1.0 Introduction

The main focus of this training session centers on Human Immunodeficiency Virus (HIV), Hepatitis B, and C Viruses (HBV, HCV), but is not limited to these viruses alone. There are many pathogens that are transmissible through human blood, body fluids and tissues that are included in this topic.

1.1 OSHA’s Bloodborne Pathogen Standard, 29 CFR 1910.1030 defines specific laboratories, procedures and pathogens that fall within this regulation; the complete Standard can be found on the OSHA website at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051, or by requesting a copy from the Biosafety Officer at 241-5169.

1.2 Definitions that are commonly used are:

1.2.1 Bloodborne Pathogens “means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV)”.

1.2.2 Other Potentially Infectious Materials “means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV”.
1.2.3 **Exposure Incident** “means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that result from the performance of an employee’s duties”.

1.2.4 **Contaminated** “means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface”.

1.3 OPIM is a catch-all definition for any and all HUMAN tissues, body fluids, blood, secretions, and excretions. Urine and feces are excluded, except when contaminated by blood; for our purposes, we will also consider these materials to fall under this definition.

1.4 All fluid, broth, solid slant cultures of bloodborne pathogens also are included under this definition for our purposes.

2.0 **Epidemiology**

2.1 **Direct contact** of the skin and mucus membranes with human blood or body fluids is the primary exposure route. Broken skin and percutaneous inoculations are chief routes of entry into the body.

2.2 **Droplets** from sprays, splatters of blood/body fluids generated from spills or certain types of laboratory activities can result in deposition on the skin, or allow introduction of blood/body fluids into eyes, nose or mouth with the possibility of further penetration of mucus membranes and conjunctiva by pathogens.

2.3 **Aerosols** If the droplets are fine enough, falling between 1-5 μ in diameter, the exposure that results is caused by an AEROSOL, (think of a fog) which can remain suspended for 30 minutes or more and allow inhalation of the droplets deep into the alveoli of
the lung. From the alveoli, many pathogens can penetrate through alveolar cells and vascular walls to enter the blood stream and disseminate to other organs in the body.

2.4 **Conidia and spores** of certain microorganisms also behave as aerosols, when the mean geometric diameter is 1-5 μ in diameter. Even though this exposure route is considered AIRBORNE, the line is blurred here; the protection from the hazard is the same.

2.5 **Needle-sticks**, bites and scratches during animal handling, cuts or lacerations all present routes of entry if the item is contaminated or the wound is contaminated subsequently with blood / body fluids.

2.6 **Infectivity of blood** - all blood is considered to be infected with any bloodborne agent at any time. Setting up an infection depends on the pathogen present, its host specificity, its contagiousness, its virulence, the route of exposure, the dose received by the host (you, if you are the recipient), the general health of the host, and the host’s susceptibility to that pathogen. With some pathogens, the stage or phase of the life cycle will determine if an infection will occur.

2.6.1 **Bacteremias** - bacteria in the blood usually associated with blood sepsis or large systemic infections of organs.

2.6.2 **Viremias** - virus particles in the blood; this condition could be from the lytic phase of the virus, or could be an eclipse phase where viruses are “hiding” in certain blood cells; Carrier states can exist where shedding will release viruses periodically over a phase or complete lifetime of a host.

2.6.3 **Parasites** - actively infectious forms of the parasite in their life cycle i.e. schizonts, trophozoites, leishmania forms, cysts, and eggs. This will vary with each parasite.
2.6.4 Fungi - generally not associated with blood, but *Candida*, *Cryptococcus neoformans*, *Sporothrix schenckii*, have been associated with blood / body fluids. Yeast-forms of the Systemic Mycoses agents i.e. *Histoplasma capsulatum* and *Blastomyces dermatitidis* are infectious from blood.

2.6.5 Incubation periods-HIV has an incubation period of as long as 6 years before signs and symptoms can be detected; HBV has a 7-26 week incubation period. During these periods individuals can look and feel “normal”. There is a possibility for a subclinical infection to occur with some agents, which can give rise to transient or permanent carrier states with viral shedding.

3.0 Risk Assessment

3.1 Many pathogens have been manipulated in laboratories over many years, and a substantial experience has been developed in Lab Acquired Infections. *Biosafety in Microbiological and Biomedical Laboratories*, a publication of the CDC-NIH, (see: [http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm](http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)) has Agent Summary Statements giving information on the types and frequency of LAI’s occurring with a given agent.

3.2 NIH *Guidelines* has Risk Group designations for many pathogens that may be use in the laboratory (see: [http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html](http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html)).

3.3 For *HUMAN* blood, body fluids, tissues, from living or dead individuals, **ALL CLINICAL SPECIMENS, INCLUDING YOUR OWN** are considered to be infectious. This is the concept of *Universal* or *Standard Precautions*. This concept should also be extended to work with animal specimens where bloodborne zoonotic agents are present or are reasonably anticipated, i.e. Herpes B Virus of monkeys.

3.4 Evaluate all of your lab practices for the potential to release droplets, aerosols, large amounts of blood if a container ruptures, or the potential for percutaneous injuries.

3.5 There is no value in testing; specimens can be too early or too late for the window of detection; sensitivity of tests may be lacking; how are false negatives or positives detected and evaluated; too costly and time consuming. It is much easier to consider
everything infectious and handle it accordingly.

4.0 Hazard Recognition / Reduction

4.1 Universal Precautions assumes a “worst case” scenario, and requires a certain minimum acceptable level of practice to protect oneself from an exposure.

4.1.1 Hand washing-breaks the “hand-to-mouth and “hand-to-object” transfer of pathogens. Removes deposited organisms after spill / splatter of contaminated droplets onto skin.

4.1.2 Protective equipment such as respirators, gloves, eyewear, face shields and clothing are used to break direct and indirect contact with fluids, droplets and aerosols.

4.1.3 Vaccinations for HBV and other pathogens for which USPHS vaccines are available, remove the risk of acquiring the infectious agent by immunizing the individual.

4.1.4 Reduction of “sharps” use, substitution of self-sheathing needles, and safe disposal of sharps into puncture-proof containers reduces the risk of sustaining a puncture wound or cut with a contaminated device.

4.1.5 Control of aerosol / droplet production through the use of a biological safety cabinet when performing activities that generate aerosols, screw-cap containers, use of sealed centrifuge rotors, and transporting specimens in leak-proof containers reduce the opportunity for exposure to bloodborne pathogens.

4.1.6 Specific laboratory practices are detailed in the OSHA standard with respect to culturing and manipulating HIV, HBV and other bloodborne pathogens in research. Refer to Section (e) HIV and HBV Research Laboratories and Production Facilities within the standard.

4.3 Good microbiological technique as outlined in the MSSM Biosafety Manual is practiced when culturing, concentrating and manipulating these pathogens.

4.4 Biological Safety cabinets must be used whenever release of droplets and aerosols is possible in a procedure. These cabinets are specifically required to be tested annually and certified.

5.0 Warning Signs and Labeling Procedures

5.1 OSHA specifies the design and colors of the Universal Biohazard
Symbol. This signage must be used when a bloodborne pathogen is cultured or handled in production quantities in a laboratory.

5.2 For laboratories working with clinical specimens of human blood, body fluids and tissues, smaller cards and labels are available for marking equipment, benches, incubators and other storage areas.

5.3 All stocks and cultures must be clearly labeled with the agent name and hazard. Refer specifically to Section (g) of the OSHA Standard for specific practices.

6.0 Spills, Exposure Reporting and Vaccinations

6.1 A spill of human blood, body fluids or contact with tissue on unprotected skin or mucus membranes is considered an exposure incident by OSHA. Report the incident to your supervisor and go to the Employee Health Service immediately.

6.2 Follow the spill procedures outlined in the MSSM Biosafety Manual. Call the Biosafety Officer at 241-5169 for assistance with a spill clean-up.

6.3 Any needlesticks, lacerations or other puncture wounds caused by “sharps” while working with human source specimens, requires immediate attention in the Employee Health Service or Emergency Department, whether the sharp is contaminated or not. These incidents must also be reported as required by OSHA.

6.4 Any and all physicians reports, and ancillary reports generated as a result of an exposure incident must be retained for the length of the employee’s service plus an additional thirty years after separation from MSSM.

6.5 If you are an MSSM employee, and you work directly with human blood, body fluids, tissues or other specimens, or occasionally come into contact with these materials, Hepatitis B Vaccination is available to you at no cost.

You may decline to be vaccinated, but in order to do so you must formally decline by completing a declination statement. You can change your mind later and accept vaccination.

7.0 Conclusion

7.1 It is your responsibility as an employee to read and understand the contents of the OSHA Standard. This presentation is not a substitute for becoming familiar with the Standard. Specific hands-on training can be arranged with the Biosafety Officer in your laboratory by calling 241-5169.
7.2 Faculty members and Principal Investigators are reminded that specific Standard Operating Procedures prepared in written format should be available at all times to their research and support staff working with bloodborne pathogens. All new employees and transient individuals working on bloodborne pathogen projects should demonstrate the required level of training and knowledge before working directly with pathogenic agents.

If you do not have access to a copy of 29CFR 1910.1030 Bloodborne Pathogen Standard, contact the Biosafety Officer for a copy at 241-5169

Part 2

HIV and HBV Research Laboratories and Production Facilities (29 CFR 1910.1030(e))

This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It 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 the standard.

Research laboratories and production facilities shall meet the following criteria:

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

**Special Practices**

- Laboratory doors shall be kept closed when work involving 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, leakproof, 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 paragraph (g)(1)(ii) of this standard.

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.
Containment Equipment

Certified biological safety cabinets (Class I, II, or III) 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.

HIV and HBV 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.

HIV and HBV 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).
Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

Labels and Signs -- .1910.1030(g)

Labels

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

Labels required by this section shall include the following legend:

![Image of Biohazard Label]

These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

Red bags or red containers may be substituted for labels.

Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.
Regulated waste that has been decontaminated need not be labeled or color-coded.

**Signs**

The employer shall post signs at the entrance to work areas specified in *HIV and HBV Research Laboratory and Production Facilities*, which shall bear the following legge:

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.