University of Kansas Lawrence Campus
Laboratory Safety Manual
Part III – Biosafety Plan

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 Biosafety. This chapter should be used together with Chapter 3 of Part I.

3.2) Lab Hazard Registration 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 EHS Dept. 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 LHR form.

3.2.3) Follow procedures of Part I: Section 3.9.3 and section 3.7 of this Part.

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 LHR 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, if 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) Work with EHS to 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 or > work,

3.4.2.1) An appropriate Biological Safety Cabinet (or other EHS approved containment device) is required for working with BSL-2 materials.

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. Biosafety cabinets must be certified annually. Contact EHS.

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 is 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 EHS before initiating work with any recombinant DNA and follow the recommendations of EHS with respect to the submission of an application.

3.6.1.2) All recombinant DNA work must be registered with and reviewed by EHS. If determined by EHS to be NIH exempt, it will be reviewed and approved by rDNA Chair. If, determined to be non-exempt, it must be reviewed and approved by full rDNA committee.

3.6.1.3) 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 rDNA application.

3.7) EHS Biosafety Authorizations

3.7.1) Introduction

The acquisition, storage and use of any biological material requires registration and approval with EHS. Authorized Laboratory Supervisor is to first register their lab utilizing the EHS lab hazard registration form. Labs that identify working with biological materials will be required to then complete additional EHS forms to receive an EHS Biosafety Authorization.

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.

3.7.3) Biological Material Risk Assessment Form

All biological material must be registered with EHS utilizing this form. EHS will review. Materials that are BSL-1 or BSL-2 will, after form and any needed LSSP's are in place, grant an EHS biosafety approval. If the material is BSL-3, the form and LSSP's will be forwarded to biosafety committee for review and approval. BSL-4 materials are prohibited.

3.7.4) rDNA Registration Form

All recombinant DNA activities must be registered with EHS utilizing this form. EHS will review. If the materials are BSL1 or BSL2 and are determined to be NIH exempt, EHS will forward to rDNA Chair for final approval. If the rDNA work is BSL3 and/or NIH covered, EHS will forward to rDNA committee for review and approval.

3.7.5) Blood-Borne Pathogens Approval/Exposure Control Plan

All work with human blood, body fluids and unfixed tissue must be registered with EHS. EHS will review. By default, work with all human materials is BSL2. As part of the EHS Biosafety approval, EHS will work with lab to also crate the necessary BBP exposure control plan. If the work is considered BSL3, then EHS will forward to biosafety committee for review and approval.