The Republic of Uganda

# LABORATORY BIOSAFETY AND BIOSECURITY MANUAL

THIRD EDITION

2021

BY

NATIONAL HEALTH LABORATORY AND DIAGNOSTIC SERVICES

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## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| ABSL | Animal Biosafety Level |
| BC | Biosafety committee |
| BSL | Biosafety Level |
| BSO | Bio Safety Officer |
| CDC | Center for Disease Control and Prevention |
| CHP | Chemical Hygiene Plan |
| CHS | Commissioner Health Services |
| COVID-19 | Corona Virus Disease of 2019 |
| CPHL | Central Public Health Laboratories |
| EMCA | Environmental Management and Coordination Act |
| GCLP | Good Clinical Laboratory Practice |
| GOU | Government of Uganda |
| HAZMAT | Hazardous Materials |
| HBV | Hepatitis B Virus |
| HCV | Hepatitis C Virus |
| HCW | Health Care Workers |
| HCWM | Health Care Waste Management |
| HEPA | High efficiency Particulate air |
| HIV | Human Immunodeficiency Virus |
| IPC | Infection Prevention and Control |
| MMR | Measles, Mumps and Rubella |
| LAI's | Laboratory Acquired Infections |
| MOH | Ministry of Health |
| MSDS | Material Safety Data Sheets |
| NBC | National Biosafety Committee |
| NCST | National Council for Science and Technology |

| | |
|---|---|
| NHLDS | Department of National Health Laboratories and Diagnostic Services |
| NHLSSP | National Health Laboratory Services Strategic Plan |
| NTRL | National Tuberculosis Reference Laboratory |
| OSH | Occupational Safety and Health |
| OSHA | Occupational Safety and Health Act |
| PEP | Post Exposure Prophylaxis |
| POE | Point of Entry |
| POC | Point of Care |
| PPE | Personal Protective Equipment |
| PTFE | Polytetrafluoroethylene |
| RG | Risk Group |
| SOP | Standard Operational Protocol/Procedure |
| TB | Tuberculosis |
| VBM | Valuable biological materials |
| WHO | World Health Organization |

# FOREWORD

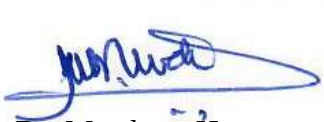
Biorisk management aims at protecting the laboratory workforce, community and the environment against unintentional and intentional exposure to hazardous biological agents and toxins.

Previous editions elaborated basic biosafety concepts and codes of practice for the safe handling of hazardous biological agents and toxins based on risk groups and biosafety/containment levels. However, the actual risk of a given scenario is influenced not only by the agent or toxin being handled, but also by the procedure being performed and the competency of the personnel engaging in the activity.

This Third Edition, emphasizes a risk assessment and evidence-based approach to Biorisk management rather than a prescriptive approach in order to ensure that laboratory facilities, safety equipment and work practices are locally relevant, proportionate and sustainable.

This document is meant to serve as a source of information for Laboratory workforce and other health care workers at all levels of laboratory service delivery, in both public and private health facilities, to implement economically feasible and sustainable laboratory biosafety and biosecurity measures that are relevant to their individual circumstances and priorities.

The manual is aligned with the WHO Biosafety Manual 4$^{th}$ Edition, ISO 15190 on Laboratory Biosafety, and ISO 350001 on Biorisk Management, and is therefore expected to improve compliance to local, national, regional and international standards in biosafety and biosecurity.



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**Commissioner Health Service**
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# INTRODUCTION

Biorisk Management (BRM) has become an integral part of the health care system aimed at establishing a safe environment for persons working in facilities handling biological agents and/or toxins. It focuses on supporting facilities establish strong Biorisk Management systems to effectively identify, assess, control, and evaluate the biosafety and biosecurity risks inherent in its activities. Recent outbreaks of emerging and re-emerging infectious disease such as Ebola, Bird flu and COVID-19 among others, affirms the critical role of biosafety and biosecurity on national economies, international trade and travel, public health and safety, global security and the trust of populace in its own government. Although the implementation of biosafety biosecurity remains a shared responsibility at the international level (GHSA; revised IHR 2005), each country is encouraged to develop and implement basic concepts in biological safety and security so as to promote the safe handling of biological agents/toxins in laboratories within their geographical borders.

In Uganda, Health care workers are at increased occupational risk from a vast array of infections that may cause substantial illness and occasional deaths. In light of the above, Uganda is implementing the BRM system in line with the Global Health Security agenda goal of establishing a comprehensive, sustainable and legally embedded national oversight program for biosafety and biosecurity, including the safe and secure use, storage, disposal, and containment of pathogens found in laboratories and a minimal number of holdings across the country, including research, diagnostic and biotechnology facilities.

To guide implementation, the Central Public Health Laboratories (CPHL) now the Department of National Health Laboratory Diagnostic services (NHLDS) under MOH developed the national biosafety biosecurity manuals edition 1 and 2 based on the based on the CEN Workshop Agreement 15793 (CWA 15793) framework and WHO biosafety manual 3$^{rd}$ edition. During the interval since the first (2008) and second (2015) edition, there have been major developments in the field of BRM. The most striking includes the transformation of the CWA 15793 to an ISO 35001:2019, publication of the revised ISO 15190:2020, the subsequent development of a new national BRM checklist based on the new standards, and the production of World Health Organization Laboratory Biosafety manual 4$^{th}$ edition.

It was deemed important to revise the previous edition to reflect the above mentioned international standards Biorisk management to better the safety and security of laboratory workers, clients and the environment, as well as to prevent intentional or unintentional release of pathogens to the environment. This manual defines minimum requirements, practices and procedures that will minimize risks to personnel, facilities, and the environment resulting from the handling of biological and chemical agents. This edition aims to guide sustainable developments in biosafety including a national oversight system, training, best working practices and risk assessment framework to promote a responsible safety culture that builds country capacity and comply with the International BRM standards.

# CHAPTER ONE

## 1.0 BIORISK (BIOSAFETY & BIOSECURITY) PROGRAMME MANAGEMENT

**Biosafety** is a set of containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their accidental release, while **Biosecurity** is a set of 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**. Biorisk** (Biosafety and Biosecurity) are associated risks of working with biological agents. For the purpose of this document, the term (Biosafety and Biosecurity) and **Biorisk management (BRM)** may be used interchangeably to mean containment principles, technologies and practices to prevent safety and security associated risks encountered while working with Biological agents.

***ISO 35001 2019 clause 4.4 requires facilities to establish, document, implement, communicate, maintain, and continually improve a Biorisk management system, including the processes needed and their interactions, in accordance with the requirements of this documen*t**. The effective management of biological risks is supported by established measures at both the national and institutional levels. Just as CPHL/NHLDS and other regulatory authorities do assess biological risks and apply nation-wide regulatory frameworks to control them, organizations in which biological agents are handled have an obligation to assess the biological risks that exist in their facility and apply appropriate control measures to protect their personnel, community and the environment. A facility-specific risk assessments can further guide the selection and implementation of appropriate control measures and mitigation strategies that reduce risks to an acceptable level. The management of this process requires an organization to develop a biosafety programme fully supported by an organization's senior management: Effective management of a structured biosafety programme ensures the following activities have been undertaken.

- There is a commitment from senior management to appropriately address and manage the risks associated with the biological agents being handled.
- All risks associated with work activities have been identified, understood and controlled to an acceptable and practical level.
- Practices and procedures necessary to control risks have been put in place and are monitored regularly to ensure continued effectiveness and relevance.

- A framework has been set up for the appropriate training of personnel in biosafety practices and biosecurity awareness.
- The roles and responsibilities of all personnel are clearly set out and understood.
- Activities related to laboratory biosafety, and its associated policies and procedures, are aligned with national and international guidelines and regulations.

## 1.1 RATIONALE

The purpose of this Biosafety and Biosecurity management (BRM) manual is to guide health professionals and the public in keeping safety and security in the laboratories. Due to the dynamic nature of emerging and re-emerging public health threats, this manual (Version 3) has been aligned to ISO 35001 2019, ISO 15190 2020 and the WHO Biosafety manual (version 4) which emphasizes a risk-based approach to management of biological hazards and threats.

This manual defines minimum requirements, practices and procedures that will minimize risks to personnel, facilities, and the environment resulting from the handling of biological and chemical agents. The manual will act as a resource to be used in Occupational Safety and health (OSH) orientation of new employees and subsequent trainings. Work practices and guidelines are based on current OSHA 2007 regulatory requirements and accepted good biosafety and biosecurity practices. Implementation of these measures aims to reduce the likelihood that an incident involving a biological and chemical agent will occur and targets the fulfillment of Uganda Occupational Safety and Health regulations and other relevant standards and guidelines. This guideline also addresses work practices to minimize, the chance of malicious use of valuable biological materials (VBM).

For an organization to establish an effective Biosafety Biosecurity program, the foundational elements discussed below need to be addressed. While the size and complexity of an organization dictates the specifics of a biosafety programme, these foundational elements, when based on a strong biosafety culture, provide a solid framework for the most effective biosafety programme.

## 1.2 BIOSAFETY POLICY

An institutional biosafety policy is a document that describes the scope, purpose and objectives of the biosafety programme. A biosafety policy in place is a demonstration of the prominence of and commitment to biosafety within the organization. A policy will establish an internal accountability system whereby the roles in managing biological risks are defined for all individuals. A strong code of

practice, and clear roles and responsibilities throughout the organization will help build a strong biosafety culture. Key considerations in developing the policy include whether ***the laboratory or organization have a safety policy, whether biosafety is included in this policy, and whether the policy includes well-defined objectives that are clear, realistic and measurable***. Facilities shall derive their Biosafety Biosecurity policies from the National Biosafety policy frameworks.

### 1.2.1 POLICY FRAMEWORK

This manual is in line with the provisions of the National Health Laboratory Policy 2017 and the National Health Laboratory Strategic Plan (NHLSSP) 2021- 2025, both of which were developed in the context of the National Health Policy II and Health Sector Strategic and Investment Plan (NHSSIP) II. During the development process, reference was also made to Uganda's commitment to regional and global efforts aimed at improving health safety and security and development in East Africa, Africa and Internationally.

The manual is therefore in line with national, regional and global health laboratory safety and security goals and priorities.

### 1.2.2 LEGAL REQUIREMENTS

The National Legal and Regulatory components of government shall ensure compliance with the national health laboratory policy provisions that have been elaborated here, namely:

1. All laboratory facilities shall have appropriate space and safe environment for health personnel, clients and the community.
2. Construction and renovation of laboratories shall be in conformity with national standards.
3. All laboratories shall have documented procedures and required resources for laboratory safety.
4. An occupational health and safety program for laboratory professionals shall be established
5. All laboratories shall employ well-trained and competent personnel.
6. All laboratories shall put in place measures to safeguard against malicious use of chemicals, infectious agents and other harmful materials.

Table 1: Existing legislation in Uganda with a bearing on biosafety and biosecurity.

| | |
|---|---|
| The Animal Diseases Act, 1918 | Requires diseased animals to be separated and reported and also states that the Minister has power to declare infected areas. |
| The Public Health Act, 1935 | Have provisions for the prevention and suppression of infectious diseases. |
| The Plant Protection Act, 1937 | Regulates the importation and exportation of plants, the soil and creates offence of release of pests and diseases. |
| The Penal Code Act, 1950 | Prohibits engaging in or carrying out acts of terrorism, aiding, financing, harboring, belonging or professing to belong to a terrorist organization. A person is presumed to be involved in acts of terrorism if he imports, sells, distributes, or is in possession, of any fire arm, explosives or ammunition. The same applies to a person involved in the spread infectious disease, adulteration of food or drink, sell of noxious food or drink, adulteration drugs or medical preparation, offering or exposing for sale such drugs; and most recently. |
| The Pharmacy and Drugs Act, 1971 | Outlines professional misconduct with respect to medicinal drugs. |
| The National Environment Act, 1995 | Provides for the preparation of guidelines for the coordination of a national response to "environmental disasters". |
| The Occupation Safety and Health Act, 2006 | States that an employer must take reasonable and practicable measures to protect employees and the general public from dangerous aspects of the undertaking and to protect the environment from pollution. |
| The Anti-Terrorism Act, 2002 | Targets people that engage in or carry out any acts of terrorisms. The Act defines an act of terrorism as the manufacture, delivery, placement, discharge or detonation |

| | |
|---|---|
| | of an explosive or lethal device in a place of public use or a state or government facility with intent to cause death or serious bodily injury or extensive destruction. Alternatively, an act of terrorism is the intentional development or production or use of, or complicity in the development or production or use or unlawful possession of explosives, ammunition, bombs or any materials for making any of the foregoing The Act also defines a lethal device as a weapon or device that is designed, or has the capability, to cause death, serious bodily injury or substantial material damage through the release, dissemination or impact of toxic chemicals, biological agents or toxins or similar substances or radiation or radioactive material. |

## 1.3 BIOSAFETY CULTURE

Biosafety culture is the set of values, beliefs and patterns of behavior instilled and facilitated in an open and trusting environment by individuals throughout the organization who work together to support or enhance best practices for laboratory biosafety. This culture is crucial for the success of a biosafety programme and is built from mutual trust and the active engagement of all personnel across the organization, with a clear commitment from the organization's management. Establishing and maintaining a biosafety culture provides a foundation upon which a successful biosafety programme can be developed. Cultivating a biosafety culture is not a defined step within the biosafety programme management cycle, but starts in the planning phase and is developed, reinforced and maintained in all laboratory activities. A biosafety culture is not easily achieved. It requires time, commitment and diligence from all personnel, supervisors and senior management, in an environment of respect and trust. The following best practices are recommended for developing and sustaining a strong biosafety culture.

1. **Demonstrated commitment of senior management through;** development of Biosafety policies, active and visible participation of senior management in biosafety-related activities and commitment to an open environment where Biosafety issues can be discussed without fear.

2. **Demonstrated commitment to biosafety throughout the organization through;** assignment of key responsibilities in Biosafety, development of the institutions code of conduct and a clear, appropriate, timely and evident response to biosafety concerns raised by personnel
3. **Active engagement of laboratory personnel and support personnel through;** consultation and cooperation with laboratory experts on issues concerning Biosafety, active involvement of laboratory directors in the institutions Biosafety committee
4. **Ongoing communication and promotion of biosafety through;** Regular and transparent communication with all BRM stakeholders and having an effective communication process, which promotes open dialogue

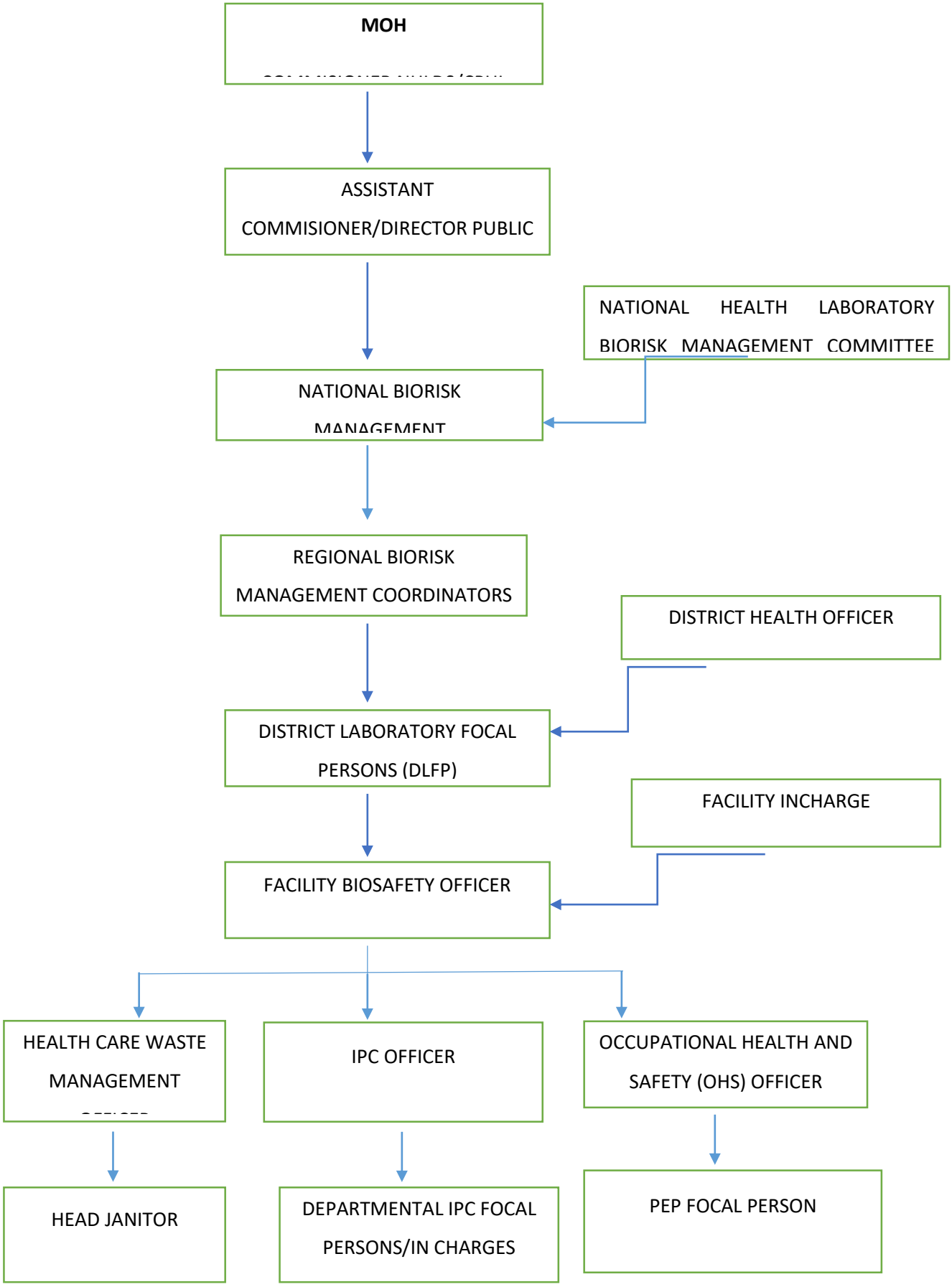
## 1.4 ASSIGNED ROLES AND RESPONSIBILITIES

Although the responsibility for establishing and managing a biosafety programme, including defining and assigning roles and responsibilities, rests with the senior management of an organization, all facility personnel who may come into contact with biological agents are responsible for actively participating in the biosafety programme. Succession planning should be in place for management, scientific, technical and administrative personnel to ensure that critical knowledge of the safe and secure operation of the facility does not lie with just one individual in the event of his/her unavailability or departure.

In Uganda, Biosafety is coordinated by a National Biorisk Management Coordinator based at CPHL/UNHLS supported by National Health Laboratory Biorisk Committee (NHLBC) to effect his/her roles. The Committee consists of 15 members drawn from various specialties and institutional backgrounds as follows:

- Laboratory Sciences
- Medical sciences (Veterinary and Human medicine)
- Bio safety/Bio security Officers
- Employers (represented by senior Administrators)
- Microbiology sciences
- Biotechnological sciences
- Epidemiology and Public Health
- Security
- Engineering and Architecture
- Bio containment designers

**Below is an organogram showing the various structures for Biorisk management in Uganda;**



**a) The National Health Laboratory Biorisk Management Advisory Committee**

The committee ensures compliance with set biosafety/biosecurity standards and provides advice and recommendations to the MoH, research Institutions, private and implementing partners on any matters relating to bio safety/Bio security. The committee also provides framework for proper and accurate monitoring of compliance, setting strategic direction to guide and direct biosafety/bio security activities and give advice to Laboratory Technical and advisory committee (LTC) and Director General Health Services (DGHS) at the Ministry of Health (MOH) on issues related bio safety/bio security

he committee serves as a focal point for collaboration between the MOH, implementing partners and other stakeholders on matters pertaining bio safety/bio security in laboratory service provision at the Ministry.

**b) The National Biorisk Management Coordinator/Advisor**

The National laboratory Biosafety and Biosecurity Focal Point at CPHL/UNHLS shall be responsible for overseeing planning, coordinating, reviewing, investigating, auditing, monitoring and budgeting for laboratory Biosafety and Biosecurity activities across the country in coordination with the regional Implementing partners and Development partners

**c) The Regional BRM Quality Assurance Committee**

The committee will provide framework for proper and accurate monitoring of compliance, investigating incidents, supervise, setting strategic direction to guide and direct biosafety/bio security activities in the region.

**d) The Role of the DLFP in BRM**

The DLFP will coordinate and ensure availability, Implementation and monitoring of use of the laboratory Biosafety and Biosecurity activities, for example: availability of biosafety guidelines, facility specific biosafety manuals, identification of training needs, technical support supervision, budgeting for biosafety activities, provision of risk reduction tools (signage's, SOPs, PPE, etc.) in the district.

**e) Senior management**; Senior management is responsible for the creation of policies and guidelines, as well as for the ongoing support of the biosafety programme. They are responsible for ensuring funding to support the programme and for providing oversight of the implementation and ongoing review of the programme components. Below is a summary of the roles and responsibilities of senior Management with respect to BRM;

- Defining the organization's commitment to biosafety through a policy and possibly a code of practice;
- Making decisions on compliance with applicable legislative or regulatory requirements, based on the organization's internal recommendations;
- Allocating sufficient funds and resources to support biosafety within the organization;

- Being aware of the overall institutional risks related to hazardous biological agents, and ensuring completion of relevant risk assessments by appropriate individuals
- Defining the roles and responsibilities for biosafety of all personnel within the organization;
- Defining the components and procedures (such as emergency/incident response, communication plan, and occupational health and safety plan) that incorporate

  feedback from frontline personnel to support the biosafety programme;
- Providing oversight of the biosafety programme through participation in review processes and committees.

**f) Institution Biosafety committee (IBC);** A biosafety committee is an institutional committee created to act as an independent review group for biosafety issues; it reports to senior management. The membership of the biosafety committee should reflect the different occupational areas of the organization as well as its scientific expertise. The committee may develop institutional policies, review risk assessments, approve protocols, identify potential dual-use or advise on biosafety-related issues. Most of the facilities within the country have constituted Infection Prevention and Control (IPC) committees whose role is equivalent to the requirement of this manual. Therefore, institutions may not need to set up separate committees but to strengthen and have an all-inclusive team to address the facility Biorisk management issues.

The responsibilities of the Institutional Biosafety Committee (IBC) include the following:

- Addressing all biosafety issues related to laboratory personnel, lab facility or Institution and environment.
- Adopting all policies or guidelines supporting the safe use of biological materials and the elimination or reduction of exposure to potentially hazardous materials and agents.
- Assessing the facilities, procedures, practices, training and expertise of lab personnel for conformity to good biosafety and biosecurity practices.
- Determining the necessity of occupational health and surveillance of laboratory work force.
- Advising lab management or institutional management on all matters concerning safety of lab staff and environment.
- Ensuring training for IBC members, management and laboratory work force.
- Reviewing all biosafety reports: accidents, incidents, biosafety audits and follow up with any corrective actions instituted to avert similar occurrences.
- Keeping a record of all biosafety meetings, providing sufficient detail to lab management and institution management for decisions to be made and appropriate actions taken.

**g) Institution Biosafety officer**; A biosafety officer should be appointed to provide advice and guidance to personnel and management on biological safety issues. Biosafety officers should have sufficient training and experience so that they are competent to perform the role, and they should be allocated enough time and resources to do the job effectively. However, depending on the size and nature of the laboratory, the biosafety officer could be a contractor or could perform the duties part time. The role and knowledge of the biosafety officer is key to developing, implementing, maintaining and continually improving a biosafety and biosecurity programme and they include;

- Conduct biosafety, biosecurity and technical consultations
- Apprising senior management and/or the biosafety committee of safety-related issues within the organization
- Ensuring risk assessments and authorizations for work are in place
- Developing and/or delivering safety-related training activities
- Periodic laboratory inspections, audits and assessments
- Reporting, investigating and following up on accidents or biosafety incidents
- Developing and maintaining the biosafety manual and standard operating procedures (SOPs) related to biosafety and biosecurity
- Promoting and monitoring compliance with legislative or regulatory requirements
- Communicating with personnel at all levels of the organization about biosafety.

**h) Laboratory personnel and support staff**; All personnel within the organization who have access to the laboratory space or to the biological agents in the facility are responsible for supporting and contributing to a biosafety programme. The laboratory director/manager is responsible for implementing and promoting biosafety to ensure the safety of all personnel, contractors and visitors to the facility, and to protect the public and the environment from hazards arising from the work being performed in the laboratory. Laboratory and support staff are responsible for applying biosafety in their daily activities.

### 1.5 Biosafety manual

A biosafety manual is a mandatory collection of all the organization-specific documents that describe the foundational elements of their biosafety programme. These may include policies, information about supporting programmes and plans, and organization-specific SOPs. ISO 15190 2020 clause 5.6 emphasizes facilities shall have Biosafety manuals readily available in the work area for all employees. The manual shall be in accordance with the facility safety and security policy and be specific to the Laboratory needs including and not limited to:

a) safety policy

b) fire prevention and Electrical safety

d) chemical safety

e) Radiation safety

f) Biological hazards

g) Hazardous waste disposal

h) Management of workplace incidents and Evacuations

i) Specimen collection, packaging and shipment

j) Disposal of damaged or expired products

k) Occupational Health and Safety

l) PPE

m) Infection prevention and control in the facility

n) Safety SOPs (BRM program management and testing infectious agents)

o) PEP Procedures

p) Equipment management (safety equipment)

q) Pathogen and toxin accountability/inventory control

***NB; Additional requirements can be got from sub-section 1.7***

**1.6 Biosafety and biosecurity risk assessment**

The main goal of a biosafety programme is to effectively manage biological and biosecurity risks. An essential activity to achieve this objective is conducting risk assessments. A biosafety/biosecurity risk assessment is a systematic process of gathering and evaluating information to identify hazards, determine the associated risks and develop appropriate control strategies that, when implemented, reduce risks to an acceptable level. For more specific information on how to conduct a risk assessment, please refer to Section 2.

**1.7 Supporting programmes and plans**

The outcomes of biosafety and biosecurity risk assessments will inform the selection of control measures that are needed to address identified risks. The correct implementation of these measures must then be managed through the development and management of several supporting programmes or systems. The details of these need to be accessible to personnel through the biosafety manual, and which may include:

- biosecurity plan and laboratory access system,
- occupational health programme,
- personnel management and training programme,
- SOP development,

- facility design plans,
- laboratory equipment purchase, installation and maintenance plan,
- decontamination and waste management system,
- emergency/incident response plan,
- record and document management system,
- inventory control plan, and
- communication plan.

The development and approval of these supporting programmes and plans are directed by senior management, with the support of relevant expertise (e.g. biosafety officer, biosafety committee, engineers, facility-specific management).

### 1.8 Reports and reviews

Biosafety programmes are dynamic and require regular assessment and flexible strategies to ensure ongoing and sustained improvement. The biosafety programme must be reviewed periodically to ensure continued suitability, adequacy and effectiveness. To do this, it is essential that organizations have record keeping and review systems which must include the features outlined in the following subsections

#### 1.8.1 Audits and inspections (internal and external)

***ISO 35001 clause 9.2 requires organizations to conduct internal audits and inspections at planned intervals to provide information on whether the Biorisk management system conforms to the set standards***. Many laboratories implement a cooperative inspection programme where laboratory personnel are directly responsible for periodic self-audits (self-assessments) coupled with a less frequent, but more in-depth, evaluation with the biosafety officer and/or members of the biosafety committee. In some cases, laboratories may also have external audits and/or inspections, for example as part of a certification process, under the national regulatory framework, or in an international mentoring programme.

These assessments can provide information on the effectiveness of a biosafety programme, and the results can be analyzed to identify weaknesses that may need to be tackled.

CPHL/NHLDS conducts annual BRM assessment as part of the BRM programme evaluation with the identified gaps and recommendations informing the subsequent course of action.

#### 1.8.2 Other reports

In addition to incident reports and laboratory assessments, a biosafety programme may also record and review other information such the outcomes of training exercises and drills and employee surveys in order to identify additional biosafety improvement opportunities.

### 1.8.3 BRM Continuous Quality Improvement

Effective management of a biosafety programme can be achieved by implementing the following project management cycle: planning – assessment – implementation – review and improvement. ***The organization shall determine opportunities for improvement (see ISO 35001 Clause 9) and implement necessary actions to achieve the intended outcomes of its Biorisk management system.*** The biorisk management system is built on the concept of continual improvement through a cycle of planning, implementing, reviewing, and improving the processes and actions that an organization undertakes to meet its goals. This is known as the Plan-Do-Check-Act (PDCA) principle:

The facility shall use the PDCA model as an iterative process to achieve continual improvement of processes and products. It can be applied to a biorisk management system, and to each of its individual elements, as follows:

- **Plan**: establish objectives, programmes, and processes necessary to deliver results in accordance with the organization's Biorisk management policy
- **Do**: implement the processes as planned;
- **Check**: monitor and measure activities and processes with regard to the biorisk management policy and objectives, and report the results;
- **Act**: take actions to continually improve the biorisk management performance to achieve the intended outcomes.

## CHAPTER TWO

## 2.0. OPERATIONAL WORKING PRACTICES AND GOOD MICROBIOLOGICAL PRACTICES AND PROCEDURES (GMPP)

### 3.1 Introduction

It is important to recognize that most important control measure to be embedded as a core requirement is that of good microbiological practices and procedures (GMPP). GMPP is a term given to a set of standard operating practices and procedures, or a code of practice, that is applicable to all types of activities with biological agents. This includes both general behaviors, best working practices and technical procedures that should always be observed in the laboratory and conducted in a standardized way. The implementation of standardized GMPP serves to protect laboratory personnel and the community from infection, prevent contamination of the environment, and provide product protection for the work with the biological agents in use.

It is essential that laboratory personnel are trained and proficient in GMPP to ensure safe working practices. GMPP should be part of academic training for biological, veterinary and medical science students and be part of the national or institutional syllabus. Without GMPP, risk cannot be controlled

sufficiently, even if other physical control measures are in place. Additional operational practices and procedures may be required for work where higher risks have been determined in the risk assessment.

Irrespective of any additional heightened control measures applied, GMPP will always be the basis on which all work is performed. However, the following additional practices can be considered, depending on to the risks identified;

- Standard biohazard symbols can be applied to laboratory entry points, and associated protocols developed to restrict access to only trained individuals and/or specified personnel in that area.
- Special entry conditions can be applied for some personnel which are a prerequisite for entering the laboratory, e.g. specific immunizations.
- Open manipulations of biological agents may need to be conducted using a primary containment device such a BSC, and/or respiratory protection may need to be used.
- A complete change of clothing and shoes is required before entering and on leaving the laboratory.
- Personnel must be trained in emergency extraction procedures in the event of personnel injury or illness. Working alone is not permitted.
- A method of communication for routine and emergency contacts must be established between personnel working in the maximum containment laboratory and support personnel outside the laboratory.
- A method to visually monitor and record the activities of personnel working inside the laboratory must be implemented.

## 3.2. Safe laboratory practices and techniques

The majority of laboratory incidents, injuries and work-related infections are caused by human error, poor laboratory techniques and misuse of equipment. A large proportion of work in the laboratory involves handling of infectious biological materials and therefore, it is important for laboratory managers to establish standard policies and procedures necessary for safe laboratory conduct, handling laboratory hazards, and contingency planning for safety issues as part of a safety program.

Laboratory personnel must have knowledge of safe laboratory procedures, awareness of potential hazards and skills for risk reduction measures. The adherence to appropriate safe practices will prevent serious laboratory accidents and these standards should apply to all the staff that are attached to the laboratory. Each person contributes to the adequacy of the safety program; therefore, each person has an obligation to him/herself and to his/her co-workers to protect the health and safety of all by strict observance of the safety regulations;

### 3.2.1. Preparing for laboratory work

Based on biosafety and Biosecurity approach, "Universal Precautions" is the term used to describe a prevention strategy in which all specimens and potentially infectious materials are treated as if they are, in fact, infectious, regardless of the perceived status of the source individual. This approach is used in all situations where exposure to blood or potentially infectious materials is possible. This also means that certain engineering and work practice controls shall always be utilized in situations where exposure may occur.

**Before starting to work in a laboratory, familiarize yourself with the following:**

- The possible hazardous materials in the laboratory, as well as appropriate safe handling, storage and emergency protocols. Read labels and material safety data sheets (MSDSs) before working with certain agents and moving, handling or opening chemicals. **Never use a product from an unlabeled container**, and report missing labels to your supervisor.
- The agents, processes and equipment in the laboratory. If you are unsure of any aspect of a procedure, check with the in-charge before proceeding.
- The location and operation of safety and emergency equipment such as fire extinguishers, eye wash and emergency shower, first aid and spill response kits, fire alarm pull stations, telephone and emergency exits
- Emergency spill response procedures for the materials you will handle
- Emergency reporting procedures and telephone numbers.

### 3.2.2. Best practices

Best practices describe behaviors that are essential to facilitate safe work practices and control biological risks. Examples of laboratory best practices are outlined below;

- Never storing food or drink, or personal items such as coats and bags in the laboratory
- Activities such as eating, drinking, smoking and/or applying cosmetics are only to be performed outside the laboratory.
- Never put materials, such as pens, pencils or gum in the mouth while inside the laboratory, regardless of having gloved hands or not.

- Thoroughly washing hands, preferably with warm running water and soap, after handling any biological material, including animals, before leaving the laboratory, or any time contamination is known or suspected to be present on the hands.
- Ensuring open flames or heat sources are never placed near flammable supplies and are never left unattended.
- Coverings should be placed over any cuts or broken skin prior to entering the laboratory.
- Ensuring prior to entry into the laboratory, supplies of laboratory equipment and consumables, including reagents, PPE and disinfectants, are sufficient and appropriate for the activities being performed.
- Ensuring supplies are stored appropriately (i.e. according to storage instructions) and safely to reduce the chance of accidents and incidents such as spills, trips or falls for laboratory personnel.
- Protecting written documents from contamination using barriers (e.g. plastic coverings), particularly those that may need to be removed from the laboratory.
- Ensuring work is performed with care, in a timely manner and without rushing.
- Working when fatigued should be avoided.
- Keeping the work area tidy, clean and free of clutter and materials not necessary for the work being done.
- Prohibiting the use of earphones, which can distract personnel and prevent equipment or facility alarms from being heard.
- Appropriately covering or removing any jewelry which could tear glove material, easily become contaminated or act as a fomite for infection. If worn regularly, cleaning and decontamination of the jewelry or spectacles should be considered.
- Refraining from using mobile electronic devices (e.g. mobile telephones, tablets, laptops, flash drives, memory sticks, cameras and/or other portable devices including those used for DNA/RNA sequencing) when not specifically required for the laboratory procedures being carried out.
- Keeping mobile electronic devices in areas where they could not easily become contaminated or act as a fomite for infection. Where close proximity of such devices to biological agents is unavoidable, ensure they are either protected by a physical barrier or decontaminated before leaving the laboratory.

### 3.2.3. Technical procedures

Technical procedures are a special subset of GMPP which relate directly to controlling risks through safe conduct of laboratory techniques. These technical procedures, when executed correctly, allow work to be performed in a manner that minimizes the likelihood of cross-contamination (i.e. contamination of other samples, or previously sterile substances or objects as well as surface contamination) and also help prevent exposure of the laboratory worker to biological agents. The following procedures help to avoid certain biosafety incidents occurring;

**Avoiding inhalation of biological agents**

- Use good techniques to minimize the formation of aerosols and droplets when manipulating samples. This includes refraining from forcibly expelling substances from pipette tips into liquids, over-vigorous mixing, and carelessly flipping open tubes. Where pipette tips are used

for mixing, this must be done slowly and with care. Brief centrifuging of mixed tubes before opening can help to move any liquid away from the cap.

- Avoid introducing loops or similar instruments directly into an open heat source (flame) as this can cause spatter of infectious material. Where possible, use disposable transfer loops, which do not need to be resterilized. Alternatively, an enclosed electric micro incinerator to sterilize metal transfer loops can also be effective.

**Avoiding ingestion of biological agents and contact with skin and eyes**

- Wear disposable gloves at all times when handling samples known or reasonably expected to contain biological agents. Disposable gloves should not be reused.
- Avoid contact of gloved hands with the face.
- Remove gloves aseptically after use and wash hands as outlined in the monograph:

**Personal Protective Equipment.**

- Shield or otherwise protect the mouth, eyes and face during any operation where splashes may occur, such as during the mixing of disinfectant solutions.
- Secure hair to prevent contamination.
- Cover any broken skin with a suitable dressing.
- Prohibit pipetting by mouth.

**Avoiding injection of biological agents**

- Wherever possible, replace any glassware with plastic-ware.
- For work needing scissors, use scissors with blunt or rounded ends in preference to those with pointed ends.
- If glassware must be used, check it on a regular basis for integrity and discard it if anything is broken, cracked or chipped.
- Minimize the risk associated with the use of syringes or with needles by using blunt syringe needles, alternative devices or engineered sharp safety devices where possible. However, be aware that sharp safety devices also pose a risk when not handled properly.
- Never use syringes with needles as an alternative to pipetting devices.
- Never re-cap, clip or remove needles from disposable syringes.
- Dispose of any sharps materials (e.g. needles, needles combined with syringes, blades, broken glass) in puncture-proof or puncture-resistant containers fitted with sealed covers. Disposal containers must be puncture-proof/-resistant, must not be filled to capacity (three-quarters full at most), must be never reused and must not be discarded in landfills.

**Preventing dispersal of biological agents**

- Discard samples and cultures for disposal in leak-proof containers with tops appropriately secured before disposal in dedicated waste containers.
- Place waste containers, preferably unbreakable (e.g. plastic, metal), at every workstation.
- Regularly empty waste containers and securely dispose of waste.
- Consider open tubes with disinfectant soaked pad/gauze.
- Decontaminate work surfaces with a suitable disinfectant at the end of the work procedures and if any material is spilled.

- When disinfectants are used, ensure the disinfectant is active against the agents being handled and is left in contact with waste materials for the appropriate time, according to the disinfectant being used.

### 3.3. Safe handling of specimens (including tissues)

Improper collection, internal transport and receipt of specimens in the laboratory carry a risk of infection to the personnel involved. All personnel should apply appropriate measures for collection, packaging and shipment as per the National Specimen Collection Packaging and Shipment Guidelines.

Table 1: Equipment related hazards and methods that can be employed to reduce or eliminate the hazard.

| Equipment | Hazard | How to Reduce/Eliminate Hazard |
|---|---|---|
| **Needles and Syringes** | Accidental needle stick, aerosol, spills | • Do not recap needles<br>• Use a luer lock syringe<br>• Minimize air bubbles and frothing on filling<br>• Avoid mixing infectious liquids<br>• Wrap the needle and stopper with cotton pad moistened with disinfectant prior to withdrawing needle from septum<br>• Expel air bubbles into a cotton pad moistened with a disinfectant |
| **Centrifuges** | Aerosols, splashing, broken tubes | • Use sealable buckets or rotors<br>• Load and unload buckets or rotors in a BSC<br>• Wait 10 minutes for aerosols to settle before opening centrifuge lid |
| **Ultracentrifuges** | Aerosols, splashing, broken tubes | • Install a HEPA filter between centrifuge and vacuum pump<br>• Load and unload buckets or rotors in a BSC<br>• Maintain a preventative maintenance program to reduce the risk of mechanical failure |
| **Anaerobic jars** | Explosion | • Ensure integrity of wire capsule around catalyst |
| **Desiccators** | Implosion, dispersing glass fragments and infectious materials | • Double contain unit |
| **Homogenizer, tissue grinder** | Aerosols, leakage and container breakage | • Operate in a BSC<br>• Wait 30 minutes before opening blender bowl to allow the aerosol to settle<br>• If manual tissue grinders are used, hold tube in a |

| | | |
|---|---|---|
| | | wad of absorbent material |
| **Sonicators, ultrasonic cleaners** | Aerosols, noise, dermatitis | • Operate and open units in a BSC or sealed unit(only if equipment does not interrupt airflow)<br>• Ensure insulation to protect against subharmonics<br>• Wear gloves to protect against high proficiency plus detergent action on skin |
| **Culture stirrers, shakers, agitators** | Aerosols, splashing and spillage | • Operate in a BSC or specially designed primary containment<br>• Use heavy duty screw-capped culture flasks |
| **Lyophilizes** | Aerosols, direct contact contamination | • Use O-ring connectors to seal the unit<br>• Use air filters to protect vacuum lines<br>• Use an appropriate method of decontamination<br>• Provide an all metal moisture trap and vapor condenser<br>• Use only glassware designed for vacuum work |
| **Water baths** | Growth of microorganisms | • Ensure regular cleaning and disinfection<br>• Autoclave |

### 3.3.1 Opening of Ampoules Containing Lyophilized Infectious Materials

Care should be taken when ampoules of freeze-dried materials are opened, as the contents may be under reduced pressure and the sudden in rush of air may disperse some of the materials into the atmosphere. Ampoules should always be opened in a biological safety cabinet.

The following procedures are recommended for opening ampoules:

- First decontaminate the outer surface of the ampoule.
- Make a file mark on the tube near to the middle of the cotton or cellulose plug, if present
- Hold the ampoule in a wad of alcohol-soaked cotton to protect hands before breaking it at a file scratch.
- Remove the top gently and treat as contaminated material.
- If the plug is still above the contents of the ampoule, remove it with sterile forceps.
- Add liquid for re-suspension slowly to the ampoule to avoid frothing.

### 3.3.2 Storage of Ampoules Containing Infectious Materials

- Ampoules containing infectious materials should never be immersed in liquid nitrogen because cracked or imperfectly sealed ampoules may break or explode on removal.
- If very low temperatures are required, ampoules should be stored only in the gaseous phase above the liquid nitrogen.
- Infectious materials should be stored in mechanical deep-freeze cabinets or on dry ice
- Laboratory workers should wear eye and hand protection when removing ampoules from cold storage.

- The outer surfaces of ampoules stored in these ways should be disinfected when the ampoules are removed from storage.

## 3.4 Special Precautions with Blood and Other Body Fluids, Tissues and Excreta

The precautions outlined below are designed to protect laboratory workers against infection by blood borne pathogens and infectious agents.

### 3.4.1 Collection, labeling and transport of specimens

- Universal precautions shall always be followed; gloves should be worn for all procedures.
- Samples shall be collected from patients and animals in accordance with SOPs.
- For blood collection, conventional needle and syringe systems should be replaced by single-use safety vacuum devices that allow the collection of blood directly into stoppered transport and/or culture tubes, automatically disabling the needle after use.
- The tubes shall be placed in adequate containers for transport to the laboratory within the hospital facility. For further guidelines for packaging and transport of specimens refer to Chapter 8.
- Request forms should be placed in separate water-proof bags or envelopes.
- Reception staff shall not open these bags.

### 3.4.2 Opening Specimen Tubes and Sampling Contents

- Specimen tubes shall be opened in a Class I or Class II biological safety cabinet.
- Gloves must be worn. Eye and mucous membrane protection is also recommended (goggles or shield (visor).
- Protective clothing should be supplemented with a plastic apron.
- The stopper should be grasped through a piece of paper or gauze to prevent splashing.

### 3.4.3 Glass and "Sharps"

- Plastics shall replace glass wherever possible. Only laboratory grade (borosilicate) glass should be used, and any article that is chipped or cracked should be discarded.
- Hypodermic needles must not be used as pipettes. Blunt cannulas are permitted.

### 3.4.4 Films and Smears for Microscopy

Fixing and staining of blood, sputum and fecal samples for microscopy does not necessarily kill all organisms or viruses on the smears. These items should be handled with forceps, stored appropriately, and decontaminated and/or autoclaved before disposal.

### 3.4.5 Decontamination

- Hypochlorite and high-level disinfectants are recommended for decontamination.
- Freshly prepared hypochlorite solutions shall contain available chlorine at 1g/l (0.001%) for general use and 10g/l (0.01%) for blood spillages.
- Glutaraldehyde or 70% alcohol may be used for decontaminating surfaces.

### 3.4.6 Proper hand washing

Hands should be washed with soap under clean running water for a minimum of 15seconds before

leaving the working area. Using hot water and soap, the hands should be rubbed together to create a lather. The hands should be thoroughly scrubbed, including wrists, between fingers, under fingernails, and the backs of the hands. Soap should be rinsed off thoroughly. Using paper towel, hands should be dried completely. Paper towel should be used to turn off the faucet and open the door. Hand sanitizers may be used if they are effective against the pathogen or toxin used.

**Procedure:**

- Wash hands after laboratory procedures and before leaving the laboratory, this is essential to avoid becoming exposed to chemical irritants and infectious agents. Hand washing is one of the most important (and easiest) practices used to prevent transmission of blood borne pathogens. Hands or other exposed skin should be washed as soon as possible following an exposure incident. Use soft, antibacterial soap, if possible. Avoid harsh, abrasive soaps, as these may open fragile scabs or other sores. The use of gloves does not replace the need for regular and proper hand washing.
- Hands must be washed after handling bio hazardous materials, animals, visiting the toilet, before leaving the laboratory, eating and between clients.
- Thorough washing of hands with ordinary soap and water is sufficient.
- The use of disinfectant or germicidal soaps is recommended in high-risk situations.
- Follow standard hand wash technique.
- Foot or elbow operated faucets are recommended at the taps.
- Alcohol-based hand rubs should be used to decontaminate lightly soiled hands when proper handwashing is not available or not convenient.


Figure 1: Proper hand washing

### 3.4.7. Use of pipettes and pipetting aids

The greatest hazard of pipetting is the potential for the creation of aerosols and splashing

- A pipetting aid should always be used. Pipetting by mouth must be prohibited.
- All pipettes should have cotton plugs to reduce contamination of pipetting devices.
- Air should never be blown through liquid containing infectious agents
- Infectious materials should not be mixed by alternate suction and expulsion through a pipette.
- Liquids should not be forcibly expelled from pipettes.
- Mark-to-mark pipettes are preferable to other types as they do not require expulsion of the last drop.
- Contaminated pipettes should be completely submerged in a suitable disinfectant contained in an unbreakable container. They should be left in the disinfectant for 18-24 h before disposal.
- A discard container for pipettes should be placed close to the work area.
- Syringes fitted with hypodermic needles must not be used for pipetting. Blunt cannulas should be used instead of needles. There are devices for opening septum-capped bottles that allow pipettes to be used and avoid the use of hypodermic needles and syringes.

- To avoid dispersion of infectious material accidentally dropped from a pipette, a disinfectant-soaked cloth or absorbent paper should be placed on the working surface; this should be autoclaved or discarded as infectious waste after use.

### 3.4.8. Specimen Containers

Plastic specimen containers are preferable to glass due to biosafety reasons and should not leak when the cap or stopper is correctly applied. No material should remain on the outside of the container. Containers should be correctly labeled to facilitate identification. Specimen request or specification forms should not be wrapped around the containers but placed in separate, preferably waterproof envelopes.

## 3.5. Prevention of infections and accidents in the laboratory

### 3.5.1 Guidelines for handling spills

In the event of a spill of infectious or potentially infectious material, the following spill clean-up procedure should be used.

1. Wear gloves and protective clothing, including face and eye protection if indicated.
2. Cover the spill with cloth or paper towels to contain it.
3. Pour an appropriate disinfectant over the paper towels and the immediately surrounding area (generally, 5% bleach solutions are appropriate; but for spills on aircraft, quaternary ammonium disinfectants should be used).
4. Apply disinfectant concentrically beginning at the outer margin of the spill area, working toward the center.
5. After the appropriate amount of time (e.g. 30 min), clear away the materials. If there is broken glass or other sharps involved, use a dustpan or a piece of stiff cardboard to collect the material and deposit it into a puncture-resistant container for disposal.
6. Clean and disinfect the area of the spillage (if necessary, repeat steps 2–5).
7. Dispose of contaminated materials into a leakproof, puncture-resistant waste disposal container.
8. After successful disinfection, inform the competent authority that the site has now been decontaminated.

### Chemical Spill Emergency Response Plan (ERP)

- Identify spill
- Prioritize personal safety
- Categorize incident as minor or major spill
- Evacuate laboratory area
- Notify safety officer or lab manger
- Read MSDS
- Know location of eye wash station or shower
- Ventilate room in case of fumes
- Report injuries to health services
- Use first aid kit

### 3.5.2 Guidelines for avoiding Dispersion of Infectious Materials

a) In order to avoid the premature shedding of their loads, microbiological transfer loops should have a diameter of 2–3 mm and be completely closed. The shanks should not be more than 6 cm in length to minimize vibration.
b) The risk of spatter of infectious material in an open Bunsen burner flame should be avoided by using an enclosed electric micro incinerator to sterilize transfer loops. Disposable transfer loops, which do not need to be re-sterilized, are preferable.
c) Catalase tests should not be performed on slides to avoid bubbling and dispersal of aerosols. The tube, capillary tube or cover-glass methods should be used instead.
Discarded specimens and cultures for autoclaving and/or disposal should be placed in leak proof containers, e.g. laboratory discard bags.\
**d)** Working areas must be decontaminated with a suitable disinfectant, at the beginning of shift, after every procedure and at the end of shift.

### 3.5.3 Separation of Serum and Plasma

a) Only properly trained staff should be employed for this work.
b) Gloves and eye and mucous membrane protection should be worn.
c) Splashes and aerosols can only be avoided or minimized by good laboratory technique. Blood and serum should be pipetted carefully, not poured. Pipetting by mouth must be forbidden.
d) After use, pipettes should be completely submerged in hypochlorite or other suitable disinfectant. They should remain in the disinfectant for at least 18 h before disposal, or washing and sterilization for reuse.
e) Discarded specimen tubes containing blood clots, etc. (with caps replaced) should be placed in suitable leak proof containers for autoclaving and/or incineration.
f) A solution of hypochlorite, freshly prepared daily, should be available for clean-up of splashes and spillages.

### 3.5.4 Guidelines for avoiding ingestion, inoculation and contact with infectious materials

Large particles and droplets (>5µm in diameter) released during laboratory testing, and mainly microbiological manipulations settle rapidly on bench surfaces and on the hands of the operator.

a) Disposable gloves should be worn.
b) Laboratory workers should avoid touching their mouth, eyes and face.
c) Food and drink must not be consumed or stored in the laboratory.
d) There should be no gum-chewing in the laboratory.
e) Cosmetics should not be applied in the laboratory.
f) The face, eyes and mouth should be shielded or otherwise protected during any operation that may result in the splashing of potentially infectious materials.

### 3.5.5Avoiding Injection of Infectious Materials

a) Accidental inoculation with broken or chipped glassware can be avoided through careful practices and procedures. Glassware should be replaced with plastic ware whenever possible.
b) Injections may result from accidents with hypodermic needles (needle-sticks), glass Pasteur pipettes and broken glass.

c) Needle-stick accidents can be reduced by (a) taking particular care, and (b) minimizing the use of syringes and needles; for many techniques, syringes with blunt cannulas may be used instead.
d) Simple devices are available for opening septum-stoppered bottles so that pipettes can be used.
e) Needles should never be recapped. Without disconnecting them from the syringe (if available), disposable articles should be discarded into puncture-proof containers fitted with covers.
f) Plastic Pasteur pipettes should replace those made of glass.

# CHAPTER THREE

## 3.0 BIOCONTAINMENT

### 4.1Introduction

Bio-containment refers to the isolation of biological agents/toxins in an environmentally and biological secure space using a set of physical barriers, facility designs and operational elements that when used alone or in combination, reduces the risks of working with biological agents/toxins as well as preventing unauthorized access to, or theft of, valuable biological samples/toxins. Selection of appropriate bio-containment element or a set of elements, will depend on a thorough facility/institution specific biosafety and biosecurity risks assessment (see risk assessment procedure in section 1).

The bio containment elements should be designed in such a way that;

(i) it lowers the risk of the lab personnel getting infected during lab procedures while at the same time protecting the agent from loss, theft and misuse by unscrupulous individuals; and

(ii) Protects the community outside the lab environment from biological agents while exempting unauthorized access to the agents/toxins by external adversaries. Two levels of containment exists:

**Primary containment**

This is the protection of laboratory personnel and the immediate laboratory environment from unintentional exposure to biological agents/toxins (biosafety) as well as protection of the biological agent/toxins from loss, theft and intentional misuse by internal staff. Primary containment is achieved through a combination of physical barriers/equipment (e.g. centrifuge, biosafety cabinets, discs, refrigerators and freezers, face shields-biosafety and biometrics, CCTV cameras-biosecurity), facility design (floor, wall and bench top finishing) and/or operational elements (e.g. adhering to good microbiological practices and procedures-biosafety and sample tracking mechanisms, having sample inventories, assigning sample inventory/section head-biosecurity).

**Secondary containment**

This refers to the protection of the environment and community external to the laboratory working space from unintentional exposure to biological agent/toxins while also protecting valuable biological materials/toxins from loss, theft and intentional misuse by external adversaries. It is achieved through the combination of facility design (e.g. CCTV cameras, HEPA filtering) and operational practices of laboratory personnel (e.g. proper waste treatment and disposal, proper sample packaging during transportation, no putting on lab coats beyond the lab space, HEPA filtering and perimeter walls, Security personnel, sample tracking during transportation for biosecurity).

It should be borne in mind that different microorganisms pose different risks to the laboratory personnel, the community and the environment. Therefore, the selection of the primary and secondary containment elements or combination of, will greatly depend on the characteristics of the organism-a phenomenon referred to as risk grouping.

## 4.2Classification of Microorganism according to Risk Groups

Classification of microorganisms according to risk group is used to categorize the relative hazards of infective organisms to personnel, community and environment and can also be used to assess the vulnerability of the organism to be used for malicious damage. The following characteristics are used to determine risk group and vulnerability of an organism. Pathogenicity
Infectious dose

1. Mode of transmission
2. Pathogenicity
3. Infectious dose
4. host range
5. Availability of effective treatment and vaccines

These classifications presume ordinary circumstances in the laboratory or growth in small volumes for diagnostic and experimental purposes. For proper characterization of risks, a thorough risk assessment should be done to document the specific work activities and associated risks. Four levels of pathogenic risks have been defined as follows

### 4.2.1 Risk Group 1 (low individual and community risk)

This is any biological agent/toxin that is unlikely to cause disease in healthy humans or animals and does not have adverse effects on the environment. These organisms are also unlikely to be a target for malicious damage. Examples includes nonpathogenic *E. coli K-12*, *S. cerevisiae* (yeast), Lactobacillus and *B. subtilis.*

### 4.2.2 Risk Group 2 (moderate individual risk, low community risk)

This is any pathogen/toxins that can cause human disease but, under normal circumstances, is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available, and does not spread by air. They may or may not be targeted/used for malicious damage. Examples includes pathogenic strains of E. coli, *Actinomyces pyogenes,* salmonella strains, *Helicobacter pylori*, *vibrio cholera*, *candida albicans*, *yellow fever virus (vaccine strain).*

### 4.2.3 Risk Group 3 (high individual risk, low community risk)

This is any bacterial, fungal or viral pathogen that usually causes serious human or animal disease or can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another, or that causes diseases treatable by antimicrobial or anti parasitic agents. They are airborne and may be targeted/used for malicious damage. Examples includes *Mycobacterium tuberculosis, Bacillus anthracis,* Rift Valley fever virus, Yellow fever virus (wild strain). There is no parasite in risk group 3.

### 4.2.4 Risk Group 4 (high individual risk, high community risk)

This is any pathogen/toxins that usually produces very serious human or animal disease, often untreatable, and is readily transmitted from one individual to another or from animal to human or vice-versa through air. This group of organisms are highly targeted/used for malicious damage. No bacteria, fungi or parasite belong to this group. All are viruses and includes Lassa fever, Crimean-Congo hemorrhagic fever, Marburg virus, Ebola virus and Tick-borne encephalitis complex.

The choice of the containment element or a combination of laboratory practice and procedure, laboratory facilities, and safety equipment when working with potentially infectious microorganisms will depend on the characteristics of the organism/biological material/toxins being handled and the procedure undertaken, and this is the conventional basis of assigning biosafety levels. However, the risk group to which an infectious agent or toxin is assigned is the primary, but not the only, consideration used in a biological risk assessment to determine the appropriate biosafety level in which a worker can handle the infectious agent or toxin. Other considerations includes the procedures performed in the laboratory, the safety equipment and design elements present in the laboratory, and the health and training of the laboratory personnel. Therefore, risk group levels do not always correspond to biosafety levels.

### 4.3 Laboratory Biosafety Levels (BSL)

Laboratory Biosafety level refers to the level of containment, equipment, practices and operational procedures required for working with infectious agents or toxins. As the relative risk of an agent or toxin increases the degree of containment, equipment, practices and procedures for working with the agent or toxin must also increase. Laboratories and other workspaces are characterized into biosafety levels 1-4, with each level affording a greater degree of containment needed for the activity based on the risk assessment.

#### 4.3.1 BSL-1

BSL-1 is the basic level of protection and is appropriate when working with agents that are not known to cause disease in normal healthy humans or animals and doe nopt have adverse consequences on the environment. BSL-1 requires the lowest level of containment and safety guidelines, which are entirely based on standard laboratory practices. Examples includes laboratories that do not work with disease-causing agents or specimens from humans or animals such as school laboratory.

#### 4.3.2 BSL-2

BSL-2 is appropriate when working with moderate-risk agents that cause human disease of varying severity where transmission is by ingestion, percutaneous or mucous membrane exposure. Most clinical diagnostic laboratories are in this level. Agents may be handled on open benches, especially if primary barriers, such as facemasks, gowns, and examination gloves are used appropriately. Some procedures may require enhanced containment which includes unidirectional air flow (Air flows from low hazard to higher hazard areas no recirculation of air to other areas of the building the building is permitted), the use of biological safety cabinets (BSCs) and safety centrifuges. Laboratory personnel must be trained in the use of equipment, personal protective gear and related SOPs.

#### 4.3.3 BSL-3

BSL-3 is appropriate for work with indigenous or unusual agents that have a known potential for aerosol transmission and that can cause serious and potentially fatal infections such as TB or varicella (chicken pox). BSL-3 is an enhanced level 2 with additional features to prevent transmission of infectious organisms that include unidirectional airflow, appropriate respiratory protection, HEPA filtration of exhausted laboratory air and strictly controlled laboratory access. Laboratory personnel must be trained in the use of equipment, personal protective gear and related SOPs.

### 4.3.4 BSL-4

BSL-4 is designed for use with exotic agents that have the potential for aerosol transmission, often having a low infectious dose and produce very serious and often life threatening disease; there is generally no treatment or vaccine available, such as hemorrhagic fever viruses. Workers who perform procedures in these laboratories require special training and they must use BSCs or wear full-body, air-supported, positive-pressure suits. In addition, the facility itself must be totally isolated from other laboratories and have specialized ventilation and waste-management systems. Laboratory personnel must be trained in the use of equipment, personal protective gear and related SOPs

**Caution:** When selecting BSC always select A2 circulating within the room for facilities that already built. Go for ducted BSC for new facilities where concentrated large amounts of chemicals are used, special approval must be sought to purchase this type of BSC from Biomedical Engineering department.

# CHAPTER FOUR

# 5.0 PERSONAL PROTECTIVE EQUIPMENTS (PPE)

## 1. Introduction

Personal protective equipment (PPE) are devices worn by laboratory / health workers for personal protection against hazards. It provides barrier against skin, mucus membrane and respiratory exposure to infectious agent to prevent the spread of contamination. However, it important to note that the use of PPE doesn't guard against all hazards. There are different types of PPEs which include; gloves, respirators and mask, lab coats, face shield, closed shoes, aprons, head gear, goggles, protective footwear, gowns and full body suites.

A through risk assessment will determine the necessity for and type of PPE. The PPE required depends on the following factors:

- characteristics of the biological agent being handled,
- volumes and concentrations of the biological agent,
- presence of additional hazards (for example, extreme temperatures, chemical or radiological hazards),
- type of work being carried out,
- other risk control measures being used, such as a biological safety cabinet (BSC),
- other PPE being worn,
- individual needs of the laboratory personnel, and
- Availability of national regulations and organizational requirement

## 5.3 Principles of selection and use of PPE

a) Familiarise with potential hazards and types of PPE available
b) Anticipate exposure
c) Durability and appropriateness of PPE to the task
d) Consider the hazard association with Environment
e) Select PPE that ensures greater level of protection than minimum requirement.
f) Fit the worker with PPE and give instructions on use and care.
g) Make workers aware of limitation of PPE.
h) If several different type of PPE are worn together, make sure they are compatible

## 5.4 Guidelines for use of PPE

PPE selection should depend on the determination of the risks associated with the laboratory and to the nature of work in progress. Appropriate PPE is desired for work that may generate aerosols, handling samples, which may contain blood and air borne pathogens. Below are guidelines when using PPEs in BSL-2:

- Laboratory PPEs should be provided to all staff and must be worn at all times for all personnel working in the laboratory
- Ensure all the PPEs under use have best fits for the lab personnel and that fit testing is done regularly with documentations.
- Followed over exposure to agents or infectious samples by immediate decontamination of the PPE and change into clean one to protect the worker performing experiments and the environment.
- Ensure Provisions of PPE to visitors and maintenance or security personnel, if applicable.
- PPE worn within the laboratory should not be worn outside the facility, for examples library, cafeteria, or other places accessible to the public.
- Personnel should be encouraged to use disposable facial tissues instead of personal handkerchiefs if it must be in the laboratory.
- Place clean or unused PPE in an appropriately designated area or container for storage, separate from the dirty ones.
- All PPE should be decontaminated before being sent to the laundry or discarded. Treat contaminated PPE with an appropriate disinfectant. Lab coats with extensive
- Contamination may be placed in a biohazard bag and autoclaved.
- Do not take PPE home to launder
- Change PPE as soon as feasible whenever it is compromised, soiled or torn.
- Wear appropriate sizes and keep an adequate supply of PPE available in the laboratory.

- Wash hands whenever PPE is removed.
- Do not touch door handles, buttons, telephones, computers or other clean surfaces or items with gloved hands, unless the existing policy says so, and lab personnel must be reminded with warning signs.
- Do not wear gloves and lab coats outside the laboratory area unless authorized or the condition dictates

**Table 2: Common PPEs**

| Type of PPE | Description |
|---|---|
| Gloves (light and heavy)<br>  <br>  | • Appropriate disposable gloves must be worn for all procedures that may involve planned or inadvertent contact with blood, body fluids and other potentially infectious materials.<br>• They must not be disinfected or reused as exposure to disinfectants and prolonged wear will reduce the integrity of the glove and decrease protection to the user.<br>• Gloves should always be inspected before use to check they are intact.<br>• Different types of glove may be needed for different applications or other occupational hazards, such as thermal protection, or protection from sharps or against chemicals.<br>• Various sizes should be available to ensure that gloves properly ft the user to allow adequate movement and dexterity for the procedures being performed.<br>• Nitrile, vinyl and latex gloves are often used for protection against biological agents. It should be noted that latex protein could cause allergy over time; low protein and powder-free options are available to minimize the occurrence of an allergy |
| Respirators and masks<br>  | • Respiratory protection is generally not required for protection against biological agents as a part of the core requirements. Where a risk assessment indicates that the use of respiratory protection is needed, this is considered a heightened control measure. |

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| | • However, there may be circumstances where respiratory protection is required for other reasons based on assessments for non-biological hazards such as chemicals or allergens. |
| Air purifying respirators<br>  | • Air purifying respirators filter the air you breath to help protect you from microorganisms including bacteria and viruses. Examples include: -<br>Powered air purifying respirator<br>Self-contained breathing apparatus |
| Gowns and Scrub suits<br>  | • Gowns offer a similar range of coverage as laboratory coats, although generally they are solid-front, back-closing garments with elasticized cuffs that can be worn on top of personal clothing or scrubs.<br>• Disposable gowns are generally intended as single-use items of PPE; however, they can on occasion be worn a few times before disposal, where the risk assessment specifies that the likelihood of contamination is low.<br>• Alternatively, wraparound reusable gowns may also be used, although they requir regular decontamination and laundering. |
| Closed Shoes with covers<br>  <br>  | • Wear shoe covers to provide a barrier against possible exposure to airbone organisms or contact with a contaminated environment |

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|---|---|
| Lab coats/Coveralls<br>  | • Coveralls cover the whole body and are generally worn on top of scrubs or personal clothes.<br>• Depending on the quality, they may be disposable or reused if properly decontaminated.<br>• Care must be taken while removing coveralls to prevent any contamination of the person wearing them.<br>• Coveralls with a zip flap should be considered for protection against splashes |
| Head gear<br>  | • Head convers provide a barrier against possible exposure within a contaminated environement.<br>• Wear Head covers to protect the hair and scalp from possible contamination when sprays or air born exposure is anticipated |
| Face shield and Goggles<br>  <br>  | • Respiratory protection is generally not required for protection against biological agents as a part of the core requirements.<br>• Where a risk assessment indicates that the use of respiratory protection is needed, this is considered a heightened control measure.<br>• However, there may be circumstances where respiratory protection is required for other reasons based on assessments for non-biological hazards such as chemicals or allergens. |
| Aprons<br>  | • Additional hazard-specific splash protection may be required for certain procedures, such as, removing specimens from liquid nitrogen, when handling liquid chemicals, during autopsy, or where large volumes of liquid are being handled. |
| Boots<br>  | • Footwear must be worn in the laboratory and must be of a design that minimizes slips and trips and can reduce the likelihood of injury from falling objects and exposure to biological agents. |

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| | • Footwear should cover the top of the foot, and should be wellftting and comfortable to allow personnel to perform their tasks without fatigue or distraction. |

# CHAPTER 6

# 6.0 OCCUPATIONAL HEALTH AND SAFETY PROGRAM

## 6.1 Introduction

An effective safety programme begins with financial and administrative support from the laboratory management that enables and assures safe laboratory practices and procedures are integrated into the training of all personnel. The employing authority, through the laboratory director, must take responsibility for ensuring that the health of laboratory personnel is adequately checked and reported. The objective is to provide a safe working environment including preventative measures (e.g. vaccination) and monitoring of employee health to enable appropriate measures to be taken in case of exposure or occupationally related disease or any other aspect of the work that affects the safety, health and social well-being of employees.

Medical examination or health status information of laboratory personnel may be required to ensure that it is safe for them to work in the laboratory. All aspects of an employee's health status must be kept confidential.
The following control measures may be required to ensure employee health and safety

1. Medical examination of all laboratory personnel who work with heightened control measures to determine their health status is not at risk in performing the work.
2. This should include a detailed medical history and an occupationally-targeted examination, which should be recorded.
3. Provision of a medical contact card to medically cleared personnel by the physician with an emergency contact point in case a sudden illness occurs outside of work hours.
4. A system must be in place to provide 24-hour help in case of an emergency.
5. Working policies should ensure that the number of hours worked in the laboratory on a single occasion is kept to a minimum to prevent physical and/or mental fatigue.
6. Injuries, in particular percutaneous injury such as from a needle-stick or bites from infected animals, sustained in the laboratory carry an elevated risk of due to the consequences of any subsequent infection because of the nature of the pathogens being handled. Such events must be reported immediately and appropriate first aid and/or prophylaxis precautions taken as applicable.

7. Depending on the incident, personnel should monitor and record body temperature and any symptoms, for example headache, fever and general malaise, for an agreed period of time. If body temperature increases or disease-specific symptoms are noted, arrangements should be made for medical advice and support and for transfer to a suitable health care facility for isolation and appropriate medical care.

Health care workers are exposed to various occupational hazards resulting from handling patients and samples at their work place. To minimize risk of exposure to these hazards, it is important to develop an occupational health and safety program. It is the responsibility of the employer to address staff induction, training, fitness to work medical tests, health surveillance program, handle exposure/accident management plans and incident reporting, investigation and mitigation plans to ensure that a sound occupational health and safety program is implemented.

## 6.2Staff induction and training

This is training is given to all new staff and staff transferred to a new job or position. This training shall be given within 30 days of initial employment or assignment to a new job. Induction training shall cover the following:

a) Introduction to the work place co-workers, facility and reporting structures.
b) Laboratory safety guidelines
c) Risk assessment of work place identifying all hazards
d) Training on specific operational procedures and manuals
e) Training on use of Personal protective equipment

## 6.3 Occupational Health and Safety Training

The Occupational Health and Safety Training will be a modular training track implemented using the Biorisk Management Training Curriculum. This will be a continuous training given to staff to create awareness of occupational health and safety hazards at the workplace.. The module will address the following areas: -

a) Risk Assessment and mitigation
b) Health and Medical Surveillance
c) Pre and Post-Exposure protocols
d) Training and competence evaluation

These trainings shall be conducted in modular sessions that shall include practical demonstrations. The training shall be facilitated by a competent and facility certified occupational health trainer.

## 6.4Medical Surveillance Program

In accordance with Occupational Safety and Health Act 2006 (OSHA 2006), arrangements should be made for appropriate fitness to work medical tests and health surveillance of all workers. For laboratory workers the following shall be put in place to ensure compliance with the Act.

### 6.4.1Pre-service Medical Examination

This is a medical evaluation of the employee carried out on request of the employer by a qualified and licensed medical officer of health to ascertain the fitness of the employee to carry out the assigned tasks. This evaluation is carried out before the employee takes up the new position.
Every facility shall appoint a qualified and licensed medical officer of health to carry out fitness to work medical tests for all new appointees.

### 6.4.2Health Surveillance Programme

This is a continuous health evaluation program for all workers within their work environment. The evaluation is dependent on occupational health risk assessment and occupational hazards identified. For laboratory workers, this evaluation shall be done annually or after an incident that could result to exposure or at the onset of symptoms of any work-related illnesses.

Health surveillance program shall include the following:

a) Evaluation of employees and job duties. This will cover evaluation of fitness to work medical tests, and employee job description.
b) Facility specific risk assessment. This will define the potential exposure and other risks based upon actual job duties.
c) Pre-placement medical history. This will include evaluation of past medical history including:
    - Medical, surgical, social and family history
    - Allergies and sensitivities (latex, drugs, etc.)
    - Previous occupation history and activity
    - Medications and other treatments
    - Active conditions and review of major body systems
    - Review and record past immunization history.

d) Fitness to work medical tests and health surveillance program records management. Every employee in the laboratory shall have a fitness to work medical tests and health surveillance file. These records shall be kept for up to 10 years following the end of occupational exposure. All

cases of disease or death identified in accordance with OSHA, 2006 as resulting from occupational hazards shall be notified to the competent authority through the Biosafety and Biosecurity AdvisoryCommittee in writing.

### 6.4.3Pre and Post exposure plans

Occupational accidents and exposures may be costly institutions through:

a) Compensation costs
**b)** Lost work time
**c)** Loss of competence staff
**d)** High staff turnover
**e)** Low staff morale

Implementing accidents/exposure management plans and establishing clear strategies for accidents/exposure reporting, investigation and mitigation help institutions prevent, control and monitor such incidents.

#### 6.4.3.1Occupational Exposure

Occupational exposures include radiation, electrical, chemical explosions, and fire, mechanical, physical and biological. Biological exposures result from exposure to biological hazards, and can result from percutaneous injury (needle-stick or other sharps injury), mucocutaneous splashing (splashing of blood or other body fluids into the eyes, nose, or mouth), specimen contact with intact or non-intact skin, or respiratory exposure by inhalation.

Health care workers are at risk of exposure. The risk shall depend on the risk assessment of the work environment and specific work activity.

#### 6.4.3.2Occupational exposure/accident management plans

These are strategies put in place by the risk managers to minimize the occurrenceof the possible occupational exposure/accident and their effects. These shall include the following:

a) Training
b) Vaccination: Health care workers must be vaccinated against vaccine preventable diseases which include HBV, yellow fever, TB, etc.
c) Personal protective equipment: Health care workers must be provided with PPE that adequately protect them from the risks they are exposed to. Proper use of PPE and training is important.

d) Post exposure prophylaxis (PEP): There shall be a documented PEP plan in place at every health facility based on risk assessment. Proper PEP management includes incident and accident reporting, management and monitoring. Health care workers shall have access to PEP 24 hours a day and seven days a week. Post exposure prophylaxis (PEP) interventions are prescribed in the Ministry of Health policy documents. Current prescribed PEPs include:

- Human Immunodeficiency Virus (HIV)
- Hepatitis B Virus (HBV)
- Hepatitis C Virus (HCV)
- Tuberculosis (TB)
- Meningococcal Meningitis
- Viral Hemorrhagic Fevers

**Note:** PEP for specific agents keep changing, so facility management shall ensure the most current version is availed.

#### 6.4.3.3Monitoring and use of safe Equipment

Most of the equipment can be source of infections, so it is very important to monitor and ensure safe use of these equipment.

#### 6.4.3.4Emergency First Aid plans

Emergencies situation are bound to occur in work places including biomedical laboratories. To minimize the impact of these situations, each facility should develop an emergency preparedness and response plan. The plan shall contain the following components:

# CHAPTER SEVEN

## 7.0 DECONTAMINATION AND WASTE MANAGEMENT

### 7.1 Introduction

Decontamination and waste management are key to safe handling of biological agents. It is therefore important to understand the basic mechanisms of the different methods of disinfection, sterilization and waste management that can be used in a laboratory.

The specific decontamination requirements depend on the nature of the biological agents being handled.

All forms of wastes from laboratories must be managed from the point of generation up to a final safe disposal, following the recommended National Guidelines for Waste Management (*2006).* A waste management program, including provisions for waste minimization, identification and segregation, packaging, storage, transport, decontamination, disposal, and documentation of those procedures should be implemented.

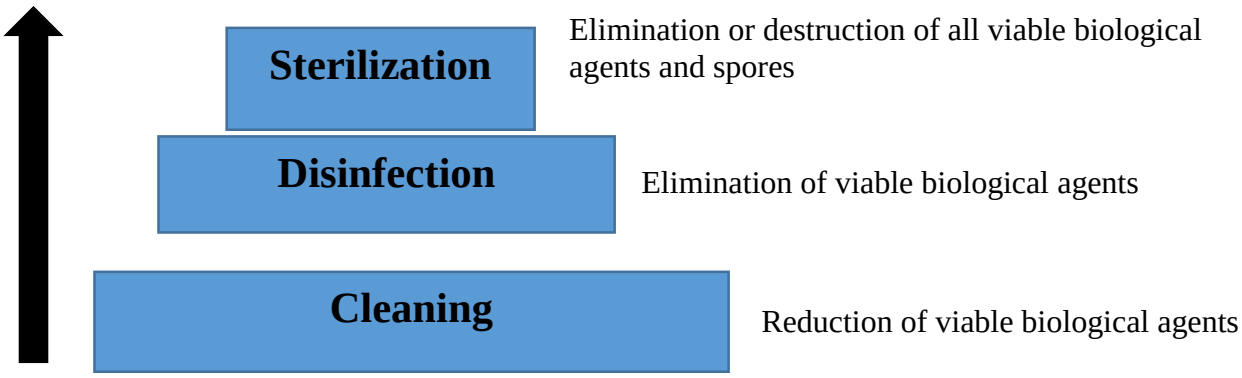
**8.2. Decontamination**

**This is a process of reducing the number of viable biological agents or other hazardous materials on a surface or object(s) to an acceptable level by chemical and/or physical means, often in combination with cleaning or physical removal of contaminants. Consideration should be given to the microorganism being targeted, the characteristics of a specific disinfectant, methods to be used, and environmental issues.**

**The following factors affect the effectiveness of decontamination:**

- **Nature of the item to be decontaminated**
- **Type and concentration of the agent**
- **Resistance of microorganisms**
- **Length of contact time with the agent**
- **Presence of organic matter and dirt**
- **Temperature**
- **Condition and nature of the surface**
- **Choice of method of decontamination**

**Figure 8.1 Methods of decontamination**




### 8.2.1 Cleaning and hand hygiene

#### 8. 2.1.1 Cleaning

Cleaning is the removal of dirt, organic matter or biological agents from surfaces. Cleaning in the context of laboratory biosafety has two functions:

i) Removes dirt and organic matter from an item that would inactivate chemical disinfectants or impede them making contact with biological agents within the item and

ii) Removes a high proportion of biological agents, making reduction to safe levels by subsequent chemical disinfection more effective.

Cleaning should not be relied on as the only decontamination process. Risk assessments for the need to clean before decontamination should be done.

The cleaning can be carried out manually by scrubbing, if possible using warm water. Cleaning includes brushing, vacuuming, dry dusting, washing or damp mopping preferably with warm water. The addition of cleaning agents (surfactant that lowers surface tension, detergent) increases the effectiveness of cleaning. Examples of common cleaning agents include soda solution (3 kg sodium carbonate (Na2CO3) per 100 L of hot water), soap solution (3 kg soap per 100 L of hot water) or commercial preparations.

Cleaning must be carried out in such a way as to keep the operator safe and prevent the spread of the disease or dispersion of contamination. Therefore, personnel must be trained and use PPE, proper techniques and adequate care.

### 8. 2.1.2 Hand hygiene

While suitable gloves provide the wearer with a high degree of protection, they do not give complete protection. Therefore, hand hygiene should be performed before and after removal of gloves. There are two types of laboratory hand hygiene:

#### i. Handwashing

A short (about 20 seconds) but thorough hand wash with soap and running water will efficiently remove laboratory-acquired contamination. Hands should be washed in running water, so a tap/faucet that mixes hot and cold water to a comfortable temperature should be used. A hands free method (infrared-operated switch, or foot, knee or elbow operated tap/faucet) is an advantage. If taps/faucets need to be turned on and off by hand, a clean paper towel should be used to turn them off. Hands should be dried with single-use paper towels and the towels should

#### ii. Alcohol hand rub

Alcohols (ethanol, propanol or isopropanol) at concentrations between 60% and 95% applied to the hands and rubbed to dryness can be effective in removing microbial contamination acquired during laboratory work. Alcohols are poor at penetrating proteins or protein-containing matter, so they should only be used on visibly clean hands. Alcohols have no activity against spores and poor activity against non-enveloped viruses; if hand contamination with these biological agents is likely, handwashing should be used instead of alcohol hand rubs.


**Figure 2.2** Hand hygiene – recommended procedure

### 8.2.2 Chemical disinfection

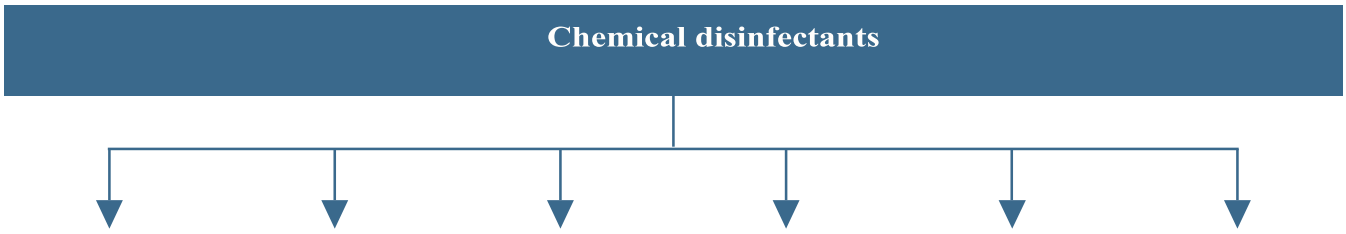
Chemical disinfection is a method of decontamination that involves the application of a chemical, or mixture of chemicals, to an inanimate surface or material to inactivate or reduce the number of viable biological agents to a safe level.

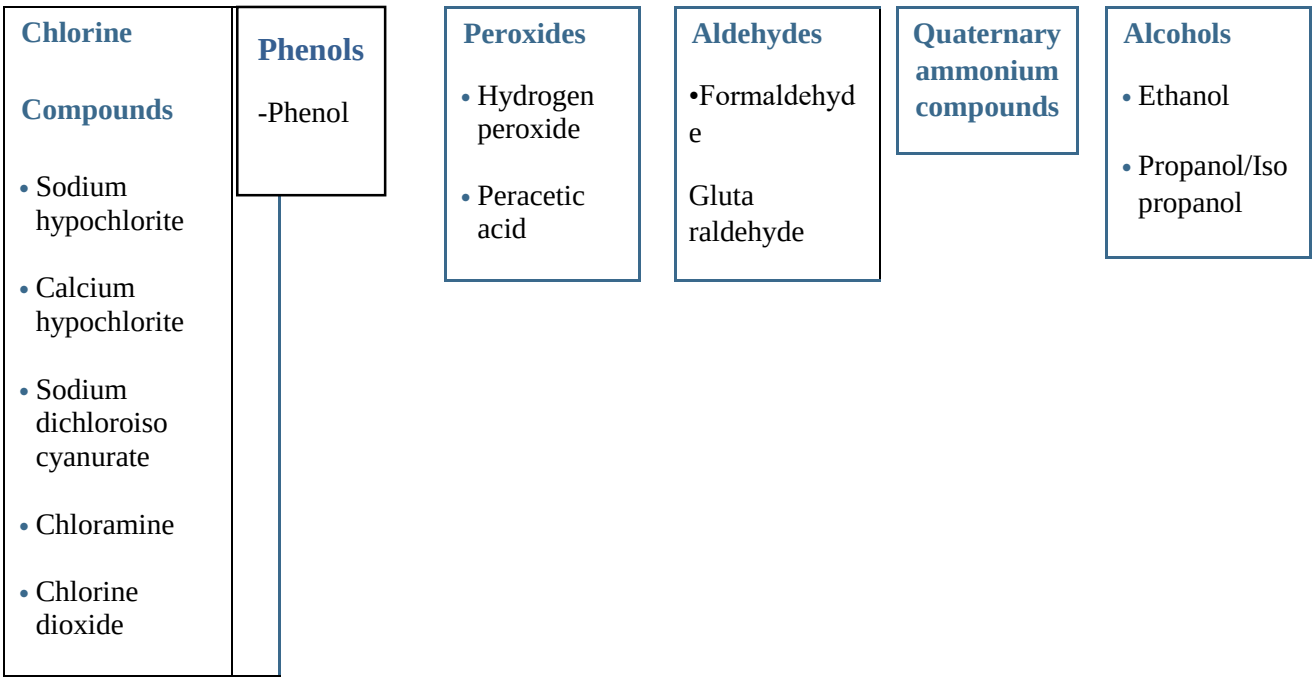
In choosing the disinfectant, three important factors must be considered for optimum effectiveness against biological risks:

- spectrum of activity (with high specificity for the biological agents to be disinfected),
- field of application (for example, application in liquids or on surfaces), and
- Application conditions (contact time, concentration of the disinfectant, temperature of the application and other important influencing factors such as the presence of an organic load, e.g. serum or blood).

#### 8.2.2.1 Types of disinfectant

A number of classes of chemical disinfectants are available (Figure 2.3).






**Chlorine compounds**

Hypochlorites are chlorine-based disinfectants but the active component is oxygen loosely bound to chlorine; this oxygen is readily lost to become available to oxidize other compounds. These disinfectants are solutions with a variety of components in equilibrium but the most active chemical species are usually sodium hypochlorite (NaOCl), the hypochlorous ion (OCl–) and hypochlorous acid (HOCl). The oxidizing capacity of hypochlorite solutions is expressed as either percentage of available chlorine, or parts per million of available chlorine (ppm av Cl).

Hypochlorites are inactivated by organic matter. The concentration needed increases as the amount of organic matter contamination increases.

Hypochlorite solutions can be prepared from a number of different starting agents such as liquid bleach. Diluted hypochlorite solutions have a limited shelf-life, about one day, depending on exposure to heat and/or sunlight.

Granules or tablets of calcium hypochlorite (Ca(ClO)2) generally contain about 70% available chlorine. Thus, solutions from tablets or granules containing, for example, 1.4 g/L calcium hypochlorite solution would contain about 1 g/L available chlorine, which equates to 1000 ppm av Cl. Sodium dichloroisocyanurate (NaDCC) is a solid that is very stable in dry storage, even at high temperatures. It contains 60% available chlorine and forms an equilibrium that contains the active chemical species of hypochlorites. Sodium dichloroisocyanurate is available in a variety of tablet forms which give a specific available chlorine concentration when dissolved in specified volumes of water.

Hypochlorites can cause severe corrosion of metals and irritation to exposed skin and mucous membranes. Their use should be avoided on metals unless the manufacturer states that the metals in their device are compatible with the concentration of hypochlorite used or if the occurrence of corrosion is not a problem, for example, the item is being disinfected before disposal.

The frequency with which working solutions of hypochlorite should be changed depends on their starting strength, the frequency and nature of use (how much organic matter is added to them), and the ambient temperature.

The adequacy of hypochlorite solutions can be checked using starch–iodine papers to show they have not been inactivated. Starch– iodine papers identify the condition and relative strength of the oxidizing agent present in solutions.

**Table 2.2 Recommended dilutions of compounds releasing chlorine**

| **HYPOCHLORITE SOURCE (PERCENTAGE available chlorine)** | **CLEAN CONDITIONS**[a] (available chlorine needed for disinfection: 1 | **DIRTY CONDITIONS**[b] (available chlorine needed for disinfection: 5 |
|---|---|---|

| | g/l – 0.1% available chlorine – 1000 ppm av cl) | g/l – 0.5% available chlorine – 5000 ppm av cl) |
|---|---|---|
| Sodium hypochlorite solution (5% available chlorine) | 20 mL | 100 mL |
| Calcium hypochlorite (70% available chlorine) | 1.4 g/L | 7.0 g/L |
| Sodium dichloroisocyanurate powder (60% available chlorine) | 1.7 g/L | 8.5 g/L |
| Chloramine powder (25% available chlorine) | 4 g/L | 20 g/L |

ppm av Cl = parts per million available chlorine. [a] Low levels of contamination. [b] High levels of contamination.

**Phenols**

Phenols, also called phenolic compounds, are a class of chemical compounds consisting of a hydroxyl group (–OH) bonded directly to an aromatic hydrocarbon group. The simplest of the class is phenol (C6H5OH). Phenol acts specifically on the cell membrane, denatures proteins and inactivates intracytoplasmic enzymes by forming unstable complexes. These interactions lead to leakage of bacterial elements or they induce lysis of the cell membrane. Phenolic compounds have greater stability than sodium hypochlorite, are less affected by higher concentrations of organic matter in the solution and are effective against vegetative bacteria, particularly Gram-positive species and enveloped viruses. However, they are not effective against spores and non-enveloped viruses. Despite these advantages, phenolic compounds can be toxic, are corrosive for the skin and are known to be respiratory irritants. Because of these major limitations, the use of phenolic compounds

has decreased in recent years, although phenolic compounds can still be found in some household disinfectant and cleaning products, often in combination with quaternary ammoniums and alcohols.

Phenol-based disinfectants are still used as tuberculocidal agents to destroy mycobacteria. This is because these disinfectants are lipophilic molecules that are efficiently trapped by the many phospholipids found on the cell membrane of mycobacteria, thereby eliminating the bacterium.

**Peroxides**

Peroxides are widely used microbiocidal agents because of their strong oxidizing activity due to the presence of highly reactive hydroxyl radicals. They denature proteins and lipids of biological agents, leading to disorganization of the membrane. Swelling of the cell of the biological agent may take place when saturated with hydrogen ions, which attract water.

**Hydrogen peroxide (H2O2)** acts as an oxidizing agent by producing hydroxyl free radicals that attack essential cell components, including lipids, proteins and DNA. It has a wide range of bactericidal, viricidal and fungicidal activity, although activity is variable against bacterial spores and mycobacteria. However, the ability of bacteria to produce catalase can increase tolerance to hydrogen peroxide when low concentrations are used. Hydrogen peroxide is considered environmentally friendly because it can rapidly degrade into the harmless products – water and oxygen. It is, however, a severe irritant to the skin, eyes and respiratory system.

**Peracetic acid (C2H4O3)** is made by mixing acetic acid with hydrogen peroxide and a strong acid catalyst. It is a stronger disinfectant than hydrogen peroxide. It denatures proteins, disrupts cell wall permeability and oxidizes sulfhydryl and sulfur bonds in proteins, enzymes and other metabolites.

As a result, peracetic acid is highly sporicidal, bactericidal, viricidal and fungicidal at low concentrations (< 0.3%). Peracetic acid also decomposes to safe by-products (acetic acid and oxygen) and has the added advantages of not being decomposed by peroxidases, unlike hydrogen peroxide, and remaining active in the presence of organic loads. It is available from the main chemical suppliers and is therefore relatively cheap, and it can be diluted at the point of use. However, as with hydrogen peroxide, peracetic acid is a severe irritant to the skin, eyes and respiratory system.

## Aldehydes

**Formaldehyde (CH2O)** is available as formalin, a stabilized solution of about 37% formaldehyde, or paraformaldehyde, a solid polymer that is heated and reacts with air to form formaldehyde gas. Formaldehyde causes irritation of the skin, eyes, nose and throat. High levels of exposure may cause some types of cancer. Its laboratory use should not expose people to contact with formaldehyde or its vapour. Formaldehyde should only be used for specific processes that require it, such as tissue fixation, but not for general disinfection. It should not be used to wipe surfaces or equipment. It should only be used to fumigate spaces (see subsection 2.3 Gaseous disinfection) if the vapour can be completely contained, properly inactivated and exhausted safely after fumigation. When formaldehyde is used, it should be in controlled conditions, such as in sealable rooms or cabinets, which limit people's exposure in accordance with national safety and environmental requirements.

**Glutaraldehyde (C5H8O2)** is normally used as a solution that is buffered (activated) to alkaline pH just before use. Before activation, glutaraldehyde is a stable solution but after activation, it has a limited shelf-life. The advantages of glutaraldehyde are its wide microbiocidal spectrum and low corrosiveness. The disadvantage of glutaraldehyde is that it is toxic and acts as a chemical sensitizer (can cause allergic reaction after exposure). If used, appropriate PPE must be used in order to limit potential exposure to either the liquid or the vapour form.

## Quaternary ammonium compounds

Quaternary ammonium compounds and similar compounds, such as triamines, are a varied family of molecules, some of which can be used as disinfectants. They work by their surfactant activity disrupting the structure of biological agents. Quaternary ammonium compounds are more stable than hypochlorites, less irritating to the respiratory tract and less toxic than phenolic compounds. However, they are affected by high levels of organic materials and anything with a large surface area that could bind the disinfectant, such as fabrics.

They have activity against bacteria in non-spore forms and enveloped (lipid containing) viruses. They are effective against a smaller range of biological agents than either hypochlorites or phenolic compounds, and have limited effectiveness against non-enveloped viruses, most Mycobacterium species and spores. However, for extended use in solutions containing mostly enveloped viruses, quaternary ammonium compounds may be the best disinfectant to use.

They are non-corrosive but more expensive than sodium hypochlorite. If being considered for laboratory use, both potential inactivation and the range of biological agents they would be expected to act against need to be considered in the risk assessment

**Alcohols**

Alcohols used for laboratory disinfection are either ethanol (usually denatured by the addition of methylated spirits, making it unsuitable for consumption), propanol (propan-1-ol) or isopropanol (propan-2-ol). The normal concentration for use is 70%, although, depending on which alcohol is used, anywhere between 60% and 90% can be effective. The activity of the three alcohols is broadly similar; they are effective against a wide range of bacteria in non-spore form and enveloped (lipid-containing) viruses. They have variable activity against non-enveloped viruses and no activity against bacteria spores. While alcohols are not inactivated by organic matter, their activity is unreliable in the presence of proteins; they can coagulate proteins, forming a barrier against their further penetration to layers inside. Alcohols evaporate quickly which make them convenient to use as surface disinfectants. However, their quick evaporation also reduces the exposure time and therefore their effectiveness.

### 8.2.3 Factors affecting the effectiveness of disinfectants

Many different factors can affect the effectiveness of chemical disinfection. The most important ones are shown in Table 2.3. These factors must be considered in the risk assessment for selecting the best decontamination process. Users should know exactly what they are using and that what they are using will be effective as determined by risk assessment.

**Table 2.3 Factors that can affect the effectiveness of chemical disinfection**

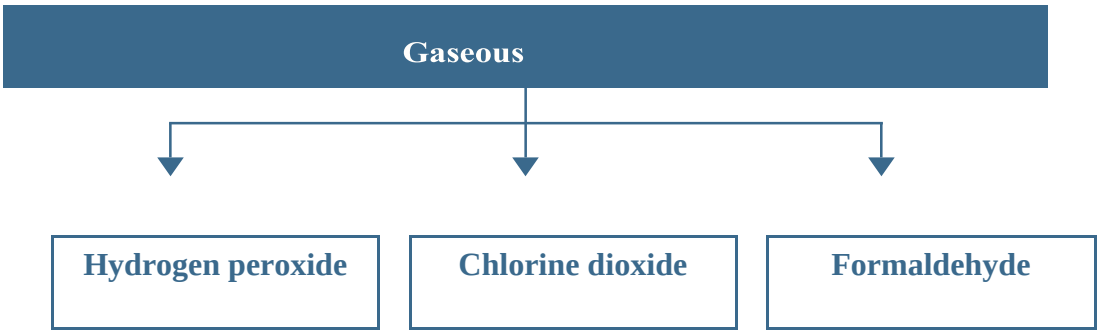
| FACTOR | REASON |
|---|---|
| **Concentration** | As illustrated with sodium hypochlorite, the amount of active compound available in a disinfectant is critical: too little active compound and decontamination is not achieved. |
| **Organic matter** | Disinfectants will react with living and non-living organic matter alike. If organic matter is present, it can inactivate the disinfectant before all the viable biological agents present have been eliminated. Solid organic matter can also inhibit the penetration of the disinfectant so it cannot reach its target. Specific organic materials are often defined in standard methods to indicate "clean" (low levels of contamination) and "dirty" (high levels of contamination) situations. |
| **pH** | Many chemical agents for decontamination are active only within a specific pH range. The manufacturer's information must be considered to keep the disinfectant within this range. |
| **Contact time** | Chemical disinfection is not immediate. Generally, the longer the disinfectant is in contact with the contamination from biological agents, the greater the microbial decontamination. Once the disinfectant dries, the disinfectant molecules can no longer migrate into their target. Rapid evaporation of a disinfectant applied to a surface can compromise efficient disinfection. Contact times used in test conditions should reflect those used in practice. |
| **Contact** | If objects to be disinfected are floating on the surface of a disinfectant, if air bubbles (for example, in tubing (hollow lumens) prevent contact between the |

| | |
|---|---|
| | disinfectant and its target, or if application of a disinfectant to a surface does not give complete coverage, the disinfectant cannot be fully effective. |
| **Range of microbiocidal activity** | Not all disinfectants decontaminate all biological agents. Vegetative bacteria, fungi (including fungal spores), enveloped (lipid-containing or lipophilic) viruses and non-encysted protozoa tend to be readily susceptible to a wide range of disinfectants. Mycobacteria, nonenveloped viruses and encysted protozoa are less susceptible. Bacterial spores are resistant to some disinfectants and have variable sensitivity to others. |
| **Temperature** | In general, the higher the temperature, the more effective the disinfectant will be, the lower the temperature, the less effective the disinfectant action. This can be important in laboratory disinfection if refrigerators or cold rooms require disinfection, or where thermal treatment is also used, such as washer disinfectors used in some laboratories. |
| **Shelf-life/stability** | Chemical compounds may degrade over time, thus reducing the efficiency of the decontamination product. The degradation rate is often accelerated when the product is exposed to air or when the product is diluted. Typically, diluted sodium hypochlorite solutions become rapidly inefficient and work should be done with freshly prepared dilutions to achieve the desired effect. |

### 8.3 Gaseous disinfection

Gaseous disinfectants also known as fumigants, are required to decontaminate the laboratory space, furniture and/or equipment.

In situations where the laboratory has widespread contamination in difficult to access areas or where equipment needs to be taken out of a contaminated area or disinfected before maintenance, then gaseous disinfectants may be needed. Rooms and equipment can be decontaminated by fumigation with formaldehyde gas generated by heating paraformaldehyde or boiling formalin solutions.




This is a hazardous process that requires specially trained personnel and should be the last resort when risk assessment concludes that surface disinfection is impractical or inefficient. A treated room should be sealable for fumigation but, at the very least, all openings in the room (windows, doors) should be sealed with gas impermeable tape before the formaldehyde gas is generated. Fumigation should be conducted at an ambient temperature of at least 20 °C and a relative humidity of more than 70%.

After a period of room aeration, a calibrated hand-held monitor or built-in device should be used wherever possible to check fumigant levels before re-entering the room. Ammonia, normally from sublimation of ammonium bicarbonate, can be used to neutralize formaldehyde fumigations before release of the fumigant.

Commercial fumigation systems using hydrogen peroxide or chlorine dioxide are also available. These systems have several advantages over formaldehyde in terms of safety, environmental protection, controllability of the fumigation process and speed but they are more expensive. Information on the use and effectiveness of commercial systems is widely available from the scientific literature.

**8.4 Heat disinfection**

Heat is the most common physical method used for the decontamination of biological agents. Both dry and moist heat can be used. The contact of the biological agents with water is essential for steam sterilization, that is, the steam must reach all the surfaces or materials to be sterilized or disinfected. Moist heat is most effective when used in autoclaving.

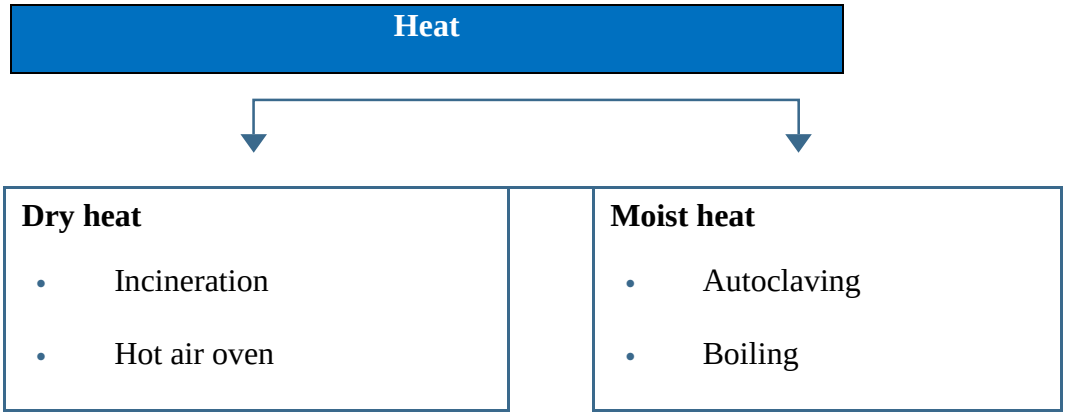



**Figure 2.5 Methods of heat disinfection**

Although dry heat can also be used for sterilization, much higher temperatures and longer periods are necessary. For example, dry heat in a hot air oven, which is totally non-corrosive, can be used to process many items that can withstand temperatures of 160 °C or more for 2–4 hours. Burning or incineration is also a form of dry heat.

### 8.4.1 Autoclaving

Saturated steam under pressure (autoclaving) is the most effective and reliable means of decontaminating/sterilizing laboratory materials and wastes. This is because, once placed in the autoclave,

treated items cannot be removed until the system has completed the cycle and the pressure and temperature within the chamber have returned to safe levels.

Autoclaves need to be able to process a wide range of materials and different types of loads which generally require different operating cycles (for example, porous loads, fluids, wrapped materials). Different cycles exist for solid and liquid material. In the risk assessment process autoclaves should be selected based on criteria defined by the user such as intended use, and type and amount of waste.

It is essential for effective decontamination by steam that all of the trapped air inside the material being autoclaved is removed and that sufficient time for decontamination and adequate means for steam penetration are provided. If these conditions are met, then autoclaving is a most reliable means of decontamination. There are two ways to remove air, passive and active.

**Passive:** Steam is either produced inside the autoclave at the bottom of the chamber or comes in at the top of the chamber and air is forced out of the chamber. This is the simpler and cheaper method, but it is only suitable for loads in which air removal is not impeded by fabrics or glassware.

**Active:** The chamber is subjected to successive pressure changes to draw air from the chamber. This is required for loads such as fabrics, glassware and other equipment where trapped air cannot reliably be removed by passive methods. The more difficult air is to remove, the more pulses will be required. This method is preferred for the decontamination of laboratory waste.

The various types of autoclave are described in Table 2.4.

**Autoclave cycles**

Autoclaving relies on two factors to decontaminate biological agents: time and temperature/pressure. These factors can be manipulated into different cycle procedures to sterilize various types of load, for example, bags, cages, animal bedding and other material. However, the cycle requirements for every load type can vary substantially. As a general principle, materials should be loosely packed in the chamber for easy steam penetration and air removal. Bags or containers need to be open enough to allow the steam to reach their

contents. Biological or chemical indicators are used to validate the autoclaving process and ensure effective decontamination of biological agents.

After a thorough risk assessment and validation, the following cycle will usually provide sterilization of correctly loaded autoclaves:

- 3 min holding time at 134 °C
- 10 min holding time at 126 °C
- 15 min holding time at 121 °C
- 25 min holding time at 115 °C.

**Table 2.4 Types of autoclave**

| Type of Autoclave | Characteristics |
|---|---|
| **Gravity displacement autoclave** | These autoclaves have a heating element fully or partially submerged in a pool of water at the bottom of the autoclave chamber. As the water in the pool is heated, it begins to evaporate, forming steam and compressing the air inside the chamber. Since steam is lighter than air, as the chamber fills with steam most of the air in the chamber is pushed to the bottom of the chamber and escapes through the fill hole, which is connected to a temperature-sensitive diaphragm that closes once it is sufficiently heated. Once the diaphragm closes pressure builds up inside the autoclave chamber. |
| **Positive-pressure displacement autoclave** | These autoclaves create the steam in a separate internal unit, called a steam generator. Once the amount of steam needed to displace air in the chamber is produced, a valve opens and a pressurized burst of steam enters the autoclave chamber. This system results in a higher percentage of air from the chamber |

| | |
|---|---|
| | being removed than with a gravity displacement autoclave, which decreases autoclave cycle times. |
| **Fuel-heated pressure cooker autoclaves Upward displacement autoclave (pressure cooker)** | These devices should only be used if a gravity displacement or vacuum-assisted autoclave is not available. They are loaded from the top and heated by gas, electricity or other types of fuel. Steam is generated by heating water in the base of the vessel and air is displaced upwards through a relief vent. When all the air has been removed, the valve on the relief vent is closed and the heat reduced. The pressure and temperature rise until the safety valve operates at a pre-set level. This is the start of the holding time. At the end of the cycle, the heat is turned off and the temperature allowed to fall to 80 °C or lower before the lid is opened. |
| **Pre-vacuum autoclaves Negative-pressure or vacuum displacement autoclaves** | These autoclaves have a separate internal steam generator, as well as a vacuum pump. After the autoclave chamber is closed, the vacuum pump removes all air from the chamber, and steam is injected into the chamber. These autoclaves are able to provide among the highest sterility levels as long as air is removed from and steam enters all parts of the load, including hollow items and bagged items. Any bagged waste must have an opening at one end which is not tightly tied to allow air removal and steam entry. The air is removed through a valve which, based on a risk assessment, may be fitted with a HEPA filter. |

HEPA = high-efficiency particulate air.

**Safety precautions**

The following general safety precautions must be taken when using steam autoclaves.

- Operation and maintenance of autoclaves must be assigned to trained, competent individuals.

- Operating instructions for the autoclave must be available. Sterilization programmes with application area (for example, solids, liquids) and the parameter conditions to be maintained (temperature, pressure, time) must be defined.
- A loading plan (with information on the contents, number, volume and mass of the items/material to be sterilized) should also be available.
- A maintenance programme must be developed, including regular visual inspection of the chamber, door seals, gauges and controls, and the inspections must be done by qualified personnel.
- A regular verification process must be developed to ensure that the autoclave is functioning as designed, including the regular use of biological indicators and, for pre-vacuum autoclaves, Bowie-Dick and vacuum leak tests that confirm the correct removal of air in such autoclaves.
- A reliable steam source must be used to provide appropriately saturated steam. The steam supply must be clean, to ensure materials are sterile after use, and free of chemicals which may inhibit the function of the autoclave or may damage the pipes or chamber of the autoclave.
- Materials placed in the autoclave must be in containers that readily allow removal of air and permit good steam penetration.
- The chamber of the autoclave must be loosely packed so that steam can penetrate evenly.
- Hazardous chemicals (for example, bleach, mercury or radioactive material) must never be treated in an autoclave.
- Operators must wear appropriate PPE including suitable gloves that provide thermal protection, protective clothing and eye and face protection when opening an autoclave, even when the temperature has fallen to levels considered safe for opening the autoclave door.
- Care should be taken to ensure that the relief valves and drains of autoclaves do not become blocked by paper, plastic or other materials included in the waste or materials for decontamination.

### 8.4.2 Incineration

Incineration is useful for disposing of animal carcasses as well as anatomical and other laboratory waste, with or without prior decontamination.

Incineration of infectious materials is an alternative to autoclaving only if the waste transport process to the incinerator is done in a controlled manner with trained personnel, suitable transport container and an SOP for

the transport container loading procedure. Mobile and transportable incinerators are available for emergency and temporary facilities. All national and environmental legislation on incineration must be followed.

Effective incineration requires an efficient means of temperature control and a way to ensure complete combustion of all flammable materials. Many incinerators and other methods to burn waste, especially those with a single combustion chamber, may not be suitable for dealing with infectious materials, animal carcasses and plastics. Such materials may not be completely destroyed and the effluent from the chimney may pollute the atmosphere with biological agents, toxic chemicals and smoke (22). For incinerators with secondary chambers, the temperature in the primary chamber should be at least 800 °C and that in the secondary chamber at least 1000 °C.

Materials for incineration, even with prior decontamination, should be transported to the incinerator in leak-proof containers. Incinerator personnel should receive proper instructions about loading, manual handling and temperature control. It should also be noted that the efficient operation of an incinerator depends greatly on the type of materials (for example, organic material, plastic and paper/cardboard) in the waste being treated. If the wastes are transported in reusable containers, decontamination of the transport containers needs to be considered as well.

**Burn pits and furnaces**

Burn pits are a traditional way of open burning using a shallow depression that is sealed with clay, cement or concrete and items for incineration are thoroughly combusted to ash. Furnaces work in a similar way and may be an effective means to burn a range of waste. These methods can potentially expose operators at the pits to harmful combustion products and extremely high temperatures.

**Disposal of incineration products (ashes)**

The incineration process can concentrate potentially hazardous chemicals (for example, toxic metals and phosphate from carcasses) and incineration ash must be disposed of in compliance with national/local regulations. Autoclaved waste may be disposed of by off-site incineration or in licensed landfill sites.

### 8.5 Sterilization

Sterilization is used when a complete elimination of any biological agent, including spores and prions, is necessary; for example, for medical items and waste if the risk assessment indicates the need for very strict decontamination procedures. Sterilization can be achieved using several decontamination methods such as autoclaving, certain chemical disinfectants and gaseous disinfection combined with a strict SOP, and irradiation. Important as the selected method is, the validation and adherence to the SOP to ensure the most efficient decontamination is equally important. To monitor the effectiveness of the sterilization process, biological indicators are used

### 8.6 Biological and chemical indicators

Indicators are routinely used to check and/or monitor the effectiveness of decontamination processes (cleaning, disinfection or sterilization). They include chemical, biological and sometimes mechanical/physical indicators.

### 8.6.1 Biological indicators

Biological indicators consist of a standardized population of microorganisms that provide a defined resistance to a specific sterilization process. Nonpathogenic bacterial endospores are commonly used as test organisms as they are highly resistant to sterilization processes and easy to detect when cultured. If the spores are not decontaminated by the sterilization process, they will germinate and grow and eventually release dipicolinic acid that can be detected by a pH indicator dye present in the growth medium. With a longer incubation period, turbidity of the medium will also indicate bacterial growth.

**Table 2.5 Sterilization processes and appropriate biological indicators**

| **TERILIZATION PROCESS** | **OLOGICAL INDICATOR** |
|---|---|
| Formaldehyde | *Geobacillus stearothermophilus* |

| | |
|---|---|
| Hydrogen peroxide | *G. stearothermophilus* |
| Moist heat | *G. stearothermophilus* |
| Dry heat | *Bacillus atrophaeus, B. subtilis* |
| Ionizing radiation | *B. pumilus* |

### 8.6.2 Chemical indicators

Chemical indicators are widely used as they give an instant result. They check for specific direct parameters that are essential for disinfection or sterilization. These parameters include verification that a minimum concentration of a disinfectant has been used or that a specific condition has been reached in the autoclave.

There are six classes chemical indicators. Depending on the parameters that need to be checked (for example, exposure control, autoclave performance, pack control monitoring, cycle monitoring), one or several indicators might be selected to gain insight into the decontamination process.

**Table 8.6 Six classes of chemical indicators for decontamination processes**

| | **TYPE 1** | **TYPE 2** | **TYPE 3** | **TYPE 4** | **TYPE 5** | **TYPE 6** |
|---|---|---|---|---|---|---|
| **Indicator type** | Process indicators,<br>"through-put indicators" | Indicators for the use in specific tests,<br>"specialty indicators" | Single variable indicators | Multivariable indicators | Integrating indicators | Emulgating indicators |

| | | | | | | |
|---|---|---|---|---|---|---|
| **What they indicate** | Exposure of item to be sterilized to minimal process conditions: used to differentiate exposed from unexposed items | That a specific process is obtained which is linked to the sterilization process, for example air removal from a pre-vacuum steam sterilizer | Change in exposure to one parameter, for example temperature, time, concentration of a biocide | Change in exposure to at least two parameters, for example:<br>-time and temperature for steam sterilization<br>-time and concentration for ethylene oxide sterilization | Change in exposure to all critical parameters for a given process | Are specific for specified sterilization cycles<br>The response of class six emulgating indicators does not necessarily correlate with a biological indicator |
| **Use** | Exposure control | Sterilizer performance | Pack control monitoring<br>Exposure control | Pack control monitoring | Pack control monitoring<br>Cycle monitoring tool | Pack control monitoring |
| **Example** | Autoclave tape | Bowie-Dick test, for example Dart® daily air removal test | Temperature tube with chemical pellet that melts at a specific temperature | Paper strips printed with a chemical indicator | | |

**8.6 Waste Management**

### 8.6.1 Considerations for waste management

During laboratory activities, different contaminated materials and liquids will be generated. Some of the materials such as glassware, equipment, devices or laboratory clothing may be reused or recycled. However, a large part of those materials will be disposed of as waste.

All contaminated materials or liquids leaving the laboratory should either be treated onsite to allow further safe handling or packed and transported safely to another treatment site.

Decontamination can be done chemically, by autoclaving or by incineration, but the method and the protocol must be based on a risk assessment and be properly validated.

Table 8.4 **Categories of bio waste.**

| **Waste Category** | **Description** |
|---|---|
| **Infectious Waste** | Waste suspected to contain pathogens e.g. laboratory cultures; waste from isolation wards; tissues (swabs), materials, or equipment that have been in contact with infected patients; excreta |
| **Pathological Waste** | Human tissues or fluids e.g. body parts; blood and other body fluids; fetuses |
| **Sharps** | Sharp waste e.g. needles; infusion sets; scalpels; knives; blades; broken glass |
| **Pharmaceutical Waste** | Waste containing pharmaceuticals e.g. pharmaceuticals that are expired or no longer needed; items contaminated by or containing pharmaceuticals (bottles, boxes) |

| | |
|---|---|
| **Genotoxic Waste** | Waste containing substances with genotoxic properties e.g. waste containing cytostatic drugs (often used in cancer therapy); genotoxic chemicals |
| **Chemical Waste** | Waste containing chemical substances e.g. laboratory reagents; film developer; disinfectants that are expired or no longer needed; solvents |
| **Wastes with High Content of Heavy Metals** | Batteries |
| **Pressurized Containers** | Gas cylinders; gas cartridges; aerosol cans |
| **Radioactive Waste** | Waste containing radioactive substances e.g. unused liquids from radiotherapy or laboratory research; contaminated glassware, packages, or absorbent paper; urine and excreta from patients treated or tested with unsealed radionuclides; sealed sources |

### 8.6.2 Waste Management Process

The following components are the WHO recommended steps for Health care waste management:

1. Minimization of waste
2. Segregation
3. Storage (Handling of waste)
4. Treatment
5. Transportation
6. Disposal

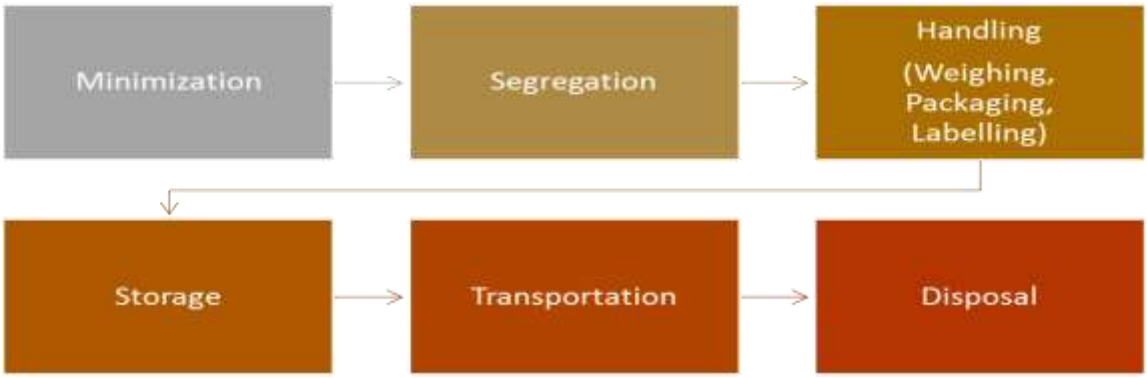



**Figure 8.3 Waste Management Process**

### 8.6.2.1Waste Minimization

Possible ways in which waste minimization can be achieved include:

- Substituting a hazardous material used in a process with a non-hazardous material
- Process changes e.g. wiping bench tops with suitable disinfectants versus use of paper bench cotes
- Reducing the amount of hazardous materials used e.g. Standard aliquots of culture media on culture plates in order to reduce waste generated.
- Recovering and reusing material**s** e.g. universal bottles.

### 8.6.2.2 Segregation

Segregation is the separation of waste generated in a facility at point of collection into the different waste categories according to the specific treatment and disposal requirements. Segregation is the key to any effective waste management as it ensures that each category of waste is treated according to each hazard type and the correct transportation equipment and disposal routes are used. Without effective segregation system, the complete waste stream must be considered hazardous.

In order for the biological wastes to be removed from a laboratory, the following procedures must be followed:

- Biological wastes derived from human sources should be placed in a red or yellow biohazard bag. Autoclave the bag under appropriate time and temperature before being taken for incineration. Facilities without access to incinerator or autoclave should consult biosafety committee and or top management on the most appropriate means disposal.
- Liquid wastes from equipment should be poured down the drain after dilution with huge amount of water. If the liquid waste contains a high concentration of acids or bases, it should first be neutralized before it is disposed.
- Sharps and sharp objects should be placed in a rigid, leak-proof, puncture-resistant container. The container should be decontaminated first before disposal.
- Non-infectious wastes should be handled according to the national guidelines for waste segregation.

**8.6.2.3 Handling (Weighing, Packing and Labeling)**

- Collected waste should be weighed by category.
- Waste should be packaged according to recommended standards.
- Use appropriate containers for packaging waste. Hazardous wastes shall be collected in containers which are compatible with the intended contents and which are in good condition.
- Label waste containers and packages properly accordingly to waste category and where required use chemical names on all labels. Chemical formulas are not acceptable.
- Waste that is inadequately packaged or labeled may be rejected by waste handling contractor and not collected for disposal.
- Materials placed in the same collection container shall be compatible with all other materials in the container.
- Containers shall be labeled, with the date of first accumulation noted.
- All chemical reactions should be complete prior to introduction into collection containers.
- Whenever possible, individual substances should be collected separately to increase disposal options and reduce cost.
- Collection containers shall be kept securely closed except when adding hazardous material.

- Containers to be submitted for disposal must not exceed 20 liters (5 liter for corrosives), unless prior approval has been obtained from your Institutional waste management. Secondary containment is strongly recommended for all liquid hazardous wastes.
- Hazardous wastes shall not be accumulated longer than three months at satellite sites such as laboratories.

#### 8.6.2.4 Storage

- Red bags should not be stored overnight without being treated or disposed of.
- Designated central storage shall be located within the laboratory or hospital premises close to the treatment unit but away from storage or food preparation areas.
- The storage area should be large enough to contain all the hazardous waste produced by the laboratory.
- Storage area shall be totally enclosed and secured from animals, insects and birds and unauthorized personnel.
- It shall be easy to clean and disinfect (with an impermeable hard standing base, good water supply drainage and ventilation).
- There should be limited access to the storage area.
- The universal biological hazard symbol should be posted on the storage area door, and waste containers.
- Containers for bio-hazardous material should be distinctive red or yellow in color.

#### 8.6.2.5 Transportation

Waste must be collected on a regular basis and transported to a central storage area within the facility before being treated or removed. There are two types of transportation: on site and off site.

1. **On site transportation:** moving waste from one point to another within the same facility using site transportation carts, wheelbarrows, and other waste containers. It is important to reduce passage of loaded carts through wards and other clean areas.

- Waste containers must be:
    - Easy to load and upload
    - Have no sharp edges
    - Easy to disinfect and clean
- Waste handlers should trained in waste management
- Waste handlers should always wear protective clothing when handling waste
- Waste handlers should wash hand after handling waste.

2. **Offsite transportation:** movement of waste away from the health facility. It requires use of dedicated vehicles for transportation.
    - Avoid spillage of waste during transportation
    - Transportation vehicle should be disinfected after each trip.

### 8.7 Waste Treatment Methods

There are different methods of decontaminating laboratory waste before disposal:

1. Autoclaving
2. Chemical inactivation/Disinfection.

#### 8.7.1 Decontamination of liquid waste

Many methods are available, all with advantages and disadvantages that need to be evaluated in a risk assessment. The choice of method is driven by the chemical composition of the waste, the biological agents to be decontaminated and the initial and ongoing cost of each method.

**Sewer system**

Based on the risk assessment, for low-risk specimens handled in a research or clinical facility attached to a technologically advanced municipal sewer system, direct emptying of liquid waste containers into the sanitary sewer may be an appropriate method of disposal. For biological agents or laboratory procedures that need heightened control measures or maximum containment measures (as determined by the risk

assessment), this is not an acceptable option. Even for less hazardous biological agents, this method may not be allowed under local or national regulations. Putting liquid biological waste in the sewage system mixed with chemicals (for example, ethanol, formaldehyde or guanidine hydrochloride) may also be prohibited. In all circumstance, strict adherence to local and national regulations is required.

**Chemical disinfection**

Most research laboratories prohibit the direct disposal of biological agents without any treatment; therefore, chemical disinfection has become a standard means of decontaminating solutions before disposal. The risk assessment helps to identify the most appropriate method for chemical disinfection of liquid waste. The activity of the chemical disinfectant against the biological agent being handled in the laboratory is the first factor to consider when selecting a chemical disinfectant. Generally, pre-defined biological agents will be used for research, but a wider range of biological agents can be found in clinical specimens. Spores and prions require a more rigorous decontamination process before disposal. The organic load (amount of organic matter mixed with the biological agents) must be considered because most chemical disinfectants, including hypochlorites, are inactivated by organic matter. The stability of ready-to-use disinfectants is important to consider as it affects how often the disinfectant needs to be changed. Consideration should also be given to the toxicity and corrosiveness of the disinfectant and the irritants in it. In addition, costs and shelf-life may need to be considered for sustainability reasons.

### 8.7.2 Decontamination of solid waste

#### 8.7.2.1 Autoclaving

Autoclaving, is a reliable way to sterilize biological agents in solid waste. However, a key concern is the need to ensure that all parts of the waste are exposed to the steam; pockets of trapped air act as insulation and may allow parts of the waste to remain potentially infectious. Completely dry items such as gloves and gowning can trap pockets of dry air and therefore disinfection will not be achieved. Therefore, waste or materials placed in the autoclave must be in containers that readily allow removal of air and permit good steam/heat penetration.

In order to reach disinfecting temperatures throughout the solid waste, it is likely that successful disinfection will require longer cycles than are normally used for sterilizing materials. Large and bulky material, large animal carcasses, sealed heat-resistant containers and other waste that impedes the transfer of heat must be avoided.

Ongoing demonstration of decontamination is necessary. Successful decontamination may be verified either: by placing biological indicators in strategically-placed test specimens of waste interspersed in actual waste containers; or by using indicators attached to rods which can be inserted and retrieved without disturbing the contents of the waste containers

**8.7.2.2 Incineration**

Incineration is a means to eliminate all known biological agents in solid waste, including spores and prions; ideally, incineration is performed in a technologically advanced incinerator. Incineration, correct temperature and length of time in the primary chamber are essential to ensure complete combustion of the solid waste and decontamination of any biological agent. In addition, incinerator operators need to be trained on the safe handling of the waste before loading it into the incinerator. If reusable containers are to be used, the means for disinfecting these containers needs to be established before starting incineration. Aside from biological agents, two additional materials need to be considered when incinerating solid waste: plastic and soda lime glass. Most plastic used in research laboratories burns hotter than paper waste and can overheat an incinerator if the amount put in the incinerator is more than that recommended by the incinerator manufacturer. Soda lime glass melts at about 550 °C and will coat the refractory brick and reduce its lifespan; therefore, minimizing the incorporation of soda lime glass in the solid waste is important. The ash from soda lime glass incineration requires special handling and disposal as it may be enriched with heavy metals and phosphate.

**8.7.2.3 Alkaline digestion**

Alkaline digestion uses elevated temperature and pressure in the presence of alkali (1 N and above) to break down most cellular materials found in carcasses into soluble forms. The process can reduce carcasses to a soluble fraction and a calcium-rich solid residue. Alkaline digestion is effective in decontaminating nearly all known biological agents. Digestion at 150 °C in the presence of 1 N sodium hydroxide (NaOH) or potassium hydroxide (KOH) has been shown to make prions non-infectious. The process requires a substantial amount of energy and time (several hours) and should only be used in institutions with a large number of carcasses (several kilograms a week).

#### 8.7.2.4 Rendering

Rendering is another method to decontaminate animal carcasses, using steam at about 130 °C in a pressure vessel to break down carcasses into fat, protein and bone. The method is traditionally used with larger animals and is effective in eliminating most biological agents. However, rendering is ineffective against prions and should not be used for animals infected with prion

# CHAPTER SEVEN

## 7.0 HAZARD AND RISK COMMUNICATION IN THE LABORATORY

**Introduction**

Communication is a vital part of biosafety and risk assessment. Risk communication is a two way process to provide, share or obtain information and to engage in dialogue with the stakeholders regarding the analysis of the risk.

Risk communication is vital to allow laboratory personnel to make informed choices about risks related to their roles in laboratories, and to establish successful biorisk management strategies. Furthermore, strong communication practices will help to establish good reporting mechanisms for any incidents, accidents, or mitigation inefficiencies. Risk communication also plays an important role in the

laboratory's communication with outside stakeholders, such as regulatory authorities and the general public.

All those working in the laboratory are responsible for following the appropriate practices and procedures of any risk reduction strategy that applies to them and for providing feedback on their effectiveness. To achieve the appropriate level of awareness, training and competency for implementation of risk control measures and safe laboratory operation requires, at a minimum, communication of the hazards (biological agents) present, communication of the risks associated with the procedures being performed and communication of exactly how the risk control measures used can most effectively reduce those risks.

Strategies for communication and outreach beyond traditional biosafety training include laboratory-specific SOPs, interactive team discussions, job aids and posters, generic awareness-raising through short publications (for example, pamphlets, handouts), briefings and email notifications.

**Hazard communication signs**

The Hazard Communication Signs will display through symbols, icons and text which types of hazards (e.g. biological, radiological, chemical, or non-ionizing radiation) are potentially present beyond the door. The signs will also list PI(s) and emergency contact information. The potential hazards in the space may provide direction on personal protective equipment (PPE) or other safety precautions that are required for entry.

**Hazard Communication Signs**

There are five different types of signs recognized by the ANSI Z535 series of standards: danger signs, warning signs, caution signs, notice signs, and safety instruction signs. The first three are considered hazard communication signs and the last two informational.


- **Danger signs:** Used for situations where there is a hazard present that will cause serious injury or death if not actively avoided. Danger signs feature a red background with white text and should be reserved for only the most dangerous hazards in the facility.
- **Warning signs:** The signs have black text surrounded by an orange background and means there is a serious hazard present that could result in injury or death.
- **Caution signs:** Caution signs, black text with a yellow background, are used for hazardous situations that if not avoided, might cause minor or moderate injury. Common caution signs include tripping hazard signs, or "Slippery When Wet" signs.
- **Notice signs:** The blue signs with white text are to convey other information not related to safety and when there is no hazard present. A "no smoking" sign for instance might be placed on a warning sign if there are flammable liquids, but a blue no smoking sign means the prohibited act is not due to safety reasons.

- **Safety instruction signs:** Safety instruction signs are a green background with white text, is informational in nature but still related to safety. The most common kind of these signs are related to first aid.

## Biological Hazard label


**The *Hazard Communication Sign* is not intended to prohibit access**, but to communicate that biohazardous materials may be present in the laboratory.

### Chemicals


The Hazard Communication Sign (shown below) incorporates the National Fire Protection Association (NFPA) 704 fire diamond to communicate the hazard of short-term, acute exposures to chemicals that could occur as a result of a fire, spill or similar emergency.

The fire diamond is color coded; **blue for Health**, **red for Fire**, and **yellow for Reactivity/Instability**. Health, Fire and Reactivity hazard severities are ranked 0-4. An area is rated according to the highest

hazard materials known to be present. The white 'special' is for only select lab spaces with water reactive (~~W~~) material that would require alternative extinguishing media in a fire emergency.

## Health Hazard

**4** - Lethal

**3** - Serious or Permanent Injury

**2** - Temporary Incapacitation/Residual Injury

**1** - Significant Irritation

**0** - No Health Hazard

## Fire Hazard

**4** - Flashpoint below 73 °F

**3** - Flashpoint between 73 °F and 100 °F

**2** - Flashpoint between 101 °F and 200 °F

**1** - Flashpoint over 200 °F

**0** - Will not burn

## Reactivity Hazard

**4** - May detonate

**3** - Shock and heat may detonate

**2** - Violent chemical change

**1** - Unstable if heated

**0** - Stable

**Radioactive Material**


The *Hazard Communication Sign* (shown below) incorporates the radiation trefoil symbol when radioactive materials are stored or used in the laboratory. Individuals entering this room who are not approved to use radioactive material, must be supervised to prohibit unauthorized removal of radioactive material or contaminated items present in the room. Laboratories bearing this sign must be locked to secure radioactive material when no one is present in the laboratory.

**The *Hazard Communication Sign* is not intended to prohibit access**, but to communicate that radioactive material may be present in the laboratory.

### Lasers

The Hazard Communication Sign (shown below) incorporates the laser symbol when Class 3B or Class 4 lasers are present in the laboratory. **Do not enter** unless accompanied by lab personnel. When the laser is in operation, individuals entering this room must wear approved laser protective eyewear provided by lab personnel, if required by lab operating procedures for safe entry.

### Strong Magnetic Fields

The Hazard Communication Sign (shown below) incorporates the magnet symbol when equipment with strong magnetic fields are located in the laboratory. **Do not enter** unless accompanied by lab personnel, and limitations of entry are understood.

***Other communication signs***

Gloves Required

This symbol means that you have to wear gloves in protection from biological agents, harmful chemicals or other materials.

h 


“Fire Extinguisher” sign and use it inform people of the existence and placement of the fire extinguisher in a building.

f


Wet Floor" sign which can be used to alert customers, employees or guests that the floor is wet in a specific area.


Toxic sign and use it to warn people and remind employees that poisonous and toxic materials are inside in either containers or in buildings.


Danger do not enter sign to indicate areas with high risk levels of injury.


Please Sanitize Your Hands sign and used it to politely ask students, visitors or employees to sanitize their hands maintaining good hygiene.

# CHAPTER EIGHT

## 9.0 INCIDENCE AND EMMERGENCY PROCEDURES

### 9.1 Introduction

Working in laboratories often involves occurrence of adverse events of various degrees. Some of these occurrences' may be of emergency nature and require immediate response. Reporting and documenting occupational incidences and accidents helps facilities to keep track of all occurrences. Incidences whether they are accidents, security-related or emergencies should be reported. Proper investigation will ensure the actual root cause of the incident and/or accident is identified so that adequate plans are put in place to prevent re-occurrence. Successful implementation of these plans requires an effective biosafety committee and/or infection control committee (ICC) with support from the facility management team.

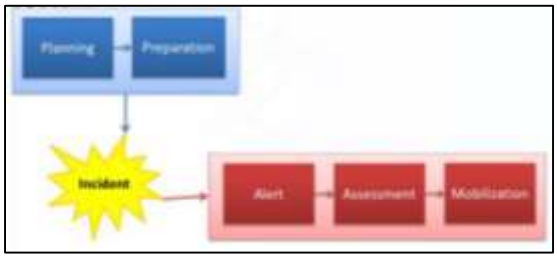
***ISO 35001 2019; clause 10.2 requires the organization to establish, implement, and maintain a process(es), including reporting, investigating, and taking action, to determine and manage incidents and nonconformities***

Even when carrying out low-risk work and following all core requirements for biosafety, incidents can still occur. To reduce the likelihood of exposure to/release of a biological agent or to reduce the consequences of such incidents, a contingency plan must be developed that provides specific 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 in order to maintain competency.

Due to constant threats caused by emerging and re-emerging diseases (e.g. SARS-COV2, Ebola Hemorrhagic fever, Marburg etc.) facilities will have to review their incident response plans regularly following a thorough risk assessment to define the likelihood, consequences and the subsequent mitigation measures to avert or minimize the effect of exposure to these organisms. Facilities that intend to analyses organisms with little/unknown etiology shall be required to conduct a thorough risk assessment and review their incident response plans before commencement of work.

Effective incident response system follows a five-step sequence which comprises of planning, preparation, alerting, assessment and mobilization.*(insert picture)*

*Fig: …Sample model of an effective Incidence Response Plan*




- **Planning** is the development of mechanisms or procedures in advance to achieve a particular goal. Without proper planning and preparation, an incident response system will be unable to alert in timely fashion, properly assess that incident, or mobilize effective response. Incident response planning is normally the responsibility of an institution's management.
- **Preparation**; This is the act of putting into effect an institution's plans, prior to an incident. Preparation includes training of personnel, acquisition of equipment, storing of supplies and physical modifications to the equipment and buildings.
- **Alerting** is the process of identifying an incident as it is occurring, or after it has occurred, and using that information to generate a response.
- **Assessment** is the evaluation of the type and severity of an incense, in order to determine an appropriate response.
- **Mobilization** is the activation of personnel on the use equipment to respond directly to an incident in order to speed its resolution.

### Goals for incidence management:

a) Prevention of incidences/accident
b) Preparedness to respond effectively to incidences
c) Minimize loss or injury
d) Treatment and recovery from incidences/accident

### 9.2 Incident/accident mitigation plans

For the facility to effectively develop and implement incident/accident mitigation plans, the following shall be required:

a) Incident/accident risk assessment reports
b) Emergency response plans addressing identified likely hazards
c) Mitigation, monitoring and evaluation tool

### 9.3 Incidence response and preparation steps

a) Risk mitigation
b) Pre-plan: procedures and personnel
c) Integration with facility plans
d) Cooperation with local responders
e) Training and drills
f) Response, report, and review

### 9.4 Incident/accident reporting and investigation

For effective occurrence reporting and investigations, the following tools shall be required to document incidence/accidents:

a) Occurrence Management Form
b) Incident/accident register

### 9.5 Emmergency preparedness and response plan

Emergencies can include those related to chemical incidents, exposure to highly infectious agents, incidents, fire, electrical breakdown, radiation incidents, pest infestation, flooding, or personal health issues of personnel (e.g. a heart attack or collapse). All laboratory facilities must have good safety standards for all such non-biological hazards to make sure that necessary non-biological risk control measures are also in place (e.g. fire alarms, extinguishers, chemical showers). Relevant authorities should be consulted where necessary. First-aid kits, including medical supplies such as bottled eye washes and bandages, must be available and easily accessible to personnel. These must be checked routinely to make sure products are within their use-by dates and are in sufficient supply. If eyewash stations with piped water are to be used, these should also be checked regularly for correct functioning.

All incidents must be reported to the appropriate personnel, usually a laboratory supervisor, in a timely manner. A written record of accidents and incidents must be maintained, in line with national regulations where applicable. Any incident that occurs must be reported and investigated in a timely manner. Results from incident investigations must be used to update laboratory procedures and emergency response plans.

#### 9.5.1 Emergency Planning

Facilities shall develop an emergency preparedness and response plans that will describe the type and level of emergency response needed for each possible emergency. The course of action may be specific

for each emergency (for example, medical, fire and explosions, spills, release of aerosols, injuries, severe weather, natural etc. The plan may include the following basic operational elements:

1. Precautions against natural disasters, e.g. fire, flood, earthquake and explosion
2. Biohazard risk assessment
3. Incident-exposure management and decontamination
4. Emergency evacuation of people from the premises
5. Emergency medical treatment of exposed and injured persons
6. Medical surveillance of exposed persons
7. Clinical management of exposed persons
8. Epidemiological investigation
9. Post-incident continuation of operations.

In the development of this plan the following items should be considered for inclusion:

1. Identification of high-risk organisms
2. Location of high-risk areas, e.g. laboratories, storage areas3. Identification of at-risk personnel and populations
3. Identification of responsible personnel and their duties, e.g. biosafety officer, safety personnel, local health authority, clinicians, microbiologists, epidemiologists, and fire and police services
4. Lists of treatment and isolation facilities that can receive exposed or infected persons
5. Transport of exposed or infected persons
6. Lists of sources of immune serum, vaccines, drugs, special equipment and supplies
7. Provision of emergency equipment, e.g. protective clothing, disinfectants, chemical and biological spill kits, decontamination equipment and supplies.

### 9.5.2 Emergency Response Procedures

The procedures spell out how the facility will respond to common emergencies. Whenever possible, develop them as a series of job aids that can be quickly accessed by senior management, department heads, response personnel and employees. Each facility shall develop its own job aids.

**a) Puncture wounds, cuts and abrasions**

- Remove protective clothing, wash the hands and any affected area(s)
- Apply an appropriate skin disinfectant
- Seek medical attention as necessary.
- Investigate and report cause of the wound and the organisms
- Keep completed medical records

**b) Ingestion of potentially infectious material**

- Remove protective clothing
- Seek medical attention
- Identify materials injected
- Report to appropriate authorities
- Keep completed medical records.

**c) Potentially infectious aerosol release (outside a biological safety cabinet)**

- Immediately vacate affected area
- Refer any exposed persons for medical advice
- Inform laboratory supervisor and the biosafety officer at once
- Do not permit anyone to enter the room for an appropriate amount of time (e.g. 1 h or per risk assessment), to allow aerosols to be carried away and heavier particles to settle.
- If the laboratory does not have a central air exhaust system, entrance should be delayed (e.g. for 24 h).
- Signs should be posted indicating that entry is forbidden.
- Decontamination should proceed, supervised by the biosafety officer.
- Wear appropriate protective clothing and respiratory protection.

**d) Broken containers and spilled infectious substances**

- Cover broken containers contaminated with infectious substances and spilled infectious substances with cloth or paper towels
- Pour disinfectant over these and leave for some time.
- Clear away cloth or paper towels and the broken material
- Handle glass fragments with forceps.
- Swab contaminated area with disinfectant.
- Autoclave or place in an effective disinfectant all dustpans used to clear away the broken material
- Place in contaminated-waste container cloths, paper towels and swabs used for cleaning
- Wear gloves for all these procedures
- Copy the information onto another form when the written matter is contaminated
- Discard the original form into contaminated-waste container.

**e) Breakage of tubes inside sealable buckets (safety cups)**

- Load and unload all sealed centrifuge buckets in a biological safety cabinet.
- Safety cap should be loosened and the bucket autoclaved if breakage is suspected within

the safety cup
- Or disinfect safety cup chemically using appropriate disinfectant.

Specific procedures might be needed for any number of situations such as bomb threats or floods, and for such functions as:

- Warning employees and customers
- Communicating with personnel and external responders e.g. police, fire brigade, ambulance
- Conducting an evacuation and accounting for all persons in the facility
- Managing response activities
- Activating and operating an emergency operations center
- Fighting fires
- Shutting down operations
- Protecting vital records
- Restoring operations

### 9.5.3 Emergency Preparedness and Response Training and Drills

After preparation of the plan all staff shall be trained as part of the implementation and thereafter staff shall be trained periodically as institution requirement, preferably annually. Drills and exercises are vital for an effective response in the event of an emergency. Facilities need to clearly streamline the drills and exercises that will be performed to prepare personnel to respond appropriately in the event of an emergency, including how often these will occur and whether or not personnel will be forewarned. The training shall cover the following:

1. Emergency response plan
2. Emergency drill
3. Employee safety
4. Documentation
5. Review of the plan

### 9.5.4 Emmergency services

Facilities shall develop procedures that must be followed when a medical emergency occurs. In an emergency situation, an easy-to-follow reference sheet or poster may help personnel in their response and may support subsequent incident investigation procedures. The contact details and addresses of the following should be prominently displayed in the facility:

1. The institution or laboratory itself
2. Director of the institution or laboratory
3. Laboratory supervisor

4. Biosafety officer
5. Fire services
6. Hospitals/ambulance services
7. Medical staff
8. Police
9. Responsible technician
10. Water, gas and electricity services.

### 9.5.5 Emergency equipment

The organization shall have procedures in place for using the facility's safety equipment. Safety equipment can include fire extinguishers, emergency eyewash stations and emergency showers The following emergency equipment must be available at the bare minimum:

1. First-aid kit, including universal and special antidotes
2. Appropriate fire extinguishers, fire blankets, water horse

The following are also suggested but may be varied according to local circumstances:

1. Full protective clothing (one-piece coveralls, gloves and head covering – for incidents involving microorganisms in Risk Groups 3 and 4)
2. Full-face respirators with appropriate chemical and particulate filter canisters
3. Room disinfection apparatus, e.g. sprays and formaldehyde vaporizers
4. Stretcher
5. Tools, e.g. hammers, axes, spanners, screwdrivers, ladders, ropes
   Hazard area demarcation equipment and notices.

### 9.5.6 Evacuation procedures

The facilities shall develop evacuation procedures, including avoiding areas of contamination and this should be made available to all personnel and visitors during orientation

### 9.5.7 Power failure

The facility shall describe the procedures to follow in the event of a power failure.

### 9.5.8 Failure of primary containment devices

Organizations shall be required to describe the procedures to follow if any of the facility's primary containment devices fail. Consider including information on requirements and procedures for back-up power, full-room decontamination and personnel decontamination.

### 9.5.9 Incident review and response improvement

Following an incident that results in an emergency response, a review of the facility's response can be conducted to determine if any improvements to the emergency response can be made.

### 9.5.10 Roles and responsibilities

The facilities shall define who is responsible for emergency response, including training, and the role of the biosafety officer and personnel shall be clearly stated

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# CHAPTER NINE

## 9.0 TRANSFER AND TRANSPORTATION OF INFECTIOUS SUBSTANCES AND BIOLOGICAL MATERIALS

### 10.1 Introduction

Transportation of samples or waste that are known or expected to contain biological agents between rooms, laboratories or facilities, cities, regions or even countries is inevitable during testing, treatment or storage. Transportation of infectious substances may be subject to various national and/or international regulations, depending on the origin, destination and/or the mode of transport being used. Independent operators involved in the process may also request additional protocols. Irrespective of the regulations that apply, the aim is always to reduce the likelihood of an exposure to and/or a release of the infectious substance in order to protect personnel and/or the surrounding environment. Transferring or transporting infectious substances within or between laboratories should always be undertaken in a way that minimizes the potential for drop, spillage, collision or similar events.

Uganda has more than 1500 laboratories and the Ministry of Health chose 100 hub laboratories that are strategically located to serve as referral laboratories for 20 to 30 health facilities within a radius of approximately 40 kilometres and enhanced their capacities to function optimally. Apart from performing routine tests for patients of the facility, a hub also conducts analysis of patients' specimens referred from other health facilities and for complex tests that the hubs are unable to perform are referred to higher level reference laboratories within the national laboratory network and results are sent through the established sample and results transport network which operates throughout Uganda. MOH has contracted green label

to transport wastes from most of health facilities to centralised collection points for final disposal. Approximately 92Kg of waste is generated per day by a general hospital while 42kg, 25Kg and 20Kg are generated by Health Centre IV, III, III respectively (Ministry of Health Uganda, 2016)**.** With this nature of complex work involving transportation of specimens and infectious substances, with a substantial potential of exposure of personnel and the public to infectious pathogens, great care and adequate safety precautions should be taken during transfer and transportation of samples and wastes to prevent the exposure or release of infectious agents.

The following subsections provide an overview of the main issues to consider in the transfer or transport of infectious substances

**10.2 Transfer within the laboratory**

Moving infectious substances within the laboratory, for example from a BSC to an incubator, should be undertaken following GMPP to prevent incidents of cross contamination and inadvertent spillage. Additional measures to consider include the following:

- Use sealed containers, such as screw-capped tubes. Snap-cap lids should be avoided as they are less secure.
- Use deep-sided and leak-proof trays or boxes made of smooth impervious material (e.g. plastic or metal), which can be effectively cleaned and disinfected.
- Locking plastic food storage containers and storage containers are an option.
- If using racks, vials or tubes, trolleys can be used for more stable transport, as they are less likely to result in multiple spillages if a worker trips or falls.
- If using trolleys, ensure they are loaded so that substances cannot fall off, e.g. by securing the load or using some form of guard rail or raised sides.
- Make sure spill kits are readily available for use in the event of a spillage during transfer, and available personnel are trained in their use.

**10.3 Transfer within a building**

In addition to the considerations above, the transfer of infectious substances between

rooms, departments or laboratories in the same building must be planned, organized and carried out in a way that minimizes transit through communal areas and public thoroughfares.

Transfer containers must be suitably labelled to identify their contents, and surfaces decontaminated before leaving the laboratory. Biohazard symbols should be used on containers as a heightened control measure, if the biological agent being handled is associated with a higher likelihood of infection.

### 10.3.1 Pneumatic air tube systems

A pneumatic air tube transport system is a network of tubes that allows the movement of cylindrical containers around a building or campus using compressed air. It can provide a safe, efficient and rapid means to transport specimens containing infectious substances around a site. Personnel using the system at dispatch and reception points must be suitably trained on its use and informed of any associated risks. Dispatch personnel must be able to identify that the specimen is suitable for transport by this method, including the appropriate size/weight/shape to travel in the system, and that it is appropriately packaged/contained to prevent any exposure to or release of the infectious substance during the process.

## 10.4 Transfer between buildings on the same site

Issues that need to be considered for containers and layers of outer packaging to minimize the risks of leakage while transferring infectious substances between buildings are outlined below.

- Sealable plastic bags, plastic screw top tubes and locking plastic food storage containers
- Redundant layers of packaging, should be considered.
- Absorbent materials should be used between layers of packaging to absorb all infectious substances, if there were leakage occurred.
- The outermost transport container should be rigid. It can vary widely depending on the resources available.

- A plastic lunch box or small plastic ice chest is one option for the transport of infectious substances between buildings on the same site, as it is also they are secure and easily decontaminated.
- Packaging should be labelled in a way that the sender, recipient and contents of the package are clearly identifiable. It should include biohazard symbols where appropriate.
- Personnel involved in the transfer must be provided with suitable awareness training on the risks present during the transfer process and how to safely reduce them.
- Spill kits must be readily available and appropriate personnel trained in their use.
- Recipients must be notified in advance of the transfer occurring.

**10.5 Off-site transport of infectious substances**

In some cases, infectious substances must be transported off site for further processing, storage or disposal. This includes transport between sites of the same organization and from one organization to another. People at risk during off-site transportation are not only those involved in the transport, but also the public whose path might be crossed in transit. For this reason, ensuring infectious substances are safety contained and handled may be of interest to local, national and/or international authorities. Different national and international transport regulations have been developed to regulate packaging, labelling, marking and documentation of infectious substances to minimize the likelihood of exposure and/or release during transit. Most national regulations are adapted from the United Nations Model Recommendations on the Transport of Dangerous Goods and overseen by independent compliance organizations or national authorities

For transport purposes, these regulations classify materials that (may) contain biological agents as dangerous goods, under the class of “toxic and infectious substances”. Infectious substances are then further classifed, based on a pathogen risk assessment, into subgroups for which different procedures are stipulated. Other regulations may also apply to the shipment depending on the mode of transportation being used, if other dangerous goods are also present, and whether any national regulations are stipulated by the country of origin and/or the country

receiving the shipment, including import or export licences as applicable.
The following subsections provide a short introduction to the regulations, classifcations and safety controls that may be applied to the off-site transport of infectious substances. For more detailed information, please refer to documents listed in the reference section.

### 10.5.1 Regulation of the transport of infectious substances

Most of the regulations for the transport of infectious substances are based upon the United Nations (UN) model regulations. These regulations are reviewed every two years, should be consulted regularly to ensure that a laboratory's protocols for packaging, labelling, marking and transporting infectious substances comply with the current regulations. However, as these regulations are not intended to supersede any local or national requirements, and it is possible some national variations exist, national regulations for transport should always be consulted first. Other international regulations for the transport of infectious substances include modal transport agreements, with variations for air, sea and land transportation.
If national requirements do not exist, these modal agreements should be followed.
Where multiple regulations exist, the more stringent ones must be applied. Other regulations or requirements may also apply to infectious substances if they are transported with other dangerous goods, including cooling materials such as dry ice or liquid nitrogen. Import and export requirements should also be considered, as should the application of other international agreements, for example material transfer agreements where applicable. Ultimately, it is the responsibility of the personnel sending the infectious substance (often referred to as the "shipper") to ensure that they are familiar with all applicable regulations and/or variations that apply to their shipment and that they comply with them. Shippers must consult the relevant authorities to determine whether they are able to comply with these requirements before starting the shipment process. All personnel who participate in any part of the transport of a dangerous good, including infectious substances, must have training on the applicable regulations to a proficiency level appropriate for their job responsibilities.This may include general familiarization and awareness training, functional training on packaging, labelling and documentation, and safety training including best practices

for handling dangerous goods to avoid incidents as well as emergency/incidence response information. For certain types of infectious substances, a formal certifcation may be legally required, proving competence in these areas.

### 10.5.2 Classification of infectious substances

For transport purposes, infectious substances (cultures, human or animal patient specimens, biological products such as vaccines, infectious genetically modified organisms or medical/clinical wastes) may be further subdivided into the following classifications based on the pathogenicity of the biological agent it contains (or is suspected to contain): Category A, Category B and Exempt human/animal specimens. Each classification is assigned identifiers which includes a proper shipping name, and/or a unique four-digit UN number, which can be used to clearly identify the substance composition and hazardous nature of the biological agent, and indicate the specific transport requirements to be applied.

**Category A and B infectious substances:**

Categories A and B infectious substances are the two most important classifications used when transporting biological agents (or material containing biological agents) off the laboratory site. The main difference between the two classifications relates to the consequences (severity of outcomes) of an infection with the biological agent being transported if an incident were to occur while in transit. Category A infectious substances are defined as any material(s) known or reasonably expected to contain, biological agents capable of causing permanent disability, or life-threatening or fatal disease to healthy humans or animals. For the purposes of transport, these substances carry the highest biosafety and biosecurity risks and are therefore subject to the largest number of control measures, including regulated packaging of materials in a triple layer configuration, strict labelling criteria and detailed documentation processes. All people involved in the shipment of Category
A infectious substances must be formally certified by an appropriate authority as determined by the relevant regulations.

Category B infectious substances are defined as any material(s) containing biologicalagents capable of causing infection in humans or animals, but which do not meet the criteria for inclusion in Category A. These substances are also subject to strict regulation, including a triple-layer of packaging materials, special labelling and documentation. However, these are generally less stringent than for Category A infectious substances, depending on the applicable national regulations.

**Exempt human (or animal) specimens:**

Substance or materials derived from human or animal patients (i.e. clinical samples) for which there is a minimal likelihood that infectious biological agents are present, are defined as exempt human or exempt animal specimens. This means they are exempt from many of the stringent criteria applied to Category A and Category B infectious substances, especially for marking, labelling and documentation. However, exempt specimens are still required to be packaged using redundant layers of packaging in a triple-layered system containing primary, secondary and outer packaging of adequate strength for the substance being transported. Triple packaging for exempt specimens must be capable of preventing leakage of any and all liquid material held inside, and should be clearly marked on the outside with either Exempt Human Specimen or Exempt Animal Specimen as appropriate. If exempt specimens are being transported with other substances that meet the criteria for inclusion in another dangerous goods class, such as dry ice or other infectious substances, the relevant regulations for those substances must be followed.

**Exclusions:**

Some biological materials being transported off the laboratory site are known to be free of, or are extremely unlikely to contain, any biological agents. Such materials are excluded from any regulation on packaging, marking, labelling or documentation.
These exclusions include:

- Materials known to be free of infectious substances,
- Biological agents within the material that have been inactivated or killed,
- Biological agents within the material that are not pathogenic to humans or animals,
- Dried blood spot or faecal occult blood sample transported for analysis,
- Environmental samples not considered to be a significant hazard to health, and

- Items for transplant or transfusion.

**Table 6.1 Summary categorization, documentation, packaging and labelling of infectious substances for transport.**

| | CATEGORY A | CATEGORY B |
|---|---|---|
| **Definition** | Containing a biological agent known, or reasonably expected, to cause permanent disability, or life-threatening or fatal disease | Containing a biological agent capable of causing infection in susceptible humans or animals, but which does not meet the criteria for inclusion in Category A |
| **Identifiers (UN number and proper shipping name)** | ▪ UN 2814: Category A infectious substances (affecting humans or zoonotic infectious substances)<br>▪ UN 2900: Category A Infectious substances<br>(affecting only animals)<br>▪ UN 3549: Category A solid medical waste | ▪ UN 3291: Category B clinical or medical waste<br>▪ UN 3373: Category B infectious substances (for all other substances or materials including human or animal material, cultures and biological products) |

| | | |
|---|---|---|
| **Documentation** | ▪ An itemized list of contents (placed between the secondary and outer packaging)<br>▪ Names and addresses of the shipper and the receiver<br>▪ A dangerous goods transport document<br>(dangerous goods declaration)<br>▪ Additional documentation may be required depending on the modal requirements (e.g.<br>air waybill for air shipments) or national regulations (e.g. import/export permits) | ▪ An itemized list of contents (placed between the secondary and outer packaging)<br>▪ Names and addresses of the shipper and the receiver<br>▪ Additional documentation may be required depending on the modal requirements (e.g. air waybill for air shipments) and/or other national requirements (e.g. import/export permits) |

| | | |
|---|---|---|
| **Packaging** | • Triple packaging required to comply with UN packing instruction P620<br>• Packaging must show a UN specification mark, indicating compliance with testing requirements for Category A infectious substances packaging | • UN 3291: single packaging acceptable provided that: enough absorbent material is present to absorb the entire amount of liquid, the package is leak-proof, and/<br>or any sharp items are contained within<br>puncture-resistant packaging<br>• UN 3373: Triple packaging required (for air transport, either the secondary or outer package must be rigid) which complies with and is packaged according to UN packing instruction P650 |

**UN = United Nations.**

### 10.5.4 Triple packaging of infectious substances

Using redundant layers of packaging is a common method for controlling any leakage or breach of containment of an infectious substance to reduce the likelihood

of exposure and/or release during transport. A triple packaging system is commonly recommended, and required by regulation, for all three classifications of infectious substances described in the previous sections.


**Figure 6.3:** Example of triple packaging for infectious substances

**A triple package** consists of three layers (see example in Figure 6.3). **The primary receptacle,** containing the infectious substance must be watertight, leakproof and appropriately labelled as to its contents. The primary receptacle must be wrapped in enough absorbent material. If multiple primary receptacles are packed together, cushioning material must be used to prevent contact between them.

**Secondary watertight, leak-proof packaging** is used to enclose and protect the primary receptacle(s). Several wrapped primary receptacles may be placed in a single secondary packaging. Some regulations may have volume and/or weight limits for packaged infectious substances.

**The third layer** protects the secondary packaging from physical damage while in transit. It is between the second and third outer layers that coolants, such as dry ice or liquid nitrogen, can be used if necessary. Such coolants are also classified as dangerous goods and may therefore be subject to additional requirements themselves, as outlined in applicable regulations. For example, when dry ice is used, the third layer must be capable of releasing carbon dioxide gas to prevent explosion. Specimen data forms, letters and other types of information that identify or describe the infectious substance and identify the shipper and receiver, and any other documentation required, must also be provided according to current applicable regulations.

The outer layer of the triple package must also be marked and labelled appropriately, to provide the correct information about the hazards of the packaged contents for both for the infectious substance and any other dangerous goods that may be present, such as dry ice. General shipping information, such as the shipper and receiver of the infectious substance, and handling information, such as orientation arrows on the box, may also be required. As the exact requirements for the composition of the triple packaging may differ depending on the classification of the substance and mode of transport being used, applicable regulations must always be consulted to ensure the correct materials are used.

More detailed information on the specific transport requirements for categories A and B infectious substances is provided in the UN model regulations as guidance's known as "packing instructions". These prescribe the components of packaging that must be used for various dangerous goods classes, as well as the standards that the material must meet to be approved for use. There are two different packing instructions that relate to infectious substances. P620 applies to all Category A shipments (both UN 2814 and UN 2900). It provides additional requirements to the basic triple packaging system. These include criteria to comply with rigorous package testing that demonstrate the ability to withstand internal pressures without leakage, and to withstand dropping, stacking and even conditioning (such as with water and temperature extremes). P620 also describes additional packaging requirements for shipments which include dry ice. An example of packaging material for Category A infectious substances is shown in Figure 6.4.

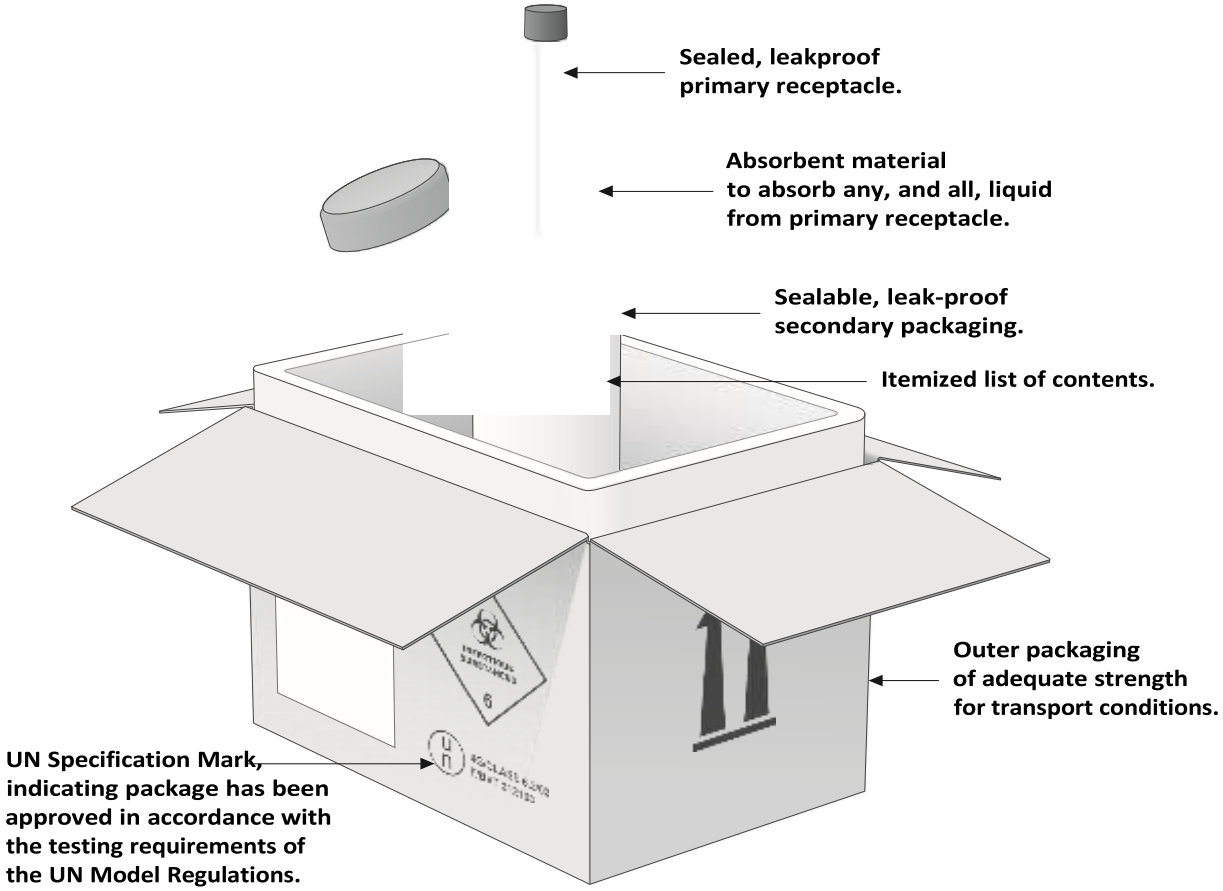


**Figure 6.4: Example of triple packaging materials suitable for**

**Category A infectious substances**

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A more basic triple packaging system P650 applies for the transport of other classifications of infectious substances—Category B (Figure 6.5) or exempt human and animal specimens. Packaging compliant with P650 must also undergo droptesting and internal pressure testing in some situations, although this is less stringent

than that required for Category A infectious substance packaging.

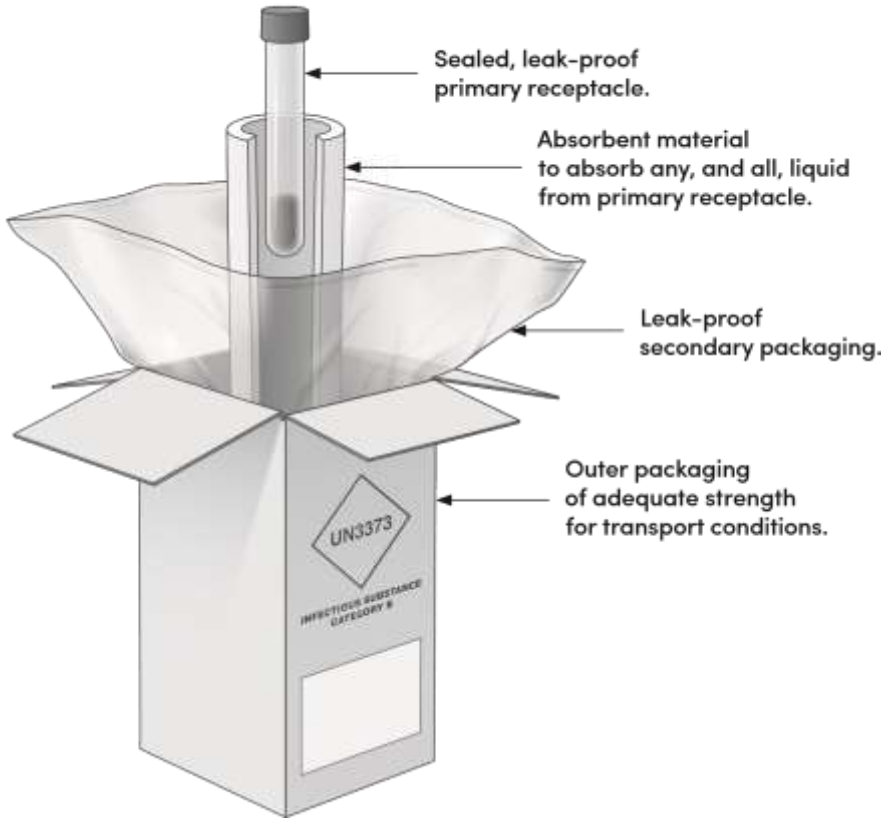



**Figure 6.5: Example of triple packaging materials suitable for Category B infectious substances**

### 10.2.1 National and International regulations for transportation of infections subtances

Handling, transport, and shipment of biological materials is governed by law, and proper care is absolutely essential.Proper Packaging of all specimens is mandatory to protect all people handling these samples and the environment. The practices and procedures described below are only guidance appropriate for domestic shipments within Uganda. For transportation outside of Uganda, appropriate international regulations such as the ICAO technical instructions for safe transport of dangerous goods by air and the International Air Transportation Association Dangerous Goods Regulations (IATA DGR) must be consulted and followed.

Transportation methods must minimize risks to employees of the carrier, the public, and the staff of the receiving laboratory. In many reported cases improper packaging of infectious substances compounds the hazaeds. . International shipments are strictly regulated by air carriers through the IATA regulations and many countries have national or federal regulations that govern the transport of dangerous goods in their country.".

Individuals who plan to transport or ship biological agents are required to complete the appropriate training offered by the Uganda National Biorisk management program. Commonly accepted international regulations biohazardous materials are considered Class 6.2 Infectious Substances (substances which are known or suspected to cause disease, may be hazardous to animals or humans or both).

In Uganda, various specialized laboratories have individuals trained and certified persons to ship IATA regulated packages containing biological agents. At least one authorized worker in each laboratory using biological agents must be trained in receiving regulated packages containing biological agents.


Figure 2: **Class 6.2 Hazard Label for Transport**

**10.2.2 Classes of Dangerous Goods related to (p4) protection level 4 laboratories**

- Class 2: Non-flammable, non-toxic gases
  Division2.2: Refrigerated liquid nitrogen (refrigeration)
- Class 3: Flammable liquids - Ethanol (preservation)
- Class 6: Toxic and infectious substances
  Division 6.1: Toxic substances
  Division 6.2: Infectious substances
- Class 9: Miscellaneous dangerous goods -
  Dry ice; Genetically Modified Microorganisms and organisms (not classified under 6.2)

# CHAPTER ELEVEN

# 11.0 LABORATORY BIOSECURITY

## 11.1 Introductions

Laboratory biosecurity refers to institutional and personnel security measures designed to prevent the loss, theft, misuse, diversion or intentional release of biological agents being handled in the laboratory. Effective biosafety practices are the foundation of laboratory biosecurity and biosecurity risk mitigation must be performed as an integral part of an institution's biosafety programme management. It is essential to properly assess potential biosecurity risks and establish appropriate mitigation measures that can reduce risks without hindering scientific processes and progress.
As with biosafety, the biosecurity risk assessment process includes the development of a strategy to manage the biosecurity risk by selecting and implementing biosecurity mitigation measures.
A biosecurity program stands upon five pillars; an inventory process, physical security, a personal reliability program, transport programs, and information security processes. The following subsection briefly describes some of the key elements of a laboratory biosecurity programme, including its risk assessment framework.

12.2 Biosecurity plan and Biosecurity risk assessment

Biosecurity risks are a type of biorisk based upon malicious intent. These risks are primarily focused on theft of a biological agent(s), equipment, or information, but can also include misuse, diversion, sabotage, unauthorized access, or intentional unauthorized release. The overall biosecurity risk varies

with the intent of the adversary (or threat) aiming to do the malicious act.

A biosecurity assessment includes defining the laboratory assets, threats, and facility vulnerabilities, as well as the existing biosecurity program in place to mitigate biosecurity risks. A biosecurity risk assessment will assess the impact or consequences of potential theft or destruction of the defined assets. Determining the potential security risks based upon these factors is the first step in implementing a biosecurity program.

The biosecurity risk assessment process is both described and illustrated below.

1. **Gather information**

The risk assessment team must identify and document the facility's assets that should be protected. Assets include anything of value to the institution or an adversary. Examples of assets may include valuable biological material, such as pathogens and toxins, valuable equipment, intellectual property, or other sensitive information, reagents, and even laboratory animals. In considering biological assets, the biochemical properties of biological materials should be considered.

The team must identify and evaluate potential adversaries who may pursue those assets. A thorough threat assessment should include a consideration of adversarial types and capabilities, motive, means, and opportunities. It should consider adversary scenarios, as well as consider the likelihood of attack. The risk assessment team should consider the vulnerabilities of the facility housing the assets. It should also review the work being performed in the laboratory and who has access to the laboratory and its assets.

2. **Evaluate the risks**

From the list of defined assets and threats, the risk assessment team can construct a series of potential risks based upon how and why an adversary may attempt to acquire (and possibly misuse or attempt to destroy) an asset. The team determines how the information gathered relates to the likelihood of someone gaining access to the identified biological agents and the consequences of a deliberate release of those agents. Compare the two factors to establish what the overall/ inherent risks are.

3. **Develop a risk strategy**

The risk assessment team, working with management and other stakeholders, should determine if the assessed risk is acceptable to the institution, individuals working in the institution, and the community. For a risk which is determined to be unacceptable, the risk assessment team, management, and other stakeholders must determine which mitigation measures are appropriate to implement.

4. **Select and implement control measures**

The results of the risk assessment will allow an institution to determine the relative level of safety and security risks they face and help guide risk mitigation decisions so they are targeted to the most

important risks. Biosecurity control measures can include both procedural and physical security systems. Assessment of the suitability of personnel, security-specific training and rigorous adherence to pathogen protection procedures are ways to enhance laboratory biosecurity.

5. **Review risks and control measures**

Successful operation of the biosecurity programme should be verified through periodic exercises and drills. Likewise, an institutional laboratory biosecurity protocol should be established to identify, report, investigate and remedy breaches in laboratory biosecurity. The involvement and roles and responsibilities of public health and security authorities in the event of a security breach must be clearly defined. All such efforts must be established and maintained through regular vulnerability, threat and biosecurity risk assessments, and regular review and updating of procedures. Checks for compliance with these procedures, with clear instructions on roles, responsibilities and remedial actions, should be integrated into a laboratory biosecurity programme.

### 12.3 Inventory control

A comprehensive programme of accountability is necessary to establish adequate control of at-risk biological agents, and to discourage theft and/or misuse. Procedures that can be used to achieve this include compilation of a detailed inventory, including description of the biological agent(s), Name of agent, Agent ID, its quantities, storage location and use, the person responsible, documentation of internal and external transfers, and any inactivation and/or disposal of the materials. A periodic review is recommended and any discrepancies should be investigated and resolved and any discrepancies should be investigated and resolved.

*The biological agent inventory should be up-to-date, complete, accurate and updated regularly to ensure that there is appropriate control and accountability.*

### 12.4 Information control

Processes and procedures must also be used to protect the confidentiality and integrity of sensitive information held in the laboratory that could be used with malicious intent. Within the scope of the biosecurity programme, it is important to identify, label and protect sensitive information against unauthorized access. Sensitive information includes research data, diagnostic results, information on animal experiments, lists of key personnel, security plans, access codes, passwords, storage locations and biological agent inventories. Sharing sensitive information with unauthorized individuals must be strictly prohibited. Facilities should have documented SOPs with detailed

procedures on how to access the laboratory information.

*Confidential: Information that is protected or restricted from unauthorized or accidental access and/or dissemination.*

### 12.5 Personnel control

The effectiveness of any procedural controls for biosecurity are ultimately determined by the training, capability, reliability and integrity of the personnel. Proper personnel management is essential for the functioning of a laboratory. It ensures that daily work practices and procedures are being performed by suitable personnel who behave in a reliable and trustworthy manner. In addition to laboratory personnel, laboratory access request and approval processes for visitors and other outside personnel must be established to ensure that there is a legitimate need for access, and that appropriate vetting and escorting procedures are followed. Laboratory biosecurity training should be provided in addition to biosafety training for all personnel according to the outcomes of the risk assessment. Such training should help personnel understand the need to protect biological agents and the rationale for the specific biosecurity measures that have been put in place. It should also include a review of relevant national standards and the institution-specific procedures. Security related roles and responsibilities of personnel in everyday and emergency scenarios should also be defined. Not all positions present the same level of biosecurity risk and training and requirements should be commensurate with those risks. Succession planning should be in place for management, scientific, technical and administrative personnel to ensure that critical knowledge of the safe and secure operation of the facility does not lie with just one individual in the event of his/her unavailability or departure. Documented procedures for terminated or departing personnel must be established (e.g. transfer of accountability for inventories and equipment, retrieval of property belonging to the laboratory, cancellation of access). Procedures that should be incorporated when implementing personnel management programmes include: establishing specifications for assessing suitability before employment, developing procedures to ensure only approved individuals are able to access at-risk biological agents and regulating the sharing of keys, combinations, codes, key-cards or passwords.

### 12.6 Physical security control

Physical security countermeasures are used to prevent unauthorized access of outside adversaries (i.e. those who do not have a legitimate presence in the facility and have malicious intent such as criminals,

terrorists and extremists/activists) and also to minimize the threat from insiders (i.e. those who have a legitimate presence in the facility such as employees and approved visitors) who do not require access to a particular asset. Physical security systems promote not only biosecurity objectives, but also directly support biosafety by limiting access to the laboratory and other potentially hazardous areas.

An effective physical security system incorporates a variety of elements to enhance a facility's capability to deter, detect, assess, delay, respond to, and recover from a security incident.

These elements include boundaries, access controls, intrusion detection, alarm assessment and response, and they are typically graded. A graded protection system increases security incrementally and forms risk-based layers of protection around the facility's assets.

The highest level of protection should be given to those assets whose loss, theft, compromise, and/or unauthorized use will have the most damaging effect on facility, national and potentially international security, and/or the health and safety of employees, the public, and the environment. In addition, these elements should be selected and implemented after a site-specific biosecurity risk assessment to ensure that they are all practical, sustainable and commensurate with identified risks.

### 12.7 Transport control

The transfer of biological agents must comply with national and international rules for packaging, marking, labelling and documentation of biological agents. This process should be controlled to a level proportionate with the assessed biosecurity risks of the biological agent being transported to ensure proper oversight within the biosecurity programme. Procedures may include ensuring that biological agents are ordered from legitimate providers and that they reach their intended destination using approved couriers. Procedures for shipper, carrier and receiver responsibilities to ensure that biosecurity risks are controlled should be written and followed as appropriate. Vulnerabilities exist from the moment items are removed from secure areas as an increased number of people may now have access to them. Transfers should be prearranged and preapproved by responsible parties and can use chain of custody documentation (or equivalent) for proper record-keeping if necessary based on the outcomes of a biosecurity risk assessment. Inventories must be updated to reflect incoming and outgoing samples, including internal and external transfers.

### 12.8 Bio security Incident and Emergency Response plan

Even the most well-prepared laboratory may experience unintentional or intentional incidents or

emergencies despite existing prevention or mitigation measures. Effective incident response is a mitigation strategy that can reduce the consequences of these unknown events through planning and preparation for potential incidents (such as discrepancies found in inventories, missing biological agents or unauthorized persons in the laboratory), and may help detect, communicate, assess, respond to and recover from actual events. An incident response protocol should be written and followed to ensure proper reporting, and to facilitate investigation, root-cause analysis, corrective action and process improvement. Drills and exercises can also be used in the planning and preparation stages to test the responses to simulated incidents or emergencies. They can help identify gaps and other improvement opportunities. Plans should be reviewed and updated at least annually, and the information obtained through drills, incident reports and investigations should be used to make necessary adjustments and improvements.

### 12.8.1 Incident and Emergency Response procedures

A protocol for reporting and investigating security incidents needs to be in place. For example missing infectious substances, unauthorized entry. A mechanism needs to be in place for the reporting and removal of unauthorized persons. Bio security incident and emergency plans should include response to intentional (theft, misuse, bomb threats, etc.), unintentional (accidental release) and natural events (power outages, severe weather).

Biosecurity training needs to be provided to all relevant personnel on different containment levels and recommended practices. Biosecurity requirements for facilities handling infectious agents at containment levels 3 and 4 will generally be more stringent than those required in clinical and research containment level 2 laboratories. Recommendations on bio security practices (e.g., storage of pathogens, inventories, and log books to record entry) and physical design security features (locks, restricted access) have been incorporated into the requirements for each containment level. Expert advice from security and/or law enforcement experts should be sought in the development of threat assessments and security protocols specific to each facility. The threat assessment and security practices should be regularly reviewed and updated to reflect new threats that may be identified.

Biological Agents in use:

- Constant surveillance and control must be maintained over biological agents in use. This means that an individual, who has received training as approved by the relevant agency is permitted to work with biological agents in the laboratory. If individuals untrained in biosafety are in the laboratory working on unrelated projects, biological agents must be secured or another individual trained in biosafety must be present in the laboratory.

Biological Agents in storage:

All biological agents in storage must be secured from unauthorized removal or access. The laboratory

must be equipped with a lock.

- When a room containing biological agents is unoccupied for periods such as lunch, meetings, after hours, etc. the room/ and or storage enclosure must be locked.
- Storage of biological agents in hallways is not permitted. The Biosafety Committee must approve any exceptions to these policy/ guidelines.
- Biohazard bags must be secure from unauthorized removal.

### 12.8.2 Emerging biological risks

Emerging biotechnology includes genetically modified microorganisms, synthetic biology, gain-of-function research, stem cell research, gene editing and gene drives.

Advances in life sciences research are inextricably linked to improvements in human, plant and animal health. Promotion of high-quality life sciences research that is conducted responsibly, safely and securely can improve global health security and contribute to economic development, evidence-informed policy-making, and public trust and confidence in science.

UNHLSD through Ministry of Health and other ministries like Ministry of Agriculture Animal Industry and Fisheries and Ministry of science and Technology considers the risks posed by incidents and/or the potential deliberate misuse of life sciences research and select appropriate control measures to minimize those risks in order to conduct necessary and beneficial life sciences research.

When conducting research with emerging technologies, for which limited information currently exists, the scientific community must:

1. Promote a culture of integrity and excellence, distinguished by openness, honesty, accountability and responsibility; such a culture is the best protection against the possibility of accidents and deliberate misuse, and the best guarantee of scientific progress and development;
2. Provide direction for biosafety/biosecurity oversight and the risk assessment process for emerging technologies in the life sciences, and as additional information is obtained over time, contribute to better understanding of their risks and biosafety/ biosecurity needs;
3. Monitor and assess the scientific, ethical and social implications of certain biotechnologies and, as warranted, monitor the development of those technologies and their integration into scientific and clinical practice.

### 12.8.3 Laboratory Bioethics and Dual use research of concern

Dual use research of concern is life sciences research that, based on current understanding, has the potential to provide knowledge, information, products or technologies that could be directly

misapplied to create a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, and the environment. Awareness of the dual use of agents, equipment and technology should also be considered in the development of laboratory biosecurity programmes where applicable. Laboratories should take responsibility for the dual-use nature of such agents and experiments, such as genetic modification, and follow national guidelines in order to decide on the adoption of appropriate biosecurity measures to protect them from unauthorized access, loss, theft, misuse, diversion or intentional release.
The potential misuse of biosciences is a global threat that requires a balanced approach to laboratory biosecurity so that legitimate access to important research and clinical materials is preserved. Administrative clearance for conducting research should be thought from responsible officers before conducting research

### 12.8.4 Mitigating the Risk of Dual-Use

1. Research oversight mechanism
2. Policies of funding agencies, publishers and editors
3. Laws and regulations
4. Codes of 'Conduct and Ethics'
5. Awareness-raising and educational initiatives

### 12.8.5 Code of Conduct and practice (Ethics)

Biosecurity requires strict practice of code of conduct from all individuals who may have access to the biological agents. The following are some guidelines for laboratory workers to adhere to;

1. Be dedicated to the science of mankind.
2. Actively seek to establish cooperative and distinctive working relationship with other health professionals.
3. Provide expertise and counsel other health professionals.
4. Safeguard the dignity and privacy of patients.
5. Be responsible for the process from the acquisition of specimen up to the production of data and final report of the test results.

6. Be accountable for the quality and integrity of the lab services.
7. Maintain strict confidentiality of patient information and results.
8. Exercise our professional judgment, skill and care to the best of our ability.
9. Uphold and maintain the dignity and respect of our profession and strive to maintain a reputation of honesty, integrity and reliability.
10. Strive to improve our professional skill and knowledge, and maintain an open mind to scientific advancements.

**12.9 Field Biosecurity**

Handling of infectious substance in field like during outbreak investigations, transportation of specimens using the National Sample and Result Transport System and any other forms of field work require observance of Biosecurity guidelines.

During outbreak investigation and response, a trained laboratory officer with biosafety training should do laboratory procedures and or specimen management. All specimens should be legibly labeled and recorded in an inventory indicating volume, type of specimens. All specimens for whom the etiology is unknown "strange disease" must be handled with utmost care and specimens should not be left with peripheral laboratories without satisfactory Biosecurity programs.

# CHAPTER TWELVE

## 12.0: PERSONNEL COMPETENCE AND TRAINING

The best safeguards can be compromised by human error and poor technical skills therefore it is important that competent and safety-conscious laboratory workers, who are well informed on how to recognize and control laboratory risks, are available for the prevention of laboratory-associated infections and/or other incidents. Personnel must have an appropriate level of laboratory experience, and a specialized, in-depth, pre-service training programme must be in place. Strict supervision and mentoring must be observed until new personnel are considered suitably competent, or existing personnel considered appropriately proficient in any new processes and procedures introduced.

Staff capacity development can be achieved through;

**5.1 Orientation/induction**

All new staff in a facility or change of roles should be oriented to the new work environment in order to make them aware of the risks related to the type of work and the appropriate mitigation measures,

location of safety equipment, their operation and functionality. It is also important to note that new staff should work under close supervision until they demonstrate ability to perform activities in a safe and secure manner. At the end of the orientation period the person is evaluated to ascertain the competence levels and necessary documentation is completed.

**The following thematic areas should be covered during orientation and induction**

- Laboratory layout, features and equipment
- Laboratory code(s) of practice
- Applicable local guidelines
- Safety or operations manual(s)
- Institutional policies
- Local and overarching risk assessments
- Legislative obligations

**5.2 Safety and security training**

- Awareness of hazards in the laboratory and associated risks,
- Safe working procedures,
- Security measures
- Emergency preparedness and response.

**5.3 Job specific trainings**

Training to be determined based on job function; training requirements may vary between personnel of the same job title but performing different functions

All personnel involved in the handling of biological agents must be trained on GMPP, Competency and proficiency assessment must be used to identify any other specific training required, for example by observation and/or qualification Proficiency in any procedure must be verified before working independently, which may require a mentorship period, Competencies must be reviewed regularly and refresher training undertaken, Information on new procedures, equipment, technologies and knowledge must be communicated to applicable personnel as and when available

**5.3.1 Refresher training**

This type of training is carried out periodically by competent staff in a particular area of interest depending on the training need. It can be in an existing procedure, equipment where there is need to re-emphasize crucial aspects which staff are becoming complacent. It can also be due to change in protocol, procedure or new hazard.

**5.3.2 Comprehensive biorisk management training**

This training will focus on empowering laboratory personnel with skills, knowledge and attitudes for proper management of biosafety and biosecurity in health facilities. The needs assessment will take into consideration the risks identified through the pathogen and biosecurity risk assessments, and the specific issues that can be mitigated through training.  Biorisk trainings should be preceded by Training Needs Assessment through which gaps in human resource are identified.

# CHAPTER THIRTEEN

# LABORATORY EQUIPMENT

## 13.0 Guidelines for Safe Usage of laboratory Equipment

This section will address safe usage of the following equipment with potential to create hazards in the laboratory (BSC, Centrifuge, Fridges, Homogenizers, shakers, sonicators, blenders, tissue grinders, and autoclave.

### 3.6.1 Biological Safety Cabinets

**General considerations:**

a) Determine the biological safety level of the laboratory, type of infectious agents or chemical hazards that may be present, and the nature of the work performed.
b) Use total exhaust safety cabinets for operations that utilize hazardous chemicals and volatile toxins.
c) Use a biological safety cabinet when performing procedures that may create an inhalation or aerosol hazard.
d) Use the correct classification of a biological safety cabinet (BSC) when working with infectious agent depending on its risk classification. Classification of infectious agents is according to Risk Groups 1-4 and the BSC are 1-4 too).
e) Biological Safety Cabinets must be inspected and certified when installed or relocated and thereafter, maintained and certified annually. Documentation of certification consists of a sticker with the certification date affixed to each BSC. Also the next due date for certification.
f) Containment
    - Diagnostic work may be done in a basic laboratory - Biosafety Level 2, preferably one dedicated for this purpose.
    - Research and development work involving propagation of large volumes or high concentrations of infectious microorganisms may require a containment laboratory - Biosafety Level 3 or higher containment level.

**Use of Biological Safety Cabinets**

**Definition**

A biosafety cabinet is a ventilated cabinet which uses a variety of combinations of high efficiency particulate absorption (HEPA) filters laminar air flow and containment to provide protection from particulates or aerosols involving bio hazardous materials to personnel, products and the environment. It is distinguished from a chemical fume hood by the presence of HEPA filtration and the laminar nature of the airflow.

HEPA filters trap 99.97% of particles of 0.3μm in diameter and 99.99% of particles of greater size. This enables the HEPA filter to effectively trap all known infectious microbes and ensure that only

safe air is discharged from the cabinet. HEPA filtered air is directed over the work surface providing protection of work surface materials from contamination.

**Classes of bio safety cabinets**

There are three classes of BSC's. The type of protection provided by the different classes of BSC's is outlined in Table 3.

**Table 3: Typical selection of BSC by types of protection**

| **Type of protection** | **BSC selection** |
|---|---|
| Personnel protection from risk groups 1-3 microorganisms | Class I, Class II, Class III |
| Personnel protection from Risk Group 4 microorganism, glove box and suit laboratory | Class III |
| Personnel protection from risk Group 4 organisms, suit laboratory | Class II |
| Product protection | Class II Class III if laminar flow included |
| Volatile radionuclide/chemical protection, minutes amounts | Class III BI, Class II A2 vented to the outside |
| Volatile radionuclide/chemical protection | Class III BI |
| *These are general recommendations that apply to typical types of activities, however a thorough risk assessment based on the pathogen characteristics and specific work activity is necessary to verify the selection of BSC. | |

**Class I BSC**

Class I BSC (Figure 3) provides partial protection to the worker and environment but no protection to the work surface or products. Room air is drawn through the front opening at a minimum face velocity of 0.38 m/s. Air passes over the work surface and is discharged from the cabinet through the exhaust duct and a HEPA filter. The directional flow of air whisks aerosol particles generated on the work surface away from the worker and into the exhaust duct. The front opening allows the operator's arms to reach the work surface inside the cabinet while the worker observes the work surface through the glass window. The window can be raised for cleaning purposes. The air from the cabinet is exhausted through a HEPA filter in one of three ways:

1. into the laboratory and then to the outside through the building exhaust
2. directly to the outside through the building exhaust, or
3. directly to the outside through a dedicated exhaust duct

The HEPA filter may be in the exhaust plenum of the BSC or the building exhaust.

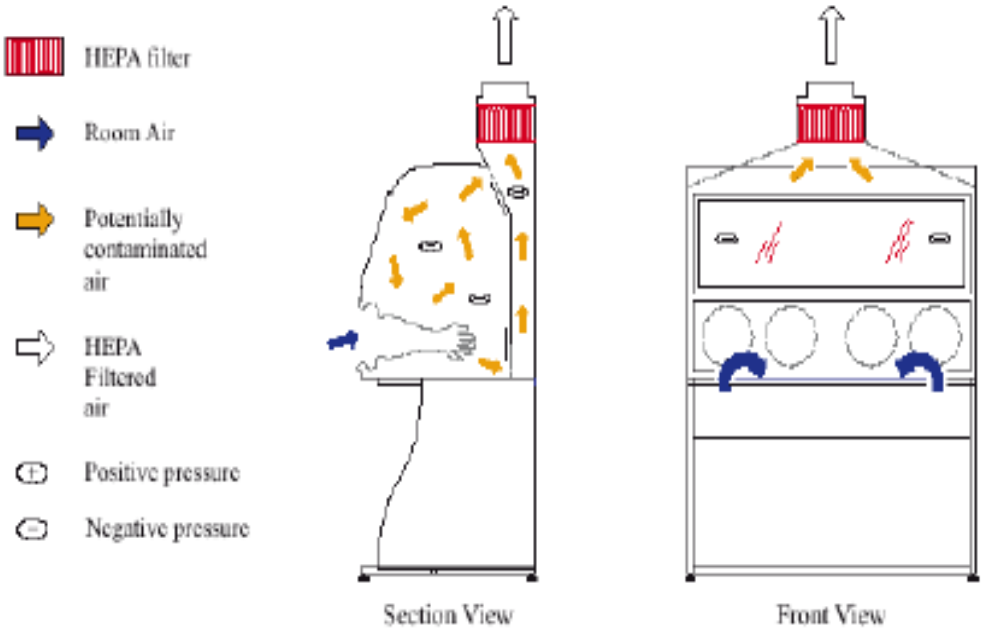



Figure 3: **Class I Biological Safety Cabinet.**

**Class II BSC**

Class II BSC (Figure 4) is designed to provide personnel and environment protection, but they also protect work surface materials from contaminated room air. Class II BSC's differ from Class I in that they allow only HEPA filtered air to flow over the work surface. Supply air is drawn downwards away from the work surface, passing though the HEPA filter prior to passing over the work surface. There are four subtypes of Class II cabinets namely: - A1, A2, B1, B2. These differ from one another by:

2. Air intake velocity
3. Amount of air re-circulated over the work surface and
4. Type IIB cabinets are hard ducted to a dedicated external exhaust

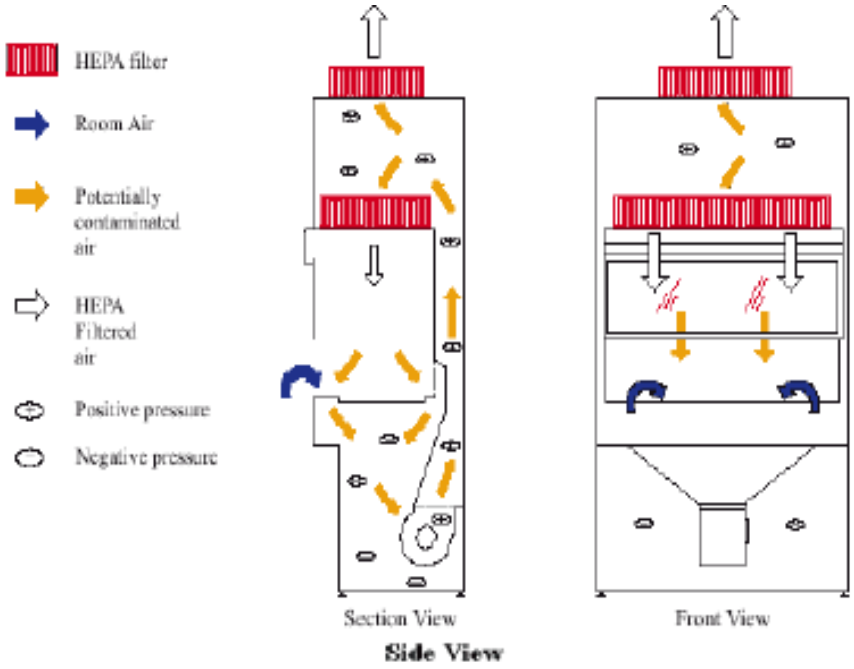



Figure 4: **Class II, Type A Biological Safety Cabinet.**

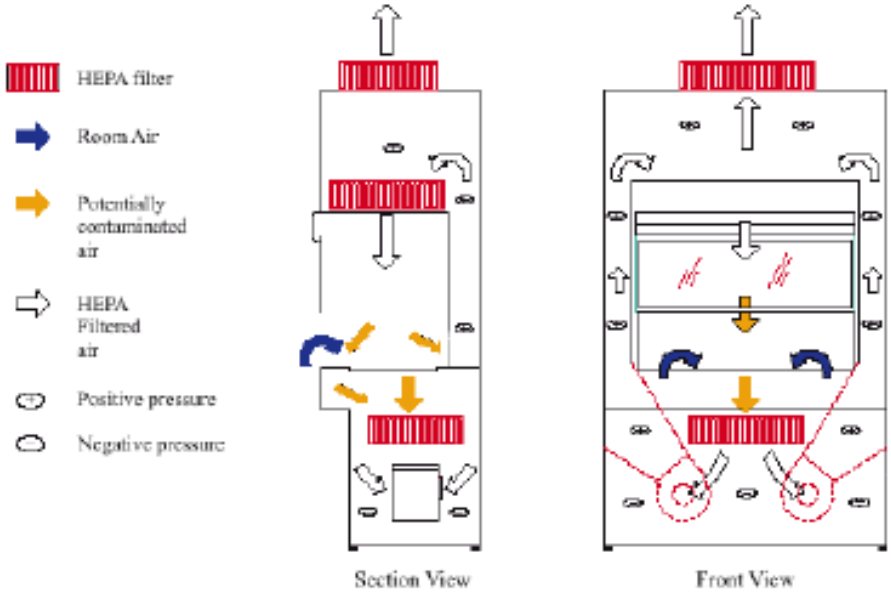



Figure 5: **Class II, Type B1 Biological Safety Cabinet (Ref WHO manual).**

**Class III BSC**

Class III cabinets (Fig 6) offer the highest level of personal protection and must be used for Risk Group 4 agents. All penetrations are sealed “gas tight”. Both air supply and exhaust are HEPA. Air flow is maintained by a dedicated exhaust system exterior to the cabinet, which keeps the cabinet interior under negative pressure. Access to the work surface is by means of heavy duty rubber gloves, attached to ports in the cabinet. The cabinet has an attached sterilizable pass-through box. The Class III cabinet may be connected to a double door autoclave used to decontaminate all materials entering or leaving the cabinet.

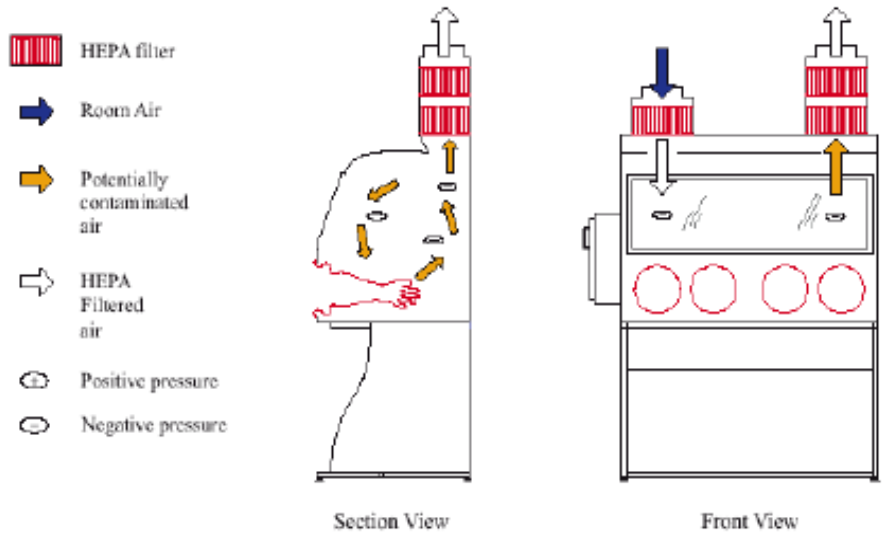



Figure 6: **Class III, Biological Safety Cabinet**

Figure 7: **Class III BSC (Photograph).**

Table 4: **Differences between class I, II and class III BSC.**

| **BSC** | **Air Flow Face Velocity (m/s)** | **% of air flow** | | **Exhaust System** |
|---|---|---|---|---|
| | | **Recirculated** | **Exhausted** | |
| Class I | 0.36 | 0 | 100 | Hard duct |
| Class II A1 | 0.38-0.51 | 70 | 30 | Exhaust to room or thimble connection |
| Class II A2 vented outside | 0.51 | 70 | 30 | Exhaust to room or thimble connection |
| Class II B1 | 0.51 | 30 | 70 | Hard duct |
| Class B2 | 0.51 | 0 | 100 | Hard duct |
| Class III | N/A | 0 | 100 | Hard duct |

Biosafety cabinets are only effective and protective if they are properly used. The following are guidelines for proper usage of BSC and proper arrangements of materials inside the cabinet as in fig5 below.

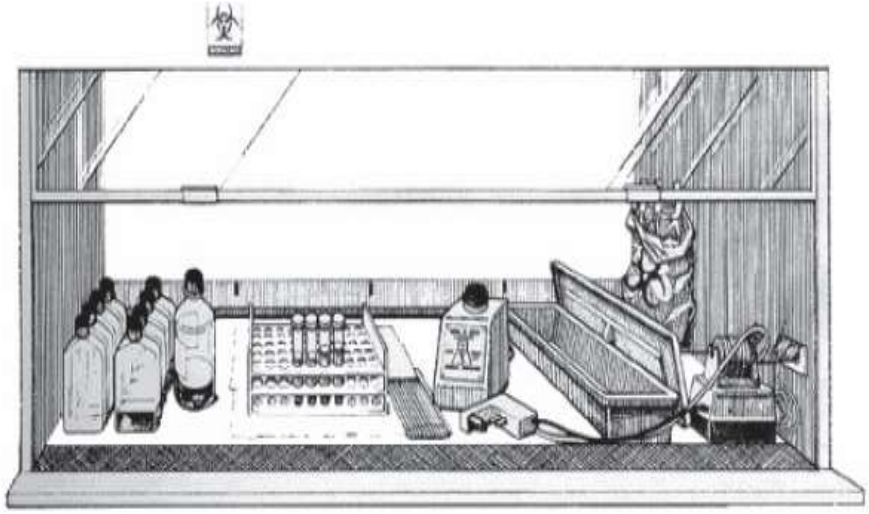


Figure 8:**Proper Use of BSC (working clean to dirty concept). Note left to right, clean to dirty work environment (WHO Manual).**

### 3.6.1.1 Effective Use of BSCs

1. Read the operator's manual and follow manufacturer's recommendations.
2. Locate the cabinet in an area where it will not be adversely affected by air currents and is away from human traffic and other ventilation devices.
3. In case the facility uses UV light to decontaminate the BSC, it should be turned off before commencing work.
4. Check for the effectiveness the UV light intensity using appropriate controls during the periodical BSC certification.
5. Turn on the fluorescent light and cabinet blower. Allow the BSC to run 15 minutes before using.
6. Wash hands thoroughly before proceeding and wear required personal protective equipment. If laboratory coats rather than gowns are worn, they must be buttoned, and the gloves pulled over the wrist of the coat.

7. Workers should double glove when working in the BSC. The outer layer of gloves must be removed after completion of work PRIOR to removing their hands from the BSC.
8. Wipe down the interior surfaces with 70% ethanol (or other suitable disinfectant) and allow to dry.
9. Arm movement into and out of the cabinet should be kept to a minimum to avoid air turbulence. Place all materials needed for the procedure inside the cabinet prior to starting. Do not bring any unnecessary items into the cabinet. If it is necessary to move arms in and out of the cabinet, do so slowly. Arms should enter/exit the BSC perpendicular to the front opening.
10. Minimize air changes in the room by avoiding opening and closing laboratory doors and pedestrian traffic.
11. Work at least 10 – 15 cm from the opening of the cabinet. Objects should not be placed such that they obstruct the front or rear grilles.
12. Adjust stool so that the worker's face is above the front opening of the cabinet.
13. The stool height should be such that the sash is level with the underarms of the worker.
14. Delay manipulation of materials for at least one minute after putting arms in the cabinet to allow the cabinet environment to stabilize.
15. Carry out work on a plastic-backed absorbent pad to contain small spills, making sure that this pad does not cover the front grille opening.
16. The use of open flames is prohibited in the BSC as they disrupt the air flow patterns and may damage the HEPA filter. To sterilize transfer loops, electronic loop incinerators, micro-incinerators, or disposable loops are an alternative.
17. Clean up spills as soon as they occur.
18. Place contaminated items to the rear of the cabinet.
19. Materials should be discarded in a waste container located towards the rear of the BSC. Do not discard items in a container that is located outside of the BSC.
20. Disinfect the cabinet after use. A bottle of appropriate disinfectant should be kept in the BSC to avoid having to move hands out of the BSC.
21. NEVER attempt to remove or change the HEPA filters.
22. Leave the fan blower on in the cabinet for five minutes after you have finished your procedure to allow the system to purge.

### 3.6.2 Specific bio-hazard containers

There are a number of accepted containers that are being used in the country and these include:

- Color coded Bins (Black, Yellow. Red and Brown.). These come in different sizes depending on the need of the user. Some have wheels and others are handle carried.
- Use of engineered sharps containers.
- The use of leak proof specimen containers during collection handling and storage.


Figure 9: **Color codes for bins used for Segregation of Medical Waste in Uganda.**

### 3.6.3 Use of Centrifuges

Centrifuges are sources of aerosol generation and should be used cautiously. The following are guidelines for proper use of centrifuges: -

a) Satisfactory mechanical performance is a prerequisite of microbiological safety in the use of laboratory centrifuges.
b) Centrifuges should be operated according to the manufacturer's instructions.
c) Centrifuges should be placed on flat and firm surface to reduce vibrations and shall not share a bench with other laboratory equipment.
d) Centrifuges should be placed at such a level that workers of less than average height can see into the bowl to place specimen tubes and buckets correctly. Buckets and specimens' tubes should be paired by weight and, with tubes in place, correctly balanced.
e) A well-functioning tachometer should be used by the lab staff to ensure the RPM is maintained.
f) Centrifuge tubes and specimen containers for use in the centrifuge should be made of thick-walled glass or preferably of plastic and should be inspected for defects before use.
g) Tubes and specimen containers should always be securely capped (screw-capped if possible) for centrifugation.
h) The buckets must be loaded, equilibrated, sealed, and opened in a biological safety cabinet or let stand for 30 minutes before opening.
i) The amount of space that should be left between the level of the fluid and the rim of the centrifuge tube should be as given in manufacturer's instructions.
**j)** Distilled water or alcohol (Isopropanol, 70%) shall be used for balancing empty buckets. **Note: Saline or hypochlorite solutions should not be used as they corrode metals.**
k) Sealable centrifuge buckets (safety cups) shall be used for microorganisms of Risk Groups 3 and 4.
l) When using angle head centrifuge rotors, care shall be taken to ensure that the tube is not overloaded as it might leak.

m) The interior of the centrifuge bowl shall be inspected daily for staining or soiling at the level of the rotor. If staining or soiling is evident then the centrifugation protocols should be re-evaluated.
n) Centrifuge rotors and buckets shall be inspected daily for signs of corrosion and for hair-line cracks.
o) Buckets, rotors, and centrifuge bowls shall be decontaminated after each use.
p) After use, buckets should be stored in an inverted position to drain the balancing fluid.
q) Infectious airborne particles may be ejected when centrifuges are used. Therefore, the usage of good centrifuge technique and securely capped tubes will offer adequate protection against infectious aerosols and dispersed particles.

**Note: It is good practice to involve the biomedical engineers when installing centrifuges.**

### 3.6.4 Use of Homogenizers, Shakers, Blenders and Sonicators

The greatest risk when performing any of these operations is the potential for aerosol production. These equipment are used for tissue processing and they produce a lot of aerosols which may be infectious. Therefore, careful usage should be always applied as follows: -

1. Perform these operations in a biosafety cabinet.
2. Use safety blenders which are designed to prevent leakage from the bottom of the blender jar, and which can withstand autoclaving.
3. Avoid the use of glass blender jars.
4. Place a towel moistened with a disinfectant over the top of the blender while it is in operation. This practice can be adapted for sonicators and grinders as well.
5. Allow aerosols to settle for at least thirty minutes before opening blenders, grinders or sonicators.
6. The vacuum pump used in the lyophilizer should exhaust through HEPA (high efficiency particulate air) filters or vent to a biosafety cabinet.
7. Use polypropylene tubes in place of glass for storing biohazardous materials in liquid nitrogen.
8. Domestic (kitchen) homogenizers should not be used in laboratories as they may leak or release aerosols. Laboratory blenders and stomachers are safer.
9. Caps and cups or bottles should be in good condition and free from flaws or distortion. Caps should be well-fitting, and gaskets should be in good condition.
10. Avoid pressure build-up in the vessel during the operation of homogenizers, shakers and sonicators.
11. Aerosols containing infectious materials may escape from between the cap and the vessel. Plastic, in particular, Polytetrafluoroethylene (PTFE) vessels are recommended because glass may break, releasing infectious material and possibly injuring the operator.
12. When in use, homogenizers, shakers and sonicators should be covered by a strong transparent plastic casing, which should be disinfected after use. Where possible, these machines should be operated under their plastic covers, in a biological safety cabinet.
13. At the end of the operation, the containers should be opened in a biological safety cabinet or let to stand for 30 minutes before opening.
14. Ear protection should be provided for people using sonicators.

### 3.6.5 Use of Tissue Grinders

a) Glass grinders should be held in a wad of absorbent material in a gloved hand. Plastic (PTFE) Grinders are safer.

b) Tissue grinders should be operated and opened in a biological safety cabinet.

### 3.6.6 Use of Automated Equipment (Sonicators, Vortex mixers)

a) Equipment should be of the closed type to avoid dispersion of droplets and aerosols.
b) Effluents should be collected in closed vessels for further autoclaving and/or disposal.
c) Equipment should be disinfected at the end of each session, following the manufacturer's instructions.

### 3.6.7 Care and Use cold chain equipment.

a) Refrigerators, deep-freezers, should be defrosted and cleaned periodically, and any ampoules, tubes, etc. that have broken during storage removed. Face protection and heavy-duty rubber gloves should be worn during cleaning. After cleaning, the inner surfaces of the cabinet should be disinfected as per manufacturer's instructions.
b) All containers stored in refrigerators, etc. should be clearly labeled with the scientific name of the contents, the date stored and the name of the individual who stored them. Unlabeled and obsolete materials should be autoclaved and discarded.
c) For the case of liquid nitrogen and solid carbon dioxide (dry ice) chests care should be taken while handling the containers to avoid cold burns
d) An inventory of the freezer's contents must be maintained.
e) Flammable solutions must not be stored in a refrigerator unless it is explosion-proof. Notices to this effect should be placed on refrigerator doors.

### 3.6.8 Sterilization equipment.

These are used based on the type of the hazardous material and technology available.
The common ones include the Steam under pressure (Autoclaves), Dry heat (Hot Air Oven), UV Light and filtration (HEPA filter)

### Autoclaving:

This is done under steam that raises the temperatures to 121$^{o}$C under pressure of 106 kPa for 20. minutes if unwrapped and 30 minutes if wrapped to kill different types of Microorganisms. The time difference is to allow penetration of heat and contact time for destruction.

**Dry heat (Oven and dry heat autoclaving)**
Dry heat is applied on the equipment such as glass ware. The temperatures applied here goes. above 200 $^{0}$C to allow heat penetration to sterilize and render the equipment safe from hazardous. materials. For effective sterilization, the following should be observed:
i. Temperatures of 300 $^{o}$C for 30 Minutes, 170 °C for 1 hour or 160 °C for 2 hours
ii. The autoclave shall not be open until the cycle is completed.
iii. Start timing when the autoclave / oven reaches the desired temperature.
All autoclaves must be monitored using autoclave tape for every run. Chemical indicators shall be used routinely as per the facility procedures to validate operation of the autoclave. Those that fail to achieve satisfactory results should be removed for repair or replacement. In addition, autoclave should be certified at least annually by a certified biomedical engineer.

### UV Light

Ultraviolet (UV) light is electromagnetic radiation in the spectral region from less than 200 nanometres to 400 nanometres (nm). Ultraviolet light is that portion of the electromagnetic spectrum that lies between the "purple" edge of the visible spectrum and x-rays. Intense or prolonged exposure to UV light can result in painful eye injury (photokeratitis, retinal burns), skin burns, premature aging of the skin, and skin cancer. Shielding and PPE should be employed. Regular glass does not afford complete protection from the harmful effects of UV light.

UV radiation is divided into several regions: UV-A (315-400 nm); UV-B (280-315 nm); UV-C (200-280 nm) and vacuum UV (40-200 nm). Germicidal lamps used in laboratory settings emit UV-C radiation. It is recommended that the time of exposure to an intensity of 100 micro watts per square centimeter to a clean surface at a wavelength of 254 nm not exceed one minute.

# CHAPTER FOURTEEN: FACILITIES DESIGN

## Laboratory Design

Physical infrastructure is an essential component of the laboratory quality management system. Laboratories are areas of aggregation and accumulation of potentially infectious biological agents, toxic chemicals and highly flammable reagents, and hence pose a potential risk to the personnel working therein, the community, as well as the environment. Design features enabling restricted access, adequate and safe work space, proper ventilation, ease of cleaning, controlled disposal of effluent and proper waste management help mitigate the infectious and chemical risk. Features to prevent, detect and fight fires limit the fallout from potential fire accidents. Ergonomic and aesthetic features such as lighting, finishings, provision for ample space and designs to accommodate work while standing or in sitting positions, provide a friendly work environment that motivates while minimizing potential injury to laboratory personnel in the course of their duties.

A well designed laboratory allows for proper workflow during testing procedure thereby minimizing errors, clutter and accidents while optimizing utilization of time. Provision of adequate space and power contributes to proper management of equipment and supplies thereby reducing interruption in service delivery.

Laboratory design should take into consideration the procedures, workload, equipment and number of personnel. In most cases, these depend on the level of care, with complexity increasing through the tiers from health centre III to national referral hospital.

Physical infrastructure improvement demands well directed and coordinated design and construction to ensure that they meet national standards.

**Facility design**

The facility design features listed below are core requirements for biosafety for all laboratories handling biological agents.

- Ample space must be provided for the safe conduct of laboratory work and for cleaning and maintenance.
- Designated hand washing basins operated by a hands-free mechanism must be provided in each laboratory room, preferably close to the exit door.
- The laboratory must be a restricted access area. Laboratory entrance doors should have vision panels (to avoid accidents during opening), appropriate fire ratings, and preferably be self-closing.
- Doors must be appropriately labelled with the international biohazard warning symbols wherever biohazardous materials are handled and stored.
- Laboratory walls, floors and furniture must be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory.
- Laboratory bench tops must be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat.
- Laboratory furniture must be fit for purpose. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning. n Laboratory lighting (illumination) must be adequate for all activities. Daylighting should be utilised effectively to save energy. Undesirable reflections and glare should be avoided. Emergency lighting must be sufficient to permit safe stopping of work as well as safe exit from the laboratory.
- Laboratory ventilation where provided (including heating/cooling systems and especially fans/local cooling split-system air conditioning units – specifically when retrofitted) should ensure airflows do not compromise safe working. Consideration must be made of resultant airflow speeds and directions, turbulent airflows should be avoided; this applies also to natural ventilation.
- Laboratory storage space must be adequate to hold supplies for immediate use to prevent clutter on bench tops and in aisles. Additional long-term storage space, conveniently located outside of the laboratory room/space, should be considered.
- Space and facilities must be provided for the safe handling and storage of chemicals and solvents, radioactive materials, and compressed and liquefied gases if used.
- Facilities for storing food and drink, personal items, jackets and outerwear must be provided outside the laboratory.
- Facilities for eating and drinking must be provided outside the laboratory.
- First-aid facilities must be readily accessible and suitably equipped/ stocked.
- Appropriate methods for decontamination of waste, for example disinfectants and autoclaves, must be available in proximity to the laboratory.
- The management of waste (solid, liquid, gas, electronic) must be considered in the design.
- Safety systems must cover fire, electrical emergencies and emergency/incident response facilities based on risk assessment.
- There must be a reliable and adequate electricity supply and lighting to permit safe exit.

- Emergency situations must be considered in the design as indicated in the local risk assessment and should include geographical/meteorological context.
- Physical, fire security and flood risk must be considered.

Further reference can be made to the National Laboratory Infrastructure Guidelines 2021.

## CHAPTER FIFTEEN

## SAMPLE MANAGEMENT

Safe handling of biological agents begins even before a sample arrives in the laboratory. When not properly packaged, samples received in the laboratory can pose a safety and security risk to personnel. The following subsections describe the controls that should be in place when receiving, storing and inactivating samples as part of the core requirements for biosafety.

Receipt of samples

A sample received by the laboratory must be accompanied by sufficient information to identify what it is, when and where it was taken or prepared, and which tests and/or procedures (if any) are to be performed. Samples must be observed on receipt to make sure they have been packaged correctly according to shipping requirements and that they are intact. Where breeches of correct packaging are observed, the package should be placed in a sealable container. This surface of the container should then be decontaminated and transferred to an appropriate location such as a BSC before opening. The breech in packaging should be reported to the sender and couriers.

Sample request or specification forms must be placed separately, preferably in waterproof envelopes, away from potential damage or contamination. Laboratories that receive large numbers of samples should consider designating a room or area specifically for receiving samples. Opening of samples must be performed with in primary containment device while wearing the appropriate PPE.

Personnel unpacking and receiving samples must be adequately trained in:

Hazards involved

How to handle broken or leaking containers to prevent exposure to biological agents.

How to handle spills and use disinfectants that manage contamination

Inactivation of samples

Wherever an inactivation step is used upon receipt of samples, before transferring the samples to other areas for further manipulation, such as for PCR analysis, inactivation methods must be appropriately validated.

Storing samples

Samples must be stored in leak proof containers that are made of adequate strength and integrity to contain the sample. Storage conditions like temperatures must be considered in order to preserve the integrity of the sample. The containers should be free of biological material on the outside of the packaging. Storage containers, must be correctly labelled, marked and recorded to facilitate identification.

Care must be taken when storing samples in liquid/vapour phase nitrogen. Only tubes specifically noted by the manufacturer as being suitable for liquid nitrogen cryogenic storage should be used to reduce the likelihood of breakage on removal from liquid nitrogen. It is important to note that liquid and vapour can enter improperly sealed or cracked tubes and can rapidly expand on removal of the tube from storage; this can lead to breakage and/or explosion. Thermal protective gloves and apron should be worn when accessing liquid nitrogen stores and a visor should be worn for splash protection.

Sample accountability

Sample accountability procedures should include inventory requirements for proper labeling, tracking of internal possession, inactivation, transfers within and outside the facility and disposal after use. These inventory controls also assist in keeping track of sample storage locations and the responsible persons. Inventories must be updated regularly to include new additions, removals and depletions or receipt of samples from other facilities. In addition, any changes in form of transfers or appropriate inactivation and disposal mechanisms should be documented. The record keeping should include sample inventory, access rights and material transfer agreements/documents. A notification process for identifying, reporting, and remediating security problems, i.e., inventory discrepancy, equipment

failure, breach of security, release of samples etc., should be in place.

# CHAPTER SIXTEEN

# RISK ASSESSMENT

## 2.1 Introduction to Laboratory Risk Assessment

Risk is defined as a function of the likelihood an adverse event involving a specific hazard and/or threat occurring, and its consequences. Likelihood and consequences occur at two different time periods of risk. The likelihood of risk affects whether or not the incident happens, and thus precedes the event. The consequences of risk occur after the incident has happened and affects the severity of the incident.

Risk assessment is a process of evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls and deciding whether or not the risk(s) is acceptable.

The primary purpose of a laboratory risk assessment is to inform the decision-making process that reduces the risks present in a laboratory. Mitigation of these risks will ultimately protect the individuals in the laboratory, in the facility and/or institution, as well as those outside the biological laboratory, including both the human and animal communities.

The results of a risk assessment provide a guide for the selection of appropriate biological safety measures (including microbiological practices and safety equipment), security measures, and other facility safeguards to mitigate the determined risks to an acceptable or manageable level.

Biological risk assessment may be a legal obligation and/or be a basis to determine required risk mitigation measures.

The benefits of risk assessment in the laboratory extend beyond risk reduction and mitigation. Laboratory risk assessments can also help to provide the following:

- Creating awareness of hazards and risks
- Identify who may be at risk
- Identification of training needs and supervision
- Effective allocation of resources to mitigate risks
- Advance planning for renovation and preventative maintenance
- Evaluation of procedural changes
- Compliance with governmental regulations
- Justification for space and equipment needs

- Evaluation of emergency plans
- Evaluation of exchanges and workflow with other laboratories/units

The quality of a risk assessment's results is entirely dependent upon the quality of its input data. A risk assessment requires the collection and input of accurate information. Personnel assigned to contribute to a risk assessment should be thoroughly familiar with the laboratory's work activities, and its biological agent holdings, procedures, equipment, and personnel, as it relates to their contribution to the risk assessment.

### 2.2 When to Perform and Review a Laboratory Risk Assessment

A periodic risk assessment should be performed when circumstances change, for instance when experiments, processes, and technology change. A risk assessment should be performed and reviewed annually although an organization should consider conducting a risk assessment more often as circumstances warrant. Risk assessment is mandatory at the commencement of new procedures and practices.

Examples of activities or events that will change risk and warrant a reassessment include:

- new infectious agents, toxins, reagents or other dangerous substances
- new animal species, model, or route of administration of biological agents
- new procedures and practices
- new equipment
- personnel changes
- aging of equipment
- advances in scientific understanding and technology
- a relocation or renovation
- a recent or "near-miss" accident, laboratory-acquired infection (LAI), theft, or security violation
- national or regional changes in disease status (endemicity of disease or disease eradication)
- national, regional or local changes in threat environment or security environment
- new local or national regulations

### 2.3 Roles and Responsibilities for Risk Assessment

Laboratory biosafety and biosecurity risk assessments should be a shared responsibility between

principal investigators, scientists, researchers (or a risk assessment team), and biorisk management advisors. Biorisk management advisors should assume responsibility for initiating the risk assessment process and be vigilant regarding their awareness of all biorisks present within the institution's laboratories; for a biosecurity risk assessment, campus security forces should also be involved, whenever possible. Descriptions of the various risk assessment users and their responsibilities are provided below:

### 2.3.1 Biorisk management advisors (biosafety officers)

These individuals are a member(s) of the staff that provides advice and guidance for laboratory biorisk management issues and workplace risk assessments. These individuals gather relevant information to define risk factors and use that information to characterize risks in terms of likelihood and consequences. The biorisk management advisor should act as a communicator to link hands-on frontline laboratory staff and contractors with managers, higher management staff, and other stakeholders. They should be knowledgeable of laboratory activities, sources of potential exposure, and means of effective control. They should also act as consultants for recommending and implementing appropriate mitigation measures resulting from the risk assessment with support by management. Further, the biorisk management advisors should have the most extensive understanding of a risk assessment's results.

### 2.3.2 Principal investigators/scientists/researchers

These individuals are the primary providers of information and data input into a risk assessment. They are expected to ensure risk assessments have been completed, understand risk assessment results, and provide input to management regarding practical implementation of recommended mitigation measures. They are also responsible for ensuring that at-risk employees have been informed of the risk assessment results, mitigation measures required, and directing them to obtain specific mitigation measures, whenever needed. The understanding and support of a risk assessment by the scientific staff is critical for effective biorisk management.

### 2.3.3 External Safety and Security personnel

These individuals are experts who may also provide valuable insight into risk assessments. For example, outside agencies such as local police departments may be able to provide information on local threats in the community. Security force personnel may be involved in implementation of biosecurity mitigation measures by management or act as inspectors to check its functionality. Other specialty agencies may also be necessary for the biosafety risk assessments, such as the Incident Response, the local fire department, and other first responders. Each group could be called on for additional help in the event of a major safety or security violation that exceeds the response capacity

of the institution.

### 2.3.4 Laboratory contractors, waste handlers, maintenance staff, and janitors

These individuals are directly affected by laboratory risks, often with limited knowledge about the hazards to which they are exposed. These individuals should be engaged regarding their concerns and understanding of the risks and how the results of the risk assessment will impact them. This is important to gain their support for implementation of any mitigation measures.

### 2.3.5 Upper management

These individuals, which may include laboratory directors and higher management, will typically not conduct or be directly engaged in the risk assessment process. However, as they are ultimately responsible for the organization's biorisk management system, it is absolutely critical that this group supports (and if necessary, directs) laboratories to conduct risk assessments, including allocating the use of staff time and resources to perform the necessary data collection and analysis.

Upper management will be ultimately responsible for building the infrastructure and capacity that, in turn, supports establishing precautions and standard procedures to minimize laboratory risks. Mutual understanding between the assessor and upper management is essential for maximizing risk assessment outcomes. Resource allocation and financial support from this group is necessary to conduct the risk assessment and implement the appropriate and necessary biosafety and biosecurity measures. Engaging upper management in dialog early in the risk assessment process can reduce confusion when interpreting the results. Early communication can help alleviate miscommunication when management receives the assessment results and must understand the results to make mitigation decisions. It will also be essential that risk assessment results be translated into straightforward terminology to facilitate understanding by upper management.

### 2.3.6 Community stakeholders

These individuals may or may not be engaged, depending on the situation. It may be prudent to inform outside visitors and family of laboratory personnel about any risks they may encounter and how the risks have been effectively managed or controlled. Community engagement should be in close collaboration with other responsible institutional parties, such as an Institutional Biosafety Committee (IBC) or Biorisk Management Committee, the department of Environmental Health and Safety, and/or any animal care and use committees

## 2.4 Steps of Risk Assessment

The risk assessment process for both biosafety and biosecurity are very similar; however, separate assessments of their risks are still necessary as the objectives for each process differ. The biosafety risk assessment is

concerned with fundamental biological properties of an agent and how the agents are used in the laboratory; for a biosecurity risk assessment, the agent's potential for malicious use are considered, including its consequences of malicious use. Results of both assessments should be similarly reviewed independently, but the implementation of any risk mitigation measures will ultimately be managed in an integrated framework.

Risk assessments must always be conducted in a standardized and systematic way to ensure they are repeatable and comparable in the same context.

The risk assessment framework (Figure 1.1) is a process with five steps or procedures based on the Plan-Do-Check-Act cycle:

- gather information,
- evaluate the risks,
- develop a risk control strategy,
- select and implement risk control measures and
- review risks and risk control measures.

A biosafety risk assessment should adhere to a structured and repeatable process and should follow the five-step technical approach described and illustrated below.

**Figure 1.1: The risk assessment framework**


### 2.4.1 Laboratory Risk Assessment Methodology

A risk assessment reviews all aspects of the work environment, including location, proposed work activities, personnel, storage, sample transfer and transport, destruction, access, and security, among others.

A biosafety risk assessment should adhere to a structured and repeatable process and should follow the five-step technical approach described and illustrated below.

**Table 2.1 Key considerations in the risk assessment framework**

| Step | Key Considerations |
|---|---|
| 1. **Gather information (hazard identification)** | • What biological agents will be handled and what are their pathogenic characteristics?<br>• What type of laboratory work and/or procedures will be conducted? |

| | |
|---|---|
| | • What type(s) of equipment will be used?<br>• What type of laboratory facility is available?<br>• What human factors exist (for example, what is the level of competency of personnel)?<br>• What other factors exist that might affect laboratory operations (for example, legal, cultural, socioeconomic, public perception)? |
| **2. Evaluate the risks** | • How could an exposure and/or release occur?<br>• What is the likelihood of an exposure and/or release?<br>• What information gathered influences the likelihood the most?<br>• What are the consequences of an exposure and/or release?<br>• Which information gathered influences the consequences the most?<br>• What is the overall initial risk of the activities?<br>• What is the acceptable risk?<br>• Which risks are unacceptable?<br>• Can the unacceptable risks be controlled, or should the work not proceed at all? |
| **3. Develop a risk strategy** | • What resources are available for risk control measures?<br>• What risk control strategies are most applicable for the resources available?<br>• Are resources sufficient to obtain and maintain those risk control measures?<br>• Are proposed control strategies effective, sustainable and achievable in the local context? |
| **4. Select and implement risk control measures** | • Are there any national/international regulations requiring prescribed risk control measures?<br>• What risk control measures are locally available and sustainable?<br>• Are available risk control measures adequately efficient, or should multiple risk control measures be used in combination to enhance efficacy? |

| | |
|---|---|
| | • Do selected risk control measures align with the risk control strategy?<br>• What is the level of residual risk after risk control measures have been applied and is it now acceptable?<br>• Are additional resources required and available for the implementation of risk control measures?<br>• Are the selected risk control measures compliant with national/international regulations?<br>• Has approval to conduct the work been granted?<br>• Have the risk control strategies been communicated to relevant personnel?<br>• Have necessary items been included in the budget and purchased?<br>• Are operational and maintenance procedures in place?<br>• Have personnel been appropriately trained? |
| **5. Review risks and risk control measures** | • Have there been any changes in activities, biological agents, personnel, equipment or facilities?<br>• Is there any new knowledge available of biological agents and/or the processes being used?<br>• Are there any lessons learnt from incident reports and investigations that may indicate improvements to be made?<br>• Has a periodic review cycle been established? |

Examples of factors that can elevate the likelihood of an exposure to and/or release of biological agents during work in the laboratory, and/or escalate its associated consequences are given in Tables 2.2 to 2.4.

**Table 2.2 Factors that affect the likelihood of an incident occurring**

| **Factors associated with high likelihood of incidents occurring** | **Rationale** |
|---|---|

| | |
|---|---|
| **Laboratory activities associated with aerosolization (for example, sonication, homogenization, centrifugation)** | When aerosols are generated by these methods, the likelihood of exposure through inhalation is increased, as is the likelihood of release of these aerosols into the surrounding environment where they might contaminate laboratory surfaces and also spread into the community. |
| **Laboratory activities associated with sharps materials** | When activities involve work with sharps, the likelihood of percutaneous exposure to a biological agent through a puncture wound is increased. |
| **Low competency of personnel carrying out the work** | Low proficiency of personnel in laboratory processes and procedures, through lack of experience, understanding or failure to comply with SOPs and GMPP, can lead to errors in performing the work which are more likely to result in exposure to and/or release of a biological agent.<br>Cleaning and maintenance personnel must be trained before working close to a biological agent. |
| **Highly environmentally stable biological agents** | Biological agents that have settled on laboratory surfaces (for example, contamination caused by poor technique that allowed settling of aerosol or droplets after release) can be a source of inadvertent exposure as long as they remain stable in the environment, even if the contamination cannot be seen. |
| **Inadequate or poor availability of electrical power, dilapidated laboratory facilities and building systems, malfunctioning equipment, damage from frequent severe weather and access of insects and rodents to the laboratory.** | All these factors may result in partial breaches in, or complete failure of, biocontainment systems designed to reduce the likelihood of exposure to and/or release of biological agents. |

**GMPP = good microbiological practice and procedure; SOPs = standard operating procedures.**

**Table 2.3 Factors that affect the consequences of an incident if it were to occur**

| Factors associated with greater consequences if an incident were to occur | Rationale |
|---|---|
| **Low infectious dose** | For infection to occur in an exposed individual, a certain quantity (volume, concentration) of biological agent must be present. Even a small amount of an agent could result in severe consequences, such as a laboratory-associated infection. Furthermore, exposure to larger quantities of that agent (greater than the infectious dose) may result in a more severe presentation of the infection. |
| **High communicability** | Even one single exposure (causing carriage or a laboratory associated infection) could rapidly spread from laboratory personnel or fomites to many individuals. |
| **High severity and mortality** | A laboratory associated infection following exposure is more likely to cause personnel to become debilitated, lose their quality of life or die. |
| **Limited availability of effective prophylaxis or therapeutic interventions** | The symptoms or outcomes of a laboratory associated infection cannot be effectively prevented, reduced or eliminated by a medical intervention. This may also include situations where medical intervention is not available, or emergency response capacity is limited. |
| **Large susceptible population (including laboratory personnel at increased risk)** | The larger the susceptible population, the more likely a laboratory-associated infection could rapidly spread and infect larger numbers of people. |
| **Lack of endemicity (such as exotic disease)** | When an agent is not endemic in the surrounding population, the population is more likely to be susceptible to the agent, leading to an increased likelihood of a laboratory-associated infection spreading to the community. |

**Table 2.4 Factors associated with both a high likelihood of and greater consequences from a potential incident**

| Factors associated with both a high likelihood of and greater consequences from a potential incident | Rationale |
|---|---|
| **High concentration or volume of the biological agent** | The more biological agent there is in the substance being handled, the more infectious particles there will be available for exposure, and the more likely the exposure volume will contain the infectious dose of that agent. Furthermore, being exposed to a higher concentration of the agent could result in a more severe infection, illness or injury. |
| **Airborne route of transmission** | Biological agents with an airborne route of transmission may be capable of remaining in aerosols for prolonged periods of time and may disseminate widely in the laboratory environment, increasing the likelihood that personnel may be exposed to the agent.<br>Furthermore, following an exposure event, aerosolized biological agents may be inhaled and deposit on the respiratory tract mucosa of the exposed individual, possibly leading to a laboratory-associated infection. |

Once the factors associated with likelihood or consequence have been defined, a risk assessment matrix can be used to determine the extent to which these factors affect the risk. A qualitative matrix-based risk evaluation approach in which both likelihood and severity are assigned a non-numerical classification, allows the ranking of risk as, for example, “low”, “medium” or “high.” With this matrix-based approach, the range of classifications for likelihood and severity can be defined as shown below.

**Likelihood of an exposure or release occurring during the proposed laboratory work**

- **Rare:** almost impossible to occur

- **Unlikely:** not very possible to occur
- **Possible:** might occur
- **Likely:** very possible to occur
- **Almost certain:** highly probable to occur

**Severity of the consequences of an exposure/release**

- **Negligible:** Trivial incident or near miss requiring reporting and follow up
- **Minor:** Incident with self-limiting consequences
- **Moderate:** Incident that requires medical treatment and/or has insignificant environmental consequences
- **Major:** Incident with potential lost time due to infection but non-permanent consequence and/or limited environmental impact
- **Severe:** Potential fatality or serious illness with permanent disability and/or serious environmental impact.

**Table 2.5 Risk assessment matrix defining the risk based on the likelihood of exposure and/or release and the consequences**

| | | **Likelihood of exposure/release** | | | | |
|---|---|---|---|---|---|---|
| | | Rare | Unlikely | Possible | Likely | Almost certain |
| **Consequences of exposure / release** | Severe | Medium | Medium | High | Very high | Very high |
| | Major | Medium | Medium | High | High | Very high |
| | Moderate | Low | Low | Medium | High | High |
| | Minor | Very low | Low | Low | Medium | Medium |
| | Negligible | Very low | Very low | Low | Medium | Medium |

### 2.4.2 Develop a risk strategy

The risk assessment team, working with management and other stakeholders, should determine if the assessed risk is acceptable to the institution, individuals working in the institution, and the community. In some situations, the minimal level of acceptable risk may be defined by national or regional policy. For a risk that is determined to be acceptable, the risk assessment results should be documented; for a risk that is determined to be unacceptable, the risk assessment team, management, and other

stakeholders must determine which mitigation measures are appropriate to implement and conduct a follow-on assessment once those measures have been implemented.

### 2.4.3 Select and implement risk control measures

The results of the risk assessment will allow an institution to determine the relative level of safety and security risks they face and help guide risk mitigation decisions so they are targeted to the most important risks.

There are a number of different strategies that may be used to reduce and control risks. Often, more than one risk control strategy may need to be applied in order to reduce the risks effectively.

Once the appropriate combination of risk control measures has been selected, necessary approvals should be obtained.

Finally, once risk control measures have been selected, approved and acquired, information about their purpose, function and use must be communicated to all applicable personnel if they are to be implemented correctly and be effective.

**Table 2.6 Types of control and examples of the risk control measures**

| STRATEGY | EXAMPLE |
|---|---|
| **Elimination** | Eliminate the hazard:<br>▪ use an inactivated biological agent,<br>▪ use a harmless surrogate. |
| **Reduction and substitution** | Reduce the risk:<br>▪ substitute with an attenuated or less infectious biological agent,<br>▪ reduce the volume/titre being used,<br>▪ change the procedure for one that is less hazardous, such as polymerase chain reaction rather than culture. |
| **Isolation** | Isolate the hazard:<br>▪ elimination and reduction might not be possible, particularly in a clinical setting, therefore isolate the biological agent(s) (for example, in a primary containment device). |
| **Protection** | Protect personnel/the environment:<br>▪ use engineering controls (for example, BSC),<br>▪ use PPE,<br>▪ vaccinate personnel. |
| **Compliance** | Have administrative controls and effective biosafety programme management in place such as:<br>▪ GMPP observed by personnel,<br>▪ good communication of hazards, risks and risk control measures, |

| | |
|---|---|
| | ▪ appropriate training,<br>▪ clear SOPs,<br>▪ an established safety culture. |

### 2.4.3 Review risks and risk control measures

Once performed, risk assessments must be reviewed routinely and revised when necessary, taking into consideration new information about the biological agent, changes in laboratory activities or equipment and new risk control measures that may need to be applied. Suitable procedures must be put in place not only to ensure implementation and reliability of the risk control measures, but also to ensure that they are sustainable. Confirmation that measures are effective and that training has been carried out appropriately can be verified through inspection, review and audit of processes and documentation. This will also provide an opportunity for improvements to be made to the processes and associated safeguards. This will include a careful review of laboratory-associated infections, incidents, accidents as well as literature reviews and relevant references.

# ANNEXES

## APPENDIX 1: GLOSSARY

**Aerosol –** a colloid of liquid or solid particles suspended in air. Biological agents can be aerosolized during many common laboratory procedures

**Allergen –** any substance that causes manifestations of allergy (e.g. dusts, pollens, fungi, fiber, latex).

an organism whose genetic material has been altered using genetic engineering techniques.

**Antimicrobial –** an agent that destroys or prevents the growth of microorganisms.

**Aseptic technique –** a procedure or operation done in such a manner as to prevent the introduction or spread of contamination.

**Autoclave –** Autoclaves use steam under pressure to decontaminate waste or sterilize materials, usually at $121^0$C for a specified period of time.

**Bacteria –** single celled, microscopic prokaryotic organisms.

**Bactericide –** an agent that kills vegetative bacteria and some less resistant spores.

**Bacteriostatic** – an agent that stops the growth and multiplication of bacteria but does not necessarily kill them.

**Biocide** – A general term for any agent that kills organisms.

**Biohazard –** the term refers to biological substances that present a risk or potential risk to the wellbeing of man, animals or plants.

**Biological Safety Cabinet (BSC) –** a ventilated containment cabinet intended to protect the user, product and the environment from the hazards associated with the handling of infected or potentially infected material.

**Blood Borne Pathogen -** is organism that can be spread through contaminated blood. E.g. HIV, hepatitis B, hepatitis C and viral hemorrhagic fevers.

**Chemical germicide** – A chemical or a mixture of chemicals used to kill micro-organisms.

**Containment –** the prevention of agent transfer from one point to another through use of suitable equipment and infrastructural design.

**Containment level –** the combination of physical and operational requirements necessary to work with a particular agent or to perform a particular procedure safely.

**Contamination –** any foreign substance that makes an unwanted incursion

**COVID-19** - the name of the disease caused by the SARS-CoV2 virus; its full form, COVID-19 stands for Corona Virus Disease of 2019

**Decontamination** – Any process for removing and/or killing microorganisms. The same term is also used for removing or neutralizing hazardous chemicals and radio-active materials.

**Disease –** a pathological condition of the body that presents with a group of symptoms

**Disinfectant –** a chemical agent that kills or inactivates most vegetative bacteria, fungi and viruses, but not necessarily spores.

**Disinfectant** – A chemical or mixture of chemicals used to kill microorganisms, but not necessarily spores. Disinfectants are usually applied to inanimate surfaces or objects.

**Disinfection –** A physical or chemical means of killing microorganisms, but not necessarily spores.

**Etiologic agent –** a viable microorganism or its toxin which causes or may cause disease.

**Fungus –** a plant-like organism that feeds on organic matter

**HEPA filter –** High Efficient Particulate Air filter, which filter contaminated air within Biological Cabinets.

**Laboratory Acquired Infection -** all infection acquired through laboratory or laboratory-related activities regardless of whether they are symptomatic or asymptomatic in nature.

**Lyophilization (freeze drying) – is** the process of rapidly freezing a substance at an extremely low temperature and then dehydrating in a high vacuum.

**Microbicide** – A chemical or mixture of chemicals that kills microorganisms. The term is often used in place of "biocide", "chemical germicide" or "antimicrobial".

**Pathogen –** a microorganism or substance capable of causing disease

**Pathogenicity – is** the state of producing or being able to produce pathological changes and disease.

**Prion -** an infectious agent that is composed primarily of protein(including Gerstmann-Straussler syndrome, Kuru and Creutzfeldt-Jakob agents), are resistant to most traditional methods of inactivation used for other microorganisms.

**Prophylaxis -** is a measure taken to maintain health and prevent the spread of disease.

**Recombinant –** a microbe or strain that has received chromosomal parts from different parental strains.

**Rickettsia –** a genus of bacteria consisting of small organisms that do not grow in cell-free media.

**Sporocide** – A chemical or mixture of chemicals used to kill microorganisms and spores.

**Standard precautions –** refers to the infection control method in which all human/primate blood, tissues, and/or body fluids are treated as if they are known to be infectious

**Sterilization** – A process that kills and/or removes all classes of microorganisms and spores.

**Sterilization –** any process which results in removal of all forms of all life in or on an object.

**Vector –** a carrier, usually an arthropod or insect that transmits causative organisms of disease from infected to non-infected individuals.

**Viable –** capable of life, generally referring to the ability of bacteria to grow and multiply.

**Virulence –** the relative power and degree of pathogenicity possessed by organisms to produce disease.

**Virus –** a term for a group of microbes which, with few exceptions, are capable of passing through fine filters that retain bacteria.

**Zoonotic diseases –** disease that is communicable from animals to humans and vice-versa under natural conditions.

## APPENDIX 2: ASSESSMENT TOOL FOR LABORATORY SAFETY MANAGEMENT

**ASSESSMENT BACKGROUND AND INSTRUCTIONS**

**Introduction:**

Biosafety and biosecurity measures are key components of laboratory management for prevention, detection and control of unintended and intended exposure to biological agents.The nature of work in laboratories is potentially risky and often exposes service providers to harm. The magnitude of the infections, injuries and contamination originating from health laboratories may vary from mild to fatal. Many laboratory workers in Uganda may have been and continue to be victims of laboratory related accidents. However, inadequate documentation makes quantification of the problem difficult.

Many laboratories lack amenities such as reliable power source, safe water and effective mechanisms for safe waste disposal and infection control. Other health system gaps include: lack of proper training, inadequate resources, faulty equipment, poor techniques and re-use of single use items.

Biorisk assessment is important to identify gaps in Biorisk management in facilities and inform mitigation measure to put in place for the prevention, detection and control of laboratory risks.

The checklist runs from section 1 to section 17. The assessment can be conducted through interviews, observations and document reviews.

**Instructions:**

- Conduct interviews by open-ended questions to clarify documentation seen and observations made. Most questions require a YES, NO answer. Tick in the provided boxes for Yes, No and where not applicable (NA) provide appropriate comments.
- Review the available national laboratory guidelines and protocols to verify that the laboratory safety manual, policies, logs, SOPs and other manuals are complete, current, accurate, and regularly reviewed.

**Section 1: General Facility Information**

| | |
|---|---|
| Unique Identifier | |
| GPS Coordinates | Longitude……..<br>Latitude…… |
| Assessment Date: | |
| Name of interviewer: | |
| Name of interviewee: | |
| Title of interviewee | |
| Duration worked in facility: | Years…….. Months…… |
| Name of facility: | |

| | |
|---|---|
| Accreditation status | Enrolled<br>Accredited<br>Not enrolled not accredited |
| Level of the facility: | National Referral Hospital<br>Regional Referral Hospital<br>Special Health training Institution lab<br>Research laboratory<br>**General** Hospital<br>Health Center 4<br>Health Center 3 |
| Type of facility: | Government<br>Private not-for-profit<br>Private<br>Faith based |
| Name of Facility In-charge: | |
| Region | Eastern<br>East central<br>Kampala<br>North East<br>North central<br>South Western<br>Western<br>West Nile<br>Central |
| District: | |
| Physical and postal address: | |
| Telephone: | |
| Email: | |
| Average Out-patient attendance per month | |
| Total number of laboratories in the health facility | |
| General notes: | |

**Section 2: Laboratory Premises and Physical security**

| Item | Yes | No | Comments: NA, Not Functional |
|---|---|---|---|
| | | | |

| | | | |
|---|---|---|---|
| 1. Have guidelines for commissioning and certification been considered for facility construction or post-construction evaluations?[1] | | | |
| 2. Is the facility protected from external and natural disasters: | | | |
| a) Lightening | | | |
| b) Secure perimeter | | | |
| c) Burglary proof | | | |
| d) Security guards? | | | |
| 3. Are the premises generally clean and well organized? | | | |
| 4. Are floors and walls smooth for easy cleaning? | | | |
| 5. Is the working space adequate for safe operation? | | | |
| 6. Are the circulation spaces and corridors adequate for the movement of people and large equipment? | | | |
| 7. Are the benches, furniture and fittings in good condition? | | | |
| 8. Are bench surfaces resistant to solvents and corrosive chemicals? | | | |
| 9. Are the premises constructed and maintained to prevent entry and harboring of rodents and arthropods? | | | |
| 10. Is there restricted access to laboratory rooms to unauthorized personnel? | | | |
| 11. Has any Biorisk assessment been conducted in this laboratory in the last 5 years? | | | |
| 12. Does the laboratory have a list of emergency responders with their contacts clearly displayed? | | | |

**Section 3: Storage facilities**

| | | | |
|---|---|---|---|
| 1. Does the laboratory have its own store room for supplies? | | | |
| 2. Are storage facilities, shelves, etc. arranged so that stores are secure against sliding, collapse or falls? | | | |
| 3. Are storage facilities kept free from accumulations of rubbish, unwanted materials and objects that present hazards from tripping, fire, explosion and harboring of pests? | | | |
| 4. Is there restricted access to sample and isolate storage areas? | | | |
| 5. Is cold chain items stored at appropriate temperatures? | | | |

**Section 4: Sanitation and staff facilities**

| | | | |
|---|---|---|---|
| 1. Do lab staffs have access to safe drinking water supply? | | | |
| 2. Are clean and adequate toilet (WC) and washing facilities provided for staffs? | | | |
| 3. Is there a changing rooms provided for staffs? | | | |

[1] Ask facility in charge

| | | | |
|---|---|---|---|
| 4. Is there accommodation (e.g. lockers) for street clothing for the staffs? | | | |
| 5. Is there a staff room for tea, break, lunch, etc.? | | | |
| 6. Is there a dedicated room for night duty staffs? | | | |

**Section 5: Lighting and ventilation**

| | | | |
|---|---|---|---|
| 1. Does the laboratory monitor environmental temperatures? | | | |
| **2.** Is the laboratory well ventilated and cross ventilated? | | | |
| 3. Does mechanical ventilation compromise airflows in and around biological safety cabinets and fume cupboards? | | | |
| 4. Are all areas well-lit (including corners of rooms and corridors)? | | | |
| 5. Are Ceiling lights mounted parallel to work surfaces? | | | |

**Section 6: Services**

| | | | |
|---|---|---|---|
| 1. Is each laboratory room provided with at least one hand washing sink and running water? | | | |
| 2. Is staining sink corrosion, acid and stain resistant? | | | |
| 3. Does the facility have electricity supply? | | | |
| 4. Is there a backup power available in case of power breakdown? | | | |
| 5. Is there an adequate inspection and maintenance program for fuses, lights, cables, pipes, etc.? | | | |
| 6. Are cleaning services available? | | | |
| 7. Is the access of cleaning personnel to various laboratory areas controlled and documented? | | | |

**Section 7: Laboratory biosecurity**

| | | | |
|---|---|---|---|
| 1. Has a qualitative risk assessment been performed to define risks that a security system should protect against? | | | |
| 2. Have acceptable risks and incidence response planning parameters been defined? | | | |
| 3. Is the whole building securely locked when unoccupied? | | | |
| 4. Are doors and windows break-proof? | | | |
| 5. Are rooms containing hazardous materials and expensive equipment locked when unoccupied? | | | |
| 6. Is access to such rooms, equipment and materials appropriately controlled and documented? | | | |

**Section 8:Fire prevention and fire protection**

| | | | |
|---|---|---|---|
| 1. Is there a fire alarm system? | | | |
| 2. Is the fire detection system in good working order and regularly tested? | | | |

| | | | |
|---|---|---|---|
| 3. Are lab rooms equipped with firefighting equipment? | | | |
| a) Fire Extinguisher | | | |
| b) Fire Blanket | | | |
| c) Sand Bucket | | | |
| d) Water Horse | | | |
| 4. Are portable fire extinguishers maintained fully charged and in working order, and kept in designated places at all times? | | | |
| 5. Is all fire-fighting equipment and apparatus easily identified by an appropriate colour code? | | | |
| 6. Does the laboratory have emergency exits? | | | |
| 7. Is access to emergency exits properly marked and illuminated? | | | |
| 8. Are all exits unobstructed by decorations, furniture and equipment, and unlocked when the building is occupied? | | | |
| 9. Is access to exits arranged so that it is not necessary to pass through a high-hazard area to escape? | | | |
| 10. Do all exits lead to an open space? | | | |
| 11. Are corridors, aisles and circulation areas clear and unobstructed for movement of staff and fire-fighting equipment? | | | |
| 12. If flammable liquids and gases are used in any room, is the mechanical ventilation sufficient to remove vapours before they reach a hazardous concentration? | | | |
| 13. Are personnel trained to respond to fire emergencies? | | | |

## Section 9: Chemical Hazards

| | | | |
|---|---|---|---|
| 1. Is there a complete inventory of chemicals which are regularly updated? | | | |
| 2. Are all chemicals labelled and MSDS available in the work place and easily accessible to every employee? | | | |
| 3. Are chemicals stored based on compatibility (acids separated from caustics, etc.) | | | |
| 4. Are lab chemicals stored in proper, ventilated containers that are made of non-combustible and corrosive materials? | | | |
| 5. Are laboratory chemicals clearly marked and stored away from fire sources? | | | |
| 6. Are personnel trained to properly use and transport laboratory chemical? | | | |
| 7. Are spill kits provided? | | | |
| 8. Are staff trained to deal with spills? | | | |

## Section 10: Compressed and liquefied gases

| | | | |
|---|---|---|---|
| 1. Is each portable gas container legibly marked with its contents and correctly colour-coded? | | | |

| | | | |
|---|---|---|---|
| 2. Are cylinders and liquid petroleum gas tanks kept away from sources of heat? | | | |
| 3. Are personnel trained to properly use and transport compressed and liquefied gases? | | | |

**Section 11: Electrical hazards**

| | | | |
|---|---|---|---|
| 1. Are sockets located above the worktop and away from sinks and other wet places? | | | |
| 2. Does the electrical cabling interfere with movement of personnel? | | | |
| 3. Is there provisions for additional sockets to allow flexibility in case of additional equipment/reorganization of floor plan? | | | |
| 4. Are the flexible connecting cables of all equipment as short as practicable, in good condition, and not frayed, damaged or spliced (inspect conditions of insulation)? | | | |
| 5. Is each electric socket outlet used for only one appliance (no adapters to be used)? | | | |

**Section 12: Personal protection**

| | | | |
|---|---|---|---|
| 1. Is protective clothing of approved design and fabric provided for all staff for normal work, e.g. gowns, coveralls, aprons, gloves? | | | |
| 2. Is additional protective clothing provided for work with hazardous chemicals and radioactive and carcinogenic substances, e.g. rubber aprons and gloves for chemicals and for dealing with spillages; heat-resistant gloves for unloading autoclaves and ovens? | | | |
| 3. Are safety glasses, goggles and shields (visors) provided? | | | |
| 4. Are there eye-wash stations? | | | |
| 5. Are there emergency showers (drench facilities)? | | | |
| 6. Are respirators (e.g. N95, N100, PAPR and SCBA) available, regularly cleaned, disinfected, inspected and stored in a clean and sanitary condition? | | | |
| 7. Are respirators fit-tested? | | | |
| 8. Are mechanical pipetting devices available for use? | | | |

**Section 13: Health and safety of staff**

| | | | |
|---|---|---|---|
| 1. Is there an occupational health service? | | | |
| a) Medical checks (HIV, X-ray, etc.) | | | |
| b) Vaccination (Hepatitis B) | | | |
| c) Post Exposure Prophylaxis (PEP) | | | |
| d) Chemicals exposure | | | |

| | | | |
|---|---|---|---|
| 2. Is there a protocol for reporting any laboratory infections? | | | |
| a) Health facility management | | | |
| b) District | | | |
| c) National | | | |
| 3. Are first-aid boxes provided at strategic locations? | | | |
| 4. Are staff trained in first-aid provision? | | | |
| 5. Are non-laboratory workers, e.g. domestic and clerical staff, oriented on lab safety? | | | |
| 6. Are proper records maintained of illnesses and accidents? | | | |
| 7. Are warning and accident prevention signs used to minimize work hazards? | | | |
| 8. Are personnel trained to follow appropriate biosafety practices? | | | |
| 9. How familiar are the staffs with national and international standards for biological laboratory safety? | | | Scale:1(low) 5(high):<br>1 2 3 4 5 |

## Section 14: Laboratory equipment

| | | | |
|---|---|---|---|
| 1. Are the following safety equipment available? | | | Check:Functionality, Documents |
| a) Biological Safety Cabinet | | | |
| b) Centrifuges | | | |
| c) Autoclaves | | | |
| d) Vortex | | | |
| e) Hot Air Oven | | | |
| f) Freezers | | | |
| g) Fume hood | | | |
| 2. Are procedures available for decontaminating equipment prior to maintenance? | | | |
| 3. Are biological safety cabinets and fume cupboards regularly tested and serviced (check for service certificate)? | | | |
| 4. When was the last time your BSC was certified? | | | |
| 5. Are autoclaves and other pressure vessels regularly inspected? | | | |
| 6. Are centrifuge buckets and rotors regularly inspected? | | | |
| 7. Are HEPA filters regularly changed? | | | |

| | | | |
|---|---|---|---|
| 8. Is cracked and chipped glassware always discarded and not reused? | | | |
| 9. Are sharps disposal containers available and being used? | | | |

**Section 15: Waste management**

| | | | |
|---|---|---|---|
| 1. Is the national protocol for waste management available? | | | |
| 2. Is there a mechanism for segregation of lab waste? | | | |
| 3. Are waste containers properly labeled and secured and inspected for integrity (leaks, cracks, worn out)? | | | |
| 4. Are waste storage and processing systems are not visible to the outside? | | | |
| 5. Are biological wastes decontaminated (Autoclave, disinfectant, etc.) prior to disposal? | | | |
| 6. Are items decontaminated off site placed in durable leak proof closed containers prior to transport? | | | |
| 7. Are the waste handlers aware of the risk to hazards? | | | |

**Section 16: Infectious materials/Biological safety**

| | | | |
|---|---|---|---|
| 1. Is there signs indicating that eating, drinking, smoking, handling contact lenses and applying cosmetics are prohibited (hazard warning symbols)? | | | |
| 2. Are specimens received in a safe condition (Inspect packaging, sample container for leakages, etc.)? | | | |
| 3. Is there a log book for all specimen referrals? | | | |
| 4. Are specimens unpacked in biological safety cabinets with care and attention to possible breakage and leakage? | | | |
| 5. Are gloves and other protective clothing worn for unpacking specimens? | | | |
| 6. Is there any laboratory staff trained to ship infectious substances according to current national and/or international regulations (Attended biosafety training)? | | | |
| 7. Are other personnel involved in shipment of infectious substances (hub sample transport network) trained in biosafety | | | |
| a) Hub coordinator | | | |
| b) Hub riders | | | |
| c) Posta staff | | | |
| 8. Is there a mechanism for tracking biological specimens? | | | |
| 9. Is there a protocol for reporting any missing biological specimen? | | | |
| 10. Are all laboratory procedures performed carefully to minimize splashes or aerosols? | | | |
| 11. Are infectious wastes/materials removed daily from the work bench and disposed of safely? | | | |
| 12. Are all staff aware of procedures for dealing with breakage and spillage of cultures and infectious materials (Check documents)? | | | |

| | | | |
|---|---|---|---|
| 13. Is the performance of sterilizers checked by the appropriate chemical, physical and biological indicators (Check documents)? | | | |
| 14. Do you have any of the following disinfectants? | | | |
| a) 5% Lysol | | | |
| b) 70% Ethanol | | | |
| c) Sodium hypochlorite (Jik) | | | |
| 15. Is there special training for staff who work in containment laboratories – Biosafety Level 3 and maximum containment laboratories – BSL 4? | | | |

**Section 17: Documentation**

| | | | |
|---|---|---|---|
| 1. Are national guidelines and protocols for laboratory waste management available, in this laboratory ( *confirm availability by asking to see copies)* | | | |
| 2. Is there a Laboratory Biosafety manual in this laboratory? *(Ask to see copy)* | | | |
| 3. Are national guidelines for specimen collection, packaging and shipment available? | | | |
| 4. Are there written national guidelines for disposal of damaged or expired products? | | | |
| 5. Are the national standard operating procedures (SOPs) for testing of infectious substances available? | | | |
| 6. Is there a national policy on infection prevention and control in the laboratory? | | | |
| 7. Do you have a laboratory safety checklist? | | | |

## APPENDIX 3: LABORATORY ERGONOMIC WORKSTATION EVALUATION CHECKLIST

This checklist can help identify risk factors that can contribute to work-related musculoskeletal problems. Contact your supervisor to obtain help or assistance with issues that are identified.

1. **Laboratory Benches:**
    a) Is the height of your bench appropriate for work tasks? Precision work above elbow height; light work just below elbow height; heavy work 6 inches below elbow height)
    b) Do you wear supportive shoes and/or have a floor mat for standing tasks?
    c) Can you prop up a foot on a stool or ledge when standing in one spot?
    d) Do you work at a bench cut-out?
    e) Does the bench have rounded or padded edges?
2. **Bench Chair or Stool:**
    a) Does your chair support your back while you work?
    b) Does the seat and seatback tilt forward?
    c) Are your feet on the floor, a foot-ring or a footrest?
    d) If you have armrests, can they be adjusted to support your arms when working?
3. **Microscopes**
    a) Can you view the eyepiece while sitting in an upright position?
    b) Is the microscope pulled out to the edge of the workbench?
    c) Are your arms supported and relaxed when using the microscope?
4. **Pipetting**
    a) Are electronic, light-touch, or latch mode pipettes available for intensive pipetting?
    b) Is the pipette designed for multiple finger use (instead of only the thumb)?
    c) Are trays, beakers and supplies placed within easy reach?
    d) Are your wrists in a straight or neutral position when working?
5. **Biological Safety Cabinets**:
    a) Are your arms relaxed when working in the fume hood?
    b) Are work supplies within easy reach in the cabinet?
    c) Are vials, tubes and receptacles as low profile as possible?
    d) Can you see your work without tilting your head and neck?
    e) Can you alternate sitting and standing while working?
6. **Miscellaneous**
    a) Can you operate your microtome with your hand in a pistol grip position?
    b) Do you alternate fingers when using pinch grips or forceps?
    c) Are vials easy to cap and thread?
    d) Are supplies and tools within easy reach?
    e) Are chemical and gas valves easy to reach and turn?
    f) Are bottle dispensers and bottom dispensing carboys available to dispense liquids?
    g) Are heavy bottles and boxes stored on low shelves?
    h) Do you try to take a break and change tasks every 20-30 minutes?

## APPENDIX 4: RISK ASSESSMENT TEMPLATES

### I. Procedure for identifying risks

The Biorisk assessment form should be completed for any activity, task, before the activity begins.

| Step | Action | Deliverable |
|---|---|---|

| | | |
|---|---|---|
| 1 | Identify hazards and their potential for causing harm. | An inventory of hazards. |
| 2 | Rank hazards by priority | A ranked list of hazards.<br>This list will be useful in planning further action. |
| 4 | Implement controls. | Controls are in place and functioning appropriately. |
| 5 | Measure the effectiveness of controls. | Monitor periodically to confirm controls continue to function. |
| 6 | Make changes to improve continuously. | Monitor for improvements. |

## II. Sample of a Biorisk assessment form

The following is a sample. Be sure to customize it for your needs at your workplace.

| **Facility Name and Address** | |
|---|---|
| Name of person doing assessment: | |
| Date: | |
| Activity / Procedure being assessed: | |
| Known or expected hazards associated with the activity: | |
| The risk of injury and its severity likely to arise from these hazards: | |
| Who/What is at risk? | |
| Measure to be taken to reduce the level of risk: | |
| Training prerequisites: | |
| Level of risk remaining: | |
| Action to be taken in an emergency: | |
| References, if any: | |
| Signature of Assessor: | |

***Adapted from Canadian Centre for Occupational Health & Safety (1997-2012)***

## APPENDIX 5: OCCURRENCE MANAGEMENT FORM

**OCCURRENCE MANAGEMENT FORM**

| | | | | |
|---|---|---|---|---|
| **Date of Occurrence:** | **Date of Reporting:** | | | |
| **Time of Occurrence:** | **Personnel Reporting:** | | | |
| **Requires immediate attention by Supervisor:** | | **Yes** | | **No** |
| **Location of Occurrence:** | **Particulars (ID No.):** | | | |

| |
|---|
| **Problem encountered (brief description of occurrence):** |

| |
|---|
| **Immediate actions taken (If any):** |

| |
|---|
| **Root cause Analysis:** |

| |
|---|
| **Corrective Action Plan:** |

| | |
|---|---|
| **Follow-Up Action/Supervisors comments:** | |
| **Signature of Reviewer/Supervisor:** | **Date:** |

## APPENDIX 6: SHIPPERS DECLARATION FOR DANGEROUS GOODS SHIPPED BY ROAD

**SHIPPER'S DECLARATION FOR DANGEROUS GOODS**
**- SHIPPED BY ROAD**

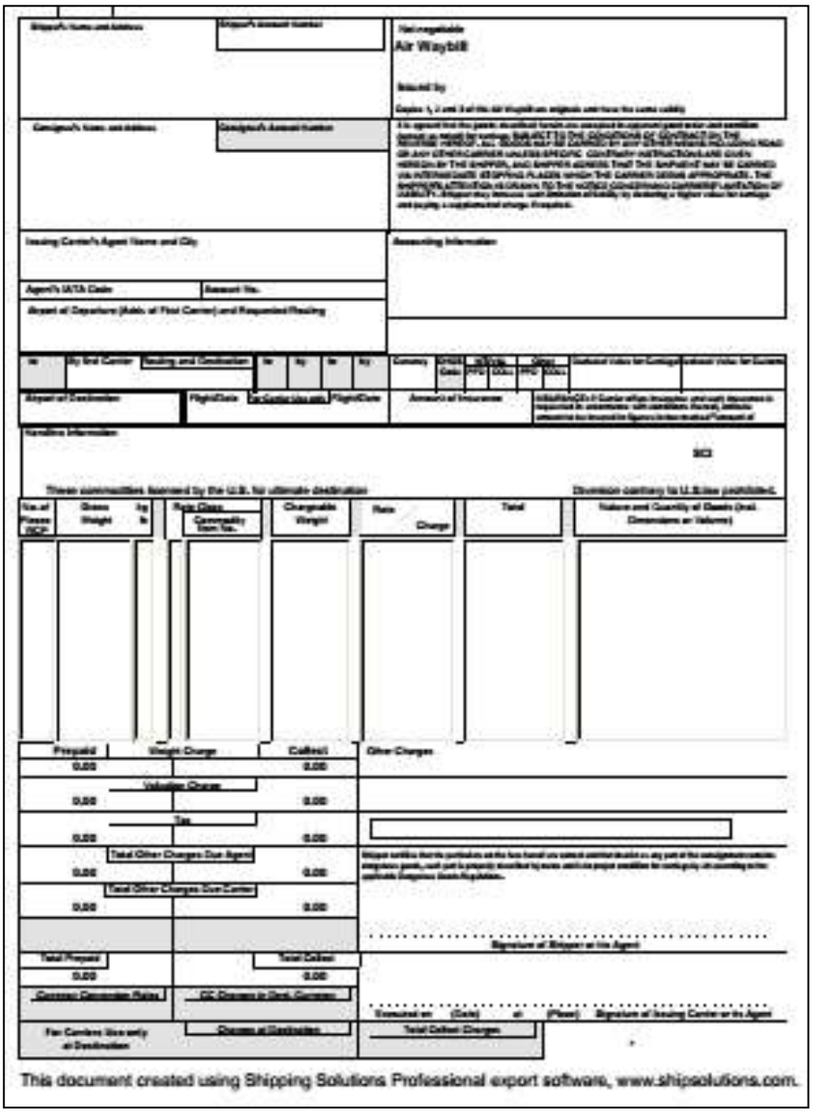
| Consignor | Consignee |
|---|---|
| | |
| **Carrier:** | **Shipping Document #:** |

| Number of Packages | Description of Articles | Weight or Volume of Package |
|---|---|---|
| | | |
| **Special Handling:** | | |
| **24 Hour Emergency Response Telephone Number:**<br>Dalhousie University Security - 902-494-4109 | | |

**Consignor's Declaration:**
"I hereby declare that the contents of this consignment are fully and accurately described by proper shipping name and are classified, packed, marked and labelled, and are in all respects in proper condition for transport by air and road according to the applicable international governmental regulations."

| Signature: | Date: | Phone Number: |
|---|---|---|
| | | |

## APPENDIX 7: SHIPPERS DECLARATION FOR DANGEROUS GOODS SHIPPED BY AIR



## APPENDIX 8: AIRWAY BILL - SHIPPERS DECLARATION FOR DANGEROUS GOODS

WARNING

Failure to comply in all aspects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

PASSENGER AND CARGO AIRCRAFT

CARGO AIRCRAFT ONLY

RADIOACTIVE

## ANNEX 9 : (INFORMATIVE)

Decontamination, cleaning and disinfection following spillage

### C. l General

This annex is intended to assist in developing specific protocols for the decontamination, cleaning and disinfection where accidents or spills have resulted in contamination. This annex can also assist in developing suitable protocols for preparing and making equipment biologically safe before service or repair.

### C. 2 Chemical spills

In the event of a spill or leak of a volatile toxic, corrosive or flammable chemical, the following steps are to be performed by trained personnel:

a) Select the appropriate eye, skin and respiratory protective equipment required for safe re-entry into spill area — refer to the SDS, suitable reference, product supplier or other resource person.
b) Determine the methods and materials required to clean up the spill as demonstrated in Table _C 1.
c) When applying adsorbents or neutralizers, start slowly and from the perimeter of the spill working inwards in order to contain the spill and to minimize the surface area.
d) Continue until the entire spill has been adsorbed or neutralized.
NOTE pH paper is useful in verifying whether neutralization of a corrosive spill is complete.
e) Wash spill area to remove any residues.
f) Package all contaminated materials in a suitable container, attach a label and submit for waste disposal.

**Table C.l — Spill clcan-up**

| Spill Type | Spill Control Pillows | Activated Charcoal | Acid Neutralizer | Caustic Neutralizer | Mercury Vacuum or spill kit |
|---|---|---|---|---|---|
| Solvents | X | X | | | |
| Acids | X | | X | | |
| Caustics (Bases) | X | | | X | |
| Other liquids | X | | | | |
| Mercury | | | | | X |

NOTE This table is based on the Laboratory Safety CSMLS Guidelines — Eighth edition.

### C.3 Biological spills C.3.1 General

The following procedures arc recommended for decontaminating spills of blood, body fluids or other infectious materials (including culture materials) that occur in the medical laboratory. Spills in other sites can require modification of these procedures.

**C.3.2 Decontamination of spills**

The factors which influence decontamination procedures are:

a) volume of spill;
b) which body fluid is spilled;
c) protein content; -
d) infectious agent present;
e) concentration of infectious agent; and
f) Nature of the surface (porous vs. water-resistant).

**C.3.3 Personal protective equipment**

Wear gloves, gown and facial protection. As aerosols inevitably exist, or arc created during spill cleanups. Respiratory protection is strongly advised. Heavyweight, puncture resistant utility gloves such as those used for house-cleaning and dishwashing are recommended.

If the spill contains broken glass or other objects, these should be removed and discarded without contact with the hands. Rigid sheets of cardboard or disposable plastic scoops with a pusher component used as a "pusher" and "receiver" may be used to handle such objects; or tongs and forceps may be used. These should be discarded, along with the objects themselves, into an appropriate puncture-resistant biohazard container.

If the spill is large and/or the worker's shoes could potentially be contaminated, water-impermeable shoe covers should be worn.

With spills of culture media and materials, the site should be covered completely with an absorbent material (see Cri). After a period of 10 min, the clean-up procedure as described below should be initiated. If droplet formation is likely to have occurred (e.g. breakage within a centrifuge), the equipment should remain closed for at least 30 min to allow hlood/body fluid droplets to settle before decontamination begins.

**C.3.4 Measures to absorb the spill**

Since most disinfectants are less active or even ineffective in the presence of high concentrations of protein as arc found in blood and serum, the bulk of the spilled liquid should be absorbed prior to decontamination.

Absorb the spilled material with disposable absorbent material (e.g. paper towels, gauze pads or tissue paper wipes). If the spill is large, granular absorbent material such as that used to absorb caustic chemical spills may be used to absorb the liquid. Finely granulated silica gels arc available which, when sprinkled on a spill, congeal the liquid immediately. The gelatinous mass may then be scraped up rather than blotted. Absorbent granular materials and silica gels containing a chemical which releases chlorine upon wetting are available. The efficacy of such material in decontamination is not known, and therefore they should not be relied upon to decontaminate a spill. After absorption of the liquid, all contaminated materials should be discarded in the biohazard waste container.

**C.3.5 Decontamination of the spill site**

Decontaminate the spill site using an appropriate hospital disinfectant, such as a 1 to 10 aqueous dilution of household bleach. Flood the spill site, or wipe down the spill site with disposable towels soaked in disinfectant to make the site "glistening wet" and then allow the site to dry.

Do not use low-level disinfectants, such as quaternary ammonium compounds. Phenolic disinfectants arc not recommended for use on contaminated medical devices which come into contact with unprotected patients or laboratory workers, but may be used on laboratory devices, floors and counter tops.

Absorb the disinfectant solution with disposable material. Alternatively, the disinfectant may be permitted to dry.

**C.3.6 cleaning of the spill site** *

When the spilled material is seen to be dry, fully absorbed, and has been decontaminated, clean the site to make it safe.

Rinse the spill site with detergent and water to remove any noxious chemicals or odours.

Dry the spill site to prevent slipping.

Place all disposable materials used to decontaminate the spill into a biohazard container. Handle the material in the same manner as other infectious waste. Any reusable materials should be decontaminated prior to storage.

A "biohazard spill kit" containing all the materials and protective equipment needed should be prepared and made readily available in all areas where spills are likely to occur. A portable "biohazard spill cart" should be available for transport to areas remote from the laboratory (e.g. the patient's bedside in case a spill occurs during phlebotomy).

**C.4 Eye exposure to hazardous chemicals**

Flush the eye immediately with water while holding the eye open with f ingers.

If wearing contact lens, remove and continue to rinse the eye with water.

Continue to flush the eye and seek immediate medical attention.

**C.5 Acid/base spills**

For a spill, not directly on human skin, do the following:

Neutralize acids with powdered sodium hydrogen carbonate (sodium bicarbonate/baking soda), or bases with vinegar (5 % acetic acid solution).

Avoid inhaling vapours.

Spread diatomaceous earth to absorb the neutralized chemicaL "

Sweep up and dispose of as hazardous waste.

For spills directly on human skin, do the following:

Flush area with copious amounts of cold water from the faucet or drench shower for at least 5 min.

If spill is on clothing, first remove clothing from the skin and soak the area with water as soon as possible.

Arrange treatment by medical personnel.

**C.6 Mercury spills**

**Evacuate the affected area.**

Close off interior doors and windows, and heating and air conditioning vents in the incident room. Open exterior doors and windows to move the inside air outside.

Review and follow specific clean-up instructions advised by the local or national authority.

ANNEX D: REFERENCES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