

# BIOSAFETY MANUAL

July 2022

# Compliance and Safety when Working with Biohazards

Texas A&M University Office of Biosafety Biosafety@tamu.edu

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### INTRODUCTION

### The Office of Biosafety

The Texas A&M University (TAMU) biosafety manual was developed by the Office of Biosafety, which is a component of the Office of Research Compliance and Biosafety in the Division of Research. The purpose of this manual is to provide information to faculty, staff, and students on how to work safely in the laboratory with biohazards and recombinant or synthetic nucleic acid molecules, and to maintain compliance with university rules. While this manual specifically addresses biological safety, it is important that personnel are aware that many other hazards (e.g., chemical hazards, radiation hazards, physical hazards, etc.) may be present in the laboratory as well. It is the responsibility of the principal investigator (PI) to ensure that personnel working in their laboratories remain informed of any and all hazards specific to their laboratory. Personnel should be familiar with the different safety programs on campus.

### Contact Information:

### Address:

228 Blocker Hall 1186 TAMU 155 Ireland Street College Station, TX 77843

### Phone:

979-862-4549

### Email addresses:

<u>biosafety@tamu.edu</u>	for any questions related to biohazards and recombinant or synthetic nucleic acid molecules
ibc@tamu.edu	for any questions related to the Institutional Biosafety Committee (IBC), IBC permits, etc.
bohp@tamu.edu	for health-related questions pertaining to work with infectious biohazards and/or animals
bsat@tamu.edu	for questions related to select agents or the select agent program
ire@tamu.edu	for questions about dual use research of concern
labsafety@tamu.edu	for all other laboratory safety-related questions (e.g., chemical, fire and life, etc.)

### 2 BIOSAFETY OVERSIGHT

As required by Texas A&M System Regulation (<u>15.99.06 Use of Biohazards in Research, Teaching and Testing</u>) and the University's Rule for Use of Biohazards and Dual Use Research of Concern (<u>15.99.06.M1</u>), Texas A&M Institutional Biosafety Committee (IBC) approval is required for all research, teaching, or testing activities conducted by faculty or staff of Texas A&M University or a Texas A&M System component that has an intrasystem agreement in place with the Texas A&M University IBC prior to initiating work with:

- a) Biological agents (bacteria, fungi, viruses, protozoa, parasites and prions) that may cause disease in humans, animals, or plants;
- Recombinant or Synthetic Nucleic Acid Molecules, including creation or use of transgenic plants and animals, as defined in the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*);
- c) Human and non-human primate blood, tissue, cells and cell lines; and
- d) Toxins of biological origin as defined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) document.

### Helpful Links

- TAMU University Rule 15.99.06.M1 Use of Biohazards, Biological Toxins and Recombinant DNA and Dual Use Research of Concern
  - https://rules-saps.tamu.edu/PDFs/15.99.06.M1.pdf
- TAMU System Regulation 15.99.06 Use of Biohazards in Research, Teaching and Testing
  - https://policies.tamus.edu/15-99-06.pdf
- Bloodborne Pathogens Exposure Control
  - https://rules-saps.tamu.edu/PDFs/24.01.01.M4.01.pdf
- NIH Guidelines
  - https://osp.od.nih.gov/wp-content/uploads/NIH\_Guidelines.pdf
- NIH Guidelines Frequently Asked Questions
  - https://osp.od.nih.gov/biotechnology/nih-guidelines-faqs/
- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
  - https://www.cdc.gov/labs/pdf/SF\_\_19\_308133-A\_BMBL6\_00-BOOK-WEB-final-3.pdf
- Laboratory Biosafety Manual, 3<sup>rd</sup> Edition (World Health Organization) Available in English, French, Spanish, Portuguese, Chinese, Russian, Italian, Georgian, Japanese, Serbian, and Vietnamese
  - https://www.who.int/csr/resources/publications/biosafety/WHO\_CDS\_CSR\_LYO\_2004\_11/en/
- Select Agents and Toxins
  - https://www.selectagents.gov/
- CDC Import Permit Program
  - https://www.cdc.gov/cpr/ipp/index.htm
- USDA Permits
  - https://www.aphis.usda.gov/aphis/resources/permits

### **3** ROLES AND RESPONSIBILITIES

Texas A&M University's biological safety program was developed from the University's commitment to protect faculty, staff, students, visitors, the general public, and the environment from the risk of potential occupational exposure to biohazardous materials and recombinant DNA and to ensure that all activities and facilities used to conduct such work are in compliance with applicable federal and state laws, regulations, and guidelines. Additionally, the University is committed to the shared responsibility of upholding the integrity of science and to reducing the risk of its misuse.

### 3.1 TEXAS A&M UNIVERSITY, THE INSTITUTION

Texas A&M University instituted and maintains a biosafety program for all faculty, staff, and students at Texas A&M at risk of exposure to biological hazards in the performance of their duties or activities. The program extends to researchers employed by institutions that maintain an intrasystem agreement with Texas A&M University for the provision of such services (e.g. Texas A&M AgriLife Research, Texas A&M Engineering Experiment Station, and Texas A&M Veterinary Medical Diagnostic Laboratory). The University also ensures access to appropriate training for the Institutional Biosafety Committee (IBC) chair and its members, the Biological Safety Officer (BSO), Principal Investigators (PIs), and staff and students conducting research, teaching, or testing activities with biohazardous materials.

### 3.2 INSTITUTIONAL OFFICIAL (IO)

The President of Texas A&M has appointed the Vice President for Research (VPR) as the IO responsible to oversee the University's biological safety program. The VPR appoints the members and the chair of the IBC. Administratively, the IBC and BSO report to the VPR. The chair of the IBC also reports directly to the VPR. The final authority for decisions pertaining to conduct of research and research compliance is the IO.

### 3.3 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The IBC is responsible, as articulated in University Rule 15.99.06.M1 Use of Biohazards, Biological Toxins and Recombinant DNA and Dual Use Research of Concern, for reviewing research involving recombinant DNA and/or biohazards conducted at or sponsored by Texas A&M and affiliated institutions for compliance with the current versions of the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines) and the Biosafety in Microbiological and Biomedical Laboratories (BMBL), as applicable, and approving those research projects which conform with these regulatory documents. The IBC's review must include an independent assessment of the containment levels required for the proposed research and an assessment of the facilities, procedures, practices, training, and expertise of personnel involved in research.

### 3.4 CHAIR OF THE IBC

The chair of the IBC presides over all meetings of the IBC and may assign additional duties to other members of the IBC as deemed necessary. The IBC Chair may approve, on behalf of the committee, submissions not requiring full committee review during a convened meeting. The chair of the IBC is responsible to ensure that all members of the committee, including alternate members and community representatives, are appropriately trained. The vice chair may preside over IBC meetings in the absence of the chair, or if the chair must recuse him/herself during a meeting.

### 3.5 BIOLOGICAL SAFETY OFFICER (BSO)

The BSO is the designated scientific-administrative officer who ensures compliance and biosafety of research involving biohazards and/or recombinant DNA conducted at Texas A&M and affiliated institutions. The BSO serves as an IBC member and provides technical advice to the IBC, as well as researchers on laboratory containment, security, and safety procedures. The BSO oversees periodic laboratory inspections to ensure that laboratory standards are followed and departures are corrected in a timely manner. The BSO reports significant problems or violations to the IBC and NIH/OBA, as necessary. The BSO reports directly to the Associate VPR.

### 3.6 RESPONSIBLE OFFICIAL (RO)

If the University manages and/or controls facilities where select agents are present or in use, the University is responsible for acquiring and maintaining a certificate of registration from the U.S. Department of Health and Human Services ("HHS") or the United States Department of Agriculture and for appointing an RO with both authority and responsibility for institutional compliance with federal laws and regulations governing the possession, use and transfer of biological select agents and toxins. The IO appoints the RO, who must be approved by the Federal Select Agent Program.

### 3.7 BIOSAFETY PROGRAM OFFICE

The Office of Biosafety (OB) provides administrative support to the IBC. On behalf of the IBC, the BSO and associate biosafety officers (ABSOs) ensure safety and compliance by regularly assessing laboratories, by conducting biosafety training, and by assisting PIs and IBC members in the review and approval process of IBC submissions. The biosafety office also includes the Biosafety Occupational Health Program (BOHP). The BOHP provides occupational health services to personnel at risk of exposure to animals or infectious biohazards (in BSL-2 and BSL-3 labs) in the course of their participation in IBC or IACUC permitted research, teaching or diagnostic activities, or to University personnel working in University facilities where animals are housed or manipulated.

### 3.8 DEPARTMENT HEADS AND DEANS

IBC applications include a sign-off by the PI's supervisor prior to submission of the application to the IBC. The supervisor's signature acknowledges that the supervisor is aware of the submission, the scope of the work with biohazards proposed, and approves of all the information as presented. Supervisors are responsible for assuring that research involving the use of biohazards and recombinant DNA is appropriately reviewed and approved by the IBC prior to the initiation of any work and that the facilities and infrastructure are adequate and available for the proposed work.

### 3.9 PRINCIPAL INVESTIGATORS (PIS) AND LABORATORY SUPERVISORS (LS)

The PI/LS is the one designated by the institution to direct a project or program and who is responsible to the institution for the scientific and technical direction of that project or program. It is the responsibility of the PI/LS to carry out their research, teaching or testing activities in compliance with all federal, state, and university requirements with approval from the IBC, as appropriate. PIs/LS must be trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling infectious agents and are responsible for the conduct of work with any infectious agents or materials taking place in their lab. They are responsible for the timely submission of annual renewals and amendments to notify the IBC of any changes to the scope of work with biohazards. Likewise, they are responsible for providing lab and agent-specific

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training to laboratory staff and for enforcement of IBC decisions pertaining to lab specific research. Finally, they are also responsible for maintaining all necessary SOPs and permits for import, transport, and/or use of biological agents and recombinant DNA.

### 4 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) COMPLIANCE

### 4.1 DO I NEED IBC APPROVAL?

The tables on the following pages were developed to assist researchers in determining whether their activities with biohazards (including the use or creation of genetically modified plants and animals) require IBC review & approval. You can always contact us with specific questions about your need for IBC approval.



### Do I Need IBC Approval?

Agent / Scope (not an inclusive list)	IBC Approval Required  full committee review at a monthly meeting	IBC Approval Required  review by IBC Chair on behalf of committee	No IBC Approval Required
Cloning and protein expression in <i>E. coli</i> K-12 derived strains (includes DH5a, Hrf strains, SURE, TOP10, etc.)		Х*	
Cloning and protein expression in non K-12 strains of <i>E. coli</i> (includes B, BL21, Rosetta, etc.)	x		
Cloning and protein expression in <i>Saccharomyces</i> and <i>Kluyveromyces</i> host-vector systems		Х*	
Cloning and protein expression in <u>asporogenic</u> Bacillus subtilis and B. licheniformis host-vector systems		Х*	
Cloning and protein expression in spore-forming Bacillus subtilis	X		
Cloning and protein expression in bacteria, viruses, fungi, protozoans, etc.	x		
Wild-type bacteria, viruses, fungi and protozoans pathogenic or		Х*	
Animal cells and cell lines /tissue /blood from uninfected			
animal cells and cell lines (issue) blood from difficeted			x
*These cells may not be recombinantly modified to retain exempt status.			'n
Human and non-human primate cells and cell lines, tissue, blood*		Х*	
("Provided these materials are not recombinantly modified.)			
primate cells and cell lines (transfected)		X*	
Animal and human cells and cell lines, including non-human primate cells and cell lines (transduced with viral vectors)	X*		
Viral vectors (e.g. Lentiviral, retroviral, baculoviral, adenoviral, adeno-associated viral vectors, etc.)	Х*		
Plant pathogens (including local, i.e. Texas, isolates)		X*	
Toxins of biological origin (e.g. aflatoxin, pertussis)		Х*	
Activities involving gene editing systems (e.g. CRISPR/Cas9, TALENS, etc.)	X**		
Large-scale experiments (greater than 10 liters of culture in a single vessel)	X		
Materials requiring federal transport/import permits		X*	
Experiments involving the introduction of synthetic nucleic acids			
(e.g. siRNA, microRNA, morpholinos, antisense oligonucleotides) <b>into animals</b> (e.g. rodents, zebrafish, drosophila, pigs, etc.)		Х*	
Experiments involving the introduction of recombinant material into animals or plants, including creation or use of genetically	X*		
modified animals or plants			

\*: some exceptions may apply \*\*: depends on method of delivery



### Genetically Modified (GM) Animals and Plants Do I Need IBC Approval?

Activity (not an inclusive list)	IBC Approval Required  full committee review at a monthly meeting	IBC Approval Required  review by IBC Chair on behalf of committee	No IBC Approval Required
GM Rodents	-	·	
Purchasing an existing line of GM rodents from a commercial vendor or			v
repository (e.g. Jackson Labs) that can be housed at BL-1 containment			^
Purchasing an existing line of GM rodents from a commercial vendor or	v		
repository (e.g. Jackson Labs) requiring BL-2 (or higher) containment	^		
The transfer of GM rodents (from one PI to another) that can be housed at			x
BL-1 containment			~
The transfer of GM rodents (from one PI to another) requiring BL-2 (or	x		
higher) containment	^		
Breeding rodents from one strain (propagation/colony maintenance) at BL-1			x
containment			X
Breeding rodents from one strain (propagation/colony maintenance)	x		
requiring BL-2 (or higher) containment	-557		-
Breeding two GM rodents to create a new GM strain that can be housed at			х
BL-1 containment (see Note A)			~
Breeding of a GM rodent and a non-GM rodent to create a new GM strain			х
that can be housed at BL-1 containment (see Note A)			
Breeding rodents from two different strains to create a new GM strain	x		
requiring BL-2 (or higher) containment	5.54 5		7
Creation of new GM rodents as a fee for service	1954		
(e.g. TIGM, Biocytogen, Cyagen, Taconic Biosciences, Applied StemCell, etc.)	X		
(see Note B)			
GM Animals (other than rodents, ir	ncluding insects)	1	
Purchase, transfer, breeding and creation of GM animals	X		
GM Plants		1	
Experiments involving nucleic acid molecule-modified whole plants	X		
Experiments involving recombinant or synthetic nucleic acid molecule-	x		
modified organisms associated with whole plants		5.6	
Creation of modified plants using biolistic bombardment		X	-
GM plants created by Agrobacterium-mediated transformation	X		

Note A: No IBC approval needed if:

- 1. Both parental rodents can be housed at BSL-1 containment and
- 2. Neither parental transgenic rodent contains the following genetic modifications:
  - a. Incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses
  - b. Incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR) and
  - c. The transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses

Note B: Either the company <u>OR</u> the researcher must have IBC approval, prior to the generation of the new rodent.

### 4.2 OBTAINING IBC APPROVAL

### 4.2.1 Registration with the TAMU IBC

- 1. The initial step for approval to work with biohazards or recombinant DNA/RNA is to submit a complete IBC application to the IBC.
  - a. Only faculty (or faculty equivalent titles see: <u>https://facultyaffairs.tamu.edu/dof/media/DOF-</u> <u>Media/Documents/DOF%20Guidelines/Faculty-Titles-Review-(June-2022)-(002) 1.pdf</u>) may apply for an IBC permit.
  - b. One IBC permit per Principal Investigator (PI); multiple permits are not typically issued, though certain exceptions may apply.
    - i. PIs using biohazardous materials in teaching labs will have a teaching permit in addition to their research permit.
    - ii. PIs working with select agents will have separate IBC permits to distinguish their select agent vs non-select agent work.
- 2. All applicable forms are available online. (https://iris.tamu.edu)
- 3. Instructions and assistance are available. (979.845.4969 or IBC@tamu.edu)

### 4.2.2 IBC Training Requirements

Initial training requirements may be completed while the IBC application is under review.

- ALL Principal Investigators (PIs) submitting an IBC application must complete training on the NIH Guidelines and University Rule for Use of Biohazards. This training is available and must be completed online in TrainTraq. Training on the NIH Guidelines and University Rule for Use of Biohazards is required once, unless the training is significantly revised and/or updated, at which time training may be reassigned.
- 2. All personnel (including the PI) who will be working in a biosafety level two (BSL-2) laboratory must be identified and listed in the IBC application. For more specific guidance on this topic, please refer to <u>Appendix M</u>. A description of everyone's role in the proposed projects must be provided. All BSL-2 personnel must complete **BSL-2 training** before being authorized to work in the BSL-2 lab. BSL-2 training must be completed online via TrainTraq once every five years.
- 3. All personnel who will be working in a biosafety level three (BSL-3) laboratory must be identified and listed in the IBC application and must complete the instructor-led *Principles of BSL-3* course, provided by Office of Biosafety staff, before being authorized to work in any BSL-3 lab. Additional, required hands-on BSL-3 training is provided by the Office of Biosafety of other Division of Research personnel. Instructor-led didactic and hands-on BSL-3 training is available upon request, as needed. Please contact the Office of Biosafety at 979.862.4549 or <u>biosafety@tamu.edu</u> for assistance. The *Principles of BSL-3* course is required annually.
- 4. All personnel listed on either BSL-2 or BSL-3 IBC permits must also be provided lab/agent specific training by the PI (or PI's designee). Documentation of this training must be provided to the IBC. The Office of Biosafety can provide PIs with a template form to fulfill this requirement;

alternatively, attestation that this training was provided by the PI is included as part of the IBC application. A description of the content of lab and agent specific training is also required within the IBC application.

- 5. **Bloodborne Pathogen (BBP) training** must be completed by all personnel at occupational risk of exposure to human (and/or non-human primate) blood, tissues, body fluids, and/or other potentially infectious materials (e.g. human feces, etc.). This includes human (or non-human primate) cell lines, even commercially available, well-characterized ones. Annual BBP refresher training is required. Initial and annual refresher BBP training may be completed online via TrainTraq.
- 6. For personnel working in BSL-2 and BSL-3 labs, a one-time, online training (available in TrainTraq) on the **use of biological safety cabinets** will also be assigned. Completion of this training is required by the IBC.
- 7. Other trainings and risk mitigations may be assigned, as required by the IBC permit.
- 8. Additional Online Training and Resources
  - NIH Guidelines and University Rule for Use of Biohazards TrainTraq Course #211485
  - Biosafety Level 1 Training TrainTraq Course #2112788
  - Biosafety Level 2 Training TrainTraq Course #211486
  - Effective Use of Class II Biological Safety Cabinets TrainTraq Course #2111531
  - Bloodborne Pathogen Training for Research Personnel TrainTraq Course #2114036
  - Bloodborne Pathogen Exposure Control Plan <u>https://vpr.tamu.edu/wp-content/uploads/2021/10/2020-12-31-TAMU-BBP-ECP\_signed.pdf</u>
  - Researchers Who Work with Pregnant Sheep Inside Facilities TrainTraq Course #2111497
  - **Powered-Air Purifying Respirator (PAPR) Training** TrainTraq Course #2111580
- 4.2.3 Laboratory Assessment and Certification
  - During the IBC review and approval process, laboratories will be assessed for biosafety standards by Office of Biosafety staff, on behalf of the IBC, using checklists developed per CDC BMBL and NIH Guidelines standards.
  - 2. Laboratory site visits will be scheduled with PIs or their designees.
  - 3. The IBC application cannot be approved until all lab spaces, identified by the PI, have been assessed and certified for the appropriate biosafety level.
    - a. Biosafety assessment checklists (BSL-1, BSL-2, etc.) are available here: (https://rcb.tamu.edu/biohazards/laboratory-and-facility-requirements)
    - b. Core facilities, for example for microscopy or flow cytometry, must also be identified in the IBC application and approved for work with biohazardous materials if viable biohazardous samples will be taken there.

4. Biohazard signage is provided by the Office of Biosafety. To request the necessary sign template, contact the Office of Biosafety at <u>biosafety@tamu.edu</u>.

Laboratories are typically re-assessed annually, as part of the annual review process, or more often, as needed.

### 4.2.4 IBC Approval

- IBC applications (initial, three-year renewals, and amendments) describing recombinant DNA (rDNA) studies that are not exempt of the NIH Guidelines, and have not been previously reviewed by the IBC, must be reviewed by the full committee during a regularly convened meeting. NOTE: An application should be submitted at least 10 business days before the meeting date in order to be considered for review during the upcoming meeting.
- 2. The IBC typically meets the fourth Wednesday of each month, with the exception of November and December, when meetings may be rescheduled to accommodate holidays. IBC meetings are open to the public.
- 3. IBC applications describing non-recombinant work with biohazards, or recombinant work that is exempt of the NIH Guidelines, must still be registered with the IBC but may not require review during a regularly convened meeting. Such submissions may be reviewed and approved by the IBC Chair (or Vice-Chairs), on behalf of the IBC.
- 4. IBC approvals are valid for a period of three (3) years. Annual review of the permit is required as described below (see Annual Review).

### 4.2.5 Other Approvals

- If your project will involve direct work with vertebrate animals, please contact the Animal Welfare Assurance Program at <u>https://rcb.tamu.edu/animals</u>, if you have not already done so.
- 2. If your research, involves human subjects or human materials, please contact the Human Subjects' Protection Program at <a href="https://vpr.tamu.edu/human-research-protection-program/">https://vpr.tamu.edu/human-research-protection-program/</a>.
- 3. If your research involves the export of materials or the inclusion of a Foreign Person, please contact the Export Controls Office at <u>https://vpr.tamu.edu/initiate-research/export-controls</u>.
- 4. If your research involves the transfer of tangible material (e.g. cell lines, cultures, bacteria, nucleotides, proteins, transgenic animals, etc.) from or to Texas A&M University from or to an outside entity, contact the Texas A&M Research Administration (TAMRA) Office at <u>negotiations@tamu.edu</u>. The exchange of research material may require a Material Transfer Agreement (MTA) before materials are provided or received.

### 4.2.6 Commencement of Work

- 1. Once the IBC approval letter, signed by the IBC Chair, is received by the PI, approved experiments may commence. A copy of the IBC approval letter will be provided to the PI's Department Head.
- 2. The IBC approval letter describes the conditions of approval and includes any special provisos or requirements necessary to retain approval.

### 4.2.7 Annual Review (Post Approval Monitoring)

- 1. An annual review questionnaire must be submitted by the PI 30-60 days prior to the first and second anniversary of the original IBC permit approval.
  - a. Annual review forms are accessible online in the iRIS program.
  - b. A laboratory site visit is usually scheduled as part of the annual review.
  - c. Completion of personnel training requirements is monitored, during the annual review to ensure that all personnel working at BSL-2/BSL-3 are current with respect to all required trainings.

### 4.2.8 3-Year Renewal

- 1. IBC approvals are valid for a period of three (3) years.
- 2. 60-90 days prior to the expiration date (third anniversary) of the IBC permit, researchers must submit a three year renewal form and attach their updated IBC application, after making all necessary revisions.
  - a. All necessary forms are found online here: <u>https://iris.tamu.edu</u>.
  - b. A laboratory site visit will be scheduled as part of the 3-year renewal.
  - c. Completion of personnel training requirements is reviewed to ensure that all personnel working at BSL-2/BSL-3 are up to date on all required trainings.

### 4.2.9 Amendments

- 1. Amendments are required prior to implementing any changes to the existing IBC approval, including changes in:
  - a. **Personnel:** Addition (or removal) of laboratory personnel to BSL-2 and BSL-3 IBC permits must be submitted online here: (<u>https://iris.tamu.edu</u>). See <u>Appendix M</u> for more information.
  - b. **Agents:** New agents, procedures, recombinant activities, etc., not previously approved must be submitted online here (<u>https://iris.tamu.edu</u>) for review by the IBC.
  - c. **Scope of work:** All proposed manipulations and activities with biohazardous agents should be described in the IBC application. If a new scope of work is proposed, e.g. live cell sorting, an amendment must be submitted first.
  - d. Locations: Any changes in location of work must be submitted to the IBC (<u>https://iris.tamu.edu</u>) for approval.
    - i. As appropriate, all new lab spaces must be assessed and certified by the Office of Biosafety, on behalf of the IBC, before work with biohazardous materials may commence in the new space.

### 4.2.10 Termination of IBC Permit

1. Investigators leaving the institution or ceasing their activities with biohazardous materials are required to submit a termination request to the IBC. The termination form is found online here: <a href="https://iris.tamu.edu">https://iris.tamu.edu</a>.

2. Requests for termination will initiate the laboratory decommissioning process described in the section below.

### 4.2.11 Laboratory Decommissioning Process

When IBC approved laboratories/rooms, where work with biohazardous materials was conducted, are being vacated, they must be properly decontaminated and biological and chemical agents must be properly disposed of (and/or secured for transport), as appropriate. Vacated labs will be inspected and decommissioned by both the Office of Biosafety and the Environmental Health and Safety Department in accordance with the <u>University Standard Administrative Procedure 24.01.01.M4.04</u>.

- 1. When does a PI need to decommission their lab?
  - a. PI is leaving Texas A&M University
  - b. PI is moving to another building and lab on campus
  - c. PI is relocating to another lab within the same building
  - d. Laboratory is undergoing general renovation
- 2. What needs to be done?
  - a. Properly dispose of, secure, or transfer all biological materials.
  - b. Empty, clean, and decontaminate (with appropriate disinfectant) all bench tops, cabinets, and drawers.
  - c. Decontaminate all equipment, e.g. incubators, shakers, centrifuges, etc. using agentappropriate disinfectant. Complete an Equipment Decontamination Form (found at https://ehs.tamu.edu/programs/laboratory-safety/) and attach to decontaminated equipment.
    - Decontaminate the Biosafety Cabinet (BSC) using agent-appropriate disinfectant. Complete an <u>Equipment Decontamination Form</u> and attach to decontaminated BSC.
    - If the BSC is to be moved from one building to another, transferred to another PI, or is being sent to surplus, it must be gas/vapor decontaminated by a trained professional, prior to relocation/transfer, using an approved and appropriate disinfectant. Such decontamination of the BSC must be completed by a certified and approved vendor.
  - d. Contact Office of Biosafety staff (<u>biosafety@tamu.edu</u>) to schedule a decommissioning inspection, as necessary.
  - e. All door or other biohazard signs previously posted in the lab will be removed by Office of Biosafety staff upon confirmation that all biohazards have been removed, appropriately disposed or transferred, and the lab and equipment have been decontaminated.

### 5 WORKING IN THE LABORATORY

### 5.1 BIOSAFETY LEVELS

Containment of potentially hazardous biological agents is a fundamental objective of any biosafety program. Containment aims to reduce the possibility of agents from being released into the environment outside the laboratory, to prevent transmission of the biological agents being handled in the lab to laboratory personnel exposure, and to protect the biological integrity of the agents in use. Containment is achieved by a combination of good laboratory practices and techniques, proper use of safety equipment and adequate facility design and construction. Four distinct biosafety levels are designed to effectively contain biohazards based on their risk; each biosafety level builds upon the controls of the preceding levels.

The CDC HHS guidance document, *Biosafety in the Microbiological and Biomedical Laboratories*, uses the designations BSL-1 through BSL-4 to define the four containment levels.

### 5.1.1 Biosafety Level One (BSL-1)

BSL-1 is the most basic level of containment and is appropriate for well-characterized agents not known to consistently cause disease in immunocompetent adults and which present no more than a minimal hazard to the environment and laboratory personnel. At BSL-1, lab work is typically conducted on the open bench. Specialized containment equipment is generally not necessary, but may be required depending upon a risk assessment. Personnel should be trained to perform all necessary procedures by qualified and experienced scientists.

### 5.1.2 Biosafety Level Two (BSL-2)

BSL-2 is suitable for work with biological agents known to cause disease (of varying severity) in humans. Biological agents requiring BSL-2 containment are not typically transmitted by aerosols in nature, rather transmission of these agents generally occurs by ingestion, percutaneous or mucous membrane exposure. BSL-2 containment differs from BSL-1 containment in that personnel require enhanced training and supervision when handling disease causing pathogens and procedures resulting in aerosol generation must be conducted inside a biosafety cabinet (BSC) or other containment equipment. Access to BSL-2 labs should be restricted to personnel who meet all entry requirements.

### 5.1.3 Biosafety Level Three (BSL-3)

BSL-3 is required for work with biologically hazardous agents transmitted by the aerosol route. Agents worked with in a BSL-3 laboratory cause serious diseases which have the potential to be lethal. Often these diseases are treatable with antibiotics and may be preventable by vaccination, but nevertheless, enhanced training and precautions are necessary to protect personnel. BSL-3 differs from BSL-2 in that all manipulations of biohazardous agents at this biosafety level must be limited to the BSC or other primary containment. Additionally, BSL-3 labs have specialized design and engineering features. Personnel who work in BSL-3 labs must receive agent- and laboratory-specific training and be part of a robust mentoring program.

### 5.1.4 Biosafety Level Four (BSL-4)

BSL-4 is required when working with exotic biohazards known to cause life threatening, generally untreatable diseases in humans for which no vaccinations are available. There are two models for BSL-4 laboratories. Personnel conduct all work with agents inside a Class III BSC or personnel must wear a positive pressure supplied-air protective suit and conduct all work with agents inside a Class II BSC. BSL-4 labs have highly specialized engineering features to contain microorganisms inside the lab and prevent their release into the environment. Personnel who work at BSL-4 require specialized training and mentoring to ensure they understand how to work safely with extremely dangerous and exotic agents and how to properly perform the procedures requiring BSL-4 containment.

### 5.1.5 Other Types of Containment

Research that involves animals, plants, and arthropods presents hazards that are not always addressed by the standard containment considerations outlined above. Sometimes there is heightened risk to personnel, but in other cases, the risk to personnel is low and the need to prevent release of the agent to the environment is of greater concern. Additional containment requirements are outlined for animal work (Animal Biosafety Levels 1-4), large volumes of agent, i.e., volumes greater than 10L in a single vessel (Good Large Scale Practices, Biosafety Levels 1 Large Scale – 3 Large Scale), work with plants and plant pests in greenhouses (Biosafety Levels 1P-4P), and arthropods such as mosquitoes and ticks (Arthropod Containment Levels 1-4). Contact the Office of Biosafety for more information about these types of containment.

### 5.2 RISK ASSESSMENTS

### 5.2.1 Risk Groups

Biohazardous agents are categorized into risk groups based on consideration of at least the following six criteria:

- Pathogenicity of the agent;
- Virulence of the agent;
- Host range of the agent;
- Route of transmission of the agent;
- Stability of the agent in the environment; and
- The availability of preventative or therapeutic measures.

Similar to the four biosafety levels, there are four risk groups within which biological agents are classified.

**Risk Group 1 (RG1)** agents are well-characterized microbes not known to cause disease in otherwise healthy, immunocompetent humans. Likewise, RG1 plant microbes are those non-exotic microorganisms (or recombinantly modified plants) with no recognized potential for rapid or widespread dissemination or for any serious, negative damage to the environment.

**Risk Group 2 (RG2)** agents are those that have the ability to cause disease in humans, but for which preventative or therapeutics are often available. RG2 agents are not typically transmitted by the aerosol route in nature. Likewise, this risk group designation may also apply to plants, modified by recombinant

DNA, that are noxious weeds or can breed with noxious weeds in the immediate environment, plants containing the whole genome of a non-exotic infectious plant pathogen, or to plant associated, non-exotic microorganisms with a recognized potential to cause damage to the environment.

**Risk Group (RG3)** agents are those microbes associated with serious disease in humans, typically transmitted by the aerosol route, and for which preventative or therapeutic interventions may be available. Risk Group 3 would also include exotic plant pathogens with a recognized potential for serious damage to the environment or plants when they contain cloned genomes of readily transmissible exotic, infectious agents posing a serious threat to the environment.

**Risk Group 4 (RG4)** agents are those agents associated with serious, often fatal, human diseases for which preventative or therapeutic treatments are usually not available. RG4 agents transmissible to humans includes a variety of viral agents only. Risk Group 4 would also include a small number of readily transmissible, exotic, infectious agents with a recognized potential of being serious pathogens of major U.S. crops.

Recognizing and managing the risks associated with the microorganisms (or recombinantly modified plants or animals) in use and identifying the optimum containment strategies to prevent personnel exposure or damage to the environment are the hallmarks of biosafety.

### 5.2.2 Routes of Transmission

The most common routes of disease transmission in the laboratory are:

- Direct exposure to skin, eyes, or mucus membranes
- Parenteral inoculation by needle stick or other contaminated sharp
- Ingestion of liquid suspension of an infectious agent or hand-to-mouth exposure
- Inhalation of infectious aerosols

Keep in mind that, because of the high concentrations and large volumes of culture used in laboratory research, opportunities for transmission exist in the lab that aren't commonly considered out in the community.

Likewise, fomites (inanimate objects such as pens and doorknobs) can become contaminated with infectious organisms in use in the laboratory and aid in their transmission from one individual to another. See <u>Appendix A</u> for guidance on controlling the spread of disease by fomites.

### 5.3 BIOHAZARD SIGNAGE

All biosafety laboratories are required to display biohazard signage on all entrance doors.



**Exit signs** are posted on the inside (lab side) of all doors exiting the laboratory space and must include:

- Universal biohazard symbol
- Biosafety level (BSL-1 to BSL-4)
- Exit instructions

Biohazard sign templates are provided by the Biosafety program upon completion of a satisfactory laboratory inspection. For questions related to biohazard signs, contact the Office of Biosafety at biosafety@tamu.edu.

**Entrance signs** are posted on the outside of all doors entering the laboratory space and must include:

- Universal biohazard symbol
- Biosafety level (BSL-1 to BSL-4)
- List of agents/organisms in use or stored in the laboratory
- Entry and PPE requirements
- Emergency contact information for the principal investigator (PI) of the lab and at least one additional senior person who is knowledgeable about lab operations and who can be reached in an emergency



### 5.4 STANDARD MICROBIOLOGICAL PRACTICES

Standard microbiological practices form the foundation for working with biohazards at any biosafety level. When working in a BSL-1 or higher lab researchers must adhere to the following standard practices:

- 1. Control access to the laboratory. The lab must have a door; it should be kept closed, and should be locked when the lab is unoccupied.
- 2. The laboratory supervisor must make sure that all personnel receive appropriate training regarding:
  - their duties in the lab
  - necessary precautions to prevent exposures
  - how and where to report injuries, accidents or incidents in the lab which may have resulted in exposure of personnel
  - how their personal health status impacts their risk of infection. Provide all personnel with information regarding immune competence and conditions that may predispose them to infection.
- 3. A safety manual must be developed to describe the biosafety and containment practices required for the organisms in use. The safety manual should describe appropriate decontamination methods and should contain instructions to follow in case of emergency, including exposures, medical emergencies, equipment or facility malfunctions, inclement weather, etc.
- 4. Wash your hands after working with biohazards and before leaving the laboratory.
- 5. Do not eat, drink, smoke, handle contact lenses, or store food for human consumption in the lab.
- 6. Do not mouth pipet. Mechanical pipetting devices must be available.
- 7. Restrain long hair so that it can't contact hands, samples, or equipment.
- 8. Wear gloves to protect hands from exposure to hazardous materials.
  - Don't wear gloves outside the laboratory.
  - Change gloves when contaminated or when glove integrity is compromised.
  - Dispose of used gloves with other contaminated laboratory waste.
- 9. Handle all sharps, including needles, scalpels, pipets and broken glassware with caution to prevent injury to personnel.
  - Do not recap, bend, or break needles. Place used needles in a punctureresistant sharps container. Sharps containers should be placed within arm's reach of your work area.
  - If absolutely necessary to recap or remove a needle, a hands-free or other comparable device (e.g. a cap holder or a pair of forceps) must be used to prevent injury.
  - Do not pick up broken glass with your hands. Use a broom and dustpan or forceps and dispose of glass in a sturdy cardboard box.
  - Store reusable sharps in a hard-walled container when not in use and during transport.
  - Post the TAMU "Stop Sticks!" sharps guidance (<u>Appendix B</u>) in your lab.

- 10. Conduct procedures carefully and in a manner that limits splashes or sprays of biohazards.
- 11. Disinfect work surfaces and equipment regularly. Keep work surfaces clear and tidy so routine decontamination is easy.
- 12. Learn about fomites; guard against creating them and releasing your agents outside of the lab. See <u>Appendix A</u> for more information about fomites.
- 13. Decontaminate all cultures, plates, and supplies that have come into contact with biohazards. This can be done by adding appropriate chemicals to liquid cultures or by autoclaving wastes using a validated and regularly verified autoclave cycle.
  - Transport wastes using a durable, leak-proof container labeled with the biohazard symbol. Disinfect the outer surface of the container prior to transport.
  - Post the TAMU Biohazardous Waste Guidance in your lab (<u>Appendix C</u>).
- 14. Make sure everyone is aware of the biohazards that are approved for use in your lab. Post a Biohazard laboratory sign on each door into the lab. Review posted signage regularly and revise as necessary to ensure signs are accurate and up to date.
- 15. The facility must have an effective integrated pest management program. If you see any insects, rodents, or other pests (or evidence of their presence) in your lab, notify your supervisor or building proctor right away. If the problem persists, notify the OBS (<u>biosafety@tamu.edu</u>).
- 16. Do not bring plants or animals to the laboratory unless they are associated with the work being performed.

### 5.5 SPECIAL MICROBIOLOGICAL PRACTICES

In addition to the standard microbiological practices, work in a BSL-2 laboratory requires the following special practices:

- 1. Access to the laboratory is controlled when work is conducted; all personal must be aware of the potential hazards and meet entry/exit requirements:
  - Personnel must complete all IBC-required trainings, enroll in the Biosafety Occupational Health Program (BOHP), and all IBC required risk mitigations (e.g. respiratory fit-testing, medical surveillance, etc.) before being allowed to work in the lab with biohazardous agents.
  - Laboratory- and agent-specific training must be provided by the PI or supervisor. PIs should summarize the content and document the provision of this training for all personnel.
  - Personnel must demonstrate proficient microbiological practices before working with risk group 2 agents.
  - Personnel must be provided agent-specific training whenever a new risk group 2 agent is being added to the permit. This training should be documented.
- 2. Incidents involving exposure to biohazards must be reported immediately to the supervisor and to the Office of Biosafety.

- 3. Perform aerosol-generating procedures involving infectious materials inside a properly maintained biosafety cabinet, unless an alternative risk mitigation (e.g. respiratory protection) has been approved by the IBC.
- 4. Use sealed rotors or safety cups when centrifuging infectious materials in the open lab. Open rotors and safety cups only when they are inside the biosafety cabinet.
- 5. Routinely decontaminate laboratory equipment after spills or splashes and before repair, maintenance or removal from the laboratory.
- 6. A method (e.g. autoclave, chemical means, incineration, or other validated decontamination method) for decontaminating laboratory wastes is available.

### 5.6 LABORATORY FACILITIES

- 1. Laboratories must have a door. BSL-2 labs require self-closing doors that can be locked.
- 2. Laboratories must have a sink for handwashing, unless special considerations prevail (e.g. microscope rooms). The sink in a BSL-2 lab should be located near an exit.
- 3. An eyewash station must be readily available (in the lab) and properly maintained by activating it weekly. This activity should be performed and documented by lab personnel.
- 4. The laboratory should be maintained in a manner that facilitates cleaning and surface disinfection. Carpets or rugs in labs are not appropriate; chairs should be covered with a non-porous material. Likewise, bench tops should be resistant to heat and chemicals and impervious to water so they stand up to frequent disinfection.
- 5. If windows are present, they should not open to the outside.
- 6. Illumination in the lab should be adequate and avoid reflections and glare that could interfere with vision.
- 7. If vacuum lines are present in BSL-2 labs, they must be protected with an in-line HEPA (or equivalent) filter.
- 8. There are no specific requirements for ventilation in BSL-1 and BSL-2 labs, but planning of new BSL-2 facilities should consider ventilation systems that provide inward, directional airflow without recirculation to other, non-laboratory areas.

### 5.7 PERSONAL PROTECTIVE EQUIPMENT (PPE)

Appropriate laboratory attire and proper selection of personal protective equipment (PPE) are important for protecting workers from exposure to the various hazards present in the laboratory. All personnel working in a biosafety laboratory must wear long pants and closed toe shoes in addition to PPE. To prevent injury and contamination, long hair should be tied back, areas of exposed skin should be minimized (i.e., no halter tops or other types of clothing that bare large areas of skin), and dangling jewelry should not be worn. The selection of PPE depends on the risks associated with all hazards, including biohazards, in use and the procedures being performed in the laboratory. PPE is considered the last line of defense and should be used in combination with proper microbiological practices and engineering controls (e.g., a biological safety cabinet).

It is the responsibility of the Principal Investigator (PI) to provide all laboratory personnel with appropriate PPE. All personnel are responsible for proper decontamination and disposal of used and/or contaminated PPE. All personnel are required to remove PPE before leaving the laboratory.

5.7.1 Minimum required PPE at BSL-1:

- Lab coats and gloves are worn when working with hazardous materials. Alternatives to latex gloves should be available.
- Eye protection is worn when conducting procedures with the potential to result in splashes or sprays of biological agents or other hazardous materials.

### 5.7.2 Minimum required PPE at BSL-2:

- Lab coats and gloves are worn when working with hazardous materials. Alternatives to latex gloves should be available.
- Eye protection is worn when conducting procedures with the potential to result in splashes or sprays of biological agents or other hazardous materials
- Additional PPE (e.g., respiratory protection) may be required based on a risk-assessment.

### 5.7.3 Lab Coat Decontamination Guidance

- Whenever possible, consider using disposable lab coats in your laboratory. Disposable lab coats negate the need for laundering and can be reused unless they become contaminated or damaged. Disposable lab coats must be disposed of as solid biohazardous waste.
- Non-disposable lab coats used in BSL-1 and BSL-2 labs should be considered to be contaminated, and must be decontaminated with an appropriate disinfectant (e.g., soaking in 1% bleach solution for 30 minutes) or by autoclaving prior to laundering. Lab coats potentially contaminated with spore-forming microorganisms must be autoclaved.
- After lab coats are decontaminated, proceed with routine laundering in the washing machine with detergent to aid physical removal of decontaminated biological material. Some departments have provided a washer and dryer for laundering lab coats. If your department uses a vendor to launder lab coats, the department is responsible for following the laundry vendor's standard operating procedures.
- If lab coats are contaminated with chemical and/or radiological hazards, contact Environmental Health and Safety (EHS) (<u>ehsd@tamu.edu</u> or 979-845-2132) for specific information regarding

the required procedure and safety considerations of decontaminating lab coats potentially contaminated with chemical and/or radiological hazards.

### 5.8 SHARPS SAFETY

Careful management of needles and other sharps (e.g. scalpels, razor blades, pipette tips, broken glass, etc.) is essential to prevent injuries when working with sharps.

The following precautions should be followed when working with sharps:

- Do not reuse or recap needles:
  - If needles must be recapped, a one-handed technique or needle recapping device must be used.
- Needles, razor blades, and other disposable sharps must be discarded in a sharps container. Please keep the following in mind:
  - The sharps container should be within arm's reach.
  - Unprotected sharps should not be passed to another person for disposal
  - Certain sharps containers cannot be autoclaved and may become compromised during the autoclave cycle resulting in potential injury to personnel handling the container. See <u>Section 5.15</u> for more information on this topic.
- Other sharps include pipette tips, serological pipettes, etc. Keep the following in mind when disposing these type of sharp items:
  - Pipette tips can readily puncture through biohazard bags.
  - Ideally, a puncture resistant container, such as a pipette keeper, should be used to collect and discard contaminated pipette tips, serological pipettes, etc. See <u>Section 5.15</u> for more.
- Don't forget about broken glass:
  - Contaminated, broken glass should always be decontaminated BEFORE being discarded.
  - Disinfected, broken glass should be discarded in a sturdy cardboard box.
  - When choosing a cardboard box, consider ease of disposal. Larger boxes take much longer to fill, will be heavier, and can pose an additional risk.

Refer to the "STOP STICKS!" Poster (<u>Appendix B</u>) for additional guidance on the safe use of sharps in the laboratory.

### 5.9 BIOSAFETY CABINETS (BSCs)

### 5.9.1 Classes and types of Biosafety Cabinets (BSCs)

BSCs are primary engineering controls typically used for microbiological studies, cell culture, pharmaceutical procedures and toxicology. Sometimes they are referred to as "hoods". It's important to know that there are several pieces of equipment in laboratories that may be commonly referred to as "hoods" and they may be very different in the types of personal and sample protection that they provide. The most common items called "hoods" in labs include:

- Chemical fume hoods protect personnel from chemical fumes by pulling air away from the user. They may be ducted to the outside or filtered and recirculating. Questions about chemical fume hoods should be directed to Environmental Health and Safety.
- Clean benches protect samples by directing filtered air across the samples and into the room. This air is often blown directly at the user. Clean benches do not provide any protection to personnel or the environment and must not be used with potentially hazardous agents.
- Biosafety Cabinets (BSCs) are sometimes called "tissue culture hoods" or "microbiology hoods". When used correctly, most BSCs protect personnel, samples, and the environment from particulate matter. Only certain types of BSCs provide limited protection from small amounts of chemical fumes. There are three classes of BSCs:
  - Class I BSCs offer protection to personnel and environment, but no sample protection. They pull air away from the user and filter it before blowing it into the room. The air on the work surface is not filtered and thus the agent being worked with is not protected.
  - Class II BSCs are the most common type of BSC in research laboratories. Air is pulled away from the user, air is filtered before flowing to the work surface, and air is filtered prior to re-entering the ambient atmosphere. There are several different types of Class II BSCs. All offer protection from particulate matter to users, samples, and the environment, but they differ in the amount of hazardous chemicals that may be used in them.
    - Type A1 and A2 BSCs work in slightly different ways, but both will protect users, samples, and the environment from particulate matter if used correctly. They offer no protection from chemical fumes if they exhaust directly into the room. If they exhaust through a canopy directly into the building exhaust system, then they offer protection from minute amounts of chemical fumes.
    - Type B1 BSCs are hard ducted into the building exhaust. They offer the same level of protection from particles as A2s, but slightly better chemical fume protection. 40% of the filtered air is still recirculated onto the work surface, so fumes can build up and concentrate.

- Type B2 BSCs exhaust 100% of filtered air into the building exhaust after a single pass of the work surface. If you need protection from particles and moderate amounts of chemical fumes in the same sample, this type of BSC is the best option.
- Class III BSCs are pressure-tested glove boxes with passive, filtered supply air exhausted through at least two filters via dedicated facility exhaust. Users do not come into direct contact with samples. Class III BSCs are primarily used in high containment laboratories.

### 5.9.2 Working in a Biosafety Cabinet

BSCs are powerful protective tools, but they must be used correctly if maximum protection is to be achieved. Follow these tips to ensure that you, your samples, and the environment are protected from contamination:

- 1. Always wear appropriate PPE (e.g. lab coats, gloves, and eye protection) when working in the BSC.
- 2. Ensure the UV lamp is turned off when people are in the lab and before working in the BSC. Note: UV lamps are not recommended for disinfection.
- 3. Ideally, leave the blower fan running at all times. If your BSC is not already running when you need to use it, allow it to run for ten minutes to establish proper airflow before working.
- 4. Turn on the light, inspect the air intake grilles for obstructions and foreign materials, and remove any obstructions found.
- 5. Disinfect the interior surfaces of the BSC using an appropriate disinfectant. Don't forget to wipe the interior walls of the BSC including the inside of the sash. If your disinfectant is corrosive (e.g. bleach, Wescodyne), make sure to rinse it thoroughly or the stainless steel will rust over time.
- 6. Place supplies at least four inches from the back and front grilles. Items should be within easy reach so you can minimize arm movements within the BSC. Never cover the front or rear grilles with equipment, papers, your arms, etc.
- 7. Segregate clean and contaminated items.
- 8. Minimize movements inside the cabinet. Any movement should be done slowly and in a direction perpendicular to the back of the cabinet. Avoid making unnecessary or side-to-side movements within the BSC. If your arms must exit the cabinet, do so in a slow and steady manner.
- 9. Never use a Bunsen burner inside a BSC. Properly used, BSCs provide semi-sterile environments that do not require the use of a flame to maintain. If you need to heat-sterilize equipment within the BSC, contact Biosafety for information about alternative devices such as Bacticinerators or Touch-o-matic burners.

- 10. When finished working, decontaminate all items with an appropriate disinfectant and remove them from the BSC. Do not store supplies in the BSC. Contaminated wastes should be collected inside the BSC and placed into the proper biohazard waste receptacle.
- 11. Disinfect all surfaces thoroughly. Leave the blower fan running. If you cannot leave the BSC running, then allow the blower to run for a minimum of 5 minutes after work has ceased and reentry into the cabinet is no longer necessary.

### 5.9.3 Annual Certification of BSCs

Biosafety cabinets must be field tested and certified at the time of installation and at least annually thereafter, using the methods detailed in Annex F, "Field Tests", of NSF/ANSI Standard 49. Additionally, BSCs must be recertified when filters are changed, repairs are made to internal parts, or the cabinet is relocated or sent to surplus.

Texas A&M University requires that certifications be performed by experienced, qualified personnel, such as NSF Accredited Biosafety Cabinet Field Certifiers. The University maintains a service contract with an appropriate third-party vendor to inspect and certify biosafety cabinets. Current contact information can be found on our website (<u>https://vpr.tamu.edu/biohazards-in-research-teaching-or-testing/resources/biosafety-cabinets/</u>). It is the PI's responsibility to schedule this required service.

### 5.9.4 Biosafety Cabinet Placement in the Laboratory

Airflow is central to the proper functioning of a BSC. Proper placement of BSCs within the laboratory is essential to ensure that proper airflow is possible. When placing a BSC in the lab:

- Maintain an undisturbed space of 40 inches around BSC.
- Maintain a distance of 12 inches to adjacent walls and columns.
- Place BSCs at least 80 inches from opposing walls.
- Place BSCs at least 60 inches to opposing bench tops or areas with occasional traffic.
- Maintain a distance of 40 inches between BSC and bench top along perpendicular wall.
- Maintain a distance of 120 inches between opposing BSCs.
- Maintain a distance of 40 inches between BSCs along the same wall.
- Maintain a distance of 48 inches between BSCs along perpendicular walls
- DO NOT place BSCs near entryways.
  - If this arrangement is absolutely necessary, maintain a distance of 60 inches to doorways behind the BSC and 40 inches to doorways adjacent to the BSC.
- DO NOT crowd bench tops and BSCs together.
  - Too much traffic produces dangerous disturbances to BSC airflow.
- DO NOT place BSCs directly perpendicular to bench tops.
  - Designated workspace around the BSC will be disturbed.
- DO NOT place BSCs directly underneath air supply diffusers or exhaust vents.

### For more information and diagrams:

https://www.orf.od.nih.gov/TechnicalResources/Bioenvironmental/Documents/BiosafetyCabinetBSCPla cementRequirements\_508.pdf

### 5.9.5 Moving Biosafety Cabinets

### 

# Are you moving a **Biosafety Cabinet (BSC)**

# out of your lab?



### **Remember to:**

- 1. Surface decontaminate the BSC with disinfectant (e.g. 70% ethanol).
- 2. Complete the <u>equipment decontamination form</u> and attach it to the BSC.

### If the Biosafety Cabinet is:

- 1. to be moved from one building to another, or
- 2. to be sent to surplus

It must be **gas/vapor decontaminated prior to relocation** by a trained professional from a certified and approved vendor.

Please contact *Precision Air Technology* (<u>andrewx338@gmail.com</u>) to schedule your gas/vapor decontamination or contact the Office of Biosafety (<u>biosafety@tamu.edu</u>).

BSCs in BSL-2 (or higher) labs must be certified at the time of installation and annually thereafter; recertification of a BSC needs to be done when HEPA/ULPA filters are changed, repairs are made to internal parts, or a BSC is relocated.

Please contact the Office of Biosafety at <u>biosafety@tamu.edu</u> if you have any questions or to obtain a copy of the equipment decontamination form.

### 5.9.6 Requirements for Vacuum Aspiration of Biohazardous Materials

Vacuum aspiration is an aerosol generating procedure that is routinely performed in cell culture labs. An optimal aspiration system includes a primary collection flask, an overflow flask, flexible tubing, a vacuum source and an in-line filter. Protecting yourself and your co-workers from exposure to potentially infectious bioaerosols during aspiration is key. The following guidance is provided to ensure personnel and environmental safety throughout this process:

- a. Avoid the use of glass and select a shatterproof primary collection flask.
  - i. Label the flask with the biohazard symbol.
  - ii. Add fresh, concentrated bleach to achieve a final concentration of 10%.
- b. Include a second, overflow flask.
- c. Select tubing that withstands disinfection or is disposable.
- d. Do not allow contaminated liquids to collect longer than one week.
  - i. Once per week, or when the primary collection flask is no more than 2/3 full (whichever is sooner), stop collection.
  - ii. Carefully swirl the flask and allow a minimum of 30 minutes following the final collection (overnight is ideal) to ensure disinfection.
  - iii. Discard decontaminated liquid down the sink with lots of water.
  - iv. Clean equipment; replace disinfectant.
- e. Ideally, the vacuum assembly should be placed inside the Biosafety Cabinet. Do not block the front or rear grille of the BSC.
  - i. If the system cannot be housed within the BSC, collection flasks must be secured and placed inside a secondary container of adequate size and depth to contain a possible spill or leak.
  - ii. Do not place collection flasks directly on the floor.
- f. Include a biological, hydrophobic, HEPA or HEPA-like filter between the collection flask and the vacuum source.
  - i. DO NOT USE the 0.2 micron filters designed for filter-sterilizing solutions. These allow liquid to pass through the filter.
  - ii. Orient the filter so that the inlet is on the fluid side and the outlet is on the vacuum side.
  - iii. Label the filter with the date of installation.
  - iv. Change filters regularly, depending on use.
  - v. Dispose of used filters as biohazardous waste.

### 5.10 CENTRIFUGE SAFETY

See <u>Appendix L</u> for a centrifuge safety quick reference poster.

### 5.10.1 Types of centrifuges

Centrifuges are used routinely in laboratories to separate substances according to size and density differences by using centrifugal forces. They can generate massive forces so it's important to use them carefully. There are several general classes of centrifuges:

- Ultra speed Floor models that spin at up to 1,000,000 x g. These require extensive special training from vendors or experienced users.
- Super speed Floor models that spin at up to 75,000 x g
- High speed Benchtop models that spin up to 24,000 x g
- Low speed Benchtop models that spin up to 7,333 x g

Rotors are the parts of the centrifuge that holds the samples and spin. They can be fixed-angle, have swinging buckets, or be highly specialized for a particular use.

### 5.10.2 Hazards of centrifugation

If used and/or maintained improperly, all centrifuges (including microcentrifuges) can present various hazards including:

- Physical hazards mechanical failure due to mechanical stress, metal fatigue, and corrosion of the rotor over time.
- Exposure hazards aerosolization of biohazardous, chemical, or radioactive materials.

Common causes of centrifuge malfunctions include:

- Incorrect loading or balancing
  - Failure to place the lid on the rotor.
  - Failure to properly secure the rotor lid.
  - Failure to properly balance the load.
  - Using a swinging bucket rotor with missing buckets.
  - Buckets hooked incorrectly and unable to swing freely.
  - Overloading the rotor's maximum mass.
- Incorrect attachment
  - Failure to properly secure the rotor to the drive.
- Consumable failure tubes, plates, etc.
  - Failure to inspect tubes carefully and to seal them adequately.
  - Tubes have maximum rated speeds. If in doubt, contact the manufacturer.
- Corrosion
  - Failure to properly clean and maintain rotors. Chemicals left in contact with rotors can cause pitting and destruction of surfaces, weakening the rotor.
- Fatigue
  - Using a rotor that's been dropped.
  - Using a rotor that has outlived its rated life span.

### 5.10.3 Preventive maintenance

- Establish a preventive maintenance schedule, including regular cleaning of the centrifuge interior and rotors to prevent damage and avoid costly repairs. Reference the centrifuge operator's manual or contact the manufacturer for guidance. Equipment repair and adjustments shall only be conducted by a qualified service technician.
- Maintain a logbook. For all ultra-speed and super-speed centrifuges, include run dates, durations, speeds, total rotor revolutions, and notes on rotor condition.
- Only use cleaning and disinfecting products that are compatible with your rotor.
- After thoroughly cleaning rotors, store them upside down so they drain and dry completely.
- Remove all adapters between spins.
- Retire rotors after manufacturer's recommended life span. Note: Rotor life span may be reduced or warranty voided if autoclaved; contact the manufacturer for guidance.
- Never use a rotor that's been dropped. If it happens, or you notice any sign of damage, report this to your laboratory Principal Investigator immediately.

### 5.10.4 Centrifuging Risk Group 2 or higher materials

Centrifuges create aerosols every time they are used. Potentially hazardous aerosols must always be properly contained. Special considerations must be made when centrifuging Risk Group 2 and 3 agents.

- Safety cups or sealed rotors must be used in order to centrifuge RG2 or higher agents. Safety cups and sealed rotors have O-rings or other compressible gaskets in the lid that form a tight seal when the lid is properly closed.
  - Gaskets must be inspected before every use. Ensure broken or cracked gaskets are replaced before using.
  - Lightly lubricate gaskets regularly to prolong their life and create a better seal.
  - Load and unload rotors only inside the BSC. Sealed containers can only protect you from aerosols if you contain them while they're opened.
  - Transport rotors to and from centrifuges on carts to prevent dropping.
  - Thoroughly decontaminate tubes as they are removed from the rotor. Thoroughly decontaminate the rotor before it is removed from the BSC.

### 5.11 GUIDELINES FOR MOVING BIOHAZARDOUS MATERIALS ON CAMPUS

The following guidelines are provided to assist you in safely moving biohazards from one location to another location. As defined by the United States Code, Title 49- Transportation, a "hazardous material" is a material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid, or gas, toxic, oxidizing, or corrosive material, and compressed gas) or a group or class of materials that, when transporting the material in a particular amount and form, may pose an unreasonable risk to health and safety or property.

Hazardous materials should not be transported in your personal vehicle or using campus buses.

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Biohazards must be properly contained and secured during transport within and between labs to prevent spills and accidents. Potentially infectious biohazardous waste should be collected and stored in sealed, leak-proof containers (i.e., waste cans located in BSL-2 labs should have lids in place) to limit opportunities for spills of untreated (potentially infectious) materials. Following the simple recommendations below will mitigate the risks associated with transportation of biohazardous agents:

- At a minimum, biological agents must be double packaged (i.e., primary container secured in a secondary container) in leak-proof containers (e.g. screw top containers, Ziploc bags, etc.).
- Container(s) should be labeled with the universal biohazard symbol to indicate the presence of a biohazard.
- An itemized list of contents must accompany the container.
- Containers must never be left unattended.
- Equipment must be decontaminated before moving.

Follow the instructions in <u>Appendix D</u> when transporting Risk Group 2 agents between laboratories.

### 5.11.1 Shipping Biohazardous Materials (nationally or internationally)

Do not attempt to ship biohazards to another institution on your own! Refer to the EHS website (<u>https://ehs.tamu.edu/programs/hazardous-material-shipping/</u>) and contact Environmental Health & Safety (EHS) at <u>ehsd@tamu.edu</u> or 979-845-2132 for assistance with any shipments of biohazardous materials within the United States or if shipping internationally.

The transport of biohazards may also require permits from the USDA and/or CDC. It is typical for interstate transport of any plant or animal pathogen or product to require a USDA transport permit. CDC import permits are typically required for importation of infectious materials. Federal agencies have more information on their respective webpages: <u>https://www.aphis.usda.gov/</u> and <u>https://www.cdc.gov/</u>. Principal investigators are responsible to obtain necessary permits, follow all conditions and provisos listed in their permit(s), to renew permits as necessary, and to provide copies of all federal permits to the Office of Biosafety.

More specific information regarding permits can be found at:

The CDC Import Permit Program tool, "Do I Need an Import Permit?": https://www.cdc.gov/cpr/ipp/etool.htm

The USDA Permits and Certification page: <u>https://www.aphis.usda.gov/aphis/resources/permits</u>

An export license may be required even if the material is being shipped within the U.S. Export control laws are complex and fact-specific, so please consult with the Export Controls office (exportcontrols@tamu.edu) and utilize the available resources, such as the Export Controls Compliance Program Manual (https://vpr.tamu.edu/initiate-research/export-controls/export-control-manual). This manual is designed to assist Texas A&M faculty, staff and students with export control compliance.

A Material Transfer Agreement (MTA) may also be needed before shipping biohazardous materials. Please consult with Research Administration - Division of Research or email <u>negotiations@tamu.edu</u> for assistance and guidance related to MTAs.

### 5.12 CORE FACILITIES

Core facilities are laboratories or centers where part of an experimental procedure is performed for a fee. If any work with viable biohazards is performed in a core facility, the IBC requires that:

- Each investigator using the core facility must include, in their IBC application, the specific scope of work involving the core facility, the facility as a location of work, and must designate which viable agents will be taken to the facility, and the mitigations specific to their work that will be followed while using the facility.
  - The PI must have permission from the core facility manager to bring viable biohazards to the facility.
  - The PI must describe the appropriate transport measures that will be taken when moving viable biohazards to and from the facility.
  - The PI is responsible for providing and documenting hazard awareness training to core facility staff.
- The core facility must have an IBC permit that outlines the general nature of the services they provide and the standard mitigations that are in place to reduce risk.
  - Core facility staff are responsible for ensuring that users have appropriate institutional approvals before they allow users to bring viable biohazards to the facility.
  - If any part of the core facility operates at BSL-2, facility staff must be identified as Authorized Personnel in the core facility's IBC application.

### 5.13 BIOLOGICAL SPILL RESPONSE

Detailed instructions for responding to spills in BSL-1 and BSL-2 laboratories are provided below. However, keep the following points in mind if you ever encounter a spill involving biohazards:

- Take care of yourself first!
- Recruit help if needed. Notify others to stay away.
- If your street clothing becomes contaminated, it must be removed and decontaminated prior to laundering. Keep a change of scrubs, coveralls, or other outerwear available in the lab to avoid embarrassment.
- Don't underestimate the magnitude of the spill. Nearby vertical surfaces (i.e., cabinets, walls, etc.) should be decontaminated.
- Bleach soaked paper towels must not be autoclaved.
- Broken glass must be decontaminated prior to disposal in the broken glass container.

Post the Spill Response poster found in <u>Appendix E</u>. Follow this procedure when responding to a spill of biohazardous materials.

### 5.13.1 Spill clean-up

Although biohazards present in a BSL-1 laboratory should not be a significant health hazard to humans, they may present a hazard to plants, animals, and the environment. Biohazards present in a BSL-2 laboratory have the potential to cause disease in humans. Regardless of whether a spill occurs in a BSL-1

or BSL-2 laboratory, you have the obligation to minimize exposure of personnel and/or the release of biohazardous material from the laboratory.

### 5.13.2 Reporting Spills:

- Notify the PI or your Laboratory Supervisor.
- All spills of risk group 2 materials outside the biosafety cabinet must be reported immediately to the Office of Biosafety by calling 979-862-4549 or emailing <u>biosafety@tamu.edu</u>. Spills of risk group 1 materials in excess of 25 ml, or spills of any recombinantly modified risk-group 1 organism, must be reported to the Office of Biosafety within 24 hours.

### 5.14 DECONTAMINATION / STERILIZATION / DISINFECTION

### 5.14.1 Sterilization / Disinfection/Decontamination

In order to manage biohazardous laboratory waste properly, it is important to understand the principles of sterilization, disinfection and decontamination and the differences between them.

Definitions:

### 5.14.1.1 Sterilization

A sterilization procedure is one that kills all microorganisms, including high numbers of bacterial endospores. The definition is categorical and absolute (i.e. an item is either sterile or it is not). Sterilization can be accomplished by heat, ethylene oxide gas, hydrogen peroxide gas, plasma, ozone, and radiation. Autoclaving is a sterilization process that relies on high-pressure steam to sterilize biohazardous laboratory waste prior to disposal.

### 5.14.1.2 Disinfection

Disinfection is generally a less lethal process than sterilization. **It eliminates nearly all microorganisms but not necessarily all microbial forms (e.g. bacterial spores) on inanimate objects.** Disinfection does not ensure an 'overkill' and therefore lacks the margin of safety achieved by sterilization procedures. The effectiveness of a disinfection procedure is influenced by a number of factors, each one of which may have a pronounced effect on the end result. Among these are:

- The nature and number of contaminating microorganisms (especially the presence of bacterial spores)
- The amount of organic matter present (e.g. soil, feces, and blood)
- The type and condition of instruments, devices, and materials to be disinfected
- Temperature

### 5.14.2 Decontamination in the Microbiological Laboratory

Decontamination renders an area, device, item, or material safe to handle (i.e. safe in the context of being reasonably free from a risk of disease transmission). The primary objective of decontamination is to protect the laboratory worker, the environment, and anyone who enters the laboratory or handles laboratory products away from the laboratory. Reduction of cross-contamination in the laboratory is an added benefit.

Responsibilities of researchers:

- 1. Researchers must properly treat solid and liquid biohazardous wastes prior to disposal.
  - a. In BSL-1 and BSL-2 laboratories: Solid biohazardous wastes must be autoclaved; liquid biohazards must be autoclaved OR chemically disinfected prior to disposal.
  - b. In BSL-3 laboratories: All biohazardous wastes must be autoclaved prior to disposal.
  - c. Refer to <u>Appendix C</u> for specific requirements related to treatment of biohazardous wastes prior to disposal.
- 2. Researchers must prepare agent appropriate disinfectants for use in the lab following manufacturer's guidelines.
- 3. Researchers must regularly disinfect work surfaces and equipment following use and especially after a spill or splash of biohazardous material.
- 4. Researchers must promptly clean and disinfect spills and report them to their supervisor and the Office of Biosafety, as described in this manual.

### 5.14.3 Disinfectants

When selecting appropriate disinfectants for your laboratory, consider the following:

- Degree of microbial killing required (how hard is your agent to kill?)
- Nature of item/surface to be disinfected
- Ease of preparation and use
- Contact time
- Safety (it should not be harmful to laboratory staff)
- Cost

Requirements for preparing and using laboratory disinfectant solutions:

- 1. Wear appropriate PPE (including lab coats, gloves and eye protection).
- 2. Prepare working stocks of disinfectants following manufacturer's guidelines:
  - 70-80% ethanol and 10% bleach are broad acting disinfectants commonly used in the laboratory.
- 3. Label disinfectants properly with:
  - Product Name
  - Concentration
  - Date of expiration
- 4. Do not use expired disinfectant.
- 5. Dispose of expired, unused disinfectant solutions down the drain, flushing with lots of water.

Summary of Commonly Used Disinfectants:

- Ethanol (optimal concentration 70-80%)
  - Mechanisms of action: Disrupts cell membranes, solubilizes lipids and denatures proteins
  - Pros: Broad-spectrum, stable disinfectant; non corrosive; non-toxic residue;
  - Once diluted, 70-80% ethanol has a shelf-life of no more than six months

- Cons: Ineffective against bacterial spores ; evaporates quickly; flammable;
- Contact time: depends on the organism; 20 minutes is generally effective

### • Chlorine Bleach (optimal concentration 10%)

- Mechanism of action: Exact mechanism unknown; oxidizing action; inhibition of protein synthesis;
- Pros: Broad spectrum, inexpensive, fast acting disinfectant;
- Cons: Inactivated by organic material; highly reactive to acid, ammonia and light; strong smell; hazardous to humans; dilute bleach loses its potency quickly;
- 10% bleach should be replaced at least weekly.
- Contact time: >10 minutes for surface disinfection; 30 minutes for immersion

### • Phenols (e.g. original Lysol concentrate, Vesphene, Amphyl)

- Mechanism of action: Phenols disrupt cell walls and precipitate cell proteins;
- Pros: Effective against vegetative bacteria, fungi, and lipid viruses; retains activity in the presence of organic matter;
- Cons: May be less effective against viruses; Phenolics are absorbed by porous materials and the residual disinfectant can irritate tissue.
- Contact time: >10 minutes; depends upon product and concentration; follow manufacturer's guidelines.

### • Quaternary Ammonium Compounds

- Mechanism of action: denaturation of essential cell proteins, and disruption of the cell membrane;
- Pros: Broad spectrum; less toxic than bleach; good surface compatibility; economical
- Cons: Not sporicidal and generally not tuberculocidal or virucidal against hydrophilic (nonenveloped) viruses; activity reduced in the presence of soaps or soap residues; "quat binding";
- Contact time: >10 minutes for surface disinfection; check product labels for directions.
- Iodophors (e.g. Wescodyne)
  - Mechanism of action: A combination of iodine and a solubilizing agent, iodophors
    penetrate the cell wall of microorganisms quickly disrupting protein and nucleic acid
    structure and synthesis;
  - Pros: broad spectrum, fast acting, stable, relatively non-toxic, leaves no residue;
  - Cons: not sporicidal; inactivated by organic material; stain skin and clothing;
  - Contact time: check product labels for directions; dilute to manufacturers' directions to achieve optimal antimicrobial activity.

### https://www.ncbi.nlm.nih.gov/books/NBK214356/

https://www.cdc.gov/infectioncontrol/guidelines/disinfection/disinfection-methods/chemical.html

### 5.14.4 Autoclaving Biohazardous Waste

### 5.14.4.1 How to prepare waste for the autoclave:

### 1. Loosely close the bag.

Do not seal the bag tightly with tape, rubber bands, or garbage bag ties; leave a small opening. Do not overfill the bag. The bag should not be more than 3/4 full when being autoclaved. This allows room for easy closing and proper steam penetration.

### 2. Deface the biohazard symbol with autoclave tape.

When the autoclave process is completed, defacing the biohazard symbol will help to define the waste as decontaminated and no longer a biohazard.

### 3. Write your lab name and your initials on the tape.

This will help with tracking any problems that may arise and with maintaining the log book.

### 4. Place the bag in a secondary container.

Use a metal tray or <u>autoclavable</u> plastic tub. The secondary container will make it easier to handle the hot bag as well as contain any possible leakage (such as melted agar from plates).

### 5. Load the autoclave.

Only load as much waste as the autoclave is validated to process in a single cycle.

### 6. Select the appropriate cycle parameters.

Use the predetermined cycle that has been validated for the type of waste you are autoclaving.

### 7. Complete the log book entry.

This log book is required to maintain accurate records to comply with Texas Administrative Code. <u>Appendix G</u> contains a template for creating a log book.

### 8. Seal the door and run the autoclave.

Be sure to properly seal the autoclave door before beginning the cycle.

## 9. When the cycle is complete, open the door and wait a few minutes before removing the waste.

Allowing a few minutes for the material to cool will reduce your risk of injury. Wear heat resistant gloves to protect your hands.

### 10. Place a treatment sticker on the processed waste.

This sticker is required as proof of compliance with the Texas Administrative Code. Place it on the bag to verify that it has been decontaminated. If you need more stickers they can be obtained from the Office of Biosafety (<u>biosafety@tamu.edu</u> or 979-862-4549). Appendix F provides additional information about proper treatment sticker use.

### **11.** Place the processed, labeled waste into a regular, black garbage bag.

The processed waste must be in a black garbage bag in order to be transported to the landfill.

### 12. Transport the black bag to the dumpster.

Transport your waste to the dumpster. Do not leave it for housekeeping staff.

### 5.14.4.2 Autoclave Cycle Validation

Autoclave cycles used in the decontamination of biohazardous waste must be tested and documented to ensure the cycle(s) and cycle parameters used will, in fact, decontaminate the load.

The loads used in the test cycles should be representative of the actual waste loads and not differ dramatically in composition, mass, or volume.

Testing is confirmed with the use of biological indicators (BIs). If BIs show no growth in three successive test runs, the cycle has been validated.

All waste must be decontaminated using validated cycle(s) only and the maximum load should be equivalent to, or less than, the tested loads in overall mass and volume.

Validation of cycles must be performed for both solid waste and liquid waste.

The tested cycles are valid until major changes to the autoclave occur, such as relocation or significant software update (in those units that have programming).

Documentation of the cycle validations must be maintained with the autoclave records. <u>Appendix G</u> contains a form you can use to document the validation of your autoclave cycles.

### 5.14.4.3 Autoclave Cycle Verification

- 1. Each validated autoclave cycle used to decontaminate biohazardous waste must be verified for effectiveness according to the Biosafety Level (BSL) of the laboratories using the autoclave.
  - a. BSL-1 waste = verification testing should be conducted once per month, or with each load of waste if the autoclave is used very infrequently.
  - b. BSL-2 waste = verification testing should be conducted every other week, or with each load of waste if the autoclave is used very infrequently.
  - c. BSL-3 waste = verification testing should be conducted once per week
- 2. Per appropriate schedule, place a biological indicator in the center of the load. For solid waste, sandwich an indicator between two bags of waste. For liquid waste, submerge an indicator in a mock vessel (water in a flask) of comparative volume to the liquid waste bottle.
- 3. Run the appropriate validated waste cycle.
- 4. After the cycle completes, incubate the test indicator and a positive control according to the manufacturer's specifications. A color change from violet to yellow indicates positive growth. Log the results, either in the general autoclave log or in a separate verification log. The log should indicate the date of the test, the cycle parameters being tested, a description of the load, and the result.
- 5. If the indicator fails, investigate to determine the reason. If no reason is apparent or if you have questions, contact the Office of Biosafety (<u>biosafety@tamu.edu</u>) for assistance.

### 5.14.4.4 Biological Indicators

Appropriate biological indicators utilize *Geobacillus stearothermophilus* spores. The Office of Biosafety recommends self-contained colorimetric indicators for ease of use and reduction of false-positives.

Recommended brands are:

• 3M Attest Biological Indicators

- EZTest Steam Biological Indicators
- SporAmpule Biological Indicators
- MagnaAmp Biological Indicators

Other brands may be acceptable. Read all manufacturer information carefully to ensure that the indicator is appropriate for your needs and follow manufacturer's instructions for use. You may need separate indicators for different cycle types. Email <u>biosafety@tamu.edu</u> with any questions.

### 5.14.5 BSL-1 / BSL-2 Biohazardous Waste Disposal

<u>Appendix C</u> contains the Texas A&M University Biohazardous Waste Disposal Guidelines. Refer to the table for the safe disposal of laboratory-generated biohazardous waste.

### 5.15 COMMONLY ENCOUNTERED BIOSAFETY ISSUES

### 5.15.1 Overfilling biohazard bags

Many problems encountered during the disposal of waste can be attributed to overfilling biohazard bags. Ensuring that bags are carefully closed and decontaminated when they are no more than 3/4 full can prevent bag spills, bag breaches, and ensure the best heat transfer when autoclaving.

### 5.15.2 Micropipette tips

Micropipette tips must be disposed of in a way that prevents them from puncturing biohazard bags before, during, or after decontamination (typically by autoclaving). The easiest way to prevent bag breaches is to collect tips in a small biohazard bag, do not overfill it, then close it and dispose of it inside a larger biohazard bag.

### 5.15.3 Serological pipets

Serological pipets must be disposed of in a way that prevents them from puncturing biohazard bags or other containment before, during, or after decontamination (typically by autoclaving). Pipet Keeper™ boxes, or similar containers, are convenient for collecting contaminated pipets inside the biosafety cabinet. Ensuring that the pipets are collected carefully while facing the same direction (like a bundle of sticks) and not overfilling the autoclave bag is typically sufficient to prevent biohazard bag breaches.



### 5.15.4 Snap-cap microcentrifuge tubes

Snap-cap tubes are very convenient for many procedures in the lab, but they pose problems when heating or freezing samples. Always use cap locks or screw-top tubes when heating samples to prevent the tops from popping open at high temperatures. Use cryotubes for freezing samples for later use. Only use tubes especially made for liquid nitrogen storage if you store samples in an LN<sub>2</sub> dewar.

### 5.15.5 Melting sharps containers

The proper way to decontaminate biohazard sharps containers at Texas A&M is by autoclaving them. Unfortunately, not all sharps containers are made to be autoclaved. Find the product number on the label of your sharps container and look it up online. On the product specifications sheet, it should specify if it is appropriate for the autoclave. If your container is not autoclavable or if you are unsure, do not use it. If it already has sharps inside it, place it inside of a container that is known to be autoclave safe before autoclaving it. Check future purchases to ensure only autoclave safe sharps containers are stocked in your lab.

### 5.15.6 Broken glass containers

- Only place decontaminated glass in the broken glass container. If necessary, chemically decontaminate the glass before placing it in the box.
- Any sturdy cardboard box can be a suitable broken glass container. Don't use a box that is so large that it is difficult to handle when it is full.
- Keep the box off the floor or place it in a tub to prevent water damage to the bottom from mopping or spills.

### 5.15.7 Non-disposable sharps

Reusable sharps such as scalpels, razor blades, etc. must be placed inside a rigid container when not in use to prevent injury to personnel. If you do not have the original packaging or a case for your non-disposable sharps, any sturdy, hard-walled container can be used. Empty tip boxes, 50 mL conical tubes, and petri dishes are convenient containers for many common reusable sharps.

### 5.15.8 Used gloves

- Gloves are single use and should not be reworn. Don't leave them on the bench to reuse later!
- Gloves should not be sprayed with disinfectant. This makes them slippery and increases the chance you will drop something. If gloves need to be disinfected, they need to be changed.
- Gloves should be disposed of as biohazardous waste. Gloves and other lab waste is not appropriate for "black bag" waste that is collected by custodial staff.

### 6 BIOSAFETY OCCUPATIONAL HEALTH PROGRAM

The Texas A&M Biosafety Occupational Health Program (BOHP) provides occupational health services to personnel at risk of exposure to infectious biohazards or to animals in the course of their participation in, or operational support of, Institutional Biosafety Committee (IBC) or Institutional Animal Care and Use Committee (IACUC) permitted research, teaching or diagnostic activities, or who work in University facilities where animals are treated or housed.

The BOHP provides eligible participants with access to educational resources, occupational health services, and to an occupational health provider. Specifically, the BOHP addresses occupational exposure to the following:

- Human pathogens or zoonotic pathogens of animals;
- Materials potentially containing human pathogens (e.g. human or non-human primate blood, body fluids, unfixed tissues, or cell lines- including commercially available lines);
- Recombinant or synthetic nucleic acid molecules and cells, organisms, and viruses containing such molecules; and
- Biological Select Agents and Toxins; and
- Animals, or their tissues, body fluids, or wastes, and animal allergens

For all chemical, radiation, or physical hazard exposures, please contact Texas A&M Environmental Health and Safety at <u>EHSD.occ.health@tamu.edu</u>

### 6.1 ENROLLMENT IN THE BIOSAFETY OCCUPATIONAL HEALTH PROGRAM

### Who should enroll in the BOHP?

Personnel at risk of exposure to infectious biohazards or to animals in the course of their participation in, or operational support of, IBC or IACUC permitted activities, or who work in University facilities where animals are treated or housed. Examples of personnel who should enroll in BOHP include the following:

- Research personnel (e.g., principal investigators, post-docs, technicians, students, etc.);
- Animal care personnel (e.g., veterinarians, vet-techs, animal husbandry staff, students, etc.);
- Operations personnel (e.g., research compliance and biosafety staff, environmental health and safety staff, Vet Med Teaching Hospital staff, etc.); and
- Visitors

### How do I enroll in the BOHP?

Personnel enroll in the BOHP by completing an online enrollment questionnaire. To access the questionnaire, personnel must log into the <u>BOHP portal</u> using their NetID and password. For additional guidance on BOHP enrollment, reference the BOHP Enrollment Guidance Document.

### **Visitor Enrollment**

Visitors that do not receive a NetID will not have access to the BOHP portal, and will not be able to complete the online enrollment questionnaire. Visitors should provide BOHP staff with documentation of enrollment in their home institution's occupational health program or complete a BOHP visitor enrollment form.

The <u>Visiting Scholars Program</u> has more information and guidelines related to hosting visitors in research and/or clinical facilities.

# 6.2 RESPIRATORY PROTECTION FOR POTENTIAL EXPOSURE TO INFECTIOUS BIOHAZARDS AND ANIMAL ALLERGENS

The Biosafety Occupational Health Program provides respiratory protection services for at risk of exposure to infectious biohazards or to animal allergens.

### How does the respiratory protection process work?

Respiratory protection requirements are based on a risk assessment of the hazards involved. The use of respiratory protection must comply with the <u>Texas A&M University Respiratory Protection Program</u>.

Respiratory protection medical clearance is required before the first use of respiratory protection, and annually thereafter, for as long as use of respiratory protection continues.

- Personnel must complete the respiratory protection medical clearance questionnaire on an annual basis.
- Based on questionnaire responses, the occupational health provider may require the individual complete a pulmonary function test (PFT) or additional medical evaluation before being cleared to wear respiratory protection.

Once the individual has been cleared to wear respiratory protection, a BOHP staff member will provide the individual with instructions, via email, on how to schedule a fit test appointment for an N95 disposable respirator or assign the individual Powered Air Purifying Respirator (PAPR) training in TrainTraq or through the TAMU External Gateway.

### What do I need to do if I require respiratory protection for potential chemical exposure(s)?

Contact <u>Environmental Health and Safety (EHS)</u> oversees the respiratory protection for personnel at risk of exposure to chemicals.

### 6.3 PRE-EXISTING OR IMMUNE-COMPROMISING CONDITIONS/MEDICATIONS

Pre-existing or immune-compromising conditions/medications may increase the risk of infection when working with animals and/or pathogens.

Immune-compromising medical conditions may include:

- Diabetes
- HIV/AIDS
- Cancer
- Autoimmune diseases
  - e.g., psoriasis, eczema, lupus, rheumatoid arthritis, multiple sclerosis, or Crohn's disease
- Liver or kidney disease
- Organ or tissue transplantation
- Splenectomy (surgical removal of the spleen)
- Pregnancy

Immune-compromising medications may include:

- Corticosteroids (e.g., cortisone or prednisone)
- Opioid pain medication
- Medications prescribed for psoriasis, asthma (including inhalers), arthritis, ulcerative colitis, irritable bowel syndrome (IBS) or herpes

Personal health consultations with an Occupational Health Provider are available to through the BOHP, at no cost to the individual. During the consult with the provider, the individual will have the opportunity to discuss their medical history and potential exposure(s) they may have to infectious biohazards and/or animals through the course of their work duties or research. Contact BOHP staff at <u>bohp@tamu.edu</u> to request a personal health consult.

### 6.4 TRAINING AVAILABLE THROUGH THE BIOSAFETY OCCUPATIONAL HEALTH PROGRAM

The Biosafety Occupational Health Program provides a variety of trainings online through the Texas A&M TrainTraq system (for employees) and the TAMU External Gateway (for students and visitors). For questions about the trainings listed below, contact BOHP staff at <u>bohp@tamu.edu</u>.

### **Researchers Who Work with Pregnant Sheep inside Facilities**

Training provides an overview of the Texas A&M IBC policy on working with pregnant sheep inside facilities and a brief summary on *Coxiella burnetti*, the etiologic agent of Q fever.

### Powered Air Purifying Respirator (PAPR) Training

Training provides an overview of the proper use of a PAPR, donning and doffing procedures, the benefits and limitations of using a PAPR, and general cleaning, maintenance, and storage procedures for a PAPR.

### **Animal Allergens and Asthma Training**

Training provides an overview of animal allergens and how to mitigate the risks of exposure in the work place.

### 6.5 INCIDENT RESPONSE AND REPORTING

Note: If an incident occurs and those involved require immediate medical attention, call 911, and follow all instructions provided by the emergency response provider. See <u>Appendix H</u> for guidance on injury response.

### **Exposure Incident Response – Small Injuries**

For small injuries (e.g. needle sticks, nicks, small cuts or punctures):

- Wash the injured area immediately with soap and water.
- For very small wounds where bleeding is minimal, encourage the injury to bleed while washing.
  - This can reduce the number of pathogens that remain in the wound to below the infection threshold.
- Notify your PI/Supervisor as soon as possible with the details of what occurred.

### Exposure Incident Response – Mucous Membrane/Open Wound Exposure

For mucous membrane or open wound exposure (e.g. a splash or spill into your eyes, nose or mouth, or onto broken skin):

- Wash the affected broken skin immediately with soap and water.
- Flush the affected mucous membrane(s) immediately at the eyewash station or at the sink with running clean water.
- Notify your PI/Supervisor as soon as possible with the details of what occurred.

### Worker's Compensation

The Texas A&M University System <u>Workers' Compensation Insurance (WCI) Program</u> was created by the State of Texas to provide reasonable and necessary medical coverage and disability payments to employees who sustain injuries or occupational diseases while in the course and scope of their employment.

All employees whose names appear on the payroll of the University are covered under the program at no personal expense. This coverage includes student and wage employees.

Employees who suffer an injury or illness as a result of and in the course and scope of employment should immediately notify his/her supervisor. Failure to report the injury within 30 days of the occurrence (or manifestation of the occupational disease) may result in the denial of the claim.

Department liaisons, supervisors, or designees are required to report any work-related injury or illness in Origami as soon as possible after the incident is reported or has been identified.

### What types of incidents should be reported to the Office of Biosafety (OBS)?

The Office of Biosafety, on behalf of the TAMU IBCs, is responsible to assess and evaluate any work related incident that may result in a potential exposure to biohazardous materials. In the event such an incident occurs, personnel covered by the services offered through the BOHP will be referred to an Occupational Health Provider (or an Emergency Department on evenings and weekends) for a confidential occupational health consultation. Examples of incidents that should be reported to the OBS include, but are not limited to the following:

- Exposure of person(s) to infectious biohazards and/or recombinantly modified materials
- An animal bite from an ABSL-2 or ABSL-3 animal
- Spill of infectious biohazards outside of the biosafety cabinet
- Loss of containment
- Sharps injuries that may result in exposure to infectious biohazards

### What types of incidents should be reported to Environmental Health and Safety (EHS)?

Examples of incidents that should be reported to EHS include, but are not limited to the following:

- Exposure of person(s) to chemical hazards
- Physical hazards
- Sharps injuries that may result in exposure to chemicals

### How do I report an incident to the OBS?

To report an incident to the OBS, email <u>biosafety@tamu.edu</u>. Specific OBS contact information can also be found here: <u>https://bohp.tamu.edu/</u>. You will be asked to complete an incident report form that will be provided to you by OBS.

### 7 APPENDICES

The following pages contain resources for training and reference on a variety of topics. You may wish to print some of these pages to post in the lab or to distribute as handouts during laboratory training sessions. Subjects include:

- <u>A: Fomite Control</u>
- <u>B: Stop Sticks! Sharps Safety</u>
- <u>C: Biohazardous Waste Disposal</u>
- D: Transporting Risk Group 2 Samples
- E: Spill Response
- F: Autoclaved Waste Handling
- <u>G: Autoclave Log Sheets and Cycle Validation Forms</u>
- H: Injury Response Guidelines
- I: Working with Zika Virus
- J: Rabies Awareness
- <u>K: Q-Fever Awareness</u>
- L: Centrifuge Safety
- <u>M: Personnel Training</u>
- <u>N: Animal Allergens and Asthma</u>

# **FOMITE CONTROL** Keep your Lab Stuff in the Lab!

**fomite:** (noun) An inanimate object (such as a pen or a doorknob) that can become contaminated with infectious organisms and aid in their transmission from one individual to another.











LABORATORY ITEMS CAN EASILY BECOME CONTAMINATED while you work. Have a set of pens, etc., that stay on your bench and make sure you only touch clean items with your bare hands.

**LEAVE PHONES, BACKPACKS, AND OTHER PERSONAL ITEMS** in a clean space, away from the lab bench. Always

wash your hands before you pick them up so you don't carry contaminants home with you!

- **ROUTINELY DECONTAMINATE** doorknobs, faucet handles, and other surfaces that are touched a lot so you don't pick up a contaminant that someone else left behind!
- ALWAYS WASH YOUR HANDS before you touch clean items and before you leave the lab. Hand sanitizer can be used to supplement but not to replace hand washing.



TEXAS A&M UNIVERSITY Division of Research

# TEXAS A&M STOP STICKS! A M

For further guidance, see: <u>http://rcb.tamu.edu/biohazards/resources/biohazardous-waste-handling</u>



# Do you NEED to use SHARPs in your program?

- SHARPs include needles of all types (cannula, IV, hypodermic), scalpels, or razor blades.
   Regularly assess the need for continued use of
  - SHARPs in the lab.
    - Review new products that can reduce or eliminate SHARPs in the lab.
- □ SHARPs also include broken glass, metal or bone. □ Have clean up tools available for broken sharps.



# Are you disposing of the SHARP correctly?

- □ Have an approved SHARPs disposal container within arm's reach of every SHARPs use area.
  - □ DO NOT dispose of any SHARP in regular trash.
- DO NOT cut, break, bend or remove needles prior
- to syringe disposal.
  - Properly and safely autoclave SHARPs containers prior to disposal.

Immediately report all needle sticks or sharps injuries to your supervisor

# Can any SHARP used be eliminated or replaced? □ Can a process be redesigned to remove the need for SHARPs?

- Can any SHARPs be replaced with safer sharps
   (e.g. self-sheathing needles, retractable needles)?
  - (e.g. sent-streating treedles, red actable treedles Can any glass object be replaced with a plastic version (such as pipettes)?



# Are you using the SHARP safely?

- If recapping of needles cannot be avoided, use a one-handed scoop method or a safety device for recapping needles.
- □ Never remove or replace needle caps by mouth.
   □ Use scalpel handles and blade changing blocks
  - when working with scalpels. Dronerly restrain animals hefore using shares
- Properly restrain animals before using sharps for injections or procedures.

TAMU BOHP V 1.1 Fall 2019



TAMU Biosafety Last Reviewed Fall 2019

		BSL-1/BS	L-2 Biohazardous Waste Texas A&M Universi Biosafety Program	Disposal Guidelines ty		-
	Solids	Liquids	Sharps	Animal Materials	Transgenic Drosophila	Transgenic Plant Material
uoudussad	Any of the following - Petri dishes, culture flasks, centrifuge tubes, gloves, bench paper, etc <b>contaminated with biohazardous</b> <b>materials</b> , including: bacteria, fungi, parasites, viruses, rDNA, human or non-human primate cells, cell lines or bodily fluids.	Liquid waste <u>contaminated with</u> <u>biohazardous materials</u> including: bacteria, fungi, parasites, viruses, rDNA, human or non-human primate cells, cell lines or bodily fluids.	Any of the following – Needles, scalpel blades, razor blades, broken glass, pripette tips, Pasteur pipettes - <u>contaminated with biohazardous</u> <u>materials</u> including: bacteria, fungi, purasites, viruses, rDNA, human or non-human primate cells, cell lines or bodily fluids.	Animal carcasses and body parts <u>if the</u> <u>animal has been exposed to biohazardous</u> <u>materials</u> including: baccria, fungi, parasites, viruses, rDNA, human or non- human primate cells, cell lines or bodily fluids <u>&amp; including transgenic animals</u> .	Genetically modified Drosophila (filies, larvae, and eggs).	Genetically modified plants (including flowers, seeds, stems, leaves, roots, and any material capable of propagation).
2981010	Collect solid waste in red or orange biohazard bags placed in a leak proof container with a tight-fitting lid. Volume of waste should not exceed <sup>34</sup> of the capacity of the container.	Collect liquid waste in a leak proof container with a lid. Volume of waste should not exceed ¾ of the capacity of the container.	For needles, razors, and scalpel blades: use an approved autoclavable sharps container. For broken glass', pipette tips and serological pipettes: Container must be rigid, leak proof, and puncture resistant. Volume of waste should not exceed % of the capacity of the container.	Collect carcasses in a red or orange biohazard bag placed in another scaled, leak proof bag. If necessary, store at 4°C or -20°C until pick-up.	Collect flies, larvae and eggs in vials or bottles. Store in red or or ange biohazard bags placed in a leak proof contairer with a tight-fitting lid. Volume of waste should not exceed <sup>4</sup> of the capacity of the container.	Collect solid waste, including soil, in red or orange biohazard bag placed in a leak proof container with a tight-fitting lid. Volume of waste should not exceed ¾ of the capacity of the container.
9.000 APT	Label the bag or container with name of PI, building and room number.	Label the container with the name of the PI, building, and room number.	Label the container with the name of the PI, building, and room number.	Label the bag or container with the name of the PI, building, and room number.	Label the bag or container with name of P1, building and room number.	Label the bag or container with the name of the P1, building, and room number.
10000800	Deface biohazard symbol with autoclave tape. Place bag in a tub and steam sterilize in the autoclave using the gravity cycle. <sup>2</sup>	Treat with household bleach (10% final volume) for 30 minutes <sup>2</sup> OR Steam sterilize in the antoclave using the liquid cycle. <sup>2</sup> Liquids treated with Bleach must never be autoclaved.	Steam sterilize in the autoclave using the gravity cycle. <sup>4</sup>	Incineration OR Biodigestion	Deface biohazard symbol with autoclave tape. Place bag in a tub and sterm sterilize in the autoclave using the gravity cycle. <sup>2,3</sup>	Autoclave <sup>3</sup> or bake materials at 65°C. Field materials may be burned or devitalized in accordance with USDA-APHIS permit requirements. <sup>4</sup>
upsodsia	Apply treatment sticker to cooled biohazard bag and place into black trash bag before disposing in the dumpster. $5^{6}$	Disinfected liquids may be disposed of down the laboratory sink.	Apply treatment sticker to the container and place into black trash hag before disposing in the dumpster $^{54}$	NA	Apply treatment sticker to cooled hug and place into black trash bag before disposing in the dumpster.	Apply treatment sticker to cooled bag, place in secondary black bag and dispose of treated waste in the dumpster. Field materials can be incorporated into the soil.

<sup>&</sup>lt;sup>1</sup> Contaminated broken glass must be decontaminated prior to disposal. Contaminated broken glass may be decontaminated by applying 10% bleach for 30 minutes.
<sup>2</sup> Autoclave cycles must be initially validated and routinely verified using biological indicators. Verification must be performed monthly on autoclaves used to sterilize BLI waste and biweekly on autoclaves used to sterilize BSL-2 waste. A treatment log must be maintained to document autoclave cycle parameters used for biohazardous waste treatment as well as frequency of autoclave testing using biological indicators.
<sup>3</sup> Contact the Office of Biosafety (<u>biosafety@famu.edu</u> or 979-862-4549) for alternative IBC approved methods for disposal of transgenic flies.
<sup>4</sup> Methods for devitalization may include compositing, descention, or chopping followed by tilling into the soil.

<sup>&</sup>lt;sup>5</sup> Contact the Office of Biosafety (biosafety@amu.edu or 979-862-4549) to replenish treatment stickers. <sup>6</sup> Alternatively, a third-party vendor may be contracted to pick up biohazardous wastes. <sup>7</sup> Always ensure that chemical disinfectants are appropriate for the agent being treated.

Division of Research Biosafety • March 2016

# Transporting Risk Group 2 samples

 Primary containment – tube, plate, etc.
 Closed securely and further sealed if necessary (with Parafilm<sup>™</sup>, etc.)





2. **Absorbent material** – paper toweling, spill batting, etc. Wrap sample with enough to soak up the entire sample if it were to spill from primary containment. *May be impossible in some situations such as transporting on ice.* 

3. Secondary containment – sealable container with Biohazard Symbol affixed. May be Ziploc-style bag, Rubbermaid-style container, or Playmate-style cooler. Should remain sealed if dropped. *May use Styrofoam coolers only if sealed with packing-style tape all around lid.* 





# **Biological Spill Response** BSL-1 and BSL-2

The following procedures are provided as guidance for responding to a spill involving biohazards (including recombinantly modified organisms) in a BSL-1or BSL-2 laboratory. Personnel have the obligation to minimize exposure of themselves and others to biohazards and to minimize the release of biohazards from the laboratory.

In the event of a spill:

- If any biohazardous material gets in your eyes, flush your eyes at the nearest eyewash immediately.
- Remove any contaminated clothing or personal protective equipment (PPE) and wash any exposed areas of skin with soap and water. Put on clean clothing (if necessary) and fresh PPE (i.e. lab coat, gloves, and eye protection).
- Assess the magnitude of the spill, denote the area, and notify others
- Cover the spill with absorbent material (e.g. paper towels, kitty litter, etc.)
- Pour agent-appropriate disinfectant over the entire area, working from just outside the margins of the spill towards the center. Allow for sufficient contact time (\*note that the minimum contact time depends on the agent and may vary).
- Pick up broken glass with forceps, tongs, or broom and dustpan. NEVER pick up glass with your bare hands. Ensure glass is decontaminated before disposing in broken glass container.
- Bleach soaked paper towels or kitty litter may be placed into the regular waste can. Other solid waste should be collected into a biohazard waste bag and autoclaved. <u>Bleach should NOT be autoclaved</u>.
- Make sure area is thoroughly cleaned and disinfected. Repeat disinfection of the spill site as necessary.
- Disinfect contaminated clothes and shoes.
- Immediately report any spill of risk group 2 materials outside the biosafety cabinet, any spill of risk-group 1 material in excess of 25 ml, and any spill of recombinantly modified risk-group 1 material to the laboratory PI and to the Office of Biosafety by calling 979-862-4529 or e-mailing biosafety@tamu.edu. For after-hours spill emergencies, please call the Communications Center at 979-845-4311 for assistance.
- Replenish Spill Kit as necessary.



# \*\*\*\*\*ATTENTION\*\*\*\*\*

It's the law!

In accordance with the Texas Administrative Code:

## Autoclaved biohazardous waste must be labeled with a TREATED sticker and placed in a black trash bag prior to disposal.



### Treated in Accordance with 25 TAC 1.136

Biosafety Program Texas A&M University 750 Agronomy Road, Suite 2701 1186 TAMU College Station, TX 77843-1186 979-862-4549: Fax 979-862-3176 <u>http://rcb.tamu.edu</u>

To request additional TREATED stickers, contact the Office of Biosafety 979-862-4549 or biosafety@tamu.edu

# **Autoclave Log**

Biological Indicator Pass/Fail										
Description of Load and Amount										
Cycle T/T										
PI/ Lab										
User Name										
Time										
Date										

\*Describe parameters of pre-programmed "liquid", "trash", "gravity", etc. cycle at front or back of log

Room

Autoclave ID \_

\_Building\_

### **AUTOCLAVE VALIDATION**

Equipment ID: make/model SSC or TAMU ID #	
Location:	
Building / room #	
Individual performing validation:	
Name / lab	
Name / lab	

### CYCLE TYPE: SOLID WASTE

CYCLE PARAMETERS

LOAD DESCRIPTION

Volume/ Mass\_\_\_\_\_

TIME:	Contents
TEMP:	PLACEMENT OF INDICATOR IN LOAD
PRESSURE:	(where)

	Run Date	Biological Incubation Date	Indicator	Reading
Validation Cycle # 1			Pass	Fail
Validation Cycle # 2			Pass	Fail
Validation Cycle # 3			Pass	Fail

### **CYCLE TYPE: LIQUID WASTE**

CYCLE PARAMETERS

LOAD DESCRIPTION
------------------

Number of vessels \_\_\_\_\_

TIME:	
TEMP:	
PRESSURE:	

Maximum volume of each vessel\_\_\_\_\_\_ Total liquid volume in each vessel \_\_\_\_\_\_

Run DateBiological Incubation DateIndicator ReadingValidation Cycle # 1PassFailValidation Cycle # 2PassFailValidation Cycle # 3PassFail

# **INJURY RESPONSE** GUIDELINES for **RESEARCH LABS**

# It's a minor injury?

### **Puncture wounds:**

- Encourage bleeding. Wash the affected area with soap and water for 15 minutes.
- **Apply first aid, if needed** (e.g. antiseptic and/or a bandage).

# Mucous membrane (eyes, nose, mouth) exposure:

• Flush the affected mucous membrane(s) immediately at the eyewash station or at the sink with running clean water for 15 minutes.



# It's an emergency?

# Call 911 and follow all instructions given by the operator.

*Note:* Do you know the location information for the lab you are in (e.g. building name and number, room number, street address)?

OR

Go to the emergency room or urgent care clinic of your choice that accepts your insurance and/or worker's compensation.

# **Reporting** IMMEDIATELY REPORT THE INJURY TO YOUR PRINCIPAL INVESTIGATOR (PI) OR SUPERVISOR.

The PI or Supervisor must complete all appropriate incident reporting paperwork. For guidance on this process, contact your HR liaison.

The Texas A&M University Biosafety Occupational Health Program (BOHP) provides occupational health services to personnel at risk of exposure to animals or infectious biohazards (in BSL-2 and BSL-3 labs) in the course of their participation in IBC or IACUC permitted research, teaching or diagnostic activities. Examples of exposure incidents that should be reported to the BOHP include, but are not limited to, the following:

- Contaminated sharps injury
- A bite from an animal infected with a human pathogen
- Spill of infectious biohazards outside of the Biosafety Cabinet
- Exposure to recombinantly modified materials

Report any injuries involving biohazardous agents or animals to the BOHP by calling 979-845-6649 or by emailing bohp@tamu.edu OR biosafety@tamu.edu.

Note: Physical injuries, chemical exposure(s), and radiation exposure(s) should be reported to Environmental Health and Safety (EHS) by calling 979-845-2132 or email: ehsd.occ.health@tamu.edu

# **ZIKA** VIRUS

### What is Zika virus?



Zika virus is a flavivirus transmitted by the *Aedes spp.* mosquito. The same genus of mosquitos also transmits other viral diseases, including dengue fever, chikungunya, West Nile, and yellow fever. In 1947, Zika virus was first found in monkeys living in the Zika forest located in the African country of Uganda. Zika virus was common mainly in Africa and Asia until a major outbreak occurred May 2015 in Brazil. There are two strains of the virus,

the African strain and the newly emerged Pacific and Americas strain. Zika virus has now spread to many other countries in the Western Hemisphere including Mexico, Bolivia, Puerto Rico, and the Dominican Republic. The World Health Organization (WHO) estimates in 2016 there could be up to four million people who become infected with Zika virus in the Americas.

### How is Zika virus impacting global travel?

The Centers for Disease Control (CDC) has issued travel notices due to Zika virus for several areas across the globe. The Caribbean, Pacific Islands, South America, Mexico, Central America, Cape Verde, and Samoa are all under Alert Level 2. Alert Level 2 means travelers should follow enhanced precautions when visiting these areas. Pregnant women should avoid traveling to areas where infected mosquitos have been identified.

Zika virus and travel information: http://wwwnc.cdc.gov/travel/notices

Local Zika virus information: http://texaszika.org/

### How can Zika virus be prevented when traveling?

- The best way to prevent Zika infection is to avoid being bitten by mosquitoes.
- Clothing should cover as much of the body as possible. Cover exposed skin by wearing long-sleeved shirts and pants.
- Treat clothing with permethrin or an Environmental Protection Agency (EPA) approved insecticide since mosquitoes can bite through clothes. DO NOT apply permethrin directly to the skin.
- Use EPA approved insect repellent on exposed skin and reapply according to label directions. Effective active ingredients in insect repellent include DEET, Picaridin,

Oil of Lemon Eucalyptus (OLE), and IR3535. Effective name brand insect repellents include Off!, Cutter, Sawyer, Ultrathon, Autan, Repel, Skin So Soft Bug Guard Plus, and SkinSmart.

- Keep windows and doors closed or use screens to prevent mosquitoes from entering.
- If staying outside or in poorly screened spaces, a World Health Organization Pesticide Evaluation Scheme (WHOPES) approved bed net to cover the sleeping area should be used.
- Drain standing water, clean clogged rain gutters, change the water in birdbaths/fountains/animal troughs weekly, and keep in mind "dump it, clean it, drain it, or fill it" to reduce the presence of mosquitoes.

### How is Zika virus transmitted?

- Bite by an *Aedes spp.* mosquito carrying the virus;
- Sexual contact with an infected individual;
- Passed by an infected mother to the fetus during pregnancy or the child during delivery; or
- Blood transfusion from an infected individual.



By Sarah Almukhtar and Mika Gröndahl | Sources: Dr. W. Augustine Dunn; Oxitec; The Anatomical Life of the Mosquito, R. E. Snodgrass

### Why is Zika virus becoming a major concern?

Zika virus rarely results in hospitalization or death; however, serious birth defects are being linked to Zika virus infection. Numerous cases of microcephaly (a brain birth defect which causes the baby's head to be smaller than normal due to incomplete brain development) among babies whose mothers were infected with the Zika virus during pregnancy are now being reported. There is also emerging evidence that Zika virus may cause Guillain-Barre Syndrome (GBS) in adults. GBS is a disorder which causes an individual's immune system to attack their own nerve cells. The damage in the nerve cells leads to muscle weakness and sometimes paralysis which can last anywhere from a few weeks to several months. GBS may result in permanent nerve damage. A significant increase in GBS cases have been seen in areas where Zika virus is prevalent.

# What are symptoms of Zika virus?

Symptoms of Zika virus typically appear three to twelve days following infection and include low-grade fever, skin rash, muscle/joint pain, and red eyes, although approximately 80 percent of infected individuals may never experience any symptoms of infection at all. Symptoms usually last from two to seven days.



# How is Zika virus diagnosed and treated?

Zika virus is diagnosed by a blood test which measures viral RNA or the presence of Zika virus antibodies. Currently there is no vaccine to prevent or medicine available to treat the Zika virus infection. To alleviate symptoms of Zika virus infection, rest, fluids, and over-the-counter medication to reduce fever and pain are recommended. Products containing aspirin are not recommended.

### Disclaimer

Be advised that as an emerging new pathogen, information about the transmission, effects, treatment, and prevention of Zika virus infection changes frequently. While this is the most current information, this is subject to change upon further scientific discovery.

# **Rabies Awareness**



### WHAT IS RABIES?

Rabies is a deadly disease caused by a virus that attacks the central nervous system. The virus lives primarily in the saliva, brain tissue, and spinal fluid of a rabid animal.

Infection from the virus causes an acute, progressive encephalomyelitis that is almost always fatal. The incubation period in humans can be several weeks to several months.

Primary routes of exposure from a rabid animal are a skin-breaking wound (bite, scratch, etc.) or contact from an animal's

### **EMPLOYEES AT RISK**

People who work with potentially infected animals, either in a clinical or field setting, have a potential to be exposed to rabies. This includes veterinary, clinical, and teaching faculty and staff, veterinary

saliva onto an open wound or person's mucous membrane.

A secondary route of rabies exposure is through unprotected contact with potentially infected brain or nervous system tissue. Blood, urine, and feces are not considered infectious. Merely handling an infected animal normally does not constitute an exposure; however, any contact with bats should be considered an exposure.

Rabies is prevalent in Texas. The disease is common in bats, skunks, foxes, raccoons,

of rabies-risk species, support staff for

agriculture animal care, and pest control

coyotes, and wolves. Rabies is also found in common household pets such as dogs, cats, and ferrets.

AS A&M ERSI

Though less prevalent, livestock such as cows and horses can be affected. Small mammals such as chipmunks, gerbils, guinea pigs, hamsters, mice, rabbits, rats, and squirrels rarely become infected with rabies.

Non-mammals such as birds, fish, insects, lizards, snakes, and turtles never get rabies.



### WORK SAFE, WORK SMART

staff.

All individuals handling animals, living or deceased, which have been identified as "rabies suspect" should wear nitrile gloves, a fluid resistant lab coat or gown, surgical mask and face shield, and goggles or safety glasses during all procedures where a potential exists for exposure to the animal's saliva, nasal secretions, or mucous membranes.

People conducting or standing within six feet of a procedure being performed on rabies suspect animals (bats, skunks, foxes, racoons, coyotes, wolves, dogs, cats, ferrets, cows, and horses) with the potential to expose brain tissue, neurological tissue, or their respective fluids, should use the following personal protective equipment: a surgical mask, eye protection, nitrile gloves, and a solid front gown or lab coat.

Consideration should be given to the use of kevlar or other cut resistant gloves to prevent cuts or sticks from instruments or bone fragments.

If possible, the number of people involved in the procedure and specimen collections should be limited.

People deemed to be at frequent risk of exposure in their general work activities, as determined by risk assessment, will be offered pre-exposure rabies immunoprophylaxis.

A series of three vaccinations over 28 days are used for pre-exposure prophylaxis. Completion of the series prior to working under potential exposure conditions is not required.

Continuing surveillance of immunity to rabies is offered to those at frequent risk of exposure in their general work activities. Rabies titers are drawn every two years and booster vaccinations are offered when needed.

People deemed to be at low risk of exposure in their general work activities, as determined by risk assessment, will be given educational information describing risk mitigations and incident response instructions for potential rabies exposure.



### POTENTIAL EXPOSURE TO RABIES

A potential exposure to rabies is:

- 1. Any skin piercing injury (bite, nip, scratch) from a bat, skunk, fox, racoon, coyote, wolf, dog, cat, ferret, cow, or horse.
- 2. Any contact with saliva, slobber, mucous membrances, any nervous system tissues or fluids (brain, spinal cord, etc.) from any of the animals listed above.
- Any known or suspected contact with a bat, with or without visible evidence of a wound.

If you believe you have been exposed to rabies at work, make sure to rinse the affected area with plenty of soap and water (if the exposure is in or near the eyes, use water only), and notify your supervisor as soon as possible.

Report the exposure immediately to the Biosafety Occupational Health Program (BOHP). You will then be referred to a qualified occupational medicine provider for consultation and any necessary treatment.

Contact the BOHP at bohp@tamu.edu. More information is available at the BOHP web page at bohp.tamu.edu Pre-exposure vaccination for rabies does not prevent the development of rabies if you are exposed to an infected animal.

Vaccination of pet animals or livestock against rabies does not completely eliminate the risk of rabies being transmitted by these animals. Even a bite from an animal which is currently or has previously been vaccinated MUST be reported.

Those people who are vaccinated and demonstrate a titer for rabies antibodies MUST receive post-exposure treatment if an exposure to rabies is confirmed. It is important not to wait for signs or symptoms of the disease to develop.

Human Rabies Prevention - United States, 2008

Recommendations of the Advisory Committee on Immunization Practices (May 23, 2008)

Authors: Susan E. Manning, MD, Charles E. Rupprecht, VMD, Daniel Fishbein, MD, Cathleen A. Hanlon, VMD, Boonlert Lumlertdacha, DVM, Marta Guerra, DVM, Martin I. Meltzer, PhD, Praveen Dhankhar, PhD, Sagar A.Vaidya, MD, Suzanne R. Jenkins, VMD, Benjamin Sun, DVM, Harry F. Hull, MD

Retrieved December 2, 2009 from the Centers for Disease Control and Prevention's online Morbidity and Mortality Weekly Report, Vol 57, pp 1-26, 28

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e507a1.htm

Rabies Prevention in Texas - 2012 (Revised 8/24/2012)

Texas Department of State Health Services Zoonosis Control

Retrieved December 12, 2012 from the Texas Department of State Health Services website

http://www.dshs.state.tx.us/idcu/disease/rabies/information/prevention/pamphlet/

TEXAS A&M UNIVERSITY BIOSAFETY OCCUPATIONAL HEALTH PROGRAM Office of Research Compliance and Biosafety • Division of Research

Phone – 979.845.6649 979.862.6455 bohp.tamu.edu bohp@tamu.edu

# Q Fever

## What is Q fever and what causes it?

Q fever (the Q stands for query) is a disease caused by the bacterium, Coxiella burnetii(Cox-EE-ell-uh burnet-EE-eye). The disease is found worldwide, except for New Zealand. It can cause reproduction problems in livestock and severe respiratory (lung) and liver disease in humans.

### What animals get Q fever?

Sheep, goats and cattle are most infection) and hepatitis (inflammalikely to get Q fever. Other animals tion of the liver) can occur in serious that can get the disease include dogs, cases. In pregnant women, infections cats, rabbits, horses, pigs, camels, buffalo, rodents, and some birds.

### How do animals get Q fever?

Animals get Q fever through contact with body fluids or secretions (milk, urine, feces or birthing products [amniotic fluid, placenta]) from infected animals. This may occur from direct contact, ingestion (oral), or indirect contact through objects contaminated with these materials (fomites). The bacteria is very hardy in the environment and can survive for long periods. This can lead to infection by inhaling (aerosol) the bacteria from contaminated barnyard dust. Ticks (vector) can also spread infection between animals.

## How does Q fever affect animals?

The most common sign of infection in animals is abortion during late pregnancy. However, most animals do not show any signs of illness with Q fever.

### Can I get Q fever?

Yes. People usually get Q fever by breathing (aerosol) contaminated barnyard dust or bydirect contact with infected animals while assisting with the delivery of newborn animals. Occasionally people can get Q fever by drinking (oral) contaminated milk or from tick bites (vector).

Symptoms of Q fever include fever, chills, night sweats, headache, fatigue and chest pains. Pneumonia (lung infection) and hepatitis (inflammation of the liver) can occur in serious cases. In pregnant women, infections can cause premature delivery, abortion and infection of the placenta. In people with pre-existing heart valve disease, endocarditis (inflammation of the heart valves) may occur.

### Who should I contact, if I suspect Q fever?

In Animals – Contact your supervisor In Humans –

Contact your physician and notify your supervisor and Biosafety Occupational Health 979-862-4549



# How can I prevent Q Fever in animals?

Keep pregnant livestock separate from other animals. Burn or bury the remaining reproductive tissues after abortions or delivery of newborn animals to reduce the spread of the disease between animals. Take great care when handling these tissues to avoid your exposure to Q fever. If you suspect Q fever contact your Supervisor for information on how properly to dispose of possibly infected tissue.

### How can I protect myself from Q fever?

Avoid contact with the placenta, birth tissues, fetal membranes and aborted fetuses of sheep, cattle and goats. If you are assisting the delivery of newborn animals, wear gloves, masks and eye protection. People with heart valve disease, who have had valve replacements or pregnant women should be especially careful around pregnant sheep, cattle and goats. Eat and drink only pasteurized milk and milk products. There is a vaccine available (in some areas) for people who work around pregnant sheep and goats.

### For More Information

CDC website. Q Fever at http://www. cdc.gov/ncidod/diseases/submenus/ sub\_q\_fever.htm



TEXAS A&M UNIVERSITY Veterinary Medicine & Biomedical Sciences

# **Centrifuge** Guidance

It is widely accepted that



### **CENTRIFUGE OPERATIONS**

- Infectious biohazards must be centrifuged using sealed rotors and centrifuge safety cups.
  - More than just having a lid -sealed rotors and safety cups have intact O-rings or gaskets between the lid and the body of the rotor/cup.
- Ensure samples are carefully balanced; do not over-fill tubes. A good rule of thumb is no more than 2/3 full.
- Rotors and/or safety cups must be loaded and unloaded inside the BSC or another containment device.
- Stay with the centrifuge until the desired speed has been reached.
- Disinfect the interior of the centrifuge, and the interior and exterior surfaces of rotors and safety cups before removal from the BSC, and on a routine basis.



### **CENTRIFUGE SAFETY**

- Inspect all O-rings, seals, and chamber gaskets before use and on a routine basis.
- Lubricate O-rings, seals, and gaskets as recommended by the manufacturer.
- Inspect rotors and safety cups for cracks, damage and cleanliness.
- Do not use a rotor or safety cup that has been dropped.
- If damage is found, notify lab staff and your supervisor.
- Label the equipment with a "do not use" sign; coordinate repair or replacement.





aerosol generating procedures in the laboratory may be a common source of laboratory-acquired infections (or LAIs). Centrifuges, a very common piece of laboratory equipment used in many procedures, have the ability to create respirable-size particles that remain airborne for extended periods of time. This guidance document describes considerations and specific procedures necessary to minimize the opportunity to generate infectious aerosols and to protect personnel during and after centrifugation.

# Laboratory PERSONNEL & TRAINING



# WHO IS CLASSIFIED AS LABORATORY PERSONNEL?

All personnel participating in laboratory activities involving the use of biohazards and/or biological toxins are classified as laboratory personnel. Examples include, but are not limited to the following:

- Undergraduate and graduate students
- Post-Doctoral Fellows
- Research Assistants/Associates
- Technicians

# HOW AND WHERE DO I COMPLETE TRAINING?

All training can be completed online through TrainTraq or the Gateway portal.

### BIOSAFETY LEVEL – 1 (BSL-1)

RECOMMENDED

• BSL-1 Training

### BIOSAFETY LEVEL – 2 (BSL-2) REQUIRED

- BSL-2 Training
- Biosafety Cabinet Training
- Enrollment in the Biosafety Occupational Health Program (BOHP)
- Bloodborne Pathogens Training\*

Please contact the Office of Biosafety at ibc@tamu.edu for additional training information.

\* Required for personnel in laboratories approved for activities involving human/non-human primate blood, tissues, cell lines, etc.



# DO I NEED TO IDENTIFY LABORATORY PERSONNEL ON MY IBC APPLICATION?

BSL-1	BSL-2	
NO, but personnel must receive laboratory-specific training from the PI or their designee.	How long will personnel participate in laboratory activities?	
	Twelve consecutive weeks or less	More than twelve consecutive weeks
	NO, but personnel must complete required biosafety training and receive laboratory-specific training from the PI or their designee.	YES, submit a Personnel Change Request or contact ibc@tamu.edu with questions.

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# **Animal Use Area**

# Exposure to animals or animal products can cause asthma and allergies

Animals or animal products such as dander, hair, scales, fur, saliva, and body wastes contain powerful allergens that can cause both respiratory and skin disorders

### Animal handlers should take steps to protect themselves from exposure to animals and animal products:

- Perform animal manipulations within cage changing stations or biosafety cabinets when possible.
- Avoid wearing street clothes while working with animals and leave work clothes at the workplace.
- Reduce skin contact with animal products by using the appropriate personal protective equipment (PPE). If you have an animal allergy, you may wish to use respiratory protection. The Biosafety Occupational Health Program (BOHP) can assist with the respiratory protection process.
- Keep cages and animal areas clean.

Individuals that do not directly handle animals, but have a need to enter an area where animals may be housed, should take steps to protect themselves from exposure to animal and animal products by following the guidelines below:

- Do not handle or touch animals.
- Follow all instructions posted at the entry door regarding the use of PPE.
- Contact the Principal Investigator and/or Lab/Facility Manager for guidance or concerns.

### TAMU Biosafety Occupational Health Program:

- Individuals that work with animals must enroll in occupational health.
- Through the TAMU BOHP, eligible participants have access to educational resources, access to occupational health services (including respiratory protection for animal allergens and asthma), and access to an occupational health provider.
- BOHP staff can be reached via email or phone.
   Website: <u>https://bohp.tamu.edu</u>
   Email: <u>bohp@tamu.edu</u>
   Phone: 979-845-6649

