

West Texas A&M University Biosafety Level 2 Facility Manual (Template)

According to Section III, Laboratory Practice and Technique, of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th Edition:

“Each laboratory should develop or adopt a biosafety or operations manual that identifies the hazards that will or may be encountered, and that specifies practices and procedures designed to minimize or eliminate exposures to these hazards. Personnel should be advised of special hazards and should be required to read and follow the required practices and procedures. A scientist, trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling infectious agents must be responsible for the conduct of work with any infectious agents or materials.”

A biosafety manual is required by the WTAMU IBC for BSL-2 proposal application approval and must also be readily available in the BSL-2 facility at all times to assist any and all personnel in routine and/or emergency operations using rDNA and/or biohazardous materials. The Biosafety Manual must also be available at all times to safety and emergency personnel in case of an incident, accident, or an emergency, and during lab inspections. It should be a working document, reviewed periodically, updated as needed, and readily accessible (kept in the work area) to all personnel working in a lab or area with rDNA and/or biohazardous agents. **Note that although required only for BSL-2 facilities, it is suggested that all facilities (e.g. BSL-1) adopt a Biosafety Manual.**

A signature sheet documenting that all appropriate personnel working with rDNA and/or biohazardous materials have read and understand the provided information and/or materials is a required part of the lab Biosafety Manual. Dates of review by personnel must be on the signature sheet. Personnel must receive annual updates or additional training by the Primary Investigator (PI), Course Instructor (CI) or Course Coordinator (CC) when procedural or policy changes occur (as per *BMBL*, Section IV).

The biosafety manual should be a living, working document that serves as an important resource for personnel engaged in the activities using rDNA and/or biohazardous materials. Its primary focus should be to provide pertinent information to help execute the operations of the facility in a safe and professional manner.

This document serves as a template for a BSL-2 Facility Biosafety Manual. It is permissible to use this document as your own, however, correct and appropriate information must be filled in where appropriate.

Contact the Biological Safety Officer (Dr. Jason Fritzler, x2642, jfritzler@wtamu.edu) or the IBC Chair (Dr. John Richeson, x2522, jricheson@wtamu.edu) if you have questions or need information regarding the facility biosafety manual.

Administrative Page:

- Key Personnel: (provide current contact information for all key personnel: phone number, email address)

Principle Investigator:

Co-Investigator(s):

Staff (excluding graduate students):

Graduate Students:

- Building Name and Lab/Class Room Number:
- rDNA and/or Biohazardous Materials in use:
- Date Manual Prepared:
- Date Last Modified:
- IBC Document Title, Number(s), and Date Approved:
- IACUC Protocol Number (if applicable):
- Containment (Biosafety) Level Assigned:

BSL-1

Animal BSL-1

BSL-2

Animal BSL-2

Other (such as plant)

- **IBC Proposal Application:** A copy of the IBC Proposal Application should be included in the Biosafety Manual (this is not necessary when submitting this manual as part of your IBC proposal application)
- **Biological Agent Information (must match that included in the IBC proposal application):**
 - Biological Agent(s) in Use:
 - Agent Location: (specify location and containment equipment for each agent by room, freezer, incubator, hood, etc.)
 - Occupational Health Information: (include targeted fact sheets that describe the agent and information on occupational risks that may be posed by the agent).
 - Known first aid procedures:
 - Effective disinfectants / neutralizing agents (include location in facility):
 - Known resistance traits introduced into agent(s):
 - Known symptoms associated with exposures to this agent(s):
- **Agent Risk Assessment:** (identify what the risks are for lab personnel or others working with the agent in the laboratory. Examples might be sharps hazards, aerosol hazards, animal bites or exposures, spills, splashes, etc.)
- **Emergency Procedures:** (list procedures to be followed in case of an accident such as a spill, injection, ingestion, aerosolization, splash, etc.)
- **Required PPE:** (lab coat, safety glasses, mask, shoe covers, face shield, etc.)
- **Aerosol Hazards:** (production of aerosols should be minimized in laboratory operations) List all procedures with the agent(s) known to have potential to generate aerosols (e.g. centrifugation, vortexing, stirring, etc). If an aerosol hazard exists, describe methods for preventing or protecting personnel from aerosols.
- **Standard Operating Procedures:** Include copies of applicable SOPs for equipment, decontamination, disposal, technical procedures, emergency procedures, handling procedures, etc. (See the WTAMU BSL-2 Laboratory SOP Template)
- **Security Provisions:** Describe agent security procedures appropriate to assigned agent BSL level.
- **Training:** Records of appropriate training (technical, safety, procedural, etc.) of lab personnel should be included in the Biosafety Manual. If not, these records must be available

Biosafety Level 2 (as per Section IV, *BMBL*)

Biosafety Level 2 builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that 1) personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the facility is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

The following standard and special practices, safety equipment, and facility requirements apply to BSL-2 facilities:

A. Standard Microbiological Practices

1. The PI, CI, or CC must enforce the institutional policies that control access to the facility.
2. Personnel must wash their hands after working with potentially hazardous materials and before leaving the facility.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in facility areas. Food must be stored outside the facility area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, the PI, CI, or CC should adopt improved engineering and work practice controls that reduce risk of sharps injuries.
6. Precautions, including those listed below, must always be taken with sharp items. These include:
 - Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
 - Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.

7. Perform all procedures to minimize the creation of splashes and/or aerosols.
8. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
9. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:
 - Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
 - Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
10. A sign incorporating the universal biohazard symbol must be posted at the entrance to the facility when infectious agents are present. Posted information must include: the facility's biosafety level, the PI, CI, or CC's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory, and agent information.
11. An effective integrated pest management program is required.
12. The PI, CI, or CC must ensure that all personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. All personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices

1. All persons entering the facility must be advised of the potential hazards and meet specific entry/exit requirements.
2. All personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the facility.
3. Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.
4. A facility-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible at all times.

5. The PI, CI, or CC must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
6. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
7. Equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
 - Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
 - Equipment must be decontaminated before repair, maintenance, or removal from the facility.
8. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the biosafety safety manual. All such incidents must be reported to the PI, CI, or CC. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
9. Animals and plants not associated with the work being performed must not be permitted in the facility.
10. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.

C. Primary Barriers and Personal Protective Equipment

1. Properly maintained BSCs (preferably Class II), other appropriate personal protective equipment, or other physical containment devices must be used whenever:
 - Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
 - High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
2. Protective coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that this clothing not be taken home.

3. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses should also wear eye protection.

4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the facility. In addition, BSL-2 facility workers should:

- Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Wear two pairs of gloves when appropriate.
- Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the facility.
- Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

5. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

D. Secondary Barriers

1. Facility doors should be self-closing and have locks with limited access.

2. Facilities must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.

3. The facility should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in facilities are not permitted.

4. Facility furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.

- Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
- Chairs used in facility work areas must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

5. Facility windows that open to the exterior are not recommended. However, if it does have windows that open to the exterior, they must be fitted with screens.

6. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.

7. Vacuum lines should be protected with High Efficiency Particulate Air (HEPA) filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.

8. An eyewash station must be readily available.

9. There are no specific requirements on ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the facility.

10. HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the facility environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the facility exhaust system by either a thimble (canopy) connection or a direct (hard) connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.

11. A method for decontaminating all wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

Emergency & Incident Response Plan (Template)

A. Emergency Contact Information (This should be posted on the BSL-2 facility door)

Name	Contact Numbers
Principal Investigator:	Office:
	Cell :
Alternate Contact:	Office:
	Cell :
WTAMU Biological Safety Officer	Office: 806-651-2642
Dr. Jason Fritzler	Cell: 801-866-4706
Emergency	911
University Police	806-651-2300
University Medical Services	806-651-3287
WTAMU Campus Facilities	
Computer/Phone Problems (ITSC)	806-651-4357 (after hours: 806-316-9037)
Physical Plant	806-651-2133
Health and Safety Office	806-651-2730
Biological Spill	806-651-2730
Radiation Spill	806-651-2730
Chemical Spill	806-651-2730

B. Personal Protective Equipment

List the personal protective equipment in the facility. For example: Personal protective equipment is provided by the University to protect personnel of hazards associated with working in the facility. The equipment provided are splash goggles, lab coats, safety glasses, shoe covers, dust masks. This equipment is kept in labeled drawers. Lab coats are kept by the facility door.

C. Protective Equipment

List the protective equipment in the lab. For example:

The laboratories are equipped with a fire extinguisher located by the lab's exit door.

The safety shower and eyewash is located in the rear right section of the facility.

The biological safety cabinet is located against the windowed wall middle section of the laboratory.

D. Fire or Evacuation Emergency

1. Fire - Call 911 -Give name, location and provide information requested. Secure biohazardous materials by locking the freezer if possible. Do not endanger yourself.

2. Pull fire alarm.
3. Evacuate building – follow exit signs (see evacuation route attached); go to rally location: _____
4. The PI, CI, or CC will take role and identify missing to emergency responder.

E. Biological Spill

A MINOR BIOLOGICAL SPILL is one that can be handled safely by facility personnel without the assistance of safety and emergency personnel. Minor spills include:

- The release of BSL-1 organisms without splashing or agitation
- The release of a small volume of BSL-2 organisms without splashing or agitation

A MAJOR BIOLOGICAL SPILL is one that requires outside assistance. These include:

- The release of BSL-2 organisms resulting in excessive splashing and agitation
- The release of a large volume of BSL-2 organisms (there is enough present to seek its own level or in other words, to run to a low point)

Spill Response

Each facility should have a Spill Response Plan and a Spill Kit on hand (see below). The Spill Response Plan should be available to all personnel and contains four elements: the use and availability of appropriate PPE, assessments of the nature and extent of various spills, the use of appropriate disinfectants, and disposal.

The kit should be maintained in a 5-gallon leak-proof bucket and contain the following:

- Concentrated household bleach or other appropriate disinfectant – check expiration dates
- Spray bottle for making 10% bleach solution
- Forceps or tongs for handling sharps
- Paper towels or other suitable absorbent
- Biohazard bags of various sizes
- Disposable gloves
- Disposable foot covers
- Face protection – at a minimum safety glasses and mask
- Disposable apron, gown or tyvek suit

Spill on Body

1. Remove contaminated clothing.
2. Vigorously wash exposed area with soap and water for at least one minute.
3. If eye exposure occurs, use eye wash per instructions.
4. Obtain medical attention if necessary.

5. Report spill to PI, CI, or CC and AR-EHS and Biological Safety Officer.

Inside the Biosafety Cabinet

1. Wait at least five minutes to allow BSC to filter aerosols.
2. Wear protective coat, sleeve guards, safety glasses, and gloves during clean-up. You may want to double glove in the event the outer pair becomes contaminated.
3. Allow BSC to run during clean-up.
4. Apply disinfectant for a minimum 20 minute contact time.
5. Wipe up spill with disinfectant-soaked paper towels or absorbent pillows.
6. Wipe the walls, work surfaces, inside of sash and any equipment with disinfectant-soaked paper towels.
7. Lift exhaust grill and tray and wipe all surfaces.
8. Discard contaminated disposable materials using appropriate biohazardous waste disposal procedures.
9. Wipe down contaminated reusable items with disinfectant then place in biohazard bags or autoclave pans with lids for autoclaving.
10. Those items that are non-autoclavable should be wiped down with disinfectant and kept wet for a minimum of 20 minutes before removal from BSC.
11. Remove protective clothing when done and place in biohazard bag for autoclaving.
12. Run the BSC for 10 minutes after clean-up before reusing.
13. WASH HANDS!

In the Facility, Outside of BSC

1. Call AR-EHS and Biological Safety Officer if a major spill.
2. Clear the room of all personnel.
3. Remove any contaminated clothing and place in biohazard bag for autoclaving.
4. Wait at least 30 minutes for aerosols to settle before reentry.
5. Put on either a Tyvek suit or disposable gown, disposable foot covers, gloves, and safety glasses.
6. Place dry paper towels on the spill then layer a second set of disinfectant-soaked towels over the spill.
7. Starting from the outside and working in, carefully soak the spill with disinfectant being careful to minimize aerosolization.
8. Decontaminate all items within the spill area. Wait at least 20 minutes contact time with the disinfectant.
9. Wipe equipment and reusable items with the disinfectant.
10. Discard contaminated disposables in biohazard bags.
11. If sharps are present, use a mechanical device such as a dust pan and brush to pick up the spill and place contaminated sharps in an approved sharps container.

Inside a Centrifuge

1. Clear area of personnel.
2. Wait at least 30 minutes for aerosols to settle before clean-up.
3. Wear a lab coat, gloves, and safety glasses during clean-up.
4. Wipe rotors and buckets with disinfectant then remove to nearest BSC for more extensive decontamination.
5. Thoroughly disinfect inside of centrifuge with a minimum contact time of 20 minutes.
6. Dispose of contaminated materials using appropriate biohazardous waste disposal procedures.

Outside the Facility, In Transit

1. To prevent or minimize a spill, transport materials in an unbreakable, leak-proof, sealed primary container placed inside a secondary unbreakable, leak-proof, sealable container. All three containers should be labeled with the universal biohazard symbol.
2. Should a spill occur in a public area, do not attempt to clean up without appropriate PPE.
3. Secure the area around the spill.
4. Call AR-EHS and Biological Safety Officer.
5. Stand by for further assistance if required.

Reporting of Accidents

Major spills and personnel exposure incidents should be reported by the PI, CI, or CC to AR-EHS and the Biological Safety Officer. The safety officer in conjunction with the IBC Chair will conduct an investigation of the laboratory accident. The goal of the investigation is to analyze the events surrounding the accident to prevent or minimize its recurrence and to identify those personnel involved in the event further medical surveillance is needed.

Incidents that did not result in an exposure should still be reported to the safety officer. Evaluation of such incidents can lead to alternative work practices and implementation of controls to minimize future incidents.

Sharps Injury

Whenever an injury occurs involving a sharp (needle, broken glass, etc.) and human material (body fluid, tissue, cell line), the safety officer must be notified. The subsequent investigation will determine if a safer device or work practice can be used to reduce or prevent the accident from reoccurring.

F. Chemical Spill

1. Evacuate area if necessary for personal safety
2. Notify safety officer and supervisor
3. Take action to contain spill if properly trained. Do not endanger yourself.

G. Radiation Spill

1. Evacuate appropriate area

2. Call AR-EHS and Biological Safety Officer.
3. Take action to contain spill if properly trained. Do not endanger yourself.

H. Medical Emergency

1. If an individual is injured, call 911.
2. Notify supervisor.
3. Do not move person or perform any first aid if you are not trained and qualified.