

Bloodborne Pathogen
Exposure Control Plan

(e)(2)(ii)(K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

(e)(2)(ii)(L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

(e)(2)(ii)(M) A Biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(e)(2)(iii) Containment Equipment.

(e)(2)(iii)(A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

(e)(2)(iii)(B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

(e)(3) HIV and HBV research laboratories shall meet the following criteria:

(e)(3)(i) Each laboratory shall contain a facility for hand washing and an eye wash facility, which is readily available within the work area.

(e)(3)(ii) An autoclave for decontamination of regulated waste shall be available.

(e)(4) HIV and HBV production facilities shall meet the following criteria:

(e)(4)(i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-door clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

(e)(4)(ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

(e)(4)(iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(e)(4)(iv) Access doors to the work area or containment module shall be self-closing.

Bloodborne Pathogen
Exposure Control Plan

(e)(4)(v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(e)(4)(vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

(e)(5) Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

(f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up -

(f)(1) General.

(f)(1)(i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

(f)(1)(ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

(f)(1)(ii)(A) Made available at no cost to the employee;

(f)(1)(ii)(B) Made available to the employee at a reasonable time and place;

(f)(1)(ii)(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

(f)(1)(ii)(D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

(f)(1)(iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

(f)(2) Hepatitis B Vaccination.

(f)(2)(i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is

Bloodborne Pathogen
Exposure Control Plan

contraindicated for medical reasons.

(f)(2)(ii) The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

(f)(2)(iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

(f)(2)(iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

(f)(2)(v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(f)(3) Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

(f)(3)(i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

(f)(3)(ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(f)(3)(ii)(A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

(f)(3)(ii)(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(f)(3)(ii)(C) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(f)(3)(iii) Collection and testing of blood for HBV and HIV serological status;

(f)(3)(iii)(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(f)(3)(iii)(B) If the employee consents to baseline blood collection, but does not give

Bloodborne Pathogen
Exposure Control Plan

consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(f)(3)(iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(f)(3)(v) Counseling; and

(f)(3)(vi) Evaluation of reported illnesses.

(f)(4) Information Provided to the Healthcare Professional.

(f)(4)(i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

(f)(4)(ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

(f)(4)(ii)(A) A copy of this regulation;

(f)(4)(ii)(B) A description of the exposed employee's duties as they relate to the exposure incident;

(f)(4)(ii)(C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(f)(4)(ii)(D) Results of the source individual's blood testing, if available; and

(f)(4)(ii)(E) All medical records relevant to the appropriate treatment of the employee including vaccination status, which are the employer's responsibility to maintain.

(f)(5) Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

(f)(5)(i) The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

(f)(5)(ii) The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

(f)(5)(ii)(A) That the employee has been informed of the results of the evaluation; and

(f)(5)(ii)(B) That the employee has been told about any medical conditions resulting

Bloodborne Pathogen
Exposure Control Plan

from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

(f)(5)(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(f)(6) Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) Communication of Hazards to Employees -

(g)(1) Labels and Signs -

(g)(1)(i) Labels.

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

(g)(1)(i)(B) Labels required by this section shall include the following legend:

(g)(1)(i)(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

(g)(1)(i)(D) Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(g)(1)(i)(E) Red bags or red containers may be substituted for labels.

(g)(1)(i)(F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

(g)(1)(i)(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

(g)(1)(i)(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(g)(1)(i)(I) Regulated waste that has been decontaminated need not be labeled or color-coded.

(g)(1)(ii) Signs.

(g)(1)(ii)(A) The employer shall post signs at the entrance to work areas specified in paragraph (e),

Bloodborne Pathogen Exposure Control Plan

HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

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

(g)(1)(ii)(B) These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

(g)(2) Information and Training.

(g)(2)(i) Employers shall ensure that all employees with occupational exposure participate in a training program, which must be provided at no cost to the employee and during working hours.

(g)(2)(ii) Training shall be provided as follows:

(g)(2)(ii)(A) At the time of initial assignment to tasks where occupational exposure may take place;

(g)(2)(ii)(B) Within 90 days after the effective date of the standard; and

(g)(2)(ii)(C) At least annually thereafter.

(g)(2)(iii) For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

(g)(2)(iv) Annual training for all employees shall be provided within one year of their previous training.

(g)(2)(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(g)(2)(vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(g)(2)(vii) The training program shall contain at a minimum the following elements:

(g)(2)(vii)(A) An accessible copy of the regulatory text of this standard and an explanation of its contents;

(g)(2)(vii)(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

Bloodborne Pathogen
Exposure Control Plan

(g)(2)(vii)(C) An explanation of the modes of transmission of bloodborne pathogens;

(g)(2)(vii)(D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

(g)(2)(vii)(E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(g)(2)(vii)(F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

(g)(2)(vii)(G) Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

(g)(2)(vii)(H) An explanation of the basis for selection of personal protective equipment;

(g)(2)(vii)(I) Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

(g)(2)(vii)(J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(g)(2)(vii)(K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

(g)(2)(vii)(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

(g)(2)(vii)(M) An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

(g)(2)(vii)(N) An opportunity for interactive questions and answers with the person conducting the training session.

(g)(2)(viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(g)(2)(ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

(g)(2)(ix)(A) The employer shall assure that employees demonstrate proficiency in

Bloodborne Pathogen
Exposure Control Plan

standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(g)(2)(ix)(B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

(g)(2)(ix)(C) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) Recordkeeping -

(h)(1) Medical Records.

(h)(1)(i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

(h)(1)(ii) This record shall include:

(h)(1)(ii)(A) The name and social security number of the employee;

(h)(1)(ii)(B) A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

(h)(1)(ii)(C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

(h)(1)(ii)(D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

(h)(1)(ii)(E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

(h)(1)(iii) Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

(h)(1)(iii)(A) Kept confidential; and

(h)(1)(iii)(B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

Bloodborne Pathogen
Exposure Control Plan

(h)(1)(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

(h)(2) Training Records.

(h)(2)(i) Training records shall include the following information:

(h)(2)(i)(A) The dates of the training sessions;

(h)(2)(i)(B) The contents or a summary of the training sessions;

(h)(2)(i)(C) The names and qualifications of persons conducting the training; and

(h)(2)(i)(D) The names and job titles of all persons attending the training sessions.

(h)(2)(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(h)(3) Availability.

(h)(3)(i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(h)(3)(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

(h)(3)(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

(h)(4) Transfer of Records.

(h)(4)(i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(h)(4)(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

(h)(5) Sharps Injury Log.

Bloodborne Pathogen
Exposure Control Plan

(h)(5)(i) The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

(h)(5)(i)(A) the type and brand of device involved in the incident,

(h)(5)(i)(B) the department or work area where the exposure incident occurred, and

(h)(5)(i)(C) an explanation of how the incident occurred.

(h)(5)(ii) The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

(h)(5)(iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

(i) Dates -

(i)(1) Effective Date. The standard shall become effective on March 6, 1992.

(i)(2) The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

(i)(3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.

(i)(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001]

APPENDIX A

TO SECTION 1910.1030 - HEPATITIS B DECLINATION (MANDATORY)

I understand that due to my occupational exposure to blood or other potentially 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 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.