Foreword

Yeshiva University and the Albert Einstein College of Medicine of Yeshiva University is committed to providing a safe and healthful environment for all its employees, faculty, students, and visitors. This Exposure Control Plan is a further indication of this commitment.

Purpose

The Occupational Safety and Health Administration (OSHA) promulgated a new standard on December 6, 1991, entitled "Occupational Exposure to Bloodborne Pathogens". (See Appendix A.) The purpose of this regulation is to limit occupational exposure to blood and other potentially-infectious materials, since any exposure could result in transmission of bloodborne pathogens which could lead to disease or death.

Scope

OSHA's Occupational Exposure to Bloodborne Pathogens standard covers all employees who could be "reasonably anticipated", as the result of performing their job duties, to have contact with blood and other potentially infectious materials. OSHA has not attempted to list all occupations where exposure could occur. It leaves this task to the employer. "Good Samaritan" acts, such as assisting a coworker with a nosebleed, would not be considered occupational exposure.

Infectious Material Defined:

Infectious material includes: human blood, human blood components, products made from human blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, amniotic fluid, saliva in dental procedures, body fluid visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. They also include any unfixed tissue or organ other than intact skin from a human (living or dead), human immunodeficiency virus (HIV)-containing cells or tissue cultures, organ cultures, HIV or Hepatitis B (HBV)-containing culture medium or other solutions, as well as blood, organs or other tissues from experimental animals infected with HIV or HBV.

Exposure Control Plan Defined:

The standard calls for the creation of an exposure control plan which is designed to identify in writing, tasks and procedures, as well as job classifications where occupational exposure to blood or other potentially infectious materials occurs. This evaluation should be without regard to personal protective clothing and equipment. It must also set forth the schedule for implementing other provisions of the standard and specify the procedure for evaluating circumstances surrounding exposure incidents. The plan must be accessible to employees and available to OSHA. Employers must review and update it at least annually and more often, if necessary, to accommodate workplace changes.

Exposure Determination

OSHA' s Occupational Exposure to Bloodborne Pathogens standard requires that each employer prepare an exposure determination for its facility. This exposure determination will include all job classifications with potential exposures and all tasks and procedures in which occupational exposure occurs and that are performed by employees listed in the at-risk job classifications.

Jobs in which all employees will have occupational exposure to bloodborne pathogens:

1. Medical Doctors
2. Dentist
3. Nurses
4. Nurses AidesPhysician Assistants
5. Technologists (Clinical)
6. Technicians (Clinical)
7. Mortuary Workers

Jobs in which some employees may have occupational exposure to bloodborne pathogens:

1. Ph.D.s
2. Post Doctoral Fellows
3. Research Technicians
4. Housekeeping Staff
5. Engineering Staff
6. Animal Caretakers
7. Security
8. Messenger

Tasks and procedures in which occupational exposure to bloodborne pathogen occurs in the job classifications listed:

Phlebotomy and injections - Handling blood specimens and other body fluid specimens X-rays of open woundsVenipuncture

Procedures involving body orifices such as pelvics and sigmoids Cleaning, maintaining and sterilizing instruments Biopsy

Catheterizations, cauterizations, lacerations Housekeeping tasks - toilets, floors, emptying infectious wastes Patient examination

Contact with saliva with the possibility of blood present Housekeeping and laundry - blood-soaked linens Diagnostic procedure involving patient bodily fluids

Clinical laboratory assays or tests involving potentially-infectious materials Cell, tissue or organ culture Blood culture

Cell separation Research procedures involving potentially-infectious material Animal injection with human pathogens

Embalming. Human tissue pathological analysis Transporting blood or related products

Cleaning blood spills Repairing and cleaning contaminated equipment Certain laboratory repair work, e.g., plumbing

We have distributed and Exposure Identification Form, (see Appendix B) to all departments to help identify individuals who may be exposed to bloodborne pathogens in the course of their work at YU or Albert Einstein College of Medicine.

Infection Control Program Coordinator:

Yeshiva University and the Albert Einstein College of Medicine of Yeshiva University have named the following:

- Albert Einstein College of Medicine - Delia Vieira-Cruz
- Yeshiva University - Steven Kozak

As Program Coordinators, charged with overall responsibility for the Exposure Control Plan in compliance with OSHA' s Occupational Exposure to Bloodborne Pathogens standard. The Program Coordinators have the full support and authority of Yeshiva University and the Albert Einstein College of Medicine to ensure compliance with the conditions of OSHA' s Bloodborne Pathogen standard is maintained.

Yeshiva University and the Albert Einstein College of Medicine is complying with this standard by determining exposure risks of personnel, implementing an infection control program, providing Hepatitis B vaccinations at no cost to our employees, and providing extensive training in the form of lecture, written material and videotapes.

The Program Coordinators have overall responsibility for the Exposure Control Plan and will review and maintain the program for Yeshiva University and the Albert Einstein College of Medicine. This is your copy of the written plan. It is a supplement to our videotape and lecture training.

The Exposure Control Plan will inform you of the contents of the OSHA standard, as it applies to Hepatitis, AIDS transmissions and other bloodborne pathogens, the use of protective clothing, safe work practices and or vaccination protocol.

The Principal Investigator or department head is ultimately responsible for the individuals under his supervision. Proper instruction and supervision is essential to the elimination of risks to the worker.

The worker, with daily contact with potentially-infectious agents, has a responsibility to remain informed and follow the guidance outlined in the Exposure Control Plan.

Introduction

Many healthcare and laboratory workers are exposed to blood and other potentially-infectious materials from patients who have active bloodborne infections or are carriers of infections. These exposures present a potential risk of disease. At Yeshiva University and the Albert Einstein College of Medicine, personnel who are at risk are identified on Page 3 of this plan. Building service personnel and other employees who handle medical waste may be exposed, if they are injured by contaminated needles and sharps.

The bloodborne disease which presents the greatest risk is Hepatitis B. According to surveys conducted by the Centers for Disease Control (CDC), an estimated 300,000 new Hepatitis B infections occur each year in the United States. Nearly 10% of those infected become long-term carriers. OSHA estimates that direct workplace exposures may produce up to 8,700 Hepatitis B infections each year in the United States, causing as many as 2,175 cases of clinical acute Hepatitis, 435 hospitalizations and 194 deaths.

The acquired immune deficience syndrome (AIDS) is also of great concern to individuals exposed to blood or other potentially-infectious materials. As of December 31, 1991, the CDC had received reports of more than 202,843 cases of AIDS, including more than 130,687 deaths. It is estimated that over one million people may be infected with the human immunodeficiency virus (HIV), the virus that causes AIDS. Many of these infected people have no symptoms of illness. While HIV infection represents a real hazard to healthcare workers, only a small number of infections have resulted from occupational exposures. The risk of infection with the Hepatitis B virus (HB) is much greater.

When healthcare workers have been infected with HIV or HBV on the job, it has usually been through accidental needlesticks or blood spills or splashes on broken skin or mucous membranes. Generally, contact with saliva, urine, sweat or tears does not pose a risk of exposure to HIV or HBV unless these substances contain visible blood.

In December, 1991, OSHA published a standard to protect employees from exposure to HIV, HBV, and other bloodborne pathogens.

OSHA' s Occupational Exposure to Bloodborne Pathogens standard focuses on two pathogens, Hepatitis B virus (HBV) and the Human Immunodeficiency Virus (HIV). There are other pathogens that can be transmitted through blood, blood products or body fluids.

Hepatitis Transmission

Hepatitis B (HBV) is a virulent infections disease which claims an estimated 300,000 new cases every year. Over one million people in the U.S. are carriers of the disease. Hepatitis B is transmitted to healthcare workers via blood and body fluids of infected patients, usually through accidental needlesticks and unprotected cuts and sores.

Hepatitis B is most prevalent among intravenous drug users sharing needles and through sexual contact among homosexually active males and female prostitutes. From these groups, it spreads to the community. It infects 18,000 healthcare employees per year, such as operating room personnel, lab

workers, surgeons, dental personnel and blood bank technicians. They are usually infected through contact with bloodborne pathogens and accidental needlestick injuries.

Hepatitis symptoms often include jaundice, a yellow hue to the skin, loss of appetite, nausea, and elevated liver function tests. AIDS and Hepatitis dangers can be prevented or reduced by:

- using protection against body fluids during at-risk procedures,
- using Disinfectants to reduce pathogens in the environment,
- taking thorough patient medical histories,
- washing hands between patient treatment contacts,
- using puncture-resistant sharps containers for needle disposal,
- using the appropriate biosafety containment and microbiological practices when working with potentially-infectious material in the laboratory.

Hepatitis Protection

OSHA enforces the CDC (Centers for Disease Control) recommendations. OSHA requires every healthcare worker, who may have any "occupational exposure" defined to include any skin, eye, mucous membrane or parenteral contact with potentially-infectious materials on the job, be offered a Hepatitis B vaccination. The Hepatitis B vaccine can be obtained through Occupational Health Service.

An employee who refuses inoculation must sign an Informed Refusal Form in the possession of Occupational Health Service.

AIDS Transmission

AIDS (HIV) is not as contagious in a healthcare or laboratory setting as Hepatitis, but it has no vaccine for prevention. It is transmitted through body fluid, so healthcare workers are exposed to it.

OSHA requires that employees be trained in prevention and be required to protect themselves during at-risk procedures.

AIDS is transmitted sexually through blood or semen. It is most commonly seen in homosexual and bisexual men, IV drug users, and hemophiliacs. However, it is being reported with increasing frequency in the heterosexual community and in children born of HIV-infected mothers.

AIDS is transmitted sexually and through blood exposure or perinatally from the mother to the child. AIDS is not transmitted through general contact with a carrier.

Symptoms of HIV infection are varied and include: fatigue, fever, weight loss, night sweats, rashes, mouth sores, or pneumonia.

Because there is no inoculation against AIDS, The CDC recommends and OSHA requires that "Universal Precautions" be instituted in all healthcare or laboratory settings where the potential for HIV infection is present.

Universal Precautions

Under "Universal Precautions", the blood and body fluids of all patients are considered potentially infected with AIDS virus (HIV), Hepatitis B virus (HBV) and other bloodborne pathogens, and must be handled accordingly.

Universal Precautions applies to blood and body fluids containing visible blood, including cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal and pericardial fluid and amniotic fluid. It does not include feces, nasal secretions, sputum, sweat, tears, urine, saliva, breast milk and vomitus, unless blood is present.

The amount of blood required to constitute an infectious risk has been variously defined by OSHA, EPA and others as "substantial", "dripping" and "significant". EPA has offered an objective definition that 15 milliliters of blood (about the size of three teaspoons), must be present to be of sufficient does to be infectious. This definition of quantity does not preclude the use of protective clothing; it only helps to define what constitutes infectious waste when disposing of blood-soaked materials. When differentiation is difficult, all bodily fluids shall be considered potentially infectious.

See Appendix D for reference chart on "Universal Precautions for Laboratory Workers".

Definitions of Infectious Conditions

Infection needs four simultaneous conditions to exist. If you take any condition away, the danger from infection will be reduced or eliminated. The conditions which must exist simultaneously are:

- A sufficiently large dose to constitute a dangerous quantity.
- A sufficient virulence, or deadliness, to be dangerous.
- A portal of entry into a host, such as through an open cut or the nasal passages.
- A susceptible resistance level of the host. For instance, if a worker is tired, has the flu or a cold, the host is more susceptible to infection.
- Infectious diseases are prevented by reducing or removing any of these conditions. For example:
- The use of gloves and masks will eliminate portals of entry.
- Regular handwashing and the use of Disinfectants will remove or reduce the dose and virulence of the disease.
- The placement of sharps and needles into commercial sharps containers and the avoidance of recapping will reduce needlestick injuries.

Engineering Controls

Use devices engineered to prevent exposures when they are available.

Such devices include: puncture-resistant sharps containers, splash guards, biological safety cabinets, safety syringes, needless IV systems, centrifuge safety cups and mechanical pipetting devices.

Protective Clothing and Equipment

Most personal protective equipment is provided by YU and Albert Einstein College of Medicine to employees when and where necessary. It is the responsibility of each employee and supervisor to be certain that the appropriate equipment is worn as necessary.

The most fundamental piece of personal protective clothing is provided by each employee for his/her own use. It is the normal clothing worn in the laboratory. Clothing should be worn to minimize exposed skin surfaces available for direct contact through splashing. Therefore, all employees should wear long sleeve/long legged clothing and avoid short sleeved shirts, short trousers or skirts.

Additional equipment is available through your supervisor and the Department of Environmental Health and Safety as follows:

- Eyewear
- Aprons
- Lab coats
- Face Shields
- Gloves
- Respirators

Personal protective equipment shall be of safe design and construction, maintained in a sanitary condition, and stored in accessible locations in the facility.

Your supervisor will provide protective clothing in the laboratory area, nurses' station area and in locations where infectious wastes may be generated. The Infection Control Coordinator will provide guidance in the appropriate selection of protective clothing commensurate with the exposure risks in each area.

The use of protective equipment is an OSHA requirement.

Gloves

Three basic glove types are provided in this facility:

1. Utility gloves or strong latex for maintenance and scrubbing work. These are reusable until they puncture, tear, or crack
2. Sterile gloves for procedures involving contact with normally sterile areas of the body or when performing sterile procedures in the laboratory.
3. Examination gloves for patient diagnostic procedures not requiring the use of sterile gloves and four routine infection prevention. Examination gloves are routinely used in a medical research setting.

After donning gloves, examine them for physical defects. Wear gloves whenever your hands might touch blood, body fluids, or surfaces which could be contaminated by them. Discard gloves after each patient,

after laboratory procedures, or if you suspect contamination. Fit gloves so they cover the cuff of your clothing, if possible to reduce the area of skin exposure. Sleeve guards are also available to use in conjunction with disposable gloves.

Gloves must be used:

- If the skin of the healthcare or laboratory worker is cut, abraded, chapped.
- When the employee' s hands might contact blood or other potentially-infectious material.
- When examining abraded or non-intact skin or patients with active bleeding.
- During invasive procedures.
- During Housekeeping and cleaning involving body fluids and decontaminating procedures. Reusable heavy utility gloves should be used for these procedures.

Gloves must be of good quality latex or vinyl, able to perform the task, and fit the healthcare worker properly. Surgical and examination gloves cannot be reused. Only general purpose utility (rubber) gloves are reusable, i.e., those gloves worn by maintenance and Housekeeping. Peeled, cracked, discolored, torn, or deteriorated gloves must be discarded, even if they have not been used. Never wear gloves that may have been exposed to infectious material outside of the laboratory or medical area, including corridors.

Gowns, Laboratory Coats & Head Covering

Gowns or laboratory coats are worn to protect street wear and the arm and neck areas from contamination. They should be changed regularly unless they become soiled or wet and then changed as soon as possible. Gowns and laboratory coats act as an additional layer of skin.

Head coverings are worn whenever procedures are performed or chemicals are handled which might create splashing or aerosolization. They should cover the hair, ears, and parts of the neck and face.

Never wear gowns or laboratory coats that may have been exposed to infectious material outside of the medical or laboratory setting, including corridors.

Protective Clothing Disposal

Linens and reusable protective clothing which are heavily soiled with body fluids shall be handled as little as possible and must be bagged at the location in leakproof, autoclave bags.

When removing protective clothing apparel, avoid contamination of your exposed body parts. If possible, autoclave this linen prior to having it cleaned.

Protective Eyewear: Goggles

Goggles protect the eyes from splashing and aerosolization of body fluids and harmful chemicals. If a procedure presents a danger of splashing or if a manufacturer recommends that goggles be worn when using their produce, the employee must wear goggles. Goggles are to be supplied by the area supervisor.

Masks

Masks are worn if there is a likelihood of splashing or aerosolization of blood or other infectious material.

Masks reduce the entry of infectious droplets into the breathing passages.

Chin-length face shields are sometimes worn in place of a mask. These are uncommon in medical offices but are more common in laboratory or hospital settings.

Standard Work Practices

Assume that blood or blood-related produces are infectious. Follow Universal Precautions outlined in Appendix D.

Wear personal protective equipment when handling blood or related products (gloves, laboratory coat, goggles, etc.).

Use a biological safety cabinet to contain procedures that generate aerosols.

Use sealed tubes and sealed centrifuge containers when centrifuging blood or other infectious materials.

Handle blood and other potentially-infectious materials carefully, in order to minimize the potential for splashing and spraying.

Do not mouth pipette. Use mechanical pipetting devices.

Clean contaminated areas with a 10% solution of Clorox in water.

Never bend or cut needles or recap them using a two-handed technique.

Do not eat, drink, smoke, apply cosmetics or lip balm, or insert/remove contact lenses in areas where you could be exposed to blood or other potentially-infectious materials.

Dispose of infectious waste properly.

Wash hands with simple soap and water or antimicrobial solution to protect against external and internal exposure to bloodborne pathogens. Hands must be washed under the following conditions:

- before gloving
- after gloves are removed
- after contact with each patient or patient sample
- before leaving the laboratory or medical office
- before eating
- after your hands have touch a possibly-contaminated surface

Hepatitis B Vaccine

HBV vaccine is provided free of charge to all potentially exposed workers through our Occupational Health Service. The vaccine is administered in a 3-dose series given over a six-month period and protects the employee for at least seven years.

If an employee does not elect to take advantage of HBV immunization measures, Occupational Health Service must record this election on an "Informed Refusal" form and it must be signed by the employee. (See Appendix C.)

All new hires listed in groups A and B will be offered the vaccine within ten days of starting their employment. All existing employees in groups A and B will be offered the vaccine by July 6, 1992.

Sharps

Needlestick injuries often occur when cleaning or disposing of sharp instruments and needles. Used needles should not be sheared, bent, broken, or recapped by hand, nor should used needles be removed from disposable syringes.

Sharps containers must be closely available at the location where infectious bioburden is generated, i.e., where the venipunctures occur or on the laboratory bench. Do not overfull sharps containers.

The CDC recommends (but does not require) that a disinfecting solution be used in the sharps container to break the chain of infection.

The Department of Environmental Health and Safety recommends that infectious sharps be autoclaved in their sharps container prior to release as medical waste. See YU' s and Albert Einstein College of Medicine' s Waste Disposal Guidelines (Appendix E) for further information on proper sharps disposal.

Infectious Waste

Infectious waste disposal is governed by Federal, State, and City regulations. Infectious waste should always be inactivated, if possible, either chemically or by autoclaving prior to disposal as regulated medical waste. If this is not possible, then the infectious waste should be sealed in a plastic bag and disposed into a regulated medical waste container.

A receptacle for putrescible solids, liquid waste or refuse, must be so constructed that it does not lead. The receptacle must be able to thoroughly cleaned and maintained in a sanitary condition and shall be equipped with a solid, tight-fitting cover.

Used needles shall not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. These sharp items must be placed in a puncture-resistant container for disposal. A commercial sharps container is suitable.

Sharps containers must be easily accessible to personnel needing them and located where needles are commonly used.

Lab specimens and body fluid specimens must be contained in a well-constructed, leakproof container during transport. Before transport, contaminated materials must be decontaminated or placed into a tight bag marked with a Biohazard tag.

See YU and Albert Einstein College of Medicine Waste Disposal Guidelines (Appendix E) for further information on proper waste disposal.

Spills

Disinfect blood spills with a freshly-prepared one in ten dilution of household bleach.

See YU and Albert Einstein College of Medicine Waste Disposal Guidelines (Appendix E) for further information on proper waste disposal.

Housekeeping

Many safety and health injuries occur because of inadequate cleaning, repair and maintenance.

Clean and disinfect the general medical or laboratory environment with a solution of at least 1 part sodium hypochlorite (bleach) to 100 parts of water, or equivalent disinfectant.

Clean exposed equipment and environmental surfaces after contact with blood and other infectious agents, and at the end of the work shift.

Apply hospital-level tuberculocidal disinfectant on blood spills. These Disinfectants should be made available in all work settings where blood and infectious materials are handled.

Disinfect medical or laboratory instruments with approved hospital Disinfectants (tuberculocidal at recommended dilutions) or in autoclaves.

Place biohazard labels on sharps containers, infectious waste containers, refrigerators and holding media containing blood and other potentially infectious materials.

Disinfectants

Tuberculocidal hospital-level Disinfectants must be used to decontaminate spills of blood and other body fluids.

After the initial clean-up of a blood spill, a solution of 5.25 percent sodium hypochlorite (household bleach) diluted between 1:10 and 1:100 with water, or other suitable disinfectant, may be used.

Warning Tags and Signs

Warning tags must be used to prevent accidental injury or illness to employees who are exposed to equipment or operations which are hazardous and are unexpected, unusual, or not readily apparent. The tags must stay in place until the hazard is eliminated.

The tags must contain the Biohazard Symbol, a SIGNAL WORD such as Biohazard and the MAJOR MESSAGE such as Blood Banking Products Inside.

The signal word must be readable at a minimum distance of 5 feet. The warning tag must be affixed as close as safely possible to the hazard string, wire, or adhesive to prevent its loss or unintentional removal.

The major message of the warning tag must be understandable by all employees who may be exposed to the hazard. It can be written in pictographs, written text, or both.

All employees in the workplace must be informed of the meaning of various tags in the workplace and what precautions to take.

Biological Hazard Tag - The biohazard symbol warns of the actual or potential presence of biological hazards. It must be displayed on equipment, containers and rooms that contain or are contaminated with hazardous biological agents.

Medical Research Laboratory Control of Bloodborne Pathogens

Yeshiva University and the Albert Einstein College of Medicine has adopted the principles of biosafety outlined in the Centers for Disease Control/National Institutes of Health guide entitled, "Biosafety in Microbiological and Biomedical Laboratories". This guide defines different Biosafety Levels based upon infectious agents involved. since a number of these agents can be considered bloodborne pathogens, a description of the different Biosafety Levels of containment will be provided. The following, Section 24.1, is an excerpt from the CDC/NIH Guide.

Biosafety Levels

Four Biosafety Levels (BSLs) are described which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and for the laboratory function or activity.

The recommended biosafety level(s) for the organisms in Section VII (Agent Summary Statements) represent those conditions under which the agent can ordinarily be safely handled. The laboratory director is specifically and primarily responsible for assessing risks and for appropriately applying the recommended Biosafety Levels. Generally, work with known agents should be conducted at the biosafety level recommended in Section VII. When specific information is available to suggest that

virulence, pathogenicity, antibiotic resistance patterns, vaccine and treatment availability, or other factors are significantly altered, more (or less) stringent practices may be specified.

Biosafety Level 1 - practices, safety equipment, and facilities are appropriate for under-graduate and secondary educational training and teaching laboratories, and for other facilities in which work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. Bacillus subtilis, Naeglera gruberi, and infectious canine hepatitis virus are representative of those microorganisms meeting these criteria. Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause infection in the young, the aged, and immunodeficient or immunosuppressed individuals. Vaccine strains which have undergone multiple in vivo passages should not be considered a virulent simply because they are vaccine strains. Biosafety Level 1 represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for handwashing.

Biosafety Level 2 - practices, equipment and facilities are applicable to clinical, diagnostic, teaching, and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided the potential for producing splashes or aerosols is low. Hepatitis B virus, the salmonellae, and Toxoplasma spp. are representative of microorganisms assigned to this containment level. Biosafety Level 2 is appropriate when work is done with any human-derived blood, body fluids, or tissues where the presence of an infectious agent may be unknown. (Laboratory personnel working with human-derived materials should refer to the Bloodborne Pathogen Standard187 for specific, required precautions.)

Primary hazards to personnel working with these agents related to accidental percutaneous or mucus membrane exposures, or ingestion of infectious materials. Extreme precaution with contaminated needles or sharp instruments must be emphasized. Even though organisms routinely manipulated at BSL2 are known to be transmissible by the aerosol route, procedures with aerosol or high splash potential may increase the risk of such personnel exposure must be conducted in primary containment equipment, or devices such as a BSC or safety centrifuge cups. Other primary barriers should be used as appropriate, such as splash shields, face protection, gowns and gloves.

Secondary barriers such as handwashing and waste decontamination facilities must be available to reduce potential environmental contamination.

Biosafety Level 3 - practices, safety equipment, and facilities are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection. Mycobacterium tuberculosis, St. Louis encephalitis virus, and Coxiella burnetti are representative of microorganisms assigned to this level. Primary hazards to personnel working with these agents relate to atuoinoculation, ingestion, and exposure to infectious aerosols.

At Biosafety Level 3, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols. For example, all laboratory manipulations should be performed in a BSC or other enclosed equipment such as a gas-tight aerosol generation chamber. Secondary barriers for this level include controlled access to the laboratory and a specialized ventilation system that minimizes the release of infectious aerosols from the laboratory.

Biosafety Level 4 - practices, safety equipment, and facilities are applicable for work with dangerous and exotic agents which pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route, and for which there is no available vaccine or therapy. Additionally, agents with a close or identical antigenic relationship to Biosafety Level 4 agents should also be handled at this level. When sufficient data are obtained, work with these agents may continue at this level or at a lower level. Viruses such as Marburg or Congo-Crimean hemorrhagic fever are manipulated at Biosafety Level 4.

The primary hazards to personnel working with Biosafety Level 4 agents are respiratory exposure to infectious aerosols, mucous membrane exposure to infectious droplets, and auto-inoculation. All manipulations of potentially-infectious diagnostic materials, isolates, and naturally or experimentally infected animals pose a high risk of exposure and infection to laboratory personnel, the community and the environment.

The laboratory worker’ s complete isolation of aerosolized infectious materials is accomplished primarily by working in a Class III BSC or a full-body, air supplied positive-pressure personnel suit. The Biosafety Level 4 facility itself is generally a separate building or completely isolated zone with complex, specialized ventilation and waste management systems to prevent release of viable agents to the environment.

The laboratory director is specifically and primarily responsible for the safe operation of the laboratory. His/her knowledge and judgement are critical in assessing risks and appropriately applying these recommendations. The recommended biosafety level represents those conditions under which the agent can ordinarily be safely handled. Special characteristics of the agents used, the training and experience of personnel, and the nature or function of the laboratory may further influence the director in applying these recommendations.

Animal Facilities - Four Biosafety Levels are also described for activities involving infectious disease work with experimental mammals. These four combinations of practices, safety equipment, and facilities are designated Animal Biosafety Levels 1,2,3, and 4 and provide increasing levels of protection to personnel and the environment.

Clinical Laboratories - Clinical laboratories, especially those in health care facilities, receive clinical specimens with requests for a variety of diagnostic and clinical support services. Typically, the infectious nature of clinical material is unknown, and specimens are often submitted with a broad request for microbiological examination for multiple agents (e.g., sputa submitted for "routine", acid-fast, and fungal cultures). It is the responsibility of the laboratory director to establish standard procedures in the laboratory which realistically address the issue of the infective hazard of clinical specimens.

Except in extraordinary circumstances (e.g., suspected hemorrhagic fever), the initial processing of clinical specimens and identification of isolates can be done safely at Biosafety Level 2, the recommended level for work with bloodborne pathogens such as Hepatitis B virus and HIV. The containment elements described in Biosafety Level 2 are consistent with the Occupational Exposure to Bloodborne Pathogens Standard187 from the Occupational Safety and Health Administration (OSHA), that requires the use of specific precautions with all clinical specimens of blood or other potentially infectious material (Universal Precautions).43 Additionally, other recommendations specific for clinical laboratories may be obtained from the National Committee for Clinical Laboratory Standards.134

Biosafety Level 2 recommendations and OSHA requirements focus on the prevention of percutaneous and mucous membrane exposures to clinical material. Primary barriers such as biological safety cabinets (Class I or II) should be used when performing procedures that might cause splashing, spraying, or splattering of droplets. Biological safety cabinets should also be used for the initial processing of clinical specimens when the nature of the test requested or other information is suggestive that an agent readily transmissible by infectious aerosols is likely to be present (e.g., M. tuberculosis), or when the use of a biological safety cabinet (Class II) is indicated to protect the integrity of the specimen.

The segregation of clinical laboratory functions and limiting or restricting access to such areas is the responsibility of the laboratory director. It is also the director' s responsibility to establish standard, written procedures that address the potential hazards and the required precuations to be implemented.

*Note that Appendix F includes a detailed description of the practices, equipment and facilities of each of the four Biosafety Levels.

Medical Research Involving HIV

Medical Research Involving HIV can be performed under Biosafety Level 2, provided that there is no attempt to concentrate the virus above the levels normally found in human blood. If the HIV virus will be concentrated or an experimental procedure may increase the likelihood of worker exposure, then Biosafety Level 3 practices and facilities should be considered. With any procedure involving HIV, care should be taken to reduce or eliminate exposure to sharps. (Needlesticks have been the major route of exposure to HIV by healthcare and laboratory workers.)

What to do in Case of HIV or HBV Exposure

If the exposure is the result of a needlestick or cut, encourage bleeding and was immediately with soap and water.

The employee must immediately report the exposure incident to the supervisor. (Time is of the essence. results can often be improved by prompt action.) The supervisor will immediately refer the potentially exposed individual to Occupational Health Service for post exposure and evaluation. Occupational Health Service will evaluate and treat the individual based on guidelines set forth in OSHA' s "Bloodborne Pathogen Standard".

Occupational Health Service will seek to identify and test the source patient for HIV and HBV infection. The New York State consent form for HIV testing must be signed.

The Program Coordinator prepares and Exposure Incident Form and an OSHA Form 101 on the event.

Go to Occupational Health Services for post-exposure evaluation and treatment. Forms which must be forwarded to, or available at, Occupational Health Service include:

- a copy of the Exposure Incident Form
- a copy of the Employee Medical Record Form of Vaccination History and Exposure Incidents
- a statement of the employee' s duties and circumstances of the exposure incident; the employee' s HBV vaccination status and other relevant information
- a copy of the OSHA standard requiring post-exposure evaluation and follow up by the health care facility.

The physician evaluating the worker will determine if prophylaxis or medical treatment is indicated. The employer does not have a specific right to know the actual results of the source individual' s blood tests. The employer is responsible for providing results of any HBV testing previously done.

Exposure Follow Up. YU and Albert Einstein College of Medicine provides testing for all employees who have had an exposure incident plus any laboratory tests by an accredited laboratory at no cost to the employee.

Follow up must include a confidential medical which documents the circumstances of exposure, identifying and testing the source individual if feasible, testing the exposed employee' s blood if he/she consents, post-exposure prophylaxis, and counseling and evaluation of the reported illnesses.

A written opinion to the employer by the physician will be provided, as required by the OSHA standard, and a confidential medical evaluation with a review of all the circumstances of exposure will be provided to the employee. If the exposed employee agrees to a baseline collection but not to HIV testing, the blood sample must be preserved for at least 90 days during which time the sample can be used for testing, should the employee wish and consent to it.

Information and Training

Each employee with occupational exposure to bloodborne pathogens will be provided with information and training during working hours.

Training shall be provided as follows:

- At the time of initial assignment to tasks where occupational exposure may take place,
- Within 90 days after the effective date of the standard and
- At least annually thereafter.

For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard. Only training with respect to the provisions of the standard which were not included need be provided.

Annual training for all employees shall be provided within one year of their previous training.

The Principal Investigator shall provide additional training when changes such as modifications of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

Material appropriate in content and vocabulary to educational level, literacy, and language of employees will be used.

The training program shall contain, at a minimum, the following elements:

An accessible copy of the regulatory test of this standard and an explanation of its contents

A general explanation of the epidemiology and symptoms of bloodborne diseases

An explanation of the modes of transmission of bloodborne pathogens

An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan

An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials

An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment

Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment

An explanation of the basis for selection of personal protective equipment

Information on the Hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated and that the vaccine and vaccination will be offered free of charge.

Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials

An explanation of the procedure to follow, if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available

Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident

An explanation of the signs and labels and/or coding required

An opportunity for interactive questions and answers with the person conducting the training session.

The person conducting the training will be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to Yeshiva University and the Albert Einstein College of Medicine Campus.

Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

The Principal Investigator or Department Chairman 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 HIV or HBV.

The Principal Investigator or Department Chairman shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

The Principal Investigator or Department Chairman shall 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.

RECORDKEEPING

A. Medical Records

YU and Albert Einstein College of Medicine will establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29CFR 1910.20.

This record will include:

- The name and social security number of the employee.
- A copy of the employee's Hepatitis B vaccination status including the dates of all the Hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required.
- A copy of all results of examinations, medical testing and follow-up procedures as required. (The actual medical record will be kept by Occupational Health Service.)
- The employer's copy of the healthcare professional's written opinion as required.
- A copy of the information provided to the healthcare professional as required.

Confidentiality. YU and Albert Einstein College of Medicine will ensure that employee medical records required are:

- Kept confidential and
- Are not disclosed or reported without the employee' s expressed written consent to any person within or outside the workplace except as required by law.

YU and Albert Einstein College of Medicine will maintain the records required for at least the duration of employment plus 30 years in accordance with 20CFR 1910.20.

B. Training Records

Training records shall include the following information:

- The dates of the training sessions
- The contents or a summary of the training sessions
- The names and qualifications of persons conducting the training
- The names and job titles of all persons attending the training sessions

Training records shall be maintained for 3 years from the date on which the training occurred.

C. Availability

YU and Albert Einstein College of Medicine will ensure that all records, required to be maintained by this section, will be made available upon request to the assistant secretary and the director for examination and copying.

Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the director, and to the assistant secretary in accordance with 29CFR 1910.20.

Employee medical records required will be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the director, and to the assistant secretary in accordance with 29CFR 1910.20.

D. Transfer of Records

YU and Albert Einstein College of Medicine will comply with the requirements involving transfer of records set forth in 29CFR 1910.20(h).

If YU and/or Albert Einstein College of Medicine ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, YU and/or Albert Einstein College of Medicine will notify the director, at least three months prior to their disposal and transmit them to the director, if required by the director to do so, within that three month period.

References

Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Public Health Service, Centers For Disease Control and Prevention and, National Institutes of Health Third Edition, May 1993.

Biohazard/Reference Manual, American Industrial Hygiene Association, 1985.

Biosafety in the Laboratory/Prudent Practices for the Handling and Disposal of Infectious Material, National Academy Press, 1989.

Occupational Exposure to Bloodborne Pathogens, Occupational Safety and Health Administration 29CFR Part 1910.1030, December 6, 1991.

Telephone Numbers

Albert Einstein College of Medicine 718-430-3560

Yeshiva University 212-960-0081

Occupational Health Services 718-430-3141

Centers for Disease Control 404-639-3311

CDC Voice Information Service 404-332-4555

National AIDS Clearing House 800-458-5231

National Institute for Occupational Safety & Health 800-356-4674

National HIV and AIDS Information Service 800-342-2437

New York State Department of Health, AIDS Institute 518-474-4284

Occupational Safety and Health Administration (OSHA) 212-2649840