Biological Safety

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1. GENERAL

To protect employees and the environment from contamination with hazardous biological materials and to comply with applicable laws and guidelines, each member shall develop and implement an effective biological safety program, as necessary. The program must also include provisions for assigning responsibilities to review and approve experimental protocols involving identified biohazardous materials.

2. PROGRAM GUIDELINES

2.1. Each member with biological materials should:

(a) Identify workplace hazards associated with biological materials;
(b) Develop programs to reduce risk to employees, students and visitors for identified hazards; and
(c) Provide and document safety training to employees, students and visitors for identified hazards.

2.2. The biological safety program shall address the issues of safe and proper shipment, storage and handling of identified biohazardous materials.

2.2.1. Biohazardous materials include the following:

(a) Etiologic agents which may cause disease in humans, animals or plants;
(b) Human and non-human primate body fluids or tissues (e.g. bloodborne pathogens);
(c) Agents and molecules involved with recombinant DNA biotechnology and genetic manipulation;
(d) Animals infected with zoonoses; and
(e) Items contaminated with etiologic agents or human body fluids or tissues.

2.2.2. For the purpose of complying with federal shipping regulations, biohazardous materials shall also include select toxins identified by the Centers for Disease Control and Prevention (42 CFR §73, Select Agents and Toxins).

2.2.3. Handling procedures should follow the guidelines listed in the latest edition of the CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories.”
2.3. The biological safety program must ensure compliance with state regulations for the treatment and disposal of medical waste (25 TAC §1.131-137 [Special Waste from Health Care-Related Facilities]; 30 TAC §330.1201-1221 [Medical Waste Management]; 30 TAC 330.11(f) [Notification Required]). Educational institution research laboratories, clinics and biomedical research laboratories are included in the definition of a health care-related facility.

2.3.1. Wastes regulated under these rules are those that are both infectious and included under one of the following categories:

(a) Animal waste (carcasses, body parts, blood, serum, plasma, blood components and bedding that have been exposed to pathogens);

(b) Bulk human blood, bulk human blood products, and bulk human body fluids;

(c) Microbiological waste (e.g., discarded cultures, culture dishes);

(d) Pathological waste (e.g., human materials, laboratory specimens of blood and anatomical remains); or

(e) Sharps (contaminated) needles, blades and sharp devices, and broken glass; uncontaminated hypodermic needles and syringes with attached needles.

2.3.2. Approved methods of treatment prior to disposal include:

(a) Chemical disinfection;

(b) Incineration;

(c) Encapsulation (sharps);

(d) Steam disinfection;

(e) Thermal inactivation;

(f) Chlorine disinfection/maceration;

(g) Moist heat disinfection; and

(h) On-site burial or rendering (only applies to non-contagious animal carcasses)

(NOTE: Not all methods are approved for all wastes; See rules for specific listings)

2.3.3. Container labeling and record keeping requirements described in the state regulations must be implemented.

2.4. The biological safety program must ensure compliance with the latest edition of the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).

2.5. Each member must evaluate the need to implement a bloodborne pathogen program in compliance with 25 TAC §96, Bloodborne Pathogen Control.