



# ***BIOLOGICAL SAFETY PROGRAM MANUAL***



November 10, 2004

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<b>Essential Contacts/Phone Numbers</b>	
UIC Biosafety Officer	413-3701
Environmental Health and Safety Emergency	996-7233
UIC Police	996-2830
UIC Office of the Vice Chancellor for Research and IBC	996-1972
University Health Services	996-7420
Building Services Grounds-West	996-7468
Building Services Grounds-East	355-1036
Hospital Environmental Service	996-3688
Biological Resource Laboratory	996-7040

**1. PURPOSE**

- 1.1 To provide guidance and procedures on the use of biological hazards involved in research, teaching laboratories, and the clinical environment at the University of Illinois at Chicago. These hazards include infectious or toxic microorganisms, specimen or tissue from humans or research animals, or the waste from handling these substances.
- 1.2 To maintain safety in the use and handling of biohazardous material without undue risk to the worker, coworkers, families and the environment.

**2. SCOPE**

- 2.1 This manual applies to all University of Illinois at Chicago faculty, staff, hosted visitors, students, visiting researchers, volunteers, outside contractors and laborers working at UIC sites, and employees of firms working at UIC facilities.

**3. REFERENCES**

- 3.1 Code of Federal Regulation 7 CFR part 331, Possession of Select Agents Federal Register, December 13, 2002
- 3.2 Code of Federal Regulations 21 part 50: Protection of Human Subjects
- 3.3 Code of Federal Regulations 21 part 56: Institutional Review Boards
- 3.4 Code of Federal Regulations 29 part 1910.1200: Hazard Communication
- 3.5 Code of Federal Regulations 29 part 1910.1450: Occupational Exposure to Hazardous Materials in the Laboratory
- 3.6 Code of Federal Regulations 29 part 1926.59: Hazard Communication for Construction
- 3.7 Code of Federal Regulations 29 part 1910.1030: Occupational Exposure to Bloodborne Pathogen Standard
- 3.8 Code of Federal Regulations 49 Part 72: Interstate Shipment of

Etiological Agents

- 3.9 CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition (May 1999)
- 3.10 Guidelines for Research Involving Recombinant DNA Molecules (January 2001), published by the National Institute of Health
- 3.11 University of Illinois at Chicago guidelines and manuals:  
Animal Users Manual  
Human Subject Protections Program Manual  
Guidelines for the Use of Recombinant DNA in Research
- 3.12 Code of Federal Regulations 7 part 331, Possession of Select Agents. Federal Register, December 13, 2002
- 3.13 Code of Federal Regulations 9 part 121, Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Select Agents and Toxins. Federal Register, December 13, 2002.
- 3.14 Code of Federal Regulation 42 part 73: Possession Use and Transfer of Select Agents and Toxins Federal Register, December 13, 2002
- 3.15 *Morbidity and Mortality Weekly Report*, December 6, 2002/  
Vol.51/ No. RR-19, Laboratory Security and Emergency Response  
Guidance for Laboratories Working with Select Agents
- 3.16 *USDA Guidance Document For Application for Laboratory  
Registration for Possession, Use and Transfer of Select Biological  
Agents and Toxins*, OMB No. 0920-0576, OMB No. 0579-0213

4. DEFINITIONS

- 4.1 Aerosol - Liquid droplets or solid particulates dispersed in a gaseous medium (e.g. air). A gaseous suspension of ultra microscopic particles of a liquid or solid.
- 4.2 Alternate Responsible Official (Alternate RO) – The designated individual who may substitute for the RO when deemed necessary by the RO or in the absence of the RO. (*Contact EHSO for name of this official*).
- 4.3 Amphotropic Packaging System - Viruses which infect several different species of host cells (e.g. human and rat) and contain

select recombinant DNA or RNA that express a desired phenotype when inoculated into an experimental model.

- 4.4 Animal Biosafety Levels (ABSL) - Designated Levels 1 through 4. The animals purposely infected or naturally carrying the organisms are placed in the ABSL risk group based on the route of infection (such as an aerosol) of that organism, and the degree of pathogenicity. The assigning of these levels are mainly considerations for human risk, but risk among other laboratory animals and the neighboring community (both human and animal) is also a factor.
- 4.5 Ampule - Small, sealable glass or plastic bulb used for sterile storage of material, esp. for subsequent analysis or hypodermic injection.
- 4.6 Antisepsis - The application of a liquid antimicrobial chemical to skin or living tissue to inhibit or destroy microorganisms. It includes swabbing an injection site or open wound on a person or animal, and washing with germicidal solutions.
- 4.7 Autoclave - A device made to hold superheated steam under pressure, used for sterilizing medical instruments and other devices.
- 4.8 Biohazardous material - Any material containing biohazardous organisms in sufficient quantity that if exposed to this material, a susceptible host may become infected or can have an adverse reaction.
- 4.9 Biohazardous organism - Includes all bacteria, fungus, parasites, rickettsia, virus, and prions that exhibit sufficient virulence and quantity to cause an adverse reaction or infection in a susceptible host, human or animal.
- 4.10 Biohazardous waste - Any waste material that has come in contact with human blood, other body fluids such as saliva, vaginal secretions, cerebrospinal, synovial, pleural, amniotic, and peritoneal fluids; this is also inclusive of any other body fluids, excretions, secretions, unfixed tissue or organs, skin from living or dead humans, cell or tissue cultures, organ cultures, culture medium or similar solutions, blood, organs and tissue from experimental animals infected with any human pathogen.
- 4.11 Biological Product - A product prepared in accordance with

- regulations that govern the manufacture of vaccines, reagents, etc.
- 4.12 Biosafety Cabinet (BSC) - A device enclosed (except for necessary exhaust purposes) on three sides, top and bottom, designed to draw air inward by means of mechanical ventilation, operated with insertion of only the hands and arms of the user, and in which virulent pathogens are used.
  - 4.13 Biosafety Level - A safety categorization used in biological research, teaching, and production assigning microorganisms into one of four safety category levels according to risk. Each level designates laboratory practices, techniques, safety equipment, and lab facilities required to work with a specific microorganisms.
  - 4.14 Biosafety Officer - A UIC safety staff person who is responsible for overseeing all aspects of biological safety on the UIC campus, has biosafety expertise and experience to oversee and address all biosafety issues and technical questions.
  - 4.15 Cell Cultures - Human or animal cells propagated out of an organism.
  - 4.16 Cryogen - A liquid or solid used as a refrigerant with a normal boiling point below  $-150^{\circ}\text{C}$  ( $-238^{\circ}\text{F}$ ) as defined by the U.S. National Bureau of Standards and having large liquid-to-gas expansion ratios (generally greater than 700).
  - 4.17 Cryostat - An apparatus for maintaining a constant low temperature often below  $0^{\circ}\text{C}$ , often working in conjunction with a microtome.
  - 4.18 Containment - The methodology of safely confining and controlling infectious agents, and the material containing them.
  - 4.19 Decontamination - A process or treatment from sterilization to simple cleaning with soap and water that renders a medical device, instrument, or environmental surface safe to handle.
  - 4.20 Diagnostic Specimens - Any human or animal material including but not limited to, excreta, secretions, blood and its components, tissue and tissue fluids, which the shipper reasonably believes may contain an etiologic agent and that is being shipped for purposes of diagnosis.
  - 4.21 Disinfection - A form of decontamination on inanimate objects

(work surfaces, equipment, etc.), that reduces pathogenic non-sporeforming microorganisms, but not all microbes, to a level where a susceptible host will not be infected

- 4.22 Engineering Controls - Tools or equipment designed to provide significant protection to the operator as well as other laboratory occupants when properly utilized. Examples include biological safety cabinets, autoclaves, sharps containers.
- 4.23 Etiological Agent - Biological agent that can cause disease in humans or animals.
- 4.24 Generator - Creator of biohazardous waste.
- 4.25 Gene Therapy - The delivery of exogenous DNA to mammalian cells to cause the expression of this material thereby altering the cells phenotype.
- 4.26 Infectious substances - Those substances containing viable microorganisms or their toxins, which are known, or are suspected to cause disease in animals or humans
- 4.27 Institutional Biosafety Committee (IBC) - A committee that reviews and approves recombinant DNA activities and other activities that may pose a biological hazard.
- 4.28 Institutional Review Board (IRB) - Defined under FDA regulation 21 CFR part 50.3 "An IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects". An IRB has the authority to approve, require modifications in (to secure approval), or disapprove research, and serves an important role in the protection of the rights and welfare of human research subjects.
- 4.29 Interstate shipping - Shipping of material over at least a four lane roadway designated by the Federal Highway Administration as part of the Interstate System. (NHTSA3), and includes interstate shipping.
- 4.30 Irradiation - Emission of electromagnetic radiation, or the state of being exposed to such radiation.
- 4.31 Knockout - The deletion of the phenotypes rendered by the inactivation (gene knockout) of various physiologic molecules, which are normally presented. These unexpressed phenotypes are

then bred into animals, to be utilized for research.

- 4.32 Lyophilizer - A unit that freeze dries tissue, microbes, and other organic matter.
- 4.33 Material containing etiological agents - Any materials known to contain or reasonably believed by the shipper to contain an etiologic agent from a list included in the Code of Federal Regulations 49 part 72.
- 4.34 Microtome - An instrument for cutting sections of tissues for microscopic examination.
- 4.35 Mycoplasma Containing Cell Lines - Tissue cultures that have been previously infected with mycoplasma organisms.
- 4.36 Oncogenic Virus - A virus capable of cause a cancerous growth of that cell and progenitor cells.
- 4.37 Personal Protective Equipment (PPE) - Attire such as protective gloves, eyewear, and lab coats, which protect employees by preventing direct contact with hazardous materials and infectious agents and also protecting the experiment from contamination.
- 4.38 Principal Investigator (PI) - A faculty member or guest member, who is assigned laboratory space in order to conduct research.
- 4.39 Prion - A protein particle that lacks nucleic acid and is believed to be the cause of various infectious diseases of the nervous system (as Bovine Spongiform Encephalopathy, Creutzfeldt-Jakob Disease, and Chronic Wasting Disease).
- 4.40 Properly secured gas cylinders - A bracket bolted to a wall with chains to contain a standing cylinder, a screw clamp bracket with intact solid straps that attaches to an installed and stable benchtop, a floor stand made to hold a standing cylinder, or a four wheeled hand cart that is made to transport a cylinder with chains or a strap are acceptable securing devices for gas cylinders.
- 4.41 Recombinant DNA - Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from replication of those synthetic DNA molecules.
- 4.42 Responsible Official (RO) – The individual who oversees all

aspects of shipping, receiving, possession, and use of all Select Agents/Toxins at the University of Illinois at Chicago. (*Contact EHSO for name of this official.*)

- 4.43 Risk Group - The safety level to which an organism is assigned, from 1 through 4, and corresponding to the number of the Biosafety level.
- 4.44 Segregation - The act of sorting Biohazardous Material into appropriate liquid, solid, and sharps containers.
- 4.45 Select Agents - A list of biological agents ("select agents") that have the potential to pose a severe threat to public health and safety, which includes approximately 40 viruses, bacteria, rickettsia, fungi, and toxins whose transfer in the U.S. is controlled. *For a list of Select Agents, see APPENDIX F of this manual.*
- 4.46 Sharp - Any object that is capable of puncturing the skin (e.g. needles, broken glass, scalpel blades, wires, etc).
- 4.47 Sterilization - A method of decontamination using physical or chemical procedures to destroy all microbial life, including highly resistant bacterial endospores.
- 4.48 Transgenic - Having chromosomes into which one or more heterologous genes have been incorporated either artificially or naturally.
- 4.49 Zoonotic Disease - A disease communicable from animals to humans under natural conditions.

## 5. PROCEDURES

### 5.1 General Considerations

- 5.1.1 All research and teaching involving biohazards will be conducted in a safe manner in order to protect all campus personnel, the environment, and the community at large.
- 5.1.2 The beginning of work upon pathogenic, other biohazardous material, a vector of a pathogen, or recombinant DNA is permitted only after review and approval by the Institutional Biosafety Committee (IBC) of the proposed protocol and containment practices.

5.1.3 Suspected violations of policies and practices outlined in this manual, NIH Guidelines, CDC-NIH BMBL, OSHA Bloodborne Pathogen Standard, University of Illinois at Chicago Exposure Control Plan for Bloodborne Pathogens, or guidelines set forth by the Office of the Vice Chancellor for Research must be reported to the UIC Biosafety Officer.

5.1.3.1 Suspected violations shall then be reported to the IBC and the Office of the Vice Chancellor for Research, and the Director of The Environmental Health and Safety Office.

5.1.3.2 No disciplinary action shall be taken against anyone reporting suspected violations.

5.1.3.3 If an incident of violation involving research that has been approved by the IBC or a biohazardous incident has arisen and been reported to the IBC, the IBC shall: review that incident, determine if any action is necessary, and proceed with that action.

## 5.2. Training

5.2.1 The following elements must be included in a biohazardous training program:

- Employees must have prior experience with human pathogens
- They must demonstrate proficiency in standard microbiological practice and technique to the satisfaction of the PI / lab supervisor
- A document for review of that proficiency must be available
- If that employee has little experience in standard micro practices, they must be trained, and their work tasks must have an acceptable degree of difficulty and risk to the experience they have

- Only after proper training must the degree of difficulty and risk of the job performance be increased
- The training must follow requirements set forth in the University of Illinois at Chicago Exposure Control Plan for Bloodborne Pathogens and the Code of Federal Regulations 29 part 1910.1030; Occupational Exposure to Bloodborne Pathogen Standard

5.2.2 When shipping or receiving of biohazardous agents training is required every 2 years regarding the shipment and reception of these agents. Contact EHSO at 996-7411 for the current schedule for training or see website [www.uic.edu/depts/envh](http://www.uic.edu/depts/envh).

### 5.3. Personal Protective Equipment

5.3.1. PPE shall be used to protect personnel from contact with biohazard material and other laboratory hazards only when engineering controls are inadequate.

5.3.2 All PPE shall be issued with out cost to personnel.

5.3.3 Face protection is required for any activity where a chemical, fomite dispersal, body fluid, or tissue manipulation is performed in a lab or setup area.

5.3.4 Chin length face shield, shield-facemask combination, goggles, or safety glasses with side shields must meet ANSI standard Z87.1. The American National Standard Practice for Occupational and Educational Eye and Face Protection.

5.3.4.1 “Street safety” glasses are not acceptable.

5.3.4.2 Safety glasses may be worn over prescription glasses and contact cleanser. If prescription safety worn, they must have side shields. Safety glasses may be obtained through any prescription eyewear provider.

5.3.5. Laboratory clothing: includes lab coats, smocks, scrub suits, gowns, and aprons, shall meet the following requirements:

- Lab coats should be resistant to liquid penetration to protect clothing from contamination
- If the garment is not disposable, it must be capable of withstanding sterilization in the event it becomes contaminated
- Clothing should be comfortable have antistatic properties, closure type and sealing of closure should be a factor in the choosing of lab wear
- Long sleeved garments shall be used to minimize contamination of skin and street-clothes
- Lab clothing shall be provided by the PI for work in the laboratory and specimen set-up area
- Disposable lab ware should be available to all visitors, maintenance, and service worker when entering the lab or specimen set-up area
- Lab clothing shall not be laundered by the lab worker, and must be laundered by a service contracted by the PI or the college department

5.3.6. Gloves are to be worn when working with biohazardous, toxic, chemical, and other physical hazardous agents. Protective gloves are to be selected based on the protection they exhibit with the hazard involved in the lab.

5.3.6.1 For protection characteristic and properties of glove materials, reference UIC Chemical Hygiene Plan.

5.3.6.2 Disposable gloves shall be used and discarded; they cannot be washed or reused.

5.3.6.3 When working with hazardous materials the lower sleeve and cuff of the laboratory garment should be overlapped by the glove. In some cases double gloving is appropriate, so that spill occurs the hand will be protected after the contaminated outer glove is removed.

5.3.6.4 For workers with a known or suspected (latex allergy) only: if latex is the glove of choice for the work in the lab, then the PI shall provide cotton glove liners or a different type of disposable glove at no charge to the employee.

5.3.7. Respirator use may not to be substituted for engineering controls and safe work practices. They may be used only if primary containment such as biosafety cabinets and specialized laboratory ventilation is inadequate to protect the worker as determined by EHSO.

5.3.7.1 The selection of a respirator is based on the hazard and protection factor required.

5.3.7.2 Personnel who require respiratory protection must have an Employee Health Services clearance exam, annual respirator training, and a respirator fit testing. The Environmental Health and Safety Office can perform the fit testing. For scheduling call EHSO at 3-7411.

5.3.7.3 If respirators are to be used in the work environment a written Respirator Program must be available for review by the employees and any inspector of that facility. It must be reviewed yearly by the PI or lab manager, and updated with any change in protocol or procedure. EHSO is responsible for maintaining a campus-wide Respirator Program

#### 5.4. Housekeeping

5.4.1 Good housekeeping is essential to reduce risks and to protect the integrity of biological experiments clinical specimens. Routine housekeeping must be practiced to ensure work areas free of significant sources of contamination.

5.4.1.1 Laboratory personnel are responsible to clean laboratory benches, equipment and

areas that require specialized technical knowledge. This must be done at the end of every work shift.

5.4.1.2 Housekeeping procedures should be based on the highest degree of risk to which personnel and experimental integrity may be subjected.

5.4.1.3 The laboratory must be kept neat and free of clutter, surfaces should be clean and free of infrequently used chemicals, glassware and equipment. Access to sinks, eyewashes, emergency showers, and fire extinguishers must not be blocked.

5.4.1.4 Aisles and corridors should be free of tripping hazards, by removing unnecessary items on floors, under benches or in corners.

5.4.1.5 Properly secure all compressed gas cylinders.

5.4.1.6 Dry sweeping and dusting is prohibited, as it may lead to the formation of aerosols. Only wet and dry canister vacuum unites equipped with HEPA filters on the exhaust are permitted, to protect personnel and equipment from aerosol generation.

5.4.2 All equipment must be properly grounded.

5.4.2.1 Avoid overloading electrical circuits.

5.4.2.2 Do not use electrical devices in wet areas.

5.4.2.3 Extension cords cannot be over 6 feet in length, and must be disconnected if unattended or when work is complete.

5.4.2.4 Powerstrips may be used only for connection of computer equipment; they must not be used for laboratory equipment.

5.4.3 Maintain prompt, proper disposal of waste chemicals.

Utilize the campus chemical redistribution system. For information on call: 413-2436.

5.4.3.2 Never use a fume hood for storage of chemicals or other materials.

5.5 Food/eating in Laboratories

5.5.1 Food in the laboratory is prohibited.

5.5.2 Food and food storage is permitted only in office areas, rooms dedicated for break-rooms, or food service.

5.5.3 No glassware, refrigerator, or microwave oven that is utilized for lab purposes shall be used in the storage and preparation of food for human consumption.

5.6 Pipettes and aspiration devices

5.6.1 Pipetting by mouth is strictly prohibited. Aspiration bulbs, and other pipette aspiration devices shall be used.

5.6.2 Deliverable pipettes (TD) are to be used; blowout pipettes (TC) are not to be used.

5.6.3 Always use a cotton plugged pipette when pipetting biohazard or toxic material, even when safety pipetting aids are used.

5.6.4 Do not prepare biohazardous material by bubbling expiratory air through a liquid with a pipette.

5.6.5 Never mix a biohazard or toxic material by suction and expulsion through a pipette.

5.6.6 Pipetting a biohazardous liquid, or performing any job function that may cause an aerosol, must be performed in a biosafety cabinet.

5.6.7 When pipetting, avoid accidental release of infectious droplets by placing a disinfectant soaked absorbent underpad on the work surface. Autoclave the underpad after use.

5.6.8 Do not discharge material from a pipette at a height.

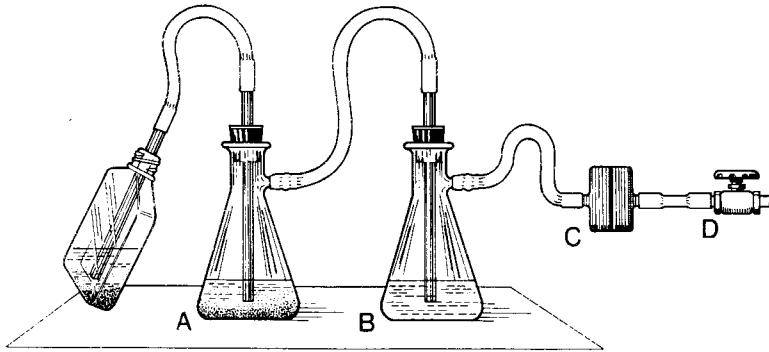
Whenever possible allow the discharge to run down the container wall.

- 5.6.9 Place contaminated reusable pipettes horizontally in a pan containing enough liquid disinfectant to completely cover them. Do not place pipettes vertically into a cylinder. Autoclave the pan and pipettes as a unit before processing them for reuse.
  - 5.6.10 Discard contaminated disposable pipettes in an appropriate sharps container. Autoclave the container when it is 2/3 to 3/4 full and dispose as infectious waste.
  - 5.6.11 Pans or sharps containers for contaminated pipettes should be placed inside the biosafety cabinet if possible.
  - 5.6.12 Needles and syringes should never be used as a substitute for pipettes.
- 5.7 Needles and Syringes
- 5.7.1 The use of needles and syringes should be restricted to procedures for which there is no alternative. Blunt cannulas should be used as alternatives to needles wherever possible (i.e., procedures such as oral or intranasal animal inoculations).
  - 5.7.2 Use disposable safety syringe units whenever possible and avoid the use of slip tip syringes whenever possible.
  - 5.7.3 Perform work in a biosafety cabinet whenever possible.
  - 5.7.4 Wear gloves when working with needles and syringes.
  - 5.7.5 Fill the syringe carefully to minimize air bubbles.
  - 5.7.6 Expel air, liquid and bubbles from the syringe vertically into a cotton pledget moistened with disinfectant.
  - 5.7.7 Do not use a syringe to mix infectious fluid forcefully.
  - 5.7.8 When filling a syringe, do not contaminate the needle hub in order to avoid transfer of infectious material to fingers.
  - 5.7.9 Wrap the needle and stopper in a cotton pledget moistened

with disinfectant when removing a needle from a rubber-stoppered bottle.

- 5.7.10 Do not recap or resheath a needle or a syringe with a needle.
  - 5.7.11 The use of needle nipping devices is prohibited. Any existing devices must be discarded as infectious waste.
  - 5.7.12 Use a separate pan of disinfectant for reusable syringes and needles. Do not place them in pans containing pipettes or other glassware for sorting later.
  - 5.7.13 Used disposable needles and syringes must be placed in appropriate sharps disposal containers and discarded as infectious waste.
- 5.8 Bunsen burners and shielded electric loop incinerators
- 5.8.1 Sterilization of inoculating loops or needles in an open flame is not permitted. It generates small-particle aerosols, which may contain viable microorganisms.
  - 5.8.2 Continuous flame gas burners should not be used in a biosafety cabinet. These burners can produce turbulence, which disturbs the protective airflow patterns of the cabinet. Additionally, the heat produced by the continuous flame may damage the HEPA filter. If a gas burner must be used, one with a pilot light should be selected.
  - 5.8.3 The use of a shielded electric incinerator is preferred over a Bunsen Burner because it minimizes aerosol production during loop sterilization.
  - 5.8.4 Disposable plastic loops and needles may be used for culture work where electric incinerators or gas flames are not available. The loops are semiquantitative and can be used for counting bacteria.
  - 5.8.5 Cloth covered tubing must be used for all Bunsen burners or similar apparatus.
- 5.9 Vacuum equipment
- 5.9.1 When using the vacuum system or a vacuum pump, place

dual aspirator flasks in series (A and B) and an in-line HEPA filter (C) between the vacuum trap and the source valve (D). See Diagram:



- 5.9.2 Use of a vacuum is best done in a biosafety cabinet.
- 5.9.3 Vacuum flasks must be on a bench or in a biosafety cabinet, never on the floor without secondary containment.

#### 5.10 Liquid nitrogen and cryogenics

- 5.10.1 Caution must be observed when working with liquid nitrogen and other cryogenics, to avoid burns from direct contact with a cryogen, uninsulated cryogen piping, or equipment containing a cryogen.
- 5.10.2 Care must be taken when handling containers which are removed from cryogenic storage, because very cold temperatures can cause some materials to become brittle and lose mechanical strength.
- 5.10.3 Safety gloves designed for handling low-temperature liquids must be used when working with a cryogen.
- 5.10.4 A face shield must be used at all times when handling liquid nitrogen, or with samples frozen in liquid nitrogen to protect against high pressures (2-7 MPa), which can cause a confining vessel to rupture or even explode if the enclosed cryogen is heated above its critical temperature.
- 5.10.5 Work with liquid nitrogen must be performed in well-ventilated areas, not in small closets, cabinets or similar confined spaces. A small liquid spill, or block of dry ice will produce a large volume of gas that can displace the air

in a confined space. This creates a serious oxygen deficiency that can suffocate occupants of the area.

5.10.6 Dry ice must be manipulated with both protective gloves and tongs.

5.11 Fixation of prion-containing specimens

5.11.1 When performing histology or cytology on pathogenic prion- containing material, hold fixed tissues in 96%-100% formic acid for 1 hour, then in 10% formalin for 48 hours, because formaldehyde has little effect on prion infectivity.

5.11.2 Whenever possible use disposable plastic ware and incinerate when working with prion contaminated material.

5.12 Biohazardous material spills

5.12.1 All departments whose employees routinely come into contact with biohazardous material must maintain adequate supplies to properly handle any anticipated spills.

5.12.2 All departments that generate biohazardous waste must develop site specific spill cleanup procedures that address containment risk of the organisms involved, and the guidelines set forth in this manual.

5.12.3 If a small spill of a biohazardous substance occurs, wipe up the spill with a disinfectant-soaked paper towel, and clean the surface with an EPA recommended disinfectant. Allow at least a 15-minute contact time with the disinfectant on the affected area.

5.12.4 For large spills outside the biosafety cabinet, use the following procedure:

- Notify other individuals in the laboratory, and evacuate the laboratory and exit to the hallway, closing the door behind you.
- Remove any contaminated clothing (turn contaminated portion inward) and place it in an autoclave bag.
- Wash all exposed skin.

- Place signs on door(s) to the laboratory warning individuals who may want to enter that a spill occurred and access is denied.
- Notify Principal Investigator or supervisor and EHSO "on call" safety officer at 996-SAFE.
- Allow the aerosols to settle for 30 minutes before re-entering the laboratory.
- Assemble supplies (disinfectant, sharps containers, towels, tongs, autoclave bags, etc.) before entering the laboratory.
- Don appropriate personal protective equipment such as disposable gown, protective eyewear, gloves, shoe coverings and respiratory protection (if needed and qualified).
- Surround spill area with disinfectant or diking material that is soaked in disinfectant.
- Place paper towels soaked in a disinfectant over the entire spill area.
- Allow 15 minute contact time with the disinfectant to ensure adequate germicidal action.
- Wipe down non-autoclavable materials with germicidal disinfectant.
- Place items designated as contaminated used sharps in an appropriate infectious waste sharps container.
- Place other disposable materials used in the cleanup process in an autoclave bag and process as infectious waste.
- Place contaminated re-usable items in biohazard bags, autoclavable pans with lids or wrap them in newspaper.
- Sterilize, preferably by autoclaving, then clean for re-use.
- Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving.
- Wash hands after gloves are removed.

5.12.5 For large spills too large to handle with normal supplies, use the following procedure:

- Housekeeping, maintenance contractors, or building service personnel assigned to the area should be contacted.
- Avoid all foot traffic through the spill and confine the area.
- When there is a delay in spill clean up, the responsible party should remain at the spill to provide assistance.

5.12.6 For large spills within a Biosafety Cabinet:

- Keep the cabinet operating during cleanup to contain aerosols and HEPA-filter exhaust air.
- Don appropriate personal protective equipment before initiating cleanup.
- Start clean-up as soon as possible using a germicidal disinfectant (phenolic, iodophor, or 1 to 10 bleach). Large quantities of alcohol increase the risk of fire.
- If the spill is contained on an absorbent underpad, remove the contaminated underpad, and discard as infectious waste.
- If the spill is on the work area surface, cover spilled material with disinfectant-soaked towels. Allow 15 minutes contact time then remove the contaminated towels and discard as infectious waste.
- Notify Principal Investigator or supervisor and EHSO "on-call" safety officer at 996-SAFE to determine whether formaldehyde decontamination of the cabinet and filters is necessary, especially if a high-risk agent or a major spill of a moderate-risk agent occurred.
- Wipe down the interior of the cabinet and any splatter on items within the cabinet with a disinfectant-soaked towel.
- Wipe down non-autoclavable materials with disinfectant. Allow at least 15 minutes of contact time with disinfectant before any items are removed from cabinet.

- Using tongs/forceps place items designated as contaminated used sharps in an appropriate infectious waste sharps container.
- Place other contaminated disposable cleanup materials used in the cleanup process in a biohazard bag, and process as infectious waste.
- Place contaminated re-usable items in biohazard bags, autoclavable pans with lids or wrap them in newspaper. Sterilize, preferably by autoclaving, and then clean for re-use.
- Manage contaminated materials as if infectious.
- Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving.
- Wash hands after gloves are removed.
- Run BSC at least 10 minutes after cleanup before resuming activity in the cabinet.

5.12.7 If a cabinet has a catch basin beneath the work surface and the spill resulted in liquids flowing into this area, then a more extensive decontamination is required as follows:

- Inspect the drain valve under the cabinet to ensure that it is closed.
- Pour disinfectant onto the work surface and through the front and rear grilles into the drain pan. Allow 20-30 minutes contact time.
- Absorb spilled fluid-disinfectant from work surface with paper towels and discard in biohazard bag.
- Place the disinfectant solution in a collection vessel
- Attach flexible tubing to the drain valve. The tube should be of sufficient length to allow the open end to be submerged in the collection vessel to minimize aerosol generation.
- Open the drain valve and empty the drain pan into the

collection vessel containing disinfectant.

- Flush the drain pan with water and remove flexible tubing.
- Manage contaminated materials as infectious.
- Remove protective clothing used during cleanup and place in biohazard bag for autoclaving.
- Wash hands after gloves are removed.
- Run BSC for at least 10 minutes after clean up before resuming activity in the cabinet.

5.12.8 For spills and breaks in a centrifuge without safety buckets:

- A spill inside a centrifuge has the potential for multiple infections from a single accident. Aerosols are created when fluid escapes from the rotor or cup while the centrifuge is operating at high speed.
- Cover all potentially contaminated material spun in a tabletop centrifuge with a test-tube cap or Parafilm® so that leakage from an improper seal will not spread into the centrifuge container. Ultracentrifuge rotors cannot be sealed in this manner, but should be constantly monitored for leaks.
- All opening of centrifuges must be performed slowly.
- If a centrifuge tube breaks while the centrifuge is running, turn off motor.
- Allow the machine to be at rest for 30 minutes before opening. If breakage is discovered after the machine has stopped, re-close the lid immediately and allow the unit to be at rest for 30 minutes.
- Unplug centrifuge before initiating clean-up.
- Don strong, thick rubber gloves and lab coat, safety glasses, and respirator (if qualified) before proceeding with clean-up.
- Flood centrifuge bowl with a germicidal disinfectant.

- Place paper towels soaked in a disinfectant over the entire spill area. Allow 15 minute contact time.
- Use mechanical means (such as forceps) to remove broken tubes and glass fragments. Place them in a sharps container for autoclaving and disposal as infectious waste.
- Remove buckets, trunnions, and rotor and place in disinfectant for 24 hours or autoclave.
- Unbroken, capped tubes may be placed in disinfectant and recovered after 15 minute contact time or autoclaved.
- Use mechanical means to remove remaining disinfectant soaked materials from centrifuge bowl and discard as infectious waste.
- Place paper towels soaked in a disinfectant in the centrifuge bowl and allow it to soak overnight, wipe down again with disinfectant, wash with water and dry.
- Discard disinfectant soaked materials as infectious waste.
- Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving.
- Wash hands after gloves are removed.

#### 5.12.9 Breaks inside centrifuges with safety buckets

- If breakage is suspected in a centrifuge with sealed safety bucket, place the sealed bucket in a biological safety cabinet before opening.
- After cleaning up the break, replace the cap on the safety cup loosely and autoclave. Notify Principal Investigator or supervisor.

#### 5.12.10 Biohazardous spills occurring during transport on campus:

- During transport (on the UIC Campus), the major emphasis should be on preventing the spill. All transport of infectious materials must be in a rigid, securely sealed,

watertight primary container, which is contained within a second rigid, leak proof sealed container.

- Sufficient absorbent should be added to the second container to take up contents in case of leakage from the primary container.
- The outer container must be labeled with the universal biohazard symbol.
- If a spill occurs during transport, don gloves and initiate cleanup immediately. Contact EHSO "on-call" safety officer at 996-SAFE if assistance is needed.
- Surround spill area with disinfectant or diking material that is soaked in disinfectant.
- Place paper towels soaked in a disinfectant over the entire spill area.
- Allow a minimum 15 minute contact time with the disinfectant to ensure adequate germicidal action.
- Place contaminated used sharps in an appropriate infectious waste sharps container.
- Place other materials used in the cleanup process (including contaminated gloves) in an autoclave bag and process as infectious waste.
- Repeat decontamination of spill area after contaminated materials are removed.
- Remove PPE and gloves.
- Wash hands as soon as possible.

#### 5.12.11 Spills of Level 3 agents.

5.12.11.1 Biosafety Level 3 Spill Protocol is listed on page 10, Appendix E.

5.12.11.2 All laboratory personnel (faculty, staff, students) working with a Risk Group 3 agent in a Biosafety Level 3

facility must be qualified to use respiratory equipment by the University Health Services and Environmental Health and Safety Office prior to beginning work.

- 5.13 Segregation of Biohazardous Waste
  - 5.13.1 Segregation of biohazardous waste from ordinary waste is the responsibility of the generator at the point of generation (where materials become waste).
  - 5.13.2 Segregate biohazardous waste into solid and liquid (such as blood and body fluids) waste.
  - 5.13.3 Contaminated liquids may be carefully poured down a drain connected to a sanitary sewer, flushing thoroughly with fresh water.
  - 5.13.4 To adequately segregate waste, generators of biohazardous waste must provide at least two receptacles for waste: one for ordinary waste, and one for biohazardous waste. The receptacles intended for biohazardous waste must have the Universal biohazard symbol. Never use a red or biohazard labeled bag unless it is inside a container.
- 5.14 Containment of Biohazardous waste
  - 5.14.1 The disposal of biohazardous waste must not compromise the strength and durability of the biowaste bag. It is imperative that objects that could potentially tear or puncture the bag be packaged in such a manner as to prevent such an occurrence (see sharps disposal).
  - 5.14.2 Biowaste bags must not be overfilled. A properly filled bag will allow the opening to be easily pulled closed and knotted, sealed, or twist-tied. If additional strength is necessary or if the bag becomes contaminated, the bag must be doubled.
- 5.15 Handling and transport of Biohazardous waste
  - 5.15.1 Bagged biohazardous waste shall be handled in accordance with procedures established by the department or contractor charged with final disposal.

- 5.15.2 Disposal procedures must be compliant with all applicable laws and standards.
- 5.15.3 When removing bags from receptacles, immediately knot, seal, or twist-tie the bag closed. Never transport a bag that is not closed.
- 5.15.4 When handling, avoid contact with skin, clothing, furniture, building fixtures, walls and floors. It is recommended that Personal Protective Equipment (PPE), such as rubber gloves and an apron be worn. The use of carts or containers is recommended to prevent damage or spillage.
- 5.15.5 Always wash hands immediately after handling.
- 5.16 Care and Handling of Sharps
  - 5.16.1 Deposit sharps directly into rigid, puncture and leak resistant containers that are designed for this use and labeled with the Universal Biohazard symbol.
  - 5.16.2 Never fill sharps containers beyond  $\frac{3}{4}$  full. Once filled, containers must have all openings securely closed.
  - 5.16.3 Always maintain sharps containers in an upright position.
  - 5.16.4 Sharps must never be bent, clipped, deformed, or broken in any manner. Devices for such purposes shall not be used.
  - 5.16.5 Needles must never be recapped or resheathed after the protective covering has been removed.
  - 5.16.6 If leakage from a sharp container is possible, the container must be placed inside another leak-proof labeled container.
  - 5.16.7 Never abandon sharps and allow them to remain unattended on furniture surface such as countertops, lab benches, chairs etc.
  - 5.16.8 Never place sharps in the regular trash or in biohazard bags.
  - 5.16.9 Broken glass contaminated with a biohazard shall be handled as a biohazardous waste.

5.16.10 Proper PPE shall be worn such as: gloves, protective eyewear, and lab coats when collecting biohazard contaminated glass.

5.16.11 The glass shall be picked up with tongs or forceps. The extremely small residual pieces of residual glass must be swept up with a dustpan and hand broom. Care must be taken when using the hand broom to avoid stirring up contaminated dust. The use of a respirator in this situation is warranted, but may only be used by qualified personnel.

5.16.12 The waste glass shall be placed either in a sharps container, or in a box that is lined with an open biohazardous waste bag. If a box with a biohazardous waste bag is used the bag must be sealed at the finish of the glass collection, and the box sealed shut and taped closed. The biohazard symbol must be affixed to the sides and top of the box. The box can now be disposed as regular biohazardous waste.

5.17 Biohazardous Waste Disposal

5.17.1 Waste pickup shall be performed by Housekeeping, maintenance contractors, or building service personnel assigned to the area. The current calling list is provided in the table below.

Location	Contact	Extension
Hospital and Clinics	Hospital Environmental Services	6-3688
West Side	Building Services	6-7468
East Side	Building Services	5-1036
College of Dentistry	Fred Chappa	6-7633
MBRB	Bernie Greski (problems only)	6-6963
BRL	Jimmy Bowers	6-7052
School of Public Health	Margit Javor	3-1241
IIDD	Dale Mitchell	3-1504

the responsibility of the Principal Investigator, Lab Manager, or Clinical Section Supervisor to call the appropriate contact (see section above) when Biohazardous waste pickup is necessary.

5.17.1.2 Hospital Biohazardous waste pickup is performed by Hospital Environmental Services. Routine Service is provided in the UIC Hospital.

5.17.2 Manifests

5.17.2.1 All biohazardous waste transportation manifests supplied by the waste hauler are to be submitted to Department of Hospital Environmental Services, and a photocopy is faxed to the Environmental Health and Safety Office at 413-3700.

5.17.3 Animal waste and carcasses: Contact the Biological Resource Laboratory regarding disposal of waste animal matter, and carcass disposal.

5.18 Decontamination and Disinfection (See Appendix C)

5.18.1 The kinds and numbers of organisms, the amount of organic matter, the object to be disinfected and chemical exposure time, temperature and concentration influence effectiveness of decontaminate.

5.18.1.1 All infectious materials and all contaminated equipment or apparatus should be decontaminated before being washed, stored or discarded.

5.18.2. Heat sterilization

- Autoclaving is the preferred method.
- Biohazardous materials should not be placed in autoclaves overnight in anticipation of autoclaving the next day.
- Autoclaves should not be operated unattended or by untrained personnel.
- Special precautions should be taken to prevent accidental removal of material from an autoclave before it has been sterilized or simultaneous opening of both doors on a double door autoclave.
- Autoclave sterility monitoring should be conducted on a weekly basis using appropriate biological indicators (G. stearothermophilus spore strips) placed at locations

throughout the autoclave.

- To monitor an autoclave run, chemicals and other materials such as autoclave tape, must be used with each load.
- Items that should not be autoclaved are: dry hypochlorites, or any other strong oxidizing material. These may react with organic materials such as paper, cloth, or oil resulting in an explosion.
- Logs should be kept on quality control results and any maintenance performed.
- Dry heat is less efficient than wet heat and requires longer times and/or higher temperatures to achieve sterilization. It is suitable for the destruction of viable organisms on impermeable non-organic surfaces such as glass, but it is not reliable in the presence of shallow layers of organic or inorganic materials which may act as insulation.
- Sterilization of glassware by dry heat can usually be accomplished at 320-338° F (160-170° C) for periods of 2-4 hours.
- Dry heat sterilizers should be monitored on a regular basis using appropriate biological indicators [*B. subtilis* (*globigii*)] spore strips.
- Incineration may be used as another effective means of decontamination by heat. As a disposal method incineration has the advantage of reducing the volume of the material prior to its final disposal.

#### 5.18.2 Irradiation

- UV lamps that are used for space decontamination should be interlocked with the general room or cabinet illumination so that turning on the lights extinguishes the UV.
- UV should be used only when areas are not occupied.
- UV lamps must be properly maintained, including weekly

cleaning.

#### 5.18.3 Prion Decontamination

- When working with a specimen from a mammal with a prion disease such as Bovine Spongiform Encephalopathy, Kuru, or Crutzfeldt-Jakob Disease, various methods of decontamination are necessary.
- Contaminated surfaces must be treated with 1molar sodium hydroxide (1M NaOH).
- Autoclave solids or liquids at 270 Deg. F. (142 Deg. C), for 4 to 5 hours, in the presence of 1M NaOH.
- Incineration, with the tissue or contaminated liquid must be exposed to 1M NaOH for 24 hours.

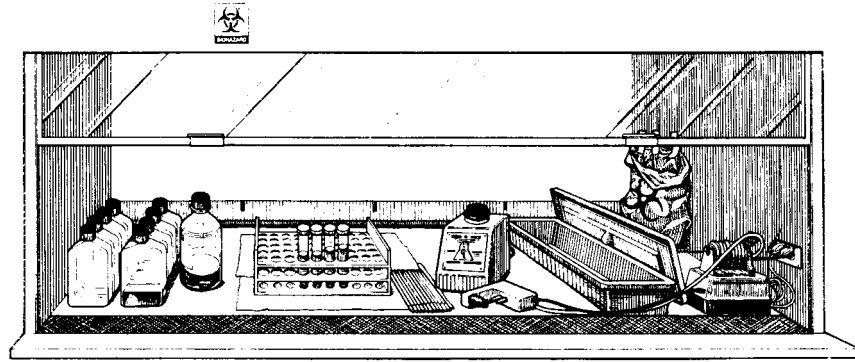
### 5.19 Laboratory Equipment Work Practices

#### 5.19.1 Biological Safety Cabinets (BSC) (See Appendix D)

5.19.1.1 Know how to operate and maintain the system and work within the cabinet volume without compromising its functions.

5.19.1.2 For cabinets used to contain Risk Group 2 or 3 agents, and preferably for all cabinets, take the following quality control measures:

- Allow the cabinet to run 5 minutes prior to starting work in it.
- At least daily, or each time the cabinet is operated, the operator or user should observe the magnahelic gauge and note its relative position. Maintain a log of this reading.
- Work from a clean side to the contaminated side as shown in the diagram below.



after working within a BSC, a cleaning should be performed.

5.19.1.3 Prior to a move, disposal, or lab abandonment all BSC's must be decontaminated by a licensed certifier.

5.19.1.4 Annually, and after a move, cabinets should be certified by an outside contractor. EHSO does not offer this service but can provide names and telephone numbers of local certifiers

5.19.1.5 Annual re-certification is essential because:

- The process is quick and relatively inexpensive.
- It ensures that the hood is meeting its operating specifications and providing maximum protection.
- Certifiers provide service and preventive maintenance for cabinets.
- It avoids large unanticipated expenses and can often forecast expensive requirements like HEPA filter replacements, allowing planning for the event.
- Unless there is reason for more frequent certification, a one-year certificate life is appropriate. The certificate will generally expire on the last day of the month in which the certification was performed.

5.19.1.5 Recertification must be completed before the current certification expires. If the certification lapses, the hood may not be used for Biosafety Level 2 (BSL2) or higher procedures until recertified.

5.19.1.6 No chemical manipulation is permitted in a Class I or a Class II A Biosafety cabinet. Limited chemical manipulation is allowed in Class II B (vented) Biosafety Cabinets. If radionuclides are to be manipulated in a Class II Biosafety Cabinet, the Radiation Safety Section must be contacted at 996-7429

5.19.1.7 The use of any devices or activity that results in aerosol production such as: blenders, cell-disrupting, lyophilizers, ampule openings, ultrasonic disrupters, and grinding equipment, should be used in a BSC when working with biohazardous materials.

5.19.2 Chemical Fume Hoods are never to be used for biohazard manipulation.

5.19.3 Centrifuge Equipment should be used with procedures that minimize the generation of aerosols.

- Use sealed tubes and safety buckets that seal with O-rings. Before use, inspect tubes, O-rings and buckets for cracks, chips, erosions, bits of broken glass, etc.
- Do not use aluminum foil to cap centrifuge tubes because it may detach or rupture during centrifugation.
- Fill and open centrifuge tubes, rotors and accessories in a BSC. Avoid overfilling of centrifuge tubes so that closures do not become wet.
- After tubes are filled and sealed, wipe them down with disinfectant.
- Always balance buckets, tubes and rotors properly before centrifugation.

- Do not decant or pour off supernatant. Use a vacuum system with appropriate in-line reservoirs and filters. (See section 5.9)
- Work in a BSC when resuspending sedimented material, using a swirling rotary motion rather than shaking. If shaking is necessary, wait a few minutes to permit the aerosol to settle before opening the tube.
- Small low-speed centrifuges may be placed in a BSC during use to reduce the aerosol escape.
- High-speed and ultracentrifuges pose additional hazards. Precautions should be taken to filter the exhaust air from vacuum lines, to avoid metal fatiguing resulting in disintegration of rotors.
- For an ultra centrifuge, a log must be maintained of time in service, speed used, and rotor change-out.
- Use proper cleaning techniques and centrifuge components. Manufacturers' recommendations must be meticulously followed to avoid metal fatigue, distortion and corrosion.
- Avoid the use of celluloid (cellulose nitrate) tubes with biohazardous materials. Celluloid centrifuge tubes are highly flammable and prone to shrinkage with age. They distort on boiling and can be highly explosive in an autoclave. If celluloid tubes must be used, an appropriate chemical disinfectant must be used to decontaminate them.

#### 5.19.4 Microtomes and Cryostats

- 5.19.4.1 Frozen sections on unfixed human tissue or animal tissue infected with an etiologic agent pose a risk because freezing tissue does not necessarily inactivate infectious agents.

5.19.4.1.1 Trimmings and sections of tissue that accumulate in the cryostat may be potentially infectious, and should be removed during

decontamination.

5.19.4.1.2 Consider the contents of the cryostat to be contaminated and decontaminate it frequently with 70% ethanol. Defrost and decontaminate the cryostat with a tuberculocidal EPA approved disinfectant once a week and immediately after tissue known to contain bloodborne pathogens, *M. tuberculosis*, or other infectious agents is sectioned.

5.19.3.2 Consider solutions for staining of potentially infected frozen sections to be contaminated.

5.19.3.3 Gloves should be worn during preparation of frozen sections.

5.19.4.4 Handle a microtome knife with extreme care. Stainless steel mesh gloves should be worn when changing knife blades.

5.19.4.5 Freezing propellants under pressure should not be sections as they may cause spattering of droplets of infectious material.

#### 5.19.5 Blenders

5.19.5.1 Safety blenders, are designed to prevent leakage from the bottom of the blender jar, to provide a cooling jacket to avoid biological inactivation and to withstand sterilization by autoclaving.

5.19.5.2 If blender rotors are not leakproof, they should be tested with sterile saline or dye solution prior to use with biohazardous material

5.19.5.3 The use of glass blender jars is not recommended because of the breakage potential. If they must be used, glass jars should be covered with a polypropylene jar to prevent spraying of glass and

contents in the event the blender jar breaks. A towel moistened with disinfectant should be placed over the top of the blender during use.

- 5.19.5.4 Before opening the blender jar, allow the unit to rest for at least one minute to allow the aerosol to settle. The device should be decontaminated promptly after use.

#### 5.19.6 Lyophilizers

- 5.19.6.1 Depending on lyophilizer design, aerosol production may occur when material is loaded or removed from the lyophilizer unit. If possible, sample material should be loaded in a BSC.
- 5.19.6.2 The vacuum pump exhaust should be filtered to remove any hazardous agents or, alternatively, the pump can be vented into a BSC.
- 5.19.6.3 After lyophilization is completed, all surfaces of the unit that have been exposed to the agent should be disinfected. If the lyophilizer is equipped with a removable chamber, it should be closed off and moved to a BSC for unloading and decontamination. Handling of cultures should be minimized and vapor traps should be used wherever possible.

#### 5.19.7 Ampules

- 5.19.7.1 Opening ampules containing liquid or lyophilized culture material should be performed in a BSC to control the aerosol produced. Gloves must be worn. To open, nick the neck of the ampule with a file, wrap it in disinfectant soaked towel, hold the ampule upright and snap it open at the nick.
- 5.19.7.2 Reconstitute the contents of the ampule by slowly adding liquid to avoid aerosolization of the dried material. Mix the contents without bubbling, and withdraw it into a fresh container. Discard the towel and ampule top and bottom as infectious waste.

5.19.7.3 Ampules used to store biohazardous material in liquid nitrogen can rupture, causing eye injuries. The use of polypropylene tubes eliminates this hazard. These tubes are available dust-free or pre-sterilized and are fitted with polyethylene caps with silicone washers. Heat sealable polypropylene tubes are also available.

## 5.20 Transfer or decommissioning of laboratory facilities

5.20.1 In order to achieve a safe and orderly transfer of laboratory space from one faculty member or department to another, the following rules must be observed by these PI's and the the department head:

- The UIC Biological/Chemical Laboratory Decommissioning Policy must be followed.
- All chemical materials, whether solids, liquids or gases, must be identified and labeled.
- If these materials are to be transferred to another faculty member or department, it must be through a mutual agreement.
- All nontransferable material must be properly disposed of as waste or surplus by the PI or the department head.
- All biohazardous waste, culture stock, and biological specimens must be properly contained, and autoclaved. The building services or independent contractor must be scheduled for waste pickup prior to lab abandonment.
- Moving, transferring, or abandoning of biosafety cabinets (according to section 5.19.1.3 and 5.19.1.4)

5.21 Clean Areas - For the purposes of protecting personnel from the hazards of the active lab, eating drinking etc. are not permitted in a working lab. Clean areas must be free not only of biohazards, but also of chemical and radiation contaminants. Areas such as offices, and inactive (and decontaminated) lab rooms are appropriate as clean areas.

- 5.22 Biohazard Sign - All laboratories that contain BSL 2 to BSL 4 materials must be posted with the following biohazard sign. This sign must also be posted on refrigerators, biosafety cabinets and other storage units that contain these materials.
- 5.23 Use of Animals in Research - See UIC Animal Users Manual or contact UIC Biological Resources Laboratory



#### 5.24 Laboratory Inspections

##### 5.24.1 EHSO Inspections

- 5.24.1.1 EHSO performs yearly safety inspections on all known labs on the UIC campus. Inspections are not limited to biosafety, but also encompass: chemical, electrical, fire, and general safety issues

##### 5.24.1.2 Aspects of a typical inspection:

###### Laboratory and closet identification card:

- Room number, building number, department, date when filled out, room use and description
- Hazard list: chemicals, gases, biologicals, laser, high voltage electricity, high pressure applications, and radioactive materials
- Emergency contacts, research contacts, lab director (PI), and department head
- Card back: unattended operations, temperature controlled environment, water cooled operations, electrical equipment on stand-by, unattended operations in progress, dates, contact, and phone number

Facilities and equipment:

- Ventilation and airflow (lower hazard to higher hazard)
- Aisle clearance/trip hazards
- Neatness of work areas
- Biosafety cabinet: setup, cleanliness, up to date certification
- Electrical safety: power cord integrity, extension cord, usage, access to circuit breaker panel, power strip usage
- Spill kit availability
- Eyewash availability, shower access, and testing schedule
- Solid and liquid chemical storage practices
- Autoclave condition, quality control documents, and shutdown procedure
- Centrifuge inspection and log review

Work practices:

- Use of lab coats
- Close toed shoes usage
- Safety glasses availability and usage
- Food in lab
- Decontamination protocol
- Hazard communication
- Hazard safety placard
- Chemical Hygiene Plan - Laboratory site-specific plan completed
- Lab and Biosafety protocol
- Review of training records
- MSDS sheets and accessibility.

Hazardous waste handling

- Rigid containers for biowaste bag
- Orange autoclave bag present
- Transportation of biowaste
- Biowaste containment, and storage practices
- PPE usage
- Chemical waste disposal practices
- Sharp disposal protocol
- Storage of biohazardous material
- Interview
- Emphasis on research work in laboratory
- Safety knowledge
- Hazards of materials in their work

- Special precautions
- Emergency response and evacuation procedures.

#### 5.24.2 Self Inspections

5.24.2.1 EHSO recommends that each department carry out a tri-annual self inspection.

#### 5.24.3 Regulatory agencies such as IDOL, EPA, NIH, FAA etc.

5.24.3.1 Upon any attempt to inspect any UIC lab by any regulatory agency, the UIC EHSO must be immediately notified. No lab may be inspected by such officials without full knowledge of EHSO management, and participation of an EHSO representative. This is for the protection of UIC, and that of the research performed in those laboratories.

5.25 Biosafety Level 3 - Biosafety LEVEL 3 Laboratories shall follow the specific practices and procedures guidelines outlined in Appendix E with written laboratory-specific protocols approved by the IBC prior to commencement

#### 5.26 Select Agents/Toxins

5.26.1 Select Agent Registration - No Select Agent/Toxin may be obtained, transferred, destroyed or used, without consultation with the EHS Office and Responsible Official/ARO for registration and reporting. See Appendix F at the end of this Manual for a list of "Select Agents."

5.26.2 A multi-disciplinary risk assessment and threat analysis of lab and work procedures must be performed initially, reviewed yearly, and updated with any change in protocol or procedure.

5.26.3 An inventory log of Select Agents must maintained under the authority and accountability of the PI. This log is required for quantifying of toxin or strains of viable organisms.

5.26.4 The PI is required to inform EHSO monthly of the Select Agent/toxin status.

- 5.26.5 If research encompasses Select Agent recombinant DNA manipulation, protocols must be submitted to and approved by the Institutional Biosafety Committee, the RO/ARO, and UIC Biosafety Officer.
- 5.26.6 If Select Agent research involves animals, the protocol must be submitted to and approved by the Animal Care Committee, the UIC Biosafety Committee, the RO (when not available the ARO), and UIC Biosafety Officer
- 5.26.7 If Select Agent research involves human trials then a protocol must be submitted to and approved by the IRB, the UIC Biosafety Committee, the RO (when not available the ARO), and UIC Biosafety Officer
- 5.26.8 The RO/ARO and the Biosafety Officer must be notified immediately if any significant problems, violations of SA biosafety practice, releases, spills or other laboratory accidents with potential SA Biohazard exposure has occurred.
- 5.26.9 Each laboratory conducting Select Agent/toxin work must have written laboratory-specific biosafety practices and procedures prior to commencement of work. It must contain practices and procedures set forth in the UIC Biosafety Manual that are adopted into the laboratory-specific practices and procedures.
- 5.26.10 The lab must have a written protocol response to adverse incident reporting such as spills, needle sticks, or other mishaps. This emergency response plan shall include:
- A “to call” list
  - Supervisor’s First Report of Accidental Injury and Illness
  - Biosafety Level 3 Spill Protocol
  - Procedure in place on theft, loss or release of the S.A/toxins.
  - Electrical blackout procedure
  - Lab fire procedure
  - Tornado earthquake, or other disasters
- 5.26.11 Occupational Health Surveillance must be provided as follows for all persons who perform SA work:

- Each person must be offered serologic testing when they begin work and at least once a year thereafter. This testing or decline of offer must be documented
- The UIC Biosafety Officer and University Health Services must be immediately notified if a person is known to or suspected of having acquired an infection resulting from work in or around the laboratory

5.26.12 The PI is responsible for ensuring attendance and training of staff and students on laboratory security and the Select Agent organisms or toxins in use. Training must include:

- Biosafety or other health and safety policies, practices and procedures to be followed for this research.
- Each new person prior to beginning work, and yearly thereafter.
- Content approved by the UIC Biosafety Officer, UIC Biosafety Committee, and RO.
- Training in accordance with section 5.2.
- Design features that make up the secondary SA Biohazard containment.
- A written lesson plan, certificate, and attendance sheet.
- An agreement to comply must be signed.

5.26.13 Workers are required to observe and monitor the work practices and procedures of others in the laboratory with any action considered to be a protocol violation reported to the lab manager or PI.

5.26.14 If a serious failure to follow the UIC Biosafety Manual guidelines occurs, placing persons at risk, the incident must be reported to the PI or the UIC Biosafety Officer

5.26.15 Any item removed from the SA laboratory but not considered to be hazardous waste must be decontaminated before removal. Items may be wiped down with a disinfectant or sealed in a bag and autoclaved.

- 5.26.16 Each person will decontaminate his/her own work surfaces (e.g., benches, sinks, doors, handles, etc.) immediately after each use and immediately after any contamination with viable material.
- 5.26.17 The floors must be clean and in good repair, cleaned at least weekly under supervision and immediately after contamination with any viable material. *See Housekeeping section 5.4.*
- 5.26.18 The autoclave must be close to the SA investigational lab (within 100 ft for BSL 2 and in the ante room for BSL 3 and 4).
- 5.26.19 All waste from a viable organism (infectious, trash, etc.) SA lab facility must be autoclaved by the end of each day and before it leaves the building.
- 5.26.20 All waste from a toxin SA lab facility must be treated with an equal quantity of a mixture that contains 2.5% NaOCl and 0.25 M NaOH. This treatment should last 4 hours. After the 4 hours test the pH and adjust the pH to 7.0 with 0.1M HCl. After final pH adjustment the mixture can be poured down the drain.
- 5.26.21 Each laboratory must post clear instructions on how SA waste will be handled. *For BSE waste see section 5.18.3.*
- 5.26.22 Prior to acquisition of a SA the PI must establish laboratory security by contacting the UIC Police for the following:
- A security risk assessment.
  - Implementation of prescribed security measures.
  - Security arrangements provided to the Biosafety Officer, UIC Biosafety Committee, and RO.
  - Periodic performance security testing of keys, locks, alarms, and evacuation exercises

performed and logged.

- Monitoring and authorized access of all persons entering the Select Agent laboratory, storage area, or SA infected animal facility by use of a written log or card swipe with a database.
- Identification badges are to be issued for visitors, maintenance personnel, and contract maintenance personnel and escorted at all times.
- Cleaning and maintenance are to be supervised and performed only during normal work hours.
- Visitors and maintenance personnel are to be advised of the potential risks, required practices, and procedures that they must follow as well as instructed about the signs and symptoms of infection or exposure conveyed through written material or as a computerized presentation.
- All personnel that are approved to work with Select Agents must wear name badges special to that lab.
- FBI security investigation and clearance for laboratory staff and the PI.

5.26.23 It is the responsibility of the PI to screen the health status of visitors/workers for increased risk of acquiring infection or for whom exposure and resulting infection might be unusually hazardous (e.g., immuno-compromised persons, pregnancy) prior to entry of the lab.

5.26.24 Written procedures must be in place in the event of theft, loss or release of the SA to notify the RO or alternate RO, UIC Biosafety Officer, and UIC Police immediately.

5.26.25 SA's must not be stored in a common freezer or Refrigerator in a communal storage area or in a common Equipment room.

5.26.26 Some conditions do not require SA registration with the CDC or USDA.

- When the PI controlled inventory of regulated toxins is below the legal government registration quantity, no government notification of possession, or FBI security check of PI and staff is necessary. The RO/ARO can identify the quantity for the specific toxin involved.
- If the organism is a select agent, but is of a strain deemed non-reportable by the CDC or USDA, no government notification of possession, or FBI security check of PI and staff is necessary. The RO/ARO can identify the strain for the specific agent involved.
- This does not exclude the PI from maintaining a Select Agent inventory for EHSO tracking.
- Occasionally a Select Agent/Toxin may be added or excluded by CDC for reportable status. It is the responsibility of the PI to notify the RO/ARO to start the written process of Select Agent exclusion or registration. The CDC website provides the most recent listing of agents at <http://www.cdc.gov>.

5.26.27 Any transfer of S.A's from a registered lab to another lab must meet all SA laboratory requirements, have prior approval by the RO/ARO, CDC/USDA registration, and personnel FBI clearance.

- Biohazardous materials transfers records must include the institution, Principal Investigator, date sent, nature and amount of material transferred and the biosafety level required for this work accompanied by the RO/ARO signature.
- SA transfer, consumption and receipt must be recorded in the laboratory SA inventory log.
- Required permits and documentation must be present for shipped and received agents.
- If a viable non-exempt organism or non exempt quantity of SA toxin is to be transferred, CDC/USDA form EA-101 must be filled out and submitted to the RO/ARO. The PI, lab workers and students with access to this material must then begin the registration process.

- Cultures, tissues, etc., sent from a SA laboratory to another laboratory shall be handled using appropriate safety practices.
- All researchers receiving SA materials must be notified in writing of the risks associated with these materials, and of the need to handle the materials using appropriate safety practices.

*See Section 5.28 Biological Agents Shipping Requirements and 5.29 Permits/Importation and Exportation*

- 5.26.28 Physical components of the laboratory such as ventilation, filtration, sanitation, security are to be working properly and properly maintained.
- 5.26.29 If the ventilation system or other physical containment component of the laboratory fails, work in the SA lab facility must be halted, call Physical Plant Services and contact the UIC Biosafety Officer to help determine appropriate action.
- 5.26.30 At the time the SA facility must be closed for maintenance, repair or decommissioning, a laboratory clearance inspection must be performed by the UIC Biosafety Officer before the work may commence or a new occupant is installed.
- 5.26.31 Routine maintenance of the SA lab that affects ventilation or containment must be scheduled with EHSO at least two weeks in advance.
- 5.26.32 Weekly tests of the required negative pressure for each room in the SA facility must be performed. (This test can be performed using a strip of tissue held in the opening of door held slightly ajar).
- All readings must be logged and kept on file to show that this test is being performed.
  - Special containment systems such as an exhaust HEPA filtration system must be tested and certified to meet National Sanitation Foundation Standard 49 no less than annually.

5.26.33 The PI must keep a log of all maintenance conducted by non-laboratory staff when the SA lab facility has NOT been closed for maintenance.

- The log must record: type of work/maintenance completed (with enough detail so those unfamiliar with the work can reconstruct the sequence of work/maintenance events), date of entry names of workers, start time, completion time, disinfection technique for contaminated tools, special personal protective equipment required to protect the workers (e.g., boots, heavy gloves, face shield etc.), work order number, and mode of disinfection or other steps taken to protect maintenance workers.
- Personal Protective equipment must be endorsed by the Environmental Health and Safety Office (EHSO)

5.26.34 All persons who enter the SA laboratory must wear all required personal protective equipment identified for that specific facility. This can include:

- wraparound gown
- gloves
- eye protection
- shoe covers
- head covers
- sleeve protectors
- face shields
- respirators such as N-95's, Powered Air Purifying Respirators, full face respirators (require special fit-testing by EHSO)
- air-pressurized suits with air-line supplied air.

5.26.35 The staff must be properly trained in the use of the PPE supplied

5.26.36 Whenever potentially infected animals or tissues are in the SA laboratory and not contained in biosafety cabinets, all persons must be provided with (and required to wear) a

HEPA-filtered respirator or pressurized suits. *See Section 5.3.7 Personal Protective Equipment.*

5.26.37 No person shall leave the SA laboratory while wearing clothing designated for wear inside the facility.

- Distinctive protective clothing (clearly different from protective clothing used in nearby areas) shall be provided to the laboratory staff for their use inside the facility.
- Persons leaving BSL 4 laboratories must doff PPE, shower and change clothes according to facility protocol.
- BSL-4 facilities may be exited in an acute emergency through the fumigation room.

5.26.38 Many Select Agent toxins are not listed for glove compatibility. In the case of no attainable information, utilize the assumption that most of the biotoxins are large molecular weight chemicals capable of being metabolized by human cells, and should not be volatile, are water soluble, and none have solvent characteristics.

- Latex or nitrile materials should not be affected by SA toxins and solvent resistant gloves are not needed, but gloves should be impervious to the toxin and medium in which the toxin is contained.
- When working with a dry form of toxin, Anti-Static gloves need to be worn.

5.26.39 All manipulations of viable SA's are to be performed in a biosafety cabinet. *See section 5.19.1 Biological Safety Cabinets and Appendix D.*

5.26.40 All manipulations of nonviable Select Agents/Toxins are to be performed in a fume hood or Class II B 1 or 2 biosafety cabinet.

5.26.41 No Select Agent or Toxin may be destroyed by the PI or laboratory personnel. A regulatory report, witnessed chain-of-custody and destruction protocol under EHSO supervision is required.

- 5.27 Precautions - Cell cultures, human tissue cultures, recombinant DNA, transgenics, and gene therapy shall have the following precautions observed:
- 5.27.1 All human and primate established or primary cell lines, blood, blood products, body fluids, tissues, and tissue cultures are considered biohazardous. Work on these specimens are considered as risk group 2 (Appendix A) and carried out in BSL - 2 laboratories (Appendix B).
- 5.27.1.1 If a cell culture contains a known etiological agent, oncogenic virus, or amphotropic packaging system, containment must be the same as recommended for that agent.
- 5.27.2 BSL 2 or greater is necessary for the following cell lines:
- Cell lines derived from lymphoid tissues
  - All mycoplasma containing cell lines
- 5.27.3 No one shall work with cells derived from themselves, or from a first degree relative, due to the possibility that a host immune system may not provide adequate protection if challenged by a pathogen or vector involved in research of these cells.
- 5.27.4 Hepatitis B vaccinations must be offered by the department to all PI's and all employees working with primary human or primate tissue and tissue cultures.
- 5.27.5 The PI must write a lab protocol / safety manual for each project.
- 5.27.6 When working with human blood, blood products, body fluids, tissue, and tissue cultures, employees and PI's must attend yearly Bloodborne Pathogen training, provided by EHSO or an EHSO approved trainer.
- 5.27.7 All work involving recombinant DNA (rDNA) requires IBC approval. The definitive reference for all rDNA work is in the Guidelines for Research Involving Recombinant DNA Molecules (April 2002), published by the National Institute of Health. The rules established by the IBC, and the guidelines set forth in the BMBL, are the standards of practice at the University of Illinois at Chicago.

5.27.8 All human gene therapy protocols must be approved by the UIC Institutional Review Board (IRB) and the UIC Institutional Biosafety Committee (IBC).

5.27.9 All knockout and transgenic animals protocol must be reviewed by the UIC Animal Care Committee.

5.27.10 Transgenic plants protocols must meet NIH rDNA Guidelines to maintain containment, and prevent environmental release of transgenic plant material and be reviewed by the IBC.

#### 5.28 Biological Agents Shipping Requirements

5.28.1 Federal and state regulations require that containers of biological/infectious materials be carefully packaged to prevent leakage or breakage and consequent exposure to package contents.

5.28.2 Although the Code of Federal Regulations 49 part 72 lists Class 2, 3 and 4 agents that must be shipped according to these regulations, any etiologic agent, such as patient specimens, should be handled according to the regulation even if it is not on the list.

5.28.3 In addition, the shipper (i.e., person with direct knowledge of what is being shipped) must receive training on the most current requirements every 2 years. EHSO provides this training call 6-7411 for further information.

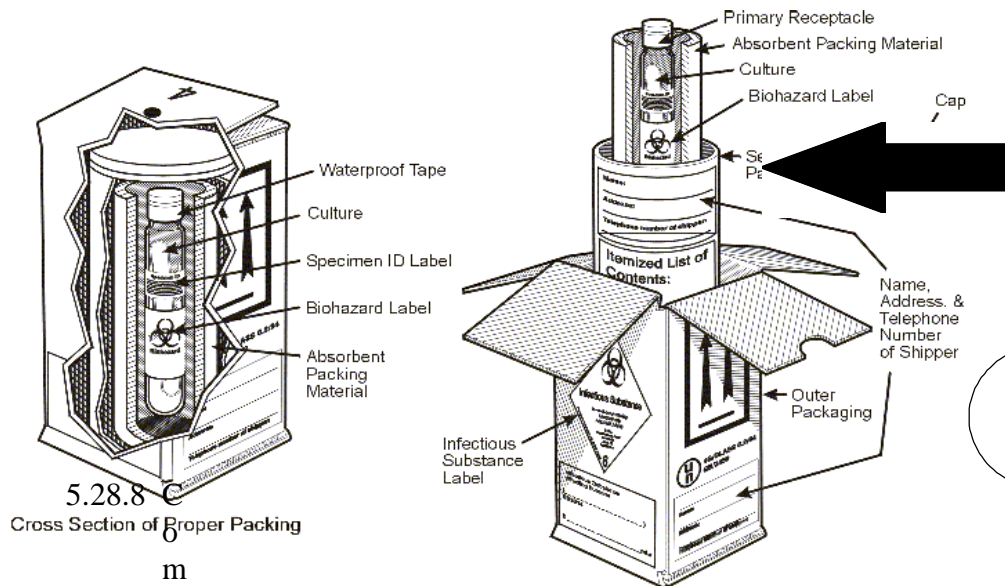
5.28.4 When a shipment of a biohazard is in transit a person or agency knowledgeable in the biohazard must be available by telephone 24 hours a day, seven days a week until that shipment has been received at its destination.

5.28.5 All packages must be labeled with the universal biohazard sign to warn package handlers of the hazardous contents.

5.28.6 Packaging requirements vary according to the volume shipped.

5.28.7 For volumes not exceeding 50 ml:

- 5.28.7.1 The material to be shipped must be placed in a securely closed, watertight primary container.
- 5.28.7.2 The primary container must be placed in a durable, watertight secondary container. Several primary containers may be placed in a single secondary container, so long as the total contents does not exceed 50 ml.
- 5.28.7.3 Absorbent material must be placed in the spaces between the primary and secondary containers, so that there is enough absorbent to absorb the entire contents of the primary container(s) should breakage or leakage occur.
- 5.28.7.4 Each set of primary and secondary containers must be placed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood or other material of equivalent strength. (Most bags and envelopes are not acceptable.)



## Packing and Labeling of Infectious Substances

Please note that the above packaging has the UN mark, indicating that this packaging is certified for shipping infectious substances. An example of the UN mark appears to the right.

5.28.8 Completion of the Shipper's Declaration and proper labeling of the shipping container is essential to assure shipment. The shipper may decline shipment if these items are not in order. (A Fedex example is provided, see next page. Formats can vary.)

5.28.8.1 Shipper - Enter the full name and address of the shipper as well as a phone number.

5.28.8.2 Consignee - Enter the full name and phone number of the consignee as well as the name and phone number of a responsible person.

5.28.8.3 Airway BM Number- Enter the appropriate airway bill number. This information may be entered or amended by the accepting operator.

5.28.8.4 Page\_of\_Pages - Enter the appropriate page number and the total number of pages of the Shipper's Declaration.

5.28.8.5 Aircraft Limit - Delete the box that does not apply by crossing it out.

5.28.8.6 Airport of Departure - Enter the full name of the airport or city of departure. This information may be entered or amended by the carrier.

5.28.8.7 Airport of Destination - Enter the full name of the airport or city of destination. This information may be entered or amended by the carrier.

5.28.8.8 Shipment Type - Delete the box that does not apply by striking it out.

5.28.8.9 Nature and Quantity of Dangerous Goods - The correct completion of this section is the most important part of the Shipper's Declaration.

**SHIPPER'S DECLARATION FOR DANGEROUS GOODS** (Provide at least two copies to the airline)

Shipper: \_\_\_\_\_ Air Waybill No. \_\_\_\_\_  
 Page 1 of 1 Pages  
 Shipper's Reference Number: \_\_\_\_\_

Consignee: \_\_\_\_\_

**FedEx**  
 Federal Express

*Two completed and signed copies of this Declaration must be handed to the operator.*

**TRANSPORT DETAILS**

This shipment is within the limitations prescribed for: \_\_\_\_\_ Airport of Departure: \_\_\_\_\_  
 (delete non-applicable)

PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY
------------------------------	---------------------

Airport of Destination: \_\_\_\_\_

**WARNING**

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder, or an IATA cargo agent.

Shipment type: (delete non-applicable)  
 NON-RADIOACTIVE  RADIOACTIVE

**NATURE AND QUANTITY OF DANGEROUS GOODS**

Dangerous Goods Identification					Quantity and type of packaging	Packing Inst.	Authorization
Proper Shipping Name	Class or Division	UN or ID No.	Pack- ing Group	Subsidi- ary Risk			

Additional Handling Information: \_\_\_\_\_

Emergency Telephone Number: \_\_\_\_\_

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations.

Name/Title of Signatory: \_\_\_\_\_  
 Place and Date: \_\_\_\_\_  
 Signature: \_\_\_\_\_  
 (see warning above)

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.

- Dangerous Goods Identification:
  - Proper Shipping Name - Enter the proper shipping name followed by the technical name in brackets. For example: Infectious Substance, affecting humans (Hepatitis B virus)
  - Class or Division, UN or ID Number and Packing Group. Enter according to the following list:

Shipping Name	Class	UN Number	Packing Group
Infectious substance affecting humans (technical name)	6.2	UN2814	None, Leave blank
Infectious substance affecting animals (technical name)	6.2	UN2900	None, leave blank
Genetically modified microorganism	9	UN3245	None, leave blank
Dry Ice	9	UN1845	III

- Subsidiary Risk - There is no subsidiary for any of the above.
- Quantity and Type of Packing - Enter the total quantity of each dangerous good & the type of material the outer box is made from.
- Packing Instructions - Enter the packing instructions from the list below:

Shipping Name	Packing Instructions
Infectious substance, affecting humans (technical name)	602
Infectious substance, affecting animals (technical name)	602
Genetically modified micro-organisms	913
Dry ice	904

- Authorization - Leave Blank

#### 5.28.8.10 Additional Information

Enter the following:

- An emergency phone number that is manned 24 hours a day by a person knowledgeable about the emergency response requirements for the material being shipped.
- The statement “Prior arrangements as required by IATA Dangerous Goods Regulation 1.3.3.1 have been made.”
- The statement “Prepared according to ICAO/IATA.”

5.28.8.11 Name/Title of Signatory - Enter the name and title of the person signing the Shipper's Declaration.

5.28.8.12 Place and Date - Enter the place and date of signing

5.28.8.13 Signature - Only the shipper must sign the Shipper's Declaration

5.28.9 For volumes greater than 50 ml

5.28.9.1 Packaging of these larger volumes must comply with the above-mentioned requirements. In addition, shock absorbent material in volume at least equal to that of the absorbent material must be placed between the secondary container and the outer shipping container.

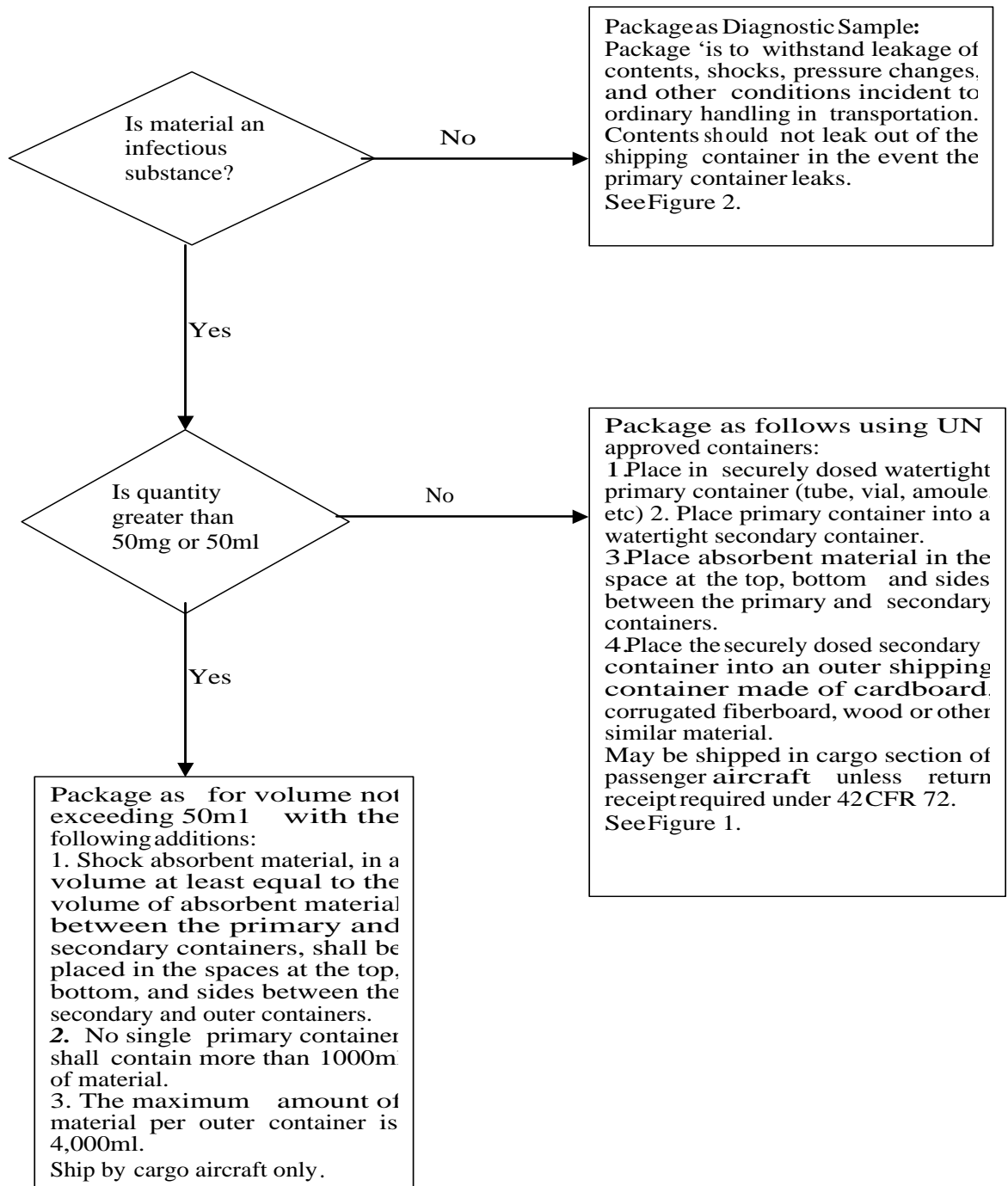
5.28.9.2 Single primary containers must not contain more than one liter of material. However, two or more primary containers, whose volumes do not exceed one-liter may be placed in a single secondary container.

5.28.9.3 The maximum amount of etiologic agent that may be enclosed within a single outer shipping container may not exceed four liters.

5.28.10 Special Handling – Class 3 and Class 4 Agents

5.28.10.1 Certain etiologic agents require special handling. These agents are in Class 3 and 4. They must be shipped by registered mail or an equivalent system, which requires or provides for sending notification of receipt to the sender immediately upon delivery. If the notice of

receipt is not received w/in 5 days following  
anticipated delivery, sender must notify CDC.



5.28.11 Dry Ice Usage - If dry ice is used, it must be placed between the secondary container(s) and the outer shipping container and the shock absorbent material placed so that

the secondary container(s) do not become loose within the outer shipping container as the dry ice sublimates. When shipping with dry ice the special hazard label must be affixed to the exterior container.

5.28.12 Labeling - A special label must be placed on the outer shipping container. This label identifies the package as containing etiologic agents and directs anyone observing damage to the package or leakage of its contents to call CDC.

## 5.29 Permits/Importation and Exportation

5.29.1 Importation of infectious materials, etiologic agents and vectors that may contain them is governed by federal regulation. In general, an import permit is required for any infectious agent known to cause disease in man. This includes but is not limited to bacteria, viruses, rickettsia, parasites, yeasts and molds. In some instances, an agent which is suspected of causing human disease also requires a permit.

5.29.2 Vectors that require import permits (regarding animal imports contact the BRL).

5.29.3 Animals known or suspected of being infected with any disease transmissible to man: Importation of turtles less than 4 inches in shell length and all nonhuman primates requires an importation permit issued by the United States Public Health Service (USPHS) Division of Quarantine, (404) 639-1437.

5.29.4 Biological materials: Unsterilized specimens of human and animal tissue (including blood), body discharges, fluids, excretions or similar material, when known or suspected to be infected with disease transmissible to man.

5.29.5 Insects: Any living insect or other living arthropod, known or suspected of being infected with any disease transmissible to man. Also, if alive, any fleas, flies, lice, mites, mosquitoes or ticks, even if uninfected. This includes eggs, larvae, pupae, and nymphs as well as adult forms.

5.29.6 Snails: Any snails capable of transmitting schistosomiasis.

No mollusks are to be admitted without a permit from either CDC or the Department of Agriculture (see below for phone numbers). Any shipment of mollusks with a permit from either agency will be cleared immediately.

- 5.29.7 Bats: All live bats and certain live animals require a permit from the U. S. Department of the Interior, Fish and Wildlife Services. Call (800) 358-2104 for further information.
- 5.29.8 When an etiologic agent, infectious material or vector containing an infectious agent is being imported to the United States it must be accompanied by an importation permit issued by the USPHS. Importation permits are issued only to the importer, who must be located in the United States. The importation permit, with the proper packaging and labeling, will expedite clearance of the package of infectious materials through the USPHS Division of Quarantine and release by U.S. Customs.
- 5.29.9 Shipping labels containing the universal biohazard symbol, the address of the importer, the permit number and the expiration date are issued to the importer with the permit. The importer must send the labels and one or more copies of the permit to the shipper. The permit and labels inform the U. S. Customs Service and the U.S. Division of Quarantine personnel of the package contents.
- 5.29.10 The importer bears responsibility for assuring that the foreign shipping personnel pack and label the infectious materials according to USPHS regulations. Transfers of previously imported material within the United States also require a permit.
- 5.29.11 Instead of an importation permit, a "Letter of Authorization" may be issued by the issuing officer after review of an "Application to Import an Etiological Agent". The letter is issued for materials that are judged to be noninfectious, but which might be construed to be infectious by U. S. Customs inspection personnel.
- 5.29.12 Letters of Authorization may be issued for items such as formalin fixed tissues, sterile cell cultures, clinical materials such as human blood, serum, plasma, urine cerebrospinal fluid, and other tissues or materials of

human origin when there is no evidence or indication that such materials contain an infectious agent. Letters of Authorization are in effect for two years, and do not require a shipping label to be issued by CDC.

5.29.13 Importation permits and Letters of Authorization are issued by the Biosafety Branch, Office of Health and Safety, CDC, after review of a completed application form. Application forms may be obtained directly from EHSO (413-7233) or by calling CDC at (404) 639-3883. Completed forms may be returned to CDC by mail or FAX. Application to CDC for the importation permit should be made 10 working days in advance of the shipment date to allow time for processing, issuance and delivery of the permit and shipping labels to the permittee.

5.29.14 Other permits

5.29.14.1 U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) permits are required for infectious agents of live stock and biological materials containing animal, particularly livestock, material.

5.29.14.2 Tissue (cell) culture techniques customarily use bovine material as a stimulant for cell growth. Tissue culture materials, and suspensions of cell culture grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origin are, therefore, controlled by the USDA due to the potential risk of introduction of exotic animal disease into the U. S. Applications for USDA/APHIS permits may be obtained from EHSO (413-7233). Further information may be obtained by calling the USDA/APHIS at (301) 436-7885.

5.29.15 Export of infectious materials may require a license from the Department of Commerce. Call (202) 482-0896 for further information.

5.30 Employee work-related incidents, injuries or illnesses should be referred in accordance with the following procedures:

- 5.30.1 An employee that is injured in a laboratory incident or contracts an illness due to a research related exposure, must report to UIC Emergency Services or their own personal physician.
- 5.30.2 If a needle stick from a contaminated needle has occurred then the employee must report to UIC Employee Health Services. If this needle stick occurred during a holiday, weekends, or when UIC Employee Health Service is closed then the employee must report to UIC Emergency Services. Follow up care will be provided through Employee Health Services
- 5.30.3 The PI or lab supervisor must fill out a "Supervisors First Report of Accidental Injury and Illness", and a copy faxed to EHSO (312-413-3700). Follow up care will be provided through Employee Health Services. If transportation assistance is required, call UIC Police at 996-HELP

6. DOCUMENTATION - Projects working with biohazardous materials should maintain the following documentation as appropriate:

UIC Forms

- Appendix A Use of Drugs, Devices and/or Biological Products in Research, (IRB)
- Appendix B Involving Children as Subjects in Research (IRB)
- Appendix C Involving Prisoners as Subjects in Research (IRB)
- Appendix D Databases/DNA/Tissue/Sample Banks (IRB)
- Appendix E Investigational Drug Service Drug Study Registration Form (IRB)
- Continuing Review of Research, (IRB)
- Application for Laboratory Registration for Possession, Use, and Transfer of Select Biological Agents and Toxins: CDC form 01319 (08/31/03); APHIS Form 2004 (08/31/03)
- Application for the Use of Recombinant DNA in Research Forms A and B(IBC)
- Autoclave Quality Control log
- Biohazardous waste manifests
- Biosafety Cabinet yearly certification
- Center for Disease Control Form EA -101
- Continuing Education Certification
- Departmental Review Committee For Research Involving Human Subjects

- Federal Bureau of Investigation Bioterrorism Preparedness and Response Act, Information Form (FD-961)
- Protocol for Animal Use Form A (IACUC)
- Shippers Declaration For Dangerous Goods
- Import/Export Manifests
- UIC Supervisors First Report of Accidental Injury and Illness
- Ultra Centrifuge usage log

## 7. RESPONSIBILITIES

### 7.1 Principal Investigators

Principal Investigators are responsible for:

- Workers such as hired technical staff, graduate students, undergraduate students, visiting scholars, interns, or volunteers must work under the direction of the Principal Investigator, in a safe and responsible manner.
- Enforcement and maintain full compliance of the practices and procedures described in this manual, The UIC Chemical Safety Manual, and The UIC Safety Standards.
- Informing all lab workers, maintenance personnel, or guests regarding the biohazardous material contained in the lab, consequences of exposure to that material, and proper behavior in that lab.
- Restricting lab access following the recommendations of the CDC- NIH BMBL, NIH Guidelines, and OSHA Bloodborne Pathogen Standard.
- The PI and support staff should be adequately trained in good microbiological technique.
- Encouragement of an attitude and environment of lab safety with employees through open discussion and reporting of any safety concerns, and poor practices regarding biosafety or general lab safety.
- While the PI may delegate authority to an employee, or graduate student working under him, ultimate responsibility rests solely upon the PI for any citation or harm due to deviation of these described practices and procedures.

- To maintain the records of continuing education and training in laboratory safety for themselves, the lab workers, and students involved in biohazardous research under their direction.
- To inform and assist in providing lab workers prophylactic medicine (i.e. vaccinations, Mantoux testing) for the research involved.
- To insure proper shipping and receiving of biohazardous material, a log of shipping and receiving must keep an up to date, and a record is required of the special training in the transport of these agents.
- To ensure that the NIH Guidelines, CDC-NIH BMBL, or any rules by an agency maintaining authority on proposed research are complied with prior to IBC approval.

## 7.2 The IBC

This committee includes persons with expertise in recombinant DNA technology, other aspects of biological, and biomedical research. It is responsible for campus:

- The safe conduct of research involving the use of infectious agents.
- Over seeing all aspects concerning the use of rDNA in research.

## 7.3 Biosafety Officer

The Biosafety Officer is responsible for:

- Bloodborne Pathogen Training and other biological safety training on campus.
- Inspections of labs for safe practices and lab situations.
- Reviewing proposed protocol for biohazardous and recombinant DNA research in concert with the IBC.

This person is a member of the IBC. This person reports to the Assistant Director Chemical Safety, and works cooperatively with the IBC.

## 7.4 IRB

The IRB is responsible for:

- Assurance that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research.
- Review of research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

#### 7.5 Director of the Environmental Health and Safety Office

The Director of the Environmental Health and Safety Office is responsible for:

- Ensuring annual review and revision of this biosafety manual,
- Authorizing resources for the communication of dissemination of the biosafety manual contents,
- Authorizing resources for biosafety officer continuing education, and
- Obtaining and communication biosafety survey violations reports to the appropriate administrative offices.

#### 7.6 Responsible Official (RO)

Responsible Official (or Alternate Responsible Official) must be identified and is responsible for:

- Overseeing that UIC has facilities meeting the requirements to work safely with Select Agents or Select Agent Toxins
- Developing and implementing safety, security and emergency response involving S. A's
- Ensures that only CDC/USDA authorized personnel have access to select agents,
- Maintains detailed records of all activities occurring with select agents/toxins.
- Provides training on select agent safety, security and emergency response plans
- Ensures compliance with select agent security
- Ensures development and implementation of safety, security and emergency response plans

- Provides and controls agent transfer to, from and within the facility.
- Provides notice to required agencies of any theft, loss or release of select agents/toxins.
- Reports identification of a select agent/toxin resulting from diagnosis, verification or proficiency testing

## 8. APPROVALS

8.1. Director,EHSO \_\_\_\_\_ Date \_\_\_\_\_

8.2. Vice Chancellor for Research \_\_\_\_\_ Date \_\_\_\_\_

8.3. IBC Chairman \_\_\_\_\_ Date \_\_\_\_\_

8.4. Biosafety Officer \_\_\_\_\_ Date \_\_\_\_\_

## LIST OF APPENDIXES

APPENDIX A - BIOSAFETY LEVELS

APPENDIX B - RISK GROUPS

APPENDIX C - CHEMICAL/PHYSICAL DECONTAMINATION AND  
DISINFECTANTS

APPENDIX D - LABORATORY EQUIPMENT

APPENDIX E - MANDATORY BIOSAFETY LEVEL-3 LABORATORY  
REQUIREMENTS

APPENDIX F - SELECT AGENTS LISTS

APPENDIX G - BIBLIOGRAPHY/FURTHER INFORMATION

## APPENDIX A BIOSAFETY LEVELS

The biosafety levels are numbered 1 through 4. Biosafety Level 1 has the lowest capacity to cause disease in humans, animals, or plants. Level 4 has high lethality and is limited in ways to treat the disease in humans, animals, or plants.

**Biosafety Level 1** has a basic level of containment and relies on good microbiological practices, and only requires a sink for hand washing.

**Biosafety Level 2** encompasses indigenous moderate risk pathogens that are present in the community. Bench top work is acceptable, but when a splash may be produced primary barriers and primary containment equipment should be utilized such as gloves, safety goggles, face shields, and Class II biosafety cabinets should be used. Secondary containment such as a hand washing station, safety shower, eyewash, and decontamination equipment (autoclaves and disinfectants) must be available.

**Biosafety Level 3** focuses on indigenous or exotic agents that have a potential for respiratory transmission. The organisms may cause a more serious and possibly lethal infection. The greatest emphasis at this biosafety level is in on containment of aerosols. Suppression of aerosols in the lab, the surrounding work area, and the community at large from infectious aerosols is a priority. All manipulations of samples are to be performed in a Class II biosafety cabinet. Specialized ventilation like negative airflow to the anteroom is required for a Level 3 lab.

**Biosafety Level 4** is the highest containment attainable. The organisms involved are extremely dangerous, may not have a vaccine available, exotic, and may be transmitted by an aerosol. Containment is obtained by the use of a Class II biosafety cabinet, or a full body, air supplied, positive pressured personnel suit. The facility is a separate building, or has a completely isolated zone within the complex. It will have specialized ventilation, and waste management systems designed to prevent the release of viable organisms into the environment.

There is no Biosafety Level 4 facility at UIC and Risk Group 4 organism shall not be obtained or reached on the UIC campus.

## APPENDIX B RISK GROUPS

The list in Appendix A must be consulted in making preliminary decisions as to the appropriate biosafety level for work with biohazardous agents.

This is derived from Guidelines For Research Involving Recombinant DNA Molecules (NIH Guidelines) January 1997.

The final assignment of the level of containment and the approval of appropriate practices and procedures to be followed is determined by the Institutional Biosafety Committee and the Office of Environmental Health and Safety. If the biohazardous agent is not listed below, contact the IBC or the Biosafety Officer (413-3701) for assistance.

**Risk Group 1 (RG1)** agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic *Bacillus subtilis* or *Bacillus licheniformis*, *Escherichia coli*-K12, and adeno-associated virus types 1 through 4.

Those agents not listed in Risk Groups 2, 3 and 4 are not automatically or implicitly classified in RG1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

**Risk Group 2 (RG2)** agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia

*Acinetobacter baumannii* (formerly *Acinetobacter calcoaceticus*)  
*Actinobacillus*  
*Actinomyces pyogenes* (formerly *Corynebacterium pyogenes*)  
*Aeromonas hydrophila*  
*Amycolata autotrophica*  
*Archanobacterium haemolyticum* (formerly *Corynebacterium haemolyticum*)  
*Arizona hinshawii* - all serotypes  
*Bacillus anthracis*  
*Bartonella henselae*, *B. quintana*, *B. vinsonii*  
*Bordetella* including *B. pertussis*  
*Borrelia recurrentis*, *B. burgdorferi*  
*Burkholderia* (formerly *Pseudomonas* spp) except those listed in App. B-III-A (RG3))  
*Campylobacter coli*, *C. fetus*, *C. jejuni*  
*Chlamydia psittaci*, *C. trachomatis*, *C. pneumoniae*  
*Clostridium botulinum*, *Cl. chauvoei*, *Cl. haemolyticum*, *Cl. histolyticum*,

*Cl. novyi*, *Cl. septicum*, *Cl. tetani*  
*Corynebacterium diphtheriae*, *C. pseudotuberculosis*, *C. renale*  
*Dermatophilus congolensis*  
*Edwardsiella tarda*  
*Erysipelothrix rhusiopathiae*  
*Escherichia coli* - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including *E. coli* O157:H7  
*Haemophilus ducreyi*, *H. influenzae*  
*Helicobacter pylori*  
*Klebsiella* - all species except *K. oxytoca* (RG1)  
*Legionella* including *L. pneumophila*  
*Leptospira interrogans* - all serotypes  
*Listeria*  
*Moraxella*  
*Mycobacterium* (except those listed in Appendix B-III-A (RG3)) including *M. avium* complex, *M. asiaticum*, *M. bovis* BCG vaccine strain, *M. chelonae*, *M. fortuitum*, *M. kansasii*, *M. leprae*, *M. malmoense*, *M. marinum*, *M. paratuberculosis*, *M. scrofulaceum*, *M. simiae*, *M. szulgai*, *M. ulcerans*, *M. xenopi*  
*Mycoplasma*, except *M. mycoides* and *M. agalactiae* which are restricted animal pathogens  
*Neisseria gonorrhoea*, *N. meningitidis*  
*Nocardia asteroides*, *N. brasiliensis*, *N. otitidiscaviarum*,  
*N. transvalensis*  
*Rhodococcus equi*  
*Salmonella* including *S. arizonae*, *S. choleraesuis*, *S. enteritidis*, *S. gallinarum-pullorum*, *S. meleagridis*, *S. paratyphi*, A, B, C, *S. typhi*, *S. typhimurium*  
*Shigella* including *S. boydii*, *S. dysenteriae*, type 1, *S. flexneri*, *S. sonnei*  
*Sphaerophorus necrophorus*  
*Staphylococcus aureus*  
*Streptobacillus moniliformis*  
*Streptococcus* including *S. pneumoniae*, *S. pyogenes*  
*Treponema pallidum*, *T. carateum*  
*Vibrio cholerae*, *V. parahemolyticus*, *V. vulnificus*  
*Yersinia enterocolitica*

Risk Group 2 (RG2) - Fungal Agents

*Blastomyces dermatitidis*  
*Cladosporium bantianum*, *C. (Xylohypha) trichoides*  
*Cryptococcus neoformans*  
*Dactylaria galopava* (*Ochroconis gallopavum*)  
*Epidermophyton*  
*Exophiala* (*Wangiella*) *dermatitidis*

Fonsecaea pedrosoi  
Microsporium  
Paracoccidioides braziliensis  
Penicillium marneffeii  
Sporothrix schenckii  
Trichophyton

Risk Group 2 (RG2) - Parasitic Agents

Ancylostoma human hookworms including *A. duodenale*, *A. ceylanicum*  
Ascaris including *Ascaris lumbricoides* suum  
Babesia including *B. divergens*, *B. microti*  
Brugia filaria worms including *B. malayi*, *B. timori*  
Coccidia  
Cryptosporidium including *C. parvum*  
Cysticercus cellulosae (hydatid cyst, larva of *T. solium*)  
Echinococcus including *E. granulosus*, *E. multilocularis*, *E. vogeli*  
Entamoeba histolytica  
Enterobius  
Fasciola including *F. gigantica*, *F. hepatica*  
Giardia including *G. lamblia*  
Heterophyes  
Hymenolepis including *H. diminuta*, *H. nana*  
Isospora  
Leishmania including *L. braziliensis*, *L. donovani*, *L. ethiopia*, *L. major*, *L. mexicana*, *L. peruviana*, *L. tropica*  
Loa loa filaria worms  
Microsporidium  
Naegleria fowleri  
Necator human hookworms including *N. americanus*  
Onchoerca filaria worms including *O. volvulus*  
Plasmodium including simian species *P. cynomologi*, *P. falciparum*, *P. malariae*, *P. ovale*, *P. vivax*  
Sarcocystis including *S. sui hominis*  
Schistosoma including *S. haematobium*, *S. intercalatum*, *S. japonicum*, *S. mansoni*, *S. mekongi*  
Strongyloides including *S. stercoralis*  
Taenia solium  
Toxocara including *T. canis*  
Toxoplasma including *T. gondii*  
Trichinella spiralis  
Trypanosoma including *T. brucei brucei*, *T. brucei gambiense*,

T. brucei rhodesiense, T. cruzi  
Wuchereria bancrofti filaria worms

Risk Group 2 (RG2) - Viruses (Viruses and Prions)

Adenoviruses, human - all types  
Alphaviruses (Togaviruses) - Group A Arboviruses  
    Eastern equine encephalomyelitis virus  
    Venezuelan equine encephalomyelitis vaccine strain TC-83  
    Western equine encephalomyelitis virus  
Arenaviruses  
    Lymphocytic choriomeningitis virus (non-neurotropic strains)  
    Tacaribe virus complex  
Bunyaviruses  
    Bunyamwera virus  
    Rift Valley fever virus vaccine strain MP-12  
Calciviruses  
Coronaviruses  
Flaviviruses (Togaviruses) - Group B Arboviruses  
    Dengue virus serotypes 1, 2, 3, and 4  
    Yellow fever virus vaccine strain 17D  
Hepatitis A, B, C, D, and E viruses  
Herpesviruses - except Herpesvirus simiae (Cercopithecine  
Herpesvirus, CHV-1, Monkey B virus)  
    Cytomegalovirus  
    Epstein Barr virus  
    Herpes simplex types 1 and 2  
    Herpes zoster  
    Human herpesvirus types 6 and 7  
Orthomyxoviruses  
    Influenza viruses types A, B, and C  
    Other tick-borne orthomyxoviruses , call EHSO  
Papovaviruses  
    All human papilloma viruses  
Paramyxoviruses  
    Newcastle disease virus  
    Measles virus  
    Mumps virus  
    Parainfluenza viruses types 1, 2, 3, and 4  
    Respiratory syncytial virus  
Parvoviruses  
    Human parvovirus (B19)

Picornaviruses  
Coxsackie viruses types A and B  
Echoviruses - all types  
Polioviruses - all types, wild and attenuated  
Rhinoviruses - all types  
Poxviruses -all types except Monkeypox virus and restricted poxviruses including Alastrim, Smallpox, and Whitepox  
Reoviruses - all types including Coltivirus, human Rotavirus, and Orbivirus (Colorado tick fever virus)  
Rhabdoviruses  
Rabies virus - all strains  
Vesicular stomatitis virus - laboratory adapted strains including VSV-Indiana, San Juan, and Glasgow  
Togaviruses (see Alphaviruses and Flaviviruses)  
Rubivirus (rubella)

**Risk Group 2 (RG2)** agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.

Risk Group 3 (RG3) - Bacterial Agents Including Rickettsia

Bartonella  
Brucella including *B. abortus*, *B. canis*, *B. suis*  
Burkholderia (*Pseudomonas*) *mallei*, *B. pseudomallei*  
Coxiella burnetii  
Francisella tularensis  
Mycobacterium bovis (except BCG strain)

Risk Group 2 (RG2) -  
Bacterial Agents Including Chlamydia), *M. tuberculosis*  
*Pasteurella multocida* type B -"buffalo" and other virulent strains  
*Rickettsia akari*, *R. australis*, *R. canada*, *R. conorii*, *R. prowazekii*,  
*R. rickettsii*, *R. siberica*, *R. tsutsugamushi*, *R. typhi* (*R. mooseri*)  
*Yersinia pestis*

Risk Group 3 (RG3) - Fungal Agents

*Coccidioides immitis* (sporulating cultures; contaminated soil)  
*Histoplasma capsulatum*, *H. capsulatum* var.. *duboisii*

Risk Group 3 (RG3) - Parasitic Agents

None

Risk Group 3 (RG3) - Viruses and Prions

- Alphaviruses (Togaviruses) - Group A Arboviruses
  - Semliki Forest virus
  - St. Louis encephalitis virus
  - Venezuelan equine encephalomyelitis virus (except the vaccine strain TC-83)
- Arenaviruses
  - Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
- Bunyaviruses
  - Hantaviruses including Hantaan virus
  - Rift Valley fever virus
- Flaviviruses (Togaviruses) - Group B Arboviruses
  - Japanese encephalitis virus
  - Yellow fever virus
  - Other viruses as listed in the reference source (see Section V-C, Footnotes and References of Sections I through IV)
- Poxviruses
  - Monkeypox virus
- Prions
  - Transmissible spongiform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents) I through IV, for containment instruction).
- Retroviruses
  - Human immunodeficiency virus (HIV) types 1 and 2
  - Human T cell lymphotropic virus (HTLV) types 1 and 2
  - Simian immunodeficiency virus (SIV)
- Rhabdoviruses
  - Vesicular stomatitis virus

**Risk Group 4 (RG4)** agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

Risk Group 4 (RG4) - Bacterial Agents

None

Risk Group 4 (RG4) - Fungal Agents

None

Risk Group 4 (RG4) - Parasitic Agents

None

Risk Group 4 (RG4) - Viral Agents

Arenaviruses (Togaviruses) - Group A Arboviruses

Guanarito virus  
Lassa virus  
Junin virus  
Machupo virus

Bunyaviruses (Nairovirus)

Crimean-Congo hemorrhagic fever virus

Filoviruses

Ebola virus  
Marburg virus

Flaviruses (Togaviruses) - Group B Arboviruses

Tick-borne encephalitis virus complex including:

Absetterov,  
Central European encephalitis  
Hanzalova  
Hypr  
Kumlinge  
Kyasanur Forest disease  
Omsk hemorrhagic fever  
Russian spring-summer encephalitis viruses  
Herpesviruses (alpha)  
Herpesvirus simiae (Herpes B or Monkey B virus  
Cercopithecine Herpesvirus, CHV-1)  
Hemorrhagic fever agents and viruses as yet undefined

The following list of animal etiologic agents is appended to the list of human etiologic agents. None of these agents is associated with disease in healthy adult humans; they are commonly used in laboratory experimental work. A containment level appropriate for RG1 human agents is recommended for their use. For agents that are infectious to human cells, e.g., amphotropic and xenotropic strains of murine leukemia virus, a containment level appropriate for RG2 human agents is recommended.

Baculoviruses

Herpesviruses

- Herpesvirus ateles
- Herpesvirus saimiri
- Marek's disease virus
- Murine cytomegalovirus

Papovaviruses

- Bovine papilloma virus
- Polyoma virus
- Shope papilloma virus
- Simian virus 40 (SV40)

Retroviruses

- Avian leukosis virus
- Avian sarcoma virus
- Bovine leukemia virus
- Feline leukemia virus
- Feline sarcoma virus
- Gibbon leukemia virus
- Mason-Pfizer monkey virus
- Mouse mammary tumor virus
- Murine leukemia virus
- Murine sarcoma virus
- Rat leukemia virus
- Murine Retroviral Vectors

Murine retroviral vectors to be used for human transfer experiments (less than 10 liters) that contain less than 50% of their respective parental viral genome and that have been demonstrated to be free of detectable replication competent retrovirus can be maintained, handled, and administered, under BSL1 containment.

The importation, possession or use of the following agents is prohibited or restricted by law or USDA regulation or administrative policy.

African horse sickness virus  
African swine fever  
Akabane virus  
Besnoitia besnoiti  
Borna disease virus  
Bovine infectious petechial fever  
Bovine spongiform encephalopathy  
Brucella melitensis  
Camel pox virus  
Cochliomyia hominivorax (screw worm)  
Ephemeral fever virus  
Foot and mouth disease virus  
Fowl plague virus (lethal avian influenza)  
Goat pox virus  
Histoplasma (Zymonema) farciminosum  
Hog cholera virus  
Louping ill virus  
Lumpy skin disease virus  
Mycoplasma agalactiae (contagious agalactia of sheep)  
Mycoplasma mycoides (contagious bovine pleuropneumonia)  
Nairobi sheep disease virus  
Newcastle disease virus  
Peste des petits ruminants (Pest of small ruminants)  
Pseudomonas ruminatum (heart water)  
Rift Valley fever virus  
Rinderpest virus  
Sheep pox virus  
Swine vesicular disease virus  
Teschén disease virus  
Theileria annulata  
Theileria bovis  
Theileria hirci  
Theileria lawrencei  
Trypanosoma vivax (Nagana)  
Trypanosoma evansi  
Vesicular exanthema virus  
Wesselsbron disease virus

## APPENDIX C CHEMICAL AND PHYSICAL DECONTAMINATION AND DISINFECTANTS (FIRST TEXTBOOK PART)

There are four main categories of physical and chemical means of decontamination. They are heat, liquid disinfection, vapors and gases and radiation. Each category is discussed briefly below.

### Using a chemical germicidal agent

Although some chemicals may be utilized as either a disinfectant or an antiseptic, adequacy for one application does not guarantee adequacy for the other.

### **Liquid disinfection**

The most practical use of liquid disinfectants is for surface decontamination and, when used in sufficient concentration, as a decontaminant for liquid wastes prior to final disposal in the sanitary sewer. If liquid disinfectants are used, they must be approved by the EPA, and have been shown to be effective against the organism(s) present.

Liquid disinfectants are available under a wide variety of trade names. In general, these can be classified as: halogens, acids, alkalis, heavy metal salts, quaternary ammonium compounds, phenolic compounds, aldehydes, ketones, alcohols, and amines. The more active a compound is, the more likely it is to have undesirable characteristics such as corrosivity. No liquid disinfectant is equally useful or effective under all conditions and for all viable agents.

### **Vapors and gas disinfectants**

A variety of vapors and gases possess decontamination properties. Vapors and gases are primarily used to decontaminate biological safety cabinets and associated systems, bulky or stationary equipment not suited to liquid disinfectants, instruments or optics which might be damaged by other decontamination methods, and rooms, buildings and associated air-handling systems.

Agents included in this category are glutaraldehyde and formaldehyde vapor, ethylene oxide gas, peracetic acid, and hydrogen peroxide vapor. When used in closed systems and under controlled conditions of temperature and humidity, excellent disinfection can be obtained. Great care must be taken during use because of the hazardous nature of many of these compounds. Contact EHSO for monitoring requirements if these compounds are to be used.

### **Heat sterilization**

Autoclaving or wet heat is the most dependable method of sterilization. Autoclaving works by saturated steam under pressure of approximately 15 psi to achieve a chamber temperature of at least 250 °F for a prescribed time, proper temperature and time, evacuation of air is also critical to achieving sterility. This is the most convenient method of rapidly achieving destruction of all forms of microbial life. Material to be sterilized must come in contact with steam and heat.

Chemical indicators, e.g. autoclave tape, must be used with each load placed in the autoclave. The use of autoclave tape alone is not an adequate monitor of efficacy, utilize biological indicators (*G. stearothermophilus* spore strips). The spores, which can survive 250° F (131° C) for 5 minutes but are killed at 250 °F in 13 minutes, are resistant to heat than most other spores. This testing provides an adequate safety margin when validating decontamination procedures.

Manufacturers' recommendations for appropriate use of the autoclave should always be followed.

### **Irradiation**

Ionizing radiation will destroy microorganisms and cells. It is of little use for gross laboratory disinfection. Available irradiators are used to irradiate tumors, leukocyte, and immune cells and cell lines. This in turn will inactivate some or all cellular function due to dosage and exposure.

Nonionizing radiation in the form of ultraviolet radiation (UV) is used for inactivating viruses, bacteria and fungi. It destroys airborne microorganisms and inactivate microorganisms on exposed surfaces, or utilized for products of unstable composition that cannot be treated by conventional means.

Ultraviolet light has low penetrating power, so microorganisms inside dust or soil particles will be protected from its action. This property limits its usefulness.

UV is used in air locks, animal holding areas, ventilated cabinets and laboratory rooms to reduce levels of airborne microorganisms and maintain good air hygiene.

UV can cause burns to the eyes and skin of people exposed for even a short period of time, proper shielding should be maintained when it is in use. If UV must be used, it should be used when areas are not occupied.

UV lamps are not recommended for decontamination unless they are properly maintained. Because UV lamp intensity or destructive power decreases with time, it should be checked with a

UV meter yearly. Cleaning every week is necessary to prevent accumulation of dust and dirt on the lamp, which also reduces its effectiveness drastically.

### **Properties of some common disinfectants**

Ethyl or isopropyl alcohol in a concentration of 70-85% by weight is often used. Alcohols denature proteins and are somewhat slow in their germicidal action. However, they are effective disinfectants against lipid-containing viruses.

Formaldehyde for use as a disinfectant is usually marketed at about 37% concentration of the gas in water solution referred to as formalin or as a solid polymerized compound called paraformaldehyde. Formaldehyde in a concentration of 5% active ingredient is an effective liquid disinfectant. Formaldehyde at 0.2 to 0.4% is often used to inactivate viruses in the preparation of vaccines. Formaldehyde is recommended for disinfecting materials labeled with 125 I or 131 I to prevent the release of vaporous radioactive iodine that might occur with use of strong oxidizing agents. Formaldehyde loses considerable disinfectant activity at refrigeration temperatures. Its pungent, irritating odor requires that care be taken when using formaldehyde solutions in the laboratory. Formaldehyde vapor generated from formaldehyde solution is an effective space disinfectant for sterilizing rooms or buildings. Formaldehyde absence of high moisture content in the air, formaldehyde released in the gaseous state forms less polymerized residues on surface and less time is required to clear treated areas of fumes than formaldehyde released in the vapor state.

Chlorine is a halogen and a universal disinfectant active against all microorganisms, including bacterial spores. Chlorine combines with protein and rapidly decreases in concentration in its presence. Free, available chlorine is the active element. It is strong oxidizing agent, corrosive to metals, and hard on plastics. Chlorine solutions will gradually lose strength so that fresh solutions must be prepared frequently. Sodium hypochlorite (household bleach) is usually used as a base for chlorine disinfectants. These bleaches usually contain 5.25 percent available chlorine or 52,500 ppm. If diluted 1 to 10, the solution will contain 5250 ppm of available chlorine; and if a nonionic detergent is added in a concentration of about 0.7 percent, a more versatile disinfectant is created. The use of chlorine to disinfect 125 I or 131 I labeled materials is not recommended because as a strong oxidizing agent, substantial vaporous radioactive iodine can be released.

Iodine has the characteristics of chlorine and is very similar. One of the most popular groups of disinfectants used in the laboratory is the iodophors, and Wescodyne® is perhaps the most widely used. The range of dilution of Wescodyne® recommended by the manufacturer is 1 oz. In 5 gal. Of water giving 25 ppm of available iodine to 3 oz. In 5 gal. giving 75 ppm. At 75 ppm, the concentration of free iodine is .0075 percent. This small amount can be rapidly taken up treated by 75 ppm available iodine, but difficulties may be experienced if an appreciable amount of protein is present. For washing the hands or for use as a sporicide, it is recommended that

Wescodyne® be diluted 1 to 10 or 10% in 50% ethyl alcohol, which will give 1,600 ppm of available iodine at which concentration relatively rapid inactivation of any and all microorganisms will occur.

### **Disinfectant guidelines, ineffectiveness, and residual properties**

Some disinfectants are much more effective than others and some organisms readily survive some disinfectants. The manufacturer or vendor can provide documentation of a disinfectant's effectiveness against specific organisms. Disinfectants are most effective when used according to the manufacturer's instructions of concentration and contact time. Keep records that prove the liquid disinfectants are effective. Your laboratory-specific practices and procedures must include detailed instructions on the type of disinfectant, proper mix proportions, contact time required and other information that will ensure effective decontamination of work surfaces. EHSO advises against the use of flammable materials or disinfectants, which may create vapors that will have toxic or adverse affects on laboratory staff.

Ineffectiveness of a disinfectant is often due to the failure of the disinfectant to contact the microorganism rather than failure of the disinfectant to act. If an item is in submersed in a liquid disinfectant, that item is covered with tiny bubbles. The area under the bubbles is dry, and microorganisms in these dry areas will not be affected by the disinfectant. If there are spots of grease, rust, dirt or organic material covering the contaminated item, the disinfectant will have limited efficacy. Scrubbing an item when immersed in a disinfectant is necessary, and many disinfectants have incorporated surface-active agents. Shelf and bench life of the disinfectant must be a consideration in storage, and reformulation (dilution of concentrate) prior to use.

Some of the chemical disinfectants have residual properties, which may be considered a desirable feature in terms of aiding in the control of background contamination. Consider those residual properties carefully. Cell cultures, as well as viruses of interest, may be inhibited or inactivated by disinfectants persisting after routine cleaning procedures. Reusable items that are routinely held in a liquid state prior to autoclaving and cleaning should receive particular attention in rinse cycles. During general area sterilization with gases or vapors it is necessary to protect new and clean items such as glassware, by removing them from the area, or by enclosure in a gas-tight bags, or by insuring adequate aeration following sterilization.

## APPENDIX D LABORATORY EQUIPMENT

### TYPES OF BIOLOGICAL SAFETY CABINETS (BSC'S)

BSCs are designed to contain aerosols generated during work with infectious material through the use of laminar airflow and high efficiency particulate air (HEPA) filtration. Three types of BSCs (Class I, II and III) are used in microbiological laboratories. Biosafety Cabinets are classified as: Class I - Provides personnel and environmental protection but no product protection, the exhaust is HEPA filtered; Class II - Provides personnel, product and environmental protection; Class III - Totally enclosed (glove box) ventilated cabinet with gas-tight construction. Open-fronted Class I and Class II BSCs are partial containment devices, which provide a primary barrier offering significant levels of protection to laboratory personnel and to the environment when used in combination with good microbiological techniques.

**The Class I BSC** is suitable for work involving low to moderate risk agents, where there is a need for containment, but not for product protection. It provides protection to personnel and the environment from contaminants within the cabinet. The Class I BSC does not protect the product from "dirty" room air. The Class I BSC has not been manufactured for several years.

**The Class II BSC** protects the material being manipulated inside the cabinet (e.g., cell cultures, microbiological stocks) from external contamination. It meets requirements to protect personnel, the environment and the product. There are two basic types of Class II BSCs: Type A, Type B. There are major differences between the two types of cabinets. The Type A recirculates the air within the cabinet back into the lab through a HEPA filter. The Type B has the air in the cabinet ducted out of the lab and the building. Type Bs have three subsets and is dependent on the amount of air recirculated within the cabinet and range from 0 (100% exhaust) to 70%.

**The Class III BSC**, or glove box is gas-tight and provides the highest attainable level of protection to personnel, the environment and the product. It is the only cabinetry, which provides a total physical barrier between the product and personnel. It is for use with high-risk biological agents and is used when absolute containment of highly infectious or hazardous material is required.

The Magnahelic gauge measure the pressure drop across the outlet HEPA filter and are thus important indicators of filter integrity. The gauge will typically indicate the same measurement over a long period of time. A significant change in the reading over a short period of time may indicate clogging or leaking of the filter. In such cases, the hood should not be used until the problem is identified and resolved.

Cleaning of the Biosafety cabinet includes the work surface, the interior walls (not including the supply filter diffuser), and the interior surface of the window should be wiped with 70% ethanol (EtOH), a 1:100 dilution of household bleach (i.e., 0.05% sodium hypochlorite), or other disinfectant as determined by the investigator to meet the requirements of the particular activity. When bleach is used, a second wiping with sterile water is needed to remove the residual chlorine, which may eventually corrode stainless steel surfaces. Wiping with non-sterile water may recontaminate cabinet surfaces, a critical issue when sterility is essential

### **CENTRIFUGE EQUIPMENT**

Hazards associated with centrifuging include mechanical failure and the creation of aerosols. To minimize the risk of mechanical failure, centrifuges must be maintained and used according to the manufacturer's instructions. Users should be properly trained and operating instructions that include safety precautions should be prominently posted on the unit.

Aerosols are created by practices such as filling centrifuge tubes, removing plugs or caps from tubes after centrifugation, removing supernatant, and resuspending sedimented pellets. The greatest aerosol hazard is created if a tube breaks during centrifugation.

## APPENDIX E MANDATORY BIOSAFETY LEVEL-3 LABORATORY REQUIREMENTS

Each laboratory conducting Biosafety Level 3 work must have written laboratory-specific biosafety practices and procedures approved by the IBC prior to commencement of work. It must be reviewed yearly, and updated with any change in protocol or procedure. Practices and procedures set forth here are to be adopted into the laboratory-specific practices and procedures and implemented as part of required performance of every individual working in the lab.

### General Principles

Biosafety Level 3 work involves agents that may cause serious and potentially lethal infection. The primary hazards to personnel working with these agents are autoinoculation, ingestion, and inhalation of aerosols. Each person who uses BSL-3 agents must know and understand the concepts of biosafety and the responsibilities of each individual. They must have an in-depth knowledge of the general and laboratory-specific practices, procedures and equipment, which form the primary biohazard containment. Each individual is expected to take an active role in maintaining the containment conditions required for safe conduct of the work, and must understand the facility (laboratory) design features that make up the secondary biohazard containment. In addition they must participate in the overall maintenance and management of the facility.

### Specific Responsibilities, Practices & Procedures

The PI must ensure that appropriate biosafety practices and procedures are rigorously followed and that the required physical containment features are maintained. If any element of biosafety is considered by the PI to be unachievable, the UIC Biosafety Officer should be notified immediately. A written report of the problem must be sent to the Biosafety Officer and the IBC within five working days. For responsibilities of the PI see Section 7.1.

All persons must conscientiously follow the laboratory-specific biosafety practices and procedures.

Failure to follow required behavior may place all workers in the laboratory in jeopardy. Workers shall observe and monitor the work practices and procedures of others in the laboratory. A serious or consistent failure to follow these guidelines must be reported to the PI or the UIC Biosafety Officer. Under no circumstances shall any adverse action be taken against a person for exercising this requirement.

The PI must monitor and authorize access of all persons entering the BSL-3 laboratory. Access is limited to those who understand the nature of the biohazard, have adequate laboratory-specific biosafety training and agree to comply with all precautions. Training and agreement to comply must be documented (e.g., in a log or person-specific file). Visitors and maintenance personnel who enter the BSL-3 laboratory must be fully informed of the potential risks, required practices and procedures that they must follow. They must be instructed about the signs and symptoms of any and all biohazardous material manipulated or stored in the laboratory.

### **Information**

Persons who may be at increased risk of acquiring infection or for whom infection might be unusually hazardous (e.g., immuno-compromised persons, pregnancy) must be advised of their special risk in terms they understand, and must be strongly discouraged from entering the laboratory.

Biosafety training must be regularly scheduled and presented to all persons who work in or who enter the Biosafety Level 3 laboratory. Comprehensive training must be provided for each new person prior to beginning work. Training shall continue for all laboratory staff, and it is the responsibility of the PI to enforce this training requirement.

Training must focus on biosafety or other health and safety policies, practices and procedures to be followed for this research. Sufficient instruction must be provided to cover the entire gamut of biosafety training at least once each year.

Cultures, tissues, etc., sent from a BSL-3 laboratory to another laboratory shall be handled using BSL-3 biosafety practices. All researchers receiving these biohazardous materials must be notified in writing of the risks associated with these materials, and of the need to handle the materials using BSL-3 practices and procedures. Documentation of biohazardous materials transfers must include the institution, Principal Investigator, date sent, nature and amount of material transferred and the biosafety level required for this work. Refer to Section 20, Shipping biohazards and section 19 "The Select agent Rule."

### **Personal Protective Equipment**

All persons who enter the BSL-3 laboratory must wear all required personal protective equipment as set forth in Section 9.1.1.2.1, and must be established for that specific facility. At a minimum, this includes wraparound gown, gloves and eye protection. Shoe covers, masks, head covers, sleeve protectors, and face shields should be added as appropriate. The PI and laboratory staff must enforce this requirement.

When ever potentially infected animals or tissues are in the Biosafety Level 3 laboratory and not contained in biosafety cabinets, all persons must be provided with (and required to wear) a

HEPA-filtered respirator. This respirator provides protection against both liquid and solid aerosols. The wearer must obtain medical clearance through Employee Health Services, the respirator must be NIOSH certified, and fit tested by EHSO.

No person shall leave the Biosafety Level 3 laboratory while wearing clothing designated for wear inside the facility. Distinctive protective clothing (clearly different from protective clothing used in nearby areas) shall be provided to the laboratory staff for their use inside the facility.

### **Biohazardous Material Waste**

All waste (infectious, trash, etc.) from a Biosafety Level 3 facility must be autoclaved by the end of each day and before it leaves the building. Each laboratory must post clear instructions on how Biosafety Level 3 waste will be handled.

### **Decontamination and Housekeeping**

Any item removed from the Biosafety Level 3 laboratory but not considered to be waste must be decontaminated before removal, even if there is only a small chance that it is contaminated. Items may be wiped down with a disinfectant or sealed in a bag and autoclaved.

Each person will decontaminate their own work surfaces (e.g., benches, sinks, doors, handles, etc.) immediately after each use and immediately after any contamination with viable material.

Storage of supplies must be in cabinets or on shelves. No boxes or supplies may be stored on the floor. The floors must be cleaned at least weekly and immediately after contamination with any viable material.

### **Laboratory Maintenance and Repair**

The PI is responsible for ensuring that the physical components of the laboratory designed to contain the biohazards associated with the research are working properly and properly maintained (e.g., ventilation, filtration, sanitation, security).

If the ventilation system or other physical containment component of the laboratory fails, work in the Biosafety Level 3 facility must be halted. Physical Plant Services and contact the UIC Biosafety Officer to help determine appropriate action.

The UIC Biosafety Officer must authorize repair of the facility or laboratory equipment that requires entry into the BSL-3 laboratory by someone other than the normal laboratory staff before work begins. For after hours emergencies, the EHSO Biosafety staff may be contacted by calling 996-SAFE.

Any time the BSL-3 facility must be closed for maintenance or repair, a laboratory clearance inspection must be performed by the UIC Biosafety Officer before the work may commence. Once clearance is granted, no further work with biohazardous materials may be conducted until all maintenance and repair work is completed. A thorough inspection of the laboratory must be conducted by the PI, and the Biosafety Officer to ensure that the laboratory is functioning properly before work with biohazardous materials may recommence.

Routine maintenance that affects ventilation, affects containment provided by the facility, or requires entry into the lab by non-laboratory staff must be scheduled with EHSO at least two weeks in advance. No maintenance or repair work may begin without prior EHSO authorization. It is expected that EHSO will conduct unannounced inspections during the maintenance.

Weekly tests of the required negative pressure for each room in the BSL-3 facility must be performed. (This test can be performed using a strip of tissue held in the opening of door held slightly ajar.) Problems must be reported without delay to Physical Plant Services and to the UIC Biosafety Officer. All readings must be logged and kept on file.

Special containment systems such as an exhaust HEPA filtration system must be tested and certified to meet National Sanitation Foundation standard 49 no less than annually. The BSC certification must be performed by an approved certification company.

The PI must keep a log of all maintenance conducted by non-laboratory staff when the BSL-3 facility has NOT been closed for maintenance. The log must record: type of work/maintenance completed (with enough detail so those unfamiliar with the work can reconstruct the sequence of work/maintenance events), date of entry names of workers, start time, completion time, disinfection technique for contaminated tools, special personal protective equipment required to protect the workers (e.g., boots, heavy gloves, face shield etc.), work order number, and mode of disinfection or other steps taken to protect maintenance workers

### **Medical Surveillance**

Occupational Health Surveillance must be provided for all persons who perform Biosafety Level 3 work. Each person must be offered serologic testing when they begin work and at least once a year thereafter. The results of this serologic screening must be made available to the IBC upon request. Results may be coded to protect the privacy of the individuals. The IBC may use the results of these tests as a tool to evaluate the effectiveness of the laboratory's biosafety program. It is the expectation of the IBC that no one will acquire a research-related infection as a consequence of the work with biohazardous materials.

### **Emergencies, Injuries, Exposures, and Infections**

The UIC Biosafety Officer, Employee Health Services, and the IBC must be immediately notified if a person is known to or suspected of having acquired an infection resulting from work in or around the laboratory.

An employee that is injured in a laboratory incident or contracts an illness due to a research related exposure, must report to UIC Emergency Services or their own personal physician.

If a needle stick from a contaminated needle has occurred then the employee must report to UIC Employee Health Services. If this needle stick occurred during a holiday, weekends, or when UIC Employee Health Service is closed then the employee must report to UIC Emergency Services. Follow up care will be provided through Employee Health Services.

The PI or lab supervisor must fill out a "Supervisor's First Report of Accidental Injury and Illness", and a copy faxed to EHSO (312-413-3700). Follow up care will be provided through Employee Health Services. If transportation assistance is required, call UIC Police at 996-HELP

The Biosafety Officer must be notified immediately if any significant problems, violations of biosafety practice, releases, spills or other laboratory accidents with potential biohazard exposure occurred. If there is any doubt, the Biosafety Officer should be notified.

### **Biosafety Level 3 Spill Protocol**

All laboratory personnel (faculty, staff, students) working with a Risk Group 3 agent in a Biosafety Level 3 facility must be trained in the use of respiratory equipment by the Environmental Health and Safety Office prior to beginning work. If spill involves radioactive materials, contact Radiation Safety Office immediately at 996-7429

#### **Large spill cleanup**

- If a large spill occurs of a biohazardous substance outside the BSC, notify other individuals in the laboratory, and evacuate the laboratory and exit to the hallway, closing the door behind you.
- Remove any contaminated clothing (turn contaminated portion inward) and place it in an autoclave bag.
- Wash all exposed skin.
- Notification of spill
  - Place signs on door(s) to the laboratory warning individuals who may want to enter that a spill occurred and access is denied.

- Notify the Principal Investigator or supervisor, EHSO at 996-SAFE, and the UIC Campus Police 996-HELP.
- Allow the aerosols to settle for 30 minutes before re-entering the laboratory.
- Assemble supplies (disinfectant, sharps containers, towels, tongs, autoclave bags, etc.) before entering the laboratory.
- Don appropriate personal protective equipment such as disposable gown, protective eyewear, gloves, shoe coverings and respiratory protection.
- Clean up spill with a suitable disinfectant as follows:
  - Surround spill area with disinfectant or diking material that is soaked in disinfectant.
  - Place paper towels soaked in a disinfectant over the entire spill area.
  - Allow 15 minute contact time with the disinfectant to ensure adequate germicidal action.
  - Pick up the paper toweling with tongs, place in an autoclave bag, and autoclave
  - Wipe down non-autoclavable materials with germicidal disinfectant.
  - Place items designated as contaminated used sharps in an appropriate infectious waste sharps container.
  - Place other disposable materials used in the cleanup process in an autoclave bag and process as infectious waste.
  - Place contaminated re-usable items in biohazard bags, autoclavable pans with lids or wrap them in newspaper.
  - Sterilize by autoclaving, then clean for re-use.
  - Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving.
- Wash hands whenever gloves are removed.

## APPENDIX F SELECT AGENTS LISTS

### CDC LIST

**Exemptions:** Select Agent exemptions are added by the CDC and USDA on a continual basis. If there is a question of exemption and the organism, strain, genetic element, or toxin that is not contained within the exemption lists please reference the CDC web site at:

<http://www.cdc.gov/od/sap/exclusion.htm> and the USDA website at:

<http://www.aphis.usda.gov/vs/ncie/bta.html>.

#### Viruses

Cercopithecine herpesvirus 1 (Herpes B virus)

Crimean-Congo haemorrhagic fever virus

Eastern Equine Encephalitis virus

#### **Ebola viruses**

Equine Morbillivirus

Hendra virus

Lassa fever virus

Marburg virus

Nipah virus

Rift Valley fever virus

South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)

Tick-borne encephalitis complex viruses (flavi viruses)

Variola major virus (Smallpox virus)

#### **Venezuelan Equine Encephalitis virus**

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan, Equine encephalitis virus strain TC-83, are exempt.

#### Bacteria

Bacillus anthracis

Brucella abortus, B. melitensis, B. suis

#### **Burkholderia (Pseudomonas) mallei**

Burkholderia (Pseudomonas) pseudomallei

Clostridium botulinum

Francisella tularensis

Yersinia pestis

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

### **Rickettsiae**

Coxiella burnetii  
Rickettsia prowazekii  
Rickettsia rickettsii

### **Fungi**

Coccidioides immitis  
Coccidioides posadasii

### **Toxins**

Abrin  
Botulinum toxins  
Clostridium perfringens epsilon toxin  
Conotoxins  
Diacetoxyscirpenol  
Ricin  
Saxitoxin  
Shigatoxin  
Shiga-like ribosome inactivating proteins  
Staphylococcal enterotoxins  
Tetrodotoxin  
T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

Exempt quantities less than:

100 mg. of Abrin  
0.5 mg. of Botulinum toxins  
100 mg. of Clostridium perfringens epsilon toxin  
100 mg. of Conotoxins  
1000 mg. of Diacetoxyscirpenol  
100 mg. of Ricin  
100 mg. of Saxitoxin

100 mg. of Shigatoxin  
100 mg. of Shiga-like ribosome inactivating proteins  
5 mg. of Staphylococcal enterotoxins  
100 mg. of Tetrodotxin  
1000 mg. of T-2 toxin

**Recombinant organisms/molecules**

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

**USDA LIST**

**Viruses**

African horse sickness virus  
African swine fever virus  
Akabane virus  
Avian influenza virus (highly pathogenic)  
Bluetounge virus (exotic)  
Camel pox virus  
Classical swine fever virus  
Foot-and-mouth disease virus  
Goat pox virus  
Japanese encephalitis virus  
Lumpy skin disease  
Malignant catarrhal fever virus (exotic)  
Menangle virus  
Newcastle disease virus (exotic)  
Peste des petits ruminants virus  
Plum pox potyvirus  
Rinderpest virus  
Sheep pox virus  
Swine vesicular disease virus  
Vesicular stomatitis virus (exotic)

**Fungi**

Peronsclerospora philippinensis  
Phakopsora pachyrhizi  
Sclerophthora rayssiae var. zeae

Synchytrium endobioticum

**Prion**

Bovine spongiform encephalopathy (BSE)

**Bacteria**

Cowdria ruminantium (Heartwater)  
Liberobacter africanus  
Liberobacter asiaticus  
Mycoplasma capricolum/ M.F38/ M. mycoides capri (contagious caprine pleuralpneumonia)  
Mycoplasma mycoides mycoides (contagious bolvine pleuralpneumonia)  
Ralstonia solanacearum, race 3, biovar 2  
Xanthomonas oryzae pv. oryzicola  
Xylella fastidiosa (citrus variegated choroisis strain)

### OVERLAP LIST (BOTH USDA AND CDC)

#### Viruses

Eastern Equine Encephalitis virus  
Equine Morbillivirus  
Hendra virus  
Nipah virus  
Rift Valley fever virus  
Venezuelan Equine Encephalitis virus

#### Bacteria

Bacillus anthracis  
Brucella abortus, B. melitensis, B. suis  
Burkholderia (Pseudomonas) mallei  
Burkholderia (Pseudomonas) pseudomallei  
Francisella tularensis

#### Rickettsiae

Coxiella burnetii

#### Fungi

Coccidioides immitis  
Coccidioides posadasii

#### Toxins

Botulinum toxins  
Clostridium perfringens epsilon toxin  
Shigatoxin  
Staphylococcal enterotoxins  
T-2 toxin

**APPENDIX G**  
**BIBLIOGRAPHY/FURTHER INFORMATION**

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