and operating procedures.

**Validation:** Systematic and documented confirmation that the specified requirements are adequate to ensure the intended outcome or results. For example, in order to prove a material is decontaminated, laboratory personnel must validate the robustness of the decontamination method by measurement of the remaining biological agents against the detection limit by chemical, physical or biological indicators.

**Verification:** Confirmation that a given item (product, process or system) satisfies the specified requirements

# Table of Contents

# 1. Introduction

The Biosafety and Biosecurity Initiative was launched by the Africa Centers for Disease Control (Africa CDC) in April 2019 with the aim of strengthening the African Union (AU) Member States' laboratory biosecurity and biosafety systems and enabling them to comply with associated international standards[2]. Recent public health emergencies (i.e. the West African Ebola outbreak and the current COVID-19 global pandemic) have highlighted the growing need for biocontainment laboratories, and for local Biosafety and Biosecurity capacity building. The World Health Organization (WHO) Joint External Evaluation (JEE) and the Global Health Security Index (GHSI) have further demonstrated the inadequacies of current biosafety and biosecurity capacity on the African continent[3].

The concept of laboratory biosafety seeks to prevent the unintentional or accidental release of pathogens and toxins which places primarily laboratory personnel handling the pathogens at risk, with the general population and the environment secondarily affected. The focus of laboratory biosecurity differs from biosafety in intent. Biosecurity aims to thwart the deliberate theft, diversion or misuse of high-consequence biological agents or toxins for malevolent purposes including bioterrorism or biological weapons proliferation. In order to ensure the safety and security of personnel and the dangerous biological agents and toxins with which they work, there is need for not only appropriate physical security measures and technologies, but also for appropriately trained personnel.

This Regulatory and Certification Framework is targeted at Institutions (and organisations) handling high risk pathogens ("the Framework"), especially those classified as being High Consequence Agents and Toxins (HCAT) as defined in the Regional Biosafety and Biosecurity Legal Framework for the African Union Member States (BSBS). HCATs are described as biological agents and toxins that have been determined to have the potential to pose a severe threat to both human, animal, and plant health[4]. The Framework sets the requirements that guide facilities handling HCATs, in the implementation of laboratory biosafety and biosecurity practices associated with the planning, design, commissioning, maintenance, routine operation of safe and secure biocontainment laboratories that are fit for purpose.

These requirements are specifically for high containment facilities, which are comparable to biosafety level 3 (BSL3), containment level 3 (CL3), or physical containment level 3 (PC3); and maximum containment facilities, which are comparable to biosafety level 4 (BSL4), containment level 4 (CL4), or physical containment level 4 (PC4) handling HCATs in the Africa Region. As defined by the Framework, the high and maximum containment facilities may or may not meet all, but are consistent with, the requirements for facilities designed with either heightened control measures or maximum containment measures respectively, as described in WHO's Laboratory Biosafety Manual (LBM), 4th edition[5]. All laboratory facilities however, must comply with applicable local and national regulations.

# 2. Rationale

Through various consultations between the Africa CDC and AU Member States, the need for a Regulatory and Certification Framework for Institutions Handling High Risk Pathogens on the African continent has been consistently raised as an area of concern and a major limitation in laboratory biosafety and biosecurity efforts. To this end, high and maximum containment laboratories are used globally to provide a

[2] Africa CDC. Biosafety and Biosecurity Initiative. https://africacdc.org/programme/laboratory-systems-andnetworks/biosafety-and-biosecurity

[3] https://africacdc.org/download/biosafety-and-biosecurity-initiative-2021-2025-strategic-plan/

[4] The Regional Biosafety and Biosecurity Legal Framework for African Union Member States, 2021

[5] WHO Laboratory Biosafety Manual (LBM), 4th edition, 2020: https://www.who.int/publications/i/item/9789240011311

safe and secure laboratory spaces for the containment of high risk pathogens. The requirements for such facilities were originally defined in the WHO Laboratory Biosafety Manual, which was first published in 1983 and is currently in its fourth edition. Globally there are several countries including the United States of America (USA), Canada, Australia, South Africa and the United Kingdom (UK) that have implemented regulatory frameworks to define the characteristics of such containment facilities, producing widely used guidance documents for the specification of their design features and procedural requirements[6].
A consequence of these specifications developed in higher income/developed countries is that the "gold-standards" have often been unattainable for resource-constrained regions that are unable to meet the energy, and maintenance requirement for running these highly complex and technologically advanced facilities. These facilities require a high degree of technical expertise to design, construct, commission, maintain, repair and re-certify to ensure their safe and secure operation. In high-income countries with developed biocontainment infrastructure, these solutions work well, but have proven to be impractical when applied in countries with economic constraints, lack infrastructure suitably trained personnel[4].

The Framework has thus been developed for recognition and endorsement by AU Member States as an assessment tool for identifying the infrastructural and operational requirements for institutions handling HCATs.

# 3. Objectives

The three (3) main objectives of the Framework include:

i. To establish minimum standards for laboratory biosafety and biosecurity based on international requirements for compliance by high and maximum containment facilities.
ii. To develop a standard checklist for assessing high and maximum containment facilities' compliance to the minimum standards for laboratory biosafety and biosecurity.
iii. To establish a Regional Certification and Recognition Framework for high and maximum containment facilities.

# 4. Scope

This Framework document covers planning, design principles, biorisk management systems, good laboratory practices, maintenance, performance testing and verification to ensure the safe and secure operation of facilities handling HCATs. It does not aim to replace any national regulations, but to provide a tool for self-assessment against internationally accepted rules and procedures for the handling of high-risk biological agents[7]. Member States with pre-existing regulations should use the Framework as a benchmarking tool to review their adequacy in scope and detail with a view to domesticate accordingly.

[6] WHO Regional Office for Africa. Assessment Tool for Key Processes associated with the Design, Construction, Operation, Maintenance and Regulation of BSL-3 Facilities in the WHO African Region, 2016: https://www.afro.who.int/publications/assessment-tool-key-processes-associated-design-construction-operation-maintenance-and

[7] Integrated European Checklist for Laboratory Biorisk Management in Handling of High Consequence Risk Group 3 and 4 Agents (ECL-Biorisk), 2015

# 5. Minimum standards for laboratory biosafety and biosecurity

The Framework aims to meet the needs of the AU Member States through the provision of the minimum requirements for the planning, design, construction, commissioning, decommissioning, maintenance, certification and safe operation of high and maximum containment laboratories handling HCATs. The high and maximum containment levels described are designed to provide the minimum containment and operational requirements needed for the safe handling of the HCATs in the laboratory setting.

## 5.1 Comparison of laboratory biosafety and biosecurity guidelines and standards

International standards and guidelines for laboratory biosafety and biosecurity have been analysed in the development of the Framework's set of requirements with greater emphasis being placed on the implementation of sustainable solutions, without compromising safe and secure facility operation, for AU member states.

Consideration should thus be made for the adoption of an alternative approach to laboratory biosafety and biosecurity[8] whereby the design, infrastructure and operation of laboratories (and related systems) are better matched to the local risks, needs and resources, including during a health crisis. The WHO Laboratory Biosafety Manual (LBM), 4th edition, 2020 - presents an evidence-and risk-based approach to applied biosafety and biosecurity as being of critical importance to allow for the optimized use of resources and adoption of sustainable laboratory biosafety and biosecurity policies and practices that are relevant to their individual circumstances and priorities, consequently advancing international health security and enabling effective response to a biological event without compromising safety or security[9].

Some of the key infrastructural design and operational features of high and maximum containment facilities that are in common among the specifications and guidelines analyzed (and mandatory in respect of the Framework) are outlined in Table 1 below.

**Table 1** Mandatory design and operational features of high and maximum containment facilities

| Requirement | High Containment | Maximum Containment (Suit) | Maximum Containment (Cabinet) |
|---|---|---|---|
| Isolation of laboratory - Containment zones and associated corridors to be separated from generally trafficked areas (e.g. public and administrative areas) by a secured door | **Y** | **Y** | **Y** |
| Restricted access into the containment zone, limited to authorized personnel | **Y** | **Y** | **Y** |
| Anteroom | **Y** | **Y** | **Y** |
| Airlock with shower | **N** | **Y** | **N** |
| Surfaces (bench, floor, walls and ceilings) impervious to water and easy to clean | **Y** | **Y** | **Y** |
| Surfaces (bench, floor) are resistant to chemicals (acid, alkali, solvents) and gaseous agents | **Y** | **Y** | **Y** |

[8] Chatham House Sustainable Laboratories Initiative.:https://www.chathamhouse.org/about-us/our-departments/global-health-programme/sustainable-laboratories-initiative

[9] WHO Laboratory Biosafety Manual (LBM), 4th edition, 2020: https://www.who.int/publications/i/item/9789240011311

| Requirement | High Containment | Maximum Containment (Suit) | Maximum Containment (Cabinet) |
|---|---|---|---|
| Sealable for decontamination, including sealed windows and any penetrations in the surface | **Y** | **Y** | **Y** |
| HVAC system - inward directional airflow/laboratory under negative pressure relative to atmosphere | **Y** | **Y** | **Y** |
| Exhaust air HEPA filtered | **Y** | **Y** | **Y** |
| BSCs/primary containment equipment | **Y** | **Y** | **Y** |
| Double-door barrier autoclave in laboratory | **Desirable** | **Y** | **Y**[1] |
| Appropriate personal protective equipment as inferred by risk assessment is used in the laboratory | **Y** | **Y** | **Y** |
| Effluent treatment system appropriate to the work being conducted to be provided | **Y** | **Y** | **Y** |
| Established biorisk management (BRM) program is in place to effectively control laboratory biological risks identified through a risk assessment | **Y** | **Y** | **Y** |

[1]Double-door, pass-through autoclave for decontaminating materials passing out of the Class III BSC(s

### 5.1.1 High Containment Facility

A high containment facility meets the minimum design features, as specified in the Framework, to safely handle HCATs that may cause serious or potentially lethal disease through the inhalation route of exposure. These minimum design features are required to limit or reduce risks of infection in laboratories when working with high-risk pathogens.

### 5.1.2 Maximum Containment Facility

A maximum containment facility is required for all activities involved in the handling of HCATs that pose a high risk to individuals through infections which may result in life-threatening, frequently fatal diseases with limited or no available effective vaccines or treatments. These high risks arise from work with high-risk pathogens that have severe consequences and when there is a high likelihood of exposure to and/or release of these pathogens. This also includes high risk pathogens with uncertain risk of transmission.

There are two (2) types of maximum containment facilities, i.e. cabinet line facility and suit facility.

i. Cabinet line facility: work is performed using more than one Class III BSC or isolator acting as a sealed primary containment device. The cabinets or isolators are interconnected in a cabinet line configuration which is used to house all the laboratory equipment and working space required.
ii. Suit facility: work with high-risk pathogens requires personnel to wear a one-piece, positive-pressure protective suit complete with a separate breathing air supply, which is fully isolated from the room air.

## 5.2 Requirements for high and maximum containment facilities

Containment laboratories must be designed and built to prevent or control the exposure of laboratory workers, other persons, and the environment to the biological agent in use[10]. The Framework focuses on building containment laboratories in resource-constrained settings and provides guidance on biosafety and biosecurity requirements that can be met and are sustainable in those environments[11]. The requirements for high and maximum containment facilities to follow cover physical design, containment management and operating practices. They are specified into the following parts:

i. Containment design and construction requirements.
ii. Management and operational practice requirements; and
iii. Maintenance, commissioning, and certification requirements.

### 5.2.1 Containment design and construction requirements

Relates to requirements for the facilities containment features designed to prevent exposure of laboratory workers, people and animals in the outer environment of the containment zone to HCATs. The containment barrier demarcates the containment zone, i.e. working area of the facility, being a boundary between the 'dirty' areas (where the high-risk pathogens are handled) from the 'clean' areas. The containment zone is established through a combination of physical features (i.e. walls, floors, ceiling and doors), sustained inward directional airflow that is maintained through having the containment zone rooms operating at cascading negative differential pressures.

| 5.2.1.1 | Containment Barrier | High Containment | Maximum Containment (Suit) | Maximum Containment (Cabinet) |
|---|---|---|---|---|
| 5.2.1.1.1 | Containment zones and associated corridors to be separated from generally trafficked areas (e.g. public and administrative areas) by a secured door. | ⊗ | ⊗ | ⊗ |
| 5.2.1.1.2 | Windows on the containment barrier to be non-opening and sealed. | ⊗ | ⊗ | ⊗ |
| 5.2.1.1.3 | Pass-through chambers and double-door autoclaves on the containment barrier to be equipped with either interlocking doors (preferred), or visual/audible alarms, or other acceptable means, to ensure that the doors are not opened simultaneously. | ⊗ | ⊗ | ⊗ |
| 5.2.1.1.4 | All penetrations of the containment barrier, including all conduits and wiring, to be sealed with a non-shrinking sealant that is compatible with the disinfectant(s) in use. | ⊗ | ⊗ | ⊗ |
| 5.2.1.1.5 | Facility to be located in a separate building or, as a minimum, in a clearly delineated zone within a secure building. | ⊗ | ⊗ | ⊗ |

[10] Standards for containment level 3 facilities, 2014: https://mrc.ukri.org/documents/pdf/ssr/standards-for-containment-level-3-facilities/

[11] WHO Regional Office for Africa. Report on the Status of EPDLN BSL-3 in Select Countries in the African Region, 2016: https://www.afro.who.int/sites/default/files/2017-08/Report%20on%20the%20Status%20of%20EDPLN%20BSL-3%20in%20Select%20Countries%20in%20the%20African%20Region.pdf

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|---|---|---|---|---|
| 5.2.1.1.6 | Entry and exit of personnel and supplies must be through an airlock or pass-through system. | ∅ | ⊗ | ∅ |
| 5.2.1.1.7 | Entry into the laboratory is through a chemical shower cubicle, which will serve to decontaminate the operator's suit upon exit. | ∅ | ⊗ | ∅ |
| 5.2.1.1.8 | All personal clothing must be removed before putting on dedicated laboratory clothing (such as scrubs) and the positive pressure suit. | ∅ | ⊗ | ∅ |
| 5.2.1.1.9 | Personnel should shower before putting their own clothes back on and leaving. | ∅ | ⊗ | ⊗ |
| 5.2.1.1.10 | On entering a cabinet line facility, personnel must remove all personal clothing and put on dedicated laboratory clothing (for example, scrubs, coveralls), and also dedicated PPE. | ∅ | ∅ | ⊗ |

| **5.2.1.2** | **Access Points and Controls** | **High Containment** | **Maximum Containment (Suit)** | **Maximum Containment (Cabinet)** |
|---|---|---|---|---|
| 5.2.1.2.1 | Restricted access into the containment zone, limited to authorised personnel, to be provided through a controlled access system (or equivalent). | ⊗ | ⊗ | ⊗ |
| 5.2.1.2.2 | Laboratory room doors to have appropriate signage (including the international biohazard warning symbol, containment level, name and telephone number(s) of contact person, and entry requirements) to be posted at the containment zone point(s) of entry. | ⊗ | ⊗ | ⊗ |
| 5.2.1.2.3 | Dedicated change area to be provided at personnel entry to the containment zone to allow for separation of personal clothing from dedicated containment zone clothing (i.e., “clean” change area separated from “dirty” change area). | ⊗ | ⊗ | ⊗ |
| `5.2.1.2.4 | Anteroom(s) to include a walk-through body shower between the “clean” and “dirty” change areas for personnel entry/ exit through the containment barrier of the containment zone. | ∅ | ⊗ | ∅ |
| 5.2.1.2.5 | Controlled entry into the containment perimeter is through an anteroom, located between the clean and dirty areas, with a system to ensure that more than one door cannot be opened at a time or two interlocking self-closing doors, alarms, and associated operating procedures to ensure the building systems function effectively at all times. | ⊗ | ⊗ | ⊗ |
| **5.2.1.3** | **Surface Finishes and Casework** | | | |
| 5.2.1.3.1 | Doors, frames, casework, bench-tops and laboratory furniture (e.g., stools, chairs) to be constructed from non-absorbent materials. | ⊗ | ⊗ | ⊗ |

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| 5.2.1.3.2 | Surfaces and interior coatings to be cleanable and resistant to scratches, stains, moisture, chemicals, heat, impact, and repeated decontamination, in accordance with function. | ⊗ | ⊗ | ⊗ |
| 5.2.1.3.3 | Floors shall be slip-resistant, impervious to liquids, and resistant to chemicals in accordance with function | ⊗ | ⊗ | ⊗ |
| 5.2.1.3.4 | The installation of seamless, sealed, resilient or poured floors, with integral cove bases should be considered. | ⊗ | ⊗ | ⊗ |

| **5.2.1.4** | **HVAC System** | **High Containment** | **Maximum Containment (Suit)** | **Maximum Containment (Cabinet)** |
|---|---|---|---|---|
| 5.2.1.4.1 | HVAC system to provide sufficient air changes per hour (AC/hr) under normal operation to maintain inward directional airflow, i.e. air will always flow towards areas of higher containment in cascade based on facility function. | ⊗ | ⊗ | ⊗ |
| 5.2.1.4.2 | Monitoring device(s) that visually demonstrate pressure differential to be provided for the containment zone. | ⊗ | ⊗ | ⊗ |
| 5.2.1.4.3 | HVAC system designed for fail-safe operation with audible and visual alarms to be provided inside and outside the containment zone to signal HVAC systems failure. | ⊗ | ⊗ | ⊗ |
| 5.2.1.4.4 | Supply and exhaust air systems to be independent of other areas. | ⊗ | ⊗ | ⊗ |
| 5.2.1.4.5 | Supply air duct to be provided with effective backdraft protection (e.g. bubble tight damper), or employ an effective alternative means to prevent airflow reversal. | ⊗ | ⊗ | ⊗ |
| 5.2.1.4.6 | Supply and exhaust air systems to be provided with automatic mechanical/electronic interlocks that prevent sustained positive pressurisation of the containment zone. | ⊗ | ⊗ | ⊗ |
| 5.2.1.4.7 | Exhaust air to be passed through a HEPA filter. | ⊗ | ⊗ | ⊗ |
| 5.2.1.4.8 | Controlled pressure differentials should be designed from the least to the most contaminated area (with potentially infectious material). | ⊗ | ⊗ | ⊗ |
| 5.2.1.4.9 | All HEPA filters must be tested and certified at least annually. The housing of the HEPA filter should be designed to allow in-situ decontamination, before filter removal. | ⊗ | ⊗ | ⊗ |

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| **5.2.1.5** | **Facility Services** | | | |
| 5.2.1.5.1 | Handwashing sinks (with "hands-free" capability) to be provided and located as close as possible to the point(s) of exit of the containment zone. | ⊗ | ∅ | ⊗ |
| 5.2.1.5.2 | Water supply services to be provided with isolation valve and backflow prevention. | ⊗ | ⊗ | ⊗ |
| 5.2.1.5.3 | Emergency eyewash and shower equipment to be provided in accordance with containment zone activities. | ⊗ | ∅ | ⊗ |
| 5.2.1.5.4 | Drain piping from laboratories handling HCATs to be separated from those of lower containment areas and directly connected to an effluent treatment system. | ⊗ | ⊗ | ⊗ |
| 5.2.1.5.5 | All potentially contaminated laboratory effluent waste must be inactivated chemically or thermally before being discharged to the municipal drain system (or similar). The effluent treatment system must be validated at least annually.<br>*Method to be used should be effective at inactivating the pathogen or toxin being handled in the laboratory* | ⊗ | ⊗ | ⊗ |
| 5.2.1.5.6 | Services and equipment critical to maintaining containment and biosecurity to be supported by emergency power systems (e.g. back-up generator, solar power), and UPS for electronic control equipment. | ⊗ | ⊗ | ⊗ |
| **5.2.1.6** | **Primary Containment - Safety Equipment & PPE** | **High Containment** | **Maximum Containment (Suit)** | **Maximum Containment (Cabinet)** |
| 5.2.1.6.1 | Certified BSCs (to be certified at least annually) and other primary containment devices to be provided, as determined by a risk assessment. Due consideration should be given to the correct placement of these devices (open front), e.g. BSCs, when present, to be located away from high traffic areas, doors, and air supply/exhaust diffusers. | ⊗ | ⊗ | ⊗ |
| 5.2.1.6.2 | A communication system to be provided between the laboratory work areas/cubicles and outside the containment zone. | ⊗ | ⊗ | ⊗ |
| 5.2.1.6.3 | Appropriate personal protective equipment (PPE) as inferred by risk assessment is used in the laboratory. | ⊗ | ⊗ | ⊗ |
| 5.2.1.6.4 | A documented procedure for verification and maintenance of non-disposable PPE is available and practiced (functional checks e.g. checking the condition of the positive | ⊗ | ⊗ | ⊗ |

| | | | | |
|---|---|---|---|---|
| | pressure suits) | | | |
| 5.2.1.6.5 | Personnel working in the laboratory are required to wear positive-pressure suits supplied with external breathing air, which forms the barrier between the operator and the HCAT material. | ∅ | ⊗ | ∅ |
| 5.2.1.6.6 | The positive-pressure suits must be designed to withstand contact with the equipment, chemicals and other materials used in the suit laboratory, and to allow tasks to be carried out safely in the laboratory environment. Detailed SOPs should be developed on safe use of the suit, with personnel receiving practice and training on how to implement the SOPs correctly. | ∅ | ⊗ | ∅ |
| 5.2.1.6.7 | An effective maintenance system needs to be in place that covers cleaning, disinfection, examination, replacement, repair and testing of the suits. The frequency of testing should be determined through the risk assessment. Before using a suit, visual checks and pressure tests of the integrity of the suit must be carried out. | ∅ | ⊗ | ∅ |
| 5.2.1.6.8 | Completely closed primary containment cabinet barrier system working under negative pressure that isolates the biological material from the surrounding laboratory environment. | ∅ | ∅ | ⊗ |
| 5.2.1.6.9 | Cabinet/isolator is equipped with filters for inlet and exhaust air, entry ports such,. Double HEPA filtration on the exhaust | ∅ | ∅ | ⊗ |
| **5.2.1.7** | **Effluent Treatment Systems (ETS)** | | | |
| 5.2.1.7.1 | An effluent treatment system appropriate to the work being conducted to be provided. | ⊗ | ⊗ | ⊗ |
| 5.2.1.7.2 | Alarm system to be provided to indicate warnings and failure of effluent treatment system. | ⊗ | ⊗ | ⊗ |
| 5.2.1.7.3 | Thermally controlled effluent treatment systems to be equipped with effective electronic temperature monitoring devices. | ⊗ | ⊗ | ⊗ |

### 5.2.2 Management and operational practice requirements

The management and operational practice requirements are aimed at mitigating and control of risks associated with the use, handling or storage of HCATs in containment facilities. Effective risk management and operational practices can be achieved through the development and implementation of a biorisk management (BRM) program[12]. The BRM program should ideally be based on a management system approach, which enables institutions to effectively identify, assess, control, and evaluate the biosafety and biosecurity risks inherent in its activities[13].

| 5.2.2.1 | Administrative Controls | High Containment | Maximum Containment (Suit) | Maximum Containment (Cabinet) |
|---|---|---|---|---|
| 5.2.2.1.1 | Established biorisk management (BRM) program is in place to effectively control laboratory biological risks identified through a risk assessment. | ⊗ | ⊗ | ⊗ |
| 5.2.2.1.2 | A risk assessment shall be conducted to identify all hazards and threats, as well as to document the appropriate mitigation strategies for the facility where activities involving HCATs are carried out. The risk assessment and mitigation strategies shall be documented clearly and records kept. All staff has been informed of the contents of the risk assessment. | ⊗ | ⊗ | ⊗ |
| 5.2.2.1.3 | A biosafety and biosecurity manual (Operations and Safety Manual) shall be developed, implemented and kept up to date. The manual shall cover the institutional biosafety policies, programmes and plans, based on facility risk assessment(s). | ⊗ | ⊗ | ⊗ |
| 5.2.2.1.4 | A biosecurity plan shall be developed based on a security risk assessment, and subsequently be implemented, evaluated and improved as necessary, and kept up to date. | ⊗ | ⊗ | ⊗ |

[12] Ministry of Health Singapore, National Biosafety Standards for Maximum Containment Facilities, 2019: https://www.moh.gov.sg/docs/librariesprovider7/useful-info-and-guidelines-documents/national-biosafety-standards-for-mcf-may-2019.pdf

[13] ISO 35001:2019 Biorisk management for laboratories and other related organisations: https://www.iso.org/standard/71293.html

| 5.2.2.2 | Work Practices - Handling of HCATs | High Containment | Maximum Containment (Suit) | Maximum Containment (Cabinet) |
|---|---|---|---|---|
| 5.2.2.2.1 | Traffic (i.e. materials and personnel) flow patterns from areas of lower contamination ("clean") to areas of higher contamination ("dirty") areas to be established and followed, as determined by a risk assessment. | ⊗ | ⊗ | ⊗ |
| 5.2.2.2.2 | Verification of the integrity of the containment barrier, inward directional airflow, and safe operation of primary containment devices to be performed routinely in accordance with SOPs. | ⊗ | ⊗ | ⊗ |
| 5.2.2.2.3 | Use Good Microbiological Practice and Procedures (GMPP) techniques when handling infectious material to minimize the formation of aerosols and droplets when manipulating specimens. | ⊗ | ⊗ | ⊗ |
| 5.2.2.2.4 | All open manipulation, involving infectious materials, is conducted in BSCs within the containment zone. No work in open vessels is conducted on the open bench. | ⊗ | ⊗ | ⊗ |
| 5.2.2.2.5 | Material containing live pathogens must be packed in safe containers with subsequent decontamination procedures of the containers before removal from containment into designated secure areas (e.g. refrigeration, liquid nitrogen storage areas). | ⊗ | ⊗ | ⊗ |
| 5.2.2.2.6 | Procedures, based on an risk assessment and in accordance with SOPs, to be in place to prevent a leak, drop, spill, or similar event, during the movement of infectious material or toxins within the containment zone, or between containment zones within a building. | ⊗ | ⊗ | ⊗ |
| 5.2.2.2.7 | Large scale cultures of infectious material or toxins to be contained within a closed system or other primary containment device. | ⊗ | ⊗ | ⊗ |
| 5.2.2.2.8 | Use of validated inactivation procedures for agents being used. | ⊗ | ⊗ | ⊗ |
| 5.2.2.2.9 | Validated transfer protocols of inactivated material or non-inactivated material with proper packaging to outside of the containment facility are in place. | ⊗ | ⊗ | ⊗ |
| 5.2.2.2.10 | Procedures for the performance of general maintenance activities in the containment zone to be in place. Personnel to conduct regular visual inspections of the containment zone to identify faults and/or deterioration; when found, corrective actions to be taken. | ⊗ | ⊗ | ⊗ |

| 5.2.2.3 | Decontamination and Waste Management | High Containment | Maximum Containment (Suit) | Maximum Containment (Cabinet) |
|---|---|---|---|---|
| 5.2.2.3.1 | Proper processes for the identification and segregation of contaminated materials must be adopted before decontamination or disposal. | ⊗ | ⊗ | ⊗ |
| 5.2.2.3.2 | Work surfaces to be cleaned and decontaminated with a disinfectant effective against the infectious material in use, or a neutralizing chemical effective against the toxins in use at a frequency to minimize the potential of exposure to infectious material or toxins. | ⊗ | ⊗ | ⊗ |
| 5.2.2.3.3 | Where decontamination is not possible in the laboratory area, or onsite, contaminated waste must be packaged in a leak-proof fashion, for transfer to another facility with decontamination capacity. | ⊗ | ⊗ | ⊗ |
| 5.2.2.3.4 | The facility must be sealable to permit effective gaseous decontamination and ensure no escape of gaseous fumigant. Procedures shall be in place to validate the efficacy of the decontamination process. | ⊗ | ⊗ | ⊗ |
| 5.2.2.3.5 | All waste from the facility must be treated, preferably by steam sterilisation (or autoclave) and/or heat or chemical treatment before removal or discharge from the facility. | ⊗ | ⊗ | ⊗ |
| 5.2.2.3.6 | Performance of all the waste treatment equipment (e.g. autoclave, ETS) shall be assessed and documented as part of the facility commissioning. Additionally, periodic review of waste treatment equipment performance shall be performed. | ⊗ | ⊗ | ⊗ |
| 5.2.2.3.7 | Sharps (if any) shall be discarded in containers that are leak-proof and puncture resistant, or specially constructed for the disposal of sharps waste. | ⊗ | ⊗ | ⊗ |
| 5.2.2.3.8 | All equipment or materials (other than waste) shall be thoroughly decontaminated at the containment barrier and labelled as decontaminated prior to removal from the facility. | ⊗ | ⊗ | ⊗ |
| 5.2.2.3.9 | The laboratory must be capable of undertaking gaseous decontamination (for example, fumigation) in order to allow for regular service and maintenance of the laboratory and any specialist equipment. | ⊗ | ⊗ | ⊗ |

| | | | | |
|---|---|---|---|---|
| 5.2.2.3.10 | All effluents from the suit area, decontamination chamber, suit shower and cabinet line (BSCs or isolators) must be decontaminated before final discharge using either heat or chemical treatment. Effluents may also require subsequent correction to a neutral pH and suitable temperature before discharge. | ⊗ | ⊗ | ⊗ |
| 5.2.2.3.11 | A double-door, pass-through autoclave must be available in the laboratory area. | ∅ | ⊗ | ⊗ |
| 5.2.2.3.12 | Other methods of decontamination must be available for equipment and items that cannot withstand steam sterilization, for example, an air lock fumigation chamber. | ⊗ | ⊗ | ⊗ |

| **5.2.2.4** | **Emergency/Incident Response Plan** | **High Containment** | **Maximum Containment (Suit)** | **Maximum Containment (Cabinet)** |
|---|---|---|---|---|
| 5.2.2.4.1 | A contingency plan is developed that provides specific standard operating procedures (SOPs) to be followed in possible emergency scenarios that apply to the work and local environment. Personnel must be trained on these procedures and have periodic refresher training to maintain competency. | ⊗ | ⊗ | ⊗ |
| 5.2.2.4.2 | All incidents must be reported to the appropriate personnel promptly. Accidents and incidents must be documented, in line with national regulations where applicable. Any incident must be reported and investigated in a timely manner and taken into consideration when updating laboratory procedures and emergency response plans. | ⊗ | ⊗ | ⊗ |
| 5.2.2.4.3 | Written procedures for cleaning and decontaminating spills must be developed for the laboratory and followed by adequate training of personnel. Laboratory staff should have immediate access to spill kits, including those containing disinfectant. | ⊗ | ⊗ | ⊗ |
| 5.2.2.4.4 | The emergency procedures and staff preparedness shall be tested through regular emergency drills, at least annually. | ⊗ | ⊗ | ⊗ |
| 5.2.2.4.5 | Because of the complexity of the engineering, design and construction of maximum containment facilities, in either cabinet or suit configuration, a separate detailed work manual should be developed and tested in training exercises. | ∅ | ⊗ | ⊗ |

| | | | | |
|---|---|---|---|---|
| **5.2.2.5** | **Occupational Health and Safety Program** | | | |
| 5.2.2.5.1 | Laboratory personnel and support staff must undergo occupational medical consultation and/or assessment by an occupational health physician and be offered all available immunisations for agents handled or potentially present in the facility, prior to starting work. | ⊗ | ⊗ | ⊗ |
| 5.2.2.5.2 | A documented procedure for post-exposure actions is available and practiced. | ⊗ | ⊗ | ⊗ |

### 5.2.3 Maintenance, commissioning and certification requirements

There shall be a system in place to maintain (both routine and corrective), service and test all critical equipment in the facility. The equipment shall be operated and maintained as specified by the respective equipment manufacturers recommendation and regulatory agencies, with the maintenance frequency and schedule being determined based on the risks that arise in the event of failure[10].

The institution shall establish and maintain documented procedures to ensure equipment and elements of physical plant installations are maintained, calibrated, certified or validated in a manner consistent with the intent and requirements of the site's operational needs. All maintenance activities are to be performed by competent individuals and that risks associated with the work must have been subjected to risk assessment.

| **5.2.3.1** | **Maintenance** | **High Containment** | **Maximum Containment (Suit)** | **Maximum Containment (Cabinet)** |
|---|---|---|---|---|
| 5.2.3.1.1 | System test and inspection lists including monitoring of all containment, safety and security features, are completed and signed off before use of laboratory (or at a predetermined interval). | ⊗ | ⊗ | ⊗ |
| 5.2.3.1.2 | Documented procedures are established and maintained to ensure equipment and elements of the facility infrastructure systems that may have an impact on its safe and secure operation are maintained in a manner consistent with the intent and requirements of the facility's design. | ⊗ | ⊗ | ⊗ |
| **5.2.3.2** | **Commissioning and Certification** | | | |
| 5.2.3.2.1 | Commissioning will ensure that the facility is constructed and performs as intended. The commissioning plan should identify all steps required before operation is commenced initially or resumed after any temporary shutdown. The commissioning process should provide the benchmark for acceptable facility operation and the description of the | ⊗ | ⊗ | ⊗ |

| | | | | |
|---|---|---|---|---|
| | programme to be put in place to maintain that level of performance. | | | |
| 5.2.3.2.2 | All performance critical design features, construction techniques, materials and equipment selected are documented in line with the facility risk assessment. | ⊗ | ⊗ | ⊗ |
| 5.2.3.2.3 | The facility design, operational parameters, and procedures are verified and documented prior to operation. Facility system performance must be re-verified and certified for use at a predetermined interval, at least annually or after significant modification to ensure operational parameters are met. | ⊗ | ⊗ | ⊗ |

## 5.3 Regional certification and recognition framework[14] for high and maximum containment facilities

To ensure compliance to the set minimum standards for biosafety and biosecurity for high and maximum containment facilities, the Framework provides a set of minimum standards and a tool for evaluating compliance to the stated requirements.

### 5.3.1 Program design

The standard tool for evaluating compliance is a scored checklist that specifies biosafety and biosecurity requirements and recognizes implementation on an incremental scale towards full compliance. At each assessment, the facility level of compliance is determined by the score and recognized on a scale of 0-5 stars rating. Each star level is associated with performance in terms of total scores in the assessment as follows: <55% points = 0 stars, 55%-64% points = 1 star, 65-74% points = 2 stars; 75-84% points = 3 stars, 85-94% points = 4 stars and ≥ 95% points = 5 stars. With this framework, facilities will progressively develop compliance towards requirements while recognized and rewarding for current efforts and encouragement towards attainment of 5 stars and full compliance.

| **No Stars** | **1 Star** | **2 Stars** | **3 Stars** | **4 Stars** | **5 Stars** |
|---|---|---|---|---|---|
| (0 – 87 pts) | (88 – 103 pts) | (104 – 119 pts) | (120 – 135 pts) | (136 – 151 pts) | (152 – 160 pts) |
| *< 55%* | *55 – 64%* | *65 – 74%* | *75 – 84%* | *85 – 94%* | *≥95%* |

Facilities will be recognized and certified as follows:

- **0-2 Stars**: Facility is not authorized to perform any functions associated with HCAT. This includes manipulation, storing, transporting or destruction of HACTs.
- **3-4 Stars**: Provisional authorization to perform functions associated with HACT. Facility is given 3 – 6 months to submit corrective actions to the ASLM Secretariat, failure of which result in withdrawal of provisional authorization. Upon evaluation of submitted corrective actions and facility score improves to 5 stars, a certification of authorization will be issued
- **5 Stars**: certificate of authorization to perform functions associated with HCAT. Certificate is valid for 5 years with surveillance assessments at 3rd and 5th year.

[14] World Health Organization. Regional Office for Africa. (2015). Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2:2015 for Clinical and Public Health Laboratories. World Health Organization. Regional Office for Africa. https://apps.who.int/iris/handle/10665/204423

### 5.3.2 Governance structure

Recognizing that Africa CDC is not an accreditation body, an Independent Advisory Committee (IAC) will be established to govern the implementation of the Certification and Recognition Program. The IAC will comprise of regional and international experts in biorisk management and biocontainment engineering. The African Society for Laboratory Medicine (ASLM) shall be the Secretariat. The Agency/Institution responsible for Biosafety and Biosecurity (under the Regional Biosafety and Biosecurity Legal Framework), facilities and assessors are the other key stakeholders to the governance structure tasked with coordinating implementation of the recognition and certification program

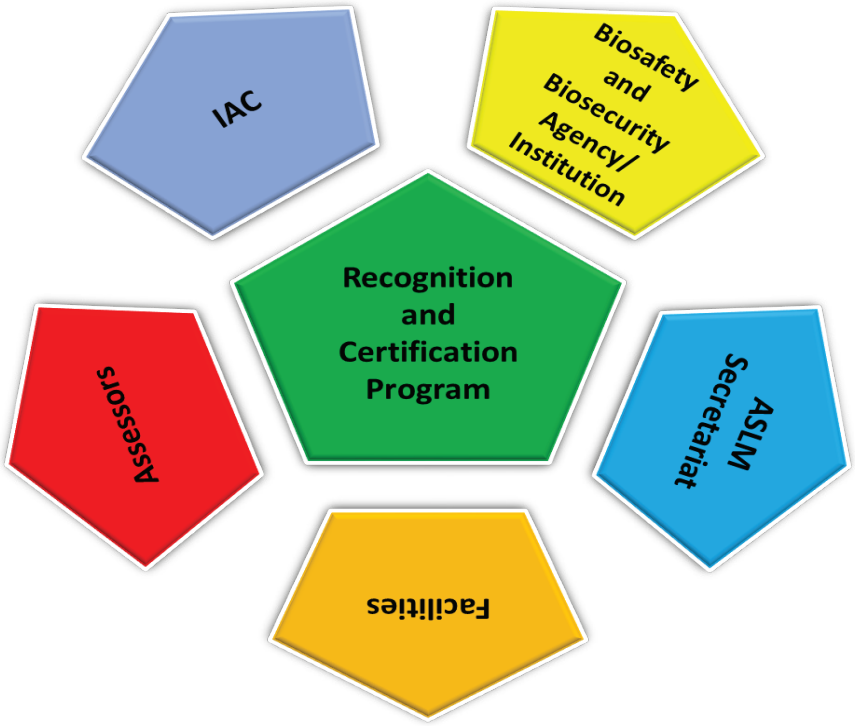


**Figure 1: Recognition and Certification Governance Structure**

#### 5.3.2.1 Independent Advisory Committee (IAC)

The Independent Advisory Committee (IAC) appointed by the Africa CDC shall comprise of experts in biosafety, biosecurity, biocontainment and biorisk management. The IAC will be responsible for:

- Development, design, review and updating of the minimum standards for high and maximum containment facilities
- Coordinating implementation of the recognition and certification program
- Set criteria for selection of assessors for training and certification
- Approves training and certification program for assessors
- Review and update the assessment checklist
- Arbitration in-cases of disputes arising from assessment and recognition process

#### 5.3.2.2 ASLM Secretariat

The ASLM will act as the program secretariat and will be responsible for:

- Training, certifying, and deploying assessors to applicant facilities
- Maintaining a register of certified assessors
- Receiving and evaluating applications and enrolling facilities into the program

- Receiving and reviewing assessor reports and awarding star level certificate
- Maintaining a register of certified facilities

#### 5.3.2.3 Lead Agency/Institution Responsible for Biosafety and Biosecurity

The Lead Agency/institution as required by the Regional Biosafety and Biosecurity Legal Framework, and where it does not exist, the lead ministry as appointed by the Government will be responsible to:

- Coordinate the implementation of the minimum requirements as stated in this framework
- Coordinate the selection of prioritized facilities and submitting application documents to the ASLM Secretariat
- Oversees the implementation of corrective actions based on assessor reports

#### 5.3.2.4 Assessors

Assessors will undergo standard training by ASLM that comprise didactic and field practicums. Only certified assessors with up-to-date registration by ASLM are authorized to conduct facility assessment. Assessors will be responsible for

- Conducting facility assessments using standard checklist
- Providing technical assistance and on-site mentoring to enrolled facilities
- Developing assessment reports with recommendations

#### 5.3.2.5 Facilities

Facilities handling HCATs are eligible for enrolment into the recognition and certification program. Facilities will be responsible for:

- Implementing minimum standards for biosafety and biosecurity
- Completing and submitting application documents to the Lead Agency/Institution for enrolment
- Receiving and providing assessors with requested documents during assessments
- Implementing corrective actions as guided by assessment reports

### 5.3.3 Assessment Checklist

High and maximum containment facilities will be assessed for compliance with the minimum requirements stipulated by this Framework using standard checklists developed for this purpose. The scored checklists cover the specified requirements for biosafety and biosecurity as specified in this Framework. The assessments will seek to check for evidence that facilities comply to the minimum requirements though the review of documented procedures and records, conducting personnel interviews and other relevant information gathering and/or verification methods.

The checklists incorporate a scoring system for each element as part of a compliance improvement process based on a facility's progress towards meeting requirements set by this Framework. This improvement process towards compliance serves as a pathway for continuous improvement and a measure of progress towards the sustainable operation of safe and secure containment facilities in AU Member States.

Each requirement element item on the checklist is awarded a score of three (3) if fully met, i.e. "yes", one (1) if partially met, i.e. "partial"; and zero (0) if not "no". This system of recognition is based on the World Health Organization (WHO) Regional Office for Africa (2015), Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) quality improvement process towards accreditation. It is provided using a five (5) star-tiered approach, based on a bi-annual on-site audit of laboratory operating procedures, practices, and performance. ***See Appendix A: Recognition and Certification Program Checklist***

# Appendix A: Recognition and Certification Program Checklist

**Regulatory and Certification Framework for Institutions Handling High Risk Pathogens**

**Evaluation Checklist**

Version 1: July 2022

**Facility Profile**

| | | | |
|---|---|---|---|
| **Country** | | **Facility Name** | |
| **Facility Address** | | **Facility Contact (email/mobile)** | |
| **Date of Assessment** | | **Date Last Assessment and Star Level** | |
| **Names of Assessors and Country** | | | |
| **Name and Designation of Principal Respondent** | | | |
| **Facility Type (Research, Human/Animal/Environmental Laboratory** | | **Facility Affiliation (Government, Private, Faith based, non-Governmental** | |

**Assessment Score Sheet**

| Section | Total Points |
|---|---|
| Section 1: Containment Design and Construction Requirements | **75** |
| Section 2: Management and Operational Practice Requirements | **70** |
| Section 3: Maintenance, Commissioning and Certification Requirements | **15** |
| **Total Score** | **160** |
| | |

| No Stars | 1 Star | 2 Stars | 3 Stars | 4 Stars | 5 Stars |
|---|---|---|---|---|---|
| (0 – 87 pts) | (88 – 103 pts) | (104 – 119 pts) | (120 – 135 pts) | (136 – 151 pts) | (152 – 160 pts) |
| *< 55%* | *55 –* | *65 – 74%* | *75 – 84%* | *85 – 94%* | *≥95%* |

For each item, please circle as relevant Not Applicable (NA), Yes (Y), Partial (P) or No (N). All elements of the item must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

| **SECTION 1: CONTAINMENT DESIGN AND CONSTRUCTION REQUIREMENTS** | | | | | |
|---|---|---|---|---|---|
| **Containment Barrier** | | | | | |
| **1.1** Are containment zones and associated corridors separated from generally trafficked areas (e.g. public and administrative areas) by a secured door? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.2** Are windows on the containment barrier non-opening and sealed? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.3** Are pass-through chambers and double-door autoclaves on the containment barrier equipped with either interlocking door or visual/audible alarms, or other acceptable means, to ensure that the doors are not opened simultaneously? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.4** Are all penetrations of the containment barrier, including all conduits and wiring, sealed with a non-shrinking sealant that is compatible with the disinfectant(s) in use? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **Access Points and Controls** | | | | | |
| **1.5** Is there restricted access into the containment zone? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| a) Is access limited to authorized personnel only? | | | | | |
| b) Is there a controlled electronic access system or doors that are mechanically lockable? | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **1.6** Do laboratory room doors have the following appropriate signage at the containment zone point (s) of entry? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| a) International biohazard warning symbol | | | | | |
| b) Containment level. | | | | | |
| c) Room name | | | | | |
| d) Telephone number(s) of contact person(s) | | | | | |
| e) Requirements for entry (e.g. PPE needed, vaccination status) | | | | | |
| | | | | | |
| **1.7** Is there a dedicated change area at personnel entry to the containment zone to allow for separation of personal clothing from dedicated containment zone clothing? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.8** Do the anteroom(s) include a walk-through body shower between the "clean" and "dirty" change areas for personnel entry/ exit through the containment barrier of the containment zone? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.9** Is there controlled entry into the containment perimeter? | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| a) Is entry through an anteroom? | | | | | |
| b) Is the anteroom located between the clean and dirty areas? | | | | | |
| c) Does the anteroom have two interlocking self-closing doors or an equivalent system? | | | | | |
| d) Do the anteroom doors set up such that more than one door cannot be opened at a time? | | | | | |
| | | | | | |
| **Surface Finishes and Casework** | | | | | |
| **1.10** Are doors, frames, casework, bench-tops and laboratory furniture (e.g., stools, chairs) constructed from non-absorbent materials? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.11** Are surfaces and interior coatings cleanable and resistant to scratches, stains, moisture, chemicals, heat, impact, and repeated decontamination, in accordance with function? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.12(a)** Is there an installation of seamless, | **Yes** | **No** | **Partial** | **Comment** | **Score** |

| | | | | | |
|---|---|---|---|---|---|
| sealed, resilient or poured floors, with integral cove bases<br>*NOTE: There should be a continuity of seal between the floor and wall; between the wall and ceiling.* | | | | | **2** |
| **1.12(b)** Are floors slip-resistant, impervious to liquids, and resistant to chemicals in accordance with function? | | | | | **2** |
| | | | | | |
| **HVAC System** | | | | | |
| **1.13** Does the HVAC system provide sufficient air changes per hour (ACH) under normal operation to maintain inward directional airflow?<br>*Note: At least 6-12ACH. HVAC design to take into consideration of the equipment in the laboratory suite(s) and their cooling requirements; also the HCATs being handled.* | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |

| | | | | | |
|---|---|---|---|---|---|
| **1.14a** Are there monitoring device(s) that visually demonstrate pressure differential and inward directional airflow at the entry to the containment zone? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| **1.14b** Are there controlled pressure differentials across adjacent laboratory rooms, designed for air movement from the least to the most contaminated area (with potentially infectious material)? | | | | | **Score 2** |
| | | | | | |
| **1.15** Does the HVAC system have a fail-safe operation with audible and visual alarms inside and outside the containment zone to signal HVAC systems failure? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.16** Is the supply and exhaust air systems independent of other areas?<br>*NOTE: High containment air systems may be combined with areas of lower containment when provided with effective (i.e. the minimum functional level determined by the risk assessment) backdraft protection.* | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.17** Does the supply air duct have effective backdraft protection (e.g. bubble tight damper), or employ an effective alternative means to prevent airflow reversal? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.18** Are supply and exhaust air systems with automatic mechanical and electronic interlocks that prevent sustained positive pressurization of the containment zone in place? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.19** Exhaust air filtration: | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| a) Is the exhaust air passed through a HEPA filter? | | | | | |
| b) Are all HEPA filters tested and certified at least annually? | | | | | |
| c) Is the exhaust HEPA filter housing designed to allow safe in-situ decontamination, before filter removal? | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Facility Services** | | | | | |
| **1.20** Are handwashing and water supply available at appropriate points? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| **a)** Handwashing sinks with "hands-free" capability at the point(s) of exit of the containment zone? | | | | | |
| b) Individual and/or dedicated main water supply with shut-off valves and other controls located and accessible from outside the containment zone | | | | | |
| | | | | | |
| **1.21a** Is there emergency eyewash equipment available and accessible in accordance with containment zone activities? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| **1.21b** Is there an emergency shower equipment available and accessible in accordance with containment zone activities? | | | | | **Score 2** |
| | | | | | |
| **1.22** Is the drain piping separated from those of lower containment areas and directly connected to an effluent treatment system? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.23** Is waste-water collected and inactivated chemically or thermally?<br>*Note: Method should be appropriate and effective at inactivating the pathogens and/or toxins handled in the laboratory as guided by a local risk assessment.* | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.24** Are services and equipment critical to maintaining containment and biosecurity supported by emergency (and back-up) uninterrupted power supply? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **Primary Containment - Safety Equipment** | | | | | |
| **1.25** Are certified BSCs and other primary containment devices provided, as determined by a risk assessment? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |

| | | | | | |
|---|---|---|---|---|---|
| **1.26 Are the following** designed to prevent the release of infectious material or toxins? | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| a) Process equipment | | | | | |
| b) Closed systems | | | | | |
| c) Other primary containment devices (including BSCs, isolators, local exhaust ventilators and ventilated working spaces) | | | | | |
| | | | | | |
| **1.27** Are the BSCs located away from high traffic areas, doors, and air supply/exhaust diffusers? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.28** Is the autoclave capable of operating at the appropriate temperature for decontamination as determined by validation? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.29** Is there a communication system between the laboratory work areas/cubicles and outside the containment zone? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **1.30** Is personal protective equipment available and used appropriately? | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| a) Is the PPE available and accessible when needed? | | | | | |
| b) Is the PPE being used as guided by the risk assessment? | | | | | |
| c) Is there a documented procedure for verification and maintenance of non-disposable PPE?<br>*Note: Waste management of disposable PPE to be addressed.* | | | | | |
| | | | | | |
| **Effluent Treatment Systems** | | | | | |
| **1.31 is there a functional** effluent treatment system? | **Yes** | **No** | **Partial** | **Comment** | **Score 5** |
| a) Is the system appropriate to the work being conducted | | | | | |
| b) Is the design of the system heat and chemical resistant consistent with intended use | | | | | |
| c) Does the system have an alarm system that indicate warnings and failure of effluent treatment system | | | | | |
| d) For thermally controlled effluent treatment systems, does it have and effective electronic temperature | | | | | |

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| monitoring device | | | | | |
| e) Does the system include devices to permit validation | | | | | |
| **TOTAL SCORE** | | | | | **75** |
| | | | | | |
| **SECTION 2: MANAGEMENT AND OPERATIONAL PRACTICE REQUIREMENTS** | | | | | |
| | | | | | |
| **Administrative Controls** | | | | | |
| **2.32** Established biorisk management (BRM) program is in place to effectively control laboratory biological risks identified through a risk Assessment | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **2.33** Has a risk assessment been conducted in accordance with the biorisk management program? | **Yes** | **No** | **Partial** | **Comment** | **Score 5** |
| a) Risk assessment conducted at least annually or as scheduled in the biorisk assessment program/plan | | | | | |
| b) Findings of the risk assessment documented for all hazards and threats | | | | | |
| c) Findings of the risk assessment communicated to all relevant personnel | | | | | |
| d) Risk assessment reviewed when there is a change in activity procedures/equipment/infrastructure, occurrence of an incident or when there is an emergence of new security threats, whichever occurs earlier | | | | | |
| e) Mitigation measures identified, documented, implemented, and monitored for effectiveness | | | | | |
| | | | | | |
| **2.34** Is an approved biosafety/biosecurity manual available and accessible to staff | **Yes** | **No** | **Partial** | **Comment** | **Score 4** |
| a) Is the Manual up to date as per facility document control procedure? | | | | | |
| b) Is the manual accessible to facility staff when needed | | | | | |
| c) Does the manual cover institutional biosafety policies, programs and plans, based on facility risk assessment(s) | | | | | |
| d) Have all staff acknowledged receipt and reading of the manual? | | | | | |

| | | | | | |
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| **2.35** Has a biosecurity plan developed based on a security risk assessment, and subsequently be implemented, evaluated and improved as necessary, and kept up to date. | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **Work Practices - Handling of HCATs** | | | | | |
| **2.36** Have traffic (i.e. movement of people and material) flow patterns from areas of lower contamination ("clean") to areas of higher contamination ("dirty") been established and followed, as determined by a risk assessment | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **2.37** Is there evidence of verifications of the integrity of the following performed and recorded routinely in accordance with SOPs available | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| a) Containment barrier | | | | | |
| b) Inward directional airflow | | | | | |
| c) Primary containment devices (including biological safety cabinets (BSCs), isolators, local exhaust ventilators and ventilated working spaces) | | | | | |
| | | | | | |
| **2.38** Are Good Microbiological Practice and Procedures (GMPP) techniques documented and used when handling infectious material to minimize the formation of aerosols and droplets when manipulating specimens. | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **2.39** Is all open manipulation, involving infectious materials, conducted in BSCs within the containment zone with no work in open vessels is conducted on the open bench? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **2.40** Is material containing suspected infectious pathogens packed in safe containers with subsequent decontamination procedures of the containers before removal from containment into designated secure areas (e.g. refrigeration, liquid nitrogen storage areas). | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |

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| **2.41** Are documented, approved and up to date procedures based on and referenced to a risk assessment available to prevent a leak, drop, spill, or similar event, during the movement of infectious material or toxins within the containment zone, or between containment zones within a building? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **2.42** Are cultures of infectious material or toxins contained within a closed system or other primary containment device? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **2.43** Are validated transfer protocols of inactivated material or non-inactivated material to outside of the containment facility are in place? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **2.44** Are inactivation procedures for agents in place | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| a) Inactivation procedures for agents documented, approved and accessible when needed | | | | | |
| b) Relevant staff acknowledge training on documented procedures | | | | | |
| c) Inactivation methods validated whenever an inactivation step is used, before transferring the specimens to other areas for further manipulation (such as PCR analysis) | | | | | |
| | | | | | |
| **2.45** Are procedures for routine housekeeping in place | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| a) Are procedures documented, approved and accessible when needed | | | | | |
| b) Relevant staff acknowledge training on documented procedures | | | | | |
| c) Cover the following areas (i) routine cleaning of the containment zone (ii) control of rodents and insects | | | | | |

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| **2.46** Are procedures for general maintenance in place? | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| **a)** Are procedures documented, approved and accessible when needed | | | | | |
| **b)** Relevant staff acknowledge receipt and reading documented procedures | | | | | |
| **c)** Cover maintenance of the containment zone that include regular visual inspections of the containment zone to identify faults and/or deterioration | | | | | |
| | | | | | |
| **2.47** Are procedures for corrective actions for identified faults that are raised and addressed in place? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **Decontamination and Waste Management** | | | | | |
| **2.48** Is contaminated waste managed appropriately | **Yes** | **No** | **Partial** | **Comment** | **Score 4** |
| a) Correctly identified identification/labelled | | | | | |
| b) Appropriately segregated at point of generation | | | | | |
| c) Treated by steam sterilization, autoclave, heat or chemical treatment before removal or discharge from the facility | | | | | |
| d) Where decontamination is not done locally, is contaminated waste packaged in a leak-proof containers (i.e. constructed and closed in a manner that prevents any loss of contents) for transfer | | | | | |
| | | | | | |
| **2.49** Are Work surfaces cleaned and decontaminated with either a disinfectant effective against the infectious material in use, or a neutralizing chemical effective against the toxins in use at a frequency to minimize the potential of exposure to these. | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **2.50** Is gaseous decontamination conducted appropriately, effectively and regularly? *NOTE: The laboratory decontamination method being used is referenced to a risk assessment and is available, or the risk assessment must* | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |

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| *explicitly determine this not required.* | | | | | |
| a) Is the facility sealable to permit effective gaseous decontamination | | | | | |
| b) Efficacy of the decontamination process validated, and results documented? | | | | | |
| c) Where faults are identified, are corrective actions documented, implemented and monitored for their effectiveness | | | | | |
| | | | | | |
| **2.51** Is there a protocol established and used for all the waste treatment equipment (e.g. autoclave, effluent treatment system)? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| a) Was all equipment assessed and documented at the time of commissioning? | | | | | |
| b) Are periodic review of waste treatment equipment performance performed and documented | | | | | |
| | | | | | |
| **2.52** Are sharps discarded in containers that are leak-proof and puncture resistant? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **2.53** Are other equipment or materials (other than waste and samples) decontaminated at the containment barrier and labelled as decontaminated prior to removal from the facility. | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **Emergency/Incident Response Plan** | | | | | |
| **2.54** Is an approved contingent plan available and implemented? | **Yes** | **No** | **Partial** | **Comment** | **Score 4** |
| a) Is the plan approved and up to date? | | | | | |
| b) Does the plan have specific operating procedures to be followed in possible emergency? | | | | | |
| c) Does the plan cover scenarios that apply to the work and local environment? | | | | | |
| d) Have all relevant personnel been trained on response plan | | | | | |
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| **2.55** Are incidents reported, investigated, documented and corrective actions instituted and monitored for their effectiveness? | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |

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| **2.56** Are cleaning and decontaminating procedure for spills available and implemented? | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| a) Are approved and up to date procedures available and accessible to relevant staff? | | | | | |
| b) Are all relevant staff been trained on the procedures? | | | | | |
| c) Are appropriate spill kits adequately available and accessible? | | | | | |
| | | | | | |
| **2.57** Has the emergency procedure and staff preparedness been tested through regular emergency drills, at least annually.<br>*NOTE: The emergency procedure must be in accordance with local legislation* | **Yes** | **No** | **Partial** | **Comment** | **Score 2** |
| | | | | | |
| **Occupational Health and Safety Program** | | | | | |
| **2.58** Is there an occupational health and safety program in place? | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| a) Have all staff undergone occupational medical consultation and/or assessment by an occupational health physician? | | | | | |
| b) Are needed immunizations for agents handled or potentially present in the facility available and applied to relevant staff prior to starting and when required? | | | | | |
| **SECTION 2 TOTAL** | | | | | **70** |
| | | | | | |
| **SECTION 3: MAINTENANCE, COMMISSIONING AND CERTIFICATION REQUIREMENTS** | | | | | |
| | | | | | |
| **Maintenance** | | | | | |
| **2.59** Are scheduled system test and inspection checks conducted (monitoring of all containment, safety and security features) consistent with the intent and requirements of the facility's design. | **Yes** | **No** | **Partial** | **Comment** | **Score 6** |
| a) Are approved, documented and up to date procedures for system checks and inspections available and accessible to relevant staff ? | | | | | |
| b) Are system checks conducted by appropriately trained and certified staff? | | | | | |
| c) Are system checks and inspections | | | | | |

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| conducted as per schedule and results signed off by authorized staff? | | | | | |
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| **Commissioning and Certification** | | | | | |
| **2.60** Is there a commissioning plan available and implemented before operations and when there is temporary shutdown? | **Yes** | **No** | **Partial** | **Comment** | **Score 6** |
| a) Is an approved report of commissioning conducted before commencement of operations or when there was temporary shutdown available? | | | | | |
| b) Has the commissioning and certification process check all aspects to ensure safe, secure acceptable facility operations (design features, construction techniques, materials and equipment selected in line with the facility risk assessment | | | | | |
| c) Where deficiencies are identified, are investigations instituted and corrective actions implemented, documented and reviewed for their effectiveness before operations are started/resumed? | | | | | |
| **2.61** Is the facility system performance re-verified and certified by appropriately trained staff at least annually or after significant modification to ensure operational parameters are met. | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| **SECTION 3: TOTAL** | | | | | **15** |

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| conducted as per schedule and results signed off by authorized staff? | | | | | |
| | | | | | |
| **Commissioning and Certification** | | | | | |
| **2.60** Is there a commissioning plan available and implemented before operations and when there is temporary shutdown? | **Yes** | **No** | **Partial** | **Comment** | **Score 6** |
| a) Is an approved report of commissioning conducted before commencement of operations or when there was temporary shutdown available? | | | | | |
| b) Has the commissioning and certification process check all aspects to ensure safe, secure acceptable facility operations (design features, construction techniques, materials and equipment selected in line with the facility risk assessment | | | | | |
| c) Where deficiencies are identified, are investigations instituted and corrective actions implemented, documented and reviewed for their effectiveness before operations are started/resumed? | | | | | |
| **2.61** Is the facility system performance re-verified and certified by appropriately trained staff at least annually or after significant modification to ensure operational parameters are met. | **Yes** | **No** | **Partial** | **Comment** | **Score 3** |
| **SECTION 3: TOTAL** | | | | | **15** |

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