

Appendix E

Special Procedures for Laboratories with Infectious Human Pathogens (such as HIV and HBV)

This section applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of infectious human pathogens such as HIV and HBV. The section does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of this program.

E1.1 Standard Microbiological Practices

All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

E1.2 Special Practices

Signs will be posted at the entrance of infectious human pathogen (HBV or HIV) research laboratories. Signs will be identical to the Labels described in this program, but also display:

- Names of any and all infectious agents.
- Special requirements for entering the area.
- Contact information of the designated area supervisor.

Laboratory doors shall be kept closed when work involving infectious agents, such as HIV or HBV, is in progress.

Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leak proof, labeled or color-coded container that is closed before being removed from the work area.

Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with signage requirements of this program.

All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

E1.3 Containment Equipment

Appropriate, certified biological safety cabinets or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

Infectious human pathogen research laboratories shall meet the following criteria:

- Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.
- An autoclave for decontamination of regulated waste shall be available.

Infectious human pathogen production facilities shall meet the following criteria:

- The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.
- The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.
- Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.
- Access doors to the work area or containment module shall be self-closing.
- An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.
- A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

E1.4 Additional Initial Training for Employees in Infectious Human Pathogen Laboratories

Employees in infectious human pathogen research laboratories and infectious human pathogen production facilities shall receive the additional initial training in addition to the other training requirements of this program. The department shall:

- Assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with infectious human pathogens.
- Assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with infectious human pathogens.
- Provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.