

**Massachusetts College of Pharmacy
and Health Sciences**



Exposure Control Plan

Department of Environmental, Health and Safety

Revised
January 2024

BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

A. Purpose

This Exposure Control Plan for the Massachusetts College of Pharmacy and Health Sciences (MCPHS) is to establish the process for compliance with the Occupational Safety and Health Administration (OSHA) regulation, "Occupational Exposure to Blood borne Pathogens; Final Rule" (29 CFR Part 1910.1030) and its amendments.

B. Policy

MCPHS is dedicated to providing a safe workplace for employees and students. It is MCPHS's policy to comply with the requirements of the OSHA Blood borne Pathogens (BBP) Standard. Academic Deans, Department Chairs/Directors, managers, supervisors, faculty, staff, and students share responsibility for minimizing their occupational exposure to human blood and other potentially infectious materials. The *Exposure Control Plan* (ECP) shall be implemented for all campuses where performance of student's and employees' duties can be expected to result in occupational exposure to human blood or other potentially infectious materials.

C. Definitions

Blood means human blood, human blood components, and products made from human blood.

Blood borne 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).

Contaminated sharps means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on a sharp item or surface.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy blood borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Engineering Controls means controls (e.g., sharp disposal containers, self-sheathing needles) that isolate or remove the blood borne pathogens hazard from the workplace.

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.

Employee refers to individuals who are at risk to occupational exposure from blood borne pathogens

D. Standard (Universal) Precautions

Standard precautions shall be observed at all times when working with human blood or other potentially infectious material. Standard precautions apply to blood, any other body fluid containing visible blood, and other potentially infectious material.

- a. Under circumstances in which differentiation between body fluids types is difficult or impossible, all body fluids shall be considered potentially infectious materials.
 - b. Standard precautions do not apply to feces, nasal secretions, sputum, saliva, sweat, tears, urine, or vomitus unless they contain visible blood.
 - c. Other potentially infectious materials means the following human body fluids:
 - i. Semen,
 - ii. Vaginal secretions,
 - iii. Pericardial fluid,
 - iv. Cerebrospinal fluid,
 - v. Synovial fluid,
 - vi. Pleural fluid,
 - vii. Peritoneal fluid,
 - viii. Amniotic fluid,
 - ix. Saliva in dental procedures,
 - x. Any body fluid that is visibly contaminated with blood,
 - xi. All body fluids in situations where it is difficult or impossible to differentiate between body fluids,
 - xii. Any unfixated tissue or organ (other than intact skin) from a human, living or dead, human immunodeficiency virus (HIV)- containing cell or tissue cultures, organ cultures, and HIV or hepatitis B virus (HBV)-containing culture medium or other solutions, and
 - xiii. Blood, organs, or other tissues from experimental animals infected with HIV, HBV, or other diseases infectious to humans.
- A. Employees must wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment, and following contact with blood or other potentially infectious materials.
 - B. Contaminated needles or other contaminated sharps must not be recapped, sheared, bent, broken or resheathed by hand. Contaminated sharps must be placed in appropriate containers until properly reprocessed or disposed. These containers shall be:
 1. Puncture resistant,
 2. Labeled or color-coded, and
 3. Leak-proof on the sides and bottom.
 - C. Specimens of blood or other potentially infectious materials should be placed in a labeled or color-coded container which prevents leakage during collection, storage, transport, or shipping. A secondary container must be used if the primary container is contaminated, punctured or leaking.
 - D. Equipment which has been in contact with blood or other potentially infected material must be examined and decontaminated by laboratory personnel as necessary prior to servicing or shipping. If the equipment cannot be completely decontaminated, a readily observable label must be

attached to the contaminated equipment and all parties who will be in contact with the equipment should be notified.

- E. Gloves must be worn when there is potential for contact with blood, or other potentially infectious materials. Disposable (single use) gloves such as surgical or examination gloves must be replaced as soon as possible when visibly soiled, torn, and punctured or when their ability to function as a barrier is compromised.
- F. Additional appropriate protective clothing should be selected and worn based upon the task and degree of exposure anticipated.
 - 1. Gowns, laboratory coats, aprons or similar clothing should be worn if there is a potential for soiling of clothes with blood or other potentially infectious materials.
 - 2. Fluid-resistant clothing should be worn if there is a potential for splashing or spraying of blood or other potentially infectious materials.
 - 3. Surgical caps or hoods should be worn if there is potential for splashing or spraying of blood or other potentially infectious materials.
 - 4. Fluid-proof shoe covers should be worn if there is potential for shoes to become contaminated and/or soaked with blood or other potentially infectious materials.
- G. Work surfaces must be decontaminated with an appropriate disinfectant after completion of procedures; for routine housekeeping or removal of soiling in the absence of visible blood contamination; when surfaces are overtly contaminated; immediately after the spill of blood or other potentially infectious materials; and at the end of the work shift. Appropriate disinfectants/germicidals include those listed in **Appendix A. Sterilization and Disinfection**.
- H. Environmental surfaces such as floors, woodwork, or countertops which have become soiled, should be cleaned and disinfected using any cleaner or disinfectant agent that is intended for environmental use (**Appendix A. Sterilization and Disinfection**):
- I. All bins, pails, cans, and similar receptacles intended for reuse that have a potential for becoming contaminated with blood or other potentially infectious materials should be inspected, cleaned, and disinfected on a regularly scheduled basis and cleaned and disinfected immediately or as soon as possible upon visible contamination (**Appendix A. Sterilization and Disinfection**).
- J. Broken glassware which may be contaminated must not be picked up directly with the hands. It shall be cleaned up by using mechanical means such as a brush and dust pan, a vacuum cleaner, tongs, cotton swabs or forceps.

Other Potentially infectious Materials:

- The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal 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..
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead). 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.

E. WHO IS COVERED

OSHA'S rule applies to all persons with occupational exposure to human blood, body fluids or tissues, or other potentially infectious materials. Occupational exposure is any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of the employee's duties.

Personnel at Risk:

- a) Laboratory Research workers in Biology, Pharmacology, Pharmaceutics, or any other laboratory where personnel exposure to blood borne pathogens exists.
- b) Experiential Faculty, Staff, Students in the Health Sciences
- c) Dental Hygiene Clinic Program
- d) Nursing Program
- e) Physician's Assistance Program
- f) Pharmacy Practice
- g) Students at experiential sites or any other experiential site(s) that involves blood borne pathogens or which possess risk of exposure to blood borne pathogens or other biohazards.
- h) Facilities personnel
- i) Public Safety personnel
- j) Resident Hall Personnel
- k) Any administrative personnel, faculty member or student assisting an injured worker or student.

F. RESPONSIBILITIES

The Director of Environmental, Health and Safety shall:

- (a) Prepare and distribute the Exposure Control Plan;
- (b) Annually review the Exposure Control Plan for effectiveness and update as necessary. The update shall be required to reflect changes in technology that eliminate or reduce exposure to blood borne pathogens.
- (c) Provide or coordinate training for all affected workers concerning occupational transmission of blood borne pathogens, as required in the standard;
- (d) Maintain training records;
- (e) Assist departments in identifying employee job classifications in which occupational exposure to human blood may occur;
- (f) Coordinate disposal of regulated waste

Affected Department Chairs/Directors shall:

- (a) Provide, at no cost to the employee, all supplies and personal protective equipment (PPE) and vaccinations that are necessary for compliance with this Exposure Control Plan;
- (b) Ensure that the Exposure Control Plan is accessible to all employees and students in the worksite and that the Employees and students comply with the requirements of the Plan;
- (c) Provide to the staff and students blood borne pathogen safety training and specific work practice training and maintain copies of those training records.
- (d) Solicit input from non-managerial employees and students who work directly with patients at off site clinics within the identification, evaluation, and selection of effective engineering and work practice controls and document the solicitation.
- (e) Create and develop specific written policies and procedures pertaining to their affected work practices within their respective departments.

MCPHS employees and students with occupational exposure to human blood or other potentially infectious material shall:

- (a) Adhere to the requirements of the Exposure Control Plan;
- (b) Complete all safety training requirements and comply with documentation, procedures; and practices
- (c) Report all suspected exposure incidents.

Director of Resident Life shall:

- (a) Provide blood borne pathogen training to the Residence Assistance Staff.
- (b) The type of training provided to the residence hall personnel is to be documented (e.g., an SOP) and available in the Office of Student Affairs and in the Environmental, Health and Safety Office.

Information

Assistance will be provided by Director of Environmental Health and Safety Office to any Department requesting guidance or training to satisfy implementation of this policy.

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G. PREVENTION

1. Recordkeeping

All records required by the OSHA standard will be maintained by the Environmental, Health Safety Office. The Directors (for academic divisions/departments) and supervisors (for other departments), will be responsible to conduct the review of safety operating procedures [SOP] with support from the Environmental, Health and Safety Office as needed. Written documentation will be obtained that inspections have been carried out with satisfactory results or with steps taken to comply with the Exposure Control Plan. The schedule for reviewing the effectiveness of the controls will be on an annual basis.

2. Protection

a. Personnel

MCPHS will provide disposable protective equipment as much as possible due to the regulations for handling and decontamination of laundry articles. Supervisors also must insure that protective equipment is properly used, cleaned, repaired or replaced as needed, or discarded. Personal protective equipment will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employees' clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. Personal protective equipment such as gloves, eye/face protective devices, lab coats, gowns, aprons, clinic jackets, or similar outer garments used at MCPHS will be provided without cost to employees.

Gloves shall be worn where it is reasonably anticipated that personnel will have hand contact with blood, other potentially infectious materials, non-intact skin, and mucous membranes. (refer to **Appendix J, Information on Gloves** for a more detailed description). Disposable gloves are not to be washed or decontaminated for re-use. The

gloves are to be replaced as soon as practical when they become contaminated, torn, punctured, or when their ability to function as a barrier is compromised.

Eye/face protective devices, such as goggles or glasses with solid side shield, or chin length face shields or masks combination with eye protective devices are required to be worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be anticipated.

The use of disposable protective equipment will eliminate the stringent requirements of laundry decontamination. If this procedure is altered in the future, it will become necessary to develop procedures for proper laundry service.

All employees who have been identified as having exposure to blood or other potentially infectious materials will be offered the Hepatitis B vaccine, at no cost to the employee. The vaccine will be offered within 10 working days of their initial assignment of work involving the potential for occupational exposure to blood or other potentially infectious materials unless the employee has previously had the vaccine or who wishes to submit to antibody testing which shows the employee to have sufficient immunity.

Employees who decline the Hepatitis B vaccine must sign a waiver. (See **Appendix B**)

Employees who initially decline the vaccine but who later wish to have it may then have the vaccine provided at no cost.

b. Workplace

The workplace must be kept clean and sanitary. A cleaning schedule that includes appropriate methods of decontamination, considers the location of the laboratory, type of surfaces to be cleaned, type of contamination present, and the tasks or procedures to be performed. Hand washing facilities are available to all employees. These facilities must be readily accessible after incurring exposure.

In work areas where there is a reasonable likelihood of exposure to blood or other potentially infectious materials, employees shall not eat, drink, apply cosmetics or lip balm, or handle contact lenses. These areas should be designated by appropriate signs and noted during training. Food and beverages shall not be kept in refrigerators, freezers, shelves, cabinets, or on counter tops or bench tops where blood or other potentially infectious materials are present.

Equipment that may become contaminated with blood or other potentially infectious material must be labeled as a **Biohazard**.

Fluorescent orange or orange-red warning labels shall be attached to containers of waste, refrigerators, freezers and other containers used to store, transport, or ship blood or other potentially infectious materials. Labeling requirements are summarized in **Appendix E**.

c. Procedures

After removal of personal protective **gloves**, employees shall wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and water. In areas where hand washing facilities are not available, either an antiseptic cleanser, such as Betadine, in conjunction with a clean cloth/paper towels or antiseptic towelettes will be provided. If these alternatives are used, the hands are to be washed with soap and running water as soon as feasible. If these alternatives are used, they must also be maintained monthly by division chairs and supervisors, or designated person.

All procedures will be conducted in a manner which will minimize splashing, spraying, splattering, and generation of droplets of blood or other potentially infectious materials. These are specified in the standard operating procedures for a particular laboratory. For example, centrifuges must have covers.

d. Disposal

All garments, including gloves and masks which are penetrated by blood, shall be removed immediately or as soon as feasible and must be removed prior to leaving the work area.

3. Needles

i. Workplace

Sharps containers should be available in each room where needles or sharps are *regularly used*. The sharps containers must be puncture resistant, labeled with a biohazard label, and be leak proof. Sharp containers will be provided by their respective departments, other departments needing access to sharps containers for occasional classroom purposes shall contact the Environmental Health and Safety Office. Sharp containers that are three quarter filled are ready for disposal and should be transported to the hazardous waste room located in the Fennell basement.

Sharps containers will be examined and maintained on a regular schedule. Any needles or other sharps that have been used for practice or instructional purposes will be treated as contaminated items.

ii. Disposal

All contaminated sharps shall be discarded as soon as feasible in sharps containers which are labeled **biohazard** and must be disposed as such. Contaminated sharps that are reusable are to be placed immediately, or as soon as possible, after use into appropriate sharps containers. Contaminated needles and other contaminated sharps will not be bent, recapped, removed, sheared or purposely broken. An exception to this is allowed if the procedure would require that the contaminated needle be recapped or removed and no alternative is feasible and the action is required by the medical procedure. If such action is required then the recapping or removal of the needle must be done by the use of a mechanical device or a one-handed technique.

Sharps containers will be checked for removal of sharps weekly by the Supervisor or employee designated locations. *The sharps containers should only be handled by persons trained for this task.*

4. Specimens

Procedures

Specimens of blood or other potentially infectious materials will be placed in a container which prevents leakage during the collection, handling, processing, storage, and transport of the specimens. The container used for this purpose will be labeled or color coded in accordance with the requirements of the OSHA standard. All blood and other potentially infectious materials should be labeled with the biohazard symbol. Any specimens which could puncture a primary container will be placed within a secondary container which is puncture resistant. If outside contamination of the primary container occurs, the primary container shall be placed within a secondary container which prevents leakage during the handling, processing, storage, transport, or shipping of the specimen.

5. Equipment

1. Procedures

Mouth pipetting/suctioning of blood or other potentially infectious materials by employees is prohibited.

Equipment which has become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary.

2. Aerosols

In addition to avoiding obvious sources of infection such as splashes, cuts, accidental inoculation or ingestion, laboratory workers should also be aware that some pathogens, when airborne, may cause infection if inhaled.

Aerosolized microorganisms are generated during most routine laboratory procedures involving manipulation of liquid suspensions: another potential source of aerosolized pathogens is from animal cages where bedding is contaminated with feces and urine. Not all pathogens can infect via the aerosol route, but for those that do, the risk of infection depends on the type and concentration of agent and on the health status of the exposed individual.

Small airborne particles evaporate rapidly: as droplet nuclei, they can remain suspended for long periods of time and can be carried throughout the laboratory and the building by air currents and ventilation systems.

The degree of penetration and retention of airborne pathogens in the respiratory tract is determined primarily by size: particles which are 10 μm in diameter or smaller are most efficiently inhaled, deposited and retained in the upper respiratory tract or in lung alveoli. Larger particles (140 μm or greater diameter) are also of concern because they can settle and contaminate work surfaces, equipment and personnel.

Safe Handling of Laboratory Equipment ¹

Selection and Use of Laboratory Equipment

Whenever lab equipment is purchased, preference should be given to equipment that

- Limits contact between the operator and the infectious agent,
- Is corrosion-resistant, easy to decontaminate and impermeable to liquids,
- Has no sharp edges or burrs,

Every effort should be made to prevent equipment from becoming contaminated. To reduce the likelihood of equipment malfunction that could result in leakage, spill or unnecessary generation of aerosolized pathogens:

- Review the manufacturer's documentation. Keep for future reference,
- Use and service equipment according to the manufacturing's instructions,
- Ensure that anyone who uses a specific instrument or piece of equipment is properly trained in setup, use and cleaning of the item.
- Decontaminate equipment before it is sent out for repairs or discarded.

The following sections outline some of the precautions and procedures to be observed with some commonly used laboratory equipment.

Centrifuges

Improperly used or maintained centrifuges can present significant hazards to users. Failed mechanical parts can result in release of flying objects, hazardous chemicals and biohazardous aerosols. The high speed spins generated by centrifuges can create large amounts of aerosol if a spill, leak or tube breakage occurs.

To avoid contaminating your centrifuge:

- Check glass and plastic centrifuge tubes for stress lines, hairline cracks and chipped rims before use. Use unbreakable tubes whenever possible,
- Avoid filling tubes to the rim,
- Use caps or stoppers on centrifuge tubes. Avoid using lightweight materials such as aluminum foils caps,
- Use sealed centrifuge buckets (safety cups) or rotors which can be loaded and unloaded in a biological safety cabinet. Decontaminate the outside of the cups or buckets before and after centrifugation. Inspect o-rings regularly and replace if cracked or dry,
- Ensure that the centrifuge is properly balanced,
- Do not open the lid during or immediately after operation, attempt to stop a spinning rotor by hand or with an object or interfere with the interlock safety device,
- Decant supernatant carefully and avoid vigorous shaking when resuspending packed cells.
- Clean spills promptly.

When using high-speed or ultra centrifuges, additional practices should include:

- Connect the vacuum pump exhaust to a disinfectant trap,

- Record each run in a log book. Keep a record of speed and run time for each rotor,
- Install a HEPA filter between the centrifuge and the vacuum pump,
- Never exceed the specified speed limitations of the rotor.

Lyophilizers (Freeze-Driers)

Aerosols may be produced during operation of a freeze drier and when material is being removed from the chamber. When lyophilizing biohazardous materials:

- Load samples in a biological safety cabinet,
- Check glass vacuum containers for nicks and scratches,
- Use only glassware which was designed for high vacuum pump exhaust,
- After completion of the run, decontaminate all accessible surfaces.

Mixing Apparatus

Homogenizers, shakers and sonicators can release significant amounts of aerosols during their operation and should be operated in a biological safety cabinet if possible.

When using any mixing equipment, remember to:

- Check condition of gaskets, caps and bottles before using,
- Allow aerosols to settle for at least one minute after use before opening containers, opening in a biological safety cabinet if possible,
- Cover tops of blenders with a disinfectant-soaked towel during operation,
- Immerse sonicator tip into solution to a depth sufficient to avoid creation of aerosols,
- Disinfect all exposed surfaces after use.

Freezing Apparatus

Spills inside freezing equipment may place laboratory and maintenance personnel at risk; for safe use of such equipment:

- Periodically check freezers, liquid nitrogen tanks and dry ice chests for broken Ampoules, tubes etc.,
- To minimize breakage and leaks, place primary containers such as test tubes inside secondary containers prior to storage in freezing units,
- For electrical safety, remember to shut down units before proceeding with decontamination.

Vacuum/Aspirating Equipment

Glass vacuum vessels may rupture and shower laboratory personnel with glass fragments and flask contents. To reduce these risks:

- Use metal flasks and vacuum traps whenever possible,
- Tape glass containers with duct or adhesive tape to contain glass shards in case of rupture, or, use a secondary metal container which is at least as tall as the vacuum flask.

To prevent exposure of lab personnel or maintenance employees who may be required to repair the central vacuum system, vacuum line connections that draw biohazardous aerosols or fluids should be fitted with:

- A HEPA filter in the line leading into the house vacuum line (or bench top vacuum pump). Cartridge-type in-line filters provide an effective barrier to

escape of aerosols into vacuum systems, and are commercially available for this purpose. When replacing the filter, autoclave the used one before discarding,

- An overflow flask in case of accidental aspiration of liquids out of collection vessel. This flask should:
 - Be of sufficient capacity,
 - Be placed between the collection flask and the air filter,
 - Contain the appropriate disinfectant
 - Contain an antifoam agent whenever air bubbling generates excessive foam.

Needles and Syringes

Hypodermic needles and syringe present hazards of spill, autoinoculation and aerosol generation, and should be used only when absolutely necessary, such as for parenteral injection or withdrawal of body fluid. When working with syringes and needles, the following precautions are recommended:

- Perform all operations with infectious material in a biological safety cabinet,
- Fill syringes carefully; avoid frothing or introduction of air bubbles
- Shield needles with disinfectant-soaked cotton pledgets when withdrawing from stoppers,
- Use luer-lock needles and syringes or units in which needles are integral to syringes. Better still; use one of the newer “safe” alternatives to needles and syringes.
- Do not bend, shear by hand, or recap needles,
- Place used needles and syringes in puncture-resistant containers and decontaminate before disposal.

When withdrawing liquids from septum-capped or diaphragm bottles, consider using an opener made especially for this type of bottle; this allows for use of a pipette rather than a syringe/needle assembly.

- Use cannulas or blunt-end needles for introduction or removal of fluids through small apertures in equipment.

Pipettes

Selection of a Mechanical Pipetting Aid

Improper handling of pipettes can lead to contamination of the user and/or to generation of hazardous aerosols. Mechanical pipetting aids should be used for all pipetting procedures: *never* pipette by mouth.

Selection of a pipetting device should be based upon:

- Intended use,
- Ease of handling,
- Delivery accuracy,
- User preference,
- Quality of seal formed with pipettes to be used; liquid should not leak from the pipette tip,
- Whether the pipetting aid can be sterilized.

Safe Use of Pipettes

If infectious aerosols are likely to be generated, perform pipetting operations in a biological safety cabinet. Handling pipettes as described below will reduce splashing and aerosolization:

- Plug pipettes with cotton
- Check pipettes before using; cracked or chipped suction ends may damage the seals of the pipetting aid
- Keep pipettes upright while in use and between steps of a procedure to prevent contamination of the mechanical aid,
- Gently expel contents close to the surface of a liquid or allow to flow down the side of the container
- Avoid mixing fluids by alternate suction and blowing, or by bubbling air from the pipette,
- Avoid forceful ejection of the contents. Use TD (short for “to deliver”, also referred to as “mark-to-mark”) rather than TC (“to contain”) pipettes, as the last drop of fluid does not have to be expelled with TD pipettes,
- Use easier-to-handle shorter pipettes when working inside a biological safety cabinet,
- Submerge used non-disposable pipettes horizontally in disinfectant solution; dropping them in vertically may force out any liquid remaining in the pipette,

Autoclave

Autoclaves are ideal for decontaminating biohazardous waste and for sterilizing surgical dressing, glassware and microbiological media and liquids. They must be loaded carefully to allow for steam penetration, since steam must contact pathogens in order to destroy them. Longer times are needed for larger loads, large volumes of liquid and denser materials. Proper loading and packing procedures include the following precautions:

- Wrap packages to allow for steam penetration. Aluminum foil does not allow steam penetration, and should not be used for wrapping,
- Do not overload the chamber,
- Avoid over packing of autoclave bags,
- Do not seal bags or close bottles and other containers tightly
- Do not stack containers.

The charges which are seen on autoclave indicator tapes following an autoclave cycle do not guarantee that the contents of containers are sterile: they indicate only that the tape on the outside of the packages has been exposed to a certain amount of heat or steam. The time required for effective sterilization depends on the size of the load, volumes of liquid and density of materials to be autoclaved. Regular use (at least monthly) of either a heat-resistant biological indicator such as *Bacillus stearothermophilus*, or a chemical indicator should be used to ensure that the cycle in use really achieves sterilization. The indicator is placed in the area least likely to reach sterilizing conditions, such as in the middle of the largest or densest package. A

subsequent color change indicates that the load has been exposed to the required conditions for a sufficient length of time.

Safe work practices when using an autoclave include the following:

- Read the operating manual and post proper work procedures near the autoclave;
- Never autoclave hazardous chemicals;
- Open the door slightly to allow escape of steam before unloading;
- Wear insulated gloves or mitts when unloading.

Miscellaneous Equipment

- **Microscopes:** disinfect the stage, eyepiece, knobs and any other contaminated parts. Select a disinfectant that will be effective on the pathogens and non-corrosive to the microscope.
- **Microtomes:** disinfect knives and anti-roll plates after use.
- **Water baths:**
 - Clean regularly, add disinfectant, such as a phenolic detergent, to the water,
 - Avoid using sodium azide to prevent growth of microorganisms; sodium azide forms explosive compounds with some metals,
 - Raise the temperature to 90C or higher for 30 minutes once a week for decontamination purposes
 - To prevent electrical shocks, unplug the unit before filling or emptying and have the continuity-to-ground checked on a regular basis.
- **Tissue grinders:** use in a biological safety cabinet; wrap glass grinders in a wad of absorbent paper and wear gloves. Polytetrafluoroethylene (PTFE, “Teflon”) grinders are safer, as they will not break.
- **Microbiological transfer loops:** to eliminate the spattering and aerosolization associated with flaming of loops, char the material before fully inserting the loop into the flame: i.e., before flaming, hold the loop close to (but not into) the flame. Alternatively, use disposable loops or a microincinerator.

6. Decontamination

Refer to **Appendix C, STANDARD OPERATING PROCEDURES FOR CLEANING AND DECONTAMINATION**

a. Employees

After removal of personal protective gloves, employees shall wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and water. EXCEPTION: Noted under Protection, Procedures, **Appendix C**, p. 14.

b. Workplace

Decontamination will be accomplished by utilizing a sterilant/disinfectant in **Appendix A. Sterilization and Disinfection**” or from the Safety Officer. In general, a material should be chosen that is effective on as many blood borne pathogens as possible. At a minimum, a usable solution is ¼ cup bleach per gallon of water. This solution must be made daily for use as a decontaminant.

All contaminated work surfaces will be decontaminated after completion of procedures and immediately or as soon as feasible after any spill of blood or other potentially infectious materials, as well as the end of each day by the employee if the surface may have become contaminated since the last cleaning. All bins, pails, cans, and similar receptacles shall be inspected and decontaminated on a weekly basis by the employee or the laboratory supervisor prior to disposal.

Any broken glassware/glass which may be contaminated will be swept up with a brush and dust pan, or picked up with tongs, and placed in a sharps container. *Vacuum cleaners are not appropriate for cleanup of contaminated broken glass or glassware.*

c. Procedures

Equipment which has become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary.

H. EXPOSURE

1. Determination

The exposure determination is made without regard to the use of personal protective equipment (i.e. employees are considered to be exposed even if they wear personal protective equipment).

2. Employee and Student Immediate Response.

If employees or students incur exposure to their skin or mucous membranes those areas shall be washed or flushed with water as appropriate as soon as feasible following contact. All garments which are penetrated by blood shall be removed immediately or as soon as feasible; and must be removed prior to leaving the work area.

I. POST-EXPOSURE EVALUATION AND FOLLOW-UP

All exposure incidents are reported, investigated, and documented. When the employee or student is exposed to blood or other potentially infectious material, the incident is reported to immediate supervisors or instructor and to the Director of Environmental Health and Safety. When an employee or student is exposed, he or she will receive a confidential medical evaluation and follow-up.

The follow-up procedure will include the following:

1. Documentation of the route of exposure and the circumstances related to the incident. (see MCPHS injury report policy and needle stick policy)
2. If possible, the identification of the source individual and the health status of the source individual. The blood of the source individual will be tested (by consent) for HIV/HBV infectivity.
3. Results of testing of the source individual will be made available to the exposed employees in addition to the information about the applicable laws and regulations concerning disclosure of the identity and infectivity of the source individual.
4. The individual will be offered the option of having their blood collected for testing of their HIV/HBV serological status. The blood sample will be preserved for at least 90 days to allow the affected individual time to decide if the blood should be tested for HIV serological status. However, if the individual decides prior to that time that testing will be conducted, then the appropriate action can be taken and the blood sample discarded.
5. The individual will be offered post-exposure prophylaxis in accordance with the current recommendations of the U.S. Public Health Service.
6. The individual will be given appropriate counseling concerning precautions to take during the period after the exposure incident. Further, the individual will also be given information on what potential illnesses to be alert for and to report any related experiences.

7. Medical Care cost including laboratory, counseling, and prophylaxis medication will be provided at no cost to the employee.

8. STUDENT PAYMENT POLICIES AND PROCEDURES FOLLOWING A BLOOD BORNE PATHOGEN EXPOSURE, ACCIDENT OR NEEDLESTICK INJURY

The purpose of this section is to clarify MCPHS's payment policies and procedures in the event of an accident, exposure, or needle stick injury while you are completing clinical requirements.

For billing purposes, when seeking treatment for accidents or injuries including needle sticks, exposures to blood or body fluids, injuries obtained in clinical work, and exposures to infectious diseases while completing clinical requirements, students must present his/her own health insurance information. Any deductible or co-payment is the student's responsibility.

If a student is enrolled in an alternate health plan, he/she must follow the claims procedures required by such insurance company.

Students are not eligible for Workers' Compensation benefits from MCPHS or any affiliated teaching hospital or clinic in which they are assigned while completing clinical requirements because students in clinical rotation are not employees.

The Director of Environmental Health and Safety has been designated to assure that the policy outlined here is effectively carried out as well as to maintain records related to this policy.

J. TRAINING

Training for all employees will be conducted prior to initial assignment to tasks where occupational exposure may occur. Training will include explanations of the following:

- The OSHA standard for Blood borne Pathogens.
- Blood borne Pathogens and Long Term Care Workers OSHA Publication 3131
- Blood borne Pathogens and Acute Care Facilities OSHA Publications 3128
- Epidemiology and symptomatology of blood borne diseases.
- Modes of transmission of blood borne pathogens.
- This Exposure Control Master Plan.
- Procedures which might cause exposure to blood or other potentially infectious materials.
- Control methods which will be used to control exposure to blood or other potentially infectious materials.
- Personal protective equipment available.
- Post-exposure evaluation and follow-up.
- Signs and labels used.
- Hepatitis B vaccine program at the facility.

All employees listed at risk [see **Section: *Who Is Covered***], must be trained. An annual refresher of this training will also be required within one year of the employee's previous training or whenever there is a change or modification in the existing exposure to blood borne pathogens. The outline for the training material is located in the Safety Office.

K. REFERENCES

1. 29 CFR 1910.1030 OSHA Blood borne Pathogens Standard, December 6, 1991.
2. Occupational Exposure to Blood borne Pathogens, OSHA Publication 3127, revision 1996
3. Blood borne Pathogens Update Manual, Pathfinder Associates, Inc., 1992.
4. Sterilization and Disinfection in the Laboratory, McGill Biosafety Manual
5. Sample Plan, U.S. Department of Labor, Occupational Safety and Health Administration, Revision 1.

*In accordance with the OSHA Blood borne Pathogens standard, 29 CFR 1910.1030, the following Exposure Control Plan has been developed.

Appendices

- A.** Sterilization and Disinfection.....
- B.** Hepatitis B Vaccination Declination Form.....
- C.** Standard Operating Procedures for Cleaning and Decontamination.
- D.** HIV/HBV Procedures.....
- E.** Labeling.....
- F.** OSHA Blood borne Standard 29 CFR 1910.1030.....
- G.** Chemical Information Resources.....
- H.** Blood borne Pathogens and Long Term Care Workers, OSHA
Publication 3131.....
- I.** Blood borne Pathogens and Acute Care Facilities, OSHA Publication
3128.....
- J.** Information About Gloves.....
- K.** NIOSH Alert: Preventing Allergic Reactions to Natural Rubber Latex
in the Workplace.....
- L.** Incident Report.....
- M.** OSHA Blood borne Pathogen Standard 1910.1030.....

Appendix A

Sterilization and Disinfection ¹

It is important to distinguish between sterilization and disinfection. Whereas sterilization results in destruction of all forms of microbial life, disinfection results in destruction of specific pathogenic microorganisms.

Microorganisms vary in their resistance to destruction by physical or chemical means. A disinfectant that destroys bacteria may be ineffective against viruses or fungi. There are differences in susceptibility between gram-negative and gram-positive bacteria, and sometimes even between strains of the same species. Bacterial spores are more resistant than vegetative forms, and non-enveloped, non-lipid-containing viruses respond differently than do viruses which have a lipid coating. Information on the susceptibility of a particular microorganism to disinfectants and physical inactivation procedures can be found in the material safety data sheet (MSDS) for that agent. MSDSs provide additional details such as health hazards associated with the microorganism, mode of transmission, containment requirement and spill response procedures. The Safety Office has available and can provide to individuals, MSDSs on a number of infectious microorganisms.

A. Physical Sterility and Disinfectants

1. Heat Sterilization and Decontamination

Generally, sterilization is best achieved by physical methods such as steam or dry heat, which are less time-consuming and more reliable than chemical germicides. A summary of physical agents which employ heat for control of microorganisms can be found in Table 2. Of these physical procedures, steam autoclaving is the most practical option for the majority of laboratories for both sterilization and decontamination purposes.

Autoclaves are ideal for decontaminating biohazardous waste and for sterilizing surgical dressings, glassware, and microbiological media and liquids. They must be loaded carefully to allow for steam penetration, since steam must contact pathogens in order to destroy them. Longer times are needed for larger loads, large volumes of liquid and denser materials. Proper loading and packing procedures include the following precautions:

- Wrap packages to allow for steam penetration. Aluminum foil, does not allow steam penetration, and should not be used for wrapping,
- Do not overload the chamber,
- Avoid overpacking of autoclave bags,
- Do not seal bags or close bottle and other containers tightly,
- Do not stack containers

The changes which are seen on autoclave indicator tapes following an autoclave cycle do not guarantee that the contents of containers are sterile: they indicate only that the tape on the outside of the packages has been exposed to a certain amount of heat or steam. The time requires for effective sterilization depends on the size of the load, volumes of liquid and density of materials to be autoclaved. Regular use (at least monthly) of either a heat-resistant biological indicator such as *Bacillus stearothermophilus*, or a chemical indicator should be used to ensure that the cycle in use

¹ adapted from McGill BioSafety Manual

really achieves sterilization. The indicator is placed in the area least likely to reach sterilizing

conditions, such as in the middle of the largest or, densest package. A subsequent color change indicates that the load has been exposed to the required conditions for a sufficient length of time.

Use safe work practices when using an autoclave and read the SOP before using the autoclave.

TABLE 1: Heat Decontamination Methods: Outline of the properties of heat decontamination methods. For everyday laboratory purposes, autoclaving is the preferred method, unless the item cannot withstand the heat and/or moisture of autoclaving.

	Principle/Conditions	Advantages	Disadvantages	Uses
Dry Heat	Thermal inactivation: destroys by oxidation	Non-corrosive Simple design and principle	Less effective than moist heat; requires longer times and/or higher temperatures	Materials that are damaged by, or are impenetrable to, moist heat
Hot Air Oven	160-180 C for 2-4 hours	Penetrates water-insoluble materials (e.g., grease and oil) Less corrosive to metals and sharp instruments than steam	Slow diffusion, penetration loading, packing critical to performance not suitable for reusable plastics	Anhydrous materials, such as oils, greases and powders laboratory glassware, instruments closed containers
Red-heat Flame	Oxidation to ashes (burning)	Rapid	Initial contact with flame can produce a viable aerosol possibility of accidental fire	Inoculating loops, needles
Incineration	Oxidation to ashes (burning) 1-60 minutes: temperatures may exceed 1000C	Reduces volume of waste by up to 95%	Improper use may lead to emission of pathogens in smoke Requires transport of infectious waste Excess plastic (>20%) Content reduces combustibility	For decontamination of waste items prior to disposal in landfill
Moist Heat	Irreversible coagulation of (microbial) proteins	More rapid and more effective than dry heat		
Pasteurization	Heating to below boiling point (generally 77C) for up to 30 minutes	Can be used on heat sensitive liquids and medical devices low cost	Not reliably sporicidal	Milk and dairy products Some heat-sensitive equipment
Tyndallization (Fractional Sterilization)	Heating to 80-100C for 30 min. on successive days, with incubation periods in between	Resistant spores germinate and are killed on the second and third days	Time consuming not reliably sporicidal	Heat sensitive materials such as bacteriologic media, solutions of chemicals, biological materials
Boiling	Maximum temperature obtainable is approximately 100C 10-30 min	Minimal equipment required	Cumbersome: not practical for everyday lab use Not reliably sporicidal	Small instruments and equipment
Autoclaving	Steam under pressure 121C at 15 psi for 15-90 min (gravity displacement autoclave) 132C at 27psi for 4-20 min (pre-vacuum autoclave)	Minimal time required most dependable sterilant for lab use	Loading and packing critical to performance Shielding dirt must first be removed Maintenance and quality control essential Damages Heat-sensitive items	Penetration of sterile glassware, media and instruments Decontamination of reusable supplies and equipment Decontamination of infectious waste

2. *Ultraviolet Light (Germicidal Lamps)*

The light (approximately 250 nm wavelength) emitted by UV lamps is germicidal, and can be used to reduce the number of pathogenic microorganisms on exposed surfaces and in air. However, UV light has poor penetrating power; accumulations of dust, dirt, grease or clumps of microorganisms may shield microorganisms from the direct exposure required for destruction. UV light presents skin and eye burn hazard, and factors such as lamp age and poor maintenance can reduce performance. For safe and reliable use of germicidal lamps:

- Clean the bulb at least every 2 weeks; turn off power and wipe with an alcohol-moistened cloth.
- Blue light output is not an indication of the lamp's effectiveness; measure radiation output at least twice yearly with a UV meter or replace the bulb when emission declines to 70% of its rated output.
- Post warning signs to discourage personnel from entering areas where there is potential exposure to UV light.
- Wear UV protective goggles, caps, gowns and gloves in rooms with UV installations.

3. *Other Physical Agents of Sterilization and Disinfection*

The procedures listed below are included for the reader's interest:

- **Infrared radiation:** used for heat treatment of small metal and glass items.
- **Microwaves:** used for treatment of liquids, nonmetallic objects, and biohazardous waste.
- **Gamma irradiation:** disrupts DNA and RNA in living organisms, and is used by hospital and laboratory suppliers for materials that do not tolerate heat and pressure (i.e., autoclaving) or chemical treatments.
- **Membrane filtration:** physically removes particulates (e.g., microorganisms) from heat-sensitive pharmaceutical and biological fluids. The size of the particles removed is determined by the pore size of the filter membrane.

B. *Chemical Sterilants and Disinfectants*

Instruments or materials which cannot withstand sterilization in a steam autoclave or dry-air oven can be sterilized with a gas such as ethylene oxide or a broad spectrum liquid chemical germicide. Chemical decontamination of surfaces may also be necessary for very large or fixed items. Since liquid chemical germicides generally require high concentrations and several hours of exposure time for sterilization purposes, they are usually used for disinfection rather than for sterilization purposes. The majority of chemical disinfectants have toxic properties: follow the manufacturer's directions for use and wear the appropriate personal protective equipment (e.g., gloves, eye protection, apron), especially when handling stock solutions.

Choice of a chemical germicide for use on contaminated equipment, supplies, laboratory surfaces or biohazardous waste depends upon a number of factors, including:

- Number and nature of microbes to be destroyed (e.g., spores vs vegetative cells, bacteria vs viruses),
- Type and configuration of item to be disinfected (fissures, crevices and enclosures may shield organisms),
- Purpose of treatment (e.g., disinfection vs sterilization),
- Interaction with other active chemicals,
- Whether the item is covered with soil which might inactivate the disinfectant,
- Contact time required for disinfection,

- Toxicity to individuals, culture systems, environment, residual toxicity on items,
- pH, temperature, hardness of available dilution water,
- cost.

Direct contact between germicide and microorganism is essential for disinfection. Microorganisms can be shielded within air bubbles or under dirt, grease, oil, rust or clumps of microorganisms. Agar or proteinaceous nutrients and other cellular material can, either directly (through inactivation of the germicide) or indirectly (via physical shielding of microorganisms) reduce the efficacy of some liquid germicides.

No one chemical germicide is effective for all disinfection or sterilization purposes. A summary of chemical germicides, their use, effective concentrations, advantages and disadvantages can be found in Tables 2, 3A and 3B.

TABLE 2: Halogen-releasing Chemical Germicides –Summary of concentrations used, contact times, advantages and disadvantages and uses of some of the halogen-releasing chemical germicides. The wide ranges of effective concentrations and contact times cited are due to a number of factors, including the interdependence of time and concentration, the variability in resistance of different microorganisms, the amount of organic material present and the desired effect (e.g., low-level vs high-level disinfection)

	Effective Concentrations, Contact Times	Advantages	Disadvantages	Examples of Uses
Chlorine Compounds: Sodium hypochlorite solution ¹ (liquid bleach)	100-10,000 ppm (.01-1%) free chlorine 10-60 minutes (>v= 3,000 ppm for broad spectrum)	Broad spectrum inexpensive widely available bactericidal at low temperature	Toxic, corrosive to skin and metals Unstable at optimum effective pH of 6 Inactivated by organic matter Deteriorates under light and heat: shelf life of dilutions is less than 1 week	General disinfectant Waste liquids Surface decontamination Emergency spill clean up Instrument disinfection
Calcium hypochlorite ² granules, powder, tablets	As for liquid bleach	As for liquid bleach but more stable	As for liquid bleach above, except shelf life is longer	As for liquid bleach
NaDCC ³ (Sodium dichloroisocynurate) powder, granules, tablets	As for liquid bleach	More stable than hypochlorites stable at pH 6.0	Toxic, corrosive Inactivated by organic matter	As for liquid bleach
Chloramine-T ⁴ (Sodium tosylchloride) powder or tablets)	As for liquid bleach	More stable, less affected by organic matter than hypochlorites longer activity than hypochlorites	Deteriorates under humidity, light and heat	As for liquid bleach
Chlorine dioxide ⁵	Demand-release of chlorine dioxide in situ	Longer activity than other chlorine compounds Less corrosive, less toxic than other chlorine compounds effective at pH 6-10	Aqueous solutions decompose under light	Instrument disinfection Gas sterilization of germ-free animal chambers
Iodine Preparations: Iodophors ⁶	30-1,000 ppm (.003-.1%) free iodine 10-30 minutes	Broad spectrum germicidal over a wide pH range generally nonstaining, less toxic and less irritating than aqueous or alcoholic iodine solutions	Not consistently sporicidal Efficacy reduced by organic matter Some iodophor solutions support growth of <i>Pseudomonas</i> ⁷	Germicidal soaps and antiseptics Surface decontamination Work surface wipedown Instrument disinfection

¹a 1/10 dilution of 5.25% bleach provides 5,250 ppm available chlorine

²"high tested" provides 70-72% available chlorine; chlorinated lime or bleaching powder provides approximately 35% available chlorine

³approximately 60% available chlorine

⁴approximately 25% available chlorine

⁵To avoid shipping of this extremely reactive product, reagents ("base" and "activator") from commercially available kits are mixed with water to generate chlorine dioxide immediately prior to use

⁶10% povidone-iodine provides 1% available iodine

⁷An iodophor stock solution may actually be a less effective germicide than its dilution. For example, a full-strength (10%) solution of povidone-iodine provides approximately 10 times less free available iodine than a 1/100 dilution. Iodophors must be used at the manufacturer's recommended concentrations.

TABLE 3A: Non-halogen-releasing Chemical Germicides: Summary of recommended concentrations, contact times, advantages and disadvantages of non-halogen chemical germicides. The wide ranges of effective concentrations and contact times cited reflect the interdependence of time and concentration as well as factors such as resistance of the particular class or strain of target microorganism(s) and desired effect. Also, some germicides are available in combinations (e.g., glutaraldehyde/phenol or peracetic acid/alcohol mixtures) which are synergistic whereby the components in combination produce a greater antimicrobial effect than the sum of their individual effects.

	Effective Concentrations and Contact Times	Advantages	Disadvantages	Examples of Laboratory Uses
Alcohols	70-80% ethanol 60-95% isopropanol 10-30 minutes	Low toxicity Rapid action Low residue Non-corrosive	Rapid evaporation limits contact time Flammable, eye irritant may damage rubber, plastic, shellac Ineffective against bacterial spores	Skin disinfectant (antiseptic) surface decontamination benchtop, cabinet wipedown
Phenolic Compounds	400-50,000 ppm (.05-1.5%) 10-30 minutes	Tolerant of organic load, "hard" dilution Water leaves an active residue (may be desirable on some surfaces) biodegradable	Pungent odor, corrosive, some forms toxic not sporicidal; limited activity against viruses leaves a residual film (undesirable in culture systems) May support growth of bacteria ¹	Instruments and equipment Disinfection Disinfection of floors and other surfaces Antiseptic soaps and lotions
Quaternary Ammonium Compounds	500-15,000 ppm (.05-1.5%) 10-30 minutes	Combined detergent and germicidal activity Stable Working dilutions have low toxicity	Non sporicidal, limited activity against viruses, mycobacteria most formulations not readily biodegradable may support growth of bacteria ²	Surface decontamination Instruments and equipment
Hydrogen Peroxide	3-30% aqueous solution 10-60 minutes 6% for 30 minutes may kill spores	Rapid action No residue Low toxicity environmentally safe	Limited sporicidal, activity corrosive to some metals potentially explosive at high concentrations stock solutions irritating to skin and eyes	Surface decontamination Instruments and equipment
Peracetic Acid (PAA)	.001-.3% aqueous solution Gas phase: 2-4% 5-120 minutes	Broad spectrum Sporicidal at low temperatures Can tolerate organic load Rapid action Nontoxic Decomposition Products leaves no residue	Pungent odor Corrosive to some metals Shelf life of dilutions is less than 1 week Stock solutions irritating to skin and eyes Stock must be protected from heat, light gas phase: respiratory irritant, fire hazard above 55C	Instruments and equipment Gas phase sterilization of chambers for germ-free animals

Table 3B: Non-halogen-releasing Chemical Germicides- Summary of recommended concentrations, contact times, advantages, and disadvantages of non-halogen chemical germicides. The wide ranges of effective concentrations and contact times cited reflect the interdependence of time and concentrations as well as factors such as resistance of the particular class or strain of target microorganisms(s) and desired effect. Also, some germicides are available in combinations (e.g., glutaraldehyde/phenol or peracetic acid/alcohol mixtures) which are synergistic whereby the components in combination produce a greater antimicrobial effect than the sum of their individual effects.

	Effective Concentrations and Contact Times	Advantages	Disadvantages	Examples of Laboratory Uses
Aldehydes:				
Glutaraldehyde	0.5-2.5% alkalinized aqueous solution 2-30 min; up to 12 hours to kill all spores	Broad spectrum Does not corrode metal Can tolerate organic load	Expensive pH, temperature dependent pungent odor toxic: skin, eye, respiratory tract irritant activated solutions have less than 2-week shelf life	Cold steriliant and fixative Surface decontamination Instruments, equipment, glassware
Formalin (37% aqueous formaldehyde)	3-27% formalin (1-10% formaldehyde) in 70-90% alcohol 10-30 minutes	Broad spectrum Inexpensive Does not corrode metal Can tolerate organic load	Pungent odor Skin, eye and respiratory tract irritant Potential carcinogen (animal studies) may require 24 hrs of more to kill all spores	Cold steriliant and fixative Surface decontamination Instruments and equipment
Formaldehyde (gas)	1-3 hours	As for formalin effective penetration	As for formalin flammable poor penetration of covered surfaces	On site Decontamination of biological safety cabinet HEPA filters enclosed areas
Ethylene Oxide Gas	50-1200 mg/L 1-12 hours	Broad spectrum No heat or moisture Evolved Penetrates packaging materials	Flammable, reactivate toxic: potential carcinogen and mutagen Some sterilized items may need more than 24 hours for outgassing	Heat or moisture Sensitive supplies, instruments and equipment

APPENDIX B

Hepatitis B Vaccination Declination Form

Date:

Employee Name:

Employee ID#:

I understand that due to my occupational exposure to blood or other potential infectious materials I may be at risk of acquiring Hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with Hepatitis B vaccine, at no charge to myself. However, I decline the Hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a serious disease. If, in the future, I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Employee's Signature

Date

Director of Environmental, Health and Safety Signature

Date

Appendix C

STANDARD OPERATING PROCEDURES FOR CLEANING AND DECONTAMINATION

Specific standard operating procedures [SOP] are available for each of the laboratories within the College. These operating codes supercede the general SOP listed below.

Standard operating procedures are intended to provide you with general guidance on how to safely work with blood borne pathogens. This SOP is generic in nature. It addresses the use and handling of substances by hazard class only. In some instances multiple SOPs may be applicable for a specific chemical (i.e., both the SOPs for flammable liquids and carcinogens would apply to benzene). If you have questions concerning the applicability of any items listed in this procedure contact the Safety Office, laboratory supervisor, or the principal investigator of your laboratory.

Schedule for Cleaning and Decontamination

Each area must be kept clean and sanitary. The supervisor must develop and implement a cleaning schedule that includes appropriate methods of decontamination and tasks or procedures to be performed. This written schedule must be based on the location, the type of surfaces to be cleaned, the type of contamination present, the tasks or procedures to be performed, and their location within the facility.

The schedule shall include a column for:

1. The Facility area, surface or equipment to clean and/or decontaminate
2. Procedure for cleaning and/or decontaminating (frequency)
3. Cleaning agents and/or disinfectants used

Decontamination procedures

- Wash hands and arms with soap and water immediately after handling potentially infectious materials.
- Inanimate surface decontamination procedures vary depending on the material being handled. [See individual laboratory's SOP]. Wear protective equipment during cleanup. Waste materials generated should be treated as a hazardous waste and disposed of in proper containers.
- Contaminated equipment should be handled by appropriate laboratory employees according to the specific SOP.

Designated Area

The room number sign for the laboratory must contain a *Designated Areas Within* identifier.

All locations within the laboratory where potentially infectious materials, carcinogens, reproductive hazards and/or acutely toxic chemicals are stored and used, should be demarcated with designated area caution tape and/or posted with designated area caution signs. This includes all fume hoods and bench tops where the potentially infectious materials are handled.

Where feasible, potentially infectious materials should be manipulated over plastic-backed disposable paper work surfaces. These disposable work surfaces minimize work area contamination and simplify clean up.

Emergency Procedures

Emergency procedures which address response actions to fires, explosions, spills, injury to employees, or the development of sign and symptom of overexposure must be developed. The procedures should address as a minimum the following:

Whom to contact: Security, laboratory supervisor or principal investigator of the laboratory including evening phone number.

The location of all safety equipment (showers, eye wash, fire extinguishers, etc.)

The method used to alert employees in nearby areas of potential hazards.

Special first aid treatment required by the type of potentially infectious materials handled in the laboratory.

Eye Protection

Eye protection in the form of splash goggles must be worn at all times when handling potentially infectious materials. Ordinary (street) prescription glasses do not provide adequate protection.

Adequate splash goggles glasses must meet the requirements of the Practice for Occupational and Educational Eye and Face Protection (ANSI Z.87. 1 1989) and must be equipped with side shields. Safety glasses with side shields do not provide adequate protection from splashes; therefore, when the potential for splash hazard exists other eye protection and/or face protection (face shields) must be worn.

Eyewash

Where the eyes or body of any person may be exposed to potentially infectious materials, suitable facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate emergency use. Bottle type eyewash stations are not acceptable.

Fume Hood

Manipulation of potentially infectious materials should be carried out in a fume hood. If the use of a fume hood proves impractical, attempt to work in a glove box or on an isolated area on the bench top.

Glove (dry) Box

Certain potentially infectious materials should be carried out in a fume hood. The Safety Office, laboratory supervisor, or the principal investigator will determine if this is required.

Gloves

Gloves must be worn when handling potentially infectious materials. The selection of glove materials should be made from **Appendix J. Information About Gloves** and **Appendix E. Gloves of the Chemical Hygiene Plan**.

Hazard assessment

Hazard assessment should focus on proper use and handling techniques, education of laboratory workers concerning the health risks posed by potentially infectious materials, and the demarcation of designated areas.

Protective Apparel

Lab coats and closed-toed shoes [not clogs] should be worn when handling potentially infectious materials. Additional protective clothing should be worn if the possibility of skin contact is likely.

Safety Shielding

Safety shielding is required any time there is a risk of a splash hazard. All manipulations of potentially infectious materials which pose this risk should occur in a fume hood with the sash in the lowest feasible position. Portable shields, which provide protection to all laboratory occupants, are acceptable.

Safety Shower

A safety or drench shower should be available in a nearby location where the potentially infectious materials are used.

Containers

All containers of potentially infectious materials must be clearly labeled with the correct chemical name. Handwritten labels are acceptable; chemical formulas and structural formulas are not acceptable. Special carcinogen labels should be attached to all primary and secondary containers.

Special Ventilation

Fume hoods provide the best protection against exposure to potentially infectious materials in the laboratory when aerosols are utilized and are the preferred ventilation control device. When possible, handle potentially infectious materials in a fume hood.

Manipulation of potentially infectious materials outside of a fume hood may require special ventilation controls in order to minimize exposure to the material. If your research does not permit the handling of potentially infectious materials in a fume hood, biological safety cabinet, or glove box, you must contact the Safety Office.

If available, consider using a Biological Safety Cabinet. The biological safety cabinet is designed to remove particulates (the carcinogen) before the air is discharged into the environment. Potentially infectious materials that are volatile must not be used in a biological safety cabinet unless the cabinet is vented to the outdoors.

Spill Response

Anticipate spills by having the appropriate clean up equipment (spill kit) on hand. The appropriate clean up supplies can be determined by consulting the material safety data sheet. This should occur prior to the use of any potentially infectious materials.

In the event of a spill, alert employees in the area that a spill has occurred. Do not attempt to handle a large spill of potentially infectious materials unless specifically trained. Vacate the laboratory immediately and call for assistance. Liquid spills should be controlled with absorbent disposable pillows. Use personal protective equipment (double gloves, splash goggles, gowns, etc.) during the cleanup.

For solids, use moist absorbent disposable gauze pads to reduce dust hazard. Use personal protective equipment (respirator, double gloves, splash goggles, gowns, etc.) during the cleanup. Dispose of contaminated supplies appropriately.

Remain on the scene, but at a safe distance, to receive and direct safety employees when they arrive.

Vacuum Protection

Mechanical vacuum pumps must be protected using cold traps and, where appropriate, filtered to prevent particulate release. The exhaust for the pumps must be vented into an exhaust hood or otherwise contained.

Waste Disposal

All materials contaminated with potentially infectious materials should be disposed of as hazardous waste in properly marked and labeled containers to distinguish from regular waste. Whenever possible, attempt to design research in a manner that reduces the quantity of waste generated. Questions regarding waste pick up should be directed to the Safety Office. This office can also assist you in minimizing waste generation.

APPENDIX D

HIV/HBV PROCEDURES

These are the minimum requirements that apply in addition to the other requirements. These additional requirements apply to research laboratories and production facilities engaged in the culture, production, concentration, experimentation and manipulation of HIV and HBV. All regulated waste is incinerated or autoclaved.

Laboratory doors are 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 are placed in a durable, leakproof, labeled container that is closed before removal from the work area.

Access to the work area is limited to authorized persons. Written policies and procedures in **Appendix D** are 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 are allowed to enter the work areas and animal rooms. Further specifications are to be found in the individual laboratory's SOP.

All access doors to the work area or containment module are posted with a hazard warning sign which includes the Universal Biohazard symbol.

No work will be conducted on the open bench. All activities involving other potentially infectious materials are conducted in a biological safety cabinet or other physical-containment device within the containment module.

Lab coats, gowns, uniforms, or other appropriate protective clothing are worn in the work area and animal rooms. Protective clothing is not to be worn outside of the work area and will be decontaminated before being laundered.

Gloves are worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

Vacuum lines are protected with liquid disinfectant traps and HEPA filters which are checked routinely and maintained or replaced as necessary.

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

All spills are immediately contained and cleaned up by properly trained employees equipped to work with potentially infectious materials. These are specified in the individual SOP.

A spill or accident that results in an exposure incident is immediately reported to the laboratory supervisor or other responsible person.

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, are used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills or aerosols.

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

Attach one copy of the biosafety manual which was prepared for this facility.

List location of handwash sink and eye wash facility. Specify whether sink is floor, elbow or automatically operated.

Specify mechanism and frequency by which proper direction of facility airflow is verified.

Outline mechanism to advise employees on potential hazards and means of assessing compliance with instructions on practices and procedures.

APPENDIX E

LABELING

The Standard requires that the fluorescent orange or orange-red warning labels be attached to containers of regulated wastes, refrigerators and freezers containing blood and other potentially infectious materials, and other containers used to store, transport, or ship blood or other potentially infectious materials.

These labels are not required when (1) red bags or red containers are use, (2) containers of blood, blood components, or blood products are labeled as to their contents and have been released for transfusion or other clinical use, and (3) individual containers of blood or other potentially infectious materials are placed in a labeled container during storage, transport, shipment or disposal.

The warning label must be fluorescent orange or orange-red, contain the biohazard symbol and the word BIOHAZARD, in a contrasting color, and be attached to each object by string, wire, adhesive, or another method to prevent loss or unintentional removal of the label.

Item	No label Needed if Universal Precautions used & specific Use of Container or Item is known to all Employees	Biohazard Label	or	Red Container
Regulated waste container (e.g., contaminated sharps containers)		X	or	X
Reusable contaminated sharps container (e.g., surgical instruments soaking in a tray)		X	or	X
Refrigerator/freezer holding blood or other potentially infectious material		X		
Containers used for storage, transport or shipping of blood		X	or	X
Blood/blood products for clinical use		No Labels Required		
Individual specimen containers of blood or other potentially infectious materials remaining in facility	X	or	X	or
Contaminated equipment needing service (e.g., dialysis equipment; suction apparatus)		X(plus a label specifying where the contamination exists)		
Specimens and regulated waste shipped from the primary facility to another facility for service or disposal		X	or	X
Contaminated laundry *		X	or	X
Contaminated laundry sent to Another facility that does not use Universal Precautions		X	or	X

*Alternative labeling or color coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

APPENDIX F

TRAINING OUTLINE

BLOODBORNE PATHOGEN TRAINING AND INFORMATION

INTRODUCTION – SAFETY OFFICE

Overview of Safety Office responsibilities: See Section II Responsibility of Occupational and Safety Health Plan

OCCUPATIONAL SAFETY and HEALTH ADMINISTRATION (OSHA): BLOODBORNE PATHOGEN STANDARD

Purpose: To minimize or eliminate occupational exposure to blood and other potentially infectious materials, (e.g., human body fluids and tissues) since an exposure could result in transmission of blood borne pathogens, which could lead to disease or death.

Scope: Covers all employees who could be “reasonably anticipated” as a result of performing their duties to have contact with blood and other potentially infectious materials. MCP/AHS examples are listed on p. 1.

NOTE: “Good Samaritan” acts such as assisting a co-worker with a nosebleed would not be considered occupational exposure.

TRAINING REQUIREMENTS

Employees receive training upon employment or assignment to tasks involving the potential for occupational exposure. Annual retraining is required.

BLOODBORNE PATHOGENS and OCCUPATIONAL TRANSMISSION

Definition: Bloodborne pathogens are microorganisms (i.e., virus) found in human blood and body fluids that may cause disease in humans.

Examples: Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV).

Occupational routes of transmission:

- Needlestick or cuts/puncture with sharp object
- Splash or splatter to face or exposed skin
- Contact with non-intact skin (chapped or dry hands)

EXPOSURE CONTROL PLAN

Review of job titles and specific job tasks where there is reasonably anticipated exposure.

Review of Standard precautions and Standard Operating Procedures (SOP):

- Engineering and work practice controls
- Personal protective equipment
- Housekeeping (cleaning/decontamination schedule)
- Labels and signs

HEPATITIS B VACCINE (HBV)

Safe and effective vaccine available for immunization against HBV.

A series of 3 vaccinations.

Vaccination against HBV is made available FREE OF CHARGE to all employees who have occupational exposure to blood and other potentially infectious materials.

Employees must sign a Declination Form if they choose not to be vaccinated, but may later request and receive the vaccine at no cost.

EXPOSURE MANAGEMENT

Review of exposure incidents (e.g., needlestick).

Procedure to follow in the event of an exposure.

- Wash the exposure area with soap and water.
- Notify your supervisor **IMMEDIATELY**.
- Go to Student Health Center

Medical assessment, treatment, counseling, follow-up:

- Confidential
- No cost to employee.

RECORDKEEPING REQUIREMENTS

Training records (Safety Office).

Medical records (Students Health Center).

ADDITIONAL INFORMATION

Contact your supervisor.

Contact Safety Office

APPENDIX J

INFORMATION ABOUT GLOVES²

While intact skin is your first line of defense against infection, gloves can provide additional hand barrier protection. Medical gloves can help protect you and your patients from infection and disease, if you use them properly. Medical gloves include surgical and patient examination gloves. With the concern about the possible transmission of the hepatitis B virus and the human immunodeficiency virus (HIV), which causes AIDS, in health care settings, you need to know as much as possible about medical gloves. Gloves will provide barrier protection so long as they are intact. Gloves will not protect you from needlestick and other sharp instrument injuries. In 1991, the *Occupational Safety and Health Administration (OSHA)* issued a standard designed to “eliminate or minimize occupational exposure to hepatitis B, HIV, and other blood borne pathogens.” Part of this standard is the requirement for employers to provide you with personal protective equipment, including gloves. This information is for all users of medical gloves who contact blood or other body fluids from patients or contact items contaminated with these substances.

Surgeon’s gloves (also called surgical gloves) are made of natural rubber latex or synthetic rubber (chloroprene, thermoplastic elastomers). These gloves are sterile in order to protect both the patient and health care worker from contamination. **Patient examination** gloves may be made of natural rubber latex, vinyl, polyethylene, thermoplastic elastomers, nitrile, or polyurethane. Examination gloves may be sterile or non-sterile. Tests have shown that intact natural rubber latex and synthetic rubber are effective barriers against the passage of the hepatitis B virus and HIV.

If the glove will be used during invasive procedures or when a sterile field is desired, choose a sterile glove. The *Centers for Disease Control and Prevention (CDC)* define an invasive procedure as, “surgical entry into tissues, cavities or organs, or repair of major traumatic injuries.”

When sterility is not critical such as for procedures involving contact with mucous membranes, you may use a non-sterile glove. It is important to note that non-sterile patient examination gloves may carry various contaminants, such as fungus, mold, and mold spores. Fungus and mold spores can become airborne and infect patients, even if the gloves are not used directly on patients. Immunocompromised patients and patients with surgical wounds are at risk for infections. **Do not use gloves that are moldy with visible black spots or smell musty.**

Non-medical gloves, commonly known as utility, industrial, or general purpose gloves, are used for tasks that do not involve contact with patients. You **MUST** carefully read the labeling on the glove box or container to make sure you use the appropriate gloves. Glove company names that include a medical term do not mean that the gloves are medical gloves. Non-medical gloves will usually be labeled *Latex Gloves* rather than *Latex Examination Gloves*. Non-medical gloves may also be labeled “for non-medical use.” Under no circumstances should you use these non-medical gloves for contact with patients because their medical barrier protection has not been tested. Non-medical gloves may be used for tasks **NOT** involving patient contact, such as housekeeping chores.

For surgical gloves, only powder that meets the specifications of an absorbable dusting powder (**cornstarch**) of the *United States Pharmacopeia (USP)* and approved by the *Food and Drug Administration (FDA)* can be used. After putting on gloves, powder should be removed by wiping

²adapted from “INFORMATION ABOUT MEDICAL GLOVES”, developed by Food and Drug Administration and the Health Industry Manufacturers Association.

gloves thoroughly with a sterile sponge or sterile towel. For patient examination gloves, cornstarch powder or silicone that meets the specifications of USP can be used for lubrication. Some gloves are chlorinated to make the gloves smooth and would not need a lubricating powder. You need to consider the circumstances under which gloves will be used in order to decide whether to remove residual powder after putting on gloves. If gloves will contact cuts, wounds, or body cavities, you may want to remove residual powder to decrease the risk of powder contamination.

If you have a skin reaction or allergy to a particular glove, stop using it immediately. Try a glove made by another manufacturer or made of another type of material. If the problem persists, consult a dermatologist who specializes in contact dermatitis or allergies. Reactions to gloves fall into three types:

- **Skin irritation-** the *most common* reaction. Symptoms are: dry, cracking skin, skin sores or bumps, and/or itching or rash under the glove area.
- **Allergic contact dermatitis-** *sensitivity to chemicals used in latex*. Symptoms are: dry, cracking skin, skin sores or bumps, and/or itching or rash under the glove and up the arm.
- **Natural rubber latex allergy-** *caused by proteins in the latex, this serious allergy can cause severe reactions*. Symptoms are: hives, skin rash, itching, swelling, sneezing, and/or difficulty breathing.

If you experience any of these symptoms when using natural rubber latex gloves or any other products containing natural rubber latex, stop using the gloves or product immediately and contact your doctor. If either **you** or **your patient** is allergic to natural rubber latex, use a non-latex glove. FDA has advised that health care workers should identify latex-sensitive patients and be prepared to treat allergic reactions promptly. For those taking patient histories, remember to ask questions about problems with latex or rubber. For example, questions about itching, a rash, or wheezing after wearing utility latex gloves or blowing up toy balloons may indicate a natural rubber latex allergy.

Because natural rubber latex allergies can be severe, FDA is proposing to require that gloves and other medical devices containing natural rubber latex carry a label stating, “*This product contains natural rubber latex.*” Many manufacturers already have this label on their products.

An allergy to glove powder is rare. During the manufacturing process, natural rubber latex protein could contaminate the glove powder and cause an allergic reaction. Most skin irritations caused by powder can be reduced by using a powder-free glove. Some reactions to gloves may be caused by hand care problems.

Hypoallergenic gloves have been designed for people who are allergic to chemicals normally used in the glove manufacturing process. FDA requires that manufacturers of gloves document the claim of “hypoallergenic” by submitting scientific studies that the claims are not false or misleading. If you do not know what your specific allergy to gloves is, using “hypoallergenic” gloves may not prevent allergy symptoms. FDA is proposing to eliminate the term, “hypoallergenic” for use with natural rubber latex products, including latex gloves. “Hypoallergenic” may be confusing because it does not mean that you can use the gloves if you are allergic to natural rubber latex proteins.

As long as the glove material is intact, it will protect you and your patients. You can help avoid tears and punctures by making sure your fingernails are well trimmed, and removing all hand jewelry. The quality of gloves also depends on how they are stored and used. Manufacturers check their gloves for leaks using a “water-leak” test. FDA inspectors also do the same test on samples of

gloves. If a sample of gloves does not pass the “water-leak” test, they cannot be sold as medical gloves.

Only hand lotions that are **water-based** can be used before putting on latex gloves. Check the labeling to make sure the lotion does not contain any oil. Oils, such as mineral oil, or petroleum-based products, such as Vaseline®, can weaken latex, allowing the glove to tear. Just because a lotion easily washes off does not mean that it is water-based. *Note: Oil-based lotions do not affect vinyl gloves.*

By checking for signs of damage. **Do not** use the gloves if the gloves or glove package shows stains, watermarks, discoloration; is moldy or musty; or the glove has white lines, holes, rips, or tears at stress points, such as folds. **Do not** use sterile gloves if the package has been opened or damaged.

Because bacteria thrive in the warm, moist environment inside the glove and can multiply quickly, you need to wash your hands both before and after each time you put on and remove gloves to prevent disease transmission. Remember to:

- Wash your hands thoroughly, using an antimicrobial handwash, or plain soap. A waterless soap substitute can be used when water is not available.
- Dry your hands thoroughly.
- Repeated handwashings, especially during the dry winter months, can lead to skin irritation. Glove use may magnify this problem.
- Make sure your hands are clean and dry before putting on gloves. Use lotions or creams regularly when not wearing gloves.

When putting on gloves, remember to:

- Avoid excessive stretching of the glove.
- Work the glove down to the base of the fingers to make sure that the glove fits comfortably. For good tactile sensitivity, the glove should neither be too tight nor too loose at the fingertips.
- Make sure the glove fits snugly across the palm and in the cuff area without being too tight.
- Check again for signs of damage to gloves.

Use your own judgment or follow your organization’s guidelines when considering double gloving. Research on the effectiveness of multiple gloving is currently underway. Glove liners worn with patient examination or surgical gloves are made of materials that are resistant to cutting or tearing. These products reduce the risk of contamination during surgical and examination procedures. No consensus has been reached, but some researchers strongly recommend double gloving for surgical procedures to reduce the risk of contact with blood or body fluids if the outer glove punctures or tears.

As a general rule, you should change gloves as often as needed for the safety and comfort of your patient and yourself. Change gloves: between procedures; between procedures on the same patient if gloves become overly contaminated with blood and other body fluids or before going to a clean site after working on a contaminated site; if gloves are torn, cut, or punctured; if using sterile gloves and gloves are contaminated by touching something non-sterile; if gloves have come into contact with chemicals that may damage them, such as acids, alkalis, solvents, oils, disinfectants, or sterilants (Note: Consult your glove supplier for information about what chemicals may damage gloves); if gloves are in prolonged contact with body fat and fluids. In these cases, you need to change them to prevent “ballooning” or swelling in the glove fingertips. There is also a **“fatigue**

factor”; the longer you wear the same pair of gloves, the less effective they may be as a barrier. You should change gloves on a regular basis during lengthy procedures.

To dispose of gloves, follow these steps:

- Peel off gloves, carefully turning them inside out and making sure that the gloves or any fluids which may be present on them do not contact your skin or any other surfaces.
- Dispose of the gloves directly in the appropriate container. **Do not** put them down on any other surface.
- Wash and dry your hands thoroughly.

Do not reuse gloves. Washing gloves does not effectively remove contamination. Disinfectants can damage gloves, reducing their barrier effectiveness. In other words, you put your patients and yourself at risk if you reuse gloves.

Glove Storage

Glove effectiveness changes over time. Gloves are affected by extreme temperatures, ultraviolet, ozone, and water.

DO: Store gloves in a cool, dry place; rotate your supply of gloves so that the oldest supply is used first; keep gloves in their original box until they are needed.

DO NOT: Store gloves where they might be exposed to extreme temperatures or light including: near circulating fan motors, air conditioners, and electric motors; in direct sunlight or near fluorescent lights; on window sills or radiators; or near x-ray equipment or in a room next to x-ray equipment that does not have a shielded wall.

Selected References

General:

- Centers for Disease Control. Recommendations for prevention of HIV transmission in health-care settings. MMWR 1987; 36 (suppl no 2S): 3S-18S.
- Centers for Disease Control. Update: Standard precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other blood borne pathogens in health-care settings. MMWR 1998; 37:377-378.
- Occupational Safety and Health Administration. Occupational exposure to blood borne pathogens; final rule. Federal Register 1991, December 6; 29 CFR Part 1910.1030; 56(235): 64004-64182.

Latex as a Barrier:

- Korniewicz DM, et al. Integrity of vinyl and latex glove procedures. Nursing Research 1989; 38(3): 144-146.
- Korniewicz DM, et al. Leakage of virus through used vinyl and latex examination gloves. J Clinical Microbiology 1990; 28(2): 787-788.
- Degroot-Kesoleharden J, Jones J. Permeability of latex and vinyl gloves to water and blood. Am J Infect Control 1989; 17: 196-201.

Natural Rubber Latex Allergy:

- Food and Drug Administration. Allergic reactions to latex-containing medical devices. FDA Alert, May 29, 1991 (MDA91-1).
- Leynadier F, Pequet C, Dry J. Anaphylaxis to latex during surgery. Anaesthesia 1989; 44:547-550.

- Slater JE, et al. Type I hypersensitivity to rubber. *Annals of Allergy* 1990; 65: 411-414.

Multiple Gloving:

- Dodds RDA, et al. Self protections in surgery: the use of double gloves. *Brit J Surgery* 1990; 77: 219-220.
- Gerberding JL, et al. Risk of exposure of surgical personnel to patients' blood during surgery at the San Francisco General Hospital. *NEJM* 1990; June: 1788-1793.