

UNIVERSITY OF KANSAS

LAWRENCE CAMPUS

LABORATORY SAFETY
MANUAL

PART III

Biosafety Plan

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PART III

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1) Introduction to the Biosafety Plan

1.1) Elements of the Kansas University, Lawrence, Biosafety Plan (BSP)

The Biosafety Plan consists of the following components:

1.1.1) The requirements, conditions and procedures of the "University's Safety and Health Manual" apply to all university personnel, students and visitors and are, therefore, part of the Biosafety Plan (BSP). See the Kansas University Safety Program.

1.1.2) The requirements, conditions and procedures of Part I of this Laboratory Safety Manual apply to all personnel, students, and visitors in laboratories and are, therefore, part of the Biosafety Plan.

1.1.3) The requirements, conditions, and procedures of this part (Part III) apply to all personnel, students, and visitors in laboratories with biological hazards. For Biosafety Levels III and IV (see Glossary), requirements, conditions, and procedures of the 3rd edition of CDC "Biosafety in Microbiological and Biomedical Laboratories" is adopted by the KU Biosafety Plan. See section 3.7 of this Part III.

1.1.4) The requirements, conditions, and procedures specified in the Recombinant DNA Guidelines (See III-3.6) shall be met by individuals working with recombinant DNA. Contact the chair of the Recombinant DNA committee for guidance. The EHS Office at 864-4089 can provide the current chair and phone number.

1.1.5) The requirements, conditions, and procedures specified in the Bloodborne Pathogen Program under the University's Safety and Health Committee shall be met by individuals who work under conditions in which contamination with human blood, fluids, or tissues is a potential problem. See III-3.5.

1.2) Biological Considerations

Since exposure by infectious agents and/or allergens may be by direct contact, oral ingestion, ocular contamination, injection by puncture, or inhalation, the safety procedures and engineered safeguards must address protection against these modes of exposure. Because the same modes of exposure apply to chemicals and radioactive materials, the "universal" safety procedures and safeguards are covered in Part I of this Laboratory Safety Manual. When animals are used, the behavior of the animals, in addition to the vectors they may carry, must also be considered in establishing safety procedures and safeguards.

1.3) Organization of Part III

1.3.1) Biosafety-specific safety procedures for Level I and Level II Laboratories and/or emphasized universal safety operating procedures (Standard Operating Procedures) are addressed in chapter 2.

1.3.2.) Biosafety-specific aspects of hazard communication and control are addressed in chapter 3.

1.3.3) How to obtain EHS Safety Authorizations for work at Biosafety Levels III and IV is described in section 3.7 and section 3.9 of Part I..

1.3.4) Biosafety-specific training requirements are outlined in chapter 4.

1.3.5) Medical factors that need to be considered in biosafety are listed in chapter 5.

1.3.6) Safe disposal of Biohazards (infectious waste, etc) is addressed in chapter 6.

2) Standard Operating Procedures/Practices in Laboratories Using Biohazards at Biosafety Levels I or II.

Note: See Glossary for definitions of Biosafety Levels I and II.

2.1) Introduction and Review of the "Seven Basic Rules of Biosafety" (Source: National Research Council, " Biosafety in the Laboratory")

Note: Since all of Part I is part of the Biosafety Plan, review and study of the standard operating procedures to be followed by Authorized Users of Biohazards includes all of Part I with special emphasis on the Standard Operating Procedures of Part I-chapter 2. The document referenced above identifies "seven basic rules of biosafety." These rules are identified and referenced in 2.1.1.

2.1.1) References identifying the "seven basic rules of biosafety"

Authorized Users shall:

2.1.1.1) Carefully follow the seven basic rules of biosafety as stated in I-2.6.3; I-2.5.3.11 & I-2.6.5; I-2.5.3.6; I-6.2.1.4; I-2.5.3.10 & I-3.6; I-2.5.3.7; I-2.5.3.5; and I-2.5.3.4.

2.1.1.2) Special comments concerning "sharps" (covered by I-2.5.3.6 & I-6.2.1.4).

Authorized Users shall:

a) Restrict the use of needles and syringes or any other "sharps" to those procedures for which there are no alternatives; use all "sharps" carefully to avoid self-inoculation; and dispose of "sharps" in leak- and puncture-resistant containers.

b) Use only needle-locking syringes or disposable syringes with needle as an integral part of syringe for injection or aspiration of Biohazards.

c) Avoid handling used needles to the extent possible and exercise special care when that is not possible.

d) Place contaminated sharps in a hard-walled container for transport to a processing area for decontamination-- preferably by autoclaving.

2.2) Biosafety-Specific Standard Operating Procedures/Practices (Levels I and II)

Note: In this Part, “contaminated” refers to “contamination with Biohazards (infectious biological agents).” If materials or animals are contaminated with chemicals or radioactive materials as well, the appropriate Standard Operating Procedures of Part II and IV shall be followed as well.

If all Standard Operating Procedures cannot mutually be followed, judgment will need to be exercised on which hazard is the greatest. Contact EHS for clarification and assistance.

2.2.1) Need for restricted or controlled access

The Authorized Laboratory Supervisor (ALS) shall:

2.2.1.1) Evaluate the need for restrictions on access to the laboratory during critical operations within the laboratory, instruct the Authorized Users and Authorized Occupants concerning the nature of those restrictions and include those instructions in the laboratory specific Standard Operating Procedures.

Note: This includes an evaluation of the need to inform visitors, authorized occupants, and even authorized users of special risk factors. There may be immunization requirements. Some individuals may be susceptible to allergic reactions to dander, animals, and other materials in the laboratory and others may be especially susceptible to infection. All of these factors may need to be considered in establishing the level of control that is needed. See also 3.3.4.2 & 3 of this Part III.

Authorized Users and Authorized Occupants shall:

2.2.1.2) Follow the instructions given by the Authorized Laboratory Supervisor concerning access restrictions.

2.2.2) Disinfection and/or Sterilization and Aseptic Techniques

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall:

2.2.2.1) Establish effective sterilization/disinfection procedures for the infectious biological agents used in the their laboratory.

Note: Appropriate procedures to be used with equipment, instruments, glassware and laboratory bench tops, etc., must be developed. Examples of types of sterilization that may be used are given in section 6.4

2.2.2.2) Train Authorized Users in these procedures and provide these in writing as part of the laboratory-specific procedures.

2.2.2.3) Enforce the use of such procedures by Authorized Users.

Authorized Users shall:

2.2.2.4) Use aseptic techniques when protection from Biohazards (infectious agents) is required.

Note: Aseptic techniques are usually required for good research results but they are important in protection as well. Inoculation loops and other similar tools must be sterilized not only before use but also after use to avoid the dispersal of infectious agents.

2.2.2.5) Isolate equipment and glassware potentially contaminated with Biohazards (infectious agents) and appropriately mark/label such materials until sterilization/disinfection is accomplished.

Note: This means that such equipment and glassware must be kept in a "reserved area that is appropriately labeled" and in appropriate containers.

2.2.2.6) Sterilize or disinfect contaminated equipment/glassware in an expedient fashion using the procedure stipulated in the laboratory-specific Standard Operating Procedures.

a) Use appropriate protective clothing and equipment in handling contaminated items.

b) Use sterilization equipment as specified by equipment manuals and/or laboratory-specific Standard Operating Procedures.

c) Use appropriate protective equipment and/or laboratory-specific procedures in loading and unloading autoclaves to protect against accidents.

2.2.2.7) Disinfect work areas at the end of an experiment or the end of the day, whichever comes first, using the laboratory-specific disinfection procedures. (Note: This is the minimum frequency. Judgment is to be used in deciding whether the frequency should be greater.)

2.2.2.8) Disinfect work areas after any known contamination episode or suspected episode.

2.2.3) Fluids with Biohazards (cultures, tissues, body fluids, etc)

The Authorized Users shall:

2.2.3.2) Collect, handle, process and store fluids with biohazard agents in leak-proof containers provided by the Authorized Laboratory Supervisor.

2.2.4) Biohazard Waste

Authorized Users and Authorized Laboratory Supervisors shall:

2.2.4.1) Follow the requirements and procedures of chapter 6 of this Part (III) and applicable portions of chapter 6 of Part I.

2.2.5) Special Requirements in the Use of Animals

Personnel/students/visitors are not Authorized Users of live animals until they have had the training required by this Laboratory Safety Manual and that required by the Policies and Procedures of the Animal Care Committee

Authorized Users shall:

2.2.5.1) Handle and care for animals and associated equipment and materials as specified by the "policies and procedures" of the Animal Care Committee.

Note: The latter specify the responsibilities for cleaning cages, the disposition of bedding materials, etc.

2.2.5.2) Not permit animals in the laboratory other than those being used in the experiments.

2.2.5.3) Appropriately decontaminate cages, preferably by autoclaving, before they are cleaned and washed. (Note: This applies to Authorized Users who have been approved or instructed to perform this function.)

2.2.5.4) Put on surgical-type masks before entering animal rooms housing nonhuman primates.

2.2.5.5) Use laboratory coats, gowns, or uniforms in the animal room and remove them before leaving the animal facility. ("Should" for Animal Biosafety Level I and "shall" for Animal Biosafety Level II)

2.2.6) Shipping and Transporting Biohazard Agents/Organisms

Authorized Users and Authorized Laboratory Supervisors **SHALL NOT**:

2.2.6.1) Ship or transport biohazard agents/organisms without prior consultation with EHS concerning DOT, EPA and other regulations that must be satisfied. Only someone with training in these regulations may prepare and send shipments or transport them.

2.3) Biosafety-Specific Standard Operating Procedures/Practices (Levels III and IV)

Any work designated or meeting the criteria of biosafety level III or IV must be performed under much more stringent safety procedures and controls. At the Lawrence Campus, biosafety level III or IV requires a written EHS Safety Authorization. Currently, biosafety level IV work is prohibited on the KU-Lawrence campus due to the lack of a proper level IV facility.

Authorized Laboratory Supervisors shall:

2.3.1) Obtain a written EHS Safety Authorizations with the associated Laboratory-Specific Safety Plans for biosafety level III or IV work in accordance with the requirements of Part III: Section 3.7 and Part I: Section 3.9 before initiating any level III or IV work.

Authorized Laboratory Supervisors, Users and Occupants shall:

2.3.2) Comply with all procedures, practices and conditions stipulated by the level III or IV Laboratory-Specific Safety Plans.

3) Biosafety-Specific Hazard Communication and Control

3.1) Introduction

This chapter provides guidance for meeting the hazard communication and hazard control requirements of Chapter 3 of Part I in the area of Biosafety. This chapter should be used together with Chapter 3 of Part I.

3.2) Lab Hazard Registration/Safety Authorization Application See Part I - Section 3.3

The Authorized Laboratory Supervisor (ALS)/Unit Safety Coordinator (USC) shall:

- 3.2.1) Determine the Biosafety Level(s) assigned to the biological agent(s) to be used in the laboratory. Consult the CDC or NRC publication listed in 3.7.1 of this Part or the attachments to the LHRSA form to make that determination.
- 3.2.2) Include a list of hazardous biological agents/organisms and the assigned biosafety level for each of these in the LHRSA form.
- 3.2.3) Follow procedures of Part I: Section 3.9.3 and section 3.7 of this Part in addition to 3.1-3.6 if a Biosafety Level of III or IV is involved.

3.3) Hazard Information Concerning Biological Agents/Organisms in the Laboratory (See I-3.4)

- 3.3.1) Inventory of Hazardous Biological Agents/Organisms (Use with I-3.4.1)

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall:

3.3.1.1) Establish and maintain an up-to-date inventory of all hazardous biological agents/organisms being used in the laboratory.

a) Include in the inventory the scientific names and the common names (if applicable) of the hazardous biological agents/organisms.

b) Not introduce a new hazardous biological agent into the laboratory unless it has been added to the inventory and all Authorized Users and Authorized Occupants have been appropriately trained and informed with respect to the new agent.

3.3.1.2) Keep the inventory readily available to any person entering the laboratory.
(Repeat of Part I-3.4.1.3)

3.3.1.3) Submit a copy of each revised inventory to EHS at the time of revision. (I-3.4.1.4)

Note: This may coincide with submission of an up-dated LHRSA form (assuming all agents/organisms are listed in the form, it may serve as the inventory.

3.3.2) Safety Information (Use with I-3.4.3)

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall:

3.3.2.1) Prepare a written safety data sheet (SDS) for each Biohazard listed on the inventory. Note: Biohazards may be grouped only if the nature and degree of the risks are very much alike for the grouped agents.

a) Include in the Safety Data Sheets the scientific name (and the common name if applicable) of the agent, the type of Biohazard, the known and suspected routes of infection and routes of infection known not to be applicable, a qualitative assessment of the ease of infection by the listed routes, symptoms associated with infections, short term and long-term risks associated with infections, availability and effectiveness of immunizations, types and general effectiveness of known treatments of infections, mandated and recommended precautions specific for the handling of the agent that are not addressed as requirements in this Laboratory Safety Manual.

Note 1) If the information specified above is not yet available because the agent has not been fully characterized with respect to one of the required items, the Safety Data Sheets shall include a written statement of that uncertainty.

Note 2) A reference to the laboratory-specific Standard Operating Procedures that address specific requirements may be used in lieu of stating the precautions in the Safety Data Sheets.

3.3.2.2) Keep the Safety Data Sheets readily available for any interested person.

3.3.2.3) Include the information on the Safety Data Sheets in training laboratory users/occupants to become Authorized Users and Authorized Occupants.

Note: For non-laboratory Authorized Occupants, the training will only address the availability of the Safety Data Sheets and the type of information on the Safety Data

Sheets. Laboratory Authorized Occupants should have the same instructions as the Authorized Users with respect to the content of the Safety Data Sheets.

3.3.3) Labeling (Use with I-3.4.4)

Authorized Users (AU) shall:

3.3.3.1) Label containers with hazardous biological agents with a label bearing the standard biohazard symbol and the name of the hazardous biological agent.

Note: Clarification -- It is understood that in some instances it may be virtually impossible to directly label certain containers often used for biohazards in the laboratory (such as test tubes, sample vials, beakers, flasks, etc.) with the information required above due to their relatively small size. Regulations do allow for labels to be affixed as close as feasible to the biohazard container by string, wire, adhesive, or other method that prevents their loss or unintentional removal, as long as the label conveys that the contents of the container is a biohazard. In some cases, labeling the tray or secondary container may suffice as a temporary measure. This is not permitted for stocks or materials stored with other agents and materials, for they must either be directly labeled or have an alternatively affixed label.

Warning: The discovery of "orphan" (unknown and unclaimed) containers with any hazardous materials, which is inclusive of hazardous biological agents, is clear non-compliance with the safety requirements of this Laboratory Safety Manual!

3.3.3.2) Clearly define and label an area reserved for work with a specific hazardous biological agent. (The label shall have the standard biohazard symbol and the name of the agent.)

Note: Authorized Occupants shall not make contact with such a reserved area or any container in such a reserved area.

3.3.4) Warning signs and Laboratory Entrance Posting (LEP) (Use this section in conjunction with I-3.4.5 and I-3.4.6.)

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall:

3.3.4.1) Post the Biohazard Sign with the LEP for Biosafety Level II that includes identification of the infectious agent(s) used in the laboratory.

Note: Additional posting requirements for Levels III and IV will be covered in the preparation of the Laboratory-Specific Safety Plan. See Part I: Section 3.9.

3.3.4.2) Post access restrictions.

Guidance Note: Access restrictions are to be evaluated by the Authorized Laboratory Supervisor for Biosafety Level II Laboratories. Access might be restricted only during certain specifically identified procedures within the laboratory. In this case, temporary signs may need to be used that forbid entrance during those times. In other cases, access might be restricted just as it is for Levels III and IV. See Chapter 5 of this Part.

3.3.4.3) Post requirements for any required medical status: required immunizations or vaccinations, exclusion of or special protection for persons with special susceptibilities--might include allergy sensitivities, etc.

Note: Additional requirements for Animal Biosafety Level III and IV will be addressed in the required Laboratory-Specific Safety Plan.
See Part I: Section 3.9.3.

3.4) Special Requirements for Laboratory Facilities with Hazardous Biological Agents/Organisms

3.4.1) Insect and rodent control

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall:

3.4.1.1) Establish and maintain an effective insect and rodent control program for the laboratories in which hazardous biological agents (microorganisms or other organisms) are used.

3.4.1.2) Obtain and maintain intact fly-proof screens if open windows are used in the facility.

3.4.2) Biological Safety Cabinets (Use with I-3.5.5.)

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall:

For Biosafety Level II work,

3.4.2.1) Evaluate the need for a Biological Safety Cabinet (Class I or II) for certain identified procedures. Consult with EHS, if in doubt.

Guidance from NRC publication -- Such containment devices are to be used whenever:

- a) Procedures with a high potential for creating infectious aerosols are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intra-nasally, and harvesting infected tissues from animals or eggs; or
- b) High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed heads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

3.4.2.2) Require Authorized Users to use the Biological Safety Cabinets for the specified procedures following laboratory-specific and/or the manufacturer's recommendations for use.

3.4.2.3) Maintain the cabinet so that the specifications are fulfilled. See specifications for Class I or II cabinets in the CDC or NRC publication listed in section 3.7.1 of this Part.

The Authorized Users shall:

3.4.2.3) Use Biological Safety Cabinets according to the laboratory-specific Standard Operating Procedures.

Note: Typical Instructions:

- a) Carefully avoid actions that might disrupt the inward airflow through the work opening. (Includes control of traffic past the cabinet--the traffic that is necessary must be gentle and slow.)
- b) Minimize the frequency of insertion and withdrawal of hands and arms into the cabinet. (Plan work ahead of time and provide necessary [but not more] supplies and equipment to perform the task before beginning the work with the agent.)
- c) Prevent or minimize opening and closing of doors to the room in which the cabinet is located--whether the lab itself or an isolation booth.
- d) Place materials inside the cabinet in such a fashion that the laminar inward flow of air is not disrupted.

3.5) Bloodborne Pathogen Program (BBPP)

3.5.1) Criteria for Required Participation in the Bloodborne Pathogen Program.

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall:

3.5.1.1) Consult with EHS concerning the need for participation in the Bloodborne Pathogen Program whenever blood, body fluids, or tissues from human or non-human primates are handled in the laboratory or there is reasonable risk of accidents in which cross-contamination of such materials between individuals exists.

3.5.2.1) Require individuals in the laboratory to follow the Bloodborne Pathogen Program procedures if the evaluation in consultation with the EHS indicates that such participation is required.

Authorized Users and Authorized Occupants shall:

3.5.2.3) Follow the Bloodborne Pathogen Program procedures if instructed to do so by the Authorized Laboratory Supervisor.

3.6) Work with Recombinant DNA

3.6.1) Application for work with Recombinant DNA

The Authorized Laboratory Supervisor shall:

3.6.1.1) Consult with the chair of the Recombinant DNA committee before initiating work with any recombinant DNA and follow the recommendations of the chair with respect to the submission of an application. (Contact EHS for the phone number of the current chair.)

Note: Although some recombinant DNA work is exempt, the exemption must be granted by the chair of the Recombinant DNA committee. The exemption may not be assumed to apply by the prospective Authorized Laboratory Supervisor.

3.6.1.2) Train prospective Authorized Users in the requirements, if any, and require adherence to the required procedures.

The Authorized User shall:

3.6.1.3) Follow the procedures specified in the approved Recombinant DNA application.

3.7) EHS Safety Authorizations for Biosafety Level III and IV Laboratories

3.7.1) Introduction

EHS Safety Authorization-Requiring Biohazards (See III: Appendix 3.7) are those that require Level III or IV safety procedures and controls as described in the 3rd edition of the CDC "Biosafety in Microbiological and Biomedical Laboratories" published by the US Department of Health and Human Services and/or the National Research Council publication, "Biosafety in the Laboratory--Prudent Practices for the Handling and Disposal of Infectious Materials" (National Academy Press).

Because work at Biosafety Levels III and IV is currently rare on the Lawrence campus of the University of Kansas and the additional controls and procedures needed for work at these levels are specialized and occasionally specific for the hazards encountered, all work on the Lawrence campus of the University of Kansas at these levels will require a written EHS Safety Authorization before such work can be initiated (see 3.7.2 below). The safety procedures and hazard controls in addition to those stipulated in Part I and Part III will be addressed in the preparation of the required Laboratory-Specific Safety Plan.

Proposed Laboratory-Specific Safety Plans will be reviewed against the requirements for such laboratories as given in the publications listed above. See Glossary for definitions and descriptions of Biosafety Levels III and IV.

3.7.2) Process for Obtaining an EHS Safety Authorization

Go to section 3.9 of Part I and follow the procedures specified in 3.9.3.

Note #1: That section describes how a Laboratory-Specific Safety Plan (LSSP) is to be developed including how the appropriate approvals may be obtained for the proposed LSSP. After the LSSP has been approved, the EHS will perform an inspection to verify that all conditions of the LSSP have been met. After that verification, the EHS will provide a written Safety Authorization that will permit the Laboratory Supervisor to begin use of the HM.

Note #2: The types of safety concerns to be addressed in the proposed LSSP can be found by comparing the hazardous biological agents/organisms to be used in the laboratory against the Agent Summary Statements of section VII of the CDC publication.

Note #3: This procedure has the intent of adopting the publications specified in 3.7.1 as part of this Laboratory Safety Manual at Biosafety Levels III and IV. Because options and guidelines are sometimes given in these publications, the procedures of 3.7 provide specific Standard Operating Procedures and hazard controls.

4) Training for Authorized Users and Authorized Occupants in Laboratories with Biohazards

4.1) Training of Authorized Users of Biohazards

Authorized Users shall have training based upon the content of the following:

4.1.1) Universal Content for the Training of Authorized Users of Biohazards

4.1.1.1) The Kansas University (Lawrence) Safety Program.

4.1.1.2) University's Health and Safety Manual.

4.1.1.3) Part I and III of the KU Laboratory Safety Manual

4.1.2) Hazard-specific Training for Authorized Users of Biohazards

Note: Content specified in this section is included, as applicable, for the activities of the prospective Authorized User. It is important for Authorized Users and Authorized Laboratory Supervisors to remember that when the activities of a user change to areas for which the hazard-specific training has not been obtained, the appropriate additional training must be documented before use begins. The Authorized User is only an Authorized Occupant with respect to specific biohazards for which training has not been accomplished.

4.1.2.1) Laboratory-specific Standard Operating Procedures (SOPs)

4.1.2.2) Requirements and conditions of all applicable Laboratory-Specific Safety Plans.

4.1.2.3) Content of Safety Data Sheets

4.1.2.4) Bloodborne Pathogen Program

4.1.2.5) Recombinant DNA Program

4.1.2.6) Policies and Procedures of the Animal Care Committee

4.2) Training of Authorized Occupants who are Laboratory Occupants

Section 4.2 and 4.3 of Part I specifies the training that is required. Part I-4.2.2 specifically addresses biohazards. Laboratory occupants shall have a clear understanding of the specific biohazards that they shall not manipulate or use and the labeling and marking system that specifies areas and equipment that are off limits to them. The laboratory-specific Standard Operating Procedures shall address the means used to accomplish these requirements.

4.3) Training of Authorized Occupants who are not Laboratory Occupants

See Glossary for definition of "Laboratory Occupant."

Sections 4.2, 4.2.2 and 4.3 of Part I specify the required training. Training shall emphasize that non-laboratory Authorized Occupants are not to touch laboratory benches and other laboratory equipment in Level I and II laboratories unless the Authorized Laboratory Supervisor has certified that it is safe to do so (surfaces or equipment free of contamination with Hazardous Materials). Non-laboratory personnel/students/visitors cannot be "Authorized Occupants" of Level III and IV labs. They are "visitors" and therefore direct supervision by the Authorized Laboratory Supervisor is required during the time services are provided.

4.4) Briefing of Visitors

Section 4.4 of Part I covers the briefing and the supervision that is required.

Note: Documentation of training and frequency of training are covered in section 4.6 and 4.7 of Part I.

5) Medical Factors to Consider in Biosafety

5.1) Introduction

This chapter identifies a number of medical factors (not necessarily complete) that may need to be considered in the establishment of laboratory-specific safety requirements and/or procedures when infectious agents and organisms are being used. This chapter should be used together with Chapter 5 of Part I on exposure assessment and medical surveillance.

5.2) Medical Factors in Evaluating Access Restriction See III-3.3.4.2.

5.2.1) Immunizations/Vaccinations

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the need for immunizations/vaccinations as a prerequisite for working in the laboratory based upon the virulence of the infectious agents being used, the availability of such immunizations/vaccinations and the risks posed by the types of procedures carried out in the laboratory and provide for such immunizations if needed. Depending upon these factors, an evaluation will need to be made to determine under what circumstances, if any, non-laboratory personnel/students/visitors (not immunized) who are Authorized Occupants should be kept out of the laboratory.

[For example] - unescorted entrance might be allowed only when no open containers with infectious agents are present in the lab or the restriction might only apply when vulnerable operations are being performed. How visitors will be controlled also would need to be addressed.

5.2.2) Individuals with special susceptibilities

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the need to identify classes of individuals who would be at special risk based upon the agents/organisms used in the laboratory and the types of activities carried out.

[For example] - Do immuno-compromised or immuno-suppressed individuals have to be warned of special hazards? If such individuals wish to be Authorized Users, is the use of special protective equipment an option and does the option provide sufficient protection? Are non-laboratory personnel/students/visitors of this type warned concerning the hazards? If the evaluation is positive, the necessary procedures shall be established.

5.2.3) Individuals with allergies

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall identify individuals who are allergic to products that are airborne in the laboratory and provide special breathing protection to such individuals if evaluation of the working conditions indicates the need for such protection. Dander, animal bedding, animals, animal residues, etc., are examples of known allergens. Do non-laboratory personnel/students/visitors have to be warned? What will the emergency response be when severe allergic reactions occur?

5.3) Medical Care

5.3.1) Emergency Response to Exposure to Hazardous Biological Agents/Organisms

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall add laboratory-specific procedures to the general emergency procedures described in I-2.9 and I-5.3 that address any actions that need to be taken very quickly in order to reduce the magnitude of the medical consequences of the emergency if an evaluation indicates the need. If appropriate, the procedures should specify when and what information should be shared with medical authorities and/or Lawrence Memorial Hospital. In some cases, advance information might be in order. In other cases, information provided at the time of the emergency may be sufficient.

5.3.2) Effects of Chronic Exposure

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the risk of long-term biological effects subject to on-going exposure to the agents/organisms being used. If there are unique symptoms that need to be monitored or if there are medical tests that can monitor the status of exposure, appropriate provisions for such monitoring must be included in the Standard Operating Procedures if the level of risk requires it.

[For example] - It may be necessary to obtain baseline serum samples for laboratory and other at-risk personnel/students/visitors. This would require procedures for collection and proper storage of the samples. It may be that periodic samples will need to be provided. (The latter is just one example of many possibilities depending upon the agents being used.)

5.3.3) Effects of Acute Exposure

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the potential risks associated with the use of the agents/organisms in the laboratory and determine whether procedures need to be in place for responding to individuals who develop symptoms associated with exposure to the agents or harm from the organisms.:-

5.3.4) Public Health Issues

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the potential for a public health risk associated with the use of the agents/organisms and the need for procedures that would minimize the risk of public health problems.

Note: Hopefully, in most cases, the evaluation will show that there is little cause for concern. The Authorized Laboratory Supervisor is held responsible for having thoroughly researched and identified what is known concerning the risks associated with the agents/organisms the Authorized Laboratory Supervisor proposes to use.

6) Safe Disposal of Biohazardous Waste

6.1) Introduction

The applicable portions of chapter 6 of Part I shall be followed by all personnel/students/visitors in the handling of biohazard waste. The conditions and requirements of this chapter are in addition to applicable portions of chapter 6 of Part I.

The generator (lab, researcher, unit) is responsible for ensuring that all biohazard waste is disposed of in a manner that minimizes the risk to health, safety, or the environment. Kansas regulations do not allow for the disposal of biohazard waste through normal trash dumpsters, unless it has been processed to render it a non-biohazard or the generating entity has a permit granted by the State (KDHE) to do so.

6.1.1) Definitions -- See the Glossary.

(biohazard, biohazard waste, bloodborne pathogens, contaminated, contaminated sharps, decontamination [inactivation], other potentially infectious agents, pathogen, "mixed" contamination or waste)

Important note: "contamination" and "contaminated" used in this chapter are restricted to potential contamination with biohazards. If the contamination also includes hazardous chemicals and/or radioactive materials, it is a "mixed" waste or contamination. The EHS office must be contacted for assistance before "mixed" contamination or waste is created or processed..

6.1.2) Sources of Infectious Wastes

6.1.2.1) Operations that involve processing and/or analysis of specimens for identification, diagnosis, separation, or purification of cells or substances from human or animal blood and body fluids (that may or do contain infectious agents).

6.1.2.2) In vitro or in vivo methods for the propagation of pathogenic microorganisms/infectious agents.

6.1.2.3) Operations involving any handling of infected animal carcasses.

6.1.2.4) Production of biological products in which pathogenic microorganisms/infectious agents are used.

6.1.3) The Two Major Principles Governing the Management of Infectious Wastes

6.1.3.1) Inactivation, at the earliest stages possible, of all infectious agents in the waste.

6.1.3.2) Total containment of the waste until inactivation has been accomplished and verified.

6.2) Inactivation of Infectious Waste

6.2.1) Establishment of Inactivation/Decontamination Procedures

The Authorized Laboratory Supervisor/USC shall:

6.2.1.1) Establish written procedures (laboratory-specific Standard Operating Procedures) for the containment of infectious waste prior to inactivation and for effective inactivation of the waste.

Note 1: This means that the selected procedure has been tested to be adequate for the inactivation of the waste. Documentation of this testing should be maintained with other survey and evaluation records. Direct testing for inactivation is frequently not possible. Where it is not possible, the methods used to measure the operational parameters must be verified initially and on a periodic interval thereafter. A written Quality Assurance program must be in place. (For example, in the case of autoclaves, maintenance of the accuracy of thermometers, pressure gauges, and timing mechanisms) There must be documented evidence for the adequacy of the selected values of the adjustable parameters for the type, configuration, nature, and volume of waste to be processed. See 6.4 below for examples of methods. However, the adequacy of any method for a particular situation must be established.

Note 2: This includes procedures for the prevention of the dispersal of aerosols or liquids during the processing of the materials by the proper use of coverings, seals and ventilation as necessary.

6.2.1.2) Include provisions in the SOPs for the segregation of all waste streams.

Note: This means that hazardous chemical waste, radioactive waste, and infectious wastes are not to be mixed or placed in the same waste storage containers. If a waste is, of necessity, "mixed," written approval from EHS for the handling of that waste is required. If at all possible, experimental procedures that do not require the generation of mixed waste should be substituted for those that do.

6.2.1.3) Provide appropriate labels for containers of infectious waste and labels or clear indicators for treated (inactivated) waste. See section I-3.4.4 and III-3.3.3.

Note: The use of bags that change color when adequately autoclaved is an example of the use of "indicators."

6.2.2) Decontamination/Inactivation of Infectious Waste

Authorized Users shall:

6.2.2.1) Follow the laboratory-specific procedures for the decontamination/inactivation of biohazard waste, including carcasses with infectious agents (See III-2.2.2). See III-6.4 for examples of types of inactivation protocols.

6.3) Disposal of Biohazard Waste

6.3.1) Establishment of Laboratory-Specific Disposal Procedures

Authorized Laboratory Supervisors shall:

6.3.1.1) Establish laboratory-specific Standard Operating Procedures for the disposal of biohazard waste as specified in this chapter.

6.3.1.2) In consultation with EHS and the Director of Animal Care, establish Standard Operating Procedures for the proper disposal of carcasses that may contain infectious agents and animal bedding materials.

Note: Any infectious waste/carcasses that must be inactivated by incineration require Standard Operating Procedures for the transport of the waste to the incinerator in a safe manner and for the precautions that shall be taken in operating the incinerator.

6.3.2) Disposal Procedures

Authorized Users shall:

6.3.2.1) Process biohazard waste according to the laboratory-specific Standard Operating Procedures.

6.3.2.2) Label containers with inactivated waste (no longer a biohazard) with a wide strip of masking tape bearing the words, "sterilized" or "decontaminated."

6.3.2.3) Personally take containers of inactivated or treated waste (no longer a biohazard) to the dumpster and **SHALL NOT** ask service personnel/students/visitors to do so.

6.3.2.4) Not dispose of viable or untreated suspensions of infectious waste in the sewer.

6.3.2.5) (May) release inactivated/treated waste liquids (no longer a biohazard) into the sanitary sewer system if the liquid would otherwise be suitable for disposal via the sewer system. (No other prohibited materials in the liquid and the material is in a physical state appropriate for release in the sewer.) Plenty of water should be used to provide proper flushing and the sink drain should be decontaminated with appropriate chemical sterilizing solution (see 6.4 below) on a periodic basis specified in the laboratory-specific procedures.

6.3.2.6) Not use external waste treatment facilities or deliver infectious waste to commercial haulers until written approval for the proposed procedures has been granted by EHS. Note: This constitutes shipment. See III-2.2.6.

6.4) Examples of Accepted Sterilization Methods

6.4.1) Sterilization of collected biohazard waste by autoclave. Several units and laboratories on campus have autoclaves. It is up to the biohazard waste generator to make arrangements for using autoclaves.

6.4.2) Sterilization by chemical treatment. Exposure to a chemical sanitizer by rinsing or immersing in one of the following chemical solutions for a minimum of 15 minutes:

6.4.2.1) Hypochlorite Solution (Bleach) - 500 ppm available chlorine (10% Clorox).

6.4.2.2) Phenolic Solution - 500 ppm active agent.

6.4.2.3) Iodophor Solution - 100 ppm available iodine.

6.4.2.4) Quaternary Ammonium Solution - 400 ppm active ammonium agent.

6.4.3) Sterilization/Destruction by Incineration. Animal Care is capable of incinerating certain biohazard waste. Contact them (864-5587) for additional information. It is the responsibility of the unit to make such arrangements.

6.4.4) Pulverization/Decontamination - There is special equipment on the market that is capable of grinding or pulverizing and chemically sterilizing contaminated sharps and biohazard waste at the same time. Contact KU Office of EHS for more information.

Note: These examples do not exclude other methods and these methods must be tested to be adequate.

7) Biosafety-Specific Record-Keeping

7.1) Auditable Records

Authorized Laboratory Supervisors and/or Unit Safety Coordinators shall:

7.1.1) Establish and maintain auditable records in accordance with the requirements of Part I: Chapter 7 - Section 7.1.

7.2) Identification and Dating of Records

Authorized Laboratory Supervisors and/or Unit Safety Coordinators shall:

7.2.1) Identify and date records in accordance with the requirements of Part I: Chapter 7 - Section 7.2

7.3) Retention of Records

Authorized Laboratory Supervisors and/or Unit Safety Coordinators shall:

7.3.1) Retain records in accordance with the requirements of Part I: Chapter 7 - Section 7.3

7.4) EHS Records

EHS shall:

7.4.1) Establish and maintain the appropriate records in accordance with the requirements of Part I: Chapter 7 - Section 7.4.

8) Part III - Appendices

8.1) Appendices for Part III Chapter 1

None - Reserved

8.2) Appendices for Part III Chapter 2

None - Reserved

8.3) Appendices for Part III Chapter 3

Appendix 8.3.7 - EHS Safety Authorization-Requiring Biohazards

8.4) Appendices for Part III Chapter 4

None - Reserved

8.5) Appendices for Part III Chapter 5

None - Reserved

8.6) Appendices for Part III Chapter 6

None - Reserved

8.7) Appendices for Part III Chapter 7

None - Reserved

Appendix 8.3.7 - EHS Safety Authorization-Requiring Biohazards

A) Bloodborne Pathogens

HIV HBV Tuberculosis

B) CDC Restricted Agents

1) Viruses

- Crimean-Congo haemorrhagic fever virus
- Eastern Equine Encephalitis virus
- Ebola viruses
- Equine Morbillivirus
- Lassa fever virus
- Marburg virus
- Rift Valley fever virus
- South American Haemorrhagic fever viruses
(Junin, Machupo, Sabia, Flexal, Guanarito)
- Tick-borne encephalitis complex viruses
- Variola major virus (Smallpox virus)
- Venezuelan Equine Encephalitis virus
- Viruses causing hantavirus pulmonary syndrome
- Yellow fever virus

2) Bacteria

- Bacillus anthracis
- Brucella abortus, B. melitensis, B. suis
- Burkholderia (Pseudomonas) mallei
- Burkholderia (Pseudomonas) pseudomallei
- Clostridium botulinum
- Francisella tularensis
- Yersinia pestis

3) Rickettsiae

- Coxiella burnetii
- Rickettsia prowazekii
- Rickettsia rickettsii

4) Fungi

- Coccidioides immitis

Appendix 8.3.7 - continued

5) Toxins

- | | |
|---|--|
| <input type="checkbox"/> Abrin | <input type="checkbox"/> Aflatoxins |
| <input type="checkbox"/> Botulinum toxins | <input type="checkbox"/> Clostridium perfringens epsilon toxin |
| <input type="checkbox"/> Conotoxins | <input type="checkbox"/> Diacetoxyscirpenol |
| <input type="checkbox"/> Ricin | <input type="checkbox"/> Saxitoxin |
| <input type="checkbox"/> Shigatoxin | <input type="checkbox"/> Staphylococcal enterotoxins |
| <input type="checkbox"/> Tetrodotoxin | <input type="checkbox"/> T-2 toxin |

6) Recombinant organisms/molecules

- Genetically modified microorganisms or genetic elements from organisms identified above, shown to produce/encode for a factor associated with a disease.
- Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed above, or their toxic subunits.

C) Other Biosafety Level 3 agents Requiring Approval

- 1) Parasitic Agents: Any not identified as a CDC restricted agent above but identified by CDC/NIH in the BMBL handbook as requiring a BSL-3 facility or procedures.
- 2) Fungal Agents: Any not identified as a CDC restricted agent above but identified by CDC/NIH in the BMBL handbook as requiring a BSL-3 facility or procedures.
- 3) Bacterial Agent: Any not identified as a CDC restricted agent above but identified by CDC/NIH in the BMBL handbook as requiring a BSL-3 facility or procedures.
- 4) Rickettsial Agents: Any not identified as a CDC restricted agent above but identified by CDC/NIH in the BMBL handbook as requiring a BSL-3 facility or procedures.
- 5) Viral Agents (nonArboviruses): Any not identified as a CDC restricted agent above but identified by CDC/NIH in the BMBL handbook as requiring a BSL-3 facility or procedures.
- 6) Viral Agents (Arboviruses, Arenaviruses, Filoviruses, etc.): Any not identified as a CDC restricted agent previously, but identified by CDC/NIH in the BMBL handbook as requiring a BSL-3 facility or procedures.

D) Biosafety Level 4 agents

- 1) The use of BSL-4 agents is prohibited on the KU-Lawrence campus because there are currently no facilities available capable of providing BSL-4 protection.