Intro Into Biosafety

Working with Biohazards

General Biosafety

- NIH Risk Groups and CDC Biosafety Levels
- Primary & Secondary containment
- Risk assessment
- Aerosol Precautions
- Needle and Sharps Precautions
- Human Blood, Tissue and Fluid
- Toxins
- Select Agents
- Security
- Waste Disposal
- Spill Clean up
- Physical/Biological Containment Levels (Plants)
- Experiments That Require IBC Review and Approval
- Import Permits
- Institutional Biosafety Committee (IBC) & Application process
- Regulatory website resources
- Additional Biosafety Training opportunities
- Emergencies & Procedures

Risk Groups - NIH

- Risk Group 1 (RG1): agents are not associated with disease in healthy adults.
- Risk Group 2 (RG2): agents are associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available.
- Risk Group 3 (RG3): agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.
- Risk Group 4 (RG4): agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

When IBC Review is Required

- Any experiment involving the use of Risk Group 2 or 3 biohazardous agents as defined by the World Health Organization in the National Institutes of Health guideline, Guidelines for the Use of Recombinant DNA Molecules. These are agents that are capable of causing disease in healthy humans or animals or plants.

- Risk Group 1 experiments may not be exempt from IBC Review

4 Levels of Biosafety - Containment

- BSL 1: Practices, Equipment and Facilities for material not known to consistently cause disease in healthy adults.
- BSL 2: Practices, Equipment and Facilities for material associated with human disease. Hazard is from percutaneous injury, ingestion, or mucous membrane exposure.
- BSL 3: Practices, Equipment and Facilities for indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences.
- BSL 4: Practices, Equipment and Facilities for dangerous/exotic agents which pose a high risk of life-threatening disease, aerosol-transmitted lab infections or related agents with unknown risk of transmission.
  - No BSL4 research will be approved at UMKC because there are no containment facilities available.

Primary Containment

- Safety Equipment (Primary containment) - the protection of personnel and the immediate laboratory environment from exposure to infectious agents, is provided by both good microbiological technique and the use of appropriate safety equipment.
  - Lab practices – standard lab practice, limited access, biohazard warning sign, sharps/needle precautions, SOPs for decontamination, waste, medicals.
  - Safety equipment – biosafety cabinets (BSC), sharps containers, sealed rotors.
  - Personal protective equipment (PPE) – lab coat, gloves, goggles.
  - Vaccines
  - Host-vector for rDNA

Biosafety Cabinet

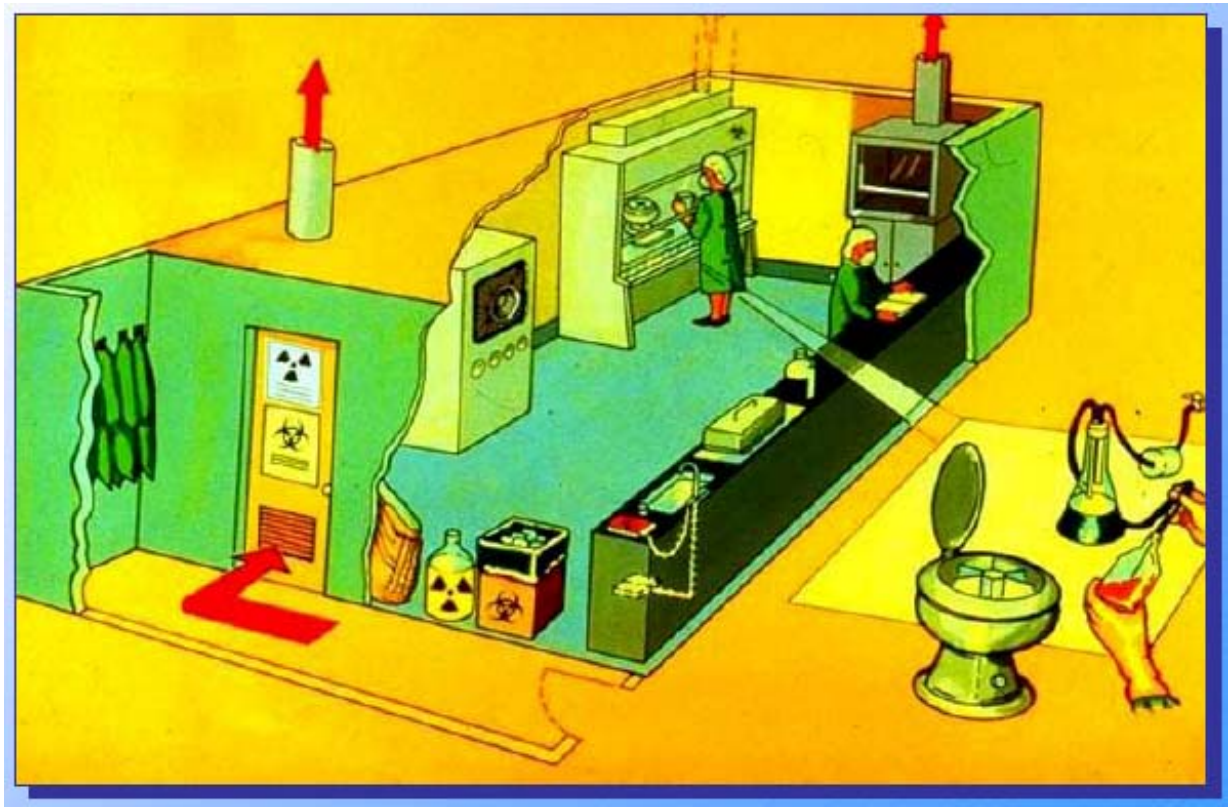
Biosafety Cabinet in Use

HEPA filtered Exhaust-Facilities
PAPR with protective suits, gloves, etc.

Laboratory Facilities (Secondary Barriers)

- The design and construction of the facility contributes to the laboratory workers‘ protection, provides a barrier to protect persons outside the laboratory, and protects persons or animals in the community from infectious agents that may be accidentally released from the laboratory.
- Laboratory directors are responsible for providing facilities commensurate with the laboratory's function and the recommended biosafety level for the agents being manipulated.
- The recommended secondary barrier(s) will depend on the risk of transmission of specific agents. For example, the exposure risks for most laboratory work in BSL-1 and BSL-2 facilities will be direct contact with the agents, or inadvertent contact exposures through contaminated work environments.
- Secondary barriers in these laboratories may include separation of the laboratory work area from public access, availability of a decontamination facility (e.g. autoclave), and hand washing facilities.

Laboratory Facilities (Second Barriers) Biosafety Level 3



Risk Assessment

- Pathogenicity of Material – disease incidence and severity
- Routes of Transmission – parenteral, airborne or ingestion
- Agent Stability – ease of decontamination
- Infectious Dose – LD50
- Concentration – infectious organisms/volume & working volume
- Origin of Material – wild type, exotic, primary cells
- Availability of Effective Prophylaxis – hepatitis B vaccine
- Medical Surveillance – exposure management
- Skill Level of Staff

Risk Assessment – Risk of Activity

- The same agent can have different containment levels at different stages of research: In Vivo
  - Procedures that produce aerosols have higher risk
  - Procedures using needles or other sharps have higher risk
  - Handling blood, serum or tissue samples may have lower risk
  - Purified cultures or cell concentrates may have higher risk
  - Larger volumes (10 L) have higher risk

Risk Assessment – Biosafety Cabinet

- Use a Biosafety Cabinet for all procedures that may generate aerosols.
  - Training – requires proper technique to conduct procedures in exposure prevention
- Use centrifuges with Biosafety Covers.
- Do not use a syringe for mixing infectious fluids.
- Cultures, tissues, specimens of body fluids, etc. are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport or shipping.

Needle & Sharps Precautions

- Precautions are for any contaminated sharp item, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
- Plasticware should be substituted for glassware whenever possible.
- Needles and syringes or other sharp instruments should be restricted to parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles.
- Only needle-locking syringes or disposable syringe-needle units (i.e. needle is integral to the syringe) are used for injection or aspiration of infectious materials. (Bloodborne Pathogen standard)
- Syringes which re-sheathe the needle, needleless systems, and other safety devices are used when appropriate

Needle & Sharps Precautions

- Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. Dispose in puncture-resistant containers which must be located near work.

- Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

- Broken glassware must not be handled directly by hand. Pick up by mechanical means such as a brush and dustpan, tongs, or forceps.

Potential Needle Stick Injury

Occupational Exposure to Bloodborne Pathogens

- Use BSL 2 work practices and procedures.
- Additional requirements for HIV work.
- Everyone needs to be offered the Hepatitis B vaccine.
- Develop specific exposure plan SOPs.
- Specific training is required.
- Review needle/syringe use and replace with “safe” devices.
- Exposure incidents must be followed up.

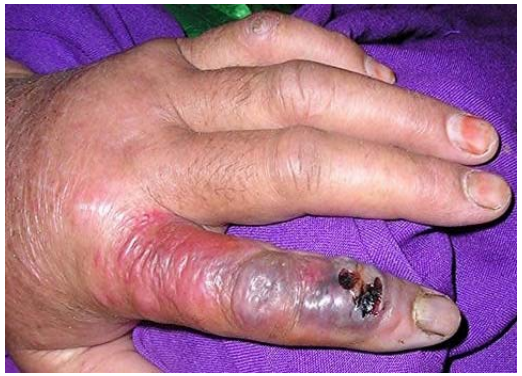
Occupational Safety & Health Administration
(OSHA) 29 CFR 1910.1030

Toxins

- Use BSL 2 work practices and procedures. See (BMBL) 5th Edition Section VIII-G: Toxin Agents specific safety issues.
- Develop a Chemical Hygiene Plan specific to the toxin used. Include containment (fume hoods, biosafety cabinets), PPE, spill management, exposure and accident response, and medical surveillance.
- Some toxins are “Select Agents” and require registration.

Select Agents

- Possession, use and transfer of specific biological agents requires registration with the CDC.
- “Restricted Persons” are not allowed to have access to these agents.
- High security and containment must be maintained. Biosafety, Security & Incident Response plans must be developed for each agent/lab.
- Web site: http://www.cdc.gov/od/sap/



Cutaneous Anthrax

Laboratory Security

- Control access to areas where biological agents or toxins are used and stored.
- Keep biological agents and toxins in locked containers.
- Know who is in the lab.
- Know what materials are being brought into the lab.
- Know what materials are being removed from the lab.
- Have a protocol for reporting incidents.
- Have an emergency plan

Spill Clean-Up

- Kits
- Decontamination
- Precautions
- Procedure

Waste Disposal

- “Red Bag” or “Regulated Medical Waste”
- What is regulated waste?
- All rDNA, Biohazardous materials including mammalian cells or anything that comes in contact with mammalian cells.
- Use Red bags & Boxes or Red Tubs for all these materials. (No Liquids)
- All BSL-2 & -3 materials or anything that comes in contact with BSL-2 & -3 materials.
- All needles/syringes regardless of use (sharps containers).
- Material may be autoclaved and disposed in EHS red bag/boxes or red tubs (some materials may require incineration).
- Autoclaved materials can be placed in a “black plastic bag” prior to disposal into regular solid waste. Refer to each location’s policy for additional information.
- Special handling maybe required for animal waste.
- Yellow label - where located boxes & tubs-requirements.

Containment & Controls: Spill Kits

- Personal Protective Equipment
  - Gloves, (latex/nitrile/rubber, extra large) face shield, safety goggles or safety glasses with side shields, disposable coveralls/suit with hood, hair covering, HEPA masks or respirator, rubber boots, shoe covers.

- Cleanup Supplies
  - 2 red bags, 2 cloth rags, 2 clear bags, brush, roll of clear tape, flashlight, barricade warning tape, anti-microbial wipes, household bleach, paper towels, absorbent-sock, decontamination pad, vermiculite, scoop, floor drain cover, mechanical means for dealing with broken glass, forceps and small dustpan and broom, and sharps container, etc.

Containment & Controls: Spill Kits

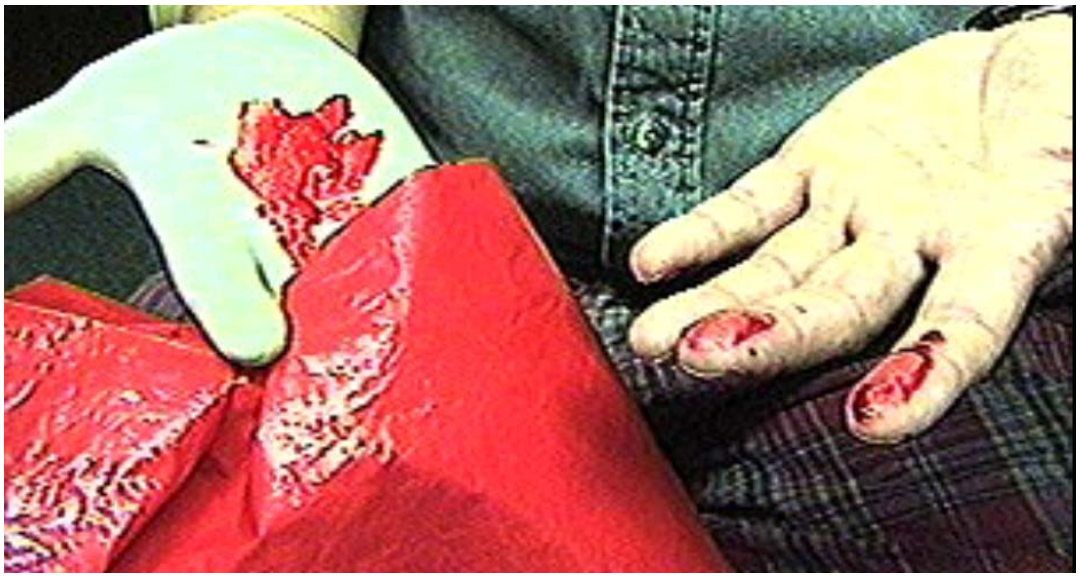
- Accessibility requirements (all BSL-2 & -3 labs are required to maintain spill kits).
- Know the locations of the kits in your work area and make sure you have easy access to them.
- Know how to use your department's kit.
- Follow directions included with the kit and use all personal protective equipment provided in it.

Containment & Controls: Spill Clean-Up

- After Assurance the room is safe to re-enter
  - Inspect and put on appropriate PPE.
  - Keep others away.
  - In an area free of contamination, position red bag so materials can be dropped in without soiling outside of bag.
  - Carefully use only as much decontaminant as you need to saturate the spill area, cover with paper towels, and allow to soak.

Containment & Controls: Spill Clean-Up

- Minimize Spread of Spill
- Avoid Splashing or Spraying
- Assume Gloved Hands are Contaminated
- Avoid Using Brushes or Brooms
- Dispose of Sharps Appropriately



Containment & Controls: Spill Clean-Up

- For non-level surfaces (e.g., walls), thoroughly clean area with 10% bleach solution (or other EPA-approved disinfectant) and allow to air dry.
- Dispose of sharp objects in a sharps container or a sturdy puncture-resistant container.
- Place all materials in red bag.
- Decontaminate area and allow to air dry.
- REMOVE PPE and place in red bag.
- Touching outside of red bag only, close and secure with twist tie.
- Arrange for pickup and disposal of red bag.
- Wash your hands with soap and water.
- Report incident to supervisor and they need to report to EHS.

Decontamination

- Use 10% bleach solution for at least 15 minute soak time
  - Mix bleach solution and use within 24 hours

- Syringes should never be reused. However, left with no other options, prewash the syringe including the needle to remove organic material, completely immerse the needle in full-strength bleach, draw the bleach into the syringe and cycle the fluid in the syringe for at least 30 seconds contact time.

- EPA-registered Tuberculocidal disinfectants.

- Check the label of the disinfectant you are using “HIV-Effective” does NOT necessarily mean it is effective against hepatitis viruses.

Plant: Physical/Biological Containment Levels

Currently, UMKC does not have Greenhouse facilities

Plant: Physical/Biological Containment Levels Biosafety Level 1-P (BSL1-P) NIH (P-II, III)

- Standard Practices: Suitable for work involving agents of unknown or minimal potential hazard to lab personnel & the environment/ecosystems. Similar to BSL1 practices cited earlier.

- Greenhouse Access:
  - (1) Access limited when experiments in progress, at discretion of Greenhouse Manager.
  - (2) Prior to entry, personnel must understand and follow BSL1-P greenhouse policies/procedures.

- Records: Records must be kept of experiments currently in progress in the Greenhouse facility.

- Decontamination & Inactivation: Experimental organisms shall be rendered biologically inactive by appropriate methods prior to disposal outside the Greenhouse facility.

Plant: Physical/Biological Containment Levels Biosafety Level 1-P (BSL1-P) NIH (P-II, III)

- Control of Undesired Species & Motile Macroorganisms:
  - (1) Program in place to control undesired species (weed, rodent, arthropod pests & pathogens) by methods appropriate to the organism and in accordance with applicable state & federal laws.
  - (2) Arthropods & other motile macroorganisms shall be housed appropriately. If macro-organisms (e.g. flying arthropods or nematodes) are released within the Greenhouse, precautions shall be taken to minimize escape from Greenhouse facility.

- Concurrent Experiments Conducted in the Greenhouse: Experiments involving organisms requiring containment level below BSL1-P may be conducted in the Greenhouse concurrently with experiments requiring BSL1-P, provided all work is conducted at the BSL1-P level.

Plant: Physical/Biological Containment Levels Biosafety Level 1-P (BSL1-P) NIH (P-II, III)

- Greenhouse Design:
  - Floor may be gravel or other porous material. Impervious (e.g. concrete) walkways are recommended.
  - Windows & other openings in walls & roofs may be open for ventilation & do not require any special barrier to contain or exclude pollen, micro-organisms or small flying animals (arthropods & birds); however, screens are recommended.

Plant: Physical/Biological Containment Levels Biosafety Level 2 -P (BSL2-P) NIH (P-II, III)

- Standard Practices: Similar to Level 1 but suitable for work involving agents of moderate potential hazard to lab personnel & the environment/ecosystems.

- Greenhouse Access:
  - (1) Access limited when experiments in progress, at discretion of Greenhouse Manager, to individual directly involved with experiments.
  - (2) Prior to entry, personnel must understand and follow BSL2-P greenhouse policies/procedures.

- Records:
  - (1) Records must be kept of experimental plants, microorganism & small animals brought into or removed from Greenhouse facility.
  - (2) Records must be kept of experiments currently in progress in the Greenhouse facility.
  - (3) PI shall report any Greenhouse accident involving inadvertent release or spill of micro-organisms to Greenhouse Manager, (UMKC Biosafety (816-235-1157) who will contact the IBC and appropriate authorities immediately (if applicable).

Plant: Physical/Biological Containment Levels Biosafety Level 2 -P (BSL2-P) NIH (P-II, III)

- Decontamination & Inactivation:
  - (1) Experimental organisms shall be rendered biologically inactive by appropriate methods prior to disposal outside the Greenhouse facility.
  - (2) Decontamination of run-off water is not necessarily required.

- Control of Undesired Species & Motile Macro-organisms:
  - (1) Program in place to control undesired species (weed, rodent, arthropod pests & pathogens) by methods appropriate to the organism and in accordance with applicable state & federal laws.
  - (2) Arthropods & other motile macro-organisms shall be housed appropriately. If macro-organisms (e.g. flying arthropods or nematodes) are released within the Greenhouse, precautions shall be taken to minimize escape from Greenhouse facility.

Plant: Physical/Biological Containment Levels Biosafety Level 2 -P (BSL2-P) NIH (P-II, III)

- Concurrent Experiments Conducted in the Greenhouse: Experiments involving organisms requiring containment level below BSL2-P may be conducted in the Greenhouse concurrently with experiments requiring BSL1-P, provided all work is conducted at the BSL2-P level.

- Signs:
  - (1) Sign required indicating restricted experiment in progress. Sign shall indicate:
    - (i) name of responsible individual,
    - (ii) the plants in use,
    - (iii) any special requirement for using the area.
  - (2) If organisms in use have recognized potential for causing serious detrimental impacts on managed or natural ecosystems, the presence of the organisms must be indicated on the sign affixed to the Greenhouse door.
  - (3) If there is a risk to human health, universal biosafety symbol must be included.

Plant: Physical/Biological Containment Levels Biosafety Level 2 -P (BSL2-P) NIH (P-II, III)

- Transfer of Materials: Materials containing experimental microorganisms, when brought into or removed from Greenhouse in a viable or intact state, must be transferred in a closed, non-breakable container.

- Greenhouse Practices Manual: Greenhouse practices manual shall be prepared/adopted. Manual shall:
  - (i) advise personnel of potential consequences if practices not followed,
  - (ii) outline contingency plans to be implemented in the event of an unintentional release.

- Greenhouse Design:
  - (1) Floor shall be of impervious material (e.g. concrete).
  - (2) Windows & other openings in walls & roofs may be open for ventilation & do not require any special barrier to contain or exclude pollen or micro-organisms; however, screens are required to exclude small flying animals (arthropods & birds).

Plant: Physical/Biological Containment Levels Biosafety Level 2 -P (BSL2-P) NIH (P-II, III)

- Autoclaves: Autoclave shall be available to treat contaminated greenhouse materials.

- Supply & Exhaust Air Ventilation Systems: If intake fans used, steps must be taken to minimize ingress of arthropods. Louvers or fans shall be constructed such that they open only when fan is on.

- Other BSL2-P: BSL2-P greenhouse containment may be satisfied using a growth chamber/room within a building provided external structure limits access/escape of micro & macro-organisms in a manner that satisfies the above clauses.

Plant: Physical/Biological Containment Levels Biosafety Level 3-P (BSL3-P) NIH (P-II, III)

- Applicable to work with plants in which work is conducted with indigenous or exotic agents which may cause serious or potentially lethal disease in the environment/ecosystems.
- Special procedures, training ,equipment and significant restrictions apply.
- UMKC has no BSL3-P level research containment facilities, thus no BSL3-P protocols will be approved.

Regulatory Permits

- Movement & Use of Plants & Plant Pathogens is regulated through APHIS / USDA.
  - URL: http://www.aphis.usda.gov/
- Exportation and importation plant pests and pathogens:
- Aphis Form PPQ526.
- Interstate movement of plants containing recombinant DNA/transgenic plants:
- Aphis Form 2000;
- Notification or courtesy letter to the USDA.
- International exportation of plant material:
- Phytosanitary permit from USDA.
- International importation of plant material:
- USDA Departmental Permit of varying type(s), depending on the plant &/or prospective use of the plant.
- Host country permitting requirements.

Import Permits

- CDC: a permit is required to import etiologic agents of human disease and any materials, including live animals or insects, that may contain them. Unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions or similar material) containing an infectious or etiologic agent require a permit in order to be imported.

- APHIS: a USDA veterinary permit is needed for materials derived from animals or exposed to animal-source materials.

IBC Review & Approval

- Experiments involve the use of biological agents and recombinant DNA and require UMKC IBC Review and Approval:
  - Involving the use of Risk Group 2 or 3 biohazardous agents as defined by the World Health Organization and the National Institutes of Health guideline, *Guidelines for the Use of Recombinant DNA Molecules*. These are agents that are capable of causing disease in healthy humans, animals or plants
  - You must complete all applicable appendices of the UMKC Recombinant DNA and Biohazardous Materials Application Form based on your choice of biological material used.

IBC Review & Approval

- Risk Group 2 agents are agents associated with human disease of moderate hazard to personnel and the environment. Common routes of exposure include:
  - Percutaneous
  - Ingestion
  - Surface Contact
  - Mucous membrane

- Examples of Risk Group 2 agents:
  - Adenovirus
  - Murine Retrovirus (MMLV)
  - Staphylococcus aureus
  - Plasmodium falciparum
  - HIV, HBV, HCV, bloodborne pathogens

IBC Review & Approval

- Biosafety Level 3 practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection.
  - Mycobacterium tuberculosis, St. Louis encephalitis virus, and Coxiella burnetii are representative of the microorganisms assigned to this level.
  - Primary hazards to personnel working with these agents relate to autoinoculation, ingestion, and exposure to infectious aerosols.
  - At Biosafety Level 3, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols. laboratory.
- All BSL-3 and ABSL-3 labs require IBC approval, special training & specific lab manuals in place prior to research.

Principle Investigator Responsibilities

- As part of this general responsibility, the Principal Investigator shall:
  - Initiate or modify no recombinant DNA research which requires Institutional Biosafety Committee approval prior to initiation. Section IV-B-7-a-(1)
  - Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable) within 30 days. Section IV-B-7-a-(3).
  - Report any new information bearing on the NIH Guidelines to the Institutional Biosafety Committee. Section IV-B-7-a-(4).

Principle Investigator Responsibilities

- Be adequately trained in good microbiological techniques. Section IV-B-7-a-(5).
- Adhere to Institutional Biosafety Committee approved emergency plans for handling accidental spills and personnel contamination. Section IV-B-7-a-(6).
- Comply with shipping requirements for recombinant DNA molecules. Section IV-B-7-a-(7).

Principle Investigator Responsibilities

- Shall ensure that all aspects of Appendix M have been appropriately addressed prior to submission of a human gene transfer experiment to NIH OBA (Office of Biotechnology Activities). Section IV-B-7-b-(6).
  - No research participant shall be enrolled in a human gene transfer experiment until the RAC review process has been completed AC Review Requirements); IBC approval (from the clinical trial site) has been obtained; Institutional Review Board (IRB) approval has been obtained; and all applicable regulatory authorization(s) have been obtained.
  - For a clinical trial site that is added after the RAC review process, no research participant shall be enrolled at the clinical trial site until the following documentation has been submitted to NIH OBA: (1) IBC approval (from the clinical trial site); (2) IRB approval; (3) IRB-approved informed consent document; (4) curriculum vitae of the principal investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

Principle Investigator Responsibilities

- Make an initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines. Section IV-B-7-c-(1).
- Select appropriate microbiological practices and laboratory techniques to be used for the research, Section IV-B-7-c-(2).
- Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system ,to the Institutional Biosafety Committee for review and approval or disapproval. Section IV-B-7-c-(3).
- Remain in communication with the Institutional Biosafety Committee throughout the conduct of the project. Section IV-B-7-c-(4).

Principle Investigator Responsibilities

- Prior to Initiating Research
  - Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken. Section IV-B-7-d-(1).
  - Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents. Section IV-B-7-d-(2).
  - Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection). Section IV-B-7-d-(3).

Principle Investigator Responsibilities

- During the Conduct of the Research
  - Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed. Section IV-B-7-e-(1)
  - Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee. Section IV-B-7-e-(2).

Principle Investigator Responsibilities

- During the Conduct of the Research
  - Correct work errors and conditions that may result in the release of recombinant DNA materials. Section IV-B-7-e-(3).
  - Ensure the integrity of the physical containment (e.g. biological safety cabinets) and the biological containment. Section IV-B-7-e-(4).
  - Comply with reporting requirements for human gene transfer experiments conducted in compliance with the NIH Guidelines. Section IV-B-7-e-(5).

Incident Reports

- The NIH Guidelines states that IBCs should report "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" to NIH OBA (Office of Biotechnology Activities) within 30 days. Section IV-B-2-b-(7)
  - Appendix G of the NIH Guidelines specifies certain types of accidents that must be reported on a more expedited basis.
  - Spills or accidents in BSL2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA (as well as the IBC). Appendix G-II-B-2-k
  - Spills or accidents occurring in high containment (BSL3 or BSL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA (as well as the IBC, and BSO). Appendix G-II-C-2-q and Appendix G-II-D-2-k

Incident Reports

- How serious must a problem be to warrant reporting to NIH/OBA (NIH Office of Biotechnology Activities)?
  - Any spill or accident involving recombinant DNA research of the nature described in Appendix G or that otherwise leads to personal injury or illness or to a breach of containment must be reported to OBA.
  - Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported.
  - Please report any potentially reportable incident as described above to EHS as soon as possible.

Acquisition of Biohazardous Material

- The UMKC Institutional Biosafety Committee (IBC) must review and approve research protocols or subsequent changes prior to initiating work with non-exempt rDNA or Biosafety Level 2 or 3 research activities. Biosafety Level 4 (BSL-4) work is not permitted within the University of Missouri – Kansas City campus.
- Principal Investigators and supervisors must submit an annual renewal (completed online) to the IBC for all rDNA and Biosafety Level 2 or 3 research activities.
- Biohazardous materials for rDNA or Biosafety Level 2 or 3 research activities may only be obtained under the authority of a Registered User.
- There are similar requirements for the acquisition of hazardous materials (see the UMKC Radiation Safety Manual).
- IBC must approve the amendment to protocol if subsequent changes are made. http://www.umkc.edu/research/Support/IBC/missionandcontac.html

Acquisition of Biohazardous Materials

- When ordering biohazardous materials for rDNA or Biosafety Level 2 or 3 research activities:
- A Registered User number must be placed on University order forms. The Registered User number can be used by any person authorized by the Registered User.
- Because information on whether a material is biohazardous material (rDNA or Biosafety Level 2 or 3 research activities) may not be readily available, EHS encourages the campus community to use the Registered User number on all potential biohazardous material purchases.
- All suppliers of biohazardous materials that require campus safety authorization prior to initiating purchase should be referred to the EHS Biological Safety Professional.

Institutional Biosafety Committee

- Review Process
  - Review all non-exempt rDNA and infectious Biological materials
- Complete application (even exempt rDNA research) for committee review
- Application assigned Primary Reviewer
- Full Committee review at convened meeting
- Committee approval or conditional approval requiring modification of research plan

- http://www.umkc.edu/research/Support/IBC/forms.html

Institutional Biosafety Committee

- Initial Registration
  - All recombinant DNA work must be registered with the Institutional Biosafety Committee, regardless of whether it is Exempt or Non-Exempt according to the NIH guidelines.
    - In addition, all Biosafety Level 2 and 3 research must be registered with the IBC regardless of whether or not it involves recombinant DNA.
  - Download a copy of the “Biohazardous Materials Application” form http://www.umkc.edu/research/Support/IBC/forms.html
    - Complete the Application according to the instructions included on the Application form (additional ”Scope of work” information will be requested, save an electronic copy on your computer, and submit an electronic copy of the completed Application (without signatures) as an email attachment.
    - A hard copy of the completed Application, including the signatures, will need to be submitted prior to research startup to the Biosafety Office, 5319 Rockhill Road, through campus mail.

Protocol Amendments

- Change in Biosafety Level
- Add Biohazardous Material
- Change in Complete Lab Location
- Delete Biohazardous Material
- Change in Protocol Name
- Delete Individual Room(s)
- Change in Animal Species
- Add\Delete Personnel
- Change in Animal Housing
- Add\Delete Procedure(s)
- Change Animal Handling Process
- Add/delete Cell Lines
- Change in Biosafety Cabinet(s)
- Time Frame of Project Change
- Change in Principal Investigator
- In vitro to Animal Use, etc.

Emergencies

- Develop and practice plans for:
  - Spills: large spills, spills inside BSC
  - Accidental exposures: needle sticks, eye/mucous membrane splash, breathing aerosols.
  - Power/Utility failures: BSC, freezers, ventilation, lights, water.
  - Fire
  - Medical emergencies
- Post Signs

Emergency Procedures

- If a serious accident occurs, call for assistance
  - Ambulance – 911
  - UMKC Police Department - 235-1515
  - Environmental Health and Safety - 235-1157
  - Workers Compensation & Risk Management - 235-6559
  - Student Health - 235-6133

Resources

- CDC Biosafety in Microbiological and Biomedical Laboratories
  http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm
- AMERICAN BIOLOGICAL SAFETY ASSOCIATION
  http://www.absa.org/reskeytop.html
- Canadian MSDSs

  http://www.phac-aspc.gc.ca/msds-ftss/index.html
- UMKC Biosafety Manual

  http://www.umkc.edu/research/Support/IBC/policyandguides.html
- Biosafety Website:
  http://www.umkc.edu/research/Support/IBC/missionandcontac.html
- Application/Amendments:
  http://www.umkc.edu/research/Support/IBC/forms.html
- Environmental Health & Safety - 235-1157

Regulatory Websites

- OSHA Bloodborne Pathogens
  http://www.osha.gov/SLTC/bloodbornepathogens/index.html
- CDC Select Agents
  http://www.cdc.gov/od/ohs/lrsat.htm
- NIH Guidelines for Research Involving Recombinant DNA Molecules
  http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html
- DOT/CDC Shipping
  http://www.cdc.gov/od/ohs/biosfty/shipregs.htm
- CDC Import Permits
  http://www.cdc.gov/od/ohs/biosfty/imprtper.htm
- USDA/APHIS Permits
  http://www.aphis.usda.gov/vs/ncie/

Biosafety Training Opportunities

- General Biosafety Overview
- Biosafety Cabinet Overview
- Risk Assessments
- Bloodborne Pathogens
- Select Agent Safety
- Ancillary Worker Training
- BSL-3 laboratory safety (Required for BSL-3 access)

Questions

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