Biosafety Manual

First Edition, December 2018

IFBA Sample Biosafety Manual

Disclaimer:
Information contained in this sample biosafety manual is provided by the International Federation of Biosafety Associations (IFBA) to their Member Biosafety Associations as an example and for reference purposes only. Prior to adopting any of the IFBA's documents, the IFBA strongly encourages its Member Biosafety Associations to develop policies and procedures that reflect their specific circumstances and applicable local guidelines, standards, and legislation. The information in the IFBA's sample biosafety manual is directed to those who have the appropriate degree of experience to use and apply its contents. The IFBA accepts no responsibility whatsoever arising in any way from use of or reliance on the information published in this document. The IFBA makes no legal representation concerning the adequacy of these policies and procedures or their compliance with local laws. In no event shall the IFBA be liable for any direct, indirect, incidental, special, or consequential damages that result from the use of or inability to use the document.

Redistribution:
The International Federation of Biosafety Associations grants permission to its Member Biosafety Associations to redistribute, use, and adapt the IFBA Sample Biosafety Manual for non-commercial use provided that the following conditions are met:

1. Redistributions of the document, or parts of document, must retain the IFBA cover page containing the disclaimer.
2. Due diligence is exercised in ensuring the accuracy of documents reproduced.
3. The IFBA is acknowledged as the source of the information and is appropriately cited as follows: "This document is based on the Sample Biosafety Manual developed by the International Federation of Biosafety Associations for use by its Member Biosafety Associations".
4. Policies and procedures developed by IFBA Member Biosafety Association are not represented as an official IFBA version, nor as having been endorsed by the IFBA.
5. The use of the IFBA logo is not permitted on policies and procedures developed by IFBA Member Biosafety Associations.

Forward

This Biosafety Manual contains information on *Laboratory ABC's* biosafety and biosecurity program to protect workers and the surrounding environment from possible risks to infectious biological materials. Specific operational procedures for the laboratory are outlined in the *Laboratory ABC's* Standard Operating Procedures. The implementation of safety and security practices to prevent laboratory-acquired infections and the spread of contamination is a part of *Laboratory ABC's* everyday routine laboratory activities. All *Laboratory ABC* employees are required to read and understand this document prior to beginning any work with biological materials in the laboratory.

Emergency Numbers

If the emergency is potentially **life-threatening or severe** then **call** ***insert phone number***

Biosafety Officer (name):	*insert phone number* (office) *insert phone number* (cell)
Laboratory Supervisor (name):	*insert phone number* (office) *insert phone number* (cell)
Laboratory ABC –	*insert phone number*

Disclaimer: The information contained in this manual is developed from a variety of recognized resources, and every effort has been made to ensure accuracy. *Laboratory ABC* views this manual as a "living" document that can continue to be improved. Any suggestions for improvement, errors or omissions should be brought to our attention.

Laboratory ABC
Insert address

Table of Contents

1.0 INTRODUCTION

1.1 Laboratory ABC

Insert description of Laboratory ABC mandate and functions.

1.2 Biosafety Program & Policy Statement

Laboratory ABC's Biosafety Program covers both biosafety and biosecurity. "Biosafety" encompasses all aspects of containment to prevent any exposure to and accidental release of an infectious biological agent. "Biosecurity" is implemented to prevent the theft, misuse, or intentional release of biological agent.

The intent of Laboratory ABC's biosafety program is to provide a safe, healthy, and secure working environment for all members of staff and visitors, and to delineate responsibility for achieving it. The program includes a formal mechanism to identify, reduce, and monitor the risks associated with potentially hazardous infectious materials. The policies and procedures of the biosafety program apply to all activities involving the storage, use, transportation, and disposal of infectious materials in the laboratory facility. The primary responsibility for ensuring safe conduct and conditions in the laboratory lies with the Laboratory Supervisor who makes sure all his/her workers are familiar with biosafety program and Standard Operating Procedures (SOPs). In addition, Laboratory ABC's Biosafety Officer has been assigned to oversee biosafety and biosecurity practices in the laboratory. Best practices in safety and security are continually evolving and Laboratory ABC is committed to keeping abreast of these changes, to communicating them to employees through the Biosafety Officer, and to ensure ongoing compliance with this manual and the SOPs.

Activities involving the handling of infectious biological materials are governed by various legislation, guidelines, and standards. Adherence to the requirements of Laboratory ABC's biosafety program will ensure work is being performed in compliance with these laws and regulations and the requirements of external agencies and regulatory bodies. They include, but are not limited to:

- *Insert list of applicable national regulatory requirements here*
- World Health Organization, Laboratory Biosafety Manual, 3rd Edition

Policy Statement

Laboratory ABC is fully committed to a safe, healthy, and secure work environment in which to carry out its activities. All possible preventive measures are taken to eliminate biosafety and biosecurity risks to personnel and the surrounding environment. It is Laboratory ABC's policy to comply with all applicable legislation and personnel are expected to follow the highest standards of safety and security.

1.3 Laboratory Staff and Emergency Contact Numbers

Insert additional contacts here

If the emergency is potentially **life-threatening or severe** then **call** ***insert phone number***

Biosafety Officer (name):	*insert phone number* (office)
	insert phone number (cell)
Laboratory Supervisor (name):	*insert phone number* (office)
	insert phone number (cell)
Laboratory ABC –	*insert phone number*

1.4 Roles & Responsibilities

Laboratory ABC

It is the responsibility of Laboratory ABC management to:

- Take every reasonable precaution to ensure the workplace is safe, healthy, and secure;
- Train employees about any potential hazards and in how to safely and secure store, use, transport, and dispose of infectious biological materials;
- Train employees on how to handle emergencies involving the laboratory;
- Ensure the laboratory is routinely inspected and action is taken as required to improve unsafe conditions;
- Ensure compliance with relevant legislation, guidelines, and standards;
- Support the Laboratory Supervisor and Biosafety Officer in the implementation of an effective biosafety program;
- Ensure adequate resources are made available to implement appropriate procedures and maintain a safe workspace; and,
- Foster a "culture of safety & responsibility" at Laboratory ABC laboratory and among employees.

Laboratory Supervisor

It is the responsibility of the Laboratory Supervisor to:

- Ensure laboratory staff are familiar with and follow the procedures in the Biosafety Manual and Standard Operating Procedures;
- Conduct risk assessments and develop specific safety and security procedures applicable to diagnostic activities carried out in the laboratory;
- In coordination with the Biosafety Officer, provide training on all safe working procedures with infectious biological materials, safe operation of the laboratory, equipment and emergency procedures;
- In coordination with the Biosafety Officer, regularly inspect the laboratory and promptly correct any unsafe work practices or hazardous conditions;

- Immediately report and investigate any accidents, injuries, and incidents; and,
- Be responsive to safety and security concerns expressed by employees and foster an atmosphere of trust.

Employees
It is the responsibility of individual employees working in the laboratory to:

- Observe all safety and security procedures established by the Laboratory Supervisor, Biosafety Officer and Laboratory ABC management;
- Use properly, and care for, all personal protective equipment, biocontainment equipment and security equipment;
- Report as soon as possible any accident, injury, incident, unsafe condition or threats to security; and,
- Be safety conscious in all activities.

Biosafety Officer
It is the responsibility of the Biosafety Officer to:

- Provide technical guidance on, coordinate and administer the biosafety program for the laboratory;
- Participate in risk assessments pertaining to the handling of infectious biological materials in the laboratory ;
- Monitor & account for biological materials that enters, is held within, or leaves the laboratory;
- Conduct periodic safety and security inspections and advise Laboratory ABC management on any matters requiring their attention;
- Keep abreast of new information and requirements related to the safe and secure handling of biological materials in a laboratory environment;
- Coordinate training for employees who are working in the laboratory;
- Advise Laboratory ABC management on personnel trained and authorized to work in the laboratory; and,
- Provide guidance and information related to compliance with applicable legislation, standards and guidelines.

1.5 Orientation & Training

Laboratory ABC requires that, as a condition of working in the laboratory, all employees have both general and activity-specific training in the safe and secure handling of biological materials in the laboratory. Training is provided prior to initiation of work and includes training on the process of a risk assessment for working with infectious materials handled in the laboratory, the laboratory physical design and operational practices, the correct use of the biosafety cabinets, disinfection and decontamination procedures, the proper use of personal protective equipment, the procedures for accidental exposures and other emergencies, and information on the legislative requirements related to activities at

Laboratory ABC. Additional and refresher training is provided based on an ongoing needs assessment and when warranted by a change in the biosafety program. All training must be documented and records kept on file.

Employees may not work unsupervised in the laboratory until they have completed the training outlined below, and demonstrated to the Laboratory Supervisor that they have fulfilled these requirements:

- Read and understand the contents of this manual and the Standard Operating Procedures; take and pass the biosafety quiz (open-book test) that is based on this material to demonstrate knowledge. All employees are required to sign a statement that they have read and understood the contents of the manual and SOPs.
- Read and be generally familiar with the content of the World Health Organization's Laboratory Biosafety Manual.
- Obtain hands-on training from the Laboratory Supervisor and Biosafety Officer on the specific operational biosafety and biosecurity procedures for working in the laboratory.
- Participate in ongoing refresher training, courses and drills that may be offered; refresher training in emergency response procedures is provided annually.

In addition to providing training for laboratory employees, safeguarding the health of maintenance and support personnel working in and around the laboratory is an essential component of the training program. Before any maintenance work is carried out, such personnel must be provided with training on the biological and other hazards that may present in the laboratory and the practices and procedures to conduct their work safely.

See Appendix A – Memorandum of Understanding for Laboratory ABC Authorized Users

Please refer to the SOP "Employee Biosafety Orientation and Training" for specific details on training program content and a copy of the "Record of Training" form.

1.6 Non-Compliance & Enforcement Policy

Laboratory ABC has developed a policy for monitoring compliance with this manual and with the requirements of the Standard Operating Procedures. Situations that do not conform to the requirements are identified and corrected to prevent undesirable consequences. Compliance violations can either be minor (i.e. poses no immediate risk to health & safety) or major (i.e. causes an immediate risk to health & safety, or could case release of biological hazards into the surrounding environment).

On the first occurrence of non-compliance, the Laboratory Supervisor will send a written notification to the Biosafety Officer outlining the nature of the infraction. Response to and correction of the violation is required within the frame specified (in the case of major infractions, an immediate correction of the infraction is required). On a second occurrence

of the same infraction or where there is no response to the first infraction, the Biosafety Officer will notify management who will suspend privileges to work in the laboratory. Privileges will be restored upon written verification from the Biosafety Officer indicating rectification of the infraction.

Laboratory ABC management shall take immediate action in cases of unacceptable risk to employees, the public, the environment, the property, security and/or gross disregard to health and safety. Action may include the immediate suspension of laboratory activity, prohibited entry to the laboratory, and/or removal of infectious material from the premises.

2.0 HAZARDS & RISKS in the LABORATORY

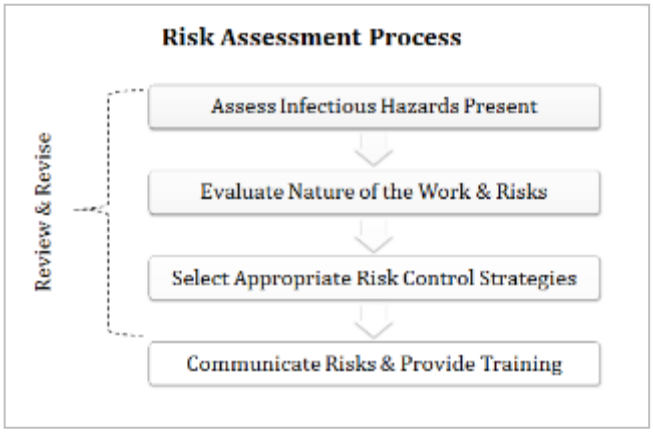
2.1 Identifying Hazards & Risk Assessment Process

Before starting any work in the laboratory, all hazards are identified and a thorough risk assessment conducted to determine the appropriate procedures in which the work can be safely and securely carried out. The risk assessment process is repeated for all new work activities, whenever there is a change that affects existing work activities, and on a regular basis for ongoing work activities. The risk assessment determines what, if any, adverse human health effects would occur from an accidental or malevolent exposure or release of an infectious agent from the laboratory. The process is accomplished by identifying the characteristics the infectious materials being handled, the events that can result in an individual's exposure, the likelihood that such exposure will cause an infection, the potential for an infected person to transmit the pathogen to contacts, and the probable health consequences in terms of infections and fatalities attributable to infectious agent.

A laboratory-acquired infection generally results from contact with an infectious materials via inhalation (i.e. aerosol), ingestion, direct contact (i.e. skin or mucous membranes), or a puncture wound from a sharp object (i.e. needles). Information available about the infectious materials (e.g. pathogenicity, virulence, infectious dose, route of transmission, stability in the environment, communicability, availability of treatment) is used as a starting point in the process. A number of additional factors associated with laboratory activities are then taken into consideration when determining the appropriate minimum safe practices that are required to mitigate identified risks (e.g. potential for aerosol generation, quantity and concentration of agent, experience of personnel). An infection can also occur as a result of contact with an infectious agent outside the laboratory setting (e.g. while materials are being transported to/from the laboratory). In addition, an infection could be acquired from contact with an infected laboratory worker resulting in a chain of secondary transmissions and spread to the community.

LABORATORY ABC uses the following questions to guide the risk assessment process:

- What could go wrong? What might be the sequence of events that could cause a laboratory acquired infection? What might be the sequence of events that could cause an infectious pathogen to escape the laboratory, set up a chain of transmission, and cause infectious disease in the surrounding community?
- What are the probabilities of such a sequence of events?
- What would be the consequences of such a sequence of events?



2.2 Laboratory ABC Risk Assessment

Insert details about the specific risk assessment for the Laboratory ABC including infectious materials likely to be manipulated, diagnostic tests to be performed, samples that may be received in the lab, unknowns, high risk samples etc.

a) Infectious materials Handled in the Laboratory

The following infectious materials will be handled and/or may be encountered in samples send to the laboratory for diagnostic testing:

- *Patient samples that are suspected of containing…….*
- *List infectious agents handled in the laboratory*

All work with infectious materials are conducted at Biosafety Level 2.
No Biosafety Level 3 or 4 activities with infectious materials are permitted.

In performing the risk assessment, the key characteristics of these infectious materials are assessed including pathogenicity, virulence, host range, infectious dose, morbidity & mortality, transmissibility, epidemiology, stability in the environment, susceptibility to inactivation, availability of effective prophylaxis and therapy, and other factors affecting their risks to human health. Relevant data is sourced from a variety of publications, books,

fact-sheets, peer-reviewed journals, on-line references, biosafety guidelines & manuals, laboratory-acquired infection data, and personal communications with leading authorities.

LABORATORY ABC's stocks of infectious materials are stored securely within the laboratory that is kept locked when unoccupied. Only authorized employees by management are allowed to enter the laboratory and work with these infectious materials (any visitors entering the laboratory must be escorted and provided with supervision commensurate with their anticipated activities). All new activities are be reviewed and approved by the Laboratory Supervisor before any new infectious materials can be brought into the laboratory and before any laboratory activities commence. In collaboration with the Biosafety Officer, the Senior Laboratory Supervisor will conduct a risk assessment & confirm if the agents and activities fall within the requirements. They will also advise laboratory staff on any unique biosafety and biosecurity procedures that may be necessary, and on any additional training that may be needed by the employees conducting the research.

b) Laboratory Activities

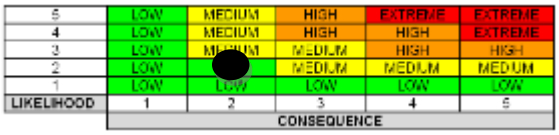
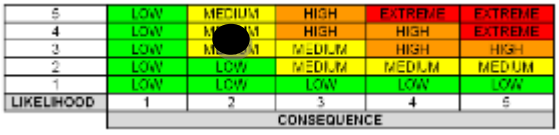
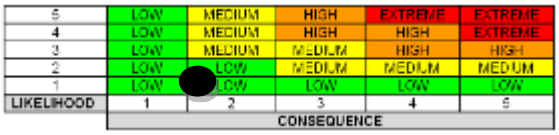
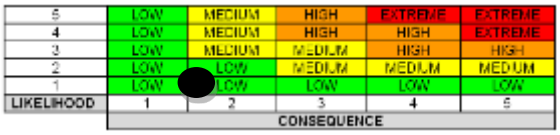
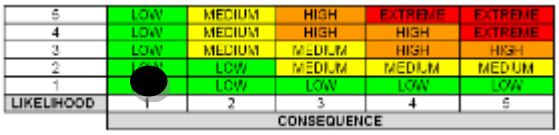
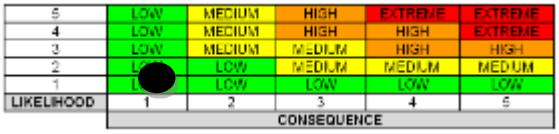
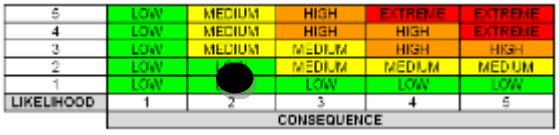
In considering the nature of the operations, risks were assessed by evaluating all situations that could reasonably and foreseeably (i.e. within the rule of reason and not based on pure conjecture) result an adverse event, exposure or release. The risk assessment considered potential effects on employees working in the laboratory and on members of the public outside the facility in the surrounding community. The assessment reviewed both normal working operations and unforeseen internally or externally initiated scenarios including:

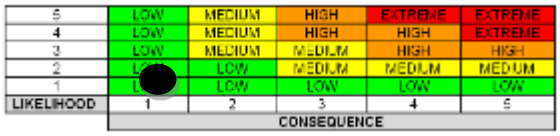
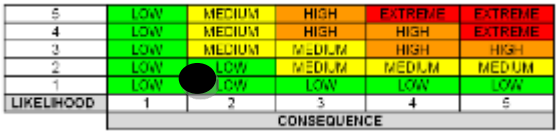
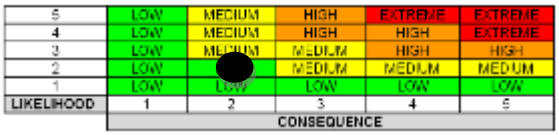
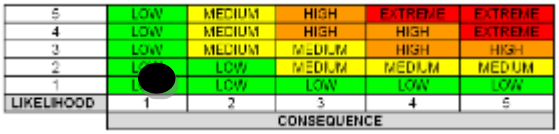
- The laboratory equipment and features of the laboratory designed to contain infectious materials
- Where the activity will be carried out (e.g. in the biosafety cabinet)
- Whether the activity could create infectious aerosols, splashes, or inoculation hazards
- What culture media is to be used (solid or liquid, glassware or plastic)
- Does the work involve high concentrations of infectious materials
- The potential for an infectious aerosol release into the laboratory environment from normal operations or accidents (e.g. spills)
- What kind of protective personal equipment and biosafety practices are employed
- The decontamination and disinfection procedures used
- The potential for exposure of the surrounding community (e.g. through secondary transmission, ventilation system, waste streams)
- The potential for unrestricted access to the laboratory and subsequent malevolent acts
- What kind of pathogen accountability procedures are in place
- External events such as loss of power and extreme weather events
- The level of experience and training of employees handling infectious materials
- Whether the procedure is routinely carried out, new, boring, or repetitive

c) Mapping BSL3 Laboratory Risks

The following risk registry categorizes the overarching biosafety & biosecurity risks identified with the work at the Laboratory ABC laboratory. Consideration is given to how likely each risk is to happen and the consequences of causing harm should it occur.

Move the black dot on each map in accordance with the risk assessment

Biological Risk Mapping		
Risk #	**Description**	**Risk Mapping***
1.	A laboratory-acquired infection occurs in an employee.	
2.	An infectious aerosol is released into the laboratory from a spill or other accident.	
3.	An infectious aerosol spreads out of the laboratory into other areas of the building.	
4.	An infectious aerosol spreads out of the laboratory into the surrounding community.	
5.	A member of the general public is infected as a result of the work.	
6.	Infectious materials are stolen from the laboratory.	
7.	An unauthorized individual gains access to the laboratory.	

8.	Infectious materials from the laboratory are used for malicious purposes.	
9.	Infectious materials are accidentally released into the community through the sewer system.	
10.	Infectious materials are accidentally released into the community through improper decontamination procedures.	
11.	Untrained employees are working with infectious materials in the laboratory.	

**Note: in evaluating the consequences and impact of an incident, consideration is not only given to health and safety consequences that might arise, but also to the possible effects on LABORATORY ABC's reputation from negative public attention as follows:*

- *Health & Safety – insignificant event requiring no medical attention; minor event requiring first aid only & no further medical attention; significant event requiring some medical intervention for one or more employees; major event causing hospitalization of employee and/or exposure of general public; severe event causing fatality among employees and/or general public*
- *Reputation – no public interest; minimal public interest with no effect on reputation; some negative local public interest requiring management time to control message; significant public interest and media attention with short-term damage to reputation; sustained media attention and extensive press coverage with inability of management to control message and long-term damage to reputation*

2.3 Managing and Controlling Risks

Laboratory ABC has implemented a comprehensive plan for avoiding and controlling biosafety and biosecurity risks following the general hierarchy of controls of as follows:

- Eliminating risks by substituting the hazard where possible (e.g. using a less virulent strain of a microorganism).
- Controlling the risks at source through good microbiological practices (e.g. to minimize the creation of infectious aerosols).

- Controlling the risks by providing appropriate laboratory facilities, engineering controls and containment equipment (e.g. using a biosafety cabinet).
- Minimizing risks through the use of appropriate biosafety and biosecurity practices and procedures (e.g. using personal protective equipment, disinfection & decontamination).
- Minimizing risks through the implementation of administrative controls (e.g. training and ensuring competence of employees, laboratory inspections).

The specific measures that are to be applied to controlling biological risks at the laboratory are outlined in this manual and in the biosafety SOPs. Procedures are included to control risks before new work is approved to commence and whenever there is a change that affects existing activities. A mechanism for monitoring compliance has also been articulated to ensure that situations that do not conform to the requirements are identified and corrected to prevent undesirable consequences. Laboratory ABC collects and analyses appropriate data (e.g. reports of inspections, accidents) to regularly review and assess the effectiveness, suitability and adequacy of these measures and to evaluate where improvement can be made. All employees must become familiar with the contents of this manual and are encouraged to provide ongoing feedback to management regarding the control of biological risks in the laboratory.

While Laboratory ABC has completed a risk assessment and outlined risk mitigation strategies, unexpected situations may arise. It is important for you to apply the risk assessment process to your day-to-day work (e.g. think about what you will be doing with infectious materials and how you can further reduce the likelihood that you or someone else may be exposed).

3.0 LABORATORY DESIGN & BIOSAFETY EQUIPMENT

Handling biological materials safely in the laboratory requires a combination of physical containment (i.e. laboratory design & primary containment equipment) and good operational practices.

3.1 Laboratory Design & Engineering Controls

The Laboratory ABC has been set up to meet the laboratory design and equipment as outlined by the World Health Organization's Laboratory Biosafety Manual. It is the general hierarchy of risk control measures that providing appropriate facilities and engineering controls (e.g. proper laboratory ventilation) should be used first to limit risks and then supplemented with operational practices and personal protective equipment. To meet this

criteria, Laboratory ABC has been designed with the following essential features of a Biosafety Level 2 laboratory:

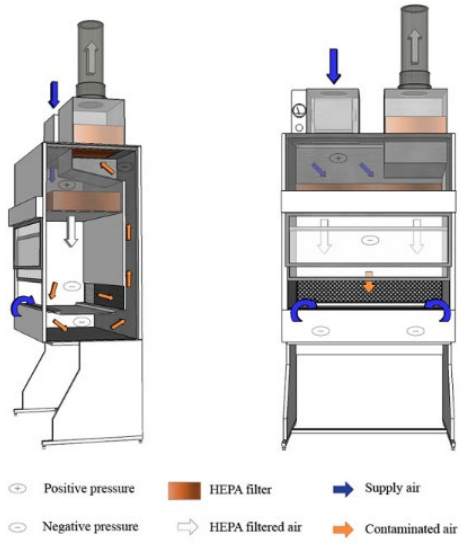
- The laboratory is separated from public areas by a door which is kept closed and locked when not occupied.
- Appropriate signage is posted at the laboratory entrance (biohazard warning, entry requirements, emergency contacts).
- An anti-room entry is provided to store outer coats and personal belongings outside of the laboratory work area
- While paperwork stations have been provided within the laboratory (away from areas where biological agents are manipulated), office work is not conducted in the laboratory areas.
- Surfaces (doors, walls, floors, benchtops, casework, furniture) are constructed of non-absorbent materials, readily cleaned and resistant to any disinfectants and chemicals in use; surfaces are continuous with adjacent and overlapping materials (i.e. no cracks or open joints).
- *Review whether or not this criteria is applicable to the laboratory - Inward directional airflow (i.e. laboratory work area is under negative pressure relative to the outside) is provided at the anti-room entry doors and back emergency exit door; sufficient air changes per hour are provided to maintain good air quality.*
- Primary containment equipment for handling biological materials is provided and certified annually (i.e. biosafety cabinet).
- An autoclave is provided for decontamination.
- An area is provided at the exit from the laboratory to hang laboratory coats.
- A handwashing sink is provided at the exit from the laboratory work area.
- An emergency eyewash is provided at the laboratory sink.

3.2 Biosafety cabinets

Primary containment equipment such as biosafety cabinets (BSC) are designed to reduce the risk of exposure to infectious materials by isolating the activities from the laboratory room environment. The BSC uses a combination of inward airflow, HEPA (high efficiency particulate air) filtration, and to protect the laboratory worker, the research and the laboratory. A biosafety cabinet does not offer protection from potentially harmful chemicals and its HEPA filter does not prevent gases and vapors from passing through. Not all BSCs are designed the same, although all protect the laboratory worker. Generally a recirculating Class II Type A2 biosafety cabinet can be used for manipulating infectious materials in the absence of volatile toxic chemicals. This type of cabinet is designed to provide product, personnel and environmental protection through 30% exhausted and 70% recirculated airflow. All biosafety cabinets are certified annually and must be decontaminated appropriately prior to any maintenance work being carried out (i.e. use of liquid chemical disinfectants to wipe down surfaces of BSC). If maintenance work requires

access to inner potentially contaminated areas of the cabinet, gaseous decontamination may be performed by trained individuals only.

The following diagram illustrates the airflow patterns within the Class II Type A2 BSC and all employees must have an understanding of how the equipment functions to maintain primary containment.



The following work practices will provide optimum containment and safety when working in the BSC:

- Only one person should be working in the BSC at a time; BSCs are designed to only have one person working in them at a time as more than one person can lead to disruption of the delicate air curtain at the front face of the cabinet.
- Check the magnehelic gauge before using the BSC to ensure it is working correctly; the gauge provides an approximate indication of HEPA filter loading. The BSC is also equipped with an alarm to indicate loss of airflow.
- Turn off the UV light if it is in use and turn on the fluorescent light; it is important to note that while exposure to UV will reduce the number of organisms in the air and exposed surfaces, it has poor penetrating power, the accumulation of dust will decrease its effectiveness, and it must be regularly tested to ensure it is emitting the correct germicidal wavelength (approximately 26nm wavelength).
- Ensure that the sash is at the appropriate height; adjust stool height so that when working, your underarms will be level with the bottom of the sash and will not rest on the front air grille.
- The blower motor should be turned on at least 5 minutes before beginning work and the work surface disinfected with 70% ethanol ensuring at least 1 minute

contact time; note that sodium hypochlorite can corrode stainless steel and should only be used for spill-clean up followed by rinsing.

- Test the airflow alarm and ensure it is switched to the "on" position; confirm inward airflow by holding a tissue at the middle of the edge of the sash to ensure that it is drawn in.
- Gather all the necessary materials for the work and place them inside the cabinet; avoid placing any non-essential items in the cabinet being careful not to overload the cabinet or obstruct any of the air grilles; use an absorbent pad to line the work surface and place the materials well back from the front of the cabinet, working from clean to dirty.
- Don appropriate protective clothing ensuring that gloves cover the cuffs of laboratory coat sleeves.
- When working in the cabinet, minimize the movement of arms in and out of the cabinet; if necessary, slowly move arms horizontally in and out instead of side-to-side motions and sweeping motions across the cabinet which can disrupt the air curtain; individuals walking quickly in front of the cabinet while someone else is working can also disrupt the air curtain.
- Work at a moderate pace; work towards the middle of the cabinet, away from the window; place contaminated items towards at the rear of the work area.
- An open flame should not be used inside the cabinet as it presents a fire and explosion hazard, can burn the supply HEPA filter, and can generate convention currents that disrupt airflow; if necessary, discuss alternatives with the Biosafety Officer (e.g. use of micro-incinerators for loops).
- When work is completed, close containers and wait 5 minutes with no activity in the cabinet to purge contaminated air.
- Remove gloves (leaving them inside the cabinet) and wash hands thoroughly.
- All waste materials (including gloves) are to be discarded into biohazard waste receptacles inside the cabinet; don a new pair of clean gloves and surface-disinfect objects before removing them from the cabinet (this step is necessary as aerosols may have contaminated the surface of objects in the cabinet).
- Disinfect the interior surfaces of the cabinet with 70% ethanol ensuring at least 1 minute contact time; turn off the cabinet blower.
- Remove gloves and protective equipment; wash hands.

Do not use the BSC if the alarm sounds when it is turned on or if there are other indications of malfunction such as no airflow, reduced pressure on BSC magnehelic gauge or unusual noises. Call the Laboratory Supervisor and/or Biosafety Officer for assistance. If the alarm sounds when working in the BSC, immediately stop work and cover the material; remove gloves and wash hands; don new gloves, close, surface disinfect and remove material; disinfect the interior of the BSC surfaces; switch off the alarm or power if the blower is making noise; and post a sign on the equipment indicating it is broken and cannot be used.

Please refer to the SOP "Use of Biosafety cabinets" for additional details on the safe working procedures for using the biosafety cabinet.

4.0 SAFETY PRACTICES

4.1 Minimizing Infectious Aerosols

Good microbiological practices are the foundation of safely working with infectious materials in the laboratory and proper techniques can significantly lower the risk of exposure to biological hazards. Poor technique can result in the creation of aerosols (fine droplets of liquid that can carry infectious materials and stay suspended in the air for long periods of time depending on their size and composition). In addition to presenting an inhalation hazard, aerosols can settle on bench tops and become an ingestion or mucosal hazard through contamination of the hands. Aerosols are produced when force is applied to a liquid. Techniques for reducing infectious aerosols during routine microbiological procedures should be followed at all times when working in the laboratory (e.g. using a loop, plating, pipetting, centrifuging, blending & homogenizing, using needles & syringes, opening tubes, pouring infectious liquids, opening ampoules of lyophilized cultures)

Careful workers who are proficient in these techniques will minimize the generation of potentially infectious aerosols while a hurried and careless worker can substantially increase the hazard.

See Appendix B – Techniques for Minimizing Infectious Aerosols

4.2 Operational Safety Practices

The following list of operational practices outlines the general requirements for working safely in the laboratory. Some of the practices listed below are covered in greater detail and/or clarified in other sections of this manual and in the biosafety SOPs.

- Access to the laboratory is restricted to authorized personnel only.
- Eating, drinking, storing food, applying cosmetics, or inserting and removing contact lenses is not permitted the laboratory
- Oral pipetting of any substance is prohibited
- Long hair is to be tied back or restrained so that it cannot come into contact with hands, biological materials, samples, containers or equipment.
- Open wounds, cuts, scratches and grazes should be covered with waterproof dressings.

- The laboratory is to be kept neat and tidy; storage of materials not pertinent to the work should be minimized; paperwork and report writing is carried out away from areas where biological materials are manipulated.
- Suitable footwear with closed toes and heels must be worn in the laboratory at all times.
- Protective laboratory clothing, properly fastened, is worn by all personnel, including visitors entering the laboratory; laboratory coats are stored separately from outer coats and other street clothing; laboratory coats are decontaminated prior to laundering; laboratory coats and other protective clothing are not worn outside of the laboratory area.
- Where there is a known or potential risk of splashes and flying objects, eye and face protection must be worn; the type of protection is carefully selected depending on the hazard and may include safety glasses, goggles and/or face shield.
- Gloves (e.g. nitrile) are worn for all procedures that might involve contact with biological agents and contaminated materials; gloves are removed at the completion of work, before leaving the laboratory and are decontaminated prior to disposal.
- Hands must be washed using the handwashing sink after removing gloves, before leaving the laboratory, and at any time after handling potentially contaminated materials.

Proper handwashing is considered one of the most important practices to prevent the spread of infection. **What is the right way to wash your hands?**

- **Wet** your hands with clean, running water (warm or cold), turn off the tap, and apply soap.
- **Lather** your hands by rubbing them together with the soap. Be sure to lather the backs of your hands, between your fingers, and under your nails.
- **Scrub** your hands for at least 20 seconds.
- **Rinse** your hands well under clean, running water.
- **Dry** your hands using a clean paper towel.

- All procedures are performed carefully to minimize the creation of aerosols and All procedures are performed carefully to minimize the creation of aerosols and spread of contamination; inoculation of mold is carried out in the biological safety cabinet; collection and detoxification of the mold is carried out in the HEPA fume hood.
- Biological agents and contaminated materials are transported within the laboratory (e.g. to and from the incubator/BSC/autoclave) using leak-proof containers and the laboratory cart.
- The use of needles, syringes and sharps should be minimized and only used for aspiration of fluids from diaphragm bottles; needles should not be bent, sheared,

recapped or removed from a syringe; they should promptly be placed in a puncture-resistant sharps container.
- Benchtops and work surfaces are decontaminated at the end of the work activity and/or at the end of the day, and after any spill of potentially infectious materials.
- All contaminated materials are decontaminated (either by disinfection or autoclaving) before disposal or re-use; the selection & use of disinfectants are efficacious against the biological agents in use; the effectiveness of the autoclave is monitored using biological indicators; no contaminated liquids are disposed of down the sanitary sewer.
- Equipment is routinely maintained in good working order; contaminated equipment that is being serviced or leaving the laboratory for disposal is decontaminated, tagged-out as such.
- Spills, accidents, potential exposures to biological agents, loss of containment in the BSC and other emergencies are immediately reported to the laboratory supervisor and/or Biosafety Officer; written records of such incidents are maintained the results of the incident investigation used for continuing education and improvement.
- An effective rodent and insect control program is maintained (i.e. regularly monitoring laboratory for evidence of vermin and insects; minimizing areas where pests can enter by sealing cracks/door sweeps; elimination of pests that enter facility).

4.3 Personal Protective Clothing & Equipment

Insert specific details about specific additional protective clothing for laboratories handling high risk specimens, based on risk assessment (Note that the personal protective clothing requirements listed here are intended for a laboratory setting, not a patient care setting)

Personal protective clothing and equipment are designed to protect employees from exposure to infectious, toxic and corrosive chemicals, heat and other physical hazards. The use of protective clothing is a “last line of defense” against unwanted exposures and should not be used as a substitute for good laboratory technique and procedures. The wearing of protective clothing and equipment is restricted to the laboratory area only and must not be worn in public areas. The type and extent of the protective clothing and equipment to be selected will depend on the particular procedure and risks involved. At a minimum, all employees working in the Laboratory ABC must wear a buttoned laboratory coat and shoes with closed toes and heels before entering the laboratory room. For high-risk specimens, additional protective clothing may also be required to be donned before entering the laboratory room depending on the activities and potential risks involved (i.e. inner gloves, back-closing gown made of impermeable fabric, outer gloves overwrapping the cuffs of the gown, shoe covers or boots, N95 respirator, Positive Air Purifying Respirator).

Soles of the shoes should be slip resistant to avoid slips and falls. Visitors entering the laboratory must also wear a properly buttoned laboratory coat. As a precaution, laboratory coats should be decontaminated prior to laundering. The legs are also a vulnerable area if left uncovered, so it is inappropriate to wear shorts or short skirts in the laboratory. Latex, vinyl, or nitrile gloves are to be worn for all procedures that might involve contact with biological agents. Gloves should overwrap the cuff and lower sleeves of the laboratory coat. It is important to remember that gloves may contain pinholes and hands need to be washed each time after gloves are removed. For protection of hands, wrists and forearms against steam and hot objects when using the autoclave, and/or when handling very cold materials (e.g. objects from -80°C freezer or liquid nitrogen) insulating long gloves should be worn. Other specialty gloves may be necessary when handling hazardous chemicals; consult the Material Safety Data Sheet for compatibility of glove materials with the chemical being handled. Where there is a known or potential risk of splashes and flying objects, eye and face protection must be worn and may include safety glasses, goggles and/or face shield. Face shields should always be worn when removing tubes from liquid nitrogen due to the risk of tubes exploding if liquid nitrogen has leaked into them.

An additional layer of protective clothing is always worn while working at the biosafety cabinet (e.g. back-closing gown made of impermeable fabric, outer gloves overwrapping the cuffs of the gown). Disposable surgical masks may also be worn to discourage the touching of the mouth and nose when working in the biosafety cabinet; however, these masks do not provide adequate respiratory protection from infectious aerosols. The following diagrams illustrate proper procedures for removing the back-closing gown and gloves to prevent the spread of infection.

Untie gown; grasp the gown at the shoulders and pull the gown forward	
Fold the gown so that the outside of the gown is folded in.	
Grasp the outer surface of one glove with the other gloved hand and pull off the glove.	
Place the fingers inside the cuff of the glove and discard the glove.	

The use of respiratory protection in the laboratory will depend on the particular procedure and risks involved and may include the use of an N95 respirator or Positive Purifying Air Respirator (PAPR). Where the laboratory supervisor and Biosafety Officer determine that

respiratory protection is required in accordance with the risk assessment, all personnel must receive specific training on donning/doffing procedures.

If wearing an N95 respirator, to ensure an adequate seal, a seal check should be done by the wearer **every time** the respirator is donned as follows:

- Positive pressure check – once the N95 respirator is donned, cover your hands over the facepiece and exhale gently into the facepiece; the facepiece should bulge slightly and no air leaks should be are detected between your face and the facepiece; if air leakage is detected, reposition the respirator on your face and/or readjust the tension of the straps and repeat the seal check.
- Negative pressure check – once the N95 respirator is donned, cover the filter surface with your hands and then inhale; the facepiece should collapse on your face and you should not feel air passing between your face and the facepiece; if air leakage is detected, reposition the respirator on your face and/or readjust the tension of the straps and repeat the seal check.

When removing the N95 respirator, as the outside of the respirator is potentially contaminated, take care not to touch the front of the facepiece; grasp bottom, then top ties or elastic bands.

Insert specific procedures for donning and doffing PAPR if used, in accordance with model and manufacturer's instructions

4.4 Housekeeping, Cleaning & Pest Control

Good housekeeping and cleaning in the laboratory reduces the likelihood of accidents and is essential to providing a work area free of sources of hazards and contamination. Moreover, a clean environment decreases the risk of negative influences on sensitive laboratory diagnostic tests (e.g. cell culture and PCR). General housekeeping procedures include ensuring that sanitary conditions are maintained at all time, materials not pertinent to the work are not brought into the laboratory, garbage and other items awaiting autoclaving are not allowed to accumulate, and access to emergency equipment (e.g. eyewashes, emergency exit) are not blocked. Attention is also paid to ensuring the

laboratory is free of physical tripping hazards. A regular schedule of laboratory cleaning includes daily disinfection of laboratory benches and work surfaces, weekly flushing of the eyewash station, weekly wet mopping of the floors and monthly thorough cleaning of the laboratory.

Pests such as insects, rodents and vermin can harbor disease, spread contaminants through a facility and cause physical damage (e.g. by gnawing and chewing). A pest control program is in place that minimizes reliance on the use of pesticides and emphasizes control of the environment to make it less conducive to pest infestation. Along with a rigorous housekeeping and cleaning schedule, the sealing of any cracks and entry points for pests should preclude any infestations within the laboratory. The program also includes regular monitoring of the laboratory for evidence of vermin and insects and elimination of any pests that enter facility.

5.0 DISINFECTION, DECONTAMINATION & WASTE DISPOSAL

Decontamination is the process of reducing the number of infectious microorganisms to an acceptable level, and can be achieved by either chemical disinfection or sterilization through autoclaving. Disinfection does not necessarily remove or result in the total destruction and killing of all organisms present, and the effectiveness of the process is highly dependent on the biological agents in use.

5.1 Chemical Disinfection

Chemical disinfectants are used in laboratory for the decontamination of benchtops and other surfaces, for decontaminating equipment that cannot be autoclaved, for disinfecting the interior surfaces of the biological safety cabinet, for surface-disinfecting objects before removing them from the BSC, for surface disinfecting sample tubes and containers prior to removal from the laboratory, and for spills of potentially infectious materials. Biological organisms can be more or less resistant to chemical disinfectants based on their innate characteristics and the biological agents likely to be encountered in the laboratory range from highly resistant bacterial spores to relatively susceptible viruses and vegetative bacteria. As such, it is important to ensure the proper selection of disinfectants based on the nature of the biological agents being manipulated at the time.

Biological organisms can be more or less resistant to chemical disinfectants based on their innate characteristics. The general order from most to least resistant is:

- Bacterial spores
- Mycobacterium
- Non-lipid viruses
- Fungi
- Vegetative bacteria
- Lipid viruses

MOST

LEAST

The effectiveness of chemical disinfectants can also be altered by a number of factors including:

- contact time (evaporation can reduce the contact time for surface disinfection)
- the presence of organic matter (which can protect organisms from contact with the disinfectant and/or neutralize the disinfectant)
- the diluent used to dilute the disinfectant (hard water can inactivate some disinfectants)
- stability (some disinfectants are susceptible to heat and light)
- the condition and nature of the surfaces involved (uneven, cracked or pitted surfaces can hide organisms and are thus difficult to disinfect)

While the final selection and concentration of disinfect used will depend on the biological agents and specimens being handled, the following guidelines can be applied to the use of common disinfectants in the laboratory:

5% Sodium Hypochlorite

Sodium hypochlorite is suitable for routine decontamination of benchtops and work surfaces at the end of the work activity and/or at the end of the day, and after any spill of potentially infectious materials. However, bleach is highly corrosive to stainless steel and such surfaces (e.g. stainless steel benchtops, surfaces of the biosafety cabinet) must be thoroughly rinsed to remove any residual sodium hypochlorite. Most classes of biological agents can be disinfected using a 1:10 dilution of sodium hypochlorite. As the concentration of sodium hypochlorite degrades rapidly, the working dilutions of should be made up fresh, stored in a light proof container and not kept for more than one week. Appropriate personal protective equipment (i.e. laboratory coat, gloves, eye protection) should be worn when preparing in-use dilutions. Sodium hypochorite must never be autoclaved as it may release dangerous chorine gas.

70% Ethanol

Ethanol is suitable for routine disinfection however it evaporates quickly from surfaces thus reducing the contact time. Care must be taken when using 70% ethanol in the BSC when the blower is running as the concentration of ethanol can accumulate to high levels and vapor may be drawn through the motor (an ignition source) and cause a fire. For spills inside the BSC, a 1:10 dilution of sodium hypochorite should be used instead, followed by rinsing with water.

Insert any additional specific disinfectants that are used in the laboratory

Purpose	Disinfectant	Recommended Use
Routine disinfection of surfaces	1:10 dilution of sodium hypochlorite	If used on stainless steel surfaces must be rinsed with water. Not recommended for routine BSC disinfection.
Routine disinfection of surfaces	70% ethanol	Evaporates quickly and may need reapplying. Care must be taken to avoid high concentrations if used while the BSC is running.
Spills outside BSC	1:10 dilution of sodium hypochlorite	Increase the concentration of the sodium hypochlorite to account for volume of spill and presence of organic material
Spills inside BSC	1:10 dilution of sodium hypochlorite	Increase the concentration of the sodium hypochlorite to account for volume of spill and presence of organic material. Thoroughly rinse stainless surface after spill clean-up.

5.2 Autoclaving & Waste Disposal

Autoclaving is a dependable sterilization process employing saturated steam under pressure (15psi) to achieve a minimum temperature of 121°C and minimum contact time of 20 minutes (measured after the centre of the load being sterilized reaches the sterilization temperature). The effectiveness of the process is influenced by the nature of the materials being autoclaved and the way in which they are loaded into the autoclave. Steam saturation of the load is essential for decontamination; air pockets will prevent adequate steam penetration. Items should be arranged in a manner that allows free circulation and penetration of steam. The more densely arranged the load, the longer it will take to achieve 121°C. Piling containers above one another and overloading can result in decontamination failure.

Materials that may give off hazardous fumes must **NOT** be autoclaved (e.g. bleach, materials containing solvents, volatile chemicals).

Standard load types and their corresponding cycle times have been established and validated using biological indicators as follows:
Insert standard load types and their corresponding cycle and sterilization time

Load Type:	Recommended Cycle:	Sterilization Time:
Dry materials – pipette tips, glassware		
Liquids		
Laboratory Waste – petrie dishes		

The following practices are to be followed for the safe use of the autoclave:

- To be consistently successful for sterilization, always process materials using the cycle times established for each load type.
- Records of each cycle log produced by the autoclave are maintained and kept on file.
- Personal protective equipment is to be worn when loading the autoclave (e.g. laboratory coat and gloves to prevent contact with contaminated materials) and unloading the autoclave (e.g. long heat-resistant and water proof gloves to protect the wrists and forearms; closed toed shoes; an apron may be necessary where a spill hazard exists for processing liquid loads).
- Chemical tape or strip indicators are used on each load to verify the load has been processed through the autoclave; however, such indicators can only verify that the autoclave has reached normal operating temperatures (i.e. are not time dependent) and do not provide an indication of sterilization.
- Leak-proof containers and autoclavable bags (e.g. polypropylene) are used for all items to be processed through the autoclave; items are placed in secondary autoclavable containers to capture any liquids that may leak out; to ensure adequate steam penetration, autoclave bags should be left partially open during autoclaving to allow steam penetrate into the bag; in cases of liquids, containers should only be half full, and, to prevent breakage as a result of pressure differentials, caps should be loosened or self-ventilating caps should be used).
- When loading the autoclave, items should be arranged in a manner that allows free circulation and penetration of steam; ensure containers do not touch each other and avoid crowding or stacking; no items should touch the top or sides of the autoclave.
- Prior to unloading the autoclave, verify that the cycle is complete; if a cycle fails to be completed, the load must be re-autoclaved.
- The chamber pressure of the autoclave must be a zero before opening the autoclave door; the door should be cracked open slightly to allow steam to escape (opening the door too quickly can cause glassware breakage).

- Great care must be taken when unloading the autoclave to not only avoid burns or scalding, but employees may also be exposed to explosion hazards from super-heated liquids if they are shaken or moved during the cooling process; if boiling or bubbling is present, wait until it subsides.
- Decontaminated material that is no longer infectious can be disposed of in the regular garbage provided that any biohazard warning labels have been defaced; the material is to be placed inside a black/green plastic regular garbage bag designed for domestic applications.
- The efficacy of the autoclave is verified routinely using biological indicators; the frequency of use depends on how frequently the autoclave is used (e.g. weekly, bi-weekly, or monthly); positive control indicators must always be used together with the test indicator; the results are recorded on the Biological Indicator Test Log.

Please refer to the SOP "Use of Autoclave and Biological Indicators" for further details and a copy of the "Biological Indicator Test Log" form.

6.0 BIOSECURITY

Infectious materials have a dual-use potential. They can be used in research for the advancement of science, but also can be misused to pose a threat to public health and safety, agriculture or the environment. The potential for dual-use of the agents and the biosecurity risks of agents handled at the laboratory are continually reassessed, based on their pathogenicity, their existence in the environment, consequence of release, risk of weaponization and level of threat (i.e. individuals with motive and opportunities to cause harm). Laboratory ABC has developed a detailed biosecurity plan to prevent theft, misuse or intentional release of infectious materials from the laboratory. Key features of the plan include restricting access to the laboratory, maintaining an inventory of infectious materials, emergency procedures for biosecurity incidents, controlling and protecting sensitive information and ensuring employees are properly trained in these biosecurity measures.

6.1 Accountability of Infectious materials

The effectiveness of a biosecurity program depends, first and foremost, on the integrity of the individuals who have access to infectious materials. Employees are carefully screened through a pre-employment screening process to ensure they have the appropriate personal suitability, reliability and competency to undertake the work at the laboratory. Laboratory doors are kept locked and only trained employees authorized by the Laboratory Supervisor are allowed to enter the laboratory and work with infectious materials. The distribution of keys to the laboratory is controlled by Laboratory ABC management and must be returned when employees no longer work at the laboratory. All employees and visitors must have and visibly display an ID badge to provide a method of identification for authorized access into laboratory.

Laboratory ABC's stocks of infectious materials are stored securely within the laboratory that is kept locked when unoccupied. An up-to-date inventory of infectious materials is maintained by the Laboratory Supervisor at all times. The inventory includes the name and description of the biological agent, the date of receipt and/or generation of the material, and storage location. The inventory of infectious materials is considered as "sensitive" information and is protected (hard copies are kept in a locked filing cabinet, electronic copies are protected with a password).

Please refer to the SOP "Biosecurity & Pathogen Accountability" for further details and a copy of the "Infectious Agent Inventory" form.

6.2 Biosecurity Incidents

All biosecurity incidents, including discrepancies in inventories, loss of keys, suspicious activity, and unauthorized individuals in the laboratory must be reported to the Biosafety Officer and/or Laboratory Supervisor as soon as possible. Once reported, Laboratory ABC management will take immediate action which may include replacing locks and/or suspending activity with infectious materials. Involvement of local law enforcement may also be required, depending on the nature of the incident.

Authorized employees are encouraged to be vigilant about against unauthorized or suspicious persons within or within the vicinity of the laboratory. Since only a few individuals will have authorized access to the laboratory, identification of unauthorized persons is simplified. Individuals who are unknown, unexpected, or unwelcome are considered unauthorized and will be asked to leave the facility. In addition, any suspicious activity displayed by persons working with biological agents will be reported to the Biosafety Officer or Laboratory Supervisor.

6.3 Information Security

Care must be taken to protect sensitive information from unauthorized release and ensure the appropriate level of confidentiality is maintained. This includes information related to the inventory of biological agents and the results of diagnostic testing. Methods for controlling such information include:

- Never leaving sensitive information either in paper format or electronic devices in plain sight when unattended.
- Keeping hard copies in locked cabinets when not in use.
- Not creating unnecessary or duplicative copies.
- Only transporting hard copies out of the laboratory when authorized to do so by the Laboratory Supervisor; sensitive information should not be taken home or to a non-approved site in either paper or electronic format.
- Encrypting and password protecting information when sending electronically.

- Protecting electronic copies with passwords; never sharing passwords and not permitting your computer to remember passwords.
- Restricting access to sensitive information to those who "need-to-know".
- Being aware of your surroundings when handling sensitive information; protecting against "shoulder surfing" or eavesdropping.
- Only sharing sensitive information when authorized by the Laboratory Supervisor.
- Using only electronic devices (laptops, USB flash drives, external hard drives) approved for such use by the Laboratory Supervisor; personally owned computers should not be used to access or store sensitive information.
- Deleting or destroying information that is no longer needed.

7.0 EMERGENCY PROCEDURES

Emergency procedures are in place for biological spills and other incidents that might occur in Laboratory ABC. All employees working in and around the laboratory must be trained in emergency response procedures. Mock emergency drills involving different types of scenarios are conducted at least annually to ensure employees are familiar with the procedures to be followed. All emergencies must be verbally reported to the Laboratory Supervisor and/or Biosafety Officer as soon as circumstances permit. Such reporting enables appropriate investigation and follow-up in order to prevent similar events or more severe incidents in the future.

7.1 Emergency Contacts

If the emergency is potentially **life threatening or severe** then **call** ***insert phone number***

Biosafety Officer (name):	*insert phone number* (office)
	insert phone number (cell)
Laboratory Supervisor (name):	*insert phone number* (office)
	insert phone number (cell)
Laboratory ABC –	*insert phone number*

If the injury is potentially **life threatening or severe** (e.g. involves significant loss of blood, loss of consciousness, broken limb, and heart attack) then **call xxx** and proceed with emergency first aid.

7.2 Exposure to Infectious Materials & Medical Emergencies

An exposure to biological agents can occur in the laboratory through:

- A puncture, cut or abrasion of the skin involving a biologically-contaminated object
- Contamination of chapped, broken or otherwise compromised skin
- Contamination of the mucus membranes of the eyes, nose or mouth
- Inhalation of infectious aerosols
- Ingestion of a contaminated liquid or by contaminated hand to mouth exposure

If you have been **exposed to a potentially infectious biological material** (via cuts, spills on chapped or broken skin, etc.), the affected area must be immediately washed thoroughly but gently with multiple applications of soap and water for at least five minutes, and the cut then covered with a sterile bandage. If splashed into the eyes, immediately wash eyes at the eyewash

Prompt medical evaluation may be necessary in instances involving potential exposures and suspected laboratory-acquired infections. These include potentially exposed employees with no symptoms, exposed employees who develop symptoms and symptomatic employees with no identifiable exposures. A high index of suspicion forpotential occupational exposures should be maintained for any unexplained acute illness or febrile disease among employees or visitors to the laboratory. Unplanned absences from work due to illness lasting more than 3 consecutive days must be reported to the Laboratory Supervisor and/or Biosafety Officer. If the employee presents to a healthcare provider or hospital emergency room other than the occupational health services provider, it is important that information regarding the nature of the biological hazards present in the employee's workplace be communicated. This enables the attending physician to remain alert for evidence of laboratory-acquired infections. An exposure assessment and medical evaluation will determine the need for post-exposure prophylaxis, active surveillance and/or clinical intervention and treatment.

Specialized planning considerations are given to responding to medical emergencies that may also occur in the laboratory such as heart attacks, falls, head injury, fainting, unconsciousness, burns and other serious incidents. It is important for the local first responder community (e.g. paramedics, ambulance, fire, police and hazmat) to be familiar with the laboratory's personnel and special operations in case they are called to respond. Mock emergency drills involving serious medical emergencies are conducted at least annually with local emergency responders in order to ensure individuals are familiar with the procedures to be followed. Such drills include practicing extrication of potentially contaminated and unconscious victims from within the laboratory room.

7.3 Biohazardous Spills

Spills of biological materials may constitute a health hazard if not handled in the appropriate manner. As part of the biosafety program, Laboratory ABC has a spill response kit with appropriate personal protective clothing and clean up materials located in the laboratory and is available for use at all times. Spills in a biological safety cabinet should present a limited hazard if clean-up is initiated appropriately and the BSC is left in operation. Spills outside of the BSC could present a health hazard. In such cases, the safest approach is to evacuate the laboratory for a sufficient time to allow aerosols to settle or be removed by the ventilation system before re-entry and cleaning up the spill.

Insert here specific list of contents of spill kit and exactly where it is located.

The recommended spill clean-up procedures are:

Spills in a Biological Safety Cabinet

- Leave the biological safety cabinet in operation.
- Remove contaminated protective clothing; place it in bags and autoclave prior to disposal or laundering.
- Wash hands with soap.
- Assemble clean-up materials and don appropriate protective clothing (gloves, laboratory coat).
- Cover the spill with paper towel; soak the paper towel with a suitable disinfectant (e.g. 1:10 dilute of sodium hypochorite), working from the outside in; gentle flooding will avoid creating aerosols.
- Allow sufficient contact time for disinfection.
- If spilled material has gone through the perforated grills then pour disinfectant through grills into the catch tray underneath; let stand for the appropriate contact time (30 minutes), drain the tray through drain cock and clean.
- Use forceps to pick up any broken glass or sharps and place in a puncture-resistant container.
- Wipe up spill and place all materials in a plastic bag inside the cabinet.
- After decontamination thoroughly rinse the surface to remove any remaining bleach because it can corrode stainless steel.
- Items in the BSC at the time of the spill must be thoroughly cleaned with 70% ethanol prior to removal from the BSC and/or bagged for removal and autoclaved.
- Wipe the inside of the cabinet with 70% ethanol and allow BSC to run for 10 minutes prior to resuming work.

Spills in Open Laboratory Area (outside of biological safety cabinet)

- Vacate area; warn others to leave.
- Remove contaminated clothing and place in bag for decontamination by autoclaving; if footwear has been contaminated, take care not to track contamination into clean areas before removing; wash hands thoroughly.
- Seek assistance from the Biosafety Officer if needed.
- Mark off area using warning signs to prevent others from entering.
- Wait at least 30 minutes to allow aerosols to settle before re-entering area.
- Don appropriate protective clothing (laboratory coat, gloves, eye protection) and assemble spill response materials from the spill response kit.
- Cover the spill with paper towel.
- Soak the paper towel with disinfectant (1:10 solution of sodium hypochorite), working from the outside in (but ensure that there are not any chemicals in the spill that would result in the release of chlorine gas); gentle flooding will avoid creating aerosols.
- Allow sufficient contact time for disinfection (30 minutes).
- Use long forceps to pick up broken glass or sharps and place in a puncture-resistant container; remove the soaked paper towels with a gloved hand and dispose of them in a plastic bag.
- Items in the vicinity of the spill must be thoroughly cleaned with a disinfectant and/or by autoclaving; disinfect protective clothing and equipment.

Spills in Centrifuge

- In case of a centrifuge malfunction, rotor failure or test tube failure, a risk exists of biological material being released due to the release of aerosols.
- If a centrifuge malfunctions while in operation it must be turned off immediately and unplugged.
- Do not open the centrifuge for 30 minutes to allow the aerosols to disperse and settle; place a note warning others not to open it.
- Don appropriate protective clothing (laboratory coat, gloves), remove all debris and disinfect (1:10 dilute of sodium hypochorite) the interior of the centrifuge and the head (or cups).
- It is important to remember that sodium hypochlorite will corrode the interior of centrifuges and rotors so extreme care must be taken to thoroughly rinse following disinfection.
- All debris must be collected, bagged, autoclaved and disposed of appropriately.

7.4 Accident & Incident Reporting

It is estimated that only 2% of all accidents occur as a result of situations which cannot be controlled. By reporting, analyzing and learning from accidents and incidents, Laboratory ABC is able to implement corrective actions and prevent, to some degree, future occurrences. Near-misses that did not result in an injury or damage but have the potential to do so, are also reported and investigated. The goal of investigating all accidents and near-misses is fact-finding to determine the casual factors and identify any trends that may be occurring. The investigation is intended to uncover contributing factors and root causes, which may not be immediately evident upon initial review of the incident. The findings of such investigations are acted upon to eliminate hazards and correct unsafe conditions and/or practices.

All spills, accidents and incidents must be reported to the Laboratory Supervisor and/or Biosafety Officer as soon as circumstances permit. Such reporting enables appropriate investigation and follow-up in order to prevent similar events or more severe incidents in the future. It is important to also report near-miss incidents which are unplanned or unanticipated events where nobody was injured or nothing was spilled or damaged but only by good fortune. These must also be investigated to prevent the set of circumstances leading to the event from arising again.

Please refer to the BSL SOP "Accident & Incident Reporting" for a copy of the reporting form.

8.0 DAILY LABORATORY CHECKS & INSPECTIONS

8.1 Daily Laboratory Checks

Daily checks of the laboratory and safety equipment is essential to ensure that the laboratory is operating in accordance with established safety parameters and procedures. Such checks are not meant as a replacement for routine maintenance and operational readiness of the laboratory systems and components but rather as a daily confirmation that the laboratory is a safe environment in which to work. It is important that laboratory scientific staff work closely with the facility maintenance team to ensure the laboratory is operationally ready and in a safe working condition. Each day before entering the laboratory, employees will perform a series of checks and activities including the following:

- Check the laboratory work areas and floors to ensure they are free of clutter, obstructions and tripping hazards.
- Check that the access to any emergency exits are not blocked.
- Check that the biosafety cabinet is in an operational state.
- Flush the eyewash for 60 seconds.

- Refill the soap dispenser for the handwashing sink as may be required.
- Check the contents of the spill control kit and restock as necessary.
- Check that there are adequate supplies of gloves and other personal protective equipment that may be needed for the day.
- Prepare fresh working dilutions of disinfectants that may be needed for the day.
- Process any waste containers awaiting autoclaving through the autoclave; disinfect the surfaces of waste containers and install new biohazard bags into waste containers.

8.2 Laboratory Inspections

Laboratory ABC is formally inspected annually by the Biosafety Officer to confirm continued compliance with the requirements and guidelines as outlined by the World Health Organization's Laboratory Biosafety Manual. The inspection process involves gathering objective evidence through asking questions to laboratory employees about what they are doing, observing how employees are carrying out laboratory activities, examining the laboratory facility and equipment, and examining records (e.g. training records, biological agent inventories, and accident & incident reports). In addition to the formal annual inspection, all employees working in the laboratory are responsible for ongoing day-to-day inspections of their work areas to identify and correct hazardous conditions, and to report them to the Biosafety Officer and/or Laboratory Supervisor. Special inspections may also be conducted as a result of changes in laboratory operations, the introduction of new equipment, or after a laboratory accident or incident.

Any identified deficiencies are rectified as soon as reasonably possible and further investigated to identify any underlying causes or problems. In cases where identified deficiencies present an unacceptable risk to employees, the public, the environment, the property, security and/or gross disregard to health and safety, Laboratory ABC management will take immediate action to rectify the situation. Action may include the immediate suspension of the laboratory activity of concern, prohibited entry to the laboratory, and/or removal of hazardous material from the premises until such time as the deficiency is corrected. Records are maintained of all laboratory inspection findings, including the action taken to address any deficiencies and opportunities for improvement.

Please refer to the SOP "Laboratory Inspections" for specific details on the inspection process and checklists used.

9.0 OCCUPATIONAL HEALTH & MEDICAL SURVEILLANCE

Every effort is taken by Laboratory ABC to reduce the potential for exposure to infectious materials through the use of engineering controls, safe work practices, personal protective equipment, and administrative controls. Health services and medical surveillance is required in additional to these control measures to protect from occupational illnesses, to monitor potential exposures and to ensure that workers who develop symptoms of illness receive appropriate medical evaluation and treatment.

Occupational health services are provided by *xxxxx (insert name of Laboratory ABC occupational health services provider)* for employees working in and around the laboratory who may be exposed to infectious materials during the course of their work. As pre-exposure intervention can be critical, the program must be met before work with biological agents and samples in the laboratory begins. Each individual working in the laboratory must have an understanding of the infectious agents they are working with, the signs and symptoms of disease related to these agents, the available medical resources and procedures for potential exposures, their personal immune system susceptibility and any pre-existing medical conditions.

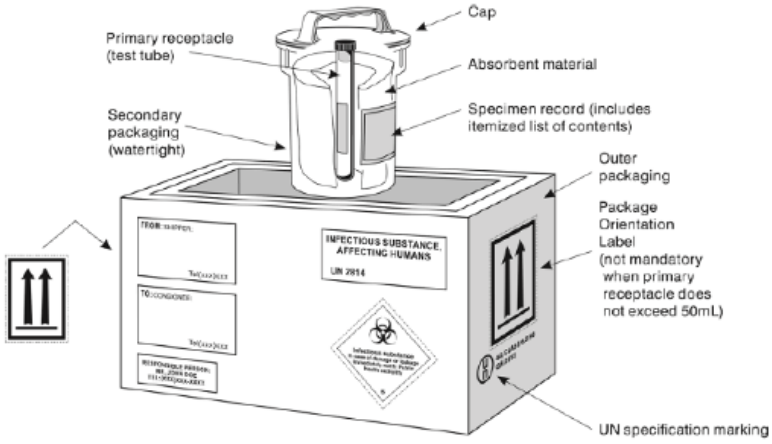
Specific test results and other personal medical information generated will be kept confidential between the employee and the physician. Only the employee's medical fitness to perform duties in the laboratory and any specific recommended precautions will be communicated to the Laboratory Supervisor. The occupational health physician, in consultation with the Laboratory Supervisor and Biosafety Officer, will determine the scope of the medical services needed which may include:

- Pre-placement medical evaluation to ascertain baseline health information, immunization status and pre-existing conditions
- Serum screening, immunizations and serum titre testing to confirm response to immunization
- Periodic medical assessments and monitoring
- Post-exposure prophylaxis

Prompt medical evaluation may be necessary in instances involving potential exposures and suspected laboratory-acquired infections. These include potentially exposed employees with no symptoms, exposed employees who develop symptoms and symptomatic employees with no identifiable exposures. Such services must be available to employees both during work hours and after normal working hours. A high index of suspicion for potential occupational exposures should be maintained for any unexplained acute illness or febrile disease among employees or visitors to the laboratory. Unplanned absences from work due to illness lasting more than 3 consecutive days must be reported to the Laboratory Supervisor and/or Biosafety Officer.

10.0 TRANSPORT OF SAMPLES & INFECTIOUS MATERIALS

All samples and biological agents transferred into and out of the laboratory must be documented in the inventory of infectious materials. Samples and infectious materials agents to be transported offsite (i.e. outside of the Laboratory ABC laboratory) must be packaged and labelled appropriately and may only be transported to another laboratory with adequate biosafety facilities to safely receive and handle the sample. All samples leaving the laboratory must be labelled, placed in leak-proof secondary containers within the laboratory, and surface disinfected. Outer packaging, labelling and documentation should be affixed to the package prior to removal off-site. International transportation of biological agents is regulated by the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air and the International Air Transport Association's Dangerous Goods Regulations. A certified packaging system suitable for the legal transport of regulated biological agents must be used as follows:



All individuals shipping infectious materials internally (i.e. Category A or Category B infectious substances) **must be trained and certified**. A certificate is valid for a period of 3 years after which the individual must undergo re-certification. Employees may only receive and package biological materials for international transport under the direct supervision of an individual who holds a valid certificate.

Please refer to the SOP "Transportation of Infectious Materials" for specific details on the procedures to be used for sample transport within Mali and externally to laboratories outside of the country.

APPENDIX A – Memorandum of Understanding for Laboratory ABC Authorized Users

I have read, understand, and will comply with the Laboratory ABC Biosafety Safety Manual and Standard Operating Procedures. I am familiar with the proper biosafety procedures for working in the laboratory and the required emergency procedures. I have been informed of the risks associated with this laboratory and I have received instruction in the use of the laboratory from the Laboratory Supervisor and Biosafety Officer.

Before transferring any biological material out of the laboratory I will seek the approval of the Laboratory Supervisor and conform to all applicable shipping and transport regulations. I will notify the Laboratory Supervisor and/or the Biosafety Officer immediately concerning any work-related accident, exposure incident or potential release of infectious materials to the environment; any problems pertaining to the implementation of biological or physical containment procedures; or any violations of biosafety requirements. I will cooperate in any investigation of any of these matters.

_____

Signature of Laboratory User

_____

Printed Name of Laboratory User

_____

Date

APPENDIX B – Techniques for Minimizing Infectious Aerosols

Using a loop:

- Use a cooled loop for insertion into a culture
- Ensure the loop is completely closed
- Use short loops: the shank should be no more than 6 cm long to avoid vibrations
- Use a micro-incinerator or pre-sterilized plastic loops rather than flaming a loop in an open flame

Plating:

- Streak plates where the surface of the medium is smooth (*i.e.* avoid bubbles)

Pipetting:

- Use "to deliver" pipettes to avoid blowing out the last drop
- Drain pipettes gently with the tip against the inner wall of the receiving vessel
- Use pipettes with plugs to reduce contamination of the pipetting device
- Work over an absorbent, plastic-backed pad to avoid aerosol dispersion from drops falling on hard surfaces
- Do not mix materials by alternate suction and expulsion through a pipette (use vortex mixer)

Centrifuging:

- Use sealed safety cups and sealed rotors
- Open cups inside a biosafety cabinet and allow cups to sit prior to opening

Blending and Homogenizing:

- Use a laboratory blender with a tight-fitting gasketed lid and leak-proof bearings (domestic kitchen blenders leak and release aerosols)
- Wait as long as possible before opening the lid after mixing

Using needles and syringes:

- When withdrawing a needle from a stoppered bottle, wrap the needle and bottle cap in a disinfectant-soaked absorbent
- Use syringes with a Luer lock connector
- Dispose of needles directly into sharps container without further manipulation (needle-cutting devices release aerosols)

Opening tubes:

- Avoid using tubes with push-in closures (when opened, the film of liquid trapped between tube and closure breaks and releases aerosols)
- Use a vortex mixer instead of inverting tubes

- Wait 30 seconds after shaking a tube before opening

Pouring infectious liquids:

- Avoid pouring off supernatant – use pipettes instead
- Pour infectious liquid waste through a funnel where the end is below the surface of the disinfectant in the discard container; pour disinfectant through the funnel after use

Opening ampoules of lyophilized cultures:

- Avoid hasty opening by snapping the neck, which can lead to sudden inrush of air and dispersal of contents – instead make a file mark near the middle of the cotton plug and apply a red-hot glass rod to crack the glass, allow time for air to seep into the ampoule and gently remove the top and plug
- Add liquid for re-suspension slowly to avoid frothing

Breakage:

- Use plastic labware where possible rather than glass (less likely to break which generates aerosols)