**Section 490.330 Safety and Sanitation**

The blood bank director shall establish a Safety and Sanitation Manual. This manual shall be consistently implemented throughout the facility and contain signed or initiated documentation that it has been reviewed at least annually to ensure that the requirements of this Part are met. The manual shall include, but need not be limited to the following items.

a) General Sanitation and Safety with respect to:

1) minimum clearance in passageways to assure that exit from and access to the blood bank are not impeded;

2) the selection of and the schedule for the use of cleaning supplies for floors, walls, ceilings, bench tops, and sinks;

3) hand washing protocol;

4) requiring that all items which are disposed of and which can cut or puncture the skin shall be placed in containers which are impervious to the flow of liquids, rigid to prevent the container from collapsing when handled in the blood bank, and puncture proof to prevent needles from penetrating the container;

5) safe storage, transport, and use of compressed gases which includes the requirements that each cylinder is shipped with a valve safety cover which shall remain in place when regulators are not attached; that gas cylinders shall be secured at all times; and that empty containers shall be labeled and removed from the laboratory;

6) requiring that smoking, eating, and drinking shall be prohibited in all areas where laboratory work is performed;

7) requiring that mouth pipeting shall be prohibited;

8) requiring that all electrical outlets shall be grounded, electrical equipment be maintained in condition to prevent shock and fire hazards, and protective fuses not be bypassed; and

9) requiring that all blood letting and collection devices shall be both sterile and disposable.

b) Warning signs shall indicate "Hazardous Materials" (radioactive, flammable, poison, irritant, carcinogen, etc.) with precautions in the use and storage of those materials.

c) Fire prevention and control with respect to:

1) the use of open flames, flammables, safety cans, safety cabinets, etc.;

2) requiring that a fire extinguisher of the CO2 or dry chemical type shall be in the blood bank;

3) actions to be taken in case of fire; and

4) requiring that provisions for unimpeded egress from the building shall be posted.

d) Chemical and radiation hazards with respect to:

1) maintenance of a list of all chemicals used in the laboratory categorized as corrosive, flammable, toxic, carcinogenic, explosive, radioactive, and mutagenic;

2) actions to be taken in the event of an accidental break or spill;

3) ventilation in accordance with the kinds of chemical fumes encountered;

4) storage requirements for chemicals which are caustic, poisonous, flammable, carcinogenic, etc.;

5) requiring that wastes discharged to any sewer shall be in accordance with the general requirements for liquids, solids, or gases as well as specific requirements for mercury and cyanide as established by the Illinois Environmental Protection Agency (35 Ill. Adm. Code 307).

6) safe use of radioactive materials, if used in the laboratory, by having a registration certificate from and validated by the U.S. Nuclear Regulatory Commission or a license from the U.S. Nuclear Regulatory Commission for the use of radioactive materials.

e) Biological hazards with respect to:

1) handling of specimens to avoid infection by air, ingestion, direct inoculation, and skin contact;

2) providing biological safety hoods and other appropriate barriers (i.e. plastic gloves) in accordance with the types of organisms encountered; and

3) disposal of cultures, specimens, and other potentially infectious materials which shall be completely incinerated or sterilized or sealed in a container as indicated below to render the materials innocuous before disposal or removal from the premises.

A) The incineration of materials shall be done in accordance with the requirements of the Illinois Environmental Protection Agency concerning the operation of an incinerator (35 Ill. Adm. Code 724).

B) The sterilization of materials shall be done by autoclaving the materials in accordance with the manufacturer's recommendations and the effectiveness of the autoclave shall be verified and documented at least weekly with a biological spore assay containing B. Stearothermophilus.

C) The disposal or removal of materials outside of the facility shall be done in the following manner:

i) Incinerated or sterilized materials shall be disposed of through routine waste disposal methods without precautions against possible contamination.

ii) Materials which have not been incinerated or sterilized shall be disposed of by a waste hauler with a proper permit from the Illinois Environmental Protection Agency (35 Ill. Adm. Code 809). These materials must be sealed, transported and stored in biohazard containers. These containers shall be marked "Biohazard," bear the universal biohazard symbol, and be orange, orange and black and red. The containers shall be rigid and puncture-resistant such as a secondary metal or plastic can with a lid that can be opened by a step-on pedal. These containers shall be lined with one or two high density polyethylene or polypropylene plastic bags with a total thickness of at least 2.5 mil. or equivalent material. The containers which are marked "Biohazard" shall be sealed before being removed from the laboratory or blood bank.

f) Handling and Disposal of HIV Contaminated Blood and Human Tissue

1) *Any blood* or blood components, organs, semen or other human tissue *showing exposure to HIV* as evidenced by two of three reactive ELISA test results (according to the package insert – product circular) *or any other identified causative agent of Aids* or originating from a patient diagnosed with AIDS or AIDS-Related Complex (ARC) as defined in 77 Ill. Adm. Code 693.20, *shall be disposed of* in accordance with the provisions of this Section, *unless a research facility licensed by the state requests, in writing, the use of such blood for Aids research.* (Section 3.1 of The Blood Labeling Act, Ill. Rev. Stat. 1987, ch. 111½, par. 620-3.1 ) Any such blood or human tissue shall be disposed of in accordance with Section 490.330(f) (2) when no longer being used for research purposes.

A) A research facility, for the purposes of this Section, shall mean any clinical laboratory licensed under the Illinois Clinical Laboratory Act, any blood bank licensed under the Blood Bank Act or any hospital licensed under the Hospital Licensing Act.

B) *Any person delivering such blood* or blood components, organs, or semen or other human tissue *to research facilities pursuant to such a request shall file with the Department a report which shall include at least the following information:*

i) *a copy of the request for blood* or human tissue;

ii) *the quantity of blood* for human tissue *delivered*;

iii) *the name and location of the research facility to which the blood* or human tissue *was delivered;* and

iv) *the date and time of delivery.* (Section 620-3.1 of The Blood Labeling Act.)

2) Any such blood and blood components or human tissue, or any materials or paraphernalia exposed to or contaminated by such blood and blood components or human tissue shall be disposed of in accordance with the provisions of subsection (e) of this Section.