I. PURPOSE, APPLICABILITY & SCOPE

The University of Tennessee, Knoxville-area campuses, including: Knoxville, the Institute of Agriculture; College of Veterinary Medicine; and Graduate School of Medicine (UTK-A hereafter); are committed to protecting faculty, staff, students, visitors, the general public and the environment from exposures (or potential exposures) to biological hazards, and to ensuring that all activities involving biological hazards and the facilities used to conduct such work are in compliance with applicable U.S. Federal, State and local laws, regulations and guidelines.

This framework is to provide resources and recommendations to laboratory coordinators and instructors with the intent of minimizing risks to students from biological hazards. It applies to teaching laboratories, practical exercises, or other experiential learning where there is a high likelihood of exposure to biological hazards, and which are conducted at UTK-A campuses (or satellites). Covered biological hazards include:

- Biological agents (bacteria, viruses, fungi, protozoa, parasites, and prions) which may cause disease in humans;
- Unfixed human or nonhuman primate blood, body fluids, or tissues;
- Biological toxins which can cause acute illness or other negative health effects, including Select Agent toxins;
- Venomous animals manipulated and/or housed in laboratories or other indoor facilities;
- Poisonous plants posing a risk to humans via dermatological contact, inhalation, or other route of exposure;
- Unfixed blood, body fluids, or tissues derived from wildlife or other animals of unknown health status per documented risk assessment;
- Environmental samples deemed likely to contain any of the above and posing a risk to human health per documented risk assessment (e.g. human/animal wastewater samples).

II. ABBREVIATIONS, ACRONYMS & DEFINITIONS

A. Abbreviations & Acronyms

1. ASM – American Society for Microbiology
2. BMBL – Biosafety in Microbiological & Biomedical Laboratories (5th ed.)
3. BSO – Biological Safety Officer
4. CDC – Centers for Disease Control and Prevention
5. DHHS – United States Department of Health & Human Services
6. IBC – Institutional Biosafety Committee
7. NIH – National Institutes of Health
8. OSHA – Occupational Safety and Health Administration
9. PPE – Personal Protective Equipment
10. TDEC – Tennessee Department of Environment & Conservation
11. USDA – United States Department of Agriculture
12. UTK-A – University of Tennessee, Knoxville-Area Campuses (Knoxville, the Institute of Agriculture, College of Veterinary Medicine, & Graduate School of Medicine)

B. Definitions

1. Biological hazard (biohazard) – any material of biological origin that may pose an infectious disease risk or otherwise cause deleterious health effects. Examples include but are not necessarily limited to: infectious agents (bacteria, viruses, fungi, etc.), biological toxins, diagnostic specimens (blood, tissue, cells, and secretions), venomous animals, poisonous plants, etc.

2. Biological Safety Officer – the individual assigned to implement and oversee the biosafety framework related to biological hazards used in teaching labs and other experiential learning environments and ensure compliance with applicable safety regulations, standards, and guidelines.

3. Laboratory Coordinator – the individual (faculty member or departmental designate) with primary responsibility for the use of biological hazards in a University teaching laboratory (or group of laboratories) and/or leading practical or experiential learning exercises.

4. Institutional Biosafety Committee – appointed committee of UTK-A faculty, technical staff, and community representatives which establishes, recommends, and/or approves policies on the proper use of biological hazards.

5. Select Agents – infectious agents and biological toxins which have been declared by the DHHS or by the USDA to have the potential to pose a severe threat to public health and safety.

III. ROLES & RESPONSIBILITIES

A. Biological Safety Officer

The BSO acts as the institutional liaison for the implementation and administrative oversight of the teaching laboratory framework. The BSO will work with laboratory coordinators to ensure that basic biosafety objectives are met. The BSO (and staff) shall:
1. Establish/implement a framework for oversight of biological hazards and associated procedures in teaching laboratories at the discretion of the UTK-A administration.

2. Perform risk assessments and provide technical advice to laboratory coordinators, course professors, or department heads as requested.

3. Review or help develop guidance documents, technical bulletins, training slides or other instructional materials used to communicate the risks of working with biological hazards, prudent laboratory practices, health evaluation recommendations, and/or other mitigation strategies.

4. Review or recommend personal protective equipment to be used for manipulation of biological hazards.

5. Review or help develop emergency plans for handling accidental spills and exposures and investigate laboratory accidents involving biological hazards.

6. Develop and implement an exposure control plan for those teaching programs handling human derived materials as stipulated by the OSHA Bloodborne Pathogens Standard.

7. Collect and maintain documents related to teaching laboratories, including: an inventory of agents/materials in use, instructional guides or tutorials, written safety procedures, inspection reports, etc.

8. Perform annual inspections of facilities where biological hazards are being used or stored to ensure safety and containment measures as outlined in the ASM’s Guidelines for Biosafety in Teaching Laboratories, the BMBL, the OSHA Bloodborne Pathogens Standard, and/or other standards or guidelines as applicable.

9. Report any significant problems or teaching-related accidents or illnesses to the IBC or other campus administrators as applicable.

B. Laboratory Coordinator

The laboratory coordinator is the individual (faculty member or departmental designate) with primary responsibility for the use of biological hazards in the University’s teaching laboratories and/or leading practical or experiential learning exercises. The laboratory coordinator shall:

1. Comply with all regulations, standards, guidelines and University policies involving handling, storage, and disposal of biological hazards.

2. Provide a list/inventory of biological hazards to the BSO (as designated).

3. Complete programmatic biosafety training, and ensure that all teaching assistants and staff have completed training as applicable. Comparable information or training materials should be provided to students/trainees. Training and/or
distribution of training materials should be documented by the laboratory coordinator.

4. As necessary, communicate to teaching staff and students/trainees the signs and symptoms which may result from accidental exposures to the biological hazards in use.

5. Stipulate the safety precautions to be followed by teaching staff and students/trainees and ensure that these are followed. Work errors and conditions that may result in accidental releases or exposures are to be corrected immediately.

6. In cooperation with the BSO, determine the proper PPE to be worn for designated procedures. The laboratory coordinator (or designate) shall ensure that PPE is worn as directed and cleaned/replaced as appropriate.

7. Immediately notify the BSO of any laboratory spills, accidents, containment failures, or violations of biosafety practice which result in the release of biological hazards and/or the exposure of laboratory personnel or students/trainees.

C. Institutional Biosafety Committee

The IBC establishes, recommends, and approves policies ensuring the prudent management of biological hazards. Policy objectives are to protect faculty, staff, students, research subjects, the general public, and the environment from biological hazards used in University research, teaching, diagnostic testing, or other specified activities. The IBC has delegated administrative oversight of this teaching laboratory framework and related policies to the BSO. Additionally, the IBC shall:

1. Ensure that adopted policies, practices and procedures for work with biological hazards meet applicable regulatory standards and guidelines.

2. At the request of the BSO, laboratory coordinator, course professor, or department head, provide review, risk assessment, and technical advice for teaching laboratory experiments or activities involving novel agents (e.g. emerging pathogens) and/or high-risk procedures or techniques.

3. At the request of the BSO, investigate, or review investigation findings of, any significant teaching-related accidents or illnesses and recommend corrective actions.

4. Review any significant violation of policies, practices, and procedures reported by the BSO and recommend corrective actions as appropriate.

IV. PROGRAMMATIC FRAMEWORK

Following the recommendations of the ASM’s Guidelines for Biosafety in Teaching Laboratories, the following are the basic programmatic components that should be present for all UTK-A teaching laboratories, practical exercises, or experiential learning involving
biological hazards. Additional components may be requested by the BSO as necessitated by risk assessment.

A. Hazard Identification & Communication
   i. A list of course-specific biological hazards is to be provided to the BSO for administrative review and record keeping.
      a. The BSO will review the proposed hazards and associated procedures to ensure that they do not pose a significant risk to individual or public health, are not Select Agents, and may be managed safely given laboratory design and available/prescribed safety controls.
      b. Biological hazards that are likely to cause severe, life-threatening illness and/or pose other unacceptable risks will be identified and communicated to the laboratory coordinator in writing.
      c. The BSO will assist the laboratory coordinator in identifying suitable surrogate agents or lower-risk biological materials as appropriate.
   ii. A mechanism for identifying and communicating biological hazards and their health effects to teaching staff and students/trainees should be established and documented. Training slides, handouts, literature references, safety data sheets, just-in-time verbal announcements, or other materials may be used at the discretion of the laboratory coordinator. The BSO will review, supplement, or provide this information as requested.

B. Training
   1. Laboratory coordinators and instructors should complete programmatic Biosafety Principles training through the UTK-A Biosafety Office (or equivalent). This may be done as an in-class (regularly scheduled) or online exercise.
   2. Laboratory coordinators should provide biosafety training to students/trainees prior to hands-on activities whenever possible. Generally, training should address specific hazards/risks associated with the laboratory or exercises; standard lab hygiene and prudent practices; personal protective equipment use; decontamination & disinfection; disposal of biohazardous waste; and emergency response procedures for spills/exposures. Training may be conducted as part of class instruction, provided as written guidance, or given as an online supplemental module at the laboratory coordinator’s discretion. The method used and delivery of information should be documented and maintained with the class records. The BSO will supplement or provide training materials if requested.

C. Medical Evaluation
   1. Students/trainees should be informed in writing that they may consult with Student Health Services, their primary healthcare provider, or other medical professional if...
they have any medical questions or request to receive health screenings prior to beginning any laboratory experience or practical exercise. Necessity of a medical consultation is at the discretion of the student/trainee. Associated costs are the financial responsibility of the student/trainee.

2. Medical evaluations should address any underlying health concerns and provide advice to students regarding the risks related to teaching activities.

3. Any medical restrictions identified by a healthcare professional should be submitted in writing to the laboratory coordinator for review. Alternative methods of instruction are at the discretion of the laboratory coordinator, course professor, and/or department head as appropriate.

D. Personal Protective Equipment

1. PPE should be determined based on the intrinsic risks of the biological hazards present, types of procedures conducted, and availability of safety controls. A long-sleeve lab coat, impact-resistant safety glasses, and fluid-resistant disposable gloves are generally sufficient when working with biological hazards in teaching environments. More or less PPE may be necessary per risk assessment. The BSO will review and provide advice on hazard- or procedure-appropriate PPE.

2. The laboratory coordinator shall communicate PPE requirements and enforce its use as prescribed. PPE may be provided by the laboratory coordinator/department (with or without cost recovery through lab fees per departmental discretion), or students may be required to purchase their own PPE.

3. PPE is to be maintained or disposed in accordance with prudent laboratory practices. The BSO will advise on PPE maintenance/disposal as necessary.

E. Spills, Exposures & Injuries

1. Students/trainees are to be informed on the emergency procedures related to biological spills, hazard exposures, or laboratory injuries.
   a. A spill kit and spill response plans appropriate for the type and amount of biological hazards present should be available to teaching staff and students/trainees. A sample plan is available at http://biosafety.utk.edu/emergency-response/.
   b. Students/trainees sustaining biological hazard exposures (e.g., puncture wounds with contaminated sharps or splashes to broken skin, the eyes, nose or mouth) or other laboratory injuries must notify the teaching staff or laboratory coordinator immediately:
      i. For major accidents/incidents, notify 911 and follow established emergency response procedures.
ii. For minor incidents, affected individuals should follow basic first aid procedures (flooding affected areas, bandaging, etc.) as appropriate.

iii. Exposed/injured students should be advised on options for medical evaluation and follow-up, generally Student Health Services during routine hours or the UT Medical Center, Knoxville if after hours or on the weekend.

iv. Personal exposures or injuries must be reported to the Office of Risk Management. Instructions and forms for reporting staff and student accidents, exposures, or injuries are available at http://riskmanagement.tennessee.edu/.

2. All spills, exposures, and injuries should be reported to the BSO as soon as possible. The BSO will do a non-punitive accident review to determine root cause and make recommendations for corrective/preventative actions going forward.

F. Laboratory Inspections

1. The BSO (and staff) shall conduct annual inspections of all physical spaces designated as teaching (or teaching support) laboratories and where biological hazards are handled.

2. Inspections will be used to verify the prudent practices outlined in the ASM Guidelines for Biosafety in Teaching Laboratories and/or BMBL as appropriate. The BSO will work with the laboratory coordinator to resolve any noted concerns or deficiencies.

3. The BSO will schedule an inspection date and time with the laboratory coordinator. Routine laboratory inspections shall not disrupt class time if at all possible. However, the BSO may review techniques/procedures during class time under extraordinary circumstances (e.g. as a follow-up to reported safety complaints/concerns or accident investigations).

G. Framework Verification

1. The BSO will work with laboratory coordinators to verify Sections IV A-F of this framework. Surveys, email, BlackBoard, or other file sharing platforms may be used to collect information during the verification phase.

2. If any gaps or deficiencies are noted, the BSO will provide corrective assistance until all components are in place. Once deficiencies have been addressed, the BSO will notify the laboratory coordinator (or designate) in writing that all framework objectives have been met.

H. Documentation, File Storage, & Retention

1. The BSO will host a shared drive or file sharing platform (e.g. BlackBoard, SharePoint) for deposition and storage of documents specific to each course utilizing
biological hazards. This information will be accessible to the BSO (and staff) and laboratory coordinators (or designates).

2. Course documents may include: training materials, completed verification checklists, lists/spreadsheets of infectious agents or other biological hazards used during the course, laboratory safety procedures, guidance documents, laboratory inspection reports, student assurance statements, and other documents deemed necessary (or useful) by the laboratory coordinator and/or the BSO. Documents may be mined and updated by all applicable parties as necessary.

3. Course information will be maintained as long as the course remains in the timetable. Should a course be suspended or eliminated, then materials will maintained for and additional three years.

4. Periodic reviews and updates to course information may be requested at the discretion of the BSO.

V. GUIDELINES, STANDARDS & REGULATORY REFERENCES

The following regulations, standards, guidelines and policies apply to the use of biological hazards in teaching laboratories and/or related exercises. In the case of conflict between requirements of the regulatory agencies, the more protective regulations shall prevail, as appropriate.

A. The ASM Guidelines for Biosafety in Teaching Laboratories (2012):
   http://www.asm.org/images/asm_biosafety_guidelines-FINAL.pdf

B. The CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 5th ed. (2009):
   http://www.cdc.gov/biosafety/publications/bmbl5/

C. Safety standards promulgated through the (Tennessee) Occupational Health & Safety Administration (OSHA; 29 CFR 1910 et al.):
   http://www.state.tn.us/labor-wfd/tosha.html

D. TDEC Rule 0400-11-01-.04(2)(k)4 covering the packaging and disposal requirements for regulated medical waste:
   http://www.tennessee.gov/environment/

E. UT System Policy SA0450: Biological Safety:
   http://policy.tennessee.edu/safety_policy/sa0450/